A Study of Motivational Interviewing In Adolescents With Type 1 Diabetes

Michelle Victoria Huws-Thomas

Thesis submitted in March 2007 in fulfilment of the degree of Doctor of Philosophy at the University of Wales

ProQuest LLC
789 East Eisenhower Parkway
P.O. Box 1346
Ann Arbor, MI 48106-1346

OUTLINE

Dedication

To my family, Steven, Rosie and Ethan for their love, sacrifices and belief in me.

To my parents and sister for their love, kindness and encouragement over the years.

ACKNOWLEDGMENTS AND ATTRIBUTIONS

I wish to acknowledge the contributions of the people involved who have made this work possible.

I wish to thank Diabetes UK for funding the project work underpinning this thesis. The funding was available between 2001-2004.

I wish to thank the young people and their families who participated in this study and allowed me to privilege to talk about their diabetes within their own homes.

I also wish to thank the specific contributions of several individuals involved in this study. The work was undertaken by a project group with collective responsibility. The principal investigators were Dr Sue Channon (Child Health, Cardiff and Vale NHS Trust), Professor John Gregory (Child Health, Wales College of Medicine) and Professor Stephen Rollnick (Department of General Practice, Wales College of Medicine), and I joined the project team as the research assistant in September 2001. This led to a joint planning and management of the project and I was given a pivotal role in this to which I am very grateful. We were clear to establish different areas of responsibility and interest within key areas of the study. Dr Sue Channon, Professor Rollnick and the candidate designed, planned and implemented the training in Motivational Interviewing (MI), the components of the MI intervention and the

control group intervention (Chapter 4). Dr Channon delivered supervision to both myself and the research assistant managing the control group intervention within the first 6 months of intervention delivery. During the latter phase of the intervention, I received supervision from Dr David Rosengren (University of Seattle, Washington) and Stephanie Ballasiotes, both experienced MI practitioners (Chapter 4). The supervision provided by these practitioners was invaluable and facilitated me in greatly in MI skill development.

I wish to acknowledge with gratitude the contributions of Dr Kerry Hood and Rebecca Cannings-John in the analysis stages of this project. Dr Hood (Senior Lecturer in Statistics and Director of Clinical Trials at the Department of General Practice, Wales College of Medicine) and Rebecca Cannings –John (Statistician at the Department of General Practice, Wales College of Medicine) played key roles regarding statistical analysis throughout the duration of the project. In particular Dr Hood and Ms Cannings-John undertook most of the analyses for sections 6.9, 6.10 and 6.11. The candidate also undertook separate descriptive and inferential analyses for sections 6.6, 6.9:2, 6.10 and 6.11 with additional advice from Dr Hood and Ms Cannings-John.

The candidate undertook the analyses of the retrospective study (Chapter 10) with supervision from Dr Hood.

I am very grateful to Mrs Karen Wood for her invaluable support on the project between September 2003- June 2004. Karen joined the team as part of the research placement during her Applied Psychology degree at Cardiff University and she

undertook most of the questionnaire coding, data entering and data management during this time. I was impressed by her tenacity and dedication to detail and without her support, the study would not have come into fruition.

Professor Ian Russell, University of Wales Bangor also gave particularly valuable advice at the early design stages of the project.

Regarding the writing of the PhD, I wish to thank my two supervisors, Professor Steve Rollnick and Professor John Gregory for their commitment, support and guidance during the phases of this thesis. I also wish to thank my manager, Linda Cooper, Director of Mental Health and Learning Disabilities who has always supported me 100% in the writing up of this thesis. Thank you Linda for those valuable breaks from work.

I am very grateful for the support received from the paediatric nurses and paediatricians within the centres we accessed and particularly to Dr Lesley Lowes (Child Health, Wales College of Medicine) for her help when recruitment was staggered within the Cardiff clinic. I wish to thank Lesley again, Professor Paul Bennett (Centre for Nursing Research, Cardiff University) and Jeff Champney-Smith (Cardiff School of Nursing Studies) for reading through a draft or two of my thesis.

On a more personal level, I wish to thank Dr Claire Lane (Centre for Nursing Research, Cardiff University) for her advice and support over the years over cups of coffee. Her infectious optimism, bright spirit and generosity have encouraged me enormously.

Summary

Motivational Interviewing (MI) has been shown to be effective in facilitating change in health-related behaviour in adults. The objective of this study was to examine the efficacy of MI for adolescents aged 14-17 years with type 1 diabetes. The study was divided into two parts. Study I was a randomised controlled trial (RCT) analysed by intention to treat. Sixty six adolescents with type 1 diabetes, attending diabetes clinics in South Wales, were randomly assigned to the MI intervention group (n=38) and to the control group (n=28) who received support counselling based on education and self management skills. All participants received individual sessions over 12 months. The main outcome measures were serum glycosylated haemoglobin (HbA_{1c}) concentrations and psychosocial measures which included quality of life and well-being. These were assessed at baseline, 12 months (end of intervention) and at 24 months (one year post intervention). Sixty patients completed data at 12 months. At 12 months the mean HbA_{1c} in the MI group was significantly lower than in the control group ($p=0.04$), after adjusting for baseline values. At 24 months follow up, this difference in HbA_{1c} had increased ($p=0.003$). There were differences in psychosocial variables at 12 months, with the MI group indicating more positive well-being, enhanced quality of life and differences in their personal models of illness (all $p<0.001$). Some of these differences were maintained at 24 months. Study II explored the relationships between quality of life and HbA_{1c} retrospectively based on *a priori* hypotheses. Better quality of life (satisfaction and impact) predicted reductions in HbA_{1c} at 24 months explaining 0.9% of the variance in HbA_{1c}.

Conclusions: Motivational Interviewing appeared to be an effective method of facilitating adolescents with type 1 diabetes to reduce their HbA_{1c}, along with enhancements in some aspects of psychosocial functioning.

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LIST OF ABBREVIATIONS

BCC *– Behaviour Change Counselling*

BECCI *– Behaviour Change Counselling Index*

CST *– Coping Skills Training*

DCCT *– Diabetes Control and Complications Trial*

DUK *– Diabetes UK*

EDIC *– The Epidemiology of Diabetes Interventions and Complications Study*

ES *– Effect size*

ETDA *- Ethylene Diamine Tetra-acetic Acid*

HbA_{1C} *- Gylcosylated haemoglobin*

HTA *– Health Technology Assessment*

ISPAD *– International Society for Paediatric and Adolescent Diabetes*

MI *– Motivational Interviewing*

MET *– Motivational Enhancement Therapy*

MRC *– Medical Research Council*

NICE- *National Institute of Clinical Excellence*

NSF- *National Service Framework*

RCT *-Randomised Controlled Trial*

UKPDS *– United Kingdom Prospective Diabetes Study*

UBHT- *United Bristol Healthcare Trust*

CHAPTER ONE: BACKGROUND - INTRODUCTION

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1:1 Introduction

Type 1 diabetes is one of the most common chronic childhood conditions affecting 18 to 20 per 100 000 children a year in the United Kingdom (Onkamo et al. 1999). It is the third most common chronic disorder in adolescence after asthma and cerebral palsy (Betts and Swift, 2003). Adolescence is a time of rapid physical, emotional and psychological growth during which children move from complete dependence on parents to a more autonomous lifestyle (Hamilton and Daneman, 2002). The move into adolescence poses a difficult time for young people with type 1 diabetes because it is the time when glycaemic control often deteriorates and self-management declines (Anderson, Ho et al. 1997; Morris et al. 1998). Adolescents with diabetes have been described as the cohort with poorest self care (Tattershall, 1987). A combination of physiological, social, psychological and cognitive changes make diabetes more difficult to control during adolescence than in younger children and adults (Wolfsdorf, 1999) and these changes pose special challenges to the successful management of type 1 diabetes (Madsen et al. 2002). The window between childhood and adulthood is thought to be an important time for establishing lifelong health habits, rendering adolescence a key period in which to substantially influence future health trajectories (Millstein, 1989). Although technological advances in insulin therapy have provided new therapeutic options for clinicians and young people (Tamborlane et al. 2001), glycaemic control as measured by glycosylated haemoglobin (HbA_{1c}) remains suboptimal despite technical and therapeutic improvements (de Beaufort and Swift, 2006). For children and adolescents with type 1 diabetes, the target for long term

glycaemic control to prevent micro-vascular complications is an HbA_{1c} value of less than 7.5% without frequent hypoglycaemia as defined by the National Institute for Clinical Excellence guidelines (NICE, 2004). However a recently published National Diabetes Audit in England and Wales (2006) demonstrated that only 15.9% of adolescents under 16 years are able to achieve this target and this figure reduces to 13.9% for young people aged between 16-24 years. Although no upper threshold value for HbA_{1c} has been established below which micro-vascular complications do not occur, the consensus agreed by the International Society for Paediatric Diabetes (ISPAD, 2000) is that the risk rises substantially at HbA_{1c} level of 7.6% and higher.

The first section of this chapter describes the aetiology and incidence of type 1 diabetes in children and adolescents along with treatment. The challenges of chronic illness in adolescence are highlighted. The epidemiology of type 1 diabetes in adolescents in the UK is then considered, followed by the economic and social burden of diabetes and adolescents. The following sections address the physical, psychological, social and cognitive changes facing adolescents with this disease. The latter sections address the challenges relating to glycaemic control in adolescents. Particular reference is paid to the landmark Diabetes Control and Complications Trial (DCCT study group, 1994), which confirmed the relationship between poor glycaemic control and micro-vascular complications in adolescents with type 1 diabetes. The final section considers the factors relating to self care that impact upon glycaemic control in adolescents.

1:2 Incidence and aetiology of type 1 diabetes

The prevalence in Europe of type 1 diabetes in children by age 15 years is about 3 per 1000 and rising at approximately 2-5% annually (Daneman, 2006; de Beaufort and Swift, 2006). The recently published National Diabetes Audit monitored between January 2004-March 2005, identified 10,059 children with type 1 diabetes under 16 years in England and Wales (National Diabetes Audit, 2006). The latter figure however is based on 64 participating paediatric clinics, comprising only 26% of paediatric units in England and 41% in Wales and is underestimated. The EURODIAB ACE collaborative study (2000), a registry that involved 44 countries in Europe, indicated an annual increase in incidence in type 1 diabetes in children of 3 - 4% with the largest increase in children 0 - 4 years of age compared with the age groups 5–9 and 10–14 years. Between the study period, 1989-1998 there was a tenfold increase in incidence of childhood diabetes in Europe, with higher incidence in north and north-western Europe and lower incidence in central, southern and eastern Europe excluding Sardinia. The international variation in incidence is recognised within the literature, with a child in Finland more likely to develop diabetes than a child in Japan and almost 100 times more likely to get diabetes than a child in the Zuni region of China (Onkamo et al. 1999; Devendra et al. 2004).

Type 1 diabetes is an endocrinological disorder characterised by disturbances of glucose, fat and protein. Specifically the disease involves the selective destruction of the insulin-producing pancreatic beta ß cells leading to insulin deficiency. By the time

of clinical symptoms, 60–80% of the ß cells are destroyed (Notkins and Lernmark, 2001). The absolute lack of insulin inhibits the metabolism and storage of glucose, resulting in high blood glucose concentrations (hyperglycaemia) (Mandrup-Poulson and Nerup, 1995). Early symptoms include increased micturition by day and night (polyuria), sometimes with uncharacteristic bedwetting, increased thirst (polydipsia), fatigue and weight loss. If undetected, severe fluid, electrolyte and acid base disturbances lead to vomiting, dehydration, coma and death (Brink, 1995). Presentation at diagnosis can vary considerably, from the acutely ill ketoacidotic child with severe dehydration to the relatively asymptomatic child whose symptoms have been recognised in the early developmental stages of the disease. Genetic and immunologic factors play a key role in the development of type diabetes. Although some researchers argue that type 1 diabetes is caused by autoimmune destruction of pancreatic beta cells (Notkins, 2002), others point to the genetic link in increased susceptibility of the disease (Field, 2002). Information regarding the development of type 1 diabetes remains poorly understood (Atkinson and Eisenbarth, 2001).

Medical interventions necessary to stabilise newly diagnosed diabetes depend upon the clinical condition of the child at presentation. Hospital admission is necessary if intravenous therapy is required to correct dehydration, electrolyte imbalance, and ketoacidosis, with progression to oral fluids and subcutaneous insulin administration as the child's condition improves (Lowes and Gregory, 2004). The treatment of type 1 diabetes is considered next.

1:3 Treatment of type 1 diabetes

People with type 1 diabetes depend on regular insulin injections and adherence to multiple self care tasks to achieve optimal glycaemic control. The principle goals of treatment of the child and adolescent are to maintain good quality of life (Hoey et al. 2001) and to prevent long term complications (DCCT, 1994). Treatment regimens vary according to local protocols and preferences. The National Institute for Clinical Excellence (NICE, 2004) guidelines on the diagnosis and management of this condition in children and adolescents advocated an insulin regime individualised for the adolescent that may vary between 2 injections a day to continuous subcutaneous insulin infusion. Whilst the standard insulin regime in the UK consists of twice daily injections (Swift, 1995; Williams and Dunger, 2004), other diabetologists have recommended that adolescents should receive 4 injections a day to allow greater freedom with diet and to allow for the complexities in treating type 1 diabetes during puberty (Dorchy, 2000). The aim of treatment is to achieve HbA_{1c} levels close to the non diabetic range of < 6.5% whilst avoiding hypoglycaemia (ISPAD consensus guidelines, 2000). Williams and Dungar (2004) argued that within clinical practice, optimising glycaemic control in adolescents without unacceptable hypoglycaemia, remains a challenge. Furthermore, insulin treatment is only one part of a comprehensive treatment strategy to achieve optimal glycaemic control (Swift, 1997) and other aspects of the regimen are described next.

Optimal management of type 1 diabetes includes a variety of self-care activities. These include; self monitoring of blood glucose regularly to help individuals monitor

symptoms that may indicate hyperglycaemia or hypoglycaemia, adjusting diet intake, and adjusting insulin doses to regulate glycaemic control on a day-to-day basis. The frequency of monitoring will depend on the individual, although at least four times a day has been recommended (Benjamin, 2002). Diet plays an important role in optimal management that includes carbohydrate counting used in conjunction with insulin dose adjustments (Waldron, 2005). Adolescents are required to adhere to their ideal body weight through healthy eating habits and physical activity. Although physiological factors such as insulin resistance can result in inadequately controlled diabetes, poor adherence to self care results in diminished glycaemic control, which has been linked to micro-vascular complications (DCCT, 1994). The findings from this landmark study are explored in greater depth in section 1:7:1 (pages: 22-25).

Micro-vascular complications of diabetes include retinopathy (damage to the retina leading to blindness), nephropathy (nephron damage leading to kidney dysfunction) and neuropathy (damage to the nerve fibres leading to loss of sensation in the extremities). Their development within adolescence is disputed within the literature. Daneman (2005) for example, suggested that although advanced complications are rare in adolescence, they begin soon after diagnosis and accelerate during adolescence. Kerr et al. (2002) meanwhile suggested that micro-vascular complications are rarely seen at diabetes out-patient clinics. What has been confirmed however is the role of poor glycaemic control in the onset and development of micro-vascular complications in adolescents longer term. This has been supported not just by the DCCT study, but also by cross sectional and epidemiological studies which will be described in section 1:7:3 (p: 26-27).

1:4 Adolescence and chronic illness

Adolescence is a complex transitional period that is developmentally distinct from childhood (Mackner and Crandall, 2006). It has been described as a prolonged developmental stage that lasts approximately 10 years between the ages of 11 – 21 years (Gutgesell and Payne, 2004). As adolescents pass through the early (11- 14 years), middle (15 to 17 years) and late (18-21 years) stages of development, rapid biological, social and cognitive changes take place which can cause difficulties (Madsen et al. 2002). Adolescents struggle with tremendous adjustments as constant changes and challenges occur in all aspects of their life. These include physical growth, surges and fluctuations in hormones, changes in sexual development (accompanied by changes in body image), peer influences, school and social pressures, family conflicts (with the struggle for independence), and many other aspects of growth and development that are a normal part of the adolescent years (Kadohiro, 2000). This developmental period between childhood and adulthood is considered an important time where health affirming habits are established and when one's developmental and health trajectories can be altered dramatically in positive or negative directions (Holmbeck, 2002; Madsen et al. 2002).

The management of any chronic condition during adolescence constitutes a major challenge for the individual, his/her family, and the healthcare team (Suris et al. 2004). Arguably the complexities increase exponentially when an adolescent has diabetes due to the complexity of the diabetes regimen.

1:5 Burden of type 1 diabetes in adolescence

1:5:1 Economic burden and mortality

The treatment of childhood onset diabetes accounts for approximately 5% of total National Health Service (NHS) resources (Feltbower et al. 2003). Hospitalization is associated with a high individual burden and high social costs (Icks et al. 2003; Gray et al. 1993). There has been a trend over the past decade in newly diagnosed children and adolescents towards reduction of hospitalization in favour of home based management with specialised nurse support (Lowes and Gregory, 2004). Young people with type 1 diabetes experience premature mortality (Milton et al. 2006) confirmed in a number of population cohort studies. The British Diabetic Association Cohort study (1972-1993) prospectively followed up 23,752 patients with type 1 diabetes diagnosed under the age of 30 years and found that mortality from acute metabolic complications and cardiovascular disease increased for all ages (Laing et al. 1999a). The mortality rates from acute complications of diabetes were much higher than any other cause-specific rates in the under 20 age group and were similar in each gender during the teenage years, accounting for 37% of the male and 49% of the female deaths. In addition males between the ages of 20 and 29 years were particularly vulnerable to acute complications, accounting for 30% of deaths in this age group (Laing et al. 1999b). The authors concluded that if mortality rates in young patients are to be reduced, attention should be focused on the prevention of acute metabolic complications and cardiovascular disease occurring at young ages. The findings corroborated a recent Swedish study (Dahlquist and Källén, 2005) which

found higher mortality in adolescents with type 1 diabetes compared to non diabetic case controls. The authors also reported a large proportion of unexplained deaths in otherwise healthy adolescents with diabetes during sleep (an observation made originally by Tattershall and Gill, 1991 coined '*dead-in-bed syndrome*').

Older studies such as the Pittsburgh insulin dependent diabetes mellitus morbidity and mortality study (Dorman et al. 1984), demonstrated the increased risk of mortality of young people with diabetes compared with the general US population. Two thousand children diagnosed with type 1 diabetes, under the age of 10 years between 1950-1981, were followed up at mean age of 21.2 years. Those under 20 years at follow up had a seven fold increase in mortality, with primary cause of death secondary to diabetes complications. Those over age 20 years had a 20 times greater risk of death with the greatest cause of death being renal complications. There is however variation in reported cause-specific mortality in cohort studies of young people between countries (DERI Mortality Study Group, 1991) and a Danish cohort study reported decreased mortality at a younger age between 1933-1972 (Borch-Johnson et al. 1986).

Measurement of HbA_{1c} has been advocated as the most valid and reliable method of determining the adequacy of glycaemic control and can stratify the risk of developing micro-vascular complications (Rohlfing et al. 2005). The test provides an index of average blood glucose levels during the previous 2-3 months. It differs from other laboratory tests in that the patient takes an active part in influencing the result by altering lifestyle habits to influence change in metabolic control (Dahl-Jørgensen et al. 2002). Until recently there was little published data on HbA_{1c} outcomes within

paediatric clinics in the UK on which to compare provision of care and outcomes (Scott and Donnelly, 2001). The National Diabetes Audit (2006) however has provided information on the demographic and HbA_{1c} outcomes of children with diabetes in England and Wales. The key findings indicated that only 15% of children under 16 years achieved HbA_{1c} targets of under 7.5%, which is the target recommended by NICE (2004). The figure dropped to 13.9% for young people age between 16-24 years. The overall mean HbA_{1c} for participating clinics was 8.9% (range 7.9% - 9.8%), which is well above the published accepted target value and corroborates the findings from the Scottish population based study DIABAUD 2 (2001). This study documented mean (±SD) HbA_{1c} levels of 9.0 % ±1.5 in 1,755 children and adolescents treated with 2 insulin injections a day, within 18 centres in Scotland.

1:5:2 Social burden

While the economic burden of childhood diabetes on NHS resources is established, relatively little is known about the social consequences of type 1 diabetes for young people (Milton et al. 2006). The risk of diabetic complications and premature mortality is exacerbated for those living in disadvantaged circumstances (Robinson, Lloyd and Stevens, 1998), although the relationship between socioeconomic status and diabetes related health problems in adolescents is contradictory. The National Diabetes Audit (2006) found that 39% of children with type 1 diabetes were from the most deprived areas in the UK (using indices of postcode and ward area to obtain a deprivation score). This decreased from 50% in the audit year between 2003-2004. A study by Overstreet et al. (1997) found that children with diabetes who were socially

disadvantaged were more likely to have poor glycaemic control. The literature suggests however that it is the structure of the family rather than indices of deprivation that are the most common predictor of poorer glycaemic control. A study by Baumer et al. (1998) found no relationship between deprivation score and prevalence of type 1 diabetes in a retrospective audit in S.W England, although living in a single parent household was more predictive of admission to hospital with hypoglycaemia, readmission with acute complications and non attendance at clinics. The DIABAUD 2 (2001) study found that the absence of one or both parents was associated with poorer control although deprivation score was not. A recent systematic review of the social and economic impact of type 1 diabetes in children found no differences in educational attainment between children with diabetes and non-diabetic controls, although poor metabolic control, early-onset, longer illness duration and serious hypoglycaemic events were associated with underachievement (Milton et al. 2006).

While the economic cost is difficult to estimate, the personal cost in terms of reduced quality of life and poorer psychosocial health is well documented (Cameron, 2003) and will be explored in greater detail in subsequent chapters. Diabetes in adolescence is considered a critical life event (Seiffke-Krenke and Stemmler, 2003) and because diabetes can be unpredictable and also difficult to manage and control by adolescents, it is perceived as highly stressful (Hauser et al. 1997). Such is the concern at the global prevalence and burden of diabetes internationally, a United Nations Resolution will be declared on November 14th 2007 (Unite for Diabetes, 2006). The resolution aims to increase world attention through education and the mass media on the

prevention, treatment and care of diabetes, with specific aims of addressing the special needs of children and adolescents.

Managing type 1 diabetes in adolescents represents a significant challenge for young people, their families and health care professionals (Channon et al. 2005). The specific biological, psychosocial, and cognitive challenges that adolescents with the disease endure are discussed in the following sections.

1:6 Developmental changes in adolescence and type 1 diabetes

1:6:1 Physiological changes

Puberty and the adolescent growth spurt pose a significant calorific and metabolic burden on the adolescent with type 1 diabetes where increased growth hormone levels cause insulin resistance (Moran et al. 2002; Goran and Gower, 2001). Significant differences in insulin resistance are present between adolescent boys and girls (Moran et al. 1999). The introduction of pubertal hormones heightens the risk for poor glycaemic control, making the disease more challenging to manage (Madsen et al. 2002; Dungar, 1992). In adolescents undergoing puberty, earlier rises in adrenal androgens and stimulation of growth hormone have been related to dimorphic insulin resistance (Dabadghoa et al. 2001; Domargard et al. 1999) requiring the need for increased insulin replacement. The combination of insulin deficiency and physical changes make day to day management difficult for young people with diabetes (Tamborlane et al. 2001).

The mechanisms underlying physical changes during puberty (e.g. weight gain) among adolescent girls with diabetes are not well understood (Leonard, 2003). It has been argued that both insulin dose and frequency of insulin injection impair growth during puberty, increasing body fat in girls, although boys appear to be relatively unaffected (Montague et al. 1997). Elevated concentrations of growth hormone and reduced amounts of insulin-like growth factor-1, both commonly observed with type 1 diabetes, may also contribute to weight gain (Salerno et al. 1997). The hormone leptin, produced by adiopocytes, is thought to provide feedback through the hypothalamic receptors to regulate satiety, appetite, and energy metabolism and therefore also to contribute to the pathogenesis of excessive weight gain. Female adolescents with diabetes are especially vulnerable to disordered eating patterns due to the cycle of weight loss at onset and subsequent weight gain with the initiation of insulin, trend towards higher body mass index and dietary changes necessitated by management of their disease (Battaglia et al. 2006; Daneman et al. 1998; Fairburn et al. 1991).

1:6:2 Psychosocial changes and adolescents with type 1 diabetes

Adolescents with chronic illness are forced to consider the psychosocial limitations resulting from their illness such as increased dependence on families and carers (Eiser, 1990), difficulties in formation of peer groups, as well as problems with management at school (Sawyer et al. 2003). Although many adolescents with chronic illness experience resilience in the face of psychosocial challenges (Olsson et al. 2003), adolescents with type 1 diabetes have a higher risk of longer term psychiatric morbidity compared to healthy controls (Northam et al. 2003).

Families play the key role in the adjustment of children to diabetes, to their level of care and to their specific management regimens (Guthrie et al. 2003) and increased parental involvement during early adolescence (10-15 years) has been shown to be associated with good adherence to self care activities (Anderson et al. 1997). A major aspect of adolescent development is increasing need for autonomy and control (Steinberg, 1990). The transfer of autonomy however brings challenges and potential conflict in the parent-adolescent relationship which has been found to impact upon diabetes management (Wysocki et al. 1996; Hauser et al. 1990; Anderson et al. 1990; Pendley et al. 2002; Schafer et al. 1986). Wysocki (2002) argued that complete autonomy in diabetes self-management is unrealistic and that pushing adolescents too hard toward autonomy in self care may actually impede their adoption of positive health values. Family relationships will also impact upon the adolescent's health and the associations between positive family behaviours and optimal diabetes health are well established in adolescents with diabetes (Lewin et al. 2006).

With the onset of adolescence, friends take on increasing importance and provide an important source of emotional support for young people with diabetes (La Greca et al. 1995). Adherence decisions made by adolescents have been found to be influenced by the adolescents' expectations, along with attributions of reactions they will receive from their friends if they follow their treatment regimens (Haines et al. 2006). It has been shown that adolescents become increasingly influenced by what they anticipate would be negative reactions or disapproval from friends in social situations that require adherence behaviours (Thomas et al. 1997). Similarly although adolescents

may be aware of potential health complications from poor adherence, they may still experience difficulty maintaining their regimen because they are apprehensive about being singled out by others (La Greca et al. 2002). Within a phenomenological study by Dickinson and O'Reilly (2004), adolescents with diabetes reported conflict with parental involvement, 'letting friends in', adjusting to living with diabetes, uncertainty about the future, ambivalence about self management, the feeling of being 'different' from the peer group and parental supervision of the self-care treatment plan.

According to Erikson's epigenetic model of development (Erikson 1950, cited in Dworetsky, 1995), adolescents strive for autonomy, ego identity (coming to terms with one's life), trust and initiative. An adolescent's sense of independence, body image, identity, sexuality, relationships, and self-esteem may thus be adversely affected by the development and treatment needs of type 1 diabetes. Self-image issues (e.g. clothes, dress and public behaviours) may be in conflict with the demands of the diabetes regime (such as the need for lunchtime injections and blood glucose monitoring). Insulin induced lipo-hypertrophy at injection sites has been identified as a frequent problem in young people with diabetes (Kordonouri et al. 2002), which may affect self image. A study of 88 adolescent girls by Maharaj et al. (2004) found that a high self concept in domains of perceived self attractiveness, social acceptance, good behavioural conduct and intimate friendships predicted good glycaemic control. Insulin pump use may affect body image and interfere with intimacy in adolescents (Weissberg-Benchell, 2003), although the negative consequences once associated with insulin pump use (Connis et al. 1989) are now less apparent within the literature.

A recent study reported few psychosocial problems with insulin pump use in adolescents (Fox et al. 2005).

The extent to which such development issues affect diabetes management will depend on the individual's motivation, coping, attitude and behaviour (Swift, 1997). It is however important to consider that psychosocial problems associated with development and diabetes are not inevitable. Jacobson et al. (1997) reported evidence from a 10 year longitudinal study that adolescents display remarkable resilience in the face of developmental and behavioural tasks with diabetes.

1:6:3 Cognitive changes and adolescents with type 1 diabetes

Adolescence is characterized by rapid transitions in cognitive processes of decision making, information processing and logical reasoning (Steinberg, 2006). This shift brings with it the start of formal operational thinking, allowing for the emergence of logical, hypothetical, and abstract reasoning abilities (Piaget & Inhelder, 1969). Cognitive changes during adolescence have implications for how the young person perceives the complexities of their disease as well as expectancies of threat. Developing cognitive skills in the middle stage, such as abstract thinking, allows the young person to fully realise the potential of the long term impact of type 1 diabetes, although increased adolescent egocentricism may create barriers between the young person and health care providers (Madsen et al. 2002).

As children enter into adolescence they become more competent at making their own decisions relating to everyday life (Lowes, 1996). This will influence how they

manage their condition. For example, the cognitive changes of adolescence make it more likely that adolescents will think differently about adherence behaviours than they did during childhood (Holmbeck, 2002). They are more able to solve problems relating to self management tasks compared to their non diabetic peers (Thomas et al. 1997). Furthermore, although developing cognitive abilities can enhance understanding of the complexities of the disease and its treatment, it can also leave adolescents vulnerable to greater worries about their disease and concern that its successful treatment may be beyond their reach (Madsen et al. 2002). Adolescents' beliefs about their illness (conceptualised as personal models of diabetes) change when young people are learning to take responsibility for their own diabetes management and are key factors influencing self-care, emotional well-being, and glycaemic control (Skinner and Hampson, 2001). The evidence from studies examining adolescent's personals models of diabetes demonstrate that it is the shorter term threat expectancies (beliefs about treatment effectiveness and the impact of diabetes) that predict well being and self care, rather than the longer term threats such as fear of complications (Skinner and Hampson, 1998; Skinner, John and Hampson 2000; Skinner and Hampson 2001; Edgar and Skinner, 2003). Adolescents with diabetes are less likely to report fear or worry about complications, describing complications as "*not being on their minds*" or as being "*in the future*" (Weinger et al. 2001). A study by Hanna and Guthrie (2000) found that adolescents with diabetes tend to ignore their vulnerability to the potential consequences of their disease in their age-appropriate pre-occupation with the present. Thus because adolescents live in the 'here-and-now', they may feel invulnerable to long-term complications. Given that health care professionals are known to use the threat of complications to motivate

improvement in self care (Edgar and Skinner, 2003) and that use of fear by professionals to promote self care has been identified as a reason for persistent non attendance by adults at diabetes out patient clinics (Lawson et al. 2005), the results suggest this style of interaction is counter-intuitive.

1:7 Glycaemic control and adolescents with type 1 diabetes

Clinical studies that have assessed the longer term clinical and psychological course of diabetes through adolescence and its relationship to glycaemic control, have demonstrated consistently poor outcomes (Bryden et al. 2001; DCCT, 1994). Several large studies have demonstrated that despite intensive management, young people have poor glycaemic control. An international cross sectional study in 17 countries examined the insulin regimens, glycaemic control and quality of life in 2,101 children and adolescents with type 1 diabetes (Mortensen for the Hvidøre Study Group, 2002). The mean HbA_{1c} of adolescents aged between 12-18 years was 8.7% ±1.7% (range 4.8-17.4). A key finding from the Hvidøre study was that there were no differences in glycaemic control treated with two, three, four or more insulin injections a day which suggested other factors were important in determining glycaemic control (Mortensen, 1998). Another study by Olsen et al. (1999) followed up 339 adolescents from previous studies undertaken in Denmark during 1987 and 1989. The mean age at follow up was 21.1 years. Despite receiving 3 or more daily insulin injections, the mean HbA_{1c} was 9.7% ±1.7% with a high prevalence of micro-vascular complications. A recently published follow up study DIABAUD 3 (Greene et al, for the Scottish study group for the care of the young with diabetes, 2006) investigated

changes in insulin regimen and effects on glycaemic control as follow up from the DIABAUD 2 study (2001). Nine hundred and eighty six children and adolescents aged between 1.1 -14.9 years were followed up in 9 out of 15 centres in Scotland. The mean HbA_{1c} was 9.2% ±1.5 (compared with 9.0% in DIABAUD 2) and only 9.7% achieved a target HbA_{1c} of < 7.5%. Intensified insulin regimen was not a significant predictor of HbA_{1c}. The authors concluded that glycaemic control remains poor and above the national target within Scotland.

Other teams have demonstrated that near normal glycaemia is a possibility in adolescents. Dorchy et al. (1997) reported mean HbA_{1c} levels of 6.6% ± 1.2% over a six month period in an unselected sample of 144 children and adolescents (mean age 11.8 years) using primarily two injections a day. The authors attributed some of the success to frequent blood glucose monitoring and high quality diabetes education. The study indicated that intensive insulin regimens are not the only key to improving control in adolescents with type 1 diabetes. Another study at the Glostrup centre in Denmark was successful in producing significant improvements in glycaemic control with children and adolescents (Dyrløv et al. 2000). Within a three year period, mean HbA_{1c} levels reduced from 9.4% to 8.5% following changes in the structure of education, increased psychological support, greater support in transition to adult services and reduced hospital admissions for ketoacidosis in children and adolescents. The study demonstrated that reductions in HbA_{1c} could be achieved with changes to the structure and process of treatment. Despite the impressive reductions in HbA_{1c} however, a mean HbA_{1c} of 8.5% remains suboptimal when referenced to the ISPAD (2000) and NICE (2004) guidelines.

The following sections will discuss the landmark Diabetes Control and Complications Trial (DCCT, 1993; 1994), which demonstrated the major impact that metabolic control has on the development and progression of micro-vascular complications in adolescents and young adults with diabetes. Firstly, brief attention is given to the DCCT (1993) study findings, followed by more detailed consideration of the findings relating to the adolescent cohort (DCCT, 1994). This is succeeded by outcomes from an observational follow up study of the DCCT [(Epidemiology of Diabetes Interventions and Complications (EDIC, 2003)]. Evidence from other smaller scale cross sectional and epidemiological studies are highlighted. Finally, aspects of self management behaviour in adolescents are considered in relation to adherence to the regimen impacting upon glycaemic control.

1:7:1 The Diabetes Control and Complications Trial (DCCT 1993; 1994).

It has been established that physiological, social and psychological factors make type 1 diabetes more difficult to control in adolescence than in younger children and adults (Wolfsdorf, 1999). The Diabetes Control and Complications Trial (DCCT, 1993; 1994) was a multi centre, longitudinal trial with dual aims; firstly prevention of complications associated with type 1 diabetes in adolescents and adults not yet experiencing them, and secondly, intervention with those whose disease had progressed. The (1993) study included 1,441 13 to 39 year olds within 29 medical centres in the US and Canada, over a mean period of 6.5 years. Participants were randomised to receive either intensive therapy comprising 3 or more insulin injections daily, along with support with self management or conventional therapy. The results

indicated a 2% glycaemic difference in HbA_{1c} between the intensive and conventional treatment groups (median level 7.3% versus 9.1% respectively) and that intensive management significantly reduced the risk of onset and progression of retinopathy and neuropathy (DCCT, 1993). Achievement of optimal glycaemic control proved difficult even with highly motivated patients who were monitored with intensive management, and only a minority of patients achieved the target value (HbA_{1c}<6. 5%), of which only 5% was able to maintain that level throughout the trial.

Recognizing the distinctive treatment-related characteristics of adolescents, DCCT researchers separately examined the effectiveness of the intervention in the adolescent cohort (ages 13 to 17 years at entry; DCCT, 1994). The participants comprised 14% of the combined DCCT sample. One hundred and ninety five adolescent participants, recruited by 29 diabetes centres, were randomly assigned to receive either (a) intensive therapy comprising 3 or more injections or external insulin pump together with frequent blood glucose monitoring and frequent psychosocial support from the multidisciplinary team or (b) conventional therapy with one or two insulin injections and once daily blood glucose monitoring. Participants were followed for an average of 7.4 years. Results indicated that, as in the combined sample, both the risk of the onset and progression of diabetic complications were significantly reduced in the adolescent intensive intervention group, compared to the conventional treatment group. The mean HbA_{1c} however in the intensively treated group remained on average 1% higher than the corresponding values in the adult participants, and few adolescents were able to consistently achieve and maintain target HbA_{1c} levels to normal plasma glucose values. A major obstacle to achieving strict targets of

glycaemic control were the three fold increase in frequency of hypoglycaemia in the intensively treated group (compared with the conventionally treated group and their adult counterparts), despite the adolescents' higher HbA_{1c} levels, younger age and shorter duration of illness. Even after becoming adults, intensively treated adolescents' HbA_{1c} levels remained higher than corresponding levels in adult participants. Few participants consistently achieved and maintained blood glucose values of < 6.5% HbA_{1c} levels. Achieving near-normal glycaemic levels proved to be difficult, although the DCCT researchers concluded that intensive treatment is currently the best option for adolescents with type 1 diabetes, the short-term increase in hypoglycaemia being offset by the demonstrated long-term health benefits of intensive treatment.

The psychosocial support offered to the intensive managed group implemented within the DCCT comprised monthly clinic visits, frequent telephone follow up and adjustment of the regimen by the multidisciplinary team involving diabetes nurses, mental health professionals, dieticians and diabetologists. Specifically this involved co-ordinated care that provided a problem solving model of working, insulin regimes tailored to the patient and based on multi-dose insulin algorithms, meal planning, psychological support by way of identifying barriers to improvement and telephone contact for emotional support. It has been documented however that the adolescents within the DCCT received a disproportionate share of the supportive care provided by the diabetes team (DCCT, 1994). Initial examination of the adolescent cohort demonstrated no significant differences in quality of life as measured by the diabetes quality of life for youths scale [(DQOLY) Ingersoll and Marrero, 1991]. Subsequent

retrospective analysis in quality of life by Madsen et al. (2002) demonstrated reduced satisfaction with school in the younger cohort (age 13-15 years) and greater psychological distress in the older cohort (age 15-17 years) within the intensive managed group. This study is described in Chapter 8 (section 8:5 p. 330).

What the DCCT study did not address was the question of what motivational variables predict long term control and how health care practitioners promote motivation in patients with diabetes. The question remains as to whether the success of the DCCT in improving patients' metabolic control was attributable primarily to the intensive insulin management, the intensive psychosocial support provided by the DCCT care teams, or a combination of both strategies. There is as yet no research to provide definitive answers to this question (Skinner and Hampson, 2001).

1:7:2 The Epidemiology of Diabetes Interventions and Complications study (EDIC, 2003)

The EDIC (2003) study was an observational exploration of the long term effects of the treatment received in the DCCT on HbA_{1c} and other treatment factors over a 10 year period (between 1993 and 2003).The sample comprised 1,375 of the original 1,441 patients in the DCCT, of which 175 of the original 195 were adolescents. After 10 years, statistically significant differences in HbA_{1c} persisted between the combined (adult and adolescent) intensively managed group and conventionally treated group, although the differences were much smaller than in the DCCT. After 4 years the adolescent group originally treated with intensive therapy had a similar mean HbA_{1c} to the former conventionally treated group (8.38% versus 8.45% respectively).

Despite the small differences in glycaemic control, within the adolescent cohort the prevalence of worsening and/or progression of micro-vascular complications were reduced significantly within the intensive therapy group. The overall conclusion was that these findings suggested that intensive treatment, even when it is not sustained, has a lasting beneficial effect on the development of, and delay in, micro-vascular complications. The study group suggested that intensive treatment therefore should be initiated as early as possible in patients with type 1 diabetes.

1:7:3 Cross sectional and epidemiological studies

The findings from the DCCT study are supported by other studies which have highlighted the relationship between optimal glycaemic control and prevention of early complications in adolescents with type 1 diabetes. A longitudinal study (Oxford Regional Prospective Study by Schultz et al. 1999) was carried out between 1985-1996, which examined the relationship between the development of micro-albuminuria (indicating early renal disease) and age, duration of diabetes and blood glucose control in 514 children. The findings indicated that onset of micro-albuminuria was associated with higher level of HbA_{1c} and younger age at diagnosis. The authors concluded that persistent micro-albuminuria over 2 years rendered the child at increased risk of renal damage in adolescence.

A cross sectional study by Holl et al. (1998) studied the relationship between age of onset, metabolic control and development of retinopathy in 441 adolescents (mean age 15.5 years). Higher HbA_{1c} values (median HbA_{1c} above 7.5%) were associated with prevalence of retinopathy. The risk was greater when children were diagnosed

before puberty. Another smaller scale retrospective study by Gorman, Sochett and Daneman (1999) examined data on 76 adolescents with type 1 diabetes studied over a 6 year period. The authors found a linear relationship between higher HbA_{1c} and risk of development and progression of micro-albuminuria in adolescents who had both micro-albuminuria and normal albuminuria at the start of the study. The authors concluded that poor metabolic control was a significant predictor of micro-albuminuria within the first decade of onset.

1:8 Self care and glycaemic control

The research consistently demonstrates that there is a worsening of metabolic control during adolescence and, although deterioration is partially attributable to physiological changes, the decline in self-care is believed to be of at least equal importance (Skinner and Hampson, 2001). In their attempt to cope with transition into adulthood adolescents with diabetes may struggle with feelings of ambivalence and may intentionally engage in health-compromising behaviours. Studies have demonstrated that adolescents with diabetes feel strained by the responsibility for self-care (Anderson, Auslander et al. 1990) and that the regimen restricts their daily activities (La Greca and Bearman, 2000). Rubin et al. (1990) identified key aspects of the diabetes regimen that pose adherence problems. These included; a) the continuous demands of injecting and finger testing, b) the unpleasantness of the regimen, c) the challenge of hypoglycaemic episodes with intensive management, d) adherence not always translating into optimal glucose control and freedom from immediate and long

term problems, and e) feeling different and isolated as a person potentially reducing motivation.

Self management with the diabetes regimen has been conceptualised in different ways within the literature (such that self care and adherence are often used interchangeably) and there is disagreement about what constitutes self care (Schilling et al. 2002). Given that a number of emotional, behavioural, and psychological factors have been associated with decline in self care, the following section will focus on the factors that have been shown to affect self care behaviours and subsequent adherence to the regimen (that directly or indirectly impact upon glycaemic control). Due to the voluminous literature relating to self management, a full review of the factors relating metabolic and psychosocial functioning is not warranted within this introductory chapter.

1:8:1 Adherence to treatment regimen

The term adherence has attracted much criticism within the literature due to the connotations with coercion and acquiescence. However for this thesis, adherence is considered within a young person's active commitment to self care and is defined as an active, intentional and responsible process of care, in which the individual works to maintain his or her health in close collaboration with health care professionals (Kyngäs, 1999). Adherence to the diabetes regime has been identified as a major challenge affecting the health of adolescents with diabetes. Evidence suggests that adherence to medical regimens in adolescents with diabetes decreases from childhood to adolescence (e.g. Anderson, Ho et al. 1997; Weissberg-Benchell et al. 1995). The

Diabetes Audit and Research in Tayside Scotland [(DARTS), Morris et al. 1998], found direct evidence of non-adherence with insulin therapy in adolescents with type 1 diabetes. The authors assessed the association between prescribed insulin and the amount dispensed in local pharmacies in 89 adolescents aged between 10-20 years (mean age 16 years) between 1993-1994. Twenty five (28%) out of the eighty nine participants obtained less insulin than their prescribed dose. There was a negative relationship between HbA_{1c} and adherence index (measured as an index of prescribed dose versus amount collected from pharmacies). The adherence index was also inversely related to hospital admissions for ketoacidosis and diabetes complications. The relationship between adherence and glycaemic control however is complex. A recent longitudinal study found a bi-directional relationship between glycaemic control and adherence behaviours in adolescents (Pasquier-Fediaevsky et al. 2005). Within this study, worsening of glycaemic control as a result of puberty preceded worsening of self care, whilst low levels of adherence become predictive of poorer HbA_{1c}, especially in late adolescence. The authors concluded that it is possible that deteriorating metabolic control during early adolescence because of pubertal factors, despite stable adherence and continued self-care, may seriously discourage adolescents' subsequent self-care behavioural efforts and lead to 'diabetes burn out' (a psychological condition characterized by chronic frustration and feelings of failure, which may negatively affect glycaemic control via the effects of stress and, indirectly, via the effects of distress on self-care behaviours).

More frequent assessment of blood glucose levels is a predictor of optimal glycaemic control in adolescents (Holmes et al. 2006) although it has been demonstrated that

adolescents monitor their blood glucose levels less frequently than younger children (Anderson, Ho et al. 1997). Invasiveness of blood glucose monitoring has been identified as a major barrier to blood glucose testing (Wagner, Malchoff and Abbott, 2005). Mollema et al. (2001) found that adults with type 1 diabetes who experienced both fear of self injecting and fear of blood glucose monitoring were less likely to adhere to the diabetes regimen and had poorer well being. The impressive results in achieving near normal HbA_{1c} levels in children and adolescents in a Belgian study (Dorchy et al. 1997) were partially attributed to increased frequency in blood glucose monitoring.

1:8:2 Social factors

While adolescents may desire independence from their parents, they are likely to not have the maturity to handle every aspect of diabetes management alone. Family cohesion (defined in the literature as support and affection) has been identified as a significant predictor of positive self management behaviour in adolescents with diabetes (Skinner and Hampson, 1998; Burroughs et al. 1997; McKelvey et al. 1993). Conversely negative interactions (such as criticism, blaming and coercive control) have been shown to lower adherence to diet, blood glucose testing and insulin administration both cross sectionally (Schafer et al. 1986) and longitudinally (Jacobson, Hauser et al. 1990). A family atmosphere that combines warmth, structure, parental involvement, and low conflict have emerged as the optimal environment conducive for achieving good glucose control during adolescence (Whittemore et al. 2002). Furthermore emotional support from peers has been shown to be associated with less depression in adolescents with diabetes (Skinner and Hampson, 2001). A

longitudinal study by Seiffke-Krenke and Stemmler (2003) on life stress, medical and psychological adaptation in adolescents with type 1 diabetes found that conflict with peers was the highest source of life stress for adolescents irrespective of metabolic control. The findings highlighted how the adolescent's social world via peers and family can support or negate illness management goals.

1:8:3 Psychological factors

The nature of the relationship between psychological functioning, self care and metabolic control is unclear, although several studies have documented the evidence of a relationship between psychological adaptation to diabetes, improved adherence with regimen and glycaemic control (Dorchy et al. 1997; Daviss et al. 1995; Lernmark et al. 1999). Adolescents however cope with the stress of diabetes in different ways. For example, maladaptive coping styles (e.g. behavioural and mental avoidance) in adolescents with diabetes has predicted poor adherence to the regimen (Hanson et al. 1989), while increased active coping is related to decreased HbA_{1c} (Graue et al. 2004). This represents a proverbial 'Catch 22' situation as adolescents who have poorer self care, are more likely to receive negative feedback from health care professionals (Kyngäs et al. 1998) and positive support from health care professionals has been identified as the most powerful predictor of adherence to the regime in adolescents with chronic illness (Kyngäs and Rissanen, 2001).

Adolescent girls with diabetes who intentionally engage in health-compromising behaviours such as smoking, alcohol and sexual intercourse may do so because of underlying stress, anxiety, peer pressure, or even depression (Leonard, 2003). Both

smoking and drug use have been associated with poorer metabolic control in type 1 diabetes (Haire-Joshu et al. 1999). The prevalence of depression is reported to be 18% in adolescents with type 1 diabetes, which ranges from two- to three-fold that of their peers without diabetes (Kokkonen and Kokkonen, 1995). Kovacs et al. (1997) followed 97 adolescents with type 1 diabetes post diagnosis and found that nearly half of the cohort experienced either depression or generalised anxiety disorders at 10 years. Depressive symptoms were highest 1 year after diagnosis. A recently published study demonstrated that depressive symptoms in adolescents with diabetes within the US were nearly double that of the highest estimate of depression in adolescents in general (Hood et al. 2006). Factors identified as responsible for depressive symptoms in adolescents within the literature include strict adherence to a daily regimen, fear of complications, controlling attitude of the parents, poor self-esteem and altered body image associated with having a chronic illness. Indeed depression in adolescents with diabetes has been associated with poor self care (Mazze et al. 1984) and poor glycaemic control (Whittemore et al. 2002). Moreover depressed adolescents with diabetes are at increased risk for hospitalization for acute complications such as ketoacidoisis (Stewart et al. 2005).

Adolescents with diabetes who are depressed are likely to have other co-morbid conditions, such as eating disorders (Vila et al. 1995). Eating disorders are almost twice as common in adolescent females with type 1 diabetes as in their non-diabetic peers (Jones et al. 2000) and insulin omission has been identified as the most common method of weight loss after dieting in a study of 356 adolescent females with type 1 diabetes (Jones et al. 2000). A longitudinal study in adolescents found significant

relationships between disordered eating during adolescence and omission of insulin to regulate weight and the prevalence of micro-vascular complications 8-12 years later (Peveler et al. 2005). The questionnaire used to assess the eating habits and attitudes of the participants was the Eating Disorder Examination (EDE) (Cooper et al. 1987). Lowes (personal communication, 2006) suggests this questionnaire addresses questions about abnormal attitudes towards diet and exercise which are integral to good daily self management (e.g. the scale measures the degree to which the adolescent avoids sugar foods and regulate their weight which is part of everyday management and not necessarily a signal of abnormal eating habits). Barber and Lowes (1998) argued that the link between eating disorders and adolescent diabetes is tenuous and called for increased awareness within diabetes care of the psychosocial issues concerning adolescents with co-existing diabetes and eating disorders.

The factors identified shed some light on the complex interrelatedness between self care, adherence, psychological health, family functioning and metabolic control in young people with type 1 diabetes. It has been argued that assessment of self-care behaviours relating to the domains of the diabetes regimen is extremely challenging with few easy to use scales with established psychometric properties (Weinger et al. 2005). Furthermore, little is known about self management of the diabetes regimen from the perspective of the adolescents themselves, such as what motivates them to take care of themselves (Dickinson and O'Reilly, 2004).

1:9 Conclusion

This chapter has explored the aetiology and incidence of type 1 diabetes in adolescence, the developmental challenges that adolescents face and the difficulties associated with management and optimal glycaemic control. The chapter has highlighted that type 1 diabetes interferes with every aspect of normal adolescent development and managing the disease represents a significant challenge for young people, their families and health care professionals. The DCCT study findings reinforced the importance of optimal glycaemic control, regular blood glucose monitoring and psychosocial support from the diabetes team concerning prevention of micro-vascular complications. The study also highlighted the challenges that adolescents face to reach target HbA_{1c} goals. Although the decline in metabolic control during adolescence is partly attributable to the physiological aspects of puberty, the research has indicated the critical impact of psychosocial influences on self care. Whatever the antecedents of risk and contributing factors, the adolescent faces a complicated multi component regimen that includes daily insulin administration, blood glucose monitoring, dietary considerations/restrictions and regular exercise. Achieving optimal glycaemic control remains a challenging problem.

The following chapter reviews the efficacy of psychosocial interventions in paediatric chronic illness and specifically with adolescents with type 1 diabetes. A review of educational and psychosocial interventions for adolescents with type 1 diabetes concluded that there was a need for more well designed trials of such interventions,

particularly in the UK healthcare context (Hampson et al. 2001). Motivational Interviewing [(MI) Miller and Rollnick, 1991; Miller and Rollnick, 2002] is a counselling approach to facilitate behaviour change that has been demonstrated to be effective in adults in some healthcare settings (Burke et al. 2003; Hettema et al. 2005). There is preliminary evidence of its effectiveness in facilitating reductions in HbA_{1c} and enhancing some aspects of psychological well-being in adolescents with type 1 diabetes in a short-term, uncontrolled trial (Channon, Smith and Gregory, 2003) on which this thesis is based. Following review of the efficacy of psychosocial interventions in paediatric chronic illness within the next chapter (Chapter 2), the succeeding chapter (Chapter 3) reviews the principles, process and efficacy of MI.

CONTENTS

2:1 Introduction

Chapter 1 highlighted the physical, psychosocial and long term impact of diabetes on the adolescent. The complex general developmental issues during adolescence have generated increased interest in the psychological aspects of paediatric chronic illness, and diabetes in particular (Bradley, 1994). In the past research on children with chronic illness tended to focus on the identification of risk factors for maladjustment. More recent research points to an increased recognition of the need to intervene, in order to provide psychological and emotional support for long term health (Northam et al. 2005; Skinner et al. 2001). However the current provision of psychosocial interventions for children and adolescents with chronic illness is sparse (Barlow et al. 1998; Beale, 2006; Hampson and Hampson, 2001) and there has been a call for interventions for young people that are distinct from those for adults (McCambridge and Strang, 2003). Addressing psychosocial issues in diabetes care is recognised as an important aspect of clinical practice (Channon et al. 2005; Snoek and Skinner, 2002), although a challenge lies in implementing interventions that target self management within paediatric teams with limited resources and time.

Although the number of studies demonstrating the efficacy of psychological interventions in children has increased, there is a dearth of recent systematic reviews and meta analysis in specific illnesses. It remains largely unclear how efficacious interventions are and for whom they work (Beale, 2006).

The aim of this chapter is to present a review of the literature in paediatric chronic illness which includes those groups of chronic conditions such as asthma, juvenile arthritis, cancer and type 1 diabetes. Special consideration will be given to the efficacy of psychosocial interventions in adolescents with type 1 diabetes. The pilot study of Channon et al. (2003) - which was instrumental in the design, implementation and dissemination of results on which this thesis is based - will be highlighted.

2:2 Psychosocial interventions and paediatric chronic illness

The particular health care needs of children and adolescents with chronic illness have spurred the development of psychosocial interventions that can help children and families cope with the burdens of their illness and subsequent self management (Plante et al. 2001; Delamater, Jacobson et al. 2001). Evaluations of the effectiveness of such interventions have emerged, although the theoretical, methodological, and practical difficulties associated with implementing this research are evident.

Given the variation in particular types of interventions studied, for the purposes of this section a broad definition of 'psychosocial intervention' has been operationalised. Educational interventions traditionally aim to teach disease-related skills and knowledge. Psychosocial interventions are more diverse and aim to provide training and support across cognitive, social, emotional and physiological domains. In practice these are frequently combined for the purpose of improving knowledge, skills and enhancing self efficacy. Included within this chapter are interventions which have

aimed to directly influence outcomes using the following techniques; cognitive – behavioural strategies, coping skills, self regulatory skills, relaxation, imagery and counselling. Studies which have been traditionally implemented as control group interventions (such as stand alone educational component and dietary counselling with no additional psychological component) have been omitted. Interventions directed only at parents and community based treatments have also been excluded.

Since 1990, there have been only a few reviews published on the effectiveness of various psychosocial treatment approaches in chronic illnesses in children and adolescents (Bauman et al. 1997; Kibby et al. 1998; Beale, 2006). The complexity of reviewing the literature is increased due to the variation in the effectiveness of interventions depending on disease type and severity and the wide variation in outcomes assessed. Moreover most intervention studies assess efficacy in terms of improved sequelae of disease as opposed to improving health psychological outcomes and self management behaviours (Kibby et al. 1998). Integrative reviews in psychosocial interventions and chronic illness will be considered in chronological order with emphasis on particular studies where relevant.

2:2:1 Reviews of studies

Although earlier reviews in paediatric chronic illness had been conducted during the 1980s, a review by Bauman et al. (1997) was the first to explore the psychological morbidity of children with chronic illness. The review studied the effectiveness of psychosocial interventions in children with chronic conditions (comprising asthma, epilepsy and cancer) on mental health and social burdens. Only fifteen studies were

identified out of a possible 266, since most failed to meet the criteria for inclusion. Ten of the fifteen studies (66%) were experimental designs, although none involved randomized controlled trials (RCTs). Of those studies that were included, the interventions comprised social skills training, peer counselling, psycho-education, coping and stress management. The results demonstrated positive outcomes in 10 of the 15 (66%) studies which included promoting self management in children with asthma, along with lastly re-integration of children within a school setting. Eleven of the studies demonstrated a positive effect on at least one psychosocial outcome. Overall the findings demonstrated that the interventions helped with the psychological and social burdens of chronic illness.

A meta analysis by Kibby et al. (1998) reviewed 42 studies implementing psychological interventions for children aged between 6-12 years with chronic medical conditions (excluding type 1 diabetes). It is not known how many of these studies were controlled designs, since the inclusion criteria for selection was stated as 'between groups' and 'within groups' designs. Studies were reviewed according to four outcome domains; disease management, emotional /behavioural problems, health promotion and lastly prevention. Thirty four percent of the studies included 1 year follow up analysis. The psychological components of the interventions were rarely specified, although broadly encompassed; cognitive - behavioural techniques, behaviour modification and didactic instruction. Interventions comprising cognitive - behavioural therapy components (such as behaviour modification, relaxation and biofeedback) were the most frequently used intervention approaches.

The overall effect size (ES) for psychological interventions was 1.12, demonstrating the overall benefit of psychological interventions in chronic illness. Interventions for disease management had a significant mean effect of 1.28, compared to an ES of 0.97 for interventions directed at emotional and behavioural outcomes. There were too few studies to identify outcomes in health promotion and prevention. Behavioural approaches produced similar effects for disease management (ES 1.20) and emotional/behavioural outcomes (ES 1.03).

Results from this meta-analysis demonstrated that psychological interventions for children with chronic medical conditions were effective and that improvements were maintained at 1 year follow up. Overall effectiveness was measured according to outcomes relating to the reduction of symptoms of disease and improvement in psychosocial adjustment. The results demonstrated that the behavioural components were equally effective for outcomes in disease management (such as reduction of pain) as well as management of procedure distress and psychosocial adjustment problems and the effects were highest in older females.

The most recent review of psychosocial interventions in children with chronic illness by Beale (2005) has demonstrated positive effects. The author evaluated interventions in chronic illness that comprised diabetes, cancer, cystic fibrosis and sickle cell disease. Studies were included that met the *Chambless criteria* (Chambless and Ollendick, 2001) by which specific types of intervention are designated a set of criteria; namely, "well established", "probably efficacious", "promising" or "experimental". These criteria facilitated valid comparisons between different studies

of particular interventions. The number of controlled studies was not specified and only two were experimental designs. The results demonstrated that overall psychological interventions were efficacious. Nineteen studies were included that incorporated a psycho-education component with combinations of skills training and information components compared with a control group. The author acknowledged the difficulty in conceptualizing and delineating the psychosocial interventions due to marked variability in the description and content of interventions offered. The mean ES for intervention groups was 0.71 compared to 0.12 in the control groups. There was no relation between ES and illness type. Outcome measures were not reported in the review and too few studies reporting individual treatment interventions were positive for specific illnesses and outcomes. The conclusion pointed to weak internal validity in regard to lack of monitoring of intervention, low sample sizes, lack of specificity of control groups, limited description of the intervention delivered and control of bias.

Although individual psychological interventions are the most common format for treatment in clinical settings, nearly half of all child and adolescent clinical treatment outcome studies have assessed the efficacy of treatments provided within a group context (Kazdin et al. 1990). Given their prominence, the next section will review the evidence of these group intervention studies.

2:2:2 Group interventions

Over the past two decades group interventions to provide psychological services to children with chronic illness have become increasingly popular (Plante et al. 2001). Group interventions for children and adolescents have been developed to increase knowledge of illness, to increase psychological adaptation and to decrease physical symptoms and side effects. There may be several reasons why group interventions are particularly beneficial for children with chronic illness. Poor social adjustment is a particular vulnerability for children with chronic illnesses (Harbeck-Weber and McKee, 1995) and interacting with peers dovetails with a child's developmental needs and typical social context (Schaefer, 1999). Groups also give participants opportunities for modelling, problem solving, helping others and relating to peers who share similar circumstances, all of which are more difficult to arrange through individual therapy (Plante et al. 2001).

A review by Plante et al. (2001) studied the efficacy of 125 studies using psychosocial group interventions in children with chronic illness. Studies were examined according to the Chambless and Ollendick (2001) criteria outlined in the Beale (2005) review. The number of randomised controlled designs was not specified and the authors reported variation in clinical populations and outcome measures that failed to meet the Chambless criteria. Group interventions were operationalised into four domains; coping/skills development, symptom reduction, psycho-education and emotional support. The outcomes from these group interventions will be considered in turn.

Fourteen studies on coping/skill development were evaluated in children with asthma, cancer and type 1 diabetes. The skills focused on improving family communication, social skills, problem solving and managing physical symptoms. Coping skills such as problem solving, stress management and behaviour change improved metabolic control and quality of life in adolescents with diabetes (Grey, Boland, Davidson et al. 1998; Grey, Boland et al. 2000). An additional component of instruction in relaxation and coping was effective in improving physical symptoms in children with asthma (Perrin et al. 1992). A cognitive-behavioural group approach to reduce anxiety and post traumatic stress disorder (PTSD) symptoms in children with cancer decreased anxiety and PTSD symptoms in all family members and improved family functioning (Kazak et al. 1999). Overall coping skills/adaptation groups that targeted coping and disease management demonstrated positive outcomes for adolescents with chronic conditions, although the authors concluded that additional studies regarding their efficacy are warranted.

Fifty nine studies reporting symptom reduction groups were reviewed for children with cystic fibrosis, diabetes, encopresis, headache and obesity. Although the number of studies and sample sizes varied by disease, taken together the symptom reduction groups were positive in improvement in patient knowledge, disease management and problem solving skills, as well as physical symptoms.

Four studies reporting psycho-educational groups were reviewed for children with asthma, HIV/AIDS and sickle cell disease. The outcomes were inconclusive due to variation in the methodological quality of the studies. Psycho-educational group interventions were however also examined as *control* interventions for children and adolescents with type 1 diabetes. When compared with behavioural family systems therapy (BFST) to reduce parent-adolescent conflict (Wysocki et al. 1999) and social learning group work over 3 weeks (Kaplan et al. 1985), the psycho-educational groups were equivalent to education-only groups in improving attitudes to the treatment regimen and were equivalent to BFST in reducing family conflict.

Twenty seven studies reporting emotional support groups were reviewed across a wide range of diseases that ranged from unstructured play to structured discussion groups. None of the studies met the Chambless criteria for validation and up to the date of this review, the authors stated that there were no well controlled studies of the psychological or physical impact of emotional support groups.

The authors concluded that group interventions were effective in addressing some of the challenges faced by children with chronic illness, as well as their families. The integrity of the research methodology however was varied. There were no controlled designs within the emotional support group studies and evaluation of psycho-educational groups was rare. Furthermore standardized measures to examine pre-post changes were absent from some studies. The symptom reduction groups demonstrated the most rigorous designs through standardised measures and randomised controlled studies. Although well established group interventions do exist, it is evident that more

work is required to establish the efficacy of group treatments for children and adolescents with chronic illness.

2:2:3 Overview of findings

Although psychosocial interventions have been found to be effective in improving outcomes, it remains unclear how useful the interventions are and for whom they are most efficacious. The reviews highlighted have focused predominantly on outcomes relating to disease management and adjustment to illness. Chronic illness however can pose immense psychological and social burdens on the child and family (Anderson, Freedland et al. 2001) and the prevalence of depression in adolescents with type 1 diabetes is well established (Hood et al. 2006; Snoek and Skinner, 2002; Northam et al. 2005). The research is lacking in interventions that target specific psychosocial outcomes and it is argued that measuring psychosocial outcomes may be a fairer evaluation of interventions that target self management behaviours. Although the Bauman et al. (1997) review specified mental health and social burden outcomes as the dependent variables, the outcomes were measured as more education and social factors such as promotion of knowledge and re-integration in school settings.

The studies highlighted across paediatric disease populations were generally weak in internal validity with little attention to the theoretical rationale for such techniques. Therefore it remains unanswered as to whether it was the content of the intervention, contact time of interventions or other unknown design factors that enhanced efficacy, making it difficult to consider the implications for research into clinical practice.

The interventions discussed within this section have focused on the psychosocial interventions in children with chronic illness with some reference to the research in children with type 1 diabetes. In addition to the psychological and social burden of chronic illness, children and their families encounter numerous challenges with adhering to complex regimes, following advice from health care providers and frequent hospitalisations. The next section will focus on the empirical literature on *adherence* within paediatric chronic illness. The efficacy of psychosocial interventions to address this problem will be examined.

2:3 Psychosocial interventions and adherence to treatment among children

Childhood conditions such as diabetes, asthma and chronic renal disease require complex management regimes which involve drug treatments, dietary restrictions and activity demands (Fielding and Duff, 1999). The regimen complexity associated with type 1 diabetes has been linked to poor adherence with treatment in adolescents (Greening et al. 2006), as well adherence to inhaler medication in children with asthma (Lemanek, 1990). Direct evidence of poor adherence to insulin was well documented in the Tayside, DARTS/MEMO collaboration study (Morris et al. 1998) highlighted in Chapter 1. Poor adherence in adolescence has been linked to severe fluctuations in metabolic control increasing the risk of longer term complications (Trigwell et al. 1997).

2:3:1 Barriers to adherence

Growing evidence suggests that average rates of adherence are less than 50% in young people with chronic illness and this is worse during adolescence (Rapoff, 1999). As described in Chapter 1, adherence to treatment in type 1 diabetes poses specific challenges for the young person because of the complexity and intensity of the regimen. Insulin injections are given up to 4 times a day and must be appropriately timed with meals. Regular exercise must be carefully co-ordinated with food intake to avoid hypoglycaemia, and regular blood testing of sugar levels needs to be carried out to enable changes in insulin, diet or other aspects of the regime that maintain blood glucose levels as near to normal as possible. Treatment regimes also mean disruptive patterns in family and school life due to attendance at out-patient clinics and hospitalisation.

There are very few studies identifying the barriers to adherence for children as many studies rely on self reporting anecdotal evidence from parents (Modi and Quittner, 2006). Disease knowledge, patient-provider communication and complex regimes have been identified as factors that affect adherence (Brown, 1999). The relationship with disease knowledge and adherence is unclear as most results from chronic illness populations are contradictory.

2:3:2 Psychosocial approaches to adherence

The psychosocial intervention approaches that have been utilised in facilitating adherence are traditionally based on techniques that incorporate social learning theory

(such as cognitive-behavioural therapy) and more recently self regulatory training (Fielding and Duff, 1999). The assumption underlying such approaches is that some behaviours (e.g. dietary habits) are difficult to change having been established over long periods of time and that lasting change is only possible by breaking down habitual behaviours and building up new patterns.

Programmes for chronically ill children (Fielding and Duff, 1999) have included:

- Self monitoring - such as documenting medication intake.
- Establishing control over stimuli that evoke habitual patterns of behaviour - such as tooth brushing and temptations for increased drinking in children on dialysis.
- Goal setting - such as frequency of glucose monitoring in diabetic children.
- Behavioural contracting - such as written agreements between physician and family members about what specific behaviours are required.
- Feedback and reinforcement - systematic encouragement or rewards for approximations to the desired goals.
- Self regulatory skills training - self control training such as self regulation of medication, planning, and problem solving skills, relapse prevention and attribution retraining.

The positive effects of behavioural modification contracts, such as rewards to increase adherence to treatment have been found to reduce hospital admissions in children with sickle cell disease [SCD] (Berkovitch et al. 1998). Further promising results of behavioural rewards were found by Stark et al. (2002) in improving daily calcium

intake in children with cystic fibrosis. Although the outcomes of individual studies have been largely effective in addressing the challenges that young people face with treatment adherence in chronic illness, there are only a handful of studies reported with a prominent absence of randomised controlled trials, systematic reviews and meta analyses. The efficacy of interventions will be explored in the next section.

2:3:3 Effectiveness of interventions

The only review examining the efficacy of interventions to improve adherence was by Rapoff (1999). Twenty seven studies were included of which 56% focused on adherence to regimens for asthma and type 1 diabetes. Most interventions implemented behavioural strategies using a token-reward system and education. The primary outcome was medication only in over half of the studies. Sample sizes ranged between 1-196 participants (median 10). The outcomes supported the use of behavioural strategies, combined with education. Eight out of the 27 studies measured concomitant changes in health status with adherence to medication. Only three of these eight studies showed clear improvements in disease outcomes, whereas three showed some improvements and two reported no improvements. The author concluded that further research is warranted into the strategies necessary for improving adherence in treating paediatric chronic illness.

A number of controlled studies have examined the effect of psychosocial interventions on adherence, mostly with the family as an integral part of the treatment (Delamater, Jacobson et al. 2001). A study by Satin et al. (1989) examined the effects of family group interventions on adolescent adherence and glycaemic control in 32

families. Adolescents within the group intervention that comprised 'stimulation of diabetes' (i.e. additional support such as positive reinforcement, supportive parental communication and behavioural contracts) displayed marked improvements in adherence to treatment and subsequent improvements in glycaemic control at 6 weeks and 6 months follow up. Similar findings have been documented in a study by Anderson, Brackett et al. (1999). However the only study to measure the child's perspective in the link between family factors and adherence to treatment was a longitudinal study by Jacobson et al. (1990). Within this study the child's perception of family conflict at baseline was the strongest predictor of poor adherence to insulin injections, blood glucose monitoring, exercise and dietary planning at 4 year follow up. The relationship between family factors and glycaemic control was not explored.

Although the above studies demonstrated the utility of short term psychosocial interventions on facilitating adherence to regimens, there are no documented studies that have highlighted the longer term effects of lifestyle changes (such as increased frequency of blood sugar testing, dietary changes and increased adherence to insulin) on outcomes. A preventative study by Stark, Janicke et al. (2005) was the first randomised controlled trial that used behavioural management interventions to improve calcium intake in children with juvenile rheumatoid arthritis (JRA) in order to improve bone mass density long term. A strength of this study was the attention paid to high internal validity such as training of the interventionists and close monitoring of the intervention. Forty nine children and their parents were educated about the importance of eating a high calcium diet. Behavioural strategies were implemented aimed at reducing the barriers to the implementation of high calcium

food intake and meeting the daily calcium intake (1500 mg) goals. These included rewards, contingency management problem solving skills and self-monitoring. The control group received dietary counselling about calcium intake without the behavioural component. The results were impressive. Children in the intervention group significantly increased their calcium intake and 92% reached the target goal of 1500mg calcium a day. These effects were maintained at 24 month follow up.

While the evidence suggests that there are some psychosocial interventions that can help children and families address the problem of adherence, criticisms are levelled at the method of the research. The child and adolescent's perspective regarding barriers to treatment is rarely studied and this is particularly important in adolescence when problems with adherence are at their greatest. Adherence research is still in its infancy (Modi and Quittner, 2006) and beset with methodological limitations (Fielding and Duff, 1999).

2:3:4 Overview of findings

Despite nearly three decades of research it has been argued that there are still very few strategies to help improve adherence (Rapoff, 2001). Although there are many factors in determining adherence to treatment, the concept has often been identified as a unitary one within the literature (Johnson, 1993) with adherence to regimes measured as a single composite score and children identified as 'compliant' or 'non compliant'. This is problematic given the multifaceted nature of adherence problems in children (Fielding and Duff, 1999). Some researchers have argued for less emphasis on research into adherence suggesting it is 'a dysfunctional concept' since it

implies specific identification of problems (i.e. blaming) and non collaborative relationships between patient, their family and health care provider (Glasgow and Anderson, 1999). Within the diabetes literature there is an increasing emphasis on 'collaborative self management' which reflects the philosophical shift to shared care, instead of a traditional compliance based medical model approach (Funnell and Anderson, 2004).

2:4 Psychosocial interventions in adults with type 1 and type 2 diabetes

2:4:1 Introduction

The review thus far has identified the research into psychosocial factors in paediatric chronic disease management. The aim of this section is to review the evidence of psychosocial interventions in adults with type 1 and type 2 diabetes. Considering the rapidly increasing number of adult patients with diabetes (mostly type 2), and the growing public health burden of diabetes, the development and clinical implementation of effective interventions are paramount (Delamater, Jacobson et al. 2001). Challenges facing patients with type 2 diabetes include achievement of tight metabolic control, adherence to lifestyle changes and adapting to an often complex regime. Studies in type 1 and type 2 diabetes have found increasing rates of depression and poor metabolic control (Anderson, Freedland et al. 2001).

A number of studies have highlighted the relationship between psychosocial factors and higher mortality. Davis et al. (1988) for example, identified psychosocial factors (associated with socio-economic status, smoking and complexity of diet regimen) as

the strongest predictors of mortality in patients with type 2 diabetes, greater than many clinical and physiological variables such as previous heart attacks and high metabolic control. A number of cohort studies have indicated that socioeconomic variables are related to overall mortality even after adjusting for the presence of other long-term complications such as renal disease (Moy et al. 1990; Robinson et al. 1998). Another study by Laing et al. (2005) indicated that psychosocial factors (smoking, lack of family support, and low social class) were the most powerful risk factors for mortality from acute events in young adults with type 1 diabetes, although not for mortality from chronic conditions. The authors argued for identification of this high risk group, suitable for targeting with preventive measures, to reduce acute event mortality.

2:4:2 Reviews of studies

A number of systematic reviews and meta analyses have demonstrated the benefits of psychosocial interventions in a wide range of clinical outcomes with adults (Steed, et al. 2003; Norris et al. 2001; Griffin et al.1999; Brown, 1999). A number of individual studies implementing a wide range of psychological interventions have been implemented with positive outcomes (e.g. Clarke and Hampson, 2001; Anderson, Funnell et al. 1995; Williams et al. 1998). However due to the diversity of psychological interventions implemented, for this chapter, only reviews and meta analyses will be considered.

Over the past decade interventions have shifted from the educational didactic approach to those that involve patient participation according to an 'empowerment'

model. In many studies, both are conceptualized under the umbrella of psychosocial interventions. The reviews that are discussed next include the most recent in psychosocial interventions and outcomes relating to improvements in glycaemic control (Norris, Lau et al. 2002), psychosocial functioning (Steed et al. 2003) and improvements in glycaemic control from controlled trials only (Ellis et al. 2004). Two recent Cochrane Reviews that examined the evidence of psychosocial interventions and outcomes in type 2 diabetes (Deakin et al. 2005 and Vermeire et al. 2005) are also considered.

2:4:3 Outcomes of reviews

A meta analysis by Norris et al. (2002) examined the efficacy of interventions targeting diabetes self management education (DSME) on HbA_{1c} in adults with type 2 diabetes. Thirty one studies were included. DSME was classified as providing knowledge and information, techniques that target lifestyle behaviours, skills to improve metabolic control and 'empowerment' techniques such as relaxation and enhancing self efficacy. The results provided evidence of the efficacy of DSME on reducing HbA_{1c}. over 1 year. Glycosylated haemoglobin decreased by 0.76% within the intervention groups, compared to a decrease of 0.26% in the controls. Therapist contact time was a significant predictor of decrease in metabolic control, with 23 hours of therapist time related to 1% absolute decrease in HbA_{1c}.

Glasgow and Osteen (1992) argued that it was important to measure more than the traditional outcomes relating to glycaemic control in diabetes research. Since then the number of studies implementing interventions that target psychosocial outcomes have

increased. Steed et al. (2003) reviewed educational, self management and psychological interventions in adults with type 1 and type 2 diabetes aimed at improving psychosocial outcomes defined as psychological well being, quality of life, depression, anxiety and emotional adjustment. A strength of this review was the attention to the 'black box' of the components of interventions that improved outcomes, and the impact of individual interventions on psychological well being and quality of life. Thirty six studies were reviewed, of which 23 (64%) were controlled trials. The mean age of participants was between 24-70 years. Most interventions were group based. The review undertook a descriptive rather than a traditional meta analytic approach and thus no effect sizes for outcomes were computed. The main components of the self management interventions were education, skills training, empowerment training, telephone support, blood glucose awareness training and behavioural therapy. Education was provided in 75% of the self management interventions, while behavioural therapy comprised 57% of interventions. Cognitive therapy was present in 71% of the psychological interventions. It should be noted that there was considerable overlap of components between the self management and psychological interventions.

Overall the results were promising. The impact of interventions on quality of life was beneficial, particularly when a diabetes specific measure was used. Out of the three interventions, self management interventions had the greatest impact. Even so the extent to which the interventions improved outcomes in well being were inconclusive, with RCT designs reporting improvements in anxiety, whilst pre-post trials reported negative results. The authors pointed to the weak internal validity of studies and poor

description of the intervention components involved. It therefore remains unclear exactly what comprised the intervention and which components had an efficacious effect.

A meta analysis was undertaken by Ellis et al. (2004) evaluating the effectiveness of education interventions to improve glycaemic control in adults with type 1 and type 2 diabetes. A feature of this review was the inclusion of RCTs only, and the reliance on a systematic taxonomy for classifying components of the intervention. Additional advantages included scrutiny of contact time, adequacy of control groups and specific components of interventions that were effective. Although the interventions were conceptualised within the review as education, on closer inspection they comprised key psychosocial and psychological components. The interventions included goal setting, problem solving, cognitive reframing, and a variety of teaching methods such as blood glucose awareness training. Outcome was measured by post intervention HbA_{1c}. Overall, the results demonstrated reductions in HbA_{1c} of 0.29% at 12 weeks follow up. At 24 weeks HbA_{1c} reduced further by 0.49% and this figure levelled off at 52 weeks (0.33%). The overall net % change in HbA_{1c} within the intervention groups was 0.32. Given the linear relationship between HbA_{1c} and micro-vascular complications [for every 1% decrease in HbA_{1c} there is a subsequent 25% reduction in risk of complications (UK Prospective Diabetes Study, 1998)] this result represents a modest improvement in glycaemic control. The interventions most efficacious in improving glycaemic control were face to face delivery, cognitive reframing and education that provided an exercise component. A key feature of this review was the subsequent improvement in HbA_{1c} in the control groups from baseline. It was

reported that the control groups had additional support with health care services, and 40% of the control groups received an equal 'dose' of educational interventions of up to 3 sessions. It therefore remains difficult to rule out alternative explanations when evaluating the efficacy of these studies.

Two recent Cochrane Collaboration systematic reviews on psychosocial interventions on outcomes in patients with type 2 diabetes produced conflicting results. Deakin et al. (2005) reviewed the effects of group based patient centred interventions on glycaemic control and psychosocial outcomes. The review included 11 RCTs and controlled trials that evaluated these interventions compared with routine treatment. The results demonstrated that the group interventions were effective in reducing mean HbA_{1c} at 12-14 months by <0.8%, and at 2 years follow up by <1.0%. Fasting blood sugar levels were reduced at 12 months and there was a significant reduction in body mass at 12-14 months. The patients also decreased their need for medication.

Conversely, Vermeire et al. (2005) reviewed the evidence of psychosocial interventions for improving adherence to treatment with type 2 diabetes. Twenty one studies were reviewed from RCTs and controlled trials that measured adherence to medication. The results were inconclusive due to the heterogeneity in study designs, outcome measures and clinical settings. The question remains unanswered how interventions can improve treatment adherence in adults with type 2 diabetes.

2:4:4 Overview of the findings

The evidence demonstrates that psychosocial factors play an integral role in the lifestyle management of diabetes in adults. Interventions that targeted improvements in regimen adherence, glycaemic control, psychosocial functioning and quality of life were overall effective. The reviews however highlighted methodological weaknesses, particularly in relation to internal validity. Studies typically reported sample sizes of less than 30 participants per intervention arm and the content of interventions was rarely disclosed. Moreover the components of interventions overlapped according to how they were described and different interventions were conceptualized as 'educational', 'self management' or 'psychological'. Contact time was rarely controlled and follow up interventions were relatively short. The longer term effects of the intervention were rarely examined. Further research is required to examine the effectiveness of these findings and how these effects translate into clinical practice 'in the real world'.

The challenges that adults with diabetes face with poor glycaemic control, adherence, and psychological morbidity are evident in adolescents with type 1 diabetes. Research consistently demonstrates that there is a marked worsening of glycaemic control during adolescence (Hoey, Mortensen et al. for the Hvidøre Study Group, 1999) and they are the cohort least likely to carry out effective self management (Skinner and Hampson, 2001). The next section will review research studies in psychosocial interventions in adolescents with type 1 diabetes.

2:5 Psychosocial interventions and adolescents with type 1 diabetes

2:5:1 Introduction

Although a number of controlled studies have demonstrated the efficacy of individual psychosocial interventions for adolescents with diabetes, the research has largely been piecemeal [(Hampson, Skinner et al. 2001) Health Technology Assessment HTA]. Systematic reviews and meta analyses conducted over the previous two decades highlighted beneficial effects, although the results pointed to methodological weaknesses within individual studies (Brown, 1992). The only recent systematic review to be conducted which exclusively evaluated the effects of educational and psychosocial interventions on diabetes self management for adolescents was by Hampson, Skinner et al. (2001). The aim of this section is to review the efficacy of interventions in adolescents. The Hampson et al. (2001) review will be considered in depth due to its prominence in evaluating psychosocial interventions. Other recent work is considered and grouped into three areas; a) group based interventions, b) those specifically targeting family based interventions, c) innovative technological approaches.

2:5:2 Review of Hampson et al. (2001)

Sixty seven studies were reviewed of which 41% comprised randomised controlled trials (RCTs). Effect sizes were calculated for 14 studies. Outcomes included measures of glycaemic control (measured as HbA_{1c}) and psychosocial measures which included measures of self efficacy for diabetes management, family

functioning, social skills and quality of life. The mean age within the reviews was 12.7 years and the interventions were operationalised broadly as any intervention that aimed to change diabetes knowledge and behaviour. The studies reported on a range of interventions used, ranging from changing the insulin regimen, a nurse giving injections, to family therapy. Other approaches included more intensive management (CSII pumps), planned admissions to hospital and cognitive behaviour therapy.

Overall the results of the systematic review indicated that educational and psychosocial interventions have small to medium effects on various diabetes management outcomes. Specifically the mean effect size (ES) for HbA_{1c} was 0.33 (95% CI -0.04-0.70). Regarding the clinical significance of this outcome, Hampson et al. (2001) reported that this effect size equates to a change of just over one half of a percent in HbA_{1c} (0.60%). However, the effect size for psychosocial outcome was slightly larger at 0.37 (95% CI 0.19-0.55). Explanations for these results pointed to the time line impacting upon outcomes. Psychosocial interventions are designed to have direct short term impacts upon self management and indirect effects upon metabolic control. Changes in glycaemic control are expected to occur over the longer term after psychological and behavioural changes have impacted upon glycaemic control.

The review indicated numerous methodological shortcomings in the literature. There were no RCTs of psychosocial or educational interventions for adolescents with type 1 diabetes conducted within the UK. Only one half of the interventions (52%) were theoretically guided and of those that specified theoretical principles most used family

therapy and behavioural principles. More than half of the studies reported less than 40 participants. Studies were unclear about the location and modes of delivery of interventions, although of those reported, most took place in out patient settings and were delivered by nurses. Most of the studies used skills training (38.7%), dietary interventions (19.4%) and psychosocial components (17.7%). Over one-half of the studies (62.9%) used HbA_{1c} as an outcome measure, although it has been argued in the diabetes literature that it is more appropriate to evaluate interventions according to the behaviours it is designed to impact upon (Glasgow and Osteen 1992; Glasgow, Vogt and Boles, 1999).

The authors further identified that 33% of the studies used psychosocial outcome measures and these included measures of self efficacy for diabetes management, family functioning, social skills and quality of life. Specific diabetes management behaviours such as adherence to diet and exercise were rarely assessed. Long term follow up assessments were relatively rare. Sample sizes were typically small and rarely based on power analyses. The effects of ethnicity and socioeconomic status were not examined, and cost-effectiveness issues were not addressed. Only a relatively small number of interventions were reported in sufficient detail to permit the calculation of effect sizes. The review indicated that these interventions were effective in the short-term and that theoretically based interventions were more effective than atheoretical interventions. Overall the review pointed to the paucity of well developed theoretically driven controlled trials that target a developmental phase such as different disease stage and different types of management problem. Since this

review, psycho-educational interventions for adolescents have increased in frequency and in both theoretical and empirical rigour (Skinner et al. 2005).

The next section will focus on the efficacy of psychosocial interventions in adolescents based on; a) group work, b) family interventions, and c) innovative technological approaches.

2:5:3 Group based interventions

Psychosocial interventions offered through groups have received increased prominence in research with adolescents. Advantages of group over individual counselling include obtaining emotional support from people with similar experiences and being able to use the experiences of others as a role model (van der Ven, 2003). Although the evidence of group interventions suggest improvements in psychological functioning, the outcomes in improvements in HbA_{1c} are contradictory. Some studies have demonstrated marked improvements (Misuraca, et al. 1996; Kaplan et al. 1985) and others no change (Gross et al. 1983; Boardway et al. 1993). For purpose of clarity within this chapter group interventions are classified as; a) peer support, b) coping skills training, and c) team work interventions.

a) Peer support groups. Research findings have shown that peer group support and problem-solving have improved short-term glycaemic control (Anderson, Wolf et al. 1989; Kaplan et al. 1985). One study that emphasized the positive aspects of peer support through a structured intervention on adjustment to illness was by Greco et al. (2001). Using a simple pre-post design, 21 adolescents (mean ages 13.1 years) and

their best friends were offered groups that included listening skills, problem solving (with a focus on support from their friends) and education. Groups comprised 10 female and 11 male pairs. Groups met for four weekly 2-hour sessions. Positive outcomes included high attendance, high self worth amongst peers, higher ratio of peer to family support and increased knowledge. The study emphasized the positive aspect of peer support in helping adolescents adjust to their illness.

To date, no controlled studies have examined the impact of peer support on adolescents' diabetes care regimen. One RCT however by Anderson, Wolf et al. (1989) demonstrated the positive impact of a peer group intervention on reductions in HbA_{1c}. Adolescents were randomly assigned to a group intervention based on problem solving and self monitoring of blood glucose (SMBG) in out patient clinics or conventional care in clinic. At 18 months, 50% of the sample within the conventional treatment group demonstrated a 1% increase in their mean HbA_{1c}, compared to 23% within the intervention group. The authors concluded that clinic-based problem-solving groups were more effective than conventional care in preventing deterioration in glycaemic control.

b) Coping skills groups. Group coping skills training has been shown to help optimize glycaemic control and quality of life for adolescents involved in intensive insulin regimens (Boland et al. 1999). In addition stress management and coping skills training has reduced diabetes-related stress (Boardway et al. 1993) and has improved social interaction in adolescents (Mendez and Belendez 1997). Two particular RCTs based on coping skills training (CST) have demonstrated dramatic improvements in

glycaemic control and self management, both in the short term and longer term. The first was delivered by Grey, Boland, Davidson et al. (1998). They evaluated the impact of a CST intervention as an adjunct for adolescents starting intensive insulin regimens, either multiple daily injections or continuous subcutaneous insulin infusion compared with intensive management alone. The aim of the intervention was to increase adolescents' sense of competence and mastery by giving training in positive coping skills for the stresses arising from intensive management. Specifically the intervention taught social problem solving, cognitive-behaviour techniques and conflict resolution skills using scenarios the adolescents generated as causing problems for intensive management. A professional educator was used for the first few group sessions and then trained adolescents with diabetes to complete the groups. The results demonstrated improved glycaemic control and psychological outcomes in the short term. Within the intervention group mean HbA_{1c} reduced from 9.1% at baseline to 7.9% at 3 months. The study was replicated by Grey, Boland, Davidson et al. (2000) to examine the sustained effects of the CST over 12 months. At 12 months follow up HbA_{1c} reduced by 1.2% within the intervention group. There were also gains in self efficacy and a reduction in perceived negative impact in diabetes related quality of life. The authors identified the challenges with the design. The intervention was designed for adolescents on intensive insulin regimens (e.g. those adolescents on injections of insulin up to 4 times daily), so although it may be a useful adjunct to the process of starting adolescents on intensive regimens, it may also restrict the applicability of this intervention to all adolescents with diabetes (i.e. those on 2 injections a day). Furthermore, although there were significant reductions in HbA_{1c} within the intervention group, there were also reductions within the control group, and

it remains to be examined which aspect of the interventions facilitated change. The positive outcomes warrant further examination.

c) Team work interventions. Over the past decade there has been an increase in interventions to promote parental involvement and support for self management with diabetes. These have taken the form of promoting parent-adolescent teamwork to improve aspects of self care. Team work interventions typically focus on the importance of shared responsibility and conflict resolution through written material, discussion and negotiating responsibility-sharing. They are appropriate for families for whom group based or other therapeutic approaches are appropriate or desirable. Anderson, Brackett et al. (1999) conducted the first controlled teamwork intervention in 85 adolescents aged between 10-15 years. Participants were allocated to a teamwork group, attention control or standard care. The intervention lasted 1 year and was assessed by glycaemic control, diabetes conflict and diabetes family behaviour scales at 12 months and 24 months. The results demonstrated no differences in HbA_{1c} at 12 months although significant reductions in HbA_{1c} in the intervention group at 24 months follow up. More notable were improvements for the intervention group in family conflict, more supportive family behaviour and increased responsibility for adherence to regimes. The comparison and standard care groups both showed deterioration in responsibility for treatment management. An encouraging finding of this study is that increasing responsibility in management of diabetes did not lead to an increase in family conflict. When this study was replicated by Laffell, Vangsness et al. (2003) with a larger number of families (105 children with mean age of 12 years), without the attention control group, the intervention reduced glycaemic control

at 12 months. No differences were found in improvements in quality of life or reductions in family conflict. The teamwork approach has since been modified by a research team within the UK [(Families, Adolescents and Children's Teamwork Study FACTS) Murphy, Wadham et al. 2006] to include coping skills training. The intervention group demonstrated reductions in HbA_{1c} of 0.26% compared to an increase of 0.26% in the control group after two sessions. A strength of this approach is its practical utility in integrating a relatively short but effective intervention in routine diabetes clinics.

2:5:4 Family based interventions

Research findings indicate that family-based behavioural programmes such as goal-setting, self-monitoring, positive reinforcement and behavioural contracts have improved regimen adherence and glycaemic control (Wysocki et al. 2000). One research group has attempted to intervene in family work by using behavioural family systems therapy (BFST) - a flexible, multi-component, family-focused intervention that targets family communication and problem solving, extreme beliefs of parents and adolescents that impede communication, and systemic barriers to problem solving (Wysocki et al. 2000). The authors conducted a RCT with 115 families of adolescents with type 1 diabetes. Ten sessions of BFST were compared with education and support group or conventional treatment with insulin over a 3-month period. The psychologists involved used standard behaviour therapy techniques of instruction, feedback, modelling, and rehearsal along with behavioural homework (i.e. encouraging families to practice targeted skills at home). The results indicated that the BFST intervention facilitated lasting improvements in parent–adolescent relationships

and family communication skills as measured by parent and adolescent report and by direct observation of structured family interactions. Conversely, BFST did not enhance treatment adherence or facilitate reductions in glycaemic control.

More recently, Wysocki et al. (2006) conducted a RCT that implemented a revised BFST intervention tailored for diabetes (BFST-D). One hundred and four families were randomly assigned to either the BFST-D group, educational support (ES) or standard care. Contact time was controlled by all participants receiving 12 sessions of 'allocated intervention' over 6 months. The BFST-D intervention was modified to include additional components such as enhanced training in behavioural contracting, advanced education in self monitoring of blood glucose training, parental simulation of diabetes (parents were required to 'live with' diabetes) and involvement of peers, teachers and significant others in the intervention. The results indicated dramatic reductions in HbA_{1c} within the BFST-D group (reduction of 1.3% at 6 months) although this was not an effect for the sample as a whole. Intervention effects were much more pronounced for adolescents with HbA_{1C} above 9.0%. It is important to note that the BFST-D and ES interventions had comparable reductions in HbA_{1C}, both of which had greater effects than standard care. This finding supports the positive impact of non specific factors such as education and support on glycaemic control. Contrary to the RCT conducted in 2000 (Wysocki et al. 2000), the BFST-D group increased their adherence to diabetes treatment, possibly reflecting the increased focus on cognitive restructuring and building skills to overcome barriers to self management that directly affect adherence and glycaemic control (Drotar, 2006).

An application of intensive home based BFST-D with poorly controlled adolescents did not find positive effects on family conflict or glycaemic control (Harris and Mertlich, 2003). Important questions relating to the internal validity of the study however remain unanswered. Drotar (2006) for example argued that although information relating to the fidelity of the intervention was reported, the implementation of diabetes specific components were not described, which included extension of the intervention to social networks. Moreover, it was not clear to what extent adolescents and their families adhered to the BFST-D protocol.

The family-based behavioural programmes described are relatively complex interventions with multiple components. In terms of clinical applicability, it remains to be studied how the BFST-D intervention can be effectively translated into clinical practice in the same way that the team work interventions model described earlier has shown.

2:5:5 Innovative technological approaches

The literature has seen a growth in innovative technological programmes targeting diabetes self management. Howells et al. (2002) explored this approach in the first randomized controlled trial to use negotiated telephone support (NTS). Seventy nine young participants ranging in age between 12-24 years were randomized into three groups; a) intervention (NTS) group which involved collaboration and active instruction in problem solving, b) routine care control which involved 3 monthly out patient follow ups and 'trouble shooting advice,' and c) a group who received care annually. NTS involved using regular telephone calls every 2 – 3 weeks designed to

provide structured counselling in using problem-solving steps. These included defining the problem, setting a realistic goal for change, brainstorming/generation of likely solutions, deciding which solution to try, plan, act and review. Participants were given autonomy to choose the subject area of the call. They were informed that diabetes management did not have to be a focus for discussion, and the calls were not used to feedback HbA_{1c} results.

The results demonstrated that although the intervention groups showed improvements in self-efficacy this was not matched by improvements in glycaemic control. Process analysis indicated that structured counselling was effective in overcoming barriers to self care and insulin use and that these were strong predictors of reduced HbA_{1c}.This suggests that using this approach to focus on issues related to diabetes management, as well as other non-diabetes issues, may be needed to show an effect on metabolic outcomes. This study also highlighted that contact time was potentially more beneficial than content. The frequency and duration of calls appeared to be more important for enhancing self efficacy than the actual content of the talks.

A recently published RCT by Franklin et al. (2006) demonstrated the utility of a novel motivational support intervention using text messaging in improving physiological and psychological outcomes in Tayside, Scotland. One hundred and twenty six children aged between 8-18 years were randomized to three groups; text messaging support service ('*Sweet Talk*') and intensive therapy (3 or more injections daily or continuous subcutaneous insulin infusion [CSII], plus regular blood glucose monitoring); '*Sweet Talk*' and conventional therapy (2 injections daily), or

conventional therapy alone. '*Sweet Talk*' was based on a unique text-messaging system designed to deliver individually targeted messages and general diabetes information. The aims were to improve self efficacy, adherence to the insulin regime and glycaemic control through regular prompts and messages. The intervention was successful in improving self efficacy and adherence in all 3 groups and glycaemic control improved in the intensive management group.

2:5:6 Overview of findings

Although psychosocial interventions demonstrated small to medium beneficial effects in metabolic and psychological outcomes, the research to date still leaves unanswered important questions regarding what works, how it works and for what disease stage. Indeed it has been argued that progress to date in the quality and quantity of educational research has not resulted in improved effectiveness of interventions (Murphy, Rayman et al. 2006). The key weaknesses are related to weak internal validity, since very few studies described the components of the intervention delivered and lacked clear descriptions of the interventionists' training. Two recent reviews on psychosocial interventions and type 1 diabetes (Winkley et al. 2006; Murphy, Rayman et al. 2006), conducted since commencement of the present study, are reviewed in Chapter 12, section 12:3 (p. 403). Tables 1(a) and 1(b) provide a summary of the psychosocial intervention studies and their outcomes in adolescent diabetes.

Table 1a : Summary of psychosocial intervention studies in adolescent diabetes (continued in Table 1b)

	Study design	Sample size and age range	Intervention	Results	Standardised effect size (Confidence interval)
Generic psychosocial interventions					
Anderson, Brackett et al. (1999)	RCT	n=85. Ages 10-15 years.	Teamwork	↑parental involvement (p<0.03). No differences in HbA1C	-0.47 (-0.98-0.04)
Laffel et al. (2003)	RCT	n=105. Ages between 10-16 years.	Teamwork	↓HbA1c (p=0.04)	0.50 (No CI reported)
Svoren et al. (2003)	RCT	n=299. Ages 7-16 years.	Teamwork + care ambassador	↓HbA1c in poorly controlled (p=0.002)	No effect size reported
Cook et al. (2002)	RCT	n=53. Ages 13-17 years.	Problem solving + education	No differences in HbA1C between the two groups.	0.19 (No CI reported)
Couper et al. (1999)	Non randomised	n=60. Ages between 11-17 years.	Home visits, diabetes self management.	No differences in HbA1C between the two groups. ↑ in diabetes knowledge.	No effect size reported
Group interventions					
Greco et al. (2001)	Non randomised.	n=21. Ages between 10-16 years	Problem solving, education and peer support.	↑ attendance, ↑ family support and knowledge. No effect on HbA1C.	No effect size reported
Grey et al. (1998)	RCT	n=65. Ages between 12-20 years	Coping Skills Training problem solving, CBT, conflict resolution skills.	↓HbA1c by 1% (p<0.001)	No effect size reported
Grey et al. (2000)	RCT	n=77. Ages between 12-20 years	Coping Skills Training problem solving, CBT, conflict resolution skills.	↓HbA1c by 1.2% (p<0.001)	-0.67 (-1.14-0.20)
Anderson, Wolf et al. (1989)	RCT	n=65. Ages between 14-17 years.	Peer group intervention and SMBG	↑parental involvement ↑peer support and perception of diabetes	No effect size reported

CBT=Cognitive Behaviour Therapy

Table 1b : Summary of psychosocial intervention studies in adolescent diabetes (continued from Table 1a)

	Study design	Sample size and age range	Intervention	Results	Standardised effect size (Confidence interval)
Family based interventions					
Wysocki et al. (2000)	RCT	n= 115 families	Behavioural family systems therapy (BFST)	↑ parent-adolescent relationships. No reductions in HbA1c.	-0.76 (-1.10-0.42)
Satin et al. (1989)	RCT	n=32 families	Multi family intervention + parental simulation of diabetes	↓HbA1c ($p<0.001$) Positive perceptions of diabetes	-1.20 (-2.14 -0.25)
Motivational Interviewing					
Channon et al. (2003)	Non randomised/pilot	n=22 14-17 years	Principles of MI	↓HbA1c ($p<0.05$)	No effect size reported
Viner et al. (2003)	Non randomised/pilot	n=77 14-17 years.	Hybrid MI and solution focused therapy.	↓HbA1c ($p<0.05$)	No effect size reported
Technological interventions					
Liesenfeldt et al. (2000)	Non randomised	n=61. Ages between 10-26 years.	Telemedicine/ individual telephone support. Data monitoring at home.	↓HbA1c ($p<0.05$)	No effect size reported
Howells et al. (2002)	RCT	n=79 Ages between 12-24 years	Negotiated telephone support	↑ self efficacy ($p=0.03$) although ↑ in HbA1c ($p<0.01$)	No effect size reported

MI= Motivational Interviewing

2:5:7 Rationale for exploring Motivational Interviewing (MI)

The Hampson et al. (2001) review highlighted the need for well designed interventions that implement strategies to improve glycaemic control and psychosocial functioning in adolescents with type 1 diabetes. Motivational Interviewing [(MI) Miller and Rollnick, 1991; Miller and Rollnick, 2002] is identified as a promising intervention for working with adolescents, although there are only a few well designed studies that have implemented the method with young people (Baer and Peterson, 2002). A pilot study by Channon et al. (2003) provided the first preliminary data on the efficacy of motivational interviewing on the wellbeing of adolescents with diabetes and paved the way for implementing the method within this study. This pilot study will be discussed in depth within the next chapter

The cognitive, emotional and social challenges that adolescents with type 1 diabetes face were deemed suitable to be explored within an MI intervention. Although it has been suggested that nearly all barriers to effective self care lie in the individual's personal and social world (Skinner, 2004), little research has examined what barriers exist and how they influence patterns of self care. Implementing an MI intervention for adolescents with diabetes seems to make sense as there is an intuitive fit between the central tenets of MI (such as rapport building, directive responding and empathy) and the adolescent need for autonomy (Channon et al. 2005). This is central to the recommendations of the National Standards for Diabetes Self-Management Education Task Force (2000) that young people should be offered support to empower and enable them to take control of their diabetes. A major step in engaging adolescents in

care is to gain their trust and the 'spirit' of collaboration and conveying of respect is particularly appealing in engaging young people. Differences in perspectives between health care provider and adolescent may become problematic when patients do not meet the goals and expectations (e.g. achieving optimal weight and glycaemic control). Misconceptions and perceived miscommunication between health care provider and young person can often reflect conflicts in the adolescent's world (Skinner and Cradock, 2001). The emphasis on addressing concerns through personal choice and decision making within MI can help the adolescent cope with the 'dilemmas' of change.

A key feature of motivational interviewing techniques is that they are consistent with the developmental stage of adolescence. The young person is in charge of behaviour change, selecting their own goals and the process by which they are achieved. This reflects the adolescent's emerging independence in self-care. This is particularly important when the adolescent feels there is a threat to personal freedom which may generate lowered motivation. The concept of ambivalence is central to MI and in clinical practice ambivalence presents as one of the key issues in adolescence (Channon et al. 2005). Although many young people are resilient and experience no problems with diabetes, there will be just as many who will have a turbulent time trying to achieve optimal glycaemic control. Although no literature on the concept of ambivalence with adolescents exists, it is evident that adolescents face difficult challenges with achieving optimal glycaemic control which will have a knock on effect on motivation. Striving to achieve and maintain blood glucose as close to normal as possible can often be too high a goal and unachievable, thereby affecting

self confidence, optimism and morale. Anderson et al. (1999) argued that adolescents need to be involved in the goal-setting process right from the beginning of their treatment, even if this means that initially goals are set at lower than normative levels. It follows, therefore, that allowing adolescents to explore their perceptions about management of diabetes seems a worthy research goal.

In summary, in order to appreciate the dilemmas young people face and to understand the decisions they make, it is arguably important to understand and explore their frame of reference for their diabetes management. From a clinical standpoint with the well established link between poor glycaemic control in adolescence and later complications (DCCT, 1994), there is a need for interventions that implement strategies to improve glycaemic control.

Motivational Interviewing was considered to be an effective and flexible counselling intervention to implement within this study in which adolescents could explore and resolve issues around behaviour change. The following chapter will explore the principles of MI, its efficacy and adaptations within the health behaviour field.

CONTENTS

3:1 Motivational Interviewing (MI)

Motivational interviewing (MI) is a directive client-centred counselling style, which aims to encourage reflection on behaviour change, in the context of personal values and goals (Miller and Rollnick, 2002). It is defined as a "*client-centred, directive method for enhancing intrinsic motivation to change by exploring and resolving ambivalence about behaviour change*" (Miller and Rollnick, 2002: p.25). Motivational interviewing is highly influenced by the work of Carl Rogers (1967), which suggests that when the critical conditions of empathy, positive regard and genuineness are combined in therapy, a client can naturally change in a healthy positive way.

3:1:1 Background

Motivational interviewing was originally developed within the context of treatment of alcohol problems by William Miller (1983). Miller observed that in traditional alcoholism treatment, it was common for therapists and clients to fall into disagreement over the nature and extent of the client's problems, which in turn led to increased client resistance. Traditional treatment approaches at this time viewed lack of client motivation to inner maladaptive defence mechanisms such as 'denial' and 'resistance'. Motivational interviewing was elaborated by Miller and Rollnick (1991) and it was proposed that instead of arguing with clients about behaviour change, counsellors would be more effective if they developed a client centred approach that elicited arguments for change from the client themselves. Thus client's responses were understood as a function of the relationship and are in turn influenced by how

the counsellor responds to the client. The concept of readiness to change (Prochaska and DiClemente, 1984) in guiding practitioners to avoid resistance was introduced in 1991, which served to complement MI in facilitating change. By 1995, Rollnick and Miller addressed the essential 'spirit' of the approach to differentiate it from other interventions with which it may be confused and the formal definition was offered around this time. More recent adaptations and applications to other health related behaviours have been developed which emphasise negotiation as central to dealing with the concept of ambivalence with respect to health behaviour change (Rollnick et al. 1999). Motivation to change is derived from the client's own values and goals and the creation of an environment through empathy facilitates contradictory thoughts and feelings to be explored and resolved (Miller and Rollnick, 2002).

3:1:3 Principles and techniques

Rollnick and Miller (1995) distinguish between the 'spirit' of MI and specific principles. Within the spirit of MI, readiness to change is seen not as a personality trait but a 'fluctuating product of interpersonal interaction' and motivation to change is viewed as something which is elicited from the patient, rather than imposed. The spirit of MI is divided into three components: collaboration, evocation and autonomy (Miller and Rollnick 2002: p.34-25). These components will be outlined in turn.

1) Collaboration refers to a partnership that provides an atmosphere that is conducive to change through exploration and support rather than coercion. A strong principle of this approach is that conflict is unhelpful and that a collaborative relationship between therapist and patient, in which they tackle the problem together, is essential.

2) Evocation describes the process of the practitioner eliciting the individual's goals, thoughts and feelings about behaviour change, rather than providing information as to how and what they should feel about change.

3) Autonomy refers to respect for the client's decision making. The therapist takes a non powerful position which emphasises the patient's autonomy and right to choose whether to accept and make use of the therapist's knowledge and skills.

The central principles upon which MI is based are:

- Express empathy
- Develop discrepancy
- Roll with resistance
- Support self efficacy

These principles are explained in the following ways (Miller and Rollnick, 2002). Empathy is expressed through reflective listening. An empathic style is fundamental to MI and the underlying attitude must be one of acceptance. Within this empathic style it is the practitioner's task to create and amplify any discrepancy between the patient's present behaviour and important goals, so that the patient presents the arguments for change. Developing discrepancy refers to raising the client's awareness regarding the perceived differences between their current situation and their hopes for the future. Developing awareness helps clients examine their behaviour. Particularly in the event of discomfort, it is therapeutic for the therapist not to present arguments

for change. It is the client that voices commitment to change and where confrontation is apparent through denying, arguing or blaming, the counsellor is encouraged to come alongside using empathic listening. Rolling with resistance is the approach taken to avoid confrontation. Where resistance is encountered in forms of arguing, blaming, interrupting, denying or ignoring, it signals that techniques and style have not been successful and a new perspective is necessary. Involvement in argument with the client is viewed as counter-productive and attempts are made to understand a patient's reluctance to change. It is important not to directly confront resistance and risk eliciting an argumentative style of responding from the client. Rolling with resistance involves a switch of direction, allowing the client to take the conversation elsewhere. Supporting self efficacy is a crucial component of the method and is achieved by helping the client recognise their strengths and past successes, along with social comparison of the success of others. The fundamental principle is that the client has self belief that he or she can carry out the desired change.

3:1:4 Specific skills in MI

In MI there is a specific emphasis on certain forms of speech (Miller and Rollnick, 2005). Along with the spirit and guiding principles of the method, the practitioner uses a number of skills to encourage the production of patient 'change talk' (patient talk about how and why they might change their behaviour). Change talk generally involves talk about the disadvantages of the current situation, the positive aspects of change, confidence in one's ability to change and the client's desire to change (Miller and Rollnick, 2002; Miller and Rollnick 2005). This is accomplished through seeking permission to talk about the behaviour, assessing a client's readiness to change,

asking open ended questions, affirming change talk, offering summaries and reflective listening statements. The therapist seeks to elicit and strengthen change talk (also referred to as self motivational statements) and by doing so evokes motivation from the client. Miller (2003: p.32) argued that the rationale for eliciting change talk is that "*the client literally talks him or herself into change*"

3:2 Adaptations of Motivational Interviewing

Many of the interventions to date in the MI field have been based on adaptations of MI (AMIs) and are not 'pure' MI as defined by Miller and Rollnick (1991; 2002). AMIs were developed from the demand for a less time consuming and more cost effective method, that required less practitioner training and could be applied in a variety of healthcare settings with diverse populations. Adaptations within the MI field include; Brief Interventions (typically the Drinker's Check- Up or DCU for problem drinkers, Miller, Sovereign and Krege, 1988; Miller and Sovereign, 1989); Motivational Enhancement Therapy (MET) Project MATCH Research group (1997; 1998); Brief Motivational Interviewing (BMI, Rollnick, Heather and Bell, 1992; Stott, Rees et al. 1996; Rollnick, Butler and Stott, 1997) and Behaviour Change Counselling (BCC, Rollnick et al. 1999).

The differences between the methods are described. Brief Interventions in the form of the Drinker's Check-Up (DCU) is an assessment based method which involves a comprehensive overview of the client's drinking patterns, followed by feedback within a client centred style of responding. This feedback, based on the severity of target symptoms on a standardized measure, is delivered within the spirit of MI and

behaviour change is elicited from the client and not imposed (Burke, Dunn et al. 2004). Motivational Enhancement Therapy [(MET) Project MATCH, 1997; 1998)] is an adaptation of MI incorporating typically four sessions of structured assessment, personalized feedback and follow-up interviews to facilitate treatment outcome evaluation. The core components of MI include; practitioner empathy, respect for differences, enhancing self efficacy, emphasising autonomy and directiveness. MET was one of the three interventions developed for Project MATCH. Brief Motivational Interviewing (BMI) consists of a set of strategies from a 'menu of strategies' which follow the spirit and techniques of MI (Rollnick et al. 1992). They are designed for use in single forty minute sessions in health care settings with emphasis on structure, readiness to change, global assessments of importance and confidence in change, goal setting and negotiation.

With the above proliferation of names, a recent position paper by Rollnick, Allison et al. (2002) proposed a simple framework for distinguishing between three interventions, a) brief advice, b) behaviour change counselling (BCC) and c) MI. The study reported in this thesis leaned quite strongly on BCC and its content and style will be considered below.

3:2:1 Behaviour Change Counselling (Rollnick, Mason, and Butler 1999)

Behaviour Change Counselling (BCC) is a method of consulting with patients about lifestyle change, which draws on the skills of MI. The method is often labelled as MI, although the techniques are somewhat different in nature. Table 1 summarises the

similarities and differences between MI and BCC according to the context, goals and style (adapted from Miller and Rollnick, 2002: p. 274).

Table 2: The similarities and differences between MI and BCC in terms of their context, goals and style

	Behaviour Change Counselling	Motivational Interviewing
Context		
Session Time	5-30 minutes	30-60 minutes
Setting	Opportunistic or help-seeking	Mostly help seeking
Goals		
	▫ Demonstrate respect ▫ Communicate risk ▫ Establish rapport ▫ Identify client goals ▫ Exchange information ▫ Choose strategies based on client readiness ▫ Build motivation for change	BCC goals, plus: ▫ Develop relationship ▫ Resolve ambivalence ▫ Develop discrepancy ▫ Elicit commitment to change
Style		
Practitioner-recipient	Counsellor – active expert	Leading partner – partner
Confront/challenge	Seldom	Never
Empathic style	Usually	Always
Information	Exchanged	Exchanged to develop discrepancy

The main difference between the two methods is the *intention of the practitioner*, rather than the skills themselves, and it is this difference that essentially makes BCC a separate construct from MI (Rollnick et al. 1999). Behaviour change counselling draws on many of the skills common to MI, but it differs in the way that those skills are used.

3:3 Efficacy of Motivational Interviewing

3:3:1 Reviews of MI

The reviews included within this section are those conducted up to and including 2002 and therefore prior to the commencement of the study which this thesis examines. More recent reviews of MI which post date the study are included in Chapter 12 (section 12:3:2). Due to the large number of studies within the MI field, the research findings will be considered according to key reviews and individual studies in chronological order.

The first multi centre randomised controlled trial (RCT) to evaluate three different interventions as a stand alone treatment for alcohol problems was Project MATCH (1997; 1998). One thousand, seven hundred and twenty six alcohol dependent participants were randomly assigned to one of three outpatient treatments: Motivational Enhancement Therapy (MET), Twelve Step Facilitation (TSF), or Cognitive Behavioural Coping Skills Training (CSBT). No support was found for the different treatment responses in comparing CSBT, MET and TSF. The MET intervention worked as well as, although no more efficacious than, the other two interventions. All three interventions led to reduced frequency in drinking patterns. Angry patients did better in MET and those who lacked social support for abstinence improved on measures following the TSF. A key aspect of this study was the high attention paid to methodological rigour, treatment integrity, follow-up retention, and data monitoring, all of which enhanced the generalisability and external validity of the findings (Miller, 2005).

The first review of MI was undertaken by Noonan and Moyers (1997). The authors reviewed 11 studies of AMIs for addictive behaviours (nine with problem drinkers and two with drug problems). Nine of these studies supported the efficacy of AMIs. One particular study by Senft et al. (1997) reported positive effects on drinking behaviours at 6 months following a relatively brief 15 minute AMI within a GP setting. The authors reported that there were several methodological factors apparent on inspection of the individual studies within this review. Many of the studies used a Drinker's Check-Up (Miller and Sovereign, 1989) type of MI intervention with structured feedback and self help manuals. Within one study many MI practitioners were involved in delivering the intervention over a short space of time (Kuchipudi et al. 1990). Some studies (Kuchipudi et al. 1990; Richmond et al. 1995) delivered an intervention that did not fit with an MI style of responding. The conclusion reported was that although MI appeared to be efficacious, there were important interaction effects of MI that were unexplored, with variation in effect sizes across studies.

Two systematic reviews (Dunn et al. 2001; Burke, Arkowitz et al. 2002) found positive effect sizes (0.33 and above) for studies delivering MI in substance misuse although the results were less conclusive for areas relating to health behaviour change such as smoking, diet, exercise and treatment adherence. Since there were no studies implementing 'pure' MI as defined by Miller and Rollnick (1991; 2002) all the studies evaluated within these reviews were AMIs. These reviews will be considered in turn.

Dunn et al. (2001) conducted a systematic review of brief interventions adapted from MI. Twenty nine studies were reviewed (17 in substance abuse, 2 in smoking cessation, 4 in HIV risk reduction and 6 in diet/exercise studies) and effect sizes were computed. The authors found that eleven AMI studies conducted in the substance abuse field showed significant effect sizes. The most effective studies in this field were those that incorporated MI into a treatment plan by conducting MI sessions with patients before they received usual care. The two studies in smoking cessation produced mixed effects. A study by Butler et al. (1999) compared the efficacy of brief MI with brief advice on smoking cessation within a GP practice and found a small but significant effect (effect size 0.23). The other study by Colby et al. (1998) examined the effect of MI on smoking cessation in adolescents treated in Accident and Emergency Department and found no significant effects. Baker et al. (1993; Baker et al. 1994) found MI to be effective in HIV risk prevention in injecting drug users by increasing condom use and reducing unprotected sex, but was not effective in reducing HIV risk by reductions in injecting or engagement in safe sex practice. There were not enough studies in the fields of smoking and diet and exercise to generalise, although increase in uptake of exercise was one outcome that emerged from the small scale studies. The study with the largest effect was by Berg-Smith et al. (1997). Twenty two overweight women with type 2 diabetes received either a weight loss programme or weight loss with an additional MI intervention. The MI intervention was successful in enhancing treatment adherence to the program and improved glycaemic control (although had no effect on weight loss) among the participants. Dunn et al. (2001) concluded that findings from the review supported the use of MI as a method of brief intervention in the context of substance abuse, particularly as an

adjunct to more intensive treatment. The authors pointed to the lack of attention to internal validity of studies, particularly level of training, duration of MI treatment and MI skill proficiency necessary for effectiveness.

Burke et al. (2002) conducted a systematic review of twenty-six randomised controlled trials of AMIs. The review comprised 11 studies in alcohol problems, 10 in the fields of smoking, drug addiction, HIV and risk behaviours and treatment adherence and 5 studies in diet, exercise and health behaviour. The greatest support for AMIs was in the treatment of alcohol problems. When used as a stand alone treatment compared to no treatment controls, the AMI intervention demonstrated improvements in drinking patterns at short term (6 weeks) and longer term follow up (3 years). When compared to alternative treatments the AMI demonstrated equal although not significantly better results (e.g. Project Match research group, 1997). When compared however to a briefer alternative, the AMI demonstrated positive outcomes at 6 months (Monti et al. 1999). The efficacy of AMIs in the longer term was mixed. Marlatt et al. (1998) reported positive outcomes at 4 years follow up while Monti et al. (1999) found no effects at 12 months follow up following a 40 minute AMI session in the Accident and Emergency department. The conclusions drawn by Burke et al. (2002) were that AMIs for alcohol problems yielded positive results within only a few sessions and most of the studies were methodologically robust with reliable and precise outcomes measures enhancing the generalisability of the results.

There was mixed support for AMIs in cigarette smoking. For example, studies examining the use of AMI in encouraging patients to reduce and/or quit smoking by

Colby et al. (1998) and Butler et al. (1999) observed no significant differences in smoking levels between those who received the AMI intervention compared to those who received brief advice. Colby et al. (1998) compared 5 minutes of brief advice to a 30 minute AMI for adolescent smokers. There were no significant differences between the two treatment groups although there were decreases in smoking dependence and the number of days smoked within the AMI group. Similarly Butler et al. (1999) compared brief advice with MI in 21 GP practices. There were no significant differences between the two groups in the number of cigarettes smoked and quit attempts. At 6 months however, the patients in the MI group had reduced their smoking in the previous 24 hours, made an attempt at quitting within the previous week and reported being in a more advanced stage of change.

Five studies were evaluated in the treatment of drug addiction and the outcomes were varied. Four out of five studies were delivered as a prelude to further treatment. Studies that were compared with briefer alternatives (such as education or a short pre-admission interview) demonstrated positive outcomes (Martino et al. 2000; Saunders et al. 1995). When AMI was used as a stand alone and compared to 14 sessions of intensive group cognitive behavioural therapy, there were no significant differences between the two treatments. Both groups however showed significant reductions in participant's marijuana use and dependence following both interventions (Stephens et al. 2000).

Just ten studies covered other health behaviours such as treatment adherence, smoking, HIV risk behaviours, diet and exercise, and the authors argued this made

conclusions about the efficacy of AMIs to produce changes in behaviour difficult to evaluate. Studies into treatment adherence (Martino et al. 2000; Swanson et al. 1999) indicated that implementation of an AMI as an adjunct to an in patient treatment programme may have beneficial effects on adherence to some aspects of treatment for psychiatric disorders. Two studies of HIV risk prevention (Baker et al. 1993, Baker et al. 1994) demonstrated no significant effects of MI on the reduction of needle sharing behaviours and the practice of unsafe sex.

Four studies were published on AMIs to promote lifestyle changes in diet and exercise which produced mixed results. Mhurchu et al. (1998) investigated an AMI intervention as a stand alone and compared with brief dietary advice intervention for patients with hyperlipidaemia. Neither intervention led to reductions in serum cholesterol. Three studies delivered an AMI as an adjunct with other treatments for patients with type 2 diabetes, hyperlipidaemia, hypertension, (Berg-Smith et al. 1997; Harland et al. 1999, and Woollard et al. 1995). The study by Berg-Smith et al. demonstrated the largest effect size (1.09). Twenty two overweight women with type 2 diabetes received a 16 week behavioural weight control intervention. When an AMI was added to a behavioural weight control intervention, patients showed significant reductions in blood glucose control and better adherence to diet and exercise activities. Harland et al. (1999) found little effect of a 6 week AMI to increase physical activity in middle age adults. Woollard et al. (1995) found mixed results following 6 sessions of an AMI compared with telephone call contact for patients with hypertension. A control group received usual care. Patients assigned to the AMI group demonstrated reductions in weight and blood pressure, although increases in

physical activity and reduction in smoking were apparent. Burke et al. (2002) concluded that AMIs appeared to be efficacious as an adjunct to usual medical care although the evidence is mixed.

3:3:2 Summary of the reviews

The outcomes from the Burke et al. (2002) and Dunn et al. (2001) reviews underscored the utility of AMIs as promising interventions for behaviour change, particularly in the alcohol and drug use field. Overall the AMIs were superior to no treatment or placebo control groups and were equal to comparison treatments. There was a paucity of research into other health behaviours, such as smoking, diet and exercise, which made conclusions about the efficacy of AMIs in promoting lifestyle change difficult to evaluate. Miller (2001) proposed that an AMI may *amplify* the effect of other treatments when it is used as an adjunct. Key conclusions from both reviews pointed to the methodological weaknesses within the research particularly the weak internal validity. Issues relating to internal validity are discussed in the next section.

3:3:3 Validity issues and Motivational Interviewing

Internal validity refers to the ability of the research design to rule out alternative explanations of the results. This involves treatment fidelity (such as how closely the intervention adhered to a manual for MI), treatment integrity through monitoring and training, supervision, quality audit, adequacy of the control group and elimination of bias (Burke et al. 2002). Within the studies reviewed by Burke et al. (2002), most failed to report exactly how MI was delivered to patients and provided little detail

regarding their adaptation. Further criticisms pointed to lack of treatment integrity by monitoring of training, paucity of supervision, poor quality audit of therapists and lack of specification of independent variables. Little detail of the training programmes provided to practitioners was given in most of the studies included in the review. Dunn et al. (2001) concluded that this made it difficult to establish the effects of training duration, content and format on the skill level of practitioners. These threats to internal validity weakened valid conclusions and comparisons about the efficacy of MI and subsequently the reviewers argued it was difficult to establish 'how' MI worked, what specific MI intervention worked best and for which population (Burke et al. 2001; Dunn et al. 2001).

Burke et al. (2002) made a number of recommendations for future studies of MI or AMIs, which included a clear description of the MI intervention under study and careful assessment of treatment fidelity and integrity. This fits in with the UK Medical Research Council (MRC, 2000) framework for the development and evaluation of complex health care interventions. The MRC proposed that complex interventions should involve clear identification of the main components or 'active ingredients' of the intervention. One of the key points from this framework was that "*it is essential to clarify as far as possible the important components.... so that readers of eventual trial results can infer from results what elements were essential and what was secondary or unimportant in producing a beneficial effect*" (p.7). This represents an important step in outlining the processes involved in the development and delivery of an intervention such as MI within RCTs.

3:3:4 Evidence of Behaviour Change Counselling (BCC)

Due to the recent development of BCC there are very few documented studies examining its effectiveness. One recent RCT that delivered a brief session of BCC demonstrated change in adolescent risk behaviour (Johnston et al. 2002). Six hundred and thirty one adolescents aged between 12 -20 years were randomly assigned to receive either BCC or standard Accident and Emergency Department (A&E) care. The aim was to examine whether a brief session of BCC offered to injured adolescents whilst undergoing treatment in A&E would reduce the risk of re-injury and injury risk behaviours. These behaviours were identified as adherence to seatbelt use, uptake of bicycle helmet use, reduction in driving after drinking, reduction in riding with an impaired driver, reduction of binge drinking or carrying a weapon. Participants within the intervention group underwent a brief session of BCC with a social worker. Participants were followed up at 3 and 6 months. The authors found that BCC conducted with injured adolescents led to a positive and sustained change in seatbelt and bicycle helmet use, although did not impact upon changes in other risk behaviours. The likelihood of positive behaviour change with respect to uptake of seatbelt use among those receiving the intervention was 47% greater than among participants in the control group.

3:4 Motivational Interviewing and adolescents with type 1 diabetes

To date there are only a few well designed studies that have implemented MI with young people (Baer and Peterson, 2002). As with MI in adult populations, the studies conducted have been AMIs, with lack of specificity of the nature of the intervention

delivered, and interventions typically compared to a 'no treatment' or 'standard treatment' group. Monti et al. (1999) delivered an AMI (consisting of feedback, therapeutic style of empathy, developing discrepancy and self efficacy) to adolescents and young adults with risk taking behaviour. The MI was efficacious in reducing alcohol related injuries and problems in the older age group (age 17-21 years) although had no impact on the teenagers (age 13-17 years). Other studies in which an AMI has proved effective have been by Colby et al. (1998) in smoking cessation and Berg –Smith et al. (1999) in adherence to dietary goals. Despite the positive outcomes, the results need to be treated with caution due to low sample sizes and lack of comparison groups (Baer and Peterson, 2002).

Lawendowski (1998) delivered MET with adolescents abusing drug substances and found that a single session of MET consisting of feedback of test results (measure of respiratory function), negotiation of goals, brief advice and follow up interview, led to reductions in use of substances and increase in treatment attendance. The results however are contradictory. Brown et al. (2003) studied the effects of motivational interviewing on smoking cessation in adolescents age 13-17 years with co-existing psychiatric disorders. MI consisted of two 45 minute individual sessions and was compared to brief advice (BA). MI did not lead to better smoking outcomes compared to BA. MI was more effective than BA for increasing self efficacy regarding ability to quit smoking thus highlighting the benefits of MI.

The first study to examine the effects of MI in adolescents with type 1 diabetes was by Channon et al. (2003). This small pilot study provided the first preliminary data on

the efficacy of motivational interviewing on the wellbeing and self-care of adolescents with the disease and provided the rationale for the present study, using a multi centre, randomised controlled study design. Due to its pivotal relationship in the design and delivery of the present study which this thesis examines, it will be explored in detail below.

3:4:1 Pilot Study of Channon, Smith and Gregory (2003)

The pilot study examined the impact of motivational interviewing on glycaemic control, wellbeing, and self-care of adolescents with type 1 diabetes. Twenty two patients aged 14–18 years, with a diagnosis of at least one year, participated in motivational interviewing sessions during a six month intervention. Data collected at baseline included HbA_{1c}, and psychosocial questionnaires namely: Diabetes Readiness to Change Questionnaire [(DRCQ), adapted from Prochaska and DiClemente 1984]; Summary of Diabetes Self Care Activities [(SDSC) Toobert and Glasgow, 1994]; Diabetes Knowledge Scale [(DKN), Dunn et al. 1984]; Well Being Questionnaire[(WBQ), Bradley, 1994]; Diabetes Family Behaviour Scale [(DFBS), McKelvey et al. 1993]; Child Health Locus of Control [(CHLC) Parcel and Meyer, 1978], Personal Models of Diabetes Questionnaire [(PMDQ) Hampson et al. 1995] and Family Adaptability and Cohesion Evaluation Scale [(FACES III) Olson, 1986). Respondents were divided into one of three groups based on their scores on the DRCQ. Pre-contemplator responses indicated that they were not ready to make any changes to their diabetes self-care. Maintainers' responses indicated that they were maintaining their diabetes self-care in line with the recommendations of the diabetes team. Those respondents whose scores put them in these two groups were excluded

from the study. The third group (which included those in the contemplation, preparation and action stages) was classified as contemplators. Respondents within this group were invited to participate in the intervention.

The initial training in motivational interviewing took place over a three month period using a combination of workshop, training videos, role play, and individual supervision. The weekly supervision using audiotapes of the sessions, continued throughout the intervention. Consideration was given to the need to adapt motivational interviewing for teenagers, although no specific changes to the spirit and techniques of MI were apparently necessary. Each participant was responsible for deciding the location and frequency of appointments, as well as the presence of others such as parents or siblings during the sessions. Appointments continued until the participant expressed a wish to discontinue or until the six month intervention phase ended. The content of the motivational interviewing sessions was as follows:

- Awareness building.
- Exploring Alternatives.
- Problem solving.
- Making choices.
- Goal-setting.
- Avoidance of confrontation.

The results at 6 month follow up indicated that mean HbA_{1c} decreased from 10.8% to 9.7% during the study and remained significantly lower after the end of the study (at 12 months follow up). At six months fear of hypoglycaemia was reduced and diabetes

was perceived as easier to live with. There were no other significant changes in the psychological measures. By contrast no reduction in HbA_{1c} values was observed in a comparison group who received standard care. The findings of this pilot study indicated that motivational interviewing may be a useful intervention in helping adolescents reduce HbA_{1c} and enhance some aspects of psychosocial functioning.

3:5 Rationale for present study

There are very few research studies that demonstrate practical, effective, and clinically useful interventions to improve metabolic control in adolescents with type 1 diabetes (Hampson et al. 2001). The emerging evidence highlights motivational interviewing as a promising intervention in health behaviour change. However well a young person may have adapted to the physical and psychological tasks of diabetes, the physiological changes of puberty, along with the pharmacological effects of insulin, often makes it difficult to achieve good glycaemic control (Tamborlane, et al. 2001). Whilst flexibility is possible in managing diabetes, it does not combine well with spontaneity and irregularity (Channon, Huws-Thomas et al. 2005).

The rationale for the study which this thesis is based upon, aimed to replicate the findings of Channon et al. (2003) in a multi centre randomised controlled design with a larger sample. A weakness in psychosocial interventions within the pre-existing literature is the lack of ability to rule out alternative explanations. Most studies in paediatric diabetes (with the exception of Wysocki et al. 2000 and Anderson, Ho et al. 1999) have not controlled for contact time with control groups. The present study

aimed to compare MI with support counselling (discussed in Chapter 5, section 5:5) provided by a paediatric nurse skilled in exploring psychosocial issues in paediatric diabetes. Contact time was given key consideration and although the adolescent self selected the frequency of sessions, it was anticipated that each intervention arm would undergo matched frequency of sessions.

In their paper on the future directions on research in paediatric chronic disease management, Glasgow and Anderson (1995: p. 213) argued that "*what are needed are prevention and intervention studies that modify (rather than describe) contextual, behavioural and psychological variables, hypothesised to facilitate or impede adherence and adjustment*". Over a decade later there are still few effective well designed interventions that facilitate self management.

The present study provides an opportunity of enhancing glycaemic control, self care and psychosocial functioning in adolescents, within a robust multi centre randomised controlled design to rule out alternative explanations. A longer and more intensive intervention period than the one delivered in the pilot study of Channon et al. (2003) would determine the utility of MI and permit scrutiny of outcomes over longer periods, within different clinical centres. Because of the paucity of literature, no previous study had developed and reported an MI intervention specifically for the needs of adolescents with type 1 diabetes with concomitant attention to internal validity. The following chapter describes the development of an MI intervention and subsequent implementation of interventionist training, supervision and quality monitoring to enhance the internal validity of the study.

CONTENTS

4:1 Introduction

This chapter introduces the methods involved in the design and implementation of the MI intervention within Study I, along with training and supervision of the interventionist (author). The subsequent chapter (Chapter 5) details the design and implementation of the research methods relating to Study I across the 24 month period. Analyses and evaluation of study outcomes are discussed in Chapters 6 and 7. Study II (Chapters 8-11) describes and evaluates the retrospective analysis of *a priori* hypotheses based on relationships between baseline quality of life, self efficacy, health locus of control and HbA_{1c}.

Chapter 3 highlighted the choice of MI as the intervention to be implemented within Study I. Since no study had implemented MI within a controlled study design in adolescents with type 1 diabetes, the challenge remained to design, pilot, implement and evaluate the intervention that allowed replication and was adequately controlled. Despite the increasing amount of intervention studies over the past decade it has been argued that little progress has been made in understanding why interventions succeed or fail (Bonetti et al. 2005). Within the MI field Burke et al. (2002) suggested that attention to the integrity of intervention delivery, components of MI, training and quality monitoring are largely missing which limits the internal validity of studies. This study is the first RCT within the MI field to carefully pay attention to these factors with the vision of enhancing the generalisability of results.

This chapter 'walks through' the development of the MI intervention, training, supervision and quality monitoring, along with subsequent refinements during implementation of the intervention. The design and implementation of the intervention ran hand in hand with the training and supervision of the author in her delivery of MI based on feedback from trainers, external supervisors and experience.

4:2 Background

4:2:1 Diabetes UK protocol

Funding for this study from Diabetes UK (DUK) was based upon a set of proposals to be implemented within the process of the study. These included; development of the method of motivational interviewing specifically for adolescents with type 1 diabetes, direct monitoring of the MI intervention delivery under investigation through tape analysis and training of the interventionist within the MI arm of the study.

4:2:2 Internal validity considerations

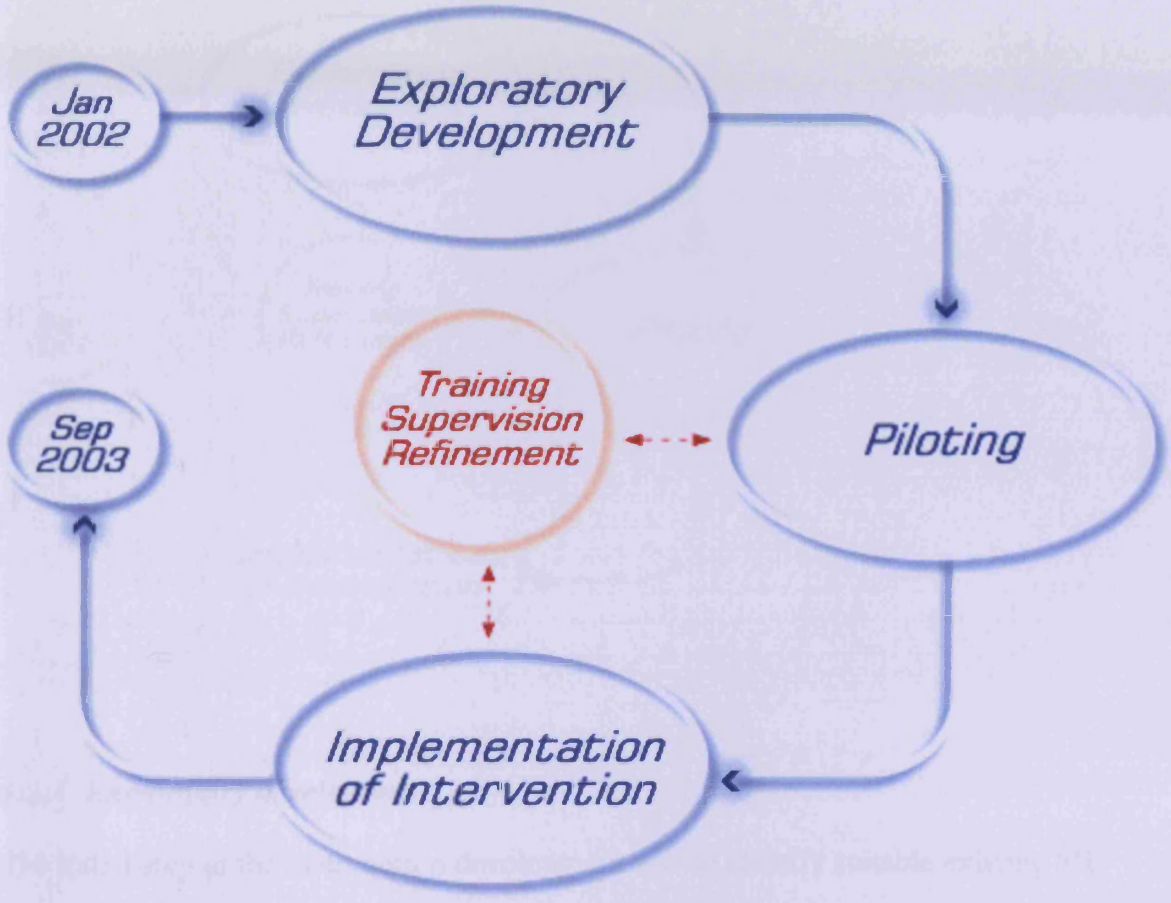
One of the main weaknesses of research within MI has been the lack of attention to what Burke et al. (2002) term treatment fidelity (attention to components of an intervention and training) and treatment integrity (process monitoring of treatment such as quality checks). This has led to calls for clear description of the components of the intervention under study and careful assessment of treatment fidelity to allow comparison and rule out alternative explanations. This study aimed to address these weaknesses by paying careful attention to the components of the MI intervention suitable for adolescents with diabetes, training of the interventionist via a standardised

intervention and subsequent supervision (quality monitoring) throughout the delivery of the intervention.

4:2:3 Overview of the process

Figure 1 provides an overview of the intervention development, practitioner training, supervision and intervention delivery process. This was a complex cyclical process rather than a linear one. Training, supervision and intervention refinement progressed whilst the intervention was being delivered as part of the study. In order to explain the complexity and inter-relationships clearly and effectively, the processes involved are described in order of the timelines of both the intervention itself and author training/supervision. The '*Exploratory Development*' phase happened first, followed by '*Piloting*' of the intervention which is described in three parts (Part 1 –section 4:4; Part 2 –section 4:5 and Part 3 –section 4:6). This is followed by '*Implementation of the Intervention*' phase which is described in two parts (Part 1–section 4:7 and Part 2–section 4:8). The phase '*Training, Supervision and Refinement*' ran concurrently with the *Piloting* and *Implementation of the Intervention* phases and subsequently is described within the identified phases.

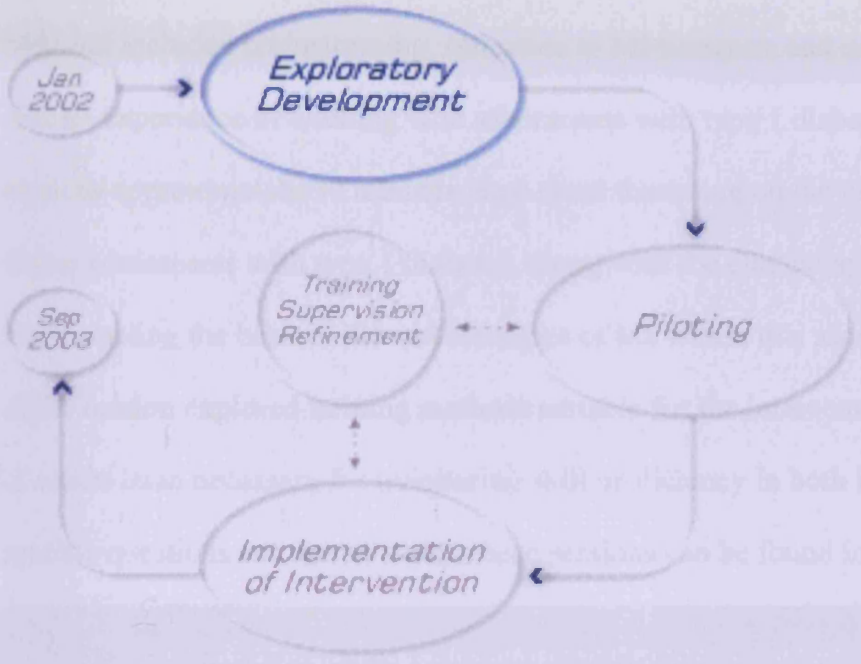
Figure 1: The time line involved in intervention development and the inter-relationships between implementation, training and supervision.



To aid comprehension, each stage of this process is described below in turn.

4:3 Exploratory development

Figure 1a: Intervention time line relevant to the exploratory development phase



4:3:1 Exploratory development

The initial step in the intervention development was to identify suitable existing MI strategies that could be used in the study, as well as identify the most suitable methods for practitioner training and supervision. To this end three one-hour brainstorming sessions were conducted between January 2002 and March 2002 within the Department of Child Health, University Hospital of Wales, Cardiff University. In addition to the author, two principal investigators were present, one of whom is the

co-founder of the Motivational Interviewing method [Professor Stephen Rollnick (SR)] and the other, a Consultant Clinical Psychologist specialising in child health and diabetes care [Dr Susan Channon (SC)].

Methods included brainstorming, reference to MI literature and decisions based on the clinical experience of working with adolescents with type 1 diabetes. During the sessions approximately 30 minutes were spent focussing on the needs and challenges facing adolescents with type 1 diabetes, along with the clinical applicability of implementing the basic skills and strategies of MI within this sample. The remainder of the session explored training methods suitable for the intervention and the structure of supervision necessary for monitoring skill proficiency in both interventions. The specific questions addressed within these sessions can be found in Box 1.

Box 1: Research questions addressed in the brainstorming sessions

1) What skills and strategies will work best to facilitate adolescents in exploring behaviour change?

2) What needs and challenges will the adolescent experience during the intervention?

3) Drawing on questions A and B, how can MI be adapted to use within this patient group?

4) What method of training, supervision and monitoring is suitable to explore components of intervention?

4:3:1:1 What skills and strategies will work best to facilitate adolescents in examining behaviour change

Table 3 summarises the existing literature sources available that were considered potentially useful in adapting MI for adolescents with type 1 diabetes. Three main sources were identified as useful;

i) 'menu of strategies approach' (Rollnick et al. 1992).

ii) 'agenda setting task' as identified by (Stott, Rollnick et al.1995; Rollnick et al. 1999).

iii) strategies recommended when adapting MI for health behaviour change contexts (Rollnick et al.1999).

Table 3: Key literature in MI that identifies menu of strategies components

Study	Components	Strengths	Weaknesses
Rollnick, Heather and Bell (1992). Development of brief MI in medical settings. Type of study: Descriptive.	Opening strategy: lifestyle, stresses and substance use. Opening strategy: Health A typical day Good things / less good things Providing information The future and the present Exploring concerns Helping with decision making.	Detailed description of 'active ingredients' of MI based on theory and practice. Adapted to readiness to change. Strategies designed for shorter consultation and have clinical applicability.	Clinical application and effectiveness not explored Degree of training involved to use strategies not addressed.
Rollnick, Butler and Stott (1997). Brief MI in GP settings with smokers. Type of study: RCT design.	Rapport building Decisional balance exercises Pros and cons strategy Brainstorming solutions Goal setting	High internal validity. Key components of method identified. Training of GPs described. Refinements of method based on qualitative data from patients & GPs. Readiness to change assessed.	Control group not described. No outcomes evaluated. Readiness to change not measured on a validated scale.
Stott, Rollnick, Rees and Pill (1995). Type of study: Exploratory	Innovative development of agenda setting chart. Readiness to change rulers Pros and cons strategy	Developed with patients with Type 2 diabetes. Method based on qualitative exploratory research. Practitioner training described. Follow up training offered.	Exploratory study. Only GPs trained in intervention. Nurse practitioners excluded. Limited generalisability.
Stott, Rees, Rollnick, Pill and Hackett (1996). Clinical technique for use in diabetes care and negotiation skills in GP settings. Type of study: Descriptive study of a RCT.	Agenda setting chart Readiness to change rulers Pros and cons strategy	High internal validity through process description of method and training involved. Tested with patients with Type 2 diabetes. Method used with GPs and nurse practitioners.	Described experiential arm only Outcomes and clinical effectiveness not reported.
Pill, Stott, Rollnick and Rees (1998). RCT of intervention designed to improve outcomes in Type 2 diabetes. Type of study: RCT design	Agenda setting chart Readiness to change rulers	RCT design Tested with 252 patients with poorly controlled Type 2 diabetes. Qualitative and quantitative analysis. Training described and involved GPs and practice nurses. Physical health status measured. Follow up clinical audit data. High internal validity – process analysis of interviews and coded. Increased collaboration.	GP practices in South Glamorgan only. Homogenous population limited generalisability of results. No significant improvements in health status (HbA_{1c}, BP, BMI, adherence to medication). Poor compliance of method by practitioners within consultations at follow up.

The MI approach considered to be most suitable for the study was the 'menu of strategies' framework (Rollnick et al. 1992). This flexible menu driven approach was designed to be used in consultations up to 30 minutes with heavy drinkers and allowed multiple use of strategies in facilitating behaviour change. Each strategy was developed to take between 5-15 minutes to complete and implemented according to the patient's readiness to change. This approach has been further developed for use in briefer, general practice settings for use with smokers in a general medical practice (Rollnick et al. 1997) designed for shorter consultations (less than 10 minute duration) and included key questions about the importance of change and the patient's confidence to achieve it.

Subsequent studies (Stott et al. 1995; Stott et al. 1996; Rollnick et al. 1997) expanded the menu approach in brief consultations within general practice settings. One key strategy developed within these studies, the 'agenda setting' task, demonstrated high levels of practitioner engagement with clients and was considered pivotal for inclusion within this study.

An additional resource considered useful in further developing the intervention was the health behaviour change selection of strategies described by Rollnick et al. (1999) which builds on the menu of strategies approach. However to date there are no documented studies evaluating the effectiveness of individual strategies and it is not known what strategies are efficacious in facilitating behaviour change for clients. The authors point to careful evaluation of the brief MI method in clinical settings such as piloting and adapting the method as appropriate and examining the

practical utility and cost effectiveness of such methods. The flexibility inherent in the menu of strategies was considered an advantage in working with adolescents with diabetes, many of whom will be struggling to make their diabetes management more flexible to fit with their lifestyle, along with the challenges of intensified regimes to improve glucose control

It was agreed between the author, SR and SC that the outcomes identified were introductory and that exploration of the specific components and piloting strategies would need to be addressed with experienced external practitioners. This would add internal validity to the process.

4:3:1:2 What needs and challenges will the adolescent experience during the intervention?

Having decided to implement an MI based intervention the question arose as to what extent the model needs to be adapted to suit the needs and challenges of adolescents with type 1 diabetes? Although the pilot study of Channon et al. (2003) was the first of its kind to implement MI with adolescents with type 1 diabetes, no study has examined the components of MI, training and supervision requirements within a RCT design.

Development of the intervention was directed by three main clinical factors. Firstly, the method would need to be flexible enough to deal with the competing demands of the diabetes regimen. It would also need to be deliverable within a 45 minute time slot, and thirdly it would need to enhance collaboration and rapport building with

adolescents at various stages of readiness to change their behaviour. The ability to address key personal and social aspects of the adolescents life (such as the role of friends, family and school), were considered important factors in adapting MI for the adolescents thereby 'normalising' the intervention within this trial context. In addition, it was hypothesised that the nature of the relationship between the author and the patient would have an impact on which aspects of MI appear more salient or more productive (Channon, personal communication 2002). In many of the studies of MI, the method has been introduced into a pre-existing healthcare relationship or as an adjunct to other interventions (Rollnick et al.1997; Berg-Smith et al. 1997). A unique aspect in the design of the present study is that there was no pre-existing relationship with the young people and no other healthcare context for the relationship outside the research. The author was independent of the paediatric diabetes clinic and the contact was time limited with a maximum of a year.

Another factor that may impact on outcomes was the structure of contact. In general, interventions based on MI reported in the literature tend to be relatively brief and clinic-based whereby frequency and location of contact is pre-determined by the practitioner/therapist. Examples of interventions range from 15 minute opportunistic interviews in primary care (Senft et al. 1995) through to the four session MET used in Project MATCH (1997; 1998). Whilst these brief interventions have yielded moderate effects (Burke et al. 2002), it was decided in the present study to apply the principle of *client choice to the structure of the contact.* The adolescents were to be in charge of when, how often and where they met with the author. This was considered desirable to facilitate autonomy and to enhance retention in the study.

It was necessary to develop the intervention and implement training of the author within a short time frame (between March 2002 – July 2002). This time frame prevented the possibility of piloting the delivery of the intervention with an adolescent sample. In order to enhance internal validity, consideration was given to deeper exploration of the specific components of the intervention, training and supervision. Outside clinical researchers known for their expertise in the design of complex interventions, took part in discussions with the study research team. These were carried out at the Department of General Practice, University of Wales College of Medicine. Key areas discussed included specific design issues of the study, intervention format, degree of flexibility allowed to ensure adherence to research protocol, therapist training within both MI and control groups and content of supervision. The outcomes of the decisions of these sessions determined the content of sections 4:3:1:3 and 4: 3:1:4 described next.

4:3:1:3 How can MI be adapted to use within this patient group?

Based on the suitable strategies selected (Rollnick et al. 1992; Stott, Rollnick et al. 1995; Rollnick et al. 1997) and the needs of the clinician and patients which whom the intervention would be conducted, an initial standardised menu of MI strategies was devised (Box 2). The menu chosen was considered to have clinical utility for adolescents in rapport building, collaboration and invitations to talk about the how and why of change.

Box 2: Initial 'menu of strategies'

Opening Strategy ('setting the scene')
Agenda Setting Task
Typical Day
Pros and Cons
Exploring Concerns
Importance and Confidence

The rationale for these strategies are described below.

Opening Strategy: 'setting the scene'

This strategy has not been explored previously in the literature in MI and diabetes. It was decided to structure the introduction of each interview to facilitate rapport, allay fears and to build on information giving. Good rapport is important for an honest discussion and understanding the patient's behaviour (Rollnick et al. 1999) and development of a strategy to put adolescents at ease and reduce anxiety was considered important. It was also considered necessary given the nature of the relationship between the patient and the author was not already established as in other studies. The key elements within this task involved explaining the nature of the tasks involved, details of the session and duration, confidentiality issues and providing reassurance to ask questions and stop at any time. An outline of this strategy is described in Appendix 1. The role of the author as a mentor or coach was emphasised to promote autonomy

Agenda Setting Task

The agenda-setting task is a pen and paper exercise encouraging a patient to choose topics of health behaviour change from a pre determined 'menu' (Appendix 2). The patient is also given the choice to select their own 'agenda' items that are not on the 'menu', which enables the patient to talk about other concerns. This collaborative task paves the way for the patient to identify areas of their lifestyle they are uncomfortable with and offers the opportunity, through skilful negotiation, for the patient to take a different perspective regarding their values and thoughts about change. The task was designed for short consultations (between 8-10 minutes) within a primary care setting. The goal is to build up an awareness of the person's lifestyle, to get them involved in talking about their life and also to be clear and open about the kind of behavioural issues the health care practitioner may want to address. This can take as little as a few minutes to complete or it can be the focal point for the whole session. It can be used in the beginning of subsequent sessions to elicit patient's concerns and for deciding what to talk about next.

Typical Day

The purpose of this task is to build rapport and understand the general context of the young person's life in relation to their diabetes (Rollnick et al. 1999). It was deemed useful to use with adolescents with diabetes because the task is short and simple (takes around 6-8 minutes) providing opportunities for exploring aspects of the young person's diabetes behaviours and areas of concern in detail.

An example is as follows:

" I am going to ask you to tell me about a typical day in your life. It may be one from last week; last month..... it's entirely up to you. I am not trying to pry into your life. I genuinely want to understand how things happen in your life and in particular your diabetes".

Pros and Cons

The strategy looks at the pros (advantages) and cons (disadvantages) of current behaviour or at desired change in a particular behaviour. This was considered a useful strategy for gaining understanding about the adolescent's ambivalence and any conflicting feelings, attitudes, thoughts about staying the same versus changing their behaviour. The strategy aims to provide structure, raise awareness and elicit thoughts and feelings about current behaviour. An example is as follows:

> *"What are the good things about your diet at the moment?"*
>
> *"What are the less good things about having to stick to your diabetes diet?"*

Exploring Concerns

This strategy relates to the costs of current behaviour and is one way of identifying areas of discontent in a person's life (Miller and Rollnick, 2002). It was considered appropriate to use within this study since adolescents may not always be aware of 'hassles' in their diabetes management (Channon, personal communication, 2002). Allowing the adolescent to identify and explore their concerns and offer opportunity to reflect on the areas of their diabetes management with which they are they are

unhappy. The adolescent may not acknowledge a type of behaviour as a 'problem' but will refer to concerns as an external entity.

An example is as follows:

"What concerns do you have about your diet?".

It was important that the young person and not practitioner voiced the concerns.

Importance and Confidence

This strategy provides a platform for understanding exactly how the person views the costs and benefits of change, what might lead to successful change and lays the foundations for talk about change (Rollnick et al. 1999). The global assessments incorporate questions which take around 2-3 minutes to complete and thus personal values about change can be captured within a short time span. Examples are as follows:

"You said earlier you weren't too happy about your blood sugar monitoring. In order for me to understand better how things are for you, is it OK for me to ask you two simple questions about this, and then see where we go from there?"

"How important is it for you to check your sugars regularly on a scale of 0-10, where 0 is not at all important, and 10 is very important?"

"How confident are you that you can check your sugars regularly on a scale of 0-10, where 0 is not at all confident, and 10 is very confident?"

It was recognised that certain aspects of intervention development such as inclusion of further strategies would evolve over the course of training and refinement.

4:3:1:4 What method of training is suitable to explore components of the intervention?

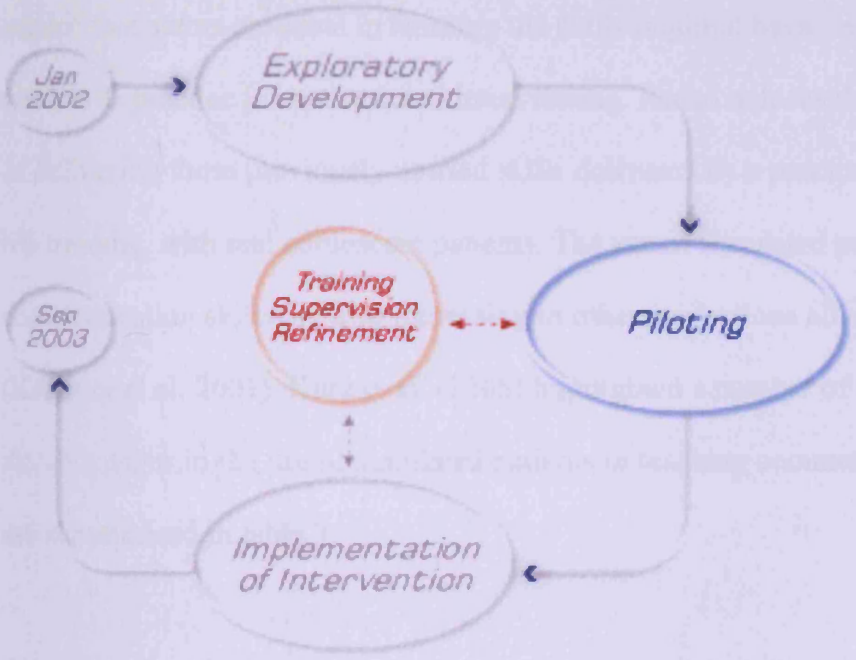
Due the limited time available it was agreed that simulated interviews involving professional actors would be used to practice and rehearse the skills to implement the MI intervention. Initial aspects of training of the author and supervision of skills delivery would take place within the simulated sessions. The principal investigators (SR and SC) would carry out the role of trainers and supervisors during piloting and in the initial months of intervention delivery. The method of supervision would be via structured feedback as 'expert coaches'. Feedback would be based on positive comments following skilful delivery and advice for improvement. These learning aids have previously been found to be effective in enhancing goal performance in the literature (Locke and Latham, 1990). An advantage of this method would be that feedback would be elicited in vivo during the simulated interviews enabling the author to rehearse skills with feedback. This would allow flexibility and offer opportunity to observe the demonstration of skills through modelling from the supervisors.

Subsequent supervision and further training in the initial months of the MI intervention delivery was considered important to identify key components, quality monitoring of adherence and provision of support to the author. To enhance internal validity of this process, external (independent) supervision and further monitoring of

intervention delivery in the later stages of the study was considered essential to enhance integrity and to provide additional coaching of the author. Although intervention development, training and supervision took place concurrently throughout the intervention, for purposes of clarity in describing these processes, the progression will be considered separately.

4:4 Piloting the intervention: Part 1

Figure 1b: Intervention time line relevant to the piloting Part 1 phase.



4:4:1 Simulated interviews and professional actors (Adults)

The nature and purpose of piloting the intervention with simulated adult actors was to provide an opportunity to identify components of the intervention based on actor feedback and for the author to receive clinical feedback on her MI delivery skills. The choice to use professional actors or patients who have been briefed to take on a particular patient role in the training of communication skills is increasingly used in medical health care settings (Spencer and Dales, 2006). Miller and Rollnick (2002) argued that actors are ideal in learning the skills required because they add a degree of realism to practice in motivational interviewing. It also reduces the ethical dilemmas of delivering these previously untried skills delivered by a practitioner with limited MI training, with real adolescent patients. The use of simulated patients in teaching communication skills are also increasing in other professions allied to medicine (Kruijver et al. 2001). Kurz et al. (2005) highlighted a number of advantages and disadvantages in the use of simulated patients in teaching communication skills which are summarised in table 3.

Table 4: Advantages and disadvantages in using simulated patients

Advantages	Disadvantages
▫ Rehearsal/experimentation with new skills	▫ Expense
▫ Improvisation – scenarios can be replayed and adapted	▫ Selection of simulated patients can take time
▫ Standardisation of cases	▫ Training of simulated patients takes time
▫ Customisation of cases	▫ Simulated patients may have hidden issues/agendas that can affect performance
▫ Can deal with specific issues and difficult situations	▫ Organisation can take up a lot of the principal investigator's time
▫ Availability of actors	
▫ Time efficiency	
▫ Can provide feedback	
▫ Can be used as facilitators, instructors and in evaluation	

The effectiveness however of the use of simulated patients is inconclusive. Krahn et al. (2002) compared the use of simulated patients with real patients in teaching introductory psychopathology to medical students. The authors found that students preferred consulting with actual patients and found it more difficult to develop empathy with simulators, suggesting that the use of simulated patients can produce as similar a problem of 'unreality' as role-play. A recent unpublished study by Lane, Hood and Rollnick (work in progress) examined practitioner's level of skillfullness in BCC following a 2 day workshop. Participants were randomly assigned to either training with simulated patients, or a fellow trainee. There were no differences in practitioner skillfulness between the two groups.

According to Knowles (1990), the more relevant the learning is to real life clinical practice, the more quickly and effectively skills should be learned. Given the author was the interventionist within the study, the use of simulations had clinical applicability.

4:4:2 Preparation of simulated interviews

Preparation of simulated interviews was co-ordinated by the author. The simulated interviews incorporated 'essential elements of experiential communication skills learning' as proposed by Kurtz et al. (2005). Methods included observation, structured feedback, audio recording practice and active small group or one to one learning. Actors were recruited from a local school of amateur drama and acting and selected according to their availability. Four actors (three female and one male) ranging in age between 35-55 years agreed to take part over a three month period and were paid a nominal fee. The advantage of using these particular actors was that they had previously worked in simulated scenarios of health behaviour change and thus had experience 'acting' the challenges people face with chronic illness and behaviour change.

Two weeks prior to commencement of simulations, the author provided a 'pack' to each actor consisting of research studies involving adolescents with diabetes, fact sheets, and generalised information on diabetes. Training of the actor's role took place over ½ day within the Department of General Practice by a diabetes nurse specialist in paediatric diabetes and a staff member with extensive knowledge of diabetes within the Department of General Practice. The training involved a didactic session

explaining the psychosocial, emotional, and physical challenges young people face with diabetes, and a question and answer session.

4:4:3 Initial simulated interviews

Each session took place in designated rooms within the Academic Centre, Department of General Practice. Two actors participated per session and sessions lasted for 3 hours over two consecutive weeks in March 2002. A total of 10 interviews were conducted over two sessions with each interview lasting between 10-25 minutes. Materials included mini disc audio recording equipment, flip chart, pens and A3 size paper for the strategy exercises.

The initial topics for simulation were 'setting the scene' and 'agenda setting task' to establish rapport and negotiate behaviours to discuss around diabetes management.

4:4:4 Briefing of roles

Trainers SR and SC provided briefing to the author and actors. Prior to each interview, the assigned actor was briefed by SR. Briefing included their 'client' name, duration of diagnosis, a real life case scenario, directions on the type of difficulties to present, and format of questions to ask. Each actor was presented with a case scenario reflecting challenges that adolescents with type 1 diabetes face enhancing the credibility of the role plays. The author had limited contact with the actors and each simulated interview was conducted in a manner that represented a real life consultation. Briefing of the author from SC involved instructions on the strategy to be rehearsed, timing and suggestions on responding techniques.

Since these were the first simulated interviews, two strategies important in rapport building and initiating the topic of behaviour change were chosen; 'setting the scene' and 'agenda setting'. This is not identified in the MI literature given the paucity of clinical studies involving MI and adolescents with type 1 diabetes.

4:4:5 Conduct of the simulated interviews

Each interview lasted between 10-25 minutes and alternated between two actors. The author would introduce herself and the strategies 'setting the scene' and 'agenda setting task' were practiced (see Appendix 1 and 2). Depending on degree of rapport established, strategies would be rehearsed until the author had reached a level of self reported competency.

4:4:6 Feedback and refinement of strategies

Actors were debriefed by SR and the author debriefed by SC and SR. Debriefing focused on elements of the interview that was based on the ease of rapport building, degree of freedom offered to choose problem areas to work upon (through agenda setting) and skills in helping the 'client' negotiate behaviour change. The simulations clearly pointed to a need to use 'setting the scene' and 'agenda setting' (see figure 2) at the beginning of each consultation, as they were pivotal in establishing rapport and enhancing negotiation.

Figure 2: The MI components: Setting the scene and agenda setting:

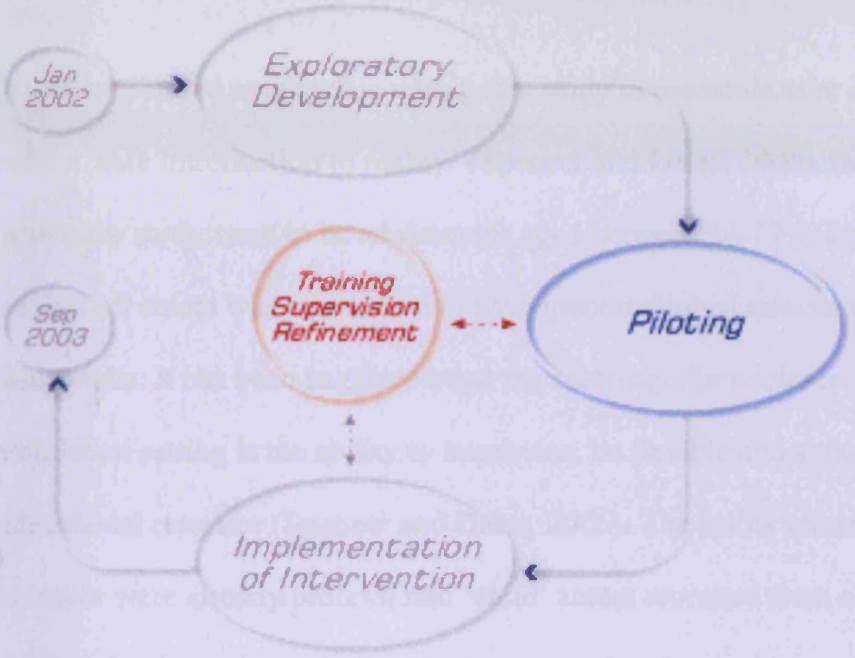
Setting the Scene	Agenda Setting
Rationale Collaboration Rapport building	**Rationale** To select topics for behaviour change
Content Outline of roles, expectations and confidentiality Emphasis on freedom of choice	**Content** Open questions Agenda Setting chart
Example see Appendix 1	**Example** see Appendix 2

4:4:7 Training of author

It was decided by the author that the trainers SR and SC would not be present in the interviews during these simulations. It was considered more useful to seek feedback from SR and SC after each interview based on observations from the interview. Sessions were audio recorded and feedback was given to SR and SC. Observations from the author and actors were provided on level perceived of skillfullness and rapport building and negotiating topics of behaviours. The author rehearsed the two strategies until a perceived level of competence had been achieved.

4:5 Piloting the intervention: Part 2

Figure 1c: intervention time line relevant to the piloting part 2 phase.



4:5:1 Simulated interviews and actors (Adolescents)

The nature and purpose of simulated interviews with adolescents was to provide the opportunity to rehearse components of the MI intervention with young people who could emulate the needs of the participants within the trial. Although the literature regarding use of simulated adult actors within medical settings is increasing, there is little written about the use of adolescent simulated actors and the effects that simulated participation may have on their welfare (Spencer and Dales, 2006). The available literature however points to benefits in using adolescents in simulations such as improved perceptions of health care professionals, improved communication with others and greater tolerance of others (Wallach, et al. 2001; Blake, Mann et al. 2000).

It has been suggested that use of adolescents requires careful attention to selection, training, ongoing support and debriefing in order to protect their welfare (Kurtz et al. 2005; Blake et al. 2006).

It was considered appropriate within this study to use adolescent actors since they offer a 'safe introduction to reality' (Spencer and Dales, 2006). Because the sample within the study were to be adolescents aged between 14-17 years, the use of adolescent actors was considered to have greater clinical relevance than simulations with adults. It has been suggested that the challenge for adolescent actors within a simulation setting is the ability to improvise, be flexible and appreciate the role as an educational resource (Spencer and Dales, 2006). The actors recruited for this study however were already professional 'child' actors recruited from a local acting and drama school and these challenges were considered to be less problematic. What was considered important was attention to the potential emotional demands of their tasks, time for exploration of personal issues raised during simulations and adequate educational training for their roles.

4:5:2 Preparation of simulated interviews

Two adolescent actors (one male and female) aged between 14-16 years were recruited based on availability. A nominal fee was paid for participation. Neither actor had previous experience in playing roles that involved behaviour change and chronic illness. Each actor was allocated one of the 'accomplished' adult actors who would act as a mentor to observe the actors psychological and emotional well being during the simulations.

The young actors received training from three of the four adult actors. This training took place at the acting school base over a two week period and included didactic teaching on the psychosocial, emotional and physical challenges young people with diabetes face and suggestions on responding to certain scenarios involved in behaviour change and challenges relating to living with diabetes.

4:5:3 Initial simulated interviews

Simulated interviews took place for 3 hours every two weeks over 1 month within the Department of General Practice. Individual interviews within the sessions lasted between 10-25 minutes. The total number of interviews completed was eight. Materials included mini disc audio recording equipment, flip chart; pens and A3 size paper for the strategy exercises.

Prior to each session the author SR and SC constructed clinical scenarios for each simulation and decided what components of the intervention needed to be rehearsed by the author. The format followed the same pattern as the preliminary enquiry sessions and addressed a number of questions such as:

a) What will work well / not so well? What will be the 'best fit'?

b) What strategies and skills will work best?

It was agreed that the strategies to be included in the Part 2 simulations were:

'Setting the scene'

'Agenda setting task'

Additional strategies were taken from the 'menu of strategies' framework (Rollnick et al. 1992) which included 'typical day', 'exploring concerns', 'exploring importance and confidence' and 'pros and cons'.

4:5:4 Briefing about roles

Each actor was briefed by SR. This included their 'patient' name, duration of diagnosis, a real life case scenario, directions on the type of difficulties to present and format of questions to ask. Each actor was presented with a case scenario, enhancing the credibility of the role plays. The actor's mentor was present through the simulation session if the actor requested this. The author had limited contact with the actors and thus, each scenario was conducted in a manner that represented a real life consultation.

4:5:5 Conduct of the interviews

Interviews were alternated between the two actors. As in Part 1 (section 4:4:5 p.125), each conversation started with the 'setting the scene' strategy followed by the 'agenda setting task'. A greater degree of exploration was given to the agenda setting task, since it was considered to be an important strategy in negotiating talk about behaviours with the adolescents in the study. After each session actors were given the opportunity to provide feedback about the interviews based on degree of rapport building, freedom offered to choose problem areas to work upon and skills in helping

them negotiate behaviour change. This strategy was rehearsed many times until the author and actor had agreed on the helpfulness of the task, that it was evident that 'client' autonomy had been respected and that the 'client' had been given the opportunity to negotiate other behaviours if appropriate.

4:5:6 Debriefing of actors

Unlike the adult actors, it was deemed important to provide additional support to the adolescent actors during their roles. After each interview the mentor would check the actor's welfare. This provided an opportunity to explore in confidence personal issues thereby avoiding the actor being exposed to situations which they might have found difficult to cope with. Actors were then debriefed by trainer SR and the author debriefed by SC.

4:5:7 Feedback and refinement of strategies

After each session actors were given the opportunity to provide feedback about the interviews based on the skill effectiveness of the author to help them identify problem areas and negotiate behaviour change. Due to time limitations only the strategies 'setting the scene' and 'agenda setting' were completed over the two sessions and it was not possible to pilot other strategies identified for inclusion. As with the adult actors, feedback pointed to the usefulness of the 'setting the scene' strategy at the beginning of the consultation. Feedback from the adolescents was pivotal in revising the agenda setting task which will be described below.

'Agenda Setting Task'

The nature of the agenda-setting task used initially within these 'interviews' was too complex, created a degree of confusion, and hampered the helpfulness of the therapeutic interaction. The degree of guidance necessary by the interventionist hampered the true spirit of collaboration and negotiation inherent in this approach. Stott et al. (1996) proposed that it was the responsibility of the patient to identify (i.e. draw the circles) as priority agendas without the additive nature of directiveness from the therapist. The difficulties experienced by the 'clients' were not related to literacy or educational ability.

Feedback from the adolescent actors highlighted a need for greater direction in problem identification from the author in the consultations. This necessitated revision of the degree of autonomy granted to the actor, without comprising collaboration. Thus the distinction between the Stott et al. (1995; 1996) agenda setting task and the one that has been modified for this study is related to the format, pace and timing of the task, degree of collaboration, emphasis placed on readiness to change and negotiation.

After discussion and feedback with SR and SC, the strategy was revised to incorporate a greater degree of directiveness from the author. This took the form of:
Using an agenda setting template (a completed agenda setting chart) as a source of reference (see Appendix 3).
The author taking control of drawing the circles and seeking permission to proceed.

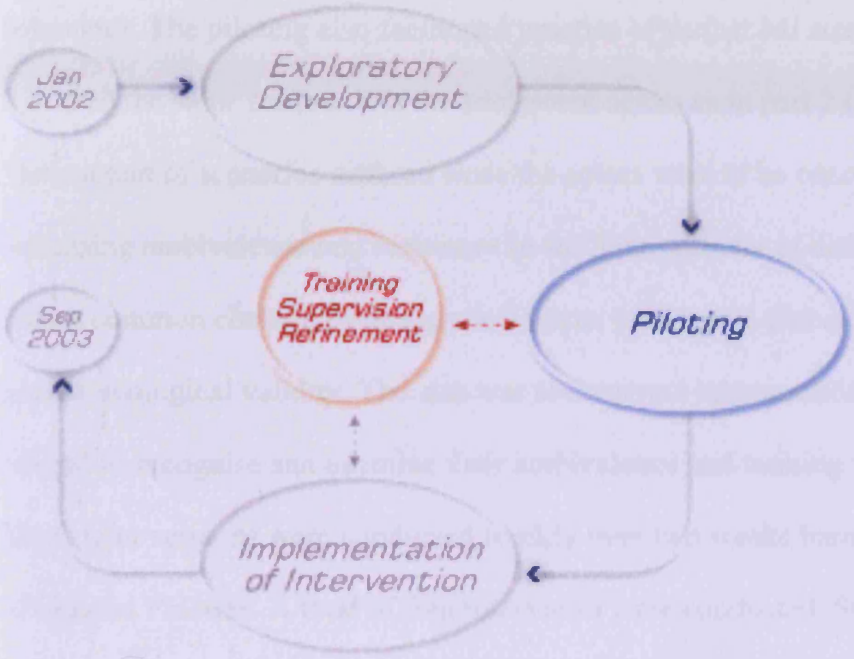
Once the revised version of the agenda setting task was implemented the 'interviews' proved far more collaborative and were more comfortable for both actor and author. The actors reported that the task helped the 'client' inform the 'practitioner' of their problems and concerns and helped them talk in detail about their diabetes

4:5:8 Training of author

It was the author's decision to include the trainer SR as an observer in the interview. Out of the eight interviews conducted over two weeks, the author requested direct supervision on four interviews. The overarching reason for seeking support from the trainer was based on additional help with responding when the actors played a more challenging role ('silent teenager'). For example, if the author encountered difficulties in responding, such as 'road-blocks', the role-play was 'frozen' and suggestions for improvement were offered by SR. The author would then repeat the task to achieve more productive ways of negotiating behaviour change.

4:6 Piloting the intervention: Part 3

Figure 1d: Intervention time line relevant to the piloting part 3 phase.



Having piloted rapport building through 'setting the scene' and negotiating topic of change through 'agenda setting' the aim of this section was to pilot other strategies such as those identified by Rollnick et al. (1992). These strategies would help build motivation for change through exploration of values and ambivalence. Simulations during this phase were designed to represent more challenging issues such as resistance in management of diabetes as well as other behaviours such as alcohol use, smoking and unsafe sex. A description of Part 3 of piloting the intervention follows.

4:6:1 Preparation of simulated interviews (Adolescents)

The nature and purpose of simulated interviews with adolescents was to practice skills with young people which involved more challenging scenarios and risk taking behaviour. The piloting also facilitated practice of further MI strategies. Preparation followed the same format with the adolescent actors as in part 2 (section 4:5:2, p 128). The content of scenarios differed since the actors were to be encouraged to verbalise increasing ambivalence and resistance in self management of diabetes. This was to reflect common challenges facing adolescents with type 1 diabetes and represent greater ecological validity. The aim was to construct conversations that helped the 'client' to recognise and examine their ambivalence and training was provided by SR. Three hour sessions were conducted weekly over two weeks based at the Department of General Practice. A total of four interviews were conducted. Strategies piloted within previous phases were included, with greater attention to exploring ambivalence through exploration of values and goals along with dealing with resistance through empathic responding.

4:6:2 Briefing of roles

To ensure the well being of the actor the adult mentor would provide support and additional explanations if required. As in section 4:5:4 (p. 130), each actor was briefed by SR prior to each interview. Each actor was encouraged to role play challenging scenarios based and provided with scripts. The challenges included ambivalence about managing diabetes, issues around risk taking behaviour and

resistance towards diabetes. The author was unaware of the scenarios presented to the actors.

4:6:3 Conduct of the interviews

Each session lasted around 35 minutes and alternated between the two actors. Typically the 'client' would be invited to talk about their lifestyle with the author gathering information through open questions and curiosity about their lifestyle. Once the 'problem areas' were understood then the client's values and subsequent resistance were explored through reflective listening techniques and other strategies identified previously. Each interview ended when it was felt by the author and 'client' that key areas identified were explored and intrinsic motivation to change had been elicited.

4:6:4 Debriefing of actors

Due to the more intensive nature of these interviews careful attention was given to debriefing by SR and the adult 'mentor' to protect the well being of the young actors. It was ensured that they adequately detached themselves from their simulated roles and they were encouraged to talk about how they dealt with the 'difficult' encounter. Neither actor encountered any problems within these interviews.

4:6:5 Outcome of piloting strategies

The usefulness of the strategies, combined with the patient centred style of responding, were considered practical, therapeutic and useful to implement with adolescents with diabetes (see figure 3).

Figure 3. A menu of strategies post piloting: Parts 1, 2 and 3:

Setting the Scene	Agenda Setting	Typical Day
Rationale Collaboration Rapport building	**Rationale** To select topics for behaviour change	**Rationale** Information exchange
Content Outline of roles; expectations; confidentiality; Emphasis on freedom of choice	**Content** Open questions Agenda Setting chart	**Content** Describes a typical day; takes 6-8 minutes
Example see Appendix 1	**Example** see Appendix 2&3	**Example** " I am going to ask you about a typical day to understand how things happen in your life"

Pros & Cons	Exploring Concerns	Importance and Confidence
Rationale To examine costs/benefits of current behaviour; to understand ambivalence.	**Rationale** Identify costs of current behaviour; to voice arguments form change.	**Rationale** To explore the confidence & importance of change.
Content Look at advantages & disadvantages of behaviour via a balance sheet.	**Content** Identify 'hassles' to daily management through open questions.	**Content** Scaling questions between range of 0-10
Example "What are the good things about change?"	**Example** "What concerns you most about your HbA_{1c} reading"?	**Example** "How do you feel at the moment about change, if 0 was not at all and 10 was very much, what number would you give yourself?"

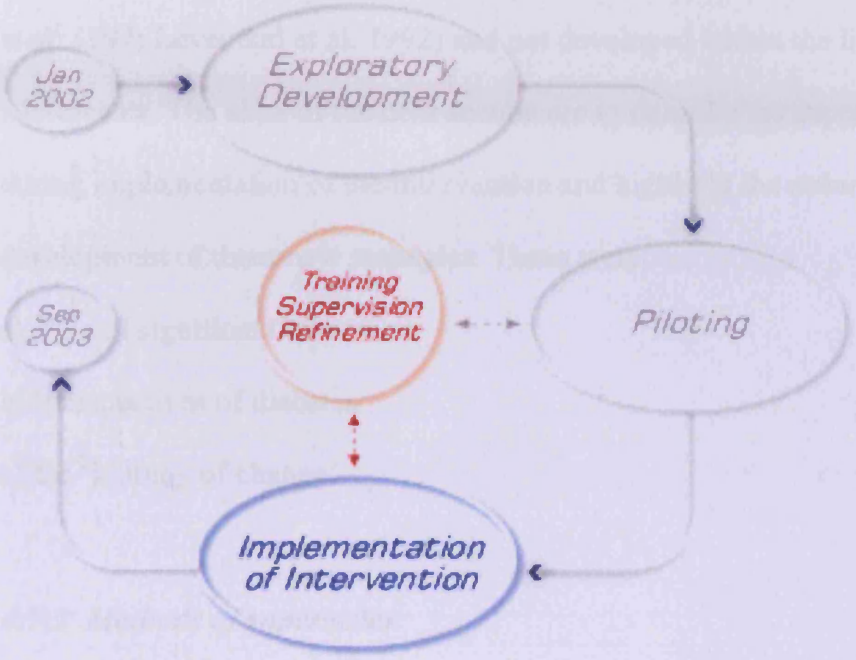
4:6:6 Training of author

Due to the more intense nature of these interviews, the author requested that SR observe and provide feedback during the interviews. At key moments it was necessary to request guidance from supervisor (SR) in practicing the principle techniques and micro-skills of motivational interviewing with the 'clients'. Typical 'roadblocks' experienced by the author included dealing with the ambivalence and resistance scenarios. Through modelling and role play, SR would demonstrate skills and techniques without reducing the autonomy of the author. A typical scenario would be a structured 'interview' where the role-play would include four players; SR, the author, an observer (staff member) and the actor. The author would interact with the 'client' and at key moments of difficulty particularly during 'missed opportunities,' SR would intervene. This would take the form of 'taking over' when there was evidence of resistance or at key moments of difficulty. SR would ask permission to try out different techniques, specify his own observations and make suggestions about proceeding skilfully with the role-play.

Direct observation of the supervisor demonstrating skillful responding techniques and dealing with difficult encounters such as coping with resistance highlighted in vivo how a challenging encounter can be turned into both a therapeutic and constructive one using simple core techniques.

4:7 Implementation of the intervention: Part 1

Figure 1e: Intervention time line relevant to the implementation of intervention Part 1 phase.



4:7:1 Introduction

Once piloting was completed in July 2002, the intervention commenced. Key components of the intervention had been established which were considered pivotal in what Miller and Rollnick (2002) term '*building motivation for change*' in the early phases of the intervention. Further training and supervision of the author were considered necessary to enhance the validity of the study which involved monitoring of the taped interviews and feedback to the author on skill proficiency. The principal investigator and trainer in the piloting phases (SC) facilitated this monitoring and supervision process. The format of monitoring of the taped interviews was designed to

offer supervision and act as a quality check rather than formal analysis of skill proficiency. Although not anticipated in the exploratory development and subsequent piloting of the intervention, an important aspect of this phase was the development of further strategies drawing from social cognition theory (Schwarzer, 1992; Leventhal et al. 1997; Leventhal et al. 1992) and not developed within the literature on MI and adolescents. The aims of the next section are to describe the supervision process during implementation of the intervention and highlight the rationale for the development of three new strategies. These were:

a) 'role of significant others'

b) 'perspectives of diabetes'

c) the 'journey of change'

4:7:2 Methods of supervision

The methods of supervision were decided collaboratively between SC and the author based on the most suitable learning strategy. Due to time constraints it was decided not to use formal MI assessment tools such as Motivational Interviewing Skill Code [(MISC) Miller, 2000]. The most preferred method of learning was based on the role of SC as an 'expert coach' with specific structured feedback based on positive reinforcement and collaborative problem solving. This structured feedback took the form of a) written observations and suggestions for improvement and b) face to face feedback during supervision. Systematic feedback has been found to be a positive strategy in enhancing learning in clinical practice (Lock and Latham, 1990). Moreover positive reinforcement for successive approximations is a well established principle of learning (Miller, Yahne et al. 2004).

4:7:3 Procedure

Permission was sought to audiotape interviews from the young person and their families, and upon agreement, a 'consent to audiotape' form was signed by both participant and their parent or guardian (Appendix 4). Interviews with adolescents were audio-taped onto mini disc format and a sample of tapes was selected for supervision. Each taped interview ranged in length from 20 – 45 minutes. The method of tape selection was decided by the author and based on perceived poorer skill delivery. It was agreed that two tapes at a time would be handed to the supervisor for monitoring. Tapes would be handed to SC in person and a date and time agreed for written feedback prior to the supervision session. Once these tapes had been monitored, further tapes were sent.

Prior to supervision, SC would provide written feedback on observations of skill delivery within the interviews which would be sent/or collected by the author. This involved written suggestions of constructive responses during the interview based on use of open questions, reframing statements and examples of positive responding. The total number of taped interviews monitored was ten. The total number of hours involved in the analysis of content and subsequent feedback process was twenty hours over four months.

The supervision was carried out within the Department of Child Health on a fortnightly basis for one hour duration. Structured feedback was given to the author in both written and oral format. The supervisor and author found that the most effective

way of spending supervision time was reviewing a selected interview, stopping the tape at key moments and carefully analysing specific responses and missed opportunities. Where the author failed to elicit salient patient responses such as exploration of values and eliciting change talk, SC provided suggestions for intervening. A positive aspect of this method was the ability to reflect on the interviews in private and cross match own responses with the suggestions provided by SC.

4:7:4 Outcome of supervision

During supervision the author and SC brainstormed salient ways of responding with the adolescents to encourage rapport building and talk about the how and why of change. It was apparent that peers, family and teachers played a prominent role in young person's diabetes self management. It was thus considered important to include strategies that included the role of significant others and how these people may have impacted upon their behaviour. Furthermore although strategies such as 'exploring concerns', 'pros and cons' and 'importance and confidence' were useful in exploring why and what of change along with understanding the adolescents underlying values, it was important to focus on the how of adapting to change. In making the 'how' of change tangible, the young person was more able to examine their own barriers and successes to change in maintaining their pattern of behaviour and preventing relapse. Subsequently some modifications were made to the 'menu of strategies' approach. These included the adoption of three new strategies a) '*role of significant others*' b) '*perspectives of diabetes*' and c) the '*journey of change*'. The theoretical background and rationale for these new strategies will be described next.

4:7:5 New strategies implemented within intervention

The journey of change (process of change)

This is a new strategy introduced for this study based on the self regulatory notion of volition (Bagozzi and Edwards 2000; Schwarzer, 1992). This strategy attempts to examine the underlying how of the change trajectory. The choice to include this strategy was to facilitate the adolescent in their understanding of the 'how' of change, compared to the 'what' they are going to change. Examples of open questions are as follows.

> *Question: "Ok, I'd like to think about how you make changes generally. Some of us need information, some need coaches, and some need more active encouragement. What about you?"*

> *Question: "When you played tennis, how did you try to improve? Was it on your own, with someone on the sidelines, or with a coach guiding you?"*

Barriers to testing (and the process of overcoming these) were explored by asking questions such as;

"So what would have to be different to make testing OK?"

The practitioner may wish to offer typical barriers such as fear of high reading, painfulness, forgetting, and embarrassment in presence of others.

Significant others

Change of lifestyle in adolescence cannot occur in a psychosocial vacuum (Karoly, 1999) and the young person's perceptions of their diabetes, lifestyle behaviour and adherence to treatment may be at odds with that of their health care providers, friends, family and teachers. This strategy was considered useful to include as it allows exploration of concerns with the adolescent who are discrepant about the status quo of health and behaviour. It highlights conflict in views and differing perceptions of the adolescent and significant others in decision-making, health behaviours and independence.

Typical open ended questions included;

> *"You are not bothered by your glucose readings even though you say they are high. How might the clinic / your mother/ friends see this?"*

> *"How would others like you to change your diabetes management?"*

A typical reflection included;

> *"So when you go to clinic, you feel as if your health care provider doesn't realise just how hard it is to achieve a HbA_{1c} of 8mmol/L."*

Perspectives of diabetes

Personal illness models (Hampson et al. 1990; Skinner and Hampson, 1998; Skinner, John and Hampson, 2000; Skinner and Hampson, 2001) are identified as patient's cognitive representations which will impact on illness related behaviour. These representations include the degree to which a person can control their illness, the cause of illness, how long the illness endures and the consequences of illness (Skinner and Hampson, 1998). It was considered useful to explore the young person's perceptions of glycaemic control and how this may influence behaviour. Thus the strategy '*perspectives of diabetes*' relates to understanding the young person's perceptions of control in managing their diabetes, such as external ("*My treatment regimen alone determines my glycaemic control*") or internal (" *Its a combination of what I do with my lifestyle and insulin that impacts on my HbA_{1c} reading*"). It is argued that understanding the young person's perspective will give greater insight into their reasons for non adherence to insulin, blood sugar testing behaviour, dietary and exercise behaviours and clinic attendance. Typical open ended questions which encouraged reflection on degree of internal versus external behaviours included;

> *"High blood sugars are affected by lots of different things. What sort of things have affected your levels in the past?"*

> *"Are you someone who responds to a high sugar reading by thinking what the heck, or does it act as a brake on your diet?"*

"You have been thinking of playing tennis for a while, but somehow it is difficult to get going. What comes in the way of getting there?"

The revised intervention (figure 4) became individualised to suit not only the author's own style of responding but also the adolescent's needs in exploring their diabetes and subsequent lifestyle changes. However despite the structured and flexible nature of the intervention, the menu of strategy approach was adhered to as agreed within the research team.

Figure 4. Revised menu of strategies post supervision:

Setting the Scene	Agenda Setting	Typical Day
Rationale Collaboration Rapport building	**Rationale** To select topics for behaviour change	**Rationale** Information exchange
Content Outline of roles; expectations; confidentiality; Emphasis on freedom of choice	**Content** Open questions Agenda Setting chart	**Content** Describes a typical day; takes 6-8 minutes
Example see Appendix 1	**Example** see Appendix 2 & 3	**Example** " I am going to ask you about a typical day to understand how things happen in your life"

(Figure 4 continues on page 147)

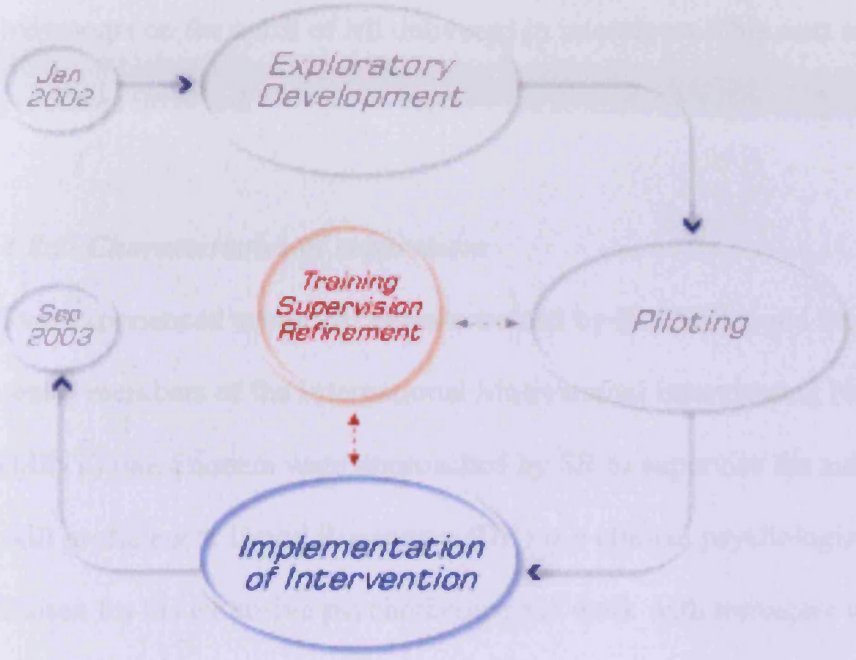
Figure 4 continued:

Pros & Cons	Exploring Concerns	Importance and Confidence
Rationale To examine costs/benefits of current behaviour; to understand ambivalence.	**Rationale** Identify costs of current behaviour; voice arguments for change.	**Rationale** To explore the confidence & importance of change.
Content Look at advantages & disadvantages of behaviour via a balance sheet.	**Content** Identify hassles to daily management through open questions.	**Content** Scaling questions between range of 0-10
Example "What are the good things about change?"	**Example** "What concerns you most about your HbA_{1c} reading"?	**Example** "How do you feel at the moment about change, if 0 was not at all and 10 was very much, what number would you give yourself?"

Role of Significant Others	Perspectives of Diabetes	Journey of Change
Rationale To explore role of others in behaviour change process.	**Rationale** Understanding control in management of diabetes.	**Rationale** To examine the 'how' of change.
Content Open questions relating to friends/family/ school	**Content** Explore locus of control (internal vs external).	**Content** Affirmations. Elaborations to understand process. Highlight positives rather than negatives in the adolescent's life.
Example "You are not bothered by clinic readings. How might clinic/your mother/friends see this?"	**Example** "What gets in the way of stopping you monitor your blood sugars?"	**Example** "When you played tennis, how did you improve? Was it on your own, or with a coach?"

4:8 Implementation of the intervention: Part 2

Figure 1f: Intervention time line relevant to the implementation of the intervention Part 2 phase.



4:8:1 Introduction

The aims of this phase were to invite new perspectives from experienced MI practitioners detached from the study, thereby enhancing the integrity and internal validity of the study and providing further supervision to the author. The intervention had also reached a crucial phase (i.e. from 6 months to 12 months completion) whereby many of the young people were moving into what Miller and Rollnick (2002) term '*developing commitment to change*' and supervision was considered instrumental for the skilful delivery of MI during the intervention. At the 6 month point of the intervention, although many young people were at differing stages of

readiness to change their behaviour, some had explored ambivalence to change and were trying out new behaviours. The goals of the supervision were to receive individual feedback on MI practice, identify and comment on specific less skilled areas, provide direction on preferred practice as appropriate and detail observational judgments on the spirit of MI delivered in interviews. This next section describes the processes involved.

4:8:2 Characteristics of supervisors

Two experienced senior MI experts trained by Bill Miller and Stephen Rollnick and senior members of the International Motivational Interviewing Network of Trainers (MINT) practitioners were approached by SR to supervise the author on intervention skill proficiency. David Rosengren (DR) is a clinical psychologist and MI trainer, chosen for his extensive psychotherapeutic work with teenagers with diabetes and would thus offer valuable and unique insights into working with adolescents within this study. Stephanie Ballasiotes (SB) is an experienced MI clinician and trainer. Both are based at the University of Seattle, Washington.

4:8:3 Methods of supervision

Once contact was established with DR and SB by the author, the structure of training and supervision was decided. It was agreed that training would take place through process (qualitative) analysis of taped sessions and that structured feedback would be offered in writing and sent electronically. The supervisors would write a transcript of the taped interview and would feed back global judgements whilst specific examples of the macro and micro skills involved would be used to measure skilfulness. Global

judgements were to involve an evaluation of the 'spirit' in which the interview was to be conducted. Key areas that would be analysed included; demonstration of respect, permission giving, observations on the client's behaviour dependent on degree of patient centeredness, degree of collaboration, tone of voice, and specific language used. Analysis of the macro skills were to involve the type of macro skills which were receptive to the client's needs such as brainstorming, opening statements, using examples to tap into values, timing and pace, type of language used. Analysis of the finer micro skills were to take the form of; frequency type, skillfullness, timing, wording, pacing, affirmation, depth and intensity and affirmation opportunities. Where appropriate, process monitoring tools such as MISC and the Resnicow Rating Scale (personal communication, Rosengren, 2003) would be used to measure skilfulness.

Each feedback report would end with a 500 word summary on advice for future directions. This would typically include; responses to avoid, advice on responding with 'teenager resistance' and expert examples of more constructive types of micro skills such as open questions, reflective listening statements and summaries.

This structured feedback format was similar to the one used in Part 1 (section 4:7:3, p.141) with greater attention to detailed analysis of macro and micro skills involved in responding. Analysis of the tapes would be coordinated between DG and SB, each stepping in if there were difficulties in analysing the tapes according to schedule.

4:8:4 Procedure

The interviews were recorded on a Sony® memory recorder digital dictation machine. These were transferred by the author onto software for Windows 1998®. It was agreed by SR and the author that for each supervision, two taped interviews in Compact Disc (CD) format would be sent by first class registered post to the supervisors by an independent coordinator based in the Department of General Practice (KE). Written feedback of supervision would take place electronically and be sent to the author two weeks after receipt of tapes. The CD's would also be returned first class to KE who would in turn transfer them to the author. Six interviews of 45 minutes duration were analysed over an eight week period.

4:8:5 Outcome of supervision

The process of supervision and feedback provided detailed qualitative feedback on the audiotapes. There were differences in the content of analysis which added validity to the feedback. Supervisor SB would provide observations on global judgements of MI as well as demarcate specific key moments in the interview and provide observations and feedback on these key moments. Typically this would take the form of stopping the tape and providing written examples of demonstrated good practice within key segments of the tape along with written examples of preferred practice. Supervisor DR provided a more constructive critical stance with a focus on dissecting key moment-to-moment dialogue in the interviews. Some interviews were scored

according to the Resnicow Rating Scale, and where appropriate a score would be given along with feedback.

It was evident from feedback and observations from the author that many of the participants were moving into what Miller and Rollnick (2002) conceptualise as,' *the second phase of MI*' where the client has made a commitment to change. DiClememete and Velasquez (2002: p. 203) pointed out in this phase, "*the clinicians job changes from one of motivating the client, to one of advising and coaching as the client develops a workable change plan, anticipates barriers to change, and identifies potential support systems*". Thus specific techniques such as goal setting were useful in moving away from negotiation and motivating the adolescent to developing workable change plans. A modification was made to the menu approach which included a new strategy called 'moving forward - *goals and action'*. This will be described in the next section.

4:8:6 Further strategy development

Moving forward: Goals and Action

This strategy aimed to move the adolescent away from negotiating behaviour change to developing and implementing a change plan. This involved discussion of what goals were to be set that would be specific, measurable, attainable, realistic and timely. A goal planning sheet (Appendix 5) was written in collaboration with the adolescent and barriers to achievement identified. The adolescent identified positive behaviours to overcome barriers and the sheet was re-appraised during subsequent meetings. An example of a type of practically oriented question was;

"You have been thinking of playing tennis for a while, but somehow it is difficult to get going. What comes in the way of getting there?"

Other examples included open questions such as;

"What ways can you increase your swimming activity"?

This conveys greater degree of optimism and respect for choice than a question about behaviour such as;

"How are you going to do that?"

The revised strategies are demonstrated in figure 5 (see page 154).

Figure 5. A flexible menu driven approach:

Setting the Scene	Agenda Setting	Typical Day	Pros & Cons	Exploring Concerns
Rationale Collaboration; Rapport building.	**Rationale** To select topics for behaviour change.	**Rationale** Information exchange.	**Rationale** To examine costs/benefits of current behaviour; to understand ambivalence.	**Rationale** Identify costs of current behaviour; to voice arguments for change.
Content Outline of roles; expectations; confidentiality; Emphasis on freedom of choice.	**Content** Open questions. Agenda Setting chart.	**Content** Describes a typical day; takes 6-8 minutes.	**Content** Look at advantages & disadvantages of behaviour via a balance sheet.	**Content** Identify 'hassles' to daily management through open questions.
Example See Appendix 1	**Example** See Appendix 3	**Example** "Perhaps you can take me through a typical day in your life and you can tell me where your diabetes management fits in"	**Example** "What are the good things about change?" "What are the less good things"?	**Example** "What concerns you most about your HbA_{1c} reading"?

Importance and Confidence	Role of Significant Others	Perspectives Of Diabetes	Journey Of Change	Moving Forward Goals Actions
Rationale To explore confidence & importance of change.	**Rationale** To explore role of important others in behaviour change process.	**Rationale** Understanding control in management of diabetes.	**Rationale** To examine the 'how' of change.	**Rationale** To develop a plan for change.
Content Scaling questions between range of 0-10	**Content** Open questions relating to friends/family/ school	**Content** Open questions that explore locus of control (internal vs. external).	**Content** Open questions that explore self efficacy; previous successes; barriers.	**Content** Goal setting chart brainstorming solutions; identification of barriers.
Example "How do you feel at the moment about change, if 0 was not at all and 10 was very much, what number would you give yourself?"	**Example** "You are not bothered by clinic readings. How might clinic/your mother/friends see this?"	**Example** "What gets in the way of stopping you monitor your blood sugars?"	**Example** "You made a change that was difficult for you. What ways helped you make that change?"	**Example** Goal setting sheet (see appendix 4).

4:9 Conclusion

The processes involved in the development of an intervention, training in its components and subsequent supervision have been described in detail in this chapter. Aspects of the intervention were directly influenced by the 'menu of strategy' approach of Rollnick et al. (1992). Other aspects were developed from strategies used in general practice settings (Rollnick et al. 1997; Stott et al. 1995; Stott et al. 1996). A key challenge in the process of intervention development and training was the absence of literature on how to guide these processes. Subsequently identifying components of the intervention, training of the author and supervision happened simultaneously during delivery of the intervention. This is the first randomised controlled study in the adolescent diabetes field that has implemented MI in adolescents with type 1 diabetes, with particular emphasis on describing and delineating the intervention and training methods. Subsequently the approach used enhances credibility, permits evaluation and enables replicability in future protocols. The following chapter (Chapter 5) describes the aims, hypotheses and methods involved in implementing the study.

CONTENTS

CHAPTER 5: STUDY PART I - AIMS, HYPOTHESES AND METHODS

5:15:6 Attrition (drop out) characteristics

5.1 Introduction

The Randomised Controlled Trial (RCT) has been described as the optimal study design to minimise bias and obtain the most accurate estimate of an intervention's beneficial effects (Medical Research Council, 2000). The strength of the RCT is its ability to facilitate causal inference (Shadish et al. 2002). In most clinical trials new interventions are compared against existing treatments to test whether additional benefits are gained. However the paucity of clinical behavioural research in the field of adolescent diabetes has meant there is no existing standardised intervention with which a trial intervention may be compared. This chapter will provide an account of the aims, hypotheses and implementation of this study which conforms to the CONSORT statement (Moher et al. 2001 for the Consolidated Standards of Reporting Trials Group). CONSORT was specifically developed to provide guidance to authors about how to improve the quality of reporting of simple two-group parallel randomised controlled trials, so that outcomes can be interpreted both readily and accurately. Firstly the study aims and hypotheses are identified, along with specific design issues relevant to this study (sections 5:1-5:3). Considerations relating to attrition in studies are explored and components of the control group intervention are outlined (sections 5:4 and 5:5). Sections 5:6 -5:14 describe the methods involved in the design, recruitment and implementation of the study. Section 5:15 concludes with the method of analysis to answer the research question.

5:2 Research aims

The purpose of the study was to replicate and extend the findings of Channon et al. (2003) within a multi centre RCT design. The study aimed to provide a comparison of the effectiveness of two interventions [(Motivational Interviewing (Miller and Rollnick, 1991; 2002) and support counselling on glycaemic control and psychosocial functioning in adolescents with type 1 diabetes. Hypotheses were divided into primary and secondary outcomes.

5:2:1 Primary hypotheses

Hypothesis 1

Motivational interviewing will be more efficacious in reducing glycosylated haemoglobin (HbA_{1c}) in the intervention group at 12 months (end of intervention) compared to a support counselling intervention.

Hypothesis 2

Motivational interviewing will be more efficacious in reducing glycosylated haemoglobin (HbA_{1c}) in the intervention group at 24 months compared to a support counselling intervention.

5:2:2 Secondary hypotheses

Hypothesis 3

Motivational interviewing will be more efficacious in enhancing psychosocial functioning at 12 months (end of intervention) compared to a support counselling intervention.

Specific directions were hypothesised for each psychosocial questionnaire which are summarised in table 5. These questionnaires are described in greater detail in section 5:11:2 (p. 177).

Hypothesis 4

Motivational interviewing will be more efficacious in enhancing quality of life and well being at 24 months compared to a support counselling intervention.

Table 5: Specific hypotheses relating to psychosocial questionnaires (according to hypotheses 3 and 4).	
Well being subscales (WBQ)	The MI group will experience less depression, anxiety, positive well being, energy and general well being at 12 and 24 months compared to a support counselling intervention.
Personal models of diabetes (PMDQ)	The MI group will experience greater illness beliefs about diabetes at 12 months. Specifically the MI group will place greater importance in controlling their diabetes to prevent complications. They will have greater beliefs that behavioural actions will prevent complications. They will have lowered perceptions of the seriousness (threat) of diabetes and will perceive their diabetes to have less negative impact on their daily lives compared to a support counselling intervention.
Diabetes family behaviour (DFBS)	Motivational interviewing will be more efficacious in diabetes family behaviour outcomes at 12 months compared to a support counselling intervention.
Quality of life (DQOLY)	Motivational interviewing will be more efficacious in enhancing quality of life on subscales satisfaction, impact and worries at 12 and 24 months compared to a support counselling intervention.
Diabetes Knowledge (DKN)	There will be increased level of diabetes knowledge within the MI group compared to the support counselling group.
Therapeutic Alliance (TAQ)	Motivational interviewing will be more efficacious in enhancing perceptions of the therapeutic alliance on subscales bond, goals and tasks at 12 months compared to a support counselling intervention.
Health locus of control (CHLC)	Motivational interviewing will be more efficacious in increasing health locus of control (i.e. internality of beliefs to control diabetes) at 12 months compared to a support counselling intervention.
Diabetes self efficacy (SED)	Motivational interviewing will be more efficacious in increasing self efficacy at 12 months compared to a support counselling intervention.
Modified health care climate (HCCQ)	Motivational interviewing will be more efficacious in enhancing satisfaction with perceptions of the health care climate at 12 months compared to a support counselling intervention.

5:3 Methodological considerations

5:3:1 The logic of randomisation

The specific purpose of randomisation is used to ensure baseline equivalence between the two groups on all known and unknown factors which may possibly confound the causal or treatment effect under study (Altman and Schultz, 2001). Indeed, randomisation has a place in assessing behavioural interventions since it seeks to balance external influences between groups so that the true effect of an applied intervention is detectable (Stephenson and Imrie 1998). Blinding to treatment allocation in clinical trials is intended to prevent the expectations of patients or researchers from influencing the outcome.

5:3:2 Specific design issues of this study

Criticisms have been levelled at methodological weaknesses within the current research in paediatric chronic illness and diabetes in particular (Glasgow, Toobert and Glasgow, 2001). These limitations include sampling issues such as small, non representative sizes (Glasgow and Anderson, 1995), over reliance on cross sectional studies (Holmbeck et al. 2006) and lack of multi centre designs (Glasgow and Anderson, 1995). These design issues will be considered in turn.

The present study addressed the issue of non representativeness by recruiting a homogenous adolescent population-based sample. Adolescents were selected who attended outpatient paediatric clinics within hospitals in South Wales. Eligibility criteria were kept wide enough to apply the 'uncertainty principle' (Sackett, 2000)

whereby there is genuine uncertainty about which treatment is best for the patient. Selection for clinical trials participation affects the characteristics of patients under study and may have an impact on the ability to generalize the results of clinical trials (Hunter et al. 1987).

A major criticism of research designs in paediatric diabetes relates to the cross sectional nature of the studies, limiting the causal nature of variables under study (Glasgow and Anderson, 1995). Longitudinal studies permit changes in health related behaviour to be examined over time. The present study employed a longitudinal design to replicate and extend the findings of the pilot study by Channon et al. (2003), permitting evaluation of longer-term outcomes (12 months post intervention). This was considered advantageous particularly as gains or decrements in metabolic control and psychosocial functioning could be examined during key developmental trajectories - early adolescence and the transition to adulthood - when the young person is changing, developing and maturing. Willett et al. (1998) proposed that because developmental change in adolescence is continuous, two data points provide little information regarding 'the patterns of change' and advocated multiple data points.

The multi centre design increases generalisability of the study and allows comparison of results across and within centres (Glasgow and Anderson, 1995). The advantages of multi centre studies are that data can be pooled according to centre to assess treatment effect and treatment-by-centre interactions. There is a problem however regarding comparability with care, even when an intervention is standardised across

sites (Patenaude and Kupst, 2005). Quality of care and population characteristics may differ across centres. Five centres were identified from hospitals in South Wales. Specialist paediatric diabetes care from a paediatric endocrinologist and from a diabetes nurse specialist was provided in 1 out of 5 centres. The remaining centres delivered care by paediatric nurses and paediatricians with an interest in diabetes.

5:4 Attrition considerations

Attrition is a major factor in longitudinal research. This is particularly problematic in studies of paediatric populations with chronic illness (Holmbeck et al. 2006).
This raises the question why it is so difficult to maintain children in paediatric studies? One explanation offered by Clay (2000) is that the rigors associated with clinical trials or intervention research place unreasonable or unacceptable demands on the children and their families. These demands may include need for numerous clinic visits, repeated medical procedures (e.g. physical examination and blood tests), completion of written questionnaires, daily recording of activities and other inconveniences. These demands result in non-adherence, refusal, dropout and consequently a lack of data on effectiveness. One design factor in this present study was to implement psychosocial interventions that were acceptable and adaptable to children and their families within the complex context of their lives, affording them autonomy to choose where and when the interventions would be delivered. This was considered a key factor in diminishing attrition and refusals to participate.

5:5 Control group intervention (support counselling)

The aim of the control intervention was to provide support and education in a patient centred style that differed sufficiently in content from the MI intervention to rule out alternative explanations. Attention to the key components was incorporated into a manual (Appendix 6). The intervention method chosen as an alternative to MI was a support counselling intervention based on education and support around self management, such as the management of increasing responsibility for diabetes from the parent to the young person and specific challenges around self care. A significant aspect of this intervention included education as it has been demonstrated that this is most effective when delivered as part of routine care (Hampson, Skinner et al. 2001). Other specific roles of the control interventionist included prevention and training in hypoglycaemic awareness (Cox et al. 1995) along with the practice of implementation intentions (Gollwitzer and Branstätter 1997). Practice of an implementation intention involved setting a time and place for a desired behaviour (e.g. blood sugar monitoring, eating snack, taking up exercise) to be implemented at chosen time. The key components are summarised in table 6. Table 7 summarises the differences in components between the MI and control groups.

Table 6: The control intervention: Support Counselling

Aims: To provide support, information and self management goal setting in a patient centred style to adolescents with type 1 diabetes

Component	Rationale	Delivery
Communication skills	To develop a therapeutic relationship	Non directive discussion Elicit information Open questions Non eliciting
Information giving	To educate the young person about diabetes and self management	Provide information based on young person's needs and check understanding. Advice giving
Practical problem solving	For the young person to be an active problem solver with self care tasks	Personalised strategies and problem solving List barriers and plans to overcome Follow up progress in sessions.
Handover of responsibility from parents to young person	To reduce conflict with increasing responsibility in self management tasks and the diabetes regimen	Devise strategies of planning self care around cognitive, emotional and motivational factors.
Assess physical and psychological problems	To reduce challenges with self management	Provide practical solutions around self management. Limited emphasis on self efficacy
Blood glucose awareness training (BGAT)	To identify and prevent hypo and hyperglycaemia	Implement adapted intervention components of Cox et al. (1995).

The differences in components between the MI and control groups are summarised in table 7.

Table 7: Differences of components between the MI and control group

Motivational Interviewing (Intervention)	Support Counselling (Control)
Directive conversation	Non-directive
Eliciting	Non-eliciting
Limited advice giving	Emphasis on advice giving
Problem solving	Problem solving
Exploring discrepancy	Absent
Limited information giving	Information giving
Supporting self efficacy	Limited emphasis on supporting efficacy

5:6 METHOD

5:6:1 Design

The design was a multi centre two arm randomised controlled trial analysed by intention to treat. Five centres were identified (one academic teaching hospital and four district general hospitals which were affiliated with teaching hospitals within South Wales).

5:7 Participants

5:7:1 Inclusion and exclusion criteria

Inclusion criteria are the standards used to determine whether the person would benefit from participation in the trial. Based on the pilot study of Channon et al. (2003), it was decided to include adolescents who had reached a developmental stage consistent with an emerging independence in self care and responsibility for setting own goals. The age point of entry was set at 14 years, since adolescents at this age were deemed to have sufficient motor, cognitive and verbal skills to cope with the demands of the intervention along with the impact of diabetes management within their social and home environment. The upper age limit of 17 years allowed contact during the one year follow up before they possibly left home for work or college.

Exclusion criteria have been identified as characteristics that may interfere with investigation of intervention effects with adolescents with diabetes. It was decided to exclude participants who were diagnosed with diabetes within a year at commencement of recruitment due to the increased emotional and practical adaptation required by the families and the young person. Furthermore, the 'honeymoon period' (a period soon after diagnosis when the body is still producing insulin) would potentially alter glycaemic control and confound results. A diagnosis of learning disabilities and communication disorders were assumed to be inconsistent with the cognitive and verbal requirements of an intervention such as MI. Co-morbid disorders such as thyroid function and cystic fibrosis were excluded due to the additional multi agency involvement necessary to manage these disorders. Additionally the potential

physiological responses affecting blood glucose control associated with these disorders were considered confounding. Participants receiving psychiatric care, the involvement of social services and other medical agencies were also excluded due to the confounding nature of multi agency working and receipt of additional psychosocial care. The formal inclusion and exclusion criteria are listed in Table 8.

Table 8: Trial Inclusion and Exclusion criteria

Inclusion criteria:	▫ Individuals aged between 14-17 with a diagnosis of Type 1 diabetes for over a year at commencement of recruitment. ▫ Participants attending paediatric or adolescent out patient clinics in the participating centres.
Exclusion criteria:	▫ Newly diagnosed diabetes within a year of commencement of recruitment. ▫ A diagnosis of learning disabilities ▫ Disorders of communication. ▫ Cystic fibrosis. ▫ Thyroid dysfunction, ▫ Psychiatric involvement ▫ Those patients whose medical care is predominately managed at another medical centre. ▫ Patients accommodated by social services.

5:7:2 Sample size

Participants were aged between 14-17 years from different social backgrounds. Eighty participants agreed to take part in the study out of an eligible sample of 169 and were randomised to the two arms (n=43 MI group, n=37 control). Sixty seven participants eventually agreed to enter the study post randomisation, with n= 38 in the intervention group (MI) and n=29 in the control group. One participant was ineligible and was excluded from the analysis (MI = 38, Control =28).

5:7:3 Ethical approval

Ethical approval for patients to participate from each of the participation centres was sought from the relevant local research ethics committees (LREC's) namely; Swansea (Swansea NHS Trust); Cardiff (Cardiff and Vale NHS Trust); Merthyr (North Glamorgan NHS Trust); Newport (Gwent NHS Trust), and Bridgend (Bro Morgannwg Health Trust).

5:8 Power and sample decisional analytical techniques

The techniques used in this study aimed to reflect clinical as well as statistical significance. Decisions made for the purpose of the calculation were based on the study of Channon et al. (2003). Three independent statistical referees' agreed the following decisions. In order to detect a difference of 1% in mean HbA_{1c} (SD = 1.2%) at a 5% significance level with 90% power, 30 patients per group would be required. To allow for a loss to follow-up rate of 25%, 80 patients were required. A nomogram was used to determine the sample size (Machin et al. 1987).

5:9 Recruitment

5:9:1 Recruitment of centres

Five eligible paediatric diabetes centres were selected by the principle investigators (PIs) within South, South East, and South West Wales. Recruitment of participating centres took part between December 2001 and August 2002. Initial contact with each proposed centre was made by one of the PIs (JG) and the study was discussed via telephone. A copy of the Diabetes UK (DUK) funded study protocol was posted by

the author once the medical team from each centre expressed an interest in participating. A request was made that each centre's consultant paediatricians and diabetes nurses be present to meet the study research team. Once a date and time were agreed to meet the prospective team an outline of the study design and methods were provided by PowerPoint presentation, followed by a question and answer session. The inclusion and exclusion criteria were handed to the diabetes nurse and the author was provided with a list of eligible participants who fulfilled the criteria. When recruitment of centres had finished, the author provided each centre with an information pack containing details of the study, information on confidentiality, and contact numbers of the researcher and diabetes personnel. All five centres agreed to take part namely; Swansea (Swansea NHT Trust); Cardiff (Cardiff and Vale NHS Trust); Merthyr (North Glamorgan NHS Trust); Newport (Gwent NHS Trust), and Bridgend (Bro Morgannwg Health Trust).

5:9:2 Recruitment of centralised HbA_{1c} testing centre

A biochemical monitoring laboratory at United Bristol Healthcare Trust (UBHT) was selected by Diabetes UK to process HbA_{1c} samples. This centre was chosen since it was independent of the centres within South Wales and the standardised methods of testing allowed comparison with another DUK trial running parallel with the study at the UBHT. A set of guidelines was implemented which ensured consistency and precision in assay measurement. These included a) the use of the central laboratory EDTA vacuettes across centres, b) that independent researchers would be responsible for the collection, processing, and sending of blood samples, c) a pre-determined minimum volume of 0.5 mls of capillary or venous blood was required, d) specified

information provided for completion of laboratory forms which included patient name, date of birth, centre, date and time of processing of sample, e) storage of specimens to be kept at room temperature and posted to the laboratory no longer than 24 hours after processing, f) specialist packages were provided for safe transport, g) transport would be via first class post Monday – Thursday to ensure samples were received by the designated person and h) feedback of results would be sent at the end of the study, when requested by the author via email in a Microsoft EXCEL® spreadsheet for Windows (Version 1998).

5:9:3 Recruitment of participants

Recruitment of participants within each centre took place between January 2002 and September 2002. The time scale was determined in part by the speed of participant entry into the study, and because of resource, time and practical constraints, a cut off time point of September 2002 was determined. Two types of recruitment methods were employed; out-patient clinic and community based recruitment. The original decision to recruit participants from out-patient clinics was revised due to significant variation in recruitment rates between each centre. Although the Cardiff and Vale NHS Trust and Gwent NHS Trust centres provided the highest number of eligible participants, the number of patients who gave consent for access to information was below minimum number required to ensure viability of study. A decision was taken within the study team to use a community based recruitment method to improve accrual rates within centres.

5:9:3:1 Out-patient clinic recruitment

A date and time were made for the author to visit each participating out-patient clinic. Upon visiting the clinic, the author introduced herself to the clinical diabetes team and administrative personnel and a room was made available. A list of eligible patients was provided. Once potential participants had been seen by the diabetes nurse and consultant paediatrician, they were asked if they would be prepared to review further information on the study. Upon agreement the potential participant and their family were taken to a room that afforded privacy. Once the author introduced herself, the aims and purpose of the study were fully explained in a sensitive way that did not interrupt clinical care. The information was kept brief to avoid overload on the patient, and the patient and their family were encouraged to ask questions. The author's language was neutral and care was taken to present details of the interventions in a balanced way, together with the rationale for random allocation. The information given was carefully prepared so that patients of all levels of education had sufficient understanding of the study.

Once the patient and their parent or guardian had been given verbal information on the study they were offered the opportunity to take home an information sheet (Appendix 7) and 'consent to participate' form (Appendix 8) to enter the study. In order to contact the young person via telephone at home, a 'consent to contact' form (Appendix 9) was signed in the presence of the author during this time. If they agreed to enter the study, they were required to sign the 'consent to participate' form and, if under sixteen years, the parent, or guardian were also required to countersign the

agreement for their child to enter into the study (Appendix 10). A stamped addressed envelope was included for return of forms. In the event that eligible participants did not attend the out-patient clinic, a letter from the clinic paediatrician was sent to the patient (Appendix 11) and the parent or guardian (Appendix 12) informing them of the study with an accompanying information sheet.

A time period of two weeks was allowed for return of forms. On return of the consent form, patient's details were entered onto a database using EXCEL® spreadsheet for randomisation. If the patient declined to participate then a letter was sent thanking them for their time. However, due to poor postal response rate, a decision was taken by the study team to follow up potential participants via home telephone calls. This had been agreed by the patient and their parent during the initial contact with the author. Each call was kept brief and care was taken to avoid coercive language. If the patient stated they wished not to be part of the study, they were thanked for their time and reassured that their contact details would be destroyed. If the patient agreed to participate, a consent form was sent with a stamped addressed envelope and a time period of two weeks allocated for return of the form. The patient and their parent or guardian were reminded that the participant's name would be forwarded for randomisation and advised that dependent on which intervention they were allocated to, they would be followed up either by the author, or another researcher delivering the control arm. In the event of no response, a follow up telephone call was made to remind the patient. A further two weeks were allocated and in the event of no response, the patient was excluded from the study and a letter was sent thanking them for their time.

5:9:3:2 Community based recruitment

The slow recruitment via out patient clinics and the poor postal response rates led to a transfer of recruitment from out patient clinics to community based recruitment. This led to a shift in the recruitment process from sole responsibility from the author to the combined responsibility of author and diabetes nurses from the chosen centres. The centre diabetes nurse or the consultant paediatrician approached each eligible patient either by telephone or in out-patient clinic to enquire if they would be interested in receiving more information about the study. If the patient agreed to receive further information they were asked for their verbal consent for the author to visit them at home or in a location of their choice. Once the potential participant or parent had given verbal agreement, the information sheet was sent.

Verbal consent was obtained by the diabetes nurse or paediatrician for the author to contact the individual by telephone prior to visit. A mutually agreed time, date and location was made that was convenient for the individual and their family. A visit was made to the participant's home as agreed by the participant and family. The author introduced herself to the individual and their family and thanked them for their consent to obtain more information about the study. Each visit lasted approximately 30 minutes and consisted of revisiting the information sheet and exploring any questions raised. Wherever possible the parent or guardian was invited to be present and was encouraged to ask questions. The patient was offered the opportunity to make a decision to participate and if the patient agreed to participate, the 'consent to participate' form was signed by participant and their parent or guardian if under 16

years. If the participant required more time to make a decision, they were requested to post their consent form within two weeks. If there was no contact then was followed up by telephone call to their home. If the potential participant decided not to take part, they were thanked for their time and reassured that they wouldn't be contacted again by the study team.

Following receipt of the consent form the patient details were logged onto a database using EXCEL® spreadsheet. In the event of no response a follow up telephone call was made to remind the patient of their decision. A further two weeks were allocated and in the event of no response, the patient was excluded from the study and a letter was sent thanking them for their time. In the event that the individual declined to participate, they were thanked for their time and assured that they would not be contacted again by the study team.

Once recruitment rates had reached the numbers consistent with the level of statistical significance sought (n=80) the recruitment process ended in September 2002.

5:10 Randomisation process

Randomisation was undertaken between May 2002 - September 2002 by an independent statistician who was not involved in determining entry of participants into the study. Once consent forms had been completed the process was staggered according to centre recruitment numbers. When the level of recruitment had reached the required number per centre, participant details were forwarded for randomisation which included; name, age, hospital number, location of recruiting centre, date of

birth, and address. A two step remote randomisation process was adopted. The first step involved the adoption of a minimization, stratification form of randomisation based on the block method, with a pre-specified sequence of treatment allocation. Participants were randomly assigned in permuted blocks of four to either group. The second step involved identifying three strata (namely, age, gender and participating centre) and randomly assigning these to groups. The sequence was concealed until interventions were assigned which avoided the problem of predictability of allocation. Randomisation data was transferred to EXCEL® software and afforded password protection for concealment of group allocation to others.

5:10:1 Allocation to intervention group

Once the randomisation process was completed, participants allocated to the intervention group were contacted by the author by letter and /or telephone to inform them of their allocated group. They were given the choice of withdrawing their consent. Clinic staff across centres were informed of the participation within the research study although were blind to which arm of the trial they had been randomised. Questionnaires were collated, allocated an identification number and sent by first class post by an independent research assistant. A stamped addressed envelope was provided and the participants advised to return the questionnaires within four weeks and prior to the author's initial (baseline) visit. However, in the event of difficulties in completion of the questionnaires, the participants were reassured that any questions would be answered during the baseline visit and that the author would be 'blind' to the content of the questionnaires. Participants were given contact details of the author and advised to telephone the author and /or the diabetes research team if

required. A letter was sent to the participant's General Practitioner (GP) informing them of their patient's entry into the study.

5:11 Assessment instruments

5:11:1 Primary outcome measures

The primary outcome measure was plasma glycosylated haemoglobin concentrations (HbA_{1c}). Measurement of glycosylated haemoglobin has been advocated as the most valid method of determining the adequacy of glycaemic control (Rohlfing et al. 2002) and quantifying the risk of complications in patients with diabetes (Manley et al. 2003). To ensure standardisation of calibration of laboratory methods, all HbA_{1c} samples were collected in local EDTA venous blood collection tubes provided by and analysed at the central laboratory (UBHT) according to UK national guidelines for methods of HbA_{1c} testing. Methods for measurement of HbA_{1c} assays included a two level calibration Auto and Adams ArkRay™ analyser reported according to DCCT aligned standardisation values (Ball 2006, personal communication; Menarini diagnostics, 2006).

5:11:2 Secondary outcome measures

The outcome measures selected aimed to assess generic, disease specific and situation specific diabetes health measures in adolescent populations. They represent the best available measures of psychological factors which have been shown to be of importance in diabetes self-care. Some measures were selected based on the pilot study of Channon et al. (2003). These included; Diabetes Family Behaviour Scale. [(DFBS), McKelvey et al. 1993]; Diabetes Knowledge Scale [(DKN) Dunn et al.

1984]; Diabetes Readiness to Change Questionnaire [(DRCQ) adapted from the stages of change model, Prochasksa and DiClemente 1984] and the Personal Models of Diabetes Questionnaire [(PMDQ), Hampson et al. 1995]. Other measures were included on the requirement of DUK to allow comparability with the parallel DUK study at the UBHT. These included; Well-Being Questionnaire [(WBQ), Bradley, 1994]; Diabetes Quality of Life Measure for Youths [(DQOLY), Ingersoll and Marrero, 1991]; The Child Health Locus of Control [(CHLC) Parcel and Meyer, 1978] and Self-efficacy for Diabetes Scale [(SED), Grossman et al. 1987].

Three measures, the Diabetes Readiness to Change Questionnaire [(DRCQ), the Therapeutic Alliance Questionnaire [adapted from Working Alliance Inventory (Horvath and Greenberg, 1989)] and the Personal Models of Diabetes Questionnaire [(PMDQ), had not been adapted especially for this study and have not been subjected to reliability and validity checks, although support for the validity of the original 8 item PMDQ was demonstrated by Glasgow, Strycker et al. (1997). All the remaining measures selected have been fully standardised and validated so that results with other studies would be comparable. A demographic questionnaire was designed by the author specifically for this study which measured age, duration of diabetes, educational attainment, family structure, and social class.

The measures selected are described below.

5:11:2:1 Well-Being Questionnaire [(WBQ), Bradley, 1994]

The WBQ (Appendix 13) is a dimension specific measure of psychological well being that has considerable application in the field of adolescent diabetes. A working group of the World Health Organisation/International Diabetes Federation (Bradley and Gamsu, 1994) advised using the WBQ as routine screening of psychological well being in diabetes care. More recently a report by the National Centre for Health Outcomes Development (Garrett, Schmidt and Fitzpatrick, 2001) suggested that the WBQ is recommended in studies where evaluation of psychological well being is required. The WBQ is a 22 item scale that measures well being over previous 7 days. Items are measured on a 4 point Likert response format where 3 = all the time and 0= not at all. The scale is subdivided into 4 domains namely; depression (6 items with a score range 0-18), anxiety (6 items with score range 0-18), energy (4 items with a score range 0-12) and positive well being (6 items with a score range 0-18). Total general well being (score range 0-66) represents the total score. Higher scores on all subscales represent better well being. The positive well being and energy subscales have been described as the most innovative features of the WBQ since they focus on positive as well as negative affect (Pouwer, van der Ploeg et al. 1999). The scales have been shown to be sensitive to well being in adolescents (Skinner and Hampson, 2001; Edgar and Skinner, 2003) and to changes in well being associated with treatment regimens (Bradley and Lewis, 1990).

5:11:2:2 Diabetes Knowledge Scale [(DKN), Dunn, Bryson, Hoskins, Alford, Handelman, and Turtle, 1984]

The DKN (Appendix 14) provides a measure of theoretical and physiological knowledge about diabetes, and is used in diabetes education and research settings where it is desirable to measure knowledge reliably and quickly. There are 15 multiple choice items, 12 of which have 4 responses and 3 items which have 5 responses where there is more than 1 correct answer. The fifteen items examine knowledge in 5 broad categories; general diabetes care, diet and food, sick day management, hypoglycaemia and insulin action. Items 1-12 are scored 1 for a correct response and 0 for an incorrect response. For items 12 -15 a combination of correct answers are scored as 1. If any combination is incorrect then a score of 0 is given. The total score possible is 15. A Cronbach's alpha of 0.80 was demonstrated by Beeney, Dunn and Welch, (1994). The scale has been used to evaluate a number of diabetes educational interventions and is sensitive to interventions designed to improve understanding of diabetes and its management (Beeney et al.1994).

5:11:2:3 Diabetes Family Behaviour Scale. [(DFBS), McKelvey, Waller, North, Marks, Schreiner, Travis and Murphy 1993]

The DFBS (Appendix 15) was designed to measure diabetes-specific family behaviours thought to be important in helping or hindering a child or adolescent in following a diabetes treatment regimen. The scale includes 47 Likert-type items (scores ranging from 1 = all the time, to 5 = never) yielding scores between 47-235. A higher score represents poorer family involvement of diabetes family behaviour. The scale is subdivided into two subscales measuring specific areas of family support:

Guidance-Control (15 items) and Warmth-Caring (15 items). Within the validation study Cronbach alpha coefficients were .86 for the total score, .81 for the guidance-control subscale, and .79 for the warmth-caring subscale. The scale has been shown to correlate with metabolic control (McKelvey et al.1993) and in longitudinal study by Jacobson et al. (1990) family conflict measured by the DFBS was the strongest predictor of poor adherence to regimen. The more recent study by Grey et al. (2000) found that an intensive coping skills intervention was associated with improved parent guidance and control behaviours measured on DFBS. In the pilot study of Channon et al. (2003) DFBS was shown to negatively correlate with HbA_{1c}.

5:11:2:4 Diabetes Readiness to Change Questionnaire [(DRCQ)]

The DRCQ (Appendix 16) was designed specifically for pilot study (Channon et al. 2003) based on Prochaska and DiClemente's Transtheoretical Stages of Change Model (1984). This postulates that the cessation of high risk behaviours such as smoking, and acquiring behaviours with a benefit to health such as exercise, involves the progression through five stages of change. Readiness to change was assessed on eight health behaviours which included; injecting, blood sugar monitoring, exercise, diet, improving metabolic control, autonomy in self care and adherence to insulin, and smoking. Each behaviour was divided into five 'stage of change' categories: Pre-contemplation, Contemplation, Preparation, Action and Maintenance. An example is as follows; 'Do you always do the amount of exercise you have been advised to do? (a) No and I do not plan to in the next 6 months (Pre-Contemplation), (b) No but I would like to in the next 6 months (Contemplation), (c) No but I plan to soon (Contemplation), (d) No but I have been trying to recently (Preparation); (e) Yes I

have been for less than 6 months (Action) and (d) Yes I have been for more than 6 months (Maintenance). There are 2 further dichotomous questions which relate to diabetes staff and the young person's perception of current weight and whether the young person smokes. Because the scale was specifically developed for this study, there are no formal scoring criteria on which to classify responses reliably.

Preliminary scoring of the scale for the purpose of the thesis was as follows.
The frequency of the participant's 'stage of change' choice was summed across the health behaviour domains and expressed as a percentage according to the 'stage of change' response category. For example, if participants scored consistently (i.e. more than 4 out of a possible 8 target behaviours on a designated category), their 'stage of change' was identified according to the pre-defined category (e.g. Contemplation). The psychometric properties of the scale have not been tested. Furthermore, it was difficult to compare with previously published stage of change questionnaires as most questionnaires do not use the same definition of stages of change (Etter and Sutton, 2002). The DRCQ was used in the Channon et al. (2003) pilot study as a screening tool to include participants who scored in the 'Pre contemplation' 'Contemplation' and 'Preparation' categories. Within this study, readiness to change of 64% of adolescents moved one stage higher in at least three out of eight behaviours. The psychometric reliability and validity of the questionnaire remains to be examined.

5:11:2:5 Modified Health Care Climate Questionnaire [(HCCQ), Williams, Grow, Freedman, Ryan and Deci, 1996]

The HCCQ (Appendix 17) is a 15-item Likert type measure that assesses patients' perceptions of the degree to which they experience their health-care providers to be autonomy supportive (i.e. patient centred) versus controlling in providing general treatment or with respect to a specific health-care issue. The scale is based on the Self Determination Theory (SDT) framework (Deci and Ryan, 1985). This model proposes that people behave in health affirming ways when they feel in control of their lives (intrinsic motivation) and are supported from others (autonomy support). Perceptions are rated on a 7 point scale ranging from 1 = Not at all true, to 7 = Very true. The range of scoring is between 21-99, with higher scores reflecting higher autonomy support. Although the HCCQ scale was validated originally by Williams et al. (1996), the item consistency and validity was not reported. Williams, Freedman et al. (1998) found that when the health care climate (measured by the HCCQ) was perceived to be rich with provision of choice, acknowledgement of patient's emotions, and minimal pressure to behave in certain ways, glycaemic control and motivation to improve glucose values improved. It has also been used to measure provider autonomy supportiveness in teenage smoking cessation (Williams, Cox et al. 1999) and to rate observations of patient – provider interactions (Williams and Deci, 2001).

5:11:2:6 Diabetes Quality of Life Measure for Youths [(DQOLY), Ingersoll and Marrero, 1991]

The DQOLY (Appendix 18) is a revised version of the DQOL (Jacobson et al. 1988) used in the Diabetes Control and Complications Trial (DCCT, 1993) and is used specifically for adolescents with diabetes. The DQOLY differs to the DQOL in a number of ways. Rather than measuring four domains the DQOLY has three inter correlated domains; diabetes life satisfaction, disease impact, disease related life worry and one general health perception question. The questionnaire comprises 52 items rather than 47 in the DQOL. Scores are subdivided according to the 3 domains, rather than a total overall score. The satisfaction subscale contains 17 items that are scored from 1 (very satisfied) to 5 (never satisfied). Scores range between 17-85. The impact subscale contains 23 items that rates impact of diabetes from 1 (no impact) to 5 (always affected) except one item where scoring is reversed. Scores range between 27-111. The disease related worries subscale contains 11 items that rates worries about diabetes from 1 (never worried) to 5 (always worried). The scores for this domain range between 11-55. There is one health perception question which is scored from 1- 4, a low score indicating better quality of life. Lower scores overall indicate a higher quality of life. Reliability and validation were demonstrated by the authors via high Cronbach's alpha coefficient scores and high test-retest correlations. Construct validity was originally demonstrated by correlations with The Symptom Checklist [(SCL-90R) Derogatis, 1994]; the Bradburn Affect Balance Scale [(ABS), Bradburn, 1969] and the Psychological Adjustment of Illness Scale and Sensitivity to Change [(PAIS) Derogatis, 1986]. However it has recently been argued that poor construct validity has hampered ability to demonstrate positive effects with metabolic control

and an international research team tested the construct validity of the DQOLY in twenty two centres, across eighteen countries in adolescents with type 1 diabetes (Skinner et al. for the Hvidøre Study Group, 2006). The authors have devised a short form (DQOLY-SF) which has demonstrated content and construct validity, as well as satisfactory internal consistency.

The DQOLY has been used extensively in studies measuring adolescents quality of life in diabetes (Grey et al. 1998; Grey et al. 2000; Vanelli et al. 2003; Hoey et al. 2001).

5:11:2:7 Self-efficacy for Diabetes Scale [(SED), Grossman, Brink, and Hauser 1987]

The SED (Appendix 19) is a 35 item Likert response questionnaire that measures self-efficacy beliefs in the young person's perceptions of ability and power to control their diabetes. Based on Bandura's (1977) theory of self efficacy, it measures three subscales; diabetes specific situations, medical situations, and general situations. The scale consists of 35 Likert-type items (scored 1 to 6) in three subscales: diabetes-specific self-efficacy (24 items), medical situations self-efficacy (five items), and general situations (six items). Participants are asked to rate their self efficacy for all items on a 5-point scale ("*Very sure I can't*" to "*Very sure I can*"). Scores range between 35-210 with a higher score representing higher self efficacy. In the original validation by Grossman et al. (1987) the coefficient alpha ranged from .90 to .92 for the total scale and the diabetes-specific subscale to .60 for the general situations subscale.

The SED asks children to rate their level of proficiency at specific diabetes tasks, such as recognizing low blood glucose levels or adjusting insulin doses based on exercise. These subscales measure self efficacy on three levels generality, task specific and general. The respondent is asked to rate their competence on a 5 point Likert scale on how much they believe they can or cannot carry out a behaviour. An example of an item is, "*I believe I can /cannot be the one in charge of giving my insulin injection to myself*". Validation of the SED was sampled on 68 adolescents ages between 12-16 years with Type 1 diabetes within US summer camps. The authors found that self efficacy scores on subscales, diabetes specific, medical situations and general situations were inversely related to metabolic control, although this finding was significant only for girls. The finding confirmed the high reliability and criterion validity of the scale. It is noted that within this study, metabolic control was measured via average blood glucose levels, urine glucose levels and urine acetone levels taken as an average over a 4 day period. It is reported however within the literature that HbA_{1c} standardised index values remain the most consistent and reliable measure of glucose control over a 2-3 month period (Kilpatrick, 2004).

5:11:2:8 The Child Health Locus of Control [(CHLC) Parcel and Meyer, 1978]

The CHLC (Appendix 20) is a 20-item binary (Agree/Disagree) response questionnaire addressing the degree of internality/externality of the child's locus of control in relation to health issues. Each item consists of a statement about the child's belief about influencing health and requires the child to indicate whether these are true by a yes/no response. The scale can be scored in a uni-dimensional (internal-

external) or in a multidimensional (internal - powerful others- chance) way. For the purpose of the present study scores were conducted on the uni-dimensional format. The range for the score is 0 (high external) to 20 (high internal). The original internal consistency of the scale was .753 with a mean score among adolescents of 31.99 (SD 3.88). Each item consists of a statement regarding the child's belief about influencing health and requires the respondent to indicate whether these are true by a yes/no response. The psychometric properties of the scale were examined in the validation study by Parcel and Meyer in 148 healthy children ages between 7 to 12 years. The scale demonstrated a Kuder-Richardson reliability co-efficient of 0.753. Older children demonstrated higher internal locus of control. The outcomes however were based on scores of healthy children and one of the recommendations of the authors was that additional work was required to demonstrate the predictive value of the scale in health situations.

Some preliminary analyses on the psychometric status of the scale were reviewed by O'Brien et al. (1989) in 1000 healthy adolescents within a high school setting. As in the original validation study, adolescents' beliefs that they had control over their own health increased as a function of age. Beliefs in internal control had low, negative correlations with measures of external control which the authors argued provided evidence of discriminant validity.

More recently the response format of the scale has been examined in 444 children and adolescents by Bases and Schonfeld (2002). The authors found a developmental progression with increasing age (ages between 9 -12 years) related to higher tendency

to report internal scores. The mean score for children ages between 11 and 15 was 31.1 (SD 3.6) (range 20-40) which corresponds to the mean of the original test by Parcel and Meyer (1978) of 31.99 SD 3.88). The authors found that changing the structure of the scale by rewording items led to different scores highlighting the limitations within the binary form. However the psychometric properties of the CHLC have yet to be established in adolescents with chronic conditions.

5:11:2:9 The Therapeutic Alliance Questionnaire [TAQ adapted from Working Alliance Inventory (WAI) (Horvath and Greenberg, 1989)]

The TAQ (Appendix 21) is a 15 item Likert response questionnaire that has been adapted specifically for this study from the Working Alliance Inventory [WAI (Horvath and Greenberg, 1989)]. The questionnaire was developed to measure the client's experience of the relationship with the therapist as being helpful in achieving goals, tasks and collaboration in the early stages of counselling and psychotherapy. There are twenty three items rated on a 5 point scale (1=Strongly disagree, 5=Strongly Agree). The questionnaire is divided into three subscales measuring the client's perceptions of the therapeutic bond, the collaborative nature of tasks set, and the collaborative nature of goal setting. The scores range between 50-83, with a higher score representing stronger therapeutic alliance. The psychometric properties of the original instrument have strong support for reliability and moderate support for validity (Horvath, 1994). Several adapted versions of the scale have been used within MI studies to measure the therapeutic alliance, although there has been no formal psychometric testing of these adapted scales to date (personal communication, Zuckoff, 2002). A consistent finding in the literature on the therapeutic alliance is that

the quality of the therapeutic relationship is directly related to subsequent therapeutic outcome (Martin et al. 2000).

5:11:2:10 Personal Models of Diabetes Questionnaire [(PMDQ), Hampson, Glasgow, and Foster, 1995)]

The PMDQ (Appendix 22) is a forty item self report instrument. It measures perceptions of four constructs based on the Self Regulation Model of Leventhal et al. (1997). The scale is developed from the Personal Models of Diabetes Interview (Hampson et al. 1990; Hampson et al. 1995). There are forty items which evaluate the following four domains; importance of behavioural actions to control diabetes and complications (*Importance*), effectiveness of treatment to control diabetes (*Treatment effectiveness*), perceived seriousness (threat) of diabetes (*Perceived seriousness*), and perceived impact of diabetes on daily life (*Impact of diabetes*). Each item has a five-point Likert scale response option (ranging from 1= not at all serious/important/likely to help, to 5=extremely serious/important/likely to help). Scores are subdivided according to each domain. The '*importance*' domain scores range between 8-40, with a higher score representing stronger beliefs in the importance to control complications. The '*perceived effectiveness*' domain scores range between 10-50 with a higher score representing stronger beliefs that the effectiveness of the treatment will control diabetes. The '*perceived seriousness*' of the threat of diabetes domain scores range between 11-55, and the scoring is reversed with a higher score representing less perceptions in the threat of diabetes. Finally the '*perceived impact*' of diabetes domain scores between 11-55, again with reversed scoring, with a higher score representing lower perceived negative impact of diabetes. The total score range

between 40-200, with a higher score representing stronger beliefs about diabetes to determine health behaviour. Personal models have been found to be key factors in influencing self care, well being and glycaemic control in adolescents with type 1 diabetes (Skinner and Hampson, 1998; Skinner et al. 2000; Skinner and Hampson, 2001). There has been no formal validation of the extended 40 item PMDQ used within the present study.

5:11:2:12 Demographic questionnaire

A demographic questionnaire (Appendix 23) was developed specifically for the study. Basic background information was gathered on the following data elements; gender, age, duration of diabetes, family structure, educational attainment according to exams passed or predicted, family employment structure and person responsible for management of diabetes. There was no formal classification of area deprivation linked to postcode. Demographic variables were not specified *a priori* to be included in outcomes such as moderating or mediating factors, and the questionnaire was not designed for comparison across studies.

5:12 Baseline visit

5:12:1 Discussion of the study

A baseline visit was arranged by the author to discuss the practicalities of the study and to offer the opportunity to ask questions prior to data collection. Participants were reminded that the content of the interviews within the study and data outcomes would be confidential to the researcher and they were requested not to disclose the allocated intervention group to their diabetes nurse or paediatrician to ensure effective blinding

of the study. The participant and their parent were reminded that in the event that sensitive issues were disclosed that were deemed to relate to child protection issues, or circumstances that would severely jeopardise their physical and mental health, the author would discuss these issues with the principal investigators for further advice. They were reminded that a letter had been sent to their GP informing of participation but that no other information would have been disclosed. Participants were reminded that the choice meeting location and frequency of contact would be determined by them. Reassurance was given that they were free to withdraw from the study at any time, and that the interview and questionnaire data would be kept in a locked drawer for safety and confidentiality. They were reassured that the researcher would be 'blind' to the responses of the questionnaires and outcomes of HbA_{1c} data. In order to ensure accurate 'blinding' of the study, any queries relating to the questionnaires were discussed during this initial interview. Once the practical issues relating to the study were explored, baseline data (HbA_{1c} and psychosocial questionnaires) were obtained.

5:12:2 Baseline data collection: Glycosylated Haemoglobin (HbA_{1c})

During the initial visit, a sample of venous or capillary blood was obtained, and the specimen posted to the laboratory according to protocol. If the centre out-patient nurse obtained the sample, then the central laboratory guidelines were explained to the nurse, and instructions were provided on accurate labelling of forms. The author ensured that the nurse was able to contact the author or control interventionist either in person or by telephone in the event of any difficulties in obtaining the sample. In all cases the author or control group researcher was responsible for the safe packaging and posting of each specimen, and a follow up telephone call was made by the author

every two weeks to the designated laboratory personnel to ensure delivery of named specimens.

5:12:3 Baseline data collection: Psychosocial questionnaires

Questionnaires that had been completed were placed in a sealed envelope and transferred to a locked drawer for future entry of data onto a computer database. On some occasions it was necessary to work through the questionnaires with the participant. To prevent bias and the possibility of a social desirability response occurring, the author intervened only to clarify questions posed by the participant. An independent research assistant was responsible for collating and coding of the data from the questionnaires. Coding frames were standardized with the DUK parallel study at UBHT to ensure consistency in outcome scores for possible future comparisons. Questionnaire data were transferred to SPSS© software Version 11.0 (Windows 98).

5:13 Follow up data collection

The participants underwent follow up assessment at 6, 12, and 24 months after the baseline interview. Wherever possible data were collected face to face. Towards the end of the study and at 24 month follow up, participants who had moved out of the area or refused face to face meetings were requested to post questionnaires to the independent research assistant. A letter was sent from the study team to the participants requesting the collection of follow up data. Arrangements were made for the local centre diabetes specialist nurse to collect an HbA_{1c} sample when the participant attended the diabetes out patient clinic which coincided with follow up

date. In a small number of cases follow up was restricted to the HbA_{1c} sample taken by the centre diabetes specialist nurse.

Follow up assessment at 6 months included:

- HbA_{1c}
- Diabetes Readiness to Change Questionnaire (DRCQ)

Follow up assessment at 12 months included:

- HbA_{1c}
- Diabetes Readiness to Change Questionnaire (DRCQ)
- Adapted Therapeutic Alliance Questionnaire (TAQ)
- Diabetes Family Behaviour Scale (DFBS)
- Diabetes Quality of Life in Youths (DQOLY)
- Well Being Questionnaire (WBQ)
- Child Health Locus of Control (CHLC)
- Self Efficacy for Diabetes Scale (SED)
- Modified Health Care Climate questionnaire (HCCQ)
- Personal Models of Diabetes Questionnaire (PMDQ)
- Diabetes Knowledge Scale (DKN)

Follow up assessment at 24 months included:

- HbA_{1c}
- Diabetes Quality of Life in Youths (DQOLY)

- Well Being Questionnaire (WBQ)

5:14 Retention strategies

Because of the threat of attrition to internal validity of the study, attempts to minimize attrition rates were made by allowing patients a longer period of time from four weeks to six weeks to complete baseline data once seen / or sent questionnaires. Retention strategies included follow up telephone calls and informal reminder cards. A newsletter describing the progress of recruitment was posted which served as a reminder particularly for those participants where the time gap between randomisation and intervention was greatest. Other incentives included sending birthday/christmas cards and providing snacks and beverages when conducting interviews at a restaurant or coffee shop. In the event that a participant wished to be excluded from the study and had informed the author face to face or by telephone, then they were thanked for their participation and a request made to complete data in the absence of receiving the intervention. Reasons for drop out were documented. If participants declined the opportunity to complete follow up data, they were thanked for their participation and reassured that they would not be contacted by the study team again. Participants who failed to attend for appointments were sent a letter asking if they still wished to take part in the study and provide follow up data. If there was no response a follow up telephone call was made. In the event of no response to the call they were removed from the study, and a letter was sent thanking them for their participation. Completed questionnaire data was kept in a locked drawer.

5:15 Method of Analysis

Data were entered onto a computer database and analysed using SPSS (Version 11.0) statistical package (SPSS In; Chicago, USA). Data were analysed by intention to treat as it gives "*unbiased and consistent estimates of a treatment and should wherever possible, be the analysis of choice*" (Heritier et al. 2003: p. 440). Although every effort was made to ensure a complete HbA_{1c} data set for each participant this was not achieved due to lost or insufficient samples, participants discontinuing the study or being unavailable for sampling. The number of participants who completed data are reported within the analyses.

5:15:1 Data screening

The data were screened for accuracy, missing values, outliers and normality prior to conducting statistical analyses. For each of the HbA_{1c} values, missing data were imputed by using the mean values of the remaining data. For the psychological scales, subjects with $\leq 20\%$ of scale items missing were imputed by using the mean values of the remaining items. Skewness, kurtosis, histograms, Q-Q plots and scatterplots were reviewed to ensure that normal assumptions were met in all the analyses (Tabachnick and Fidell, 1996). Histograms, Q-Q plots and indices of skewness and kurtosis were used to evaluate assumptions of normality and a conservative index of 3.0 for skewness and 10.0 for kurtosis was set (Kline, 2000). The CHLOC demonstrated marked negative skewness (baseline skewness =-.579, SE.302; 12 months skewness -.805 SE .327). The HbA_{1c} measurements and other questionnaire data were considered to be normally distributed. The CHLOC data (baseline and 12 months)

were transformed using reflection and square root transformation as recommended by Tabachnick and Fidell (1996). The transformed distribution was examined via Q-Q plots.

5:15:2 Internal consistency of measures

The internal consistency reliability estimation of the psychosocial questionnaires were analysed using Cronbach's alpha reliability coefficient (Cronbach, 1951). The DRCQ was excluded due to paucity of information on scoring the scale. Internal consistency analyses were conducted for baseline DQOLY subscales, SED, DFBS, DKN, CHLC, WBQ subscales, PMDQ subscales, HCCQ, and TAQ. Cronbach's alpha coefficient (Cronbach 1951) was determined to establish reliability. Nunnally (1978) regarded an alpha of 0.9 as the minimum acceptable for making decisions about individuals, but 0.8 adequate for comparing groups. Others consider that an acceptable minimum alpha can be 0.7 – 0.8, or even lower for short subscales (Todd and Bradley, 1994).

5:15:3 Baseline data

Descriptive statistics for both HbA_{1c} and psychosocial questionnaires were analysed using means, standard deviations and confidence interval for the difference between two group means. Due to the normal distribution of the data, parametric analyses were used. A one way Analysis of Variance (ANOVA) using a significance value of $p<0.05$ was conducted to compare mean differences between the MI and control group in HbA_{1c}. Significance testing for the psychosocial questionnaires were not conducted since testing for baseline differences is statistically unjustified (Roberts and Torgerson, 1999; Altman and Dore, 1990).

5:15:3:1 HbA_{1c} at follow up

Descriptive analysis of HbA_{1c} at 6, 12 and 24 months were undertaken using the mean, standard deviations and confidence interval for the mean difference between the two groups. To compare the differences in HbA_{1c} between the MI and control group between baseline, 12 months and 24 months, a repeated measures analysis of covariance (ANCOVA) was performed with the baseline HbA_{1c} treated as the covariate (i.e. controlling for baseline HbA_{1c}). To examine the descriptive data of HbA_{1c} across the study period, two sets of analyses were undertaken;

1) mean HbA_{1c} concentrations analysed at each time point (i.e. baseline, 6 months, 12 months and 24 months).

2) mean HbA_{1c} based on participants with complete HbA_{1c} data across these time points (n=47 participants in total).

5:15:3:2 Psychosocial questionnaires at follow up

Descriptive analyses of the 12 month questionnaire data were undertaken using the mean, standard deviation and confidence interval for the mean difference between the two groups.

Inferential analyses were conducted using repeated measures ANCOVA to compare differences in means between the MI and control groups. Baseline data of each questionnaire was treated as the covariate. To allow for tests of multiple comparisons

(9 questionnaires in total), the Bonferroni correction factor was used (Bland, 2002). Significance values less than p=0.006 were considered significant.

Follow up data at 24 months were analysed on the well being (WBQ) and quality of life (DQOLY) subscales only. To compare differences in well being and quality of life subscales between the MI and control groups, repeated measures ANCOVA was conducted with baseline quality of life and well being scores treated as the covariate.

5:15:4 Excluded data

The Diabetes Readiness to Change questionnaire (DRCQ) was completed by participants at baseline, 6 months and 12 months although scores have not been included in the study analyses. This was due to paucity of information on how to code and analyse the different categories, along with absence of piloting prior to data collection within the study.

5:15:5 Sub-group analyses

Subgroup analyses were undertaken and these were analysed and reported according to guidance within the literature (Brookes et al. 2001; Moher et al, 2001 for the CONSORT Group) to avoid a 'data dredging' approach. Due to the low sample sizes on which analyses are based, a more cautious interpretation of conclusions drawn was warranted.

5:15:5:1 Insulin measurements

Sub group analyses of available data on daily insulin dosage per body weight in kilograms were conducted between the MI and control group over the 24 months study period to analyse differences between the MI and control group. This data was collected from available notes or databases retrospectively and not specified *a priori.* To analyse the mean differences between the two groups on baseline insulin dosage, a one way ANOVA was conducted. To analyse differences in means across study period (baseline, 12 months and 24 months), a repeated measures ANCOVA was conducted with daily insulin dose at baseline treated as the covariate.

5:15:5:2 Poorly controlled participants

Further sub group analyses were conducted on young people who were defined as poorly controlled with baseline HbA_{1c} measurements of ≥9.0%. Although there is no benchmark HbA_{1c} value defining poor control, this figure represents a defining value signified by ISPAD (2000) that is suboptimal and renders the young person at risk for future complications. Descriptive analyses were conducted on demographic characteristics between participants defined as poorly controlled and adequately controlled (i.e. HbA_{1c} measurements <9.0%). Descriptive data for the MI and control group are presented for those questionnaires that were statistically significant. Inferential analyses on HbA_{1c} were conducted using repeated measures ANCOVA with baseline HbA_{1c} treated as the covariate and intervention group as the between groups factor. Psychosocial questionnaires were analysed using non parametric Mann Whitney *U* tests, since the small sample sizes (n=32) violated assumptions for repeated measures ANOVA.

5:15:6 Attrition (drop out) characteristics

Data from participants who dropped out of the interventions (n=10) were analysed to identify demographic, HbA_{1c} and psychosocial characteristics within this group. This included descriptive analyses and exploration of differences between the two groups on HbA_{1c} and psychosocial questionnaires. Non parametric methods were conduced using the Mann Whitney *U* Test since assumptions for parametric analyses were not met due to small sample sizes. Although the DRCQ data were not analysed for the main trial, preliminary examination of the participant's allocation of 'stage of change' (SOC) category was carried out according to each of the eight health behaviour domains (see section 5:11:2:4, p.183-184 for outline of coding).

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6:1 Introduction

This chapter presents the findings from the RCT along with exploratory sub-group analysis and participant characteristics analysed retrospectively. The presentation of findings is structured as follows. The first three sections (6:2-6:6) present findings relating to data transformation, internal consistency of measures, participant flow and attrition rates. Sections 6:5-6:7 provide findings on demographic data, along with baseline data of HbA_{1c} and psychosocial questionnaires. Sections 6:7-6:9 provide findings on the primary outcome HbA_{1c} in relation to hypothesis testing 1 and 2. Sections 6:9 – 6:10 provide findings on the secondary outcomes, psychosocial questionnaires and in particular specific outcomes in relation to hypotheses testing of each questionnaire. Section 6:10-6:12 present sub-group analysis of insulin measurements and poorly controlled participants, along with sample characteristics of participants who dropped out of the study. The chapter concludes with a summary statement of the findings.

6:2 Data transformation

The CHLC demonstrated marked negative skewness (baseline skewness =-.579, SE.302; 12 months skewness -.805 SE .327). The HbA_{1c} measurements and other questionnaire data were considered to be normally distributed. The CHLC data (baseline and 12 months) were transformed using reflection and square root transformation as recommended by Tabachnick and Fidell (1996). The transformed distribution was examined via Q-Q plots. Mean baseline scores post transformation

[(MI= 10.87(SD 2.53), Control 11.47 (SD2.11)] and post intervention [(MI = 11.29 (2.59) Control 11.82 (1.95)] displayed greater tendency to normality.

6:3 Internal consistency of measures

The internal consistencies of all scales were satisfactory, except the CHLC and Impact of Diabetes Subscale on the PMDQ. The alpha coefficient for each questionnaire is displayed in table 9 (see following page)

Table 9: internal consistency of baseline questionnaires, number of items, their minimum and maximum scores and sample size

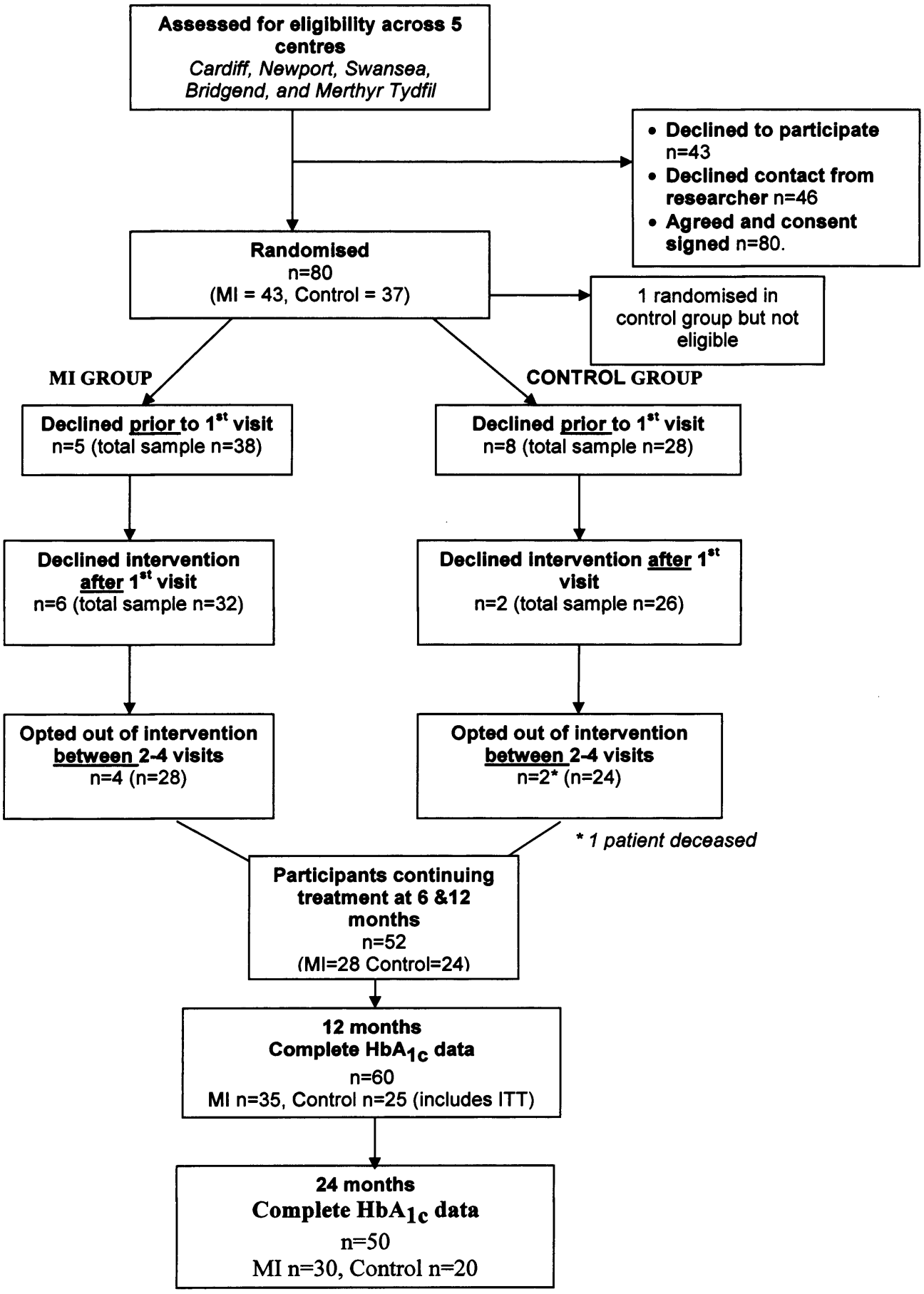
Baseline data				
Questionnaire	**N (based on cases excluded listwise deletion)**	**No of items**	**Alpha (α)**	**Min-Max score**
WBQ				
Anxiety	59	6	.863	0-18
Depression	59	6	.767	0-18
Energy	59	4	.767	0-12
Positive well being	59	6	.846	0-18
Total general well being	59	22		0-66
SED	36	35	.871	35-210
DFBS	47	32	.726	47-235
CHLC	63	20	.605	0-20
DQOLY				
Satisfaction	65	17	.918	17-80
Impact	33	23	.869	27-111
Worries	53	11	.839	11-55
PMDQ				
Importance to prevent complications	65	8	.756	8-40
Effectiveness of treatment	58	10	.731	10-50
Perceived seriousness	58	11	.892	11- 55
Impact of diabetes	61	11	.666	11-55
TAQ	50	23	.850	50-83
HCCQ	64	15	.909	21-99
DKN	64	15	.719	0 -15

Note: DQOLY = Diabetes quality of life in youths; SED = Self Efficacy for Diabetes Scale; DFBS= Diabetes Family behaviour Scale; HCCQ = Health Care Climate Questionnaire; PMDQ= Personal Models of Diabetes Questionnaire; CHLC = Child Health Locus of Control; DKN = Diabetes Knowledge Questionnaire; WBQ = Well Being Questionnaire and TAQ= Therapeutic Alliance Questionnaire

6:4 Participant flow

The flow diagram (Figure 6) shows the trial profile. From the original 169 eligible patients, 80 agreed to participate and were randomly allocated to either MI (n=43) or support counselling (n=37). One participant randomised to the control group was ineligible (n=36). A total of 13 patients randomised (5 in MI group, 8 in control group) declined to participate prior to the first visit (MI group n=38, control group n=28). Analyses were based on the remaining 66 participants of whom 60 had completed HbA_{1c} data at 12 months (end of intervention) and 50 at 24 months.

Figure 6: Flow chart of participants through each stage of the trial (see following page)


Assessed for eligibility across 5 centres
Cardiff, Newport, Swansea, Bridgend, and Merthyr Tydfil
• Declined to participate n=43
• Declined contact from researcher n=46
• Agreed and consent signed n=80.
Randomised
n=80
(MI = 43, Control = 37)
1 randomised in control group but not eligible
MI GROUP
CONTROL GROUP
Declined prior to 1st visit
n=5 (total sample n=38)
Declined prior to 1st visit
n=8 (total sample n=28)
Declined intervention after 1st visit
n=6 (total sample n=32)
Declined intervention after 1st visit
n=2 (total sample n=26)
Opted out of intervention between 2-4 visits
n=4 (n=28)
Opted out of intervention between 2-4 visits
n=2* (n=24)
* 1 patient deceased
Participants continuing treatment at 6 &12 months
n=52
(MI=28 Control=24)
12 months
Complete HbA1c data
n=60
MI n=35, Control n=25 (includes ITT)
24 months
Complete HbA1c data
n=50
MI n=30, Control n=20

6:5 Demographic characteristics

Participants in both groups were well matched for age (mean age 15.3 and 15.4 years in MI and controls respectively), gender and duration of diabetes (6 years, 4 months MI; 6 years, Controls). Socio- economic status was slightly higher in the control arm (median rank social class 4 in MI group and class 3 in control). Mean HbA_{1c} was slightly higher in the intervention group at baseline (MI group=9.21 and 9.12 for controls). Table 10 demonstrates the demographic characteristics between the MI and control groups.

Table 10 : Baseline demographic characteristics of the sample according to MI and control groups. n=66

	MI group (n=38)	Control group (n=28)
Age	15.3 (0.97)	15.4 (1.25)
Duration of diabetes	6.45 (4.02)	6.03 (3.46)
Drop-out rate	10 (26%)	4* (10%)
Gender		
Male	18 (47%)	15 (52%)
Female	20 (53%)	13 (48%)
Social Class		
1 (professional)	1 (3%)	6 (21%)
2 (intermediate-semi professional)	11 (29%)	5 (21%)
3 (skilled manual and non manual)	6 (16%)	7 (24%)
4 (semi skilled)	7 (18%)	6 (21%)
5 (unskilled)	13 (34%)	4 (14%)
Mean HbA1c (baseline)	9.21 (1.96)	9.12 (1.46)
		*1 deceased

6:5:1 Attrition

More participants withdrew from the MI intervention in the first six months (n=10) than in the control group (n=4) although this was not statistically significant (p=0.24). One participant died within the control group from accidental death unrelated to diabetes, 4 months before intervention was completed. The pattern of drop out was as follows. Within the MI group, 6 participants dropped out between the 1st baseline visit and 2nd visit (4-6 weeks after baseline visit) and 4 dropped out between 6-8 months into the intervention. Within the control group, 2 participants dropped out after the baseline visit and 1 participant dropped out 3 months after commencement of the intervention. The reasons for attrition cited within the MI group were dissatisfaction with the focus on aspects of behaviour change (n=3), dislike of completion of questionnaires (n=4), fear of having blood taken for sampling (n=1) and intrusion of participants' time (n=2). Within the control group the reasons cited for attrition included intrusion of participants' time (n=1), reasons not connected to study (n=1) and change of circumstances (n=1).

6:6 Baseline outcomes

6:6:1 Descriptive analysis HbA_{1c}

Data were analysed on 63 participants (36 within the MI group and 27 in the control group) out of a total eligible 66. The mean HbA_{1c} for the MI group was 9.21(SD 1.96) and control group =9.12 (SD 1.47) [mean difference between the two groups 0.09 (SD 0.32) 95% CI, -0.06, 0.24].

6:6:2 Inferential outcomes HbA_{1c}

A one way ANOVA demonstrated no significant differences between the two groups in HbA_{1c} at baseline $F(1,63)=0.037$ $p>0.05$.

6:6:3 Descriptive analysis: Psychosocial questionnaires

Table 11 demonstrates the means, standard deviations and 95% confidence interval (CI) for the difference between group means for the psychosocial questionnaires. Sample sizes are shown in italics. (See following page)

Table 11: Means, standard deviations and differences in 95% CI on baseline psychosocial questionnaires according to MI and control groups

Questionnaire	Intervention	Control	95% confidence interval (CI) for the difference between group means	
	Mean (SD)	Mean (SD)	Mean (SD)	95% CI
Diabetes Quality of Life Measure for Youths (DQOLY)				
Satisfaction*	40.05 (13.93) n=38	33.88 (9.88) n=26	6.17 (12.45)	(-0.02, 12.36)
Impact*	54.14 (14.35) n=36	47.83 (9.52) n=25	6.31(12.74)	(-0.83, 12.14)
Worries*	20.39 (10.24) n=37	14.74 (6.31) n=25	5.65 (7.87)	(1.67, 9.62)
Children's Health Locus of Control (CHLC)	10.87 (2.53) n=35)	11.47 (2.11) n=27	0.6 (2.35)	(-0.57, 0.70)
Modified Health Care Climate Questionnaire (HCCQ)	78.48 (15.29) n=37	86.79 (7.68) n=26	8.31(9.18)	(3.72, 12.89)
Diabetes Knowledge Scale (DKN)	10.57 (1.74) n=37	10.65 (1.65) n=26	0.08 (1.70)	(-0.76, 0.92)
Self Efficacy for Diabetes Scale (SEDS)	162.61 (24.42) n=35	164.75 (19.37) n=26	2.14 (22.23)	(-9.13, 13.41)
Well Being Questionnaire (WBQ)				
Depression	12.70 (3.25) n=33	13.72 (3.14) n=25	1.02 (3.20)	(-0.62, 2.66)
Anxiety	12.88 (4.40) n=33	12.88 (4.42) n=25	0 (4.41)	(-1.78, 1.78)
Energy	7.48 (2.50) n=33	7.80 (2.80) n=25	0.32 (2.68)	(-0.18, 0.82)
Positive Well Being	12.42 (3.74) n=33	12.92 (3.67) n=25	0.5(3.71)	(-9.6, 1.01)
Total General Well Being	30.73 (4.60) n=33	30.12 (4.04) n=25	0.61	
Diabetes Family Behaviour Scale**	135.07 (13.98) n=35	137.76 (13.97) n=24	2.69 (13.85)	(2.18, 3.20)
Personal Models of Diabetes Scale (PMDQ)				
Importance to prevent complications	30.83 (4.93) n=37	31.51 (4.52) n=27	0.38 (4.76)	(-1.97, 2.73)
Treatment effectiveness	42.25 (4.92) n=33	42.30 (4.35) n=27	0.05 (4.67)	(-2.20, 2.40)
***Perceived Seriousness	31.95 (5.07) n=36	33.56 (7.21) n=27	1.61 (6.07)	(-1.41, 4.62)
***Impact of diabetes	29.99 (10.05) n=37	25.87 (8.46) n= 27	4.12 (8.99)	(-0.31, 8.56)
PMDQ all scale total	135.24 (10.11) n=33	133.24 (11.89) n=27	2.00 (10.94)	(-3.55, 7.55)
Therapeutic Alliance Questionnaire (TAQ)				
Bond	33.42 (2.96) n=35	33.48 (3.05) n=22	0.06(2.96)	(-1.58, 1.71)
Task	28.27 (2.84) n=33	27.45 (3.40) n=22	0.82(3.07)	(-0.81, 2.46)
Goals	15.91 (2.49) n=34	15.45 (1.99) n=22	0.46 (1.43)	(-0.30, 0.35)
Total	77.47 (5.48) n=33	76.39 (6.79) n=22	1.08 (6.22)	(-2.27, 4.43)

*Lower score = better quality of life ** Lower score = better family functioning *** Higher score = lower perceived seriousness/impact

6:7 Primary outcome results

The results for the HbA_{1c} outcomes are presented in relation to hypotheses 1 and 2. Descriptive data are presented followed by inferential analysis. There are two sets of descriptive outcomes for HbA_{1c} data. One includes values *at each time point* over study period and the other includes values with complete HbA_{1c} data *over the study period.* Both are presented for clarity followed by the inferential analysis. For the inferential analysis, data are reported on completed data over the study period that excludes missing analysis.

6:7:1 Hypothesis 1

Hypothesis 1	
	Motivational interviewing will be more efficacious in reducing glycosylated haemoglobin (HbA_{1c}) at 12 months and 24 months follow up compared to a support counselling intervention.

6:7:1:1 Descriptive analysis

Descriptive data were analysed initially on participants which included values *at each time point;* baseline, 6 months, 12 months. The means, standard deviations and differences in confidence intervals are demonstrated in table 12. The results indicated that the MI group HbA_{1c} measurements on average reduced over 12 months, while the control group measurements increased at 6 months and reduced at 12 months to just under the baseline value.

Table 12: Means and standard deviations of HbA_{1c} levels between MI and control groups at baseline, 6, and 12 months *on values at each time point*

	Intervention		Control		95% confidence interval (CI) for the difference between group means	
	N	Mean (SD)	N	Mean (SD)	Mean (SD)	95% CI
Baseline	36	9.21 (1.96)	27	9.12 (1.47)	0.09 (0.32)	(-0.06, 0.24)
6 months	31	9.01 (1.52)	26	9.56 (1.77)	-0.55 (1.13)	(-0.02, 1.12)
12 months	35	8.91 (1.91)	25	8.95 (1.72)	-0.04 (1.83)	(-0.88, 0.92)

When the data were analysed for participants *with completed data* across the three time points, the sample size was reduced, although the pattern of results were similar (table 13). The results demonstrated that whilst the intervention group HbA_{1c} measurements on average reduced over the 12 months, the control groups measurements increased at 6 months, although continued to decrease at 12 months to a value marginally above the baseline figure.

Table 13: Means and standard deviations of HbA1c levels between MI and control groups at baseline, 6, and 12 months *with completed data* across time points

Time	Intervention		Control		95% confidence interval (CI) for the difference between group means	
	N	Mean (SD)	N	Mean (SD)	Mean (SD)	95% CI
Baseline	27	9.33 (2.11)	20	9.00 (1.56)	0.3 (1.90)	(-0.80, 1.40)
6 months	27	9.00 (1.63)	20	9.53 (1.93)	-0.5 (1.76)	(-1.52, 0.52)
12 months	27	8.68 (1.84)	20	9.14 (1.78)	-0.4 (1.81)	(-1.55, 0.55)

6:7:1:2 Inferential outcomes

The hypotheses were supported at 12 months. Motivational Interviewing appeared to be more efficacious in reducing HbA_{1c} than the support counselling group. At 12 months, there was a significant difference between the MI and control groups in HbA_{1c} F (1, 50) = 4.276 p=0.04 after adjusting for baseline HbA_{1c}.

6:7:2 Hypothesis 2

Hypothesis 2	
	Motivational interviewing will be more efficacious in reducing glycosylated haemoglobin (HbA_{1c}) at 24 months compared to a support counselling intervention.

6:7:2:1 Descriptive analysis

As in section 6:7:1 two sets of descriptive data for HbA_{1c} are presented. The first table presents data analysed on participants which included values *at each time point* baseline, 6 months, 12 months and 24 months. The means, standard deviations and differences in confidence intervals are demonstrated in table 14. The results indicated that the MI group HbA_{1c} measurements on average reduced over the 24 months, while the control group measurements increased at 6 months, reduced at 12 months to just under the baseline value and increased again at 24 months to the baseline value.

Table 14: Means and standard deviations of HbA_{1c} levels between MI and control groups at baseline, 6, 12 and 24 months *on values at each time point*

	Intervention		Control		95% confidence interval (CI) for the difference between group means	
	N	Mean (SD)	N	Mean (SD)	Mean (SD)	95% CI
Baseline	36	9.21 (1.96)	27	9.12 (1.47)	0.09 (0.32)	(-0.06, 0.24)
6 months	31	9.01 (1.52)	26	9.56 (1.77)	-0.55 (1.13)	(-0.02, 1.12)
12 months	35	8.91 (1.91)	25	8.95 (1.72)	-0.04 (1.83)	(-0.88, 0.92)
24 months	30	8.77 (1.86)	20	9.13 (1.51)	0.36 (1.70)	(0.16, 0.55)

The outcomes for *completed data only* across 4 time points are presented in table 15. Within the control group, HbA_{1C} at 24 months remained unchanged from baseline. Meanwhile HbA_{1c} decreased from baseline within the MI group by 0.6%.

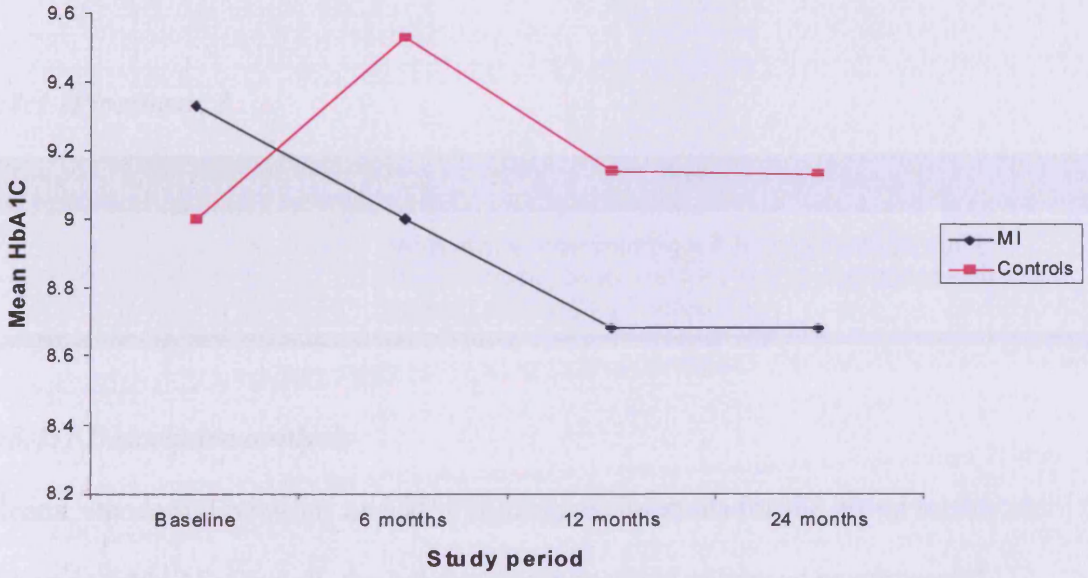
Table 15: Means and standard deviations of HbA1c levels between MI and control groups at baseline, 6, 12 and 24 months *with completed data* across time points

Time	Intervention		Control		95% confidence interval (CI) for the difference between group means	
	N	Mean (SD)	N	Mean (SD)	Mean (SD)	95% CI
Baseline	27	9.33 (2.11)	20	9.00 (1.56)	0.3 (1.90)	(-0.80, 1.40)
6 months	27	9.00 (1.63)	20	9.53 (1.93)	-0.5 (1.76)	(-1.52, 0.52)
12 months	27	8.68 (1.84)	20	9.14 (1.78)	-0.4 (1.81)	(-1.55, 0.55)
24 months	27	8.68 (.188)	20	9.13 (1.51)	-0.4 (1.73)	(-1.40, 0.60)

Figure 7 demonstrates the mean HbA_{1c} values of the MI and control group over the study period.

Figure 7: HbA_{1c} measurements of the MI and control group, over a two year period. Data represents participants with completed data across study period.

N=47



6:7:2:2 Inferential outcomes

The hypothesis was supported. At 24 months follow up the results demonstrated a significant difference between MI and control groups in HbA_{1c} F (1, 44) =9.707 p=0.003 after adjusting for baseline. The MI group significantly reduced their HbA_{1c} at 24 month follow up.

6:8 Secondary outcome results

The results for the psychosocial questionnaires outcomes are presented in relation to hypotheses 3 and 4. The following sections demonstrate the descriptive and inferential outcomes of the psychosocial questionnaires at 12 months followed by descriptive and inferential analysis of the well being and quality of life outcomes at 24 months. Outcomes for each questionnaire and hypothesis testing of each questionnaire are presented in sections 6.9 to 6:10.

6:8:1 Hypothesis 3

Hypothesis 3 : Psychosocial functioning at 12 months	
	Motivational interviewing will be more efficacious in enhancing psychosocial functioning compared with a support counselling intervention.

6:8:1:1 Descriptive analysis

Means, standard deviations and 95% confidence intervals for the group means are shown in table 16. Overall, the MI group experienced enhanced psychosocial

functioning on most of the scales, although the control group perceived the health care climate to be more autonomy supportive than the MI group.

Table 16: Means, standard deviations and confidence interval (CI) for the difference between group means on psychosocial questionnaires at 12 months. Sample sizes are in italics.

Questionnaire	Intervention	Control	95% confidence interval (CI) for the difference between group means.	
	Mean (SD)	Mean (SD)	Mean (SD)	95% CI
Diabetes Quality of Life Measure for Youths				
Satisfaction*	33.28 (9.88) n=36	45.55 (10.79) n=20	12.27 (10.21)	(6.69,17.85)
Impact*	50.49 (12.05) n=35	61.05(18.48) n=19	10.56 (14.60)	(2.41,18.71)
Worries*	17.71 (7.15) n=35	30.23 (11.59) n=20	12.52(9.00)	(7.58,17.46)
Children's Health Locus of Control	11.29 (2.59) n=32	11.82 (1.95) n=21	0.53(2.33)	(-0.74, 1.80)
Modified Health Care Climate Questionnaire	78.06 (20.34) n=35	84.25(13.30) n=24	6.19 (17.84)	(-3.08, 15.46)
Diabetes Knowledge Scale	11.16 (1.86) n=31	11.75 (1.77) n=20	0.59 (1.83)	(-0.44, 1.62)
Self Efficacy for Diabetes Scale	175.92 (22.73) n=37	169.85 (27.45) n=20	6.07(24.46)	(-7.24, 19.38)
Well Being Questionnaire				
Depression	10.08 (2.25) n=34	11.85(1.81) n=19	1.77 (2.11)	(0.59, 2.95)
Anxiety	6.03(2.23) n=33	11.55 (3.69) n=20	5.52 (2.86)	(3.93, 7.11)
Energy	6.19(1.86) n=32	7.20 (2.31) n=20	1.01(2.04)	(-0.13, 2.15)
Positive Well Being	14.48(3.20) n=33	10.24 (3.27) n=21	4.24(3.23)	(2.47, 6.01)
Total General Well Being	40.56 (4.51) n=31	30.31(5.90) n=17	10.25 (5.04)	(7.27, 13.23)
Diabetes Family Behaviour Scale**	145.56(20.64) =32	155.57(16.45) n=21	10.01 (19.11)	(-0.51, 20.53)
Personal Models of Diabetes Scale (PMDQ)				
Importance to prevent complications	32.58 (5.06) n=37	22.84(4.02) n=25	9.74 (4.67)	(7.37,12.11)
Treatment effectiveness	41.46 (6.25) n=37	29.52 (5.54) n=25	11.94 (5.98)	(8.91, 14.97)
***Perceived seriousness	33.19 (8.76) n=37	24.78 (5.98) n=25	8.41 (7.77)	(4.47, 12.35)
***Impact of diabetes	28.32 (5.66) n=37	34.52 (6.23) n=25	6.20 (5.89)	(3.21, 9.19)
Total	135.55 (15.30) n=37	111.66 (10.97) n=25	23.89 (12.73)	(16.92, 30.86)
Therapeutic Alliance				
Bond	38.35 (4.60) n=35	37.86 (5.07) n=20	0.48 (4.77)	(-2.14, 3.10)
Task	34.68 (5.63) n=35	33.65 (6.13) n=20	1.04 (5.82)	(-2.16, 4.24)
Goals	19.69(3.09) n=34	18.65 (3.18) n=20	1.04 (3.38)	(-0.83, 2.91)
Total	93.20 (11.44) n=34	90.17 (14.15) n=20	3.03 (12.50)	(-3.87, 9.94)

*Lower score = better quality of life ** Lower score = better family functioning *** Higher score = lower perceived seriousness/impact

6:8:1:2 Inferential outcomes

To compare differences between the MI and control group between baseline and 12 months, a repeated measures analysis of covariance (ANCOVA) was performed with baseline psychosocial scores treated as the covariate. Table 17 demonstrates the *F* statistic, degrees of freedom and significance values for the psychosocial questionnaires.

Table 17: *F* statistic, degrees of freedom and significance values across the MI and control group on psychosocial questionnaires at 12 months

Questionnaire	Degrees of Freedom	*F* statistic and significance value
Diabetes Quality of Life Measure for Youths.		
Satisfaction	50, 1	F= 31.769 p<0.001
Impact	46, 1	F=9.553 =0.003
Worries	47, 1	F=22.209 p<0.001
Children's Health Locus of Control	46, 1	F=.034 p>0.05
Modified Health Care Climate Questionnaire	52, 1	F=.010 p>0.05
Diabetes Knowledge Scale		F=1.406 p>0.05
Self Efficacy for Diabetes Scale	48, 1	F=.733 p>0.05
Well Being Questionnaire		
Depression	43, 1	F=4.325 p=0.044
Anxiety	44, 1	F=41.267 p<0.001
Energy	41, 1	F=2.086 p=0.156
Positive Well Being	43, 1	F=22.923 p<0.001
Total General Well Being	41, 1	F=39.419 p<0.001
Diabetes Family Behaviour Scale	42, 1	F=1.162 p>0.05
Personal Models of Diabetes Scale (PMDQ)		
Importance to prevent comps	56, 1	F=64.776 p<0.001
Treatment effectiveness	52, 1	F=59.056 p<0.001
Perceived seriousness	56, 1	F=13.605 p<0.001
Impact of diabetes	55, 1	F=13.845 p<0.001
Total	52, 1	F=44.642 p<0.001
Therapeutic Alliance		
Bond	48, 1	F=.771 p>0.05
Task	46,1	F = .204 p>0.05
Goals	46, 1	F=4.02 p>0.05
Total	45, 1	F=2.84 p>0.05

Section 5:2:2 identified the specific directions hypothesised for individual questionnaires and these were summarised in table 5 (p. 162). The results of the hypothesis testing for each of the psychosocial questionnaires are discussed in the following section.

6:9 Psychosocial questionnaires: hypotheses revisited.

Outcomes for each of the questionnaires are presented with significant outcomes presented first followed by the non significant outcomes.

6:9:1 Outcomes at 12 months

6:9:1:1 Well Being

Hypothesis: Well being 12 months	
	The hypothesis was that on the well being subscales, the MI group will experience less depression, anxiety, positive well being, energy and general well being at 12 months compared to support counselling.

The hypothesis was partially supported at 12 months. At 12 months significant differences were found between the MI and control group on overall well being (F=39.419 p<0.001). Specifically the MI group experienced less depression (F=4.325 p=0.044), less anxiety (F=41.267 p<0.001), more positive well being (F=22.923 p<0.001). The well being energy subscale was not significant (F=2.086 p>0.05).

6:9:1:2 Quality of Life

Hypothesis: Quality of life at 12 months
Motivational interviewing will be more efficacious in enhancing quality of life on subscales satisfaction, impact and worries at 12 months compared to a support counselling intervention.

The hypothesis was supported. At 12 months the MI group had higher life satisfaction with diabetes (F=31.76 p<0.001), perceived their diabetes to have less impact on their lives (F=9.553 p=0.003) and experienced lower life worry about diabetes (F=22.209, p<0.001).

6:9:1:3 Personal Models of Diabetes

Hypothesis: Personal models of diabetes at 12 months
The MI group will experience greater illness beliefs about diabetes at 12 months. Specifically the MI group will place greater importance in controlling their diabetes to prevent complications. They will have greater beliefs that behavioural actions will prevent complications. They will have lowered perceptions of the seriousness (threat) of diabetes and will perceive their diabetes to have less negative impact on their daily lives compared to a support counselling intervention.

The hypotheses were that participants within the MI group will develop greater illness beliefs about diabetes were partially supported. There were significant differences at 12 months between the MI and control groups regarding their overall illness beliefs about their diabetes (F=44.64, p<0.001). Specifically the MI group placed greater importance on controlling their diabetes (importance to control diabetes) to prevent future complications (F=64.78 p<0.001) and had stronger beliefs that certain

behavioural actions (treatment effectiveness) were more likely to help prevent future complications of diabetes (F=59.05 p<0.001). They also perceived diabetes be a less serious threat to their health (perceived seriousness) (F=13.605 p<0.001). The MI group however perceived their diabetes to have a greater impact negative impact (impact of diabetes) on their lives (F= 13.84 p<0.001) which is opposite to the one hypothesised.

6:9:1:4 Diabetes family behaviour

Hypothesis: Diabetes family behaviour at 12 months
Motivational interviewing will be more efficacious in diabetes family behaviour outcomes at 12 months compared to a support counselling intervention.

The hypothesis that MI will be more efficacious in diabetes family behaviour outcomes at 12 months, compared to a support counselling intervention, was not supported. There were no significant differences between the two groups in diabetes family behaviours (F=1.162, p>0.05).

6:9:1:5 Self Efficacy

Hypothesis: Diabetes self efficacy at 12 months
Motivational interviewing will be more efficacious in enhancing self efficacy outcomes at 12 months compared to a support counselling intervention.

The hypothesis was not supported. Although the mean self efficacy increased from baseline within the MI group, there were no significant differences between the two groups in perceived self efficacy with diabetes (F=0.733, p>0.05).

6:9:1:6 Health locus of control

Hypothesis: Health locus of control at 12 months
Motivational interviewing will be more efficacious in increasing health locus of control (i.e. internality of beliefs to control diabetes) at 12 months compared to a support counselling intervention.

The hypothesis was not supported. There were no significant differences between the two groups in perceptions of health locus of control (F=0.034, p>0.05).

6:9:1:7 Health care climate

Hypothesis: Perceptions of the health care climate at 12 months
Motivational interviewing will be more efficacious in reducing glycosylated haemoglobin (HbA_{1c}) at 24 months compared to a support counselling intervention.

The hypothesis was not supported. There were no significant differences between the two groups in perceptions of the health care climate (F=0.010, p>0.05).

6:9:1:8 Therapeutic Alliance

Hypothesis: Perceptions of the therapeutic alliance at 12 months
Motivational interviewing will be more efficacious in enhancing perceptions of the therapeutic alliance between participant and interventionist on subscales bond, goals and tasks at 12 months compared to a support counselling.

The hypothesis was not supported. There were no significant differences between the two groups in perceptions of helpfulness of the therapeutic alliance (Bond F= .771

p>0.05; Task, F=.204 p>0.05; Goals F=4.017 p>0.05 and overall total perceptions F= 2.837 p>0.05).

6:9:1:9 Diabetes knowledge

Hypothesis: Diabetes knowledge at 12 months	
	There will be increased level of diabetes knowledge within the MI group compared to the support counselling group at 12 months.

The hypothesis was not supported. There were no significant differences between the two groups in diabetes knowledge at 12 months (F=1.406, p>0.05).

6:9:2 Outcomes at 24 months

The following section demonstrates the descriptive and inferential outcomes of the well being and quality of life outcomes at 24 months in relation to hypothesis 4.

6:9:2:1 Descriptive analysis: Well being and quality of life

Means, standard deviations and 95% confidence intervals of the mean for the well being and quality of life subscales are presented in Table 18. Data are represented on completed data across time points; baseline, 12 and 24 months. There is very little difference between the two groups in scores on the well being subscales, although there were marked differences in means between the control and MI group on quality of life subscales. The MI group experienced worse quality of life on all subscales compared to the control group, particularly on satisfaction with quality of life.

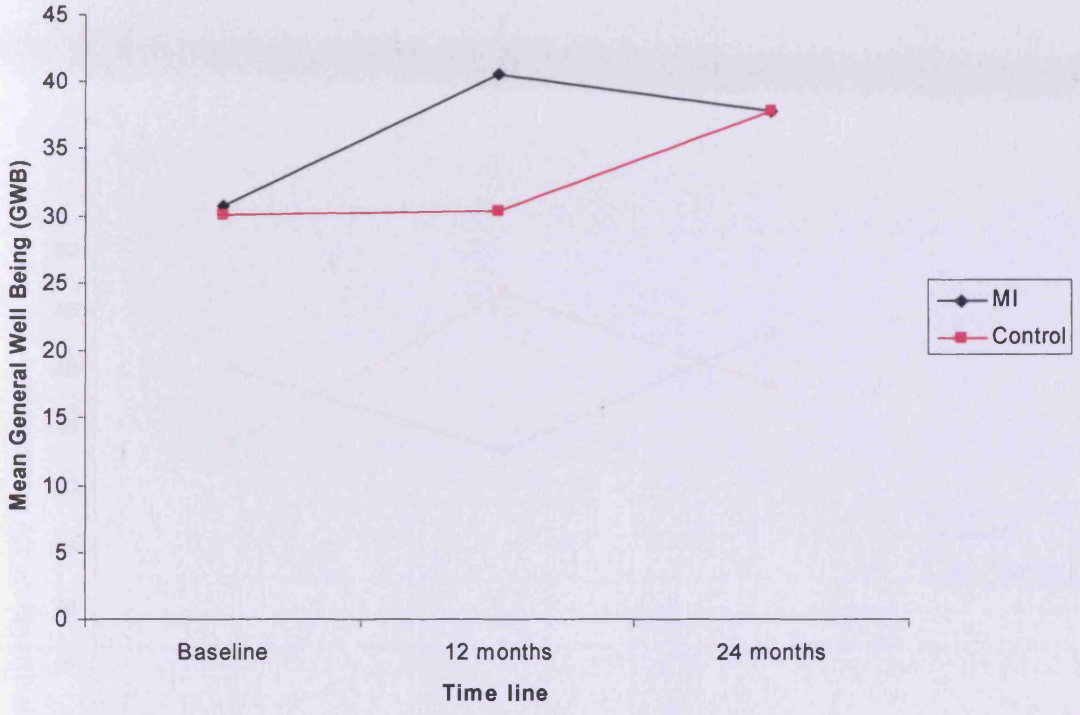
Table 18: Means, standard deviations and 95% CI for the differences in group means across the MI and control group at 24 months

Questionnaire	Intervention	Control	Confidence interval (CI) for the difference between group means.
	Mean (SD)	Mean (SD)	Mean (SD) 95% CI
Diabetes Quality of Life Measure for Youths.			
Satisfaction*	43.32 (9.77) n=27	38.70 (11.99) n=11	4.62(8.36) (-1.26, 10.5)
Impact*	52.58 (11.91) n=22	52.06 (12.18) n=9	0.52 (11.59) (-8.45, 9.49)
Worries*	16.83 (5.50) n=22	14.57 (10.35) n=7	2.26 (6.87) (-3.58, 8.10)
Well Being			
Depression	10.20 (1.74) n=23	10.32 (1.92) n=11	0.12 (1.82) (-1.17, 1.41)
Anxiety	5.78 (2.39) n=21	6.47 (2.83) n=11	0.69 (2.50) (-1.13, 2.51)
Energy	5.31 (1.62) n=16	5.78 (1.39) n=9	0.47 (1.48) (-0.72, 1.66)
Positive Well Being	12.30 (3.76) n=22	12.41 (4.99) n=12	0.11(3.27) (-2.18, 2.40)
Total General Well Being	37.83 (4.83) n=15	37.87 (7.97) n=8	0.04(6.98) (-1.19, 1.27)

* lower score indicates better quality of life

The mean scores for well being over the study period according to the MI and control group are demonstrated in figure 8.

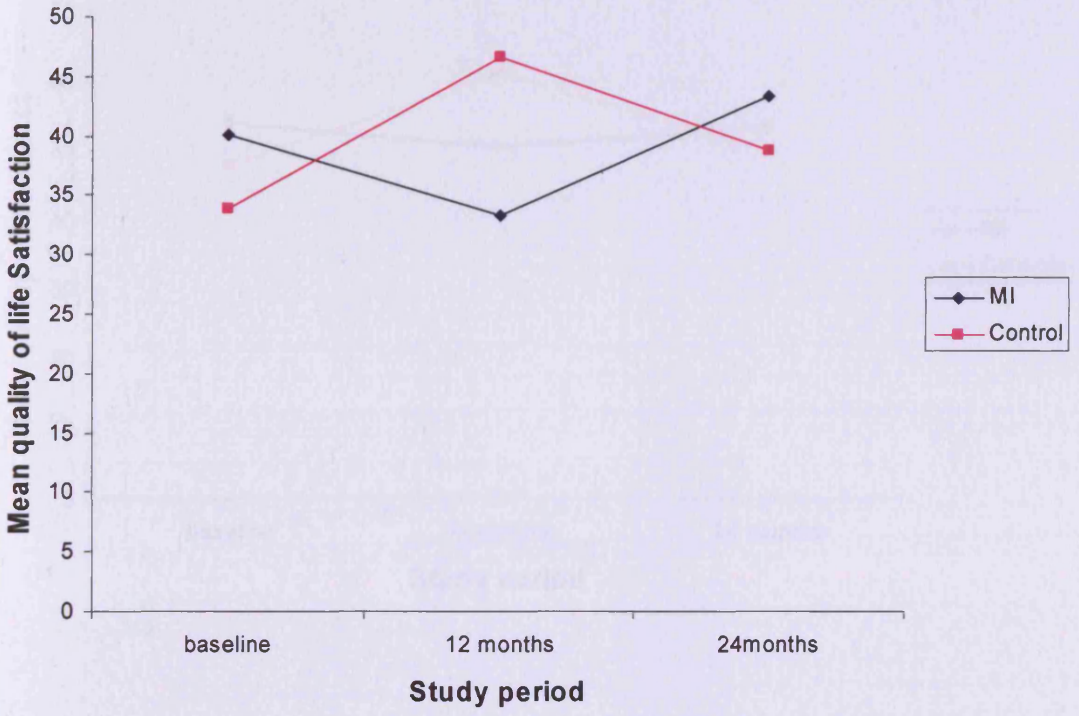
Figure 8: The mean scores for total general well being between the MI and control group over the study period.



Figures 9, 10, and 11 demonstrate the mean scores on quality of life subscales according to MI and control groups at baseline, 12 and 24 months.

Figure 9: Quality of life satisfaction outcomes of the intervention and control groups over study period. *

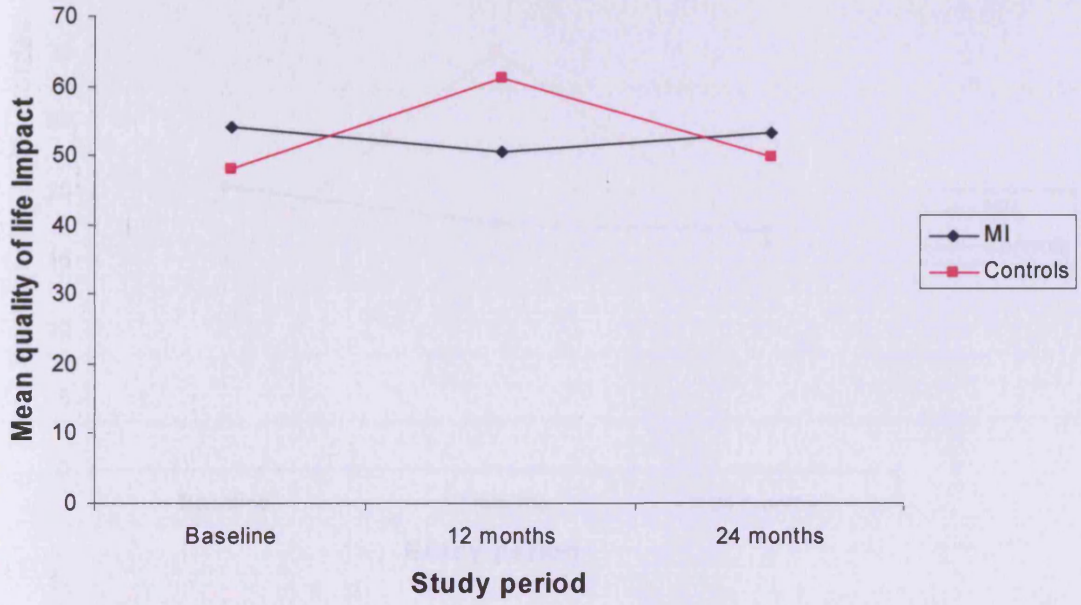
N=47



* Lower score = better quality of life

Figure 10: Quality of life impact outcomes of the intervention and control group over study period*.

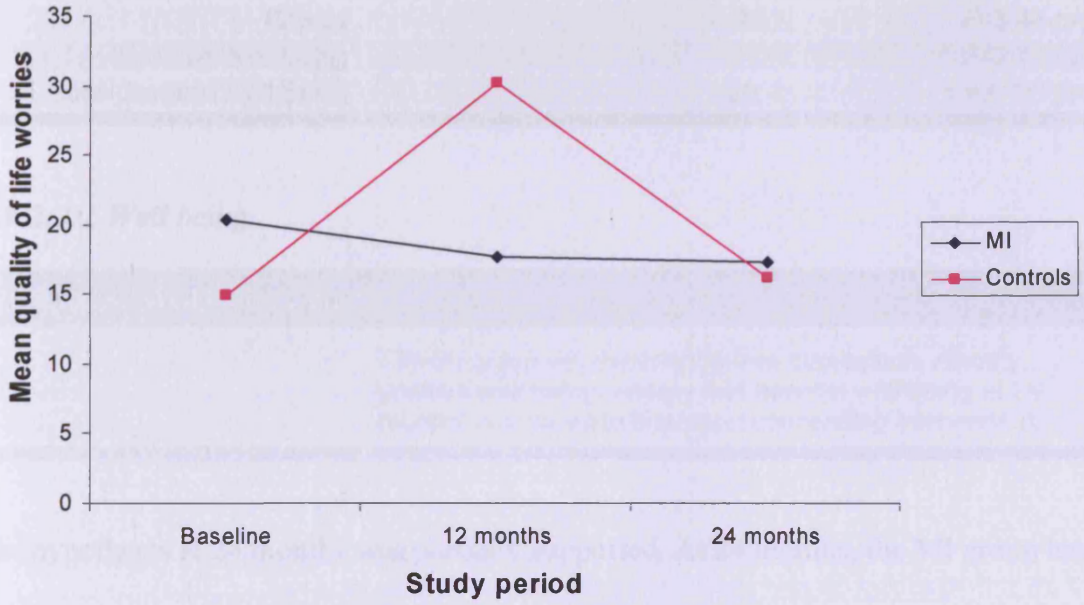
N=47



* Lower score = better quality of life

Figure 11: Quality of life worries outcomes of the MI and control group across study period*

N=47



* Lower score = better quality of life

6:9:2:2 Inferential outcomes

To compare differences between the MI and control group between 12 and 24 months, a repeated measures analysis of covariance (ANCOVA) was performed with baseline quality of life and well being scores treated as the covariate. The results are demonstrated in table 19.

Table 19: *F* statistic, degrees of freedom and significance values of the Quality of Life and Well Being subscales at 24 months		
	Degrees of Freedom	***F* Value and significance value**
Diabetes Quality of Life Measure for Youths		
Satisfaction	35, 1	F=7.007 p=0.012
Impact	28, 1	F=8.129 p=0.008
Worries	26, 1	F=17.795 p<0.001
Well Being		
Depression	29,1	F=1.399 p>0.05
Anxiety	29, 1	F=18.908 p<0.001
Energy	22,1	F=3.44 p=0.077
Positive Well Being	31, 1	F=2.403 p>0.05
Total General Well Being	20, 1	F=3.128 p=0.092

6:9:2:2:1 Well being

Hypothesis: Well being 24 months	
	The MI group will experience less depression, anxiety, positive well being, energy and general well being at 24 months compared to a support counselling intervention.

The hypothesis at 24 months was partially supported. At 24 months, the MI group had had less anxiety (F=18.908, p<0.001). There were no significant differences between the two groups in depression (F=1.399 p>0.05), energy (F=3.44, p=0.077), positive well being (F =2.403 p>0.05) and total general well being (F=3.128 p>0.05).

6:9:2:2:2 Quality of life

Hypothesis: Quality of life at 24 months	
	Motivational interviewing will be more efficacious in enhancing quality of life on subscales satisfaction, impact and worries at 24 months compared to a support counselling intervention.

The hypothesis was not supported. There were significant differences between the MI and control group on all three subscales satisfaction with diabetes (F=7.007, p=0.012) impact of diabetes (F=8.129 p=0.008) and worries about diabetes (F=17.795, p=0.001), although these were in the opposite direction hypothesised. Specifically satisfaction with diabetes related quality of life was lower in the MI group compared to controls. The MI group perceived their diabetes to have a higher impact on their lives and experienced more diabetes related worries compared to the control group.

6:10 Sub-group analysis

6:10:1 Insulin measurement

6:10:1:1 Descriptive analysis

Data were analysed retrospectively on a sub-sample of 46 participants for whom daily dose of insulin was available via the medical notes. Out of these 46 participants, 34 had measurements across the three time points, baseline, 12 months and 24 months. The means and standard deviations of the insulin measurements across time points are shown in Table 20. The mean insulin dosage per body weight between the MI and control groups over the study period are shown in figure 12 (page 235).

Table 20: Means and standard deviations of insulin measurements (daily dose/kg body weight) across the two groups at baseline, 12 and 24 months.

	MI group		Control group	
	N	Mean (SD)	N	Mean (SD)
Baseline	20	1.08 (0.22)	14	1.14 (0.32)
12 months	20	1.07 (0.23)	14	1.11 (0.29)
24 months	20	1.07 (0.23)	14	1.08 (0.28)

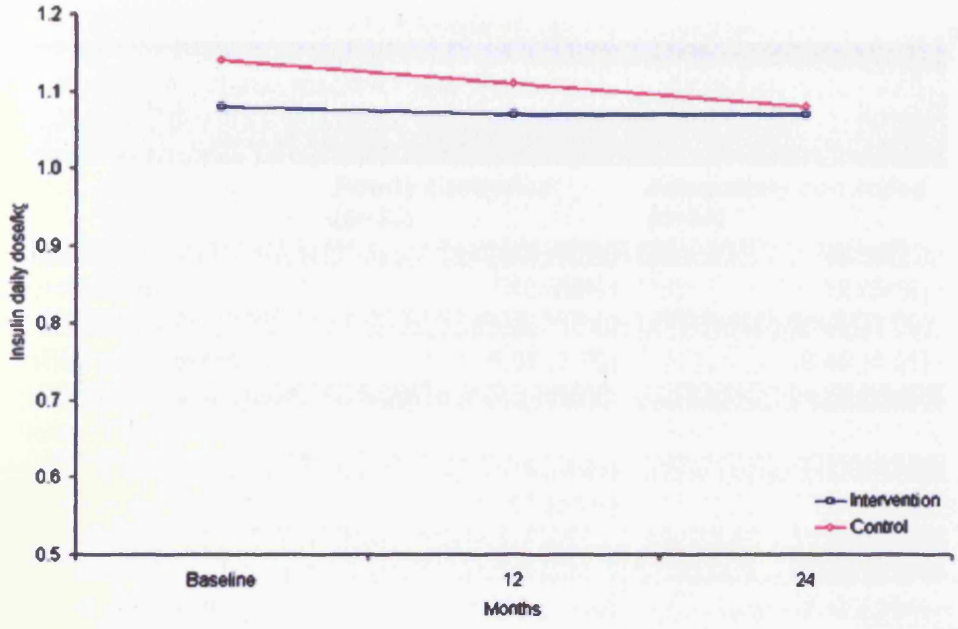
6:10:1:2 Inferential analysis

A one way analysis of variance was performed to compare differences between the two groups on baseline insulin dose. There were no significant differences between the two groups F (1,41) =.976 p>0.05 on insulin dose received.

At one year after completion of the intervention (24 months after starting the study), the mean insulin dosages between the two groups were not significantly different (F=0.136, p=0.715), after adjusting for baseline insulin dose.

Figure 12: Mean insulin dosages (u/kg) between the MI and control group, over the two year period.

N=34.



6:10:2 Poorly controlled sample

The following analyses are based on a sub-group of participants that were defined as poorly controlled (i.e. had a baseline HbA_{1c} measurement of > 9.0). The subgroup comprised 32 participants of whom 16 were in the intervention group and 16 in the control group. Demographic characteristics comparing poorly controlled group with those who were adequately controlled are presented. These are followed by descriptive and inferential analyses of poorly controlled participants between the MI and control groups.

6:10:2:1 Demographic characteristics

Descriptive statistics (means, standard deviations and percentages) are presented for the poorly controlled and adequately controlled groups in table 21.

Table 21: Descriptive statistics (means, standard deviations and percentages) of poorly controlled sample with $HbA_{1c} \geq 9.0$ and adequately controlled groups

	Poorly controlled (n=32)	Adequately controlled (n=34)
MI group	16 (50%)	22 (63%)
Control group	16 (50%)	12 (34%)
Age	15.16 (1.05)	15.47 (1.02)
Duration of diabetes	6.36 (3.75)	6.40 (4.01)
Drop-out rate	11(26%)	7 (23%)
Gender		
Male	15 (46%)	17 (50%)
Female	17 (53%)	17 (50%)
Social Class (mean rank)	36.09	28.69
HbA_{1c} at baseline	10.48 (1.29)	7.17 (.766)

6:10:2:2 Inferential analysis on demographic data

There were no significant differences between the poorly controlled and adequately controlled groups with respect to their age, social class, gender and duration of diabetes.

6:10:3 Glycosylated haemoglobin

6:10:3:1 Descriptive analysis

Table 22 and figure 8 below demonstrate the means and standard deviations of HbA_{1c} measurements for MI and control groups. The mean HbA_{1c} measurement within the

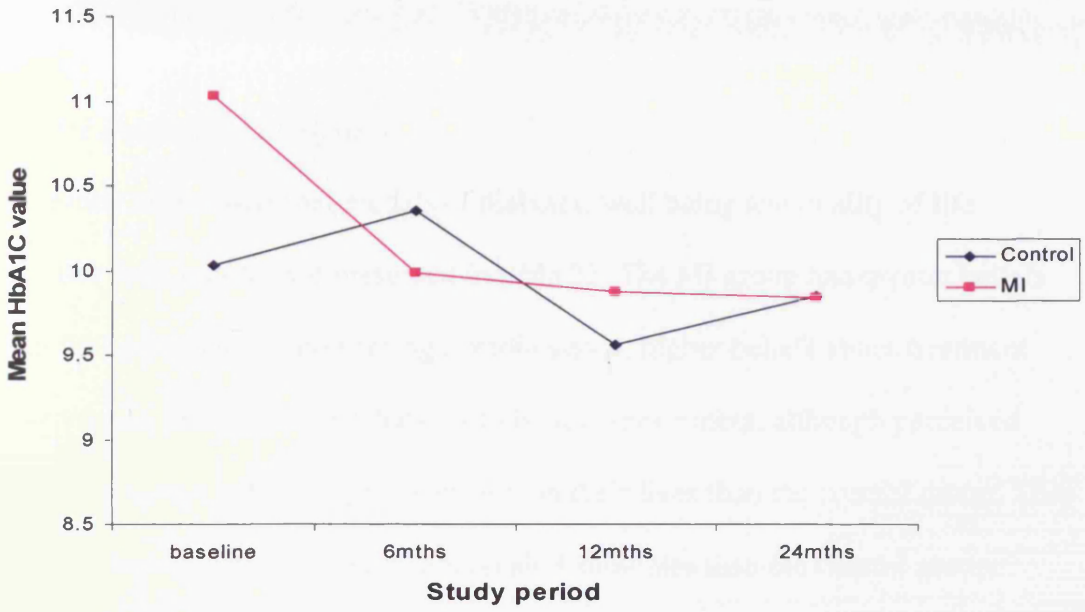
MI group was higher at baseline than the control group, although decreased at 6 and 12 months. Within the MI group there was a mean decrease of 1.16% at 12 months and 1.19% at 24 months. The mean decrease in HbA_{1c} within the control group was 0.47% at 12 months and 0.18% at 24 months. However, within the MI group the mean HbA_{1c} did not decrease below 9.5% indicating that this group continued to be defined as poorly controlled. The control group followed a similar pattern as within the main trial analysis with HbA_{1c} increasing at 6 months before decreasing at 12 months.

Table 22: Means and standard deviations of poorly controlled participants across MI and control groups (with baseline HbA_{1c} measurements >=9.0%)

	Intervention		Control		Difference in means (SD) and 95% Confidence Interval	
	N	Mean (SD)	N	Mean (SD)	Mean difference (SD)	CI
Baseline	16	11.03 1.32)	16	10.03 (1.06)	1.00 (1.18)	(0.03, 1.96)
6 months	14	9.99 (1.49)	15	10.35 (1.79)	0.36 (1.65)	(-0.83, 1.55)
12 months	16	9.87 (2.22)	14	9.56 (1.83)	0.31 (2.05)	(-1.16, 1.78)
24 months	15	9.84 (2.03)	11	9.85 (1.41)	0.01 (1.83)	(-1.46, 1.48)

Figure 13: Mean HbA_{1c} measurements at each time point by intervention group for poorly controlled participants (with baseline HbA_{1c} measurements >=9.0%).

N=32.



6:10:3:2 Inferential analysis

To compare differences between the MI and control group between baseline and 12 months, a repeated measures analysis of covariance (ANCOVA) was performed with baseline HbA_{1c} treated as the covariate. There were no significant differences between the MI and control group over the study period in reductions in HbA_{1c} within the poorly controlled sub-sample F (1,23) =1.148 p>0.05.

6:10:4 Psychosocial questionnaire outcomes

Due to the small sample sizes, only data for the personal models of diabetes, well being and quality of life subscales are presented. The descriptive outcomes are presented first followed the outcomes from inferential testing of all the questionnaires.

6:10:4:1 Descriptive analysis

The results for the personal models of diabetes, well being and quality of life subscales at 12 months are presented in table 23. The MI group had greater beliefs about the importance of preventing complications, higher beliefs about treatment effectiveness, perceived their diabetes to be less seriousness, although perceived diabetes to have a greater negative impact on their lives than the control group. They also experienced better quality of life on all 3 subscales than the control group. Regarding their well being, apart from the energy subscale, they experienced gains in depression, anxiety, positive well being and overall general well being.

Table 23: Means and standard deviations according to MI and control groups on the PMDQ, WBQ and DQOLY for poorly controlled participants

Questionnaire		Intervention	Control
		Mean (SD)	Mean (SD)
Personal Models of Diabetes Scale (PMDQ)			
Importance to prevent complications	Baseline	31.00 (6.52) n=16	32.15 (5.14) n=15
	12mths	33.73 (6.12) n=16	23.15 (5.14) n=14
Treatment effectiveness	Baseline	44.07 (4.59) n=14	43.07 (4.00) n=14
	12mths	43.92 (5.38) n=16	28.85 (6.14) n=14
Perceived seriousness	Baseline	28.87 (11.66) n=16	27.62 (7.93)n=15
	12mths	37.00 (9.30) n=16	27.27 (3.48) n=14
Impact of diabetes	Baseline	31.61 (1.91)n=16	30.15 (2.06)n=14
	12mths	27.85 (1.45) n=16	37.16 (1.57) n=14
Well Being Questionnaire (WBQ)			
Energy	Baseline	7.64 (2.10) n=14	7.40(3.27) n=15
	12 months	6.14(1.96) n=14	6.87 (2.17) n=8
Positive well being	Baseline	12.43 (3.22) n=14	12.33 (4.17) n=15
	12mths	14.80 (3.29) n=14	8.75 (2.18) n=8
Depression	Baseline	12.21 (3.81) n=14	13.00 (3.46) n=16
	12mths	9.60 (2.64) n=15	12.64 (1.65) n=9
Anxiety	Baseline	11.93 (4.83) n=16	11.69 (4.82) n=16
	12mths	6.00 (2.28) n=14	11.33 (2.73) n=9
General well being	Baseline	31.93 (4.93) n=14	31.47 (3.98) n=15
	12mths	41.31 (5.85) n=13	27.65 (5.51) n=8
Diabetes Quality of Life for Youths (DQOLY)			
*Satisfaction	Baseline	44.12 (14.17) n=16	36.00 (10.09) n =14
	12mths	35.25(10.60) n=16	50.22 (6.88) n=9
*Impact	Baseline	57.80 (17.09) n=14	49.96 (10.85) n=14
	12mths	51.27 (13.99) n=15	68.89 (11.27) n=9
*Worries	Baseline	18.95 (12.17) n=15	15.32 (7.43) n=14
	12mths	17.20 (7.47) n=15	32.88 (7.50) n=9
* lower score = better quality of life			

6:10:4:2 Inferential analysis

There were statistically significant differences between the two groups on personal models of diabetes, well being subscales (excluding energy), quality of life subscales and the therapeutic alliance. The results are summarised in table 24.

Table 24: *U* statistic and significance value of the PMDQ, WBQ & DQOLY in the poorly controlled sample at 12 months

Questionnaire	*U* statistic and significance value
Personal Models of Diabetes (PMDQ)	
Importance to prevent complications	19.00 p<0.001
Perceptions of treatment effectiveness	14.00 p<0.001
Perceived seriousness	34.50 p<0.001
Impact of diabetes	21.00 p<0.001
Total PMDQ	19.50 p<0.001
Well Being Questionnaire (WBQ)	
Depression	18.50 p=0.005
Anxiety	5.50 p<0.001
Positive well being	10.50 p<0.001
Energy	43.50 p>0.05
General well being	19.50 p<0.001
Diabetes Quality of Life for Youths (DQOLY)	
Satisfaction	11.50 p<0.001
Impact	18.00 p=0.002
Worries	10.50 p<0.001
Therapeutic Alliance Questionnaire (TAQ)	26.00 p=0.012

The remaining questionnaires failed to reach statistical significance (self efficacy U= 53.50 p>0.05; diabetes family behaviour U=38.00 p>0.05; health locus of control U=79.00 p>0.05 and health care climate U=74.00 p>0.05 respectively).

The results demonstrated that compared to the control group, the poorly controlled MI group placed greater importance in controlling their diabetes, had stronger beliefs that

their behavioural actions would control their diabetes, perceived their diabetes to be less serious, although considered diabetes to have a greater impact on their daily lives. On the well being subscales, the MI group experienced more positive well being, less anxiety and less depression. Quality of life was enhanced on all three subscales on quality of life, with the greatest enhancements in satisfaction with quality of life. The total score on the therapeutic alliance scale reached statistical significance, with the greatest gains within the MI group [increase in mean from baseline 79.38 (4.69) to 97.20 (13.36) compared to control, baseline increase in mean from 75.59 (6.57) to 82.22 (13.13)].

6:11 Outcomes on attrition participants

This section reports the results for HbA_{1c} and psychosocial functioning on participants who dropped out of the interventions of whom 10 were in the MI group and 4 in the control group. Descriptive analyses for HbA_{1c} across time points, baseline, 6 months and 12 months and psychosocial questionnaires at baseline and 12 months are presented. Inferential analyses were not conducted due to the small sizes. The participants 'stages of change' measured on the DRCQ are also reported. Demographic, HbA_{1c} and psychosocial questionnaire outcomes are shown in table 25.

6:11:1 Descriptive analysis

The descriptive results are reported in table 25 below. At baseline the mean HbA_{1c} was lower within the MI group which continued to decrease at 12 months and 24 months. Within the control group, there was a decrease in HbA_{1c} values at 12 months for the 2 participants. There is only one data value available for 24 months.

Table 25: Means and standard deviations of HbA_{1c} and psychosocial outcomes for participants who dropped out of the study. N=14

Variable		**MI group**	**Control group**
Age (in years)		15.33 (.924)	15.79 (1.49)
Duration of diabetes (in years)		5.00	4.00
Social class (Mean rank)		7.85	6.63
HbA_{1c}			
	baseline	**8.72 (1.30) *n=9***	9.23 (1.10) *n=3*
	6 months	8.67 (.763) *n=4*	9.15 (.49) *n=2*
	12 months	8.58 (1.57) *n=7*	8.20 (1.13) *n=2*
	24 months	8.15 (.74) *n=4*	10.30 (*n=1*)
Weil Being Questionnaire			
Depression	**baseline**	**14.63 (2.20) n=9**	13.25 (1.25) *n=4*
	12 months	9.51 92.36) n=7	9.70 (.98) *n=2*
Anxiety	**baseline**	**15.25 (1.90) n=9**	12.75 (2.50) *n=4*
	12 months	6.71 (.95) n=7	10.00 (4.24) *n=2*
Energy	**baseline**	**9.13 (1.35) n=9**	7.00 (2.45) *n=4*
	12 months	8.00 (1.15) n=7	6.00 (*n=1*)
Positive well being	**baseline**	**13.63 (4.10) n=9**	11.75 (2.63) *n=4*
	12 months	15.28(3.09) n=7	11.40 (.84) *n=2*
General well being	**baseline**	**28.88 (3.94) n=9**	28.75 (6.12) *n=4*
	12 months	43.06 (3.92) n=7	38.00 (*n=1*)
Diabetes Quality of Life Scale*			
Satisfaction	**baseline**	**39.71 (18.59) n=10**	34.90 (8.55) n=4
	12 months	35.50 (9.63) n=7	41.29 (n=1)
Impact	**baseline**	**54.40 (12.8) n=9**	53. 75 (3.50) n=4
	12 months	43.86 (9.54) n=7	33.00 (n=1)
Worries	**baseline**	**20.10 (8.85) n=10**	11.50 (4.04) n=4
	12 months	21.14 99.83) n=7	14.00 (n=1)
Self Efficacy Scale			
	baseline	**164.14 (29.84) n=10**	155.76 (19.72) n=4
	12 months	173.40 (26.41) n=10	183.00 (n=1)
Personal Models of Diabetes			
	baseline	**133.16 (18.20) n=10**	135.35 (18.96) *n=4*
	12 months	137.82 (14.17) n=9	103.50 (4.94) *n=2*
Diabetes Knowledge Scale			
	baseline	**10.00 (2.21) n=10**	9.75 (1.25) *n=4*
	12 months	10.86 (1.57) n=7	12.50 (.707) *n=2*
Diabetes Family Behaviour Scale**			
	baseline	**136.29 (18.20) =10**	130.91 (20.08) *n=4*
	12 months	152.29(17.22) n=6	129.00 *(n=1)*
Therapeutic Alliance Questionnaire			
	baseline	**78.39 (5.21) n=7**	69.91 (3.00) n=3
	12 months	80.71 (2.12) n=7	Missing data

*Lower score = better quality of life ** Lower score = better family functioning

Although some aspects of psychosocial functioning increased in both groups, gains were more marked within the MI group. The most evident increases in functioning were in self efficacy and general well being within both groups.

Preliminary data were analysed on all participants that dropped out and the one participant deceased on baseline DRCQ. The results demonstrated that within the MI group, 8/10 participants scored mainly on the 'contemplation' and 'preparation' categories, with 2 participants fluctuating between categories according to diabetes specific health behaviour. Within the four participants in the control group, 2 participant's scores fluctuated between the different stage of change categories on various health behaviour domains, and the remaining 2 scored mainly within the 'contemplation' category.

6:12 Summary statement of data

The data demonstrated reductions within the MI group at 12 and 24 months. Causal effects cannot be assumed to the relatively small sample size and absence of examination of *changes in* HbA_{1c} across the study period. However, the data provides preliminary evidence of the potential of MI in facilitating positive reductions in HbA_{1c}.

The data demonstrated positive short term enhancements in quality of life, well being and in personal beliefs about diabetes. The effects of well being on the anxiety subscale were sustained at 24 months. The outcomes of quality of life at 24 months were contrary to expectation, although are unsurprising given the emphasis within MI

on creating dissonance between actual and desired behaviour. There were no significant gains in self efficacy, diabetes family behaviour, health locus of control, the therapeutic alliance or the health care climate. The most surprising finding was in self efficacy since a key component of the MI intervention was enhancing the adolescent's self efficacy to initiate and maintain behaviour change. Examination of subgroup analysis, although exploratory, identified key enhancements in well being, quality of life and personal models of diabetes within the poorly controlled MI group. Due to the small sample sizes, these results however need to be interpreted with caution.

The following chapter (Chapter 7) discusses these findings in relation to comparison with the literature, internal and external validity, along with strengths and weaknesses of the study design.

CONTENTS

CHAPTER 7: STUDY 1 DISCUSSION

7:1 Introduction

The study produced some positive findings with implications to facilitate the health of young people with type 1 diabetes. The findings demonstrated significant decreases in HbA_{1c} in the MI intervention group at 12 and 24 months and these changes were not linked to changes in insulin therapy. The gains in quality of life, some aspects of well being and personal models of diabetes are also promising. Detailed scrutiny of the results reported in the previous chapter is undertaken within this chapter. This discussion is organised into three main sections:

1) Exploration of the findings in relation to the aims and hypotheses. A discussion is provided and comparisons made with the literature.

2) Discussion of the internal and external validity of the findings.

3) Strengths and weaknesses of the study design.

In Chapter 12, further attention will be given to the most recent findings within the MI and adolescent diabetes field, along with implications for future research and practice.

7:2 Primary hypothesis

7:2:1 Hypothesis 1 outcomes: Primary outcome measure HbA_{1c}

Hypothesis 1 revisited	
	Motivational interviewing will be more efficacious in reducing glycosylated haemoglobin (HbA_{1c}) in the intervention group at 12 months and 24 months follow up, compared to a support counselling intervention.

The hypothesis was supported for metabolic control at 12 and 24 months. Whilst on average the MI group HbA_{1c} measurements reduced over the twenty four months, the control group measurements increased at 6 months, reduced at 12 months and continued to decrease at 24 months. However the means of the control group at 12 and 24 months remained slightly higher than the baseline values. Examination of the results shows a rise, albeit statistically non-significant, of HbA_{1c} concentrations in the control group during the first six months with a return to baseline levels after one year. This is a phenomenon that persists whether data sets are analysed for all participants with missing data or those with completed data. A possible explanation for this phenomenon (not seen in those receiving MI) is a seasonal effect as the time period for this data collection coincided with winter. There is a demonstrated link between seasonal changes and HbA_{1c} (Nordfeldt and Ludvigsson 2000; Hinde et al. 1989). Glycosylated haemoglobin has been shown to be lower during spring and summer months, attributed to increased exercise, dietary changes and reduced frequency of minor illnesses.

An explanation for the absence in rise in HbA_{1c} at 6 months (seen in control group) may lie with the nature of the MI intervention. It is possible that the empowering nature of the intervention, with the focus specifically on talk about values of behaviour change, translated indirectly into improved self care which mediated any subsequent increases in HbA_{1c} during the winter months. The more intensive and potentially challenging part of the MI intervention occurred in the first six months (between July 2002 - January 2003) which coincided with a mean reduction of 0.33% in HbA_{1c} in the MI group over the 6 months (referring to table 13, section 6:7:1:1, p.

216). Given that HbA_{1c} reflects levels of glycaemia over previous 6-12 weeks, it is possible that the young person could have changed some aspect of their behaviour which was indicated in decreased HbA_{1c} during these months. Without measuring changes in psychological functioning between baseline and 6 months, it is difficult to establish whether improved psychosocial functioning led to improvements in glycaemic control in the MI group. However the results open up the opportunity to explore causal changes in psychosocial functioning and their relationship to changes in HbA_{1c}.

A possible explanation for the reductions in HbA_{1c} in those receiving MI over the course of the study may have related to changes in the insulin regimen (such as more intensive regimens within the MI group facilitating better metabolic control) rather than a consequence of beneficial effects of psychological functioning. The results from the DCCT study (1994) clearly demonstrated the relationship between those patients in the intensive therapy group (receiving 3 or more injections daily) with tight control and reduced HbA_{1c}. However examination of the outcomes relating to daily insulin dosage per weight, demonstrated no significant differences between the MI and control groups.

7:2:2 Comparison with the literature

The findings supported the previous observation of reductions in HbA_{1c} within the pilot study by Channon et al. (2003) on which this present study was based. The mean decrease in HbA_{1c} over the study period of 0.65% versus an increase of 0.1% in the control group (referring again to table 13) represents an important clinical change.

The HbA_{1c} levels achieved within the MI group compare quite favourably with the mean HbA_{1c} level achieved by intensively treated adolescents in the DCCT study (10.0% on entry to study to 8.1% over the 7.5 year period), especially when differences in HbA_{1c} assay methods are taken into consideration. When the reductions in HbA_{1c} are compared to the UKPDS (1998) findings (a prospective study of blood glucose control and risk of micro-vascular complications in adults with type 2 diabetes), the outcomes demonstrate the clinical importance. It was established within the UKPDS study that a 0.5% reduction in HbA_{1c}, is clinically sufficient to reduce the possibility of longer term micro-vascular complications. The findings from the present study are also consistent with the outcomes from the Hampson et al. (2001) systematic review whereby psychosocial interventions in children and adolescents with type 1 diabetes were associated with an overall mean effect size of 0.33 change (equivalent to a mean reduction in HbA_{1c} of 0.6 %). Within the MI group, the mean reduction in HbA_{1c} to 8.68% at 24 months was similar to the mean HbA_{1c} of 8.7% found for the 2,101 children and adolescents in the Hvidøre study group (Mortensen, for the Hvidøre Study Group, 1998) outlined in Chapter 1 (section 1:7).

There is a paucity of literature with which to compare these results since this is the first multi centre RCT to examine the utility of MI in adolescents with type 1 diabetes. The two controlled studies delivering coping skills training (CST) by Grey, Boland, Davidson et al. (1998) and Grey, Boland, Davidson et al. (2000) are the most suitable studies on which to make comparisons. The reductions in HbA_{1c} within the present study are modest when compared with these two studies (already discussed in section 2:5:3, p. 66-67).Within the Grey et al. (1998) study, mean HbA_{1c} reduced by 0.7%

over 3 months with the greatest reduction in HbA_{1c} evident within the 1st month. This study was replicated a year later, to examine the effects of CST over 1 year (Grey et al. 2000). The results demonstrated a mean HbA_{1c} reduction of 1.6% (from 9.1% at baseline to 7.5%) over 1 year with the greatest reduction occurring in first 3 months. Both studies however delivered CST as an adjunct to intensive insulin management and there were also significant reductions in HbA_{1c} within the control group. It is thus difficult to delineate the effects of the CST from the positive effects of intensive management with insulin therapy. Studies in adolescent diabetes have yet to examine the effectiveness of psychosocial interventions comparing those with and without intensive insulin therapy.

The benefits of a psychological intervention on glycaemic control and psychosocial functioning for adolescents with poorly controlled diabetes was demonstrated by Viner et al. (2003). They examined the effects of a combined MI and solution focused therapy intervention in 21 self selecting adolescents with poorly controlled diabetes. The results demonstrated a reduction of 1.3% in HbA_{1c} within 3 months, which was maintained at 7-12 months (reduction in 1.1% from baseline). The study however lacked a control group and the 'active ingredients' of the intervention were not identified. Given that solution focused therapy has not been examined previously in diabetes, it remains unanswered what components of the intervention facilitated change.

Interim analyses on the study by Murphy, Wadham et al. (2006) described in Chapter 2 (section 2:5:3, p. 68) has demonstrated the positive effects of a combined coping

skills and educational intervention in diabetes clinics both in the delivery of group therapy and individual sessions. Outcomes from the 1st part of this intervention have demonstrated a mean decrease of 0.27% in HbA_{1c} after 2 sessions, which are similar to the effects found within the MI group in this present study. Although many of the components of the intervention differ from those delivered in the present study, both are designed to be structured into routine care with the similar goals of enhancements in self efficacy and beneficial effects on self care.

7:3 Secondary hypotheses

The hypotheses are revisited according to those summarised in table 5 (section 5:2:2, p.162). The outcomes which demonstrated significant findings are considered first, before exploration of the non significant outcomes.

7:3:1 Well being at 12 and 24 months

Hypotheses revisited	
Well being subscales (WBQ)	The MI group will experience less depression, anxiety, positive well being, energy and general well being at 12 and 24 months compared to a support counselling intervention.

The results for well being within the MI group at 12 and 24 months were encouraging. At 12 months the MI group experienced less depression, more positive well being, less anxiety and an overall improvement in general well being. At 24 months the MI group experienced less anxiety, although there were no significant differences between the two groups on the subscales depression, energy, positive well being and overall general well being.

These results at 12 months regarding improvements in well being are particularly promising. The prevalence of depression is increased in adolescents with diabetes (Snoek and Skinner, 2002). Depression also affects quality of life (Talbot and Nouwen 2000) and is associated with poor glycaemic control and risk for long term complications (Lustman and Clouse, 2005). Depression and anxiety have been identified as key factors to barriers in self management and decreased quality of life (Glasgow et al. 2001). Within the Diabetes Attitudes, Wishes and Needs (DAWN) study, an international study of 5,104 participants with type 1 and type 2 diabetes, 41% of the sample experienced poor psychological well being related to their diabetes (Peyrot et al. 2006). Within the present study, it is possible that lowered depression, less anxiety and more positive well being may have facilitated better self management and subsequent better metabolic control through a positive reciprocal cycle. Skinner and Hampson (2001) argued that anxiety is an important index of an individual's emotional well-being, and is as important as physiological indices in successful diabetes management.

The findings support the pilot study of Channon et al. (2003) which found no effect on well being following an MI intervention. There are no other studies within paediatric diabetes on which to compare the findings. The positive results at 12 months however support the large scale population findings of Naess et al. (1995). This population study (Nord Trondelag Health Survey) found significant relationships between positive well being (measured on the WBQ) and lower HbA_{1c} (below 7.5%) in 74, 977 adult patients with type 1 and type 2 diabetes. Furthermore a study by

Pouwer, Snoek et al. (2001) reported that participants' general and energy well being increased (measured on a computerised version of the WBQ) following an intervention that used active listening skills and exploration of feelings over 6 months. There were no subsequent improvements in glycaemic control.

The results at 24 months demonstrated that although the MI group experienced less anxiety, there were no subsequent gains in depression, energy, positive well being and overall total well being. These results corroborate with the consistently weak associations between well being subscales and glycaemic control found elsewhere in the literature with adults with type 2 diabetes (Wredling et al. 1995; Petterson et al. 1998). Diabetes however is a psychologically challenging disease due to the complexity of the regimen. During the year long intervention, the young person would have been given opportunities to voice their emotional discontent with their regimen and other aspects of their management. The increased attention to the self care necessary to continue to reduce HbA_{1c}, may also have increased the psychological burden of the diabetes management, which may be reflected in the non significant outcomes.

The WBQ demonstrated good internal consistency within this study (α= .871), although within the literature evidence of its responsiveness is limited (Garrett et al. 2000). Moreover, it is a generic measure of psychological well being and does not measure diabetes specific well being. Consequently diabetes related emotional problems such as fear of hypoglycaemia or worries about complications may not have been detected. This is an important issue given the results from a qualitative study in

adolescents with diabetes by Weinger et al. (2001). The authors found that fear of low blood sugar reactions and fear of severe complications were both key themes to emerge from adolescent's stories about diabetes (although this latter finding is contrary to the findings highlighted in section 1:6:3, p. 19). To date there is no diabetes specific measure of well being within the literature, although a shortened 12 item version of the WBQ has been validated with patients with diabetes (Pouwer, van der Ploeg et al. 1999). Despite the increasing literature, not much is known about the effect of psychological well being and outcomes in diabetes (Pouwer, Snoek et al. 2001) and this is an area worthy of further study.

7:3:2 Quality of life findings at 12 and 24 months

Hypotheses revisited	
Quality of life (DQOLY)	**Motivational interviewing will be more efficacious in enhancing quality of life on subscales satisfaction, impact and worries at 12 and 24 months compared to a support counselling intervention.**

The findings from the quality of life outcomes at 12 months were promising and highlighted the utility of examining specific quality of life constructs in adolescents with diabetes. At 12 months the MI group perceived greater satisfaction with diabetes quality of life, experienced less negative impact of their diabetes and had fewer worries about diabetes. It is interesting that the MI group started at baseline with lower quality of life on all three subscales (satisfaction, impact and worries), although experienced better quality of life at 12 months compared to the control group. Conversely, within the control group, quality of life diminished on all three subscales and the most dramatic finding was in satisfaction (increase in baseline mean 33.28,

SD 9.88 to 45.55, SD 10.79 at 12 months where a higher score represents poorer quality of life).

At 24 months, quality of life findings within the MI group were in the opposite direction to the ones hypothesised and represent some surprising findings. Whereas the MI group had lower levels of satisfaction, higher impact of diabetes and more worries at 24 months, the control group experienced better quality of life on all three subscales (all statistically significant). The MI group returned to the approximate quality of life mean values observed at baseline. Given that levels of anxiety on the well being scale were significantly reduced in the MI group, it is perplexing that the results demonstrated increased worries and less satisfaction with diabetes related quality of life. Some explanations are offered for these findings.

Increased attention to self management required to achieve better glycaemic control may negatively impact adolescent's perception of their quality of life. This may negate the potential for improvement in satisfaction over a two year period, which is a brief period of time compared to the chronic course of diabetes. Although the intervention may have facilitated reductions in HbA_{1c}, this doesn't automatically mean that the young people were necessarily content with the increased attention to self management, the treatment regimen or other aspects of their diabetes life following an intense psychosocial intervention. This is similar to the theoretical explanations by Draycott and Dabbs (1998) who mapped the principles of cognitive dissonance onto the principles and method of MI. The method of MI incorporates the principle of 'deploying discrepancy' in which the patients core values and personal

aspirations are contrasted, through empathic listening, with the behavioural problem under discussion. Although this experience of discrepancy could trigger the motivation to change behaviour, it argued that this may not have resulted in satisfaction with quality of life. It is possible that the young people became more dissatisfied with their diabetes self management through focus on exploring concerns, identifying barriers to change and developing discrepancy beliefs about their diabetes lifestyle.

Regarding the nature of the intervention, MI may have facilitated significant changes and appraisals in the adolescent's life regarding diabetes self management, the perceived impact of diabetes and worries about diabetes. Some adolescents would have moved to resolution of barriers to self management, while others would have still been moving towards resolution and resolving ambivalence long after the intervention ended. This may have been reflected in their quality of life scores. It is difficult to compare these explanations with other studies since no other study has examined the impact of MI on quality of life outcomes.

The psychological benefits of good management may not always be immediate and may take longer to be realised (longer than the year follow up as in the present study). Intense adherence to diabetes regimen and good glycaemic control have been shown to be related to poorer quality of life and well being when measured by the SF-36 (Nerenz et al. 1992). The authors however found that this was not due to the behavioural demands of the regimen but an interaction between age, education level and number of daily insulin injections. Irrespective, there are costs to achieving good

The imbalance of scores on baseline quality of life subscales between the MI and control groups is considered. There were marked imbalances in the means and standard deviations, with the control group experiencing better quality of life on all three subscales. Similarly the standard deviations in the MI group were larger than the control group. This increased the likelihood that the imbalance would be reversed at follow up due to regression to the mean. The outcome of the randomisation process meant that any imbalance in groups was due to chance and the small sample size and subsequent sampling error may have accounted for the imbalance (chance bias). Because of these imbalances, it was important that the analyses at follow up accounted for the potential confounding aspect of this difference. This was achieved by controlling for baseline quality of life score on 12 and 24 months outcomes in subsequent analyses using repeated measures analysis of covariance (ANCOVA). ANCOVA adjusts each participant's follow up score for their baseline score and has the advantage of being unaffected by baseline differences. This improved the external validity and generalisability of the quality of life findings.

To date most of the studies examining quality of life in young people with diabetes have been cross sectional with low sample sizes and the results are contradictory (Hoey et al. 2001). There are only a few studies that have examined the outcomes of intervention effectiveness on quality of life and metabolic control. Within the coping skills training (CST) studies by Grey et al. (1998; Grey et al. 2000) there were significant enhancements in satisfaction with quality of life and reduced negative impact following the CST intervention and these will be outlined further in Chapter 8.

self care and metabolic control. 'Tight' glycaemic control often necessitates strict adherence to the regimen along with an increased incidence of hypoglycaemia as found in the DCCT study (1994). Fear of hypoglycaemia can also bring its own behavioural challenges such as reduction of insulin dose, excessive eating and avoidance behaviours (Kamps et al. 2006).

The discrepancy in outcomes in well being and quality of life at 24 months (i.e. gains in anxiety related well being although decrements in quality of life) are also considered. The findings demonstrated that within the MI group, whilst anxiety (well being) decreased, there were corresponding increases in worries about diabetes, decreased satisfaction and a higher perception of negative impact of diabetes on the quality of life scales, all of which appear contradictory. However, the principles of MI are to develop discrepancy, often resulting in increased awareness of conflicting values and dissatisfaction with current 'self'. Rollnick, Allison et al. (2002) argued that consultations about behaviour change are not always smooth and that feelings of tension, disengagement and conflict are often apparent, even if not expressed explicitly. Given the focus on dissonance within the adolescent's values about change, the results are consistent with the fundamental goals of MI. The conceptual overlap between the two constructs, well being and quality of life, has been addressed within the literature such that both constructs are often measured interchangeably as 'psychological well being' (Snoek, 2000). Eiser and Morse (2001) suggested that because quality of life and well being are multidimensional and complex constructs that involve objective health status, as well as subjective perceptions of the individual, further exploration of these dimensions are required in paediatric diabetes.

7:3:3 Personal Models of Diabetes at 12 months

Hypotheses revisited	
Personal models of diabetes (PMDQ)	**The MI group will experience greater illness beliefs about diabetes at 12 months compared to a support counselling intervention. Specifically the MI group will place greater importance in controlling their diabetes to prevent complications. They will have greater beliefs that behavioural actions will prevent complications. They will have lowered perceptions of the seriousness (threat) of diabetes and will perceive their diabetes to have less negative impact on their daily lives.**

The positive findings represent valuable insight into the adolescents understanding and perceptions of their diabetes which may have been facilitated by the MI intervention. The results at 12 months demonstrated that the MI group placed greater importance on controlling their diabetes (*importance to control diabetes*), had greater beliefs that certain behavioural actions were more likely to help prevent future complications of diabetes (*treatment effectiveness*), perceived their diabetes to be less serious and a threat to their lives (*perceived seriousness*), although perceived their diabetes to have a greater overall impact on their daily lives (*impact of diabetes*). It is encouraging that the MI group placed greater importance on the need to control their diabetes, perceived the importance of certain behavioural actions to prevent future complications and perceived their diabetes to be less of a threat to their lives at 12 months compared to the control group. It is surprising however that the MI group perceived their diabetes to have a greater impact on their daily lives than the control group which is in the opposite direction to the one hypothesised. The greatest gains for the control group in personal models were in the Impact subscale (baseline mean

25.87 to 12 months 34.52). The findings reflect the often contradictory nature of outcomes in personal models studies and these will be outlined briefly below.

It is possible that key elements within the MI intervention, such as increased awareness of personal values about diabetes and focus on concerns, facilitated the adolescent in restructuring their cognitive representations of their diabetes and management. The patient - centred style of the MI intervention meant that concerns around vulnerability and threat would have been dealt with sensitively rather than the use of fear communication as a way of facilitating behaviour change. The findings may have positive implications for adolescents in examining their beliefs about their regimen, which may have a direct effect upon self management.

An exhaustive account of the literature is not warranted in this section and only key findings that are relevant to the outcomes will be considered. Personal models of illness have been found to be predictive of positive well being and anxiety in adolescents with diabetes (Edgar and Skinner, 2003). Furthermore Skinner et al. (2000) found that beliefs about treatment to effectively control diabetes were consistently related to improved dietary self care over and above their beliefs about the importance to control complications in adolescents with diabetes. The authors also found that stronger beliefs about the perceived impact of diabetes were also shown to be related to greater anxiety.

As already discussed in Chapter 1 (section 1:6:3, p. 19), the evidence from studies examining adolescent's personals models of diabetes demonstrate that it is the shorter

term threat expectancies (beliefs about treatment effectiveness and the impact of diabetes) that predict well being and self care, rather than the longer term threats such as fear of complications and seriousness of diabetes (Skinner and Hampson, 1998; Skinner and Hampson, 2001; Edgar and Skinner, 2003). The influence of stronger beliefs about the seriousness (threat) of diabetes has produced inconsistent findings on self care. Studies by Hampson et al (1990; 1995) and Glasgow, Strycker et al. (1997) found that increased perception of the seriousness of diabetes was a determinant of improved dietary self care. The results however are contradictory. Perceptions of seriousness of diabetes have been related to poorer dietary self care and well being (Skinner et al. 2000; Skinner and Hampson 2001). These latter findings substantiate a study by Bond et al. (1992) which found a relationship between stronger perceptions of seriousness and lowered adherence to treatment. Skinner and Hampson (2001) argued that the conflicting results may be a result of the way beliefs are measured. The authors suggested that it is important to distinguish between the short term beliefs (such as perceived impact of diabetes and effectiveness of treatment) and longer term threat expectancies (such as seriousness of diabetes and importance to control complications) in adolescent research on personal models. Although the research on personal models of diabetes has yielded important insights into self management outcomes, further exploration of these constructs are warranted.

The overall psychometric properties of the PMDQ are considered. The scale is an extended version of a validated 8 item PMDQ developed from the Personal Models of Diabetes Interview (Hampson et al. 1990; Hampson et al. 1995). The extended version used within this study has not been subjected to psychometric validation and

hence the psychometric properties need to be treated with caution. The low Cronbach's alpha of the Impact subscale (α =.666) within the present study may be a function of the sample's responses to the items for perceived impact of diabetes rather than inherent characteristics of the items, although further examination of reliability and validity needs to be established. Despite these limitations the results confirm the utility of examining personal models in determining the adolescents' response to illness.

7:3:4 Diabetes family behaviour outcomes at 12 months

Hypotheses revisited	
Diabetes family behaviour (DFBS)	**Motivational interviewing will be more efficacious in diabetes family behaviour outcomes at 12 months compared to a support counselling intervention.**

It is surprising that there were no significant differences between the two groups on measures of diabetes family behaviour functioning. It was anticipated that any subsequent improvements in psychosocial functioning and metabolic control within the MI group would have facilitated greater adherence to self care which indirectly would have increased scores on family functioning. The DFBS demonstrated good internal consistency (α =.726) which is similar to the psychometric properties established within another recent study (Lewin et al. 2006).

The coping skills training (CST) studies by Grey et al. (1998; Grey et al. 2000) demonstrated that continuing parental support and guidance indirectly through the CST appeared to help adolescents achieve success in improving metabolic control

over 1 year of follow-up. A possible explanation offered by the authors was that CST allowed these adolescents to negotiate a comfortable amount of parental involvement in their diabetes care that did not detract from their developing sense of identity and autonomy.

Other studies have supported the relationship between family factors (supportive and guidance behaviours) and improved regimen adherence and metabolic control (Lewin et al. 2006; Schafer et al. 1986). However the correlations between individual family processes (such as responsibility and warmth) with metabolic control are small and Lewin et al. (2006) argued that in order to demonstrate greater insight into family constructs and outcomes, multiple diabetes behaviours need to be measured which include diabetes specific and general family functioning.

7:3:5 Self efficacy outcomes at 12 months

Hypotheses revisited	
Diabetes self efficacy (SED)	Motivational interviewing will be more efficacious in increasing self efficacy at 12 months compared to a support counselling intervention.

The non significant findings within the MI group were surprising. Although the mean self efficacy scores were higher at 12 months in the MI group compared to the control group, these were not statistically significant. One of the key strategies in the MI intervention was supporting the adolescents self efficacy relating to their personal beliefs about their ability to carry out and succeed with a specific task. This involved facilitating the adolescents' confidence in his or her ability to cope with the barriers to

change. Given the importance of this key strategy within the intervention, it was anticipated that adolescents self efficacy to cope with their diabetes would be increased within the MI group.

The outcomes are in contrast to the findings in the literature. The study by Viner et al. (2003) demonstrated increases in self efficacy measured with the SED scale following the hybrid MI/solution focused therapy intervention in adolescents with type 1 diabetes. Significant gains in self efficacy and metabolic control in adults with type 1 diabetes following an empowerment approach intervention were demonstrated by Anderson et al. 1995). The empowerment model used within this study has many similarities with the MI intervention used within present study, particularly with the emphasis on exploring ambivalence, empathic responding using reflective listening, eliciting 'outcome' talk and exploring costs and benefits to change. Furthermore, within the studies by Grey et al. (1998; 2000) the greatest effects of the CST intervention were in gains in self efficacy measured by the SED.

A possible explanation for the non significant results may be related to measurement and construct specificity of the SED. The scale measures diabetes situation specific items which relate to self management. Although the scale assesses self efficacy expectations (such as perception of ability to carry out a situation specific behaviour), there was no emphasis on outcome expectancies (perceptions of the effects of behaviours on specific outcomes such as metabolic control or reduction of complications). Self efficacy is a complex construct that involves behavioural, personal and environmental factors that facilitate the adolescent to live with and

manage their diabetes. Although it is recognised that the measure demonstrated adequate internal consistency (α =.871), it is possible that the measure was not comprehensive enough to capture the 'holistic' aspect of self efficacy, particularly in areas of the adolescents social world, barriers to self care, goal setting and seeking social support.

Specific adherence to the diabetes regimen such as diet and blood sugar testing represent a complex set of behaviours. For instance, anecdotal reports from the present study suggested that adolescent's barriers to blood sugar testing involved the pain associated with finger prick test. Diet involves complex meal planning, calorie counting and different methods of meal preparation which may be more difficult for the adolescent to evaluate. Additionally for the adolescent living with diabetes whose sense of well being is reliant on a complex health care regimen, specific self efficacy beliefs may take time to increase to the level at which self management behaviours (indirectly influencing glycaemic control) are sustained in the face of setbacks. Glycaemic control mechanisms are complex and are influenced by physiological factors independent of behavioural choices (McCaul et al. 1987).

Given that low self efficacy has been identified as one of the strongest barriers to self management (Glasgow et al. 2001), further exploration of this important construct is warranted in adolescents. Furthermore future research could be designed to inquire more directly about regimen specific efficacy beliefs, in addition to evaluation of the adolescents' diabetes efficacy beliefs concerning their social world.

7:3:6 Child health locus of control at 12 months

Hypotheses revisited	
Health locus of control (CHLC)	**Motivational interviewing will be more efficacious in increasing health locus of control (i.e. internality of beliefs to control diabetes) at 12 months compared to a support counselling intervention.**

The results demonstrated no significant differences between the MI and control groups regarding locus of control beliefs about diabetes. These are surprising since it was anticipated the MI group would have greater perceptions about ability to control events relating to their diabetes health (internal beliefs) rather than perceive outcomes due to chance, fate or luck (external beliefs). Key aspects of the MI intervention such as supporting autonomy and self efficacy would have increased the young person's intrinsic motivation to change (i.e. change arises from within rather than imposed from a practitioner or significant other). The increase in responsibility for behaviour would lead the young person to draw on their own personal resources, perceptions, goals and values which are concordant with an internal locus of control belief system. Given the focus on self efficacy within the MI intervention, it seems surprising that it didn't evoke greater beliefs about intrinsic motivation through internal locus of control. Bandura (1997: p.19) argued "*behaviour is influenced by generalised expectations that outcomes are determined whether by one's actions or forces outside one's control*", highlighting that self efficacy and locus of control work in concert together.

The poor internal consistency of the CHLC scale (α =.605) may have hampered the ability of the scale to demonstrate a significant effect. In the original study, Parcel and

Meyer (1978) found an overall reliability co-efficient (measured by the Kuder-Richardson co-efficient) of 0.753 based on the 20 items completed by 168 schoolchildren ages between 7-12 years. A six week test-retest reliability coefficient demonstrated a co-efficient of 0.62. The scale however was measured with healthy children and one of the recommendations of the authors was that additional work was required to demonstrate the predictive value of the scale in children with chronic disease.

The lack of significant findings maybe related to the response format of the binary YES/NO format and item wording. For example, many of the statements are worded in terms of response decisions according to adult authority figures (e.g., only my doctor can prevent me from being sick; only the dentist can take care of my teeth) indicating an external locus of control decision. Adolescents may have difficulty with this because it indicates agreement with authority figures when adolescence is a developmental period that challenges authority and strives for autonomy. Furthermore the artificial dichotomized responses have limitations. Adolescents with scores in the centre of the continuum (such as interacting beliefs on dimensions of internal, chance, powerful others, god, doctors) were artificially dichotomized in the high or low category. Such dichotomous classifications are arguably too simplistic, as young people may have interacting beliefs within in a situation.

Moreover 14 of the 20 items are worded in an external direction. This may have caused the originally negative skewed results on the scale at baseline [MI =15.45 (SD 2.53), Control = 15.90 (SD 2.00)] (range 0-20). Due to the ceiling effect it was

necessary to transform the mean value of the scale using square root transformation due to the negatively skewed distribution of the data (baseline skewness = -.579). The mean scores post transformation were ([MI =10.87 (SD 2.53), Control = 11.47 (2.11)] which demonstrated normality. Due to the poor internal consistency of the scale within this present study the outcomes need to be interpreted with caution.

The author is not aware of any study that has examined the impact of a psychosocial intervention on health locus of control in the paediatric diabetes literature. The relationship however between health locus of control and psychosocial outcomes in patients with diabetes has been mixed (Aalto et al. 1998; Coates and Boore, 1998). Furthermore, most of the studies examining the relationships between locus of control and metabolic control are cross sectional with small sample sizes and the evidence is inconsistent (Surgenor et al. 2000; O'hea et al. 2005; Auerbach et al. 2002). Greater attention to the evidence is given in section 8:16:2.

7:3:7 Health care climate outcomes at 12 months

Hypotheses revisited	
Modified health care climate (HCCQ)	**Motivational interviewing will be more efficacious in enhancing satisfaction with perceptions of the health care climate at 12 months compared to a support counselling intervention.**

There were no significant differences between the two groups in perceptions of the health care climate and very little differences in the mean values of each centre. It is not known if different centres had diverse philosophies of care and interpersonal styles of working and whether this affected the patient's level of motivation,

behaviour and subsequent health. Across the five centres, it is possible that the adolescents would have been seen by several health care providers during the year long intervention (dieticians, doctors and diabetes nurses) making it difficult to reflect on the perceptions of one health care provider as specified in the HCCQ. Within the study some young people reported having known their health care provider for several years (since diagnosis as small children), whilst others would have been relatively unfamiliar with the health care providers in their clinic. Furthermore during the intervention some adolescents transferred to adult services, although this distinction wasn't analysed within the results. Therefore some responses may have been confounded by these factors.

The HCCQ has not been validated with adolescents with diabetes and items are not specific to diabetes treatment. Despite this the internal consistency of the scale was high ($\alpha = .909$) which is consistent with the psychometric properties of the scale tested in a recent study by Williams et al. (2006). It is difficult however to make comparisons of the HCCQ outcomes across studies, since most examine social determination theory (SDT) variables on which the scale is based, using a shortened 4 item version of the HCCQ.

A small scale study *conducted by adolescents with diabetes* regarding the quality of local diabetes services demonstrated that the interpersonal environment was one of the key areas identified for improvement (Lamb and Laing, 2004). Other research points to differences in concordance between patients and health care professionals perceptions of what is important in diabetes management (Parkin and Skinner, 2002).

Such findings have important implications for the development of patient centred care highlighted in recent government guidelines which are discussed in greater detail in Chapter 12.

7:3:8 Therapeutic Alliance outcomes at 12 months

Hypotheses revisited	
Therapeutic Alliance (TAQ)	**Motivational interviewing will be more efficacious in enhancing perceptions of the therapeutic alliance between participant and interventionist on subscales bond, goals and goals at 12 months compared to a support counselling intervention.**

There were no significant differences between the two groups on perceptions of helpfulness of the therapeutic alliance on the subscales bond, task and goals. These results were perplexing since it was anticipated that perceptions of helpfulness of the therapeutic alliance would be greater within the MI group given the greater emphasis on collaboration, attention to personal goals, values and problem solving tasks. Ackerman and Hilsenroth (2003: p.2-3) argued that "*key aspects of the therapeutic alliance such as connecting with the patient and conveying an adequate sense of competence...are related to the development and maintenance of the alliance*".

Some weaknesses relating to the measurement of the construct were apparent. The scale was specifically adapted for the study from Bordin and Horvath's working alliance inventory (WAI). Specific items were reworded to be adapted to the study. For example, in the original version one item specified *'What I am doing in therapy gives me new ways of looking at a problem'* was changed to *'What I do in this research study gives me a new way of looking at my diabetes'*. One item was

specifically biased towards a strategy within the MI intervention. Question 11, *'The experience helps me see the pros and cons of what I am doing with my diabetes'* was clearly leading given that the 'Pros and Cons' strategy was a key technique used within the MI intervention to explore ambivalence about change.

Although the therapeutic alliance has been used in studies with adolescents in general (Horvath and Greenberg, 1994), this is the first study within the MI and adolescent diabetes field to use an adapted version of the therapeutic alliance questionnaire. A strong therapeutic alliance, usually defined as the quality and strength of the relationship, as well as specific attributes such as therapist affirmation, understanding and empathy, has consistently predicted outcomes across a range of treatment approaches and problems, although the relationship is moderate (Martin et al. 2000; Ackerman and Hilsenroth, 2003). The scale was not subjected to piloting prior to use within this present study and although achieved a satisfactory Cronbach's alpha of α =.850, the good psychometric outcomes of the original cannot be assumed. One study evaluated the psychometric properties of the WAI (Cecero et al. 2001) and found satisfactory alpha co-efficients for the WAI subscales. The scale however has yet to be tested within the therapeutic alliance with young people experiencing diabetes. A goal for future research is to pilot an adapted version of the WAI and identify which personal attributes and techniques positively influence the level and maintenance of the alliance within relationships with diabetes nurse specialists, paediatricians and dieticians.

7:3:9 Diabetes Knowledge outcomes at 12 months

Hypotheses revisited	
Diabetes Knowledge (DKN)	**There will be increased level of diabetes knowledge within the MI group compared to the support counselling group at 12 months.**

There were no significant differences between the two groups on diabetes knowledge. This may seem surprising given that a key focus of the control intervention was in diabetes specific information provision. The MI intervention however placed little or no emphasis on the exchange of information and thus it is unsurprising that there were no gains within this group. The internal consistency of the scale was good (α =.719) which corresponds to the Cronbach's alpha of α=0.82 and above reported within the original validation study (Dunn et al. 1984). The findings may reflect the format of the DKN scale which may have lacked precision in detecting changes in diabetes knowledge following the MI or control interventions. The wording of the questionnaire specifically focused on knowledge about aspects of diabetes *per se* and not about diabetes specific management behaviour or the processes involved in diabetes self management. Seven out of fifteen items asked about knowledge relevant to diet (e.g. item 7; '*Butter is mainly* a) protein b) carbohydrate c) fat d) mineral/vitamin e) I don't know'). It is possible that the adolescents had sufficient knowledge about diet since most of the paediatric outpatient clinics in the study employed a dietician. The DKN in this instance would have failed to evaluate increases in knowledge in this important area. Thus it is possible that within the present study the DKN lacked the responsiveness to capture key gains in diabetes

knowledge relating to specific diabetes management behaviours. It may have been more appropriate within this study to assess follow up diabetes knowledge via open ended questions to measure the complexity of knowledge relating to the diabetes regime and self management. Although Dunn et al. (1984) reported bias within their validation of the DKN using open ended questions, due to verbal ability and recall memory problems within their sample, it is argued that within the present study this type of response format would have been more appropriate.

Although low levels of diabetes knowledge has been associated with hyperglycaemia, hypercholesterolemia and hypertension in adults with type 2 diabetes (Norris et al. 2002; Brown, 1990) the relationship however between diabetes knowledge and improved self care is contradictory. It has been demonstrated that improving a person's level of knowledge has rarely led to positive self care behaviours and improved diabetes self management (Brown, 1990; Dunn et al. 1990). Semiz et al. (2000) found no effect of diabetes knowledge on metabolic control 6 months post attendance of a 10 day summer camp. A recent study at the Duke Clinical Research Institute (Sanchez et al. 2005) found little evidence between diabetes knowledge measured on a 14 item assessment scale and outcomes (i.e. blood sugar control, cholesterol, weight management or mortality rates) in a sample of 200 adult patients with diabetes. Furthermore it has been found that patients and providers differ in their views about what constitutes essential diabetes knowledge, with patients emphasising social and lifestyle issues, and health care providers focusing on physiological aspects (Cohen et al. 1994). Garcia et al. (2001) argued that most clinicians develop their own diabetes knowledge scales to determine effectiveness of interventions and

consequently there are few reliable and valid instruments to measure knowledge. A recent study by Vincent et al. (2006) using focus groups with adult patients with type 2 diabetes found that 'being in the dark' about diabetes self management was the most important identified concern, with patients requesting timely up to date access to current knowledge about how to manage their diabetes.

7:4 Sub group analysis

7:4:1 Insulin measurements

Analysis of daily insulin dose/kg body weight between the MI and control group was considered important to explain the reductions in HbA_{1C} within the MI group. The non significant findings of differences in insulin dosage between the two groups ruled out insulin dose as a contributory factor in facilitating reductions in HbA_{1C} at 12 and 24 months. The DCCT (1994) confirmed the utility of intensive management (multiple daily injections with both long and short acting insulin formulations) in reducing HbA_{1c} within the adolescent cohort. Modified intensified insulin therapy (MDII) and continuous subcutaneous insulin infusion (CSII) are increasingly used in adolescents with type 1 diabetes (Torrance et al. 2003) and a meta analysis has demonstrated the superiority of intensified insulin regimes over conventional therapy (i.e. 2 injections a day of mixed insulin formulation) (Pickup et al. 2002). The benefits of MDII versus conventional therapy were further demonstrated in a recently published RCT (Soliman et al. 2006).

7:4:2 Poorly controlled sample

The ISPAD consensus guidelines (2000) suggested that HbA_{1c} value of > 9.0 % renders the adolescent at risk for complications and this was the figure used as the cut off point for analysis of poor control within this present study. Exploratory analysis of the poorly controlled subgroup demonstrated a reduction in mean values within the MI group by 1.16% over 12 months and 1.19% over 24 months. The control group reduced their HbA_{1c} over 24 months by 0.18%. There were however no statistically significant differences between the two groups in HbA_{1c} over the study period. Within the quality of life subscales, similar to the results within the main analysis, there were statistically significant enhancements within the MI group on all subscales at 12 months. Statistically significant gains were also seen in well being, personal models of diabetes and on the therapeutic alliance questionnaire. These results need to be interpreted with caution however due to the exploratory nature of the findings and the low sample sizes.

Despite the low sample sizes however, the results highlight the potential to examine the effects of MI within a poorly controlled cohort. Snoek (2006) argued that the most important question to address within diabetes research is not whether psychological interventions are effective for improving glycaemic control *per se*, but rather whether psychosocial interventions help to improve glycaemic control in patients who are poorly controlled. Specific psychosocial intervention effects have been found to be more pronounced in poorly controlled groups in recent studies (Wysocki et al. 2000; Svoren et al. 2003). Epidemiological analysis of the DCCT (1994) findings with adolescents demonstrated that for each 1% decrease in HbA_{1c} such as from 9.0% to

8.0%, there was a 39% decrease in risk of micro-vascular complications (DCCT group, 1995), highlighting the clinical significance of the group difference within the present study. The results provide preliminary support for the potential to target 'at risk' young people and suggest that a psychological intervention such as MI may be beneficial to facilitate gains in glycaemic control in young people if the goals of HbA_{1C} less than 7.6% (advocated by ISPAD, 2000 and NICE, 2004) are to be achieved.

Although the poorly controlled adolescents represent a potential subgroup who may benefit most from an MI approach, they comprised 32.0 % of the sample and therefore caution is warranted in generalising these findings to other adolescents with poor glycaemic control.

7:5 Validity of the reported results

7:5:1 Design issues

7:5:1:1 Inclusion and exclusion criteria

Permissive inclusion criteria were set to ensure a representative trial population and increase the generalisability of results to the wider population of adolescents with type 1 diabetes. Inclusion of young people with varying levels of metabolic control, representing a mixed patient population however can be viewed as a weakness in the study design. Adolescents with poorer metabolic control (i.e. those with HbA_{1c} of > 9.0%) have a greater risk of developing micro-vascular complications as demonstrated in the DCCT (1994). It is possible that a proportion of adolescents with poor control failed to participate within the study and it is these adolescents who

would have benefited clinically from the interventions. Poorer controlled adolescents are disproportionately more likely to come from disadvantaged families (Delamater, 1999), have more frequent school absences (Orr et al. 1983) and have higher rates of behavioural, emotional and physical problems (Leonard et al. 2002). Moreover diabetic ketoacidosis (DKA) during the post-diagnostic period is often caused by non adherence to insulin regimen (Smith et al. 1998). These factors raise challenges within participation in psychosocial studies which often require a high degree of volition and commitment to complete data.

The pilot study of Channon et al. (2003) included only adolescents who were motivated to change their behaviour (adolescents who identified themselves within the 'contemplation' 'preparation' and 'action' phases of the DRCQ adapted specifically for the study. Those participants in the 'maintenance' category (i.e. those who felt they didn't have any aspect of self care to change) were excluded. Within this present study, the adolescent's stage of change was not incorporated in the inclusion / exclusion criteria. The study therefore included young people who were willing to take part but maybe did not perceive the need for changes in any area of self care. Exploratory analysis on the participants readiness to change for those who dropped out, demonstrated that most of the participants were in the 'pre-contemplation' and 'contemplation' motivational stages. This suggests that the adolescents were thinking about changing `but had not yet made a commitment to take action. Although the MI intervention was tailored to meet the needs of these adolescents in these stages (more focus on awareness raising and less on developing discrepancy), it is possible that the MI intervention facilitated movement through

different stages prematurely. Participants were asked early on in the intervention to highlight their satisfaction and dissatisfaction with diabetes through the 'Agenda Setting' task and while some young people welcomed this opportunity to identify and explore personal values about diabetes others felt it did not suit their personal needs.

7:5:1:2 Attrition

Despite innovative ways of approaching participants to seek knowledge about the study (such as enlisting the support from a paediatric nurse to interview participants at home), the number of participants who agreed to enter the study was still relatively small (n=80 out of a possible n=169). A further 13 participants dropped out prior to the first baseline visit. Attrition rate amongst the MI group was higher than controls (n=10 MI versus n= 4 controls, not significant). One participant died of accidental death within the control group which was not related to diabetes.

Although a possible explanation of the increased attrition rate within the MI group may lie with the adolescents 'readiness to change', it is also possible that adolescents lacked the personal resources and social support to achieve behaviour change. Another reason for attrition may have been related to the perceived intensity of the MI intervention which may be viewed in a positive and negative direction. The control group intervention by its nature was non directive and designed to provide low key support to the young person to talk about their diabetes. This included talk about the young person's life such as school and peer relationships. Many of the interviews took place in cafes and parks. As such it was relatively non challenging and required less commitment than the MI intervention, apart from attendance of sessions. The MI

intervention on the other hand required very active participation of the young person and may have been perceived as challenging especially in exploring personal values and the dilemma of change. This may have been uncomfortable for some adolescents who were not ready to explore their values. For the four participants who received 2-3 sessions of MI prior to dropping out (see flow chart, section 6:4, p. 208), however the focus on awareness raising, exploration of values and eliciting sense of importance of change early on in the intervention may have empowered them to towards a fulfilling lifestyle in the absence of the intervention.

Within the exploratory analysis of the 'stage of change', it is interesting that within the MI group, despite the majority of participants being in an 'earlier' motivational stage, they had a baseline mean HbA_{1c} of 8.72 (SD 1.30). Although this is considered suboptimal when referenced to ISPAD (2000) guidelines, it is lower that the baseline HbA_{1c} mean of the MI and control groups (9.21 and 9.12 respectively). This 'lower' HbA_{1c} finding is contrary to previous unpublished research by Waddington (1993, cited in Trigwell, Grant and House, 1997) which demonstrated a relationship between higher metabolic control with earlier motivational stage. The findings from the present study substantiate the outcomes by Trigwell et al. (1997) which found lower HbA_{1c} levels were associated with an earlier motivational stage in adults with diabetes. It is possible within the present study that feedback from recent HbA_{1c} results at out patient clinic influenced the young person's beliefs about their readiness to change, such that lower HbA_{1c} levels facilitated lowered expectations of the need to change. This is speculative however and further exploration is warranted on stage of change, motivation and glycaemic control in adolescents with diabetes,

By the end of the 12 months the sample size had reduced to n=52 with 28 adolescents completing the MI and 24 completing the control interventions. Although attrition was inevitable within a multi centre RCT, it is possible this attrition could have been minimised by screening young people on an established reliable and valid 'stages of change' such as the Stages of Change Readiness and Treatment Eagerness Scale [(SOCRATES) Trigwell et al. 1997]. This scale was especially adapted by the authors for assessing motivational stage in diabetes and it would have been feasible in the present study to exclude those participants who scored in the 'maintenance' category for whom improvements in behaviour change may have been less salient.

7:5:1:3 Sample size, alpha level and power analysis

In order to detect a difference in mean HbA_{1c} of 1% at a 5% significance level, the power was 90%. Thirty participants were required to be randomised to each group and to allow for loss to follow up of 25% the aim was to increase to 80. Although 80 participants were recruited, this dropped to 67 once randomisation took place (with one participant being ineligible resulting in 66 participants). This figure decreased to 52 participants at 12 months follow up (who completed the interventions) which is below the number required for adequate power within the study. Subsequently it is possible that the failure to reach statistical significance on the psychosocial questionnaires may have been the result of a type 2 error (i.e. that no effect or difference is declared, while in fact there is an effect). The use of Bonferroni correction factor adjusted for the potential of spurious significant outcomes in multiple testing of the psychosocial questionnaires.

The target 1% difference sought in HbA_{1c} was based on clinical judgement and the pilot findings of Channon et al. (2003) which found a 1.1% reduction in HbA_{1c} over 6 months following an MI intervention. Other research guided this target (i.e. DCCT study findings, 1994). Although a mean reduction of 1% was not achieved within the present study, the sample size was large enough to give sufficient power to detect significant differences in the primary outcome measure HbA_{1c}.

7:5:1:4 Recruitment

Slow early recruitment jeopardised the progress of the trial. This was due to non attendance at out patient clinics and reluctance from patients to seek further information about the study itself. The solution to enlist the support of other staff and undertake community based recruitment within the Cardiff and Bridgend clinics improved the recruitment rate dramatically (an increase of 50% within the Cardiff clinic). Many of the recruitment meetings took part in the home environment and it is possible that this led to acquiescent participation, particularly when the parents were present. The common clinical challenge of engaging poorly controlled young people remains a barrier in participation in studies and it has been suggested by Viner et al. (2003) that those young people who require the most help with diabetes are often the most difficult to engage.

7:5:1:5 End points and follow up data

Two time points were specified for follow up within the Diabetes UK protocol; 12 months post baseline and 24 months with an additional measurement of HbA_{1c} at 6

months. The 12 month intervention phase and follow up analysis at 24 months allowed the adolescents to be assessed prospectively. Because of the time delay in changes in self management /lifestyle behaviours and translation of these practices into glycaemic control, long term follow up is preferable to identify development and persistence of clinical benefits and increase generalisability of the findings. Although longer term follow up increased the potential for the loss of data due to participants moving out of the home and/or attending university, this was far less evident than originally anticipated. Fifty participants completed HbA_{1c} data at 24 months (MI = 30 and control =20). Out of the participants who completed the MI intervention at 12 months, 24 /28 (93%) completed HbA_{1c} data at 24 months. Out of the 10 participants who dropped out, 4/10 (40%) provided HbA_{1c} data at 24 months. This figure was slightly lower for the control group with 18/24 (75%) participants who completed intervention providing HbA_{1c} data at 24 months. One participant within the control group, who dropped out, provided HbA_{1c} data at 24 months. These figures were lower for the quality of life and well being questionnaires and missing data varied between the subscales within the questionnaires.

One method of improving mailed response rate of the questionnaires is to offer monetary incentives. A recent meta analysis by Edwards et al. (2005) found that by offering money within a mailed questionnaire via cash or cheque, respondents were more likely to return the questionnaire and this response increased in the absence of follow up reminders. It is not known how this method of incentive impacts upon the validity of the self report data. Furthermore the responsiveness of the questionnaires to detect clinically relevant changes in measurement is unknown. Response shift

(changes in cognitive appraisal as a result of changes in internal standards over time) is considered later in this section.

7:5:2 Internal validity

One of the key criticisms within the MI field is the lack of attention to internal validity (Burke et al. 2002) and the present study is one of the few that have identified and explored the components of the MI intervention, devised a manualised control intervention and afforded attention to interventionist training, supervision and quality monitoring. Attention to these methodological issues adheres to the framework of the MRC (2000) for development and evaluation of RCTs for complex interventions to improve health.

7:5:2:1 MI intervention development

A strength of developing the MI intervention through simulated interviews was the opportunity for rehearsal and the degree of flexibility allowed. Key strategies that were considered important within the intervention were practiced within the simulations until the author reached a level of sound skill competency in MI. A drawback related to the process of developing the MI components, whilst simultaneously receiving training in MI and implementation of the intervention. Although key strategies were identified during the piloting phases (and prior to commencement of the intervention), some were developed *during* implementation of the intervention and subsequently, the MI intervention was modified as appropriate. Developing components during intervention delivery, whilst simultaneously receiving training, may have led to adolescents in receipt of the intervention at the later phases

receiving a more skilful intervention than in the earlier phases. It is not known how this learning curve effect may have affected delivery of the intervention or indeed affected outcomes. Bradley, Wiles et al. (1999: p. 713) commented that "*there is always a learning curve in developing new interventions but it is usually hidden*".

A preferable method would have been to develop the intervention distinct from the training. This could have taken the form of an exploratory or pilot trial, whereby the intervention could have been defined through simulated interviews and then implemented as part of a small scale pilot trial. This would have enabled standardisation of the MI components and allowed the practitioner to skilfully practice the strategies and skills identified. An important weakness of this method however is in developing a 'one size fits all' model of intervention which doesn't take into account the participants underlying needs and values as well as the degree of self efficacy and willingness to talk about behaviour change. Additionally MI goals such as exploring deeply held values can be accomplished through a variety of processes that may not be anticipated in a procedural checklist (Moyers, Martin et al. 2005). Given that the spirit and style of MI are fundamental elements or 'active ingredients' of MI they are also difficult to quantify. One approach to conducting exploratory trials which is in accord with the MRC (2000) framework is through the use of *Intervention Modelling Experiments*. In such experiments key elements of an intervention are manipulated to simulate 'real world' settings using interim endpoints as the outcome measure, instead of actual behaviour. Although short term laboratory effects in psychological studies have been replicated in 'real world' studies of health outcomes

(Matthews et al.1981; Bandura, 1969), the validity of using modelling experiments in relation to clinician's implementation behaviour has yet to be established (Bonetti et al. 2005). Designing and defining an intervention that incorporates principles and strategies of MI as the main component is an under reported area within the MI literature and requires further investigation.

7:5:2:2 Interventionist training

The goals of the training were to develop and enhance MI skills and strategies through modelling, feedback and rehearsal, via the use of simulated patients and supervision. This form of training is unique in MI studies in terms of the content and methods used. Most MI skills are taught through 2-5 day workshops using a combination of didactic and experiential methods which involve pre-post training evaluations. The use of simulated interviews provided an objective and reliable approach and enabled skills to be rehearsed without the ethical problems of involving patients. It is possible that the simulated patients introduced bias in terms of socially desirable responding although this was controlled through trainer observation and careful briefing prior to each interview. As far as possible the author had minimal contact with the actor prior to each interview.

A key advantage of the simulated interviews was the author's ability to listen to the taped sessions away from the simulations and reflect upon the skills used. The actors invariably simulated an adolescent experiencing entrenched negative habits and poor self management with their diabetes which involved greater ambivalence and resistance to behaviour change. This portraying of difficult clients has been found to

be far less responsive to MI than those encountered in clinical practice (Miller et al. 2004). However it was the author's experience that these interviews with 'difficult patients' facilitated smoother and more skilled interactions in the real life setting, since the author had practice encountering potential difficulties within the simulated interviews.

The initial 4-6 months of the intervention were the most challenging in that during this period the author would have been exploring the young person's personal values along with eliciting and strengthening arguments for behaviour change. Client commitment speech (higher percentage of talk about the how and why of change with concomitant less resistance) has been found to be a predictor of sustained behaviour change (Amrhein et al. 2003) and it is possible that this was diminished through lack of author proficiency in MI. However Miller, Yahne et al. (2004) found that even short duration of MI training (via 2 day workshops) has produced immediate effects in proficiency in MI, particularly in the spirit of MI, and that these effects were maintained with follow up feedback and/or coaching post training. The author has many years experience in patient centred counselling methods and thus the style of responding would have been consistent with the 'spirit' of MI. Rollnick and Miller (1995) emphasised that MI is a skilled style of counselling rather than a set of techniques and argued that clinicians and trainers who become too focused on matters of technique can lose sight of the spirit and style that are central to the approach. The next section focuses on the integrity of the MI and control interventions.

7:5:2:3 Integrity and discriminability of interventions

A strength of the design of the intervention was the attention to identified components and regular supervision during intervention delivery. The control group intervention was originally designed to be based on active self management strategies through assessment, provision of specific information, goal setting, active problem solving and follow up action plans. Feedback however from the interventionist detailed a less structured intervention with focus on non directive general support and talk around school, friends and social activity, rather than specific diabetes related problem solving strategies around self management.

Difficulties arose in comparing the MI intervention as qualitatively different to the control intervention. Although it was anticipated that the majority of the interviews would be audio-taped, eventually 60 out of a possible 120 interviews were carried out. While some adolescents declined consent there were some technical difficulties in the early phases of the study which hampered taping all the planned interviews. Furthermore some interviews were conducted in parks and cafes where it was not appropriate to audio-tape the dialogue. Within the control group only 10 interviews were audio-taped and the quality of 5 of these was too poor to be analysed. Preliminary analysis of MI skilfulness was undertaken by an independent researcher skilled in Behaviour Change Counselling (Rollnick et al. 1999) and described in section 3:2:1. A selection of five tapes was selected by the author from the MI group, based on what were perceived to be 'good' and 'poorer' skill quality. The five tapes selected within the control group were audible enough for the coder to analyse. The tapes were analysed on the Behaviour Change Counselling Index [(BECCI) Lane,

Huws-Thomas et al. 2005]. The scores (not reported for study) suggested that the control interventionist practiced a style of counselling which differed from an MI style of responding and provided preliminary evidence of adherence to an approach sufficiently distinct from MI within the interviews. One caveat to the coding of these tapes rests with the selection bias of coder and tapes. The coder was not blind to the study hypotheses and interventionists' style, so it is possible that that the coder's pre-existing expectations of the author to practice MI consistent skills biased the scoring. Although efforts were made to select tapes that required greater skill proficiency in certain areas, it is still possible this method confounded the scores.

Although much consideration was given to quality monitoring there were too few audiotapes analysed to distinguish between the two interventions thus limiting the discriminant validity of the study. Although the control intervention was manualised, it remains unanswered as to whether the control interventionist adhered to the components of the intervention, or slipped into a person centred style of counselling. Although non specific effects such as therapist characteristics were not measured within the tapes, the integrity of the MI training, along with frequent supervision and evaluation of the fidelity of the intervention were sufficiently observed and analysed to demonstrate interventionist skill efficacy in MI. Until these non specific factors are adequately controlled or analysed reliably the question of discriminability remains unanswered.

The personal characteristics of each interventionist may have influenced outcomes over the 5 centres, irrespective of adherence to components of the interventions.

Outcomes may have also have been influenced by demand characteristics (conscious adherence to please the experimenter/researcher) or psychotherapeutic demand characteristics (non conscious changes in clinically relevant behaviour). The quality of care within each centre and different population characteristics may also have influenced outcomes. Using multiple therapists across sites may have increased the generalisability of the study and permitted examination of more detailed therapist-outcome interactions and how they relate to improvements in outcomes.

7:5:2:4 Supervision and quality monitoring

The internal supervision which took place within the first 6 months of the intervention enabled the author to reflect on interviews that had poorer skill fidelity. Where 'roadblocks' and difficulties in responding were encountered, feedback was provided about how to interact skilfully. The 'coaching' and 'feedback' method enabled greater confidence in responding in challenging situations. The external supervision made a positive contribution to enhancement of skilful MI delivery. The written feedback on the micro and macro skills of MI greatly enhanced the author's skillfulness in responding and provided new ways of approaching situations. A weakness of the methods of supervision were that the taped interviews were not analysed and scored on a validated MI process measure such as Motivational Interviewing Skill Code [(MISC) Miller et al. 2003] or the newer and shorter version Motivational Interviewing Treatment Integrity Scale [(MITI) Moyers, Martin et al. 2005]. Within the external supervision a selection of interviews were analysed on Resnicow's rating system (personal communication, Rosengren, 2003). This unpublished tool analyses global ratings of empathy, behaviour counts of MI adherent behaviours and

reflections/open questions. Subsequently the external supervisors were able to provide detailed and structured feedback on whether the author adhered to an MI style of working.

7:5:2:5 Outcome measures

Glycosylated haemoglobin

Measurement of glycosylated haemoglobin has been advocated as the most valid method of determining the adequacy of glycaemic control (Rohlfing et al. 2005). A further strength is that the HbA_{1c} tool can also be used to stratify the risk of developing micro vascular complications, since there is an exponential rise in the rate of complications with increasing HbA_{1c} (DCCT group, 1995). One drawback using HbA_{1c} as a measure may have been inadvertent feedback of HbA_{1c} values to the interventionists by the young person. This practice may have led to the adolescent interpreting and changing behaviour according to the result and not the intervention, while the interventionist may have inadvertently adapted her communication style to affect the adolescent's cognitive and behavioural expectancies. Feedback of HbA_{1c} within the out patient clinic may have been a determinant of the young person's motivational level. For example, young people who were in the stages of change 'contemplation' stage of readiness and who had a relatively low HbA_{1c} reading during the intervention may have been less motivated to work on changes in lifestyle behaviour and viewed change as unnecessary. It remains unanswered how feedback on HbA_{1c} influenced scores on the psychosocial questionnaires.

Psychosocial questionnaires

The psychosocial questionnaires used represented some of the most psychometrically robust measures within the child and adolescent literature, whilst they also measured a range of outcomes to evaluate the interventions. However feedback from the participants and their families revealed that the number and length of the questionnaires at the time points were burdensome, and in some cases required assistance from the researchers to complete. Although the DRCQ was completed by participants at baseline, 6 months and 12 months, paucity of information on how to reliably code and analyse the scale prevented inclusion for analysis. Similarly the Therapeutic Alliance Questionnaire was adapted through rewording specific items, although shortness of time prevented the pilot of this questionnaire in an adolescent sub sample to test the validity. Subsequently although the outcomes are reported, the results need to be treated with caution. Unreliable outcome measures inflate standard errors and make less likely the detection of differences between two groups (Shadish et al. 2002).

7:5:2:5 Reliability of self report data

To date there are no known studies of the reliability, validity and unique contributions of self report in the context of diabetes treatment in adolescents. However it has been argued that because adolescents have knowledge of their behavioural repertoire (Larson and Richards, 1994) and have the potential for introspection (Offer and Sabshin, 1984) they are able to provide clinically important information that in most cases is not available from adults or other sources. Inaccuracies in self reporting in questionnaire surveys have been identified as problematic with adolescents (Fan et al.

2006), although arguably within the present study that this would have been more likely in the report of problem behaviours rather than on reflection of perceptions of one's health, as was the case with the questionnaires. Given there was no measure of lifestyle behaviour patterns or identification of risk behaviours, the young people may have been less inclined to report inaccurate data. Moreover, accuracy of self report with young people participating in research studies has been found to be reliable in studies which assure confidentiality and value of the data at the outset of the study (Harrison, 1995). Within the present study, these factors were emphasised frequently. The emphasis on adolescent, and not parent, self report reflected the autonomy of the adolescent within the study.

Criticisms of self report methods to measure health have been levelled at response instability and different conceptualisations of health (Bowling, 2005). A new approach to measurement of health constructs has been via the use of anchoring vignettes. These are fixed descriptions of each response choice level, which increases consistency of respondents' interpretations of them. Anchoring vignettes are linked to self assessment which aims to detect and adjust for differences in expectations between individuals. Salomon et al. (2004) found that individual ratings of hypothetical vignettes related to expectations for health in similar ways as self assessments, and they adjust for the influence of varying expectations on self ratings of health. The utility of this method for assessing health appears interesting, although their use in adolescents with chronic disease has yet to be examined.

7:5:3 External validity

The external validity of the study is strengthened by the relatively strong attention to internal validity. However there were a number of threats to external validity and these will be considered in turn.

7:5:3:1 Intervention duration

The mean number of sessions provided within the MI group was 4 with an average duration of 40 minutes. The mean number of sessions provided to the control group was six, with a mean duration of 45 minutes. Although it was anticipated within the study design that contact time would be controlled to ensure equivalence between both groups, in reality it was difficult to adequately control the frequency of sessions across groups as the frequency of contact was determined by the young person. It was also difficult to anticipate the number of sessions required, since the intervention within the pilot study (Channon et al. 2003) was of much shorter duration. The MI group demonstrated positive effects with shorter interview time and fewer visits over intervention period. It is still not known however what 'dose effect' of MI constitutes positive outcomes (Burke et al. 2002). It is possible that longer duration MI sessions on a more frequent basis would have increased the superiority of the MI outcomes. The author however suggests however that the frequency and timing of the sessions were consistent with the adolescents' needs and wishes. Moreover it is suggested that the degree of autonomy offered to the adolescents in deciding '*where and how many*' sessions within both MI and control groups enhanced adherence and commitment.

7:5:3:2 Temporal direction of effects

There were significant gains within the MI group on quality of life, well being and personal models of illness beliefs during the course of the intervention when significant change occurred in HbA_{1c}. It is difficult to conclude that changes in these psychosocial factors led to the reduction in HbA_{1c}, because changes were occurring simultaneously and were not measured. Reductions in glycaemic control may have preceded gains in psychological functioning. The maintenance effects in quality of life and well being and reduction in metabolic control at 24 months in the absence of an intervention is clinically important. The maintenance of healthy self management behaviour is crucial in diabetes for minimising long term complications which includes reduction in blindness, kidney failure, and neuropathy (DCCT, 1994). As such the study provides initial support for the role of quality of life, well being and cognitive representations about diabetes in exerting their effects indirectly through diabetes self care and better metabolic control. It is speculative whether the MI intervention had a causal effect on metabolic control and psychological functioning given the relatively small sample size.

7:5:3:3 Response shift and quality of life

Response shift is a phenomenon in quality of life research that has been demonstrated to affect self ratings of quality of life over time (Rapkin and Schwartz, 2004) and refers to a change in the meaning of one's evaluation as a result of a change in own internal standards of measurement (e.g. such as change in values) (Sprangers and Schwartz, 1999). During the study period the adolescents may have viewed their quality of life differently over the intervention period due to more broadened life

experience, disease progression, personal circumstances, changes in social support and peer relationships and cognitive development. Response shift in quality of life measured by the Problem Area in Diabetes scale [(PAID) Welch, Jacobson et al. 1997] has been demonstrated in adolescents with diabetes following attendance at a summer camp, and scale calibration at 1 year follow up was positively related to metabolic control (Wagner, 2005). Within the present study it is possible that the quality of life outcomes within the MI and control groups were confounded by changes in cognitive appraisal and conceptualization of quality of life between baseline and follow up. This may be particularly salient in adolescent research with young people who are undergoing key transitional changes in the biological, emotional, social and psychological domains. Schwartz, Feinberg et al. (1999) found that following a psychosocial intervention, adolescents who survived childhood cancer conceptualised their quality of life differently one year post intervention. The authors suggested that the response shift may have been due to the changes in cognitive appraisals of how they perceived their cancer and outcomes. Assessing appraisal parameters as an adjunct to the quality of life scores and the potential interaction effect of response shift was beyond the scope of the study, although sophisticated structural equation modelling methods to understand and measure response shifts in quality of life are emerging within the literature (Rapkin and Schwartz, 2004; Oort, 2005).

7:5:3:4 Patient characteristics

The inclusion criteria were as wide as possible to allow for a representative population of young people with diabetes, whilst at the same time restricting access to

the study for those whom participation would have been inappropriate. Further study is required to establish whether MI is suitable for certain sub-groups of children with diabetes (such as those with co-existing medical disorders such as cystic fibrosis). Furthermore it is not known if the same effects would have been found if the interventions were delivered within another setting (e.g. out-patient clinics). The study was conducted in centres across South Wales, which is one of the poorest areas in the UK (BBC News, 2004). This poverty has been shown to exist not just in the former coal and steel heartlands of the South Wales Valleys, but also within the cities. It is difficult therefore to generalise findings from this homogenous group to other geographically diverse areas of the UK.

7:5:3:5 Data collection

The independent researcher who collated the baseline 12 month and 24 month questionnaires provided a control for potential bias. There were however other threats to external validity and these will be addressed. The author was responsible for recruitment into the study, implementing the questionnaires to the MI group at baseline, delivering the MI intervention and administering questionnaires at 12 and 24 months follow up. Within both groups, although both interventionists attempted to avoid bias by encouraging self completion of the questionnaires, there were times when the younger adolescents required assistance with completion. Inadvertent unreliable reporting may have been encouraged by this face to face method rather than self completion in the absence of the interventionist. An exception was the therapeutic alliance questionnaire which was not seen by the interventionists in both groups and was sent independently by the participants to the researcher for collation.

Self completion of the questionnaires and collection by an independent researcher separate from the face to face contact of the interventionist may have been preferable. Furthermore although participants were informed that neither the author, physician or parent would see the responses on their questionnaires, there was potential for report bias on the study measures.

Shadish et al. (2002) identified experimenter expectancies, hypothesis guessing and evaluation apprehension as possible sources of bias. This potential may well have been exacerbated by the presence of the author collecting follow up questionnaire data after delivering the intervention. Although the interventionist within the control group delivered the intervention and collected 12 month follow up data, an independent researcher collected data at 24 months. Experimenter expectancies are difficult to evaluate particularly when supporting self efficacy is integral to the spirit of the intervention.

Although care was taken to prevent the paediatric diabetes staff within clinics knowing to which group each participant had been allocated, there were occasions when the adolescent or their parent informed clinic staff inadvertently. Furthermore although precautions were taken to avoid the control interventionist being aware of the study hypotheses, it is possible that these were made known unintentionally.

7:5:3:6 Therapist allegiances

It is possible that the control interventionist became familiar with MI by personal initiative throughout the intervention period. Given the lack of taped analysis of the

support counselling intervention, it is difficult to rule out this potential bias. Furthermore, although the superiority of MI over support counselling was not known, it is possible that the author had her own subconscious biases in favour of MI (through previous research and knowledge of MI study outcomes) and these 'therapist allegiances' as identified by Luborsky et al. (1999) may have provided a threat to validity. Allegiance (therapist preference for a type of treatment) has been found to account for nearly half of the variance between the preferred treatment and non preferred treatment (Horvath, 2001). There are very few studies that systematically control for therapist allegiance and results from studies have documented that within psychotherapy research, the therapeutic alliance accounts for much of the variance in outcomes in RCTs and naturalistic studies (Hovarth, 2001; Wampold, 2001). Evaluation of the taped sessions within the MI group and adherence to a set of principles and strategies provided partial control over this factor.

7:6 Strengths and weaknesses of the study

The study is the first multi centre RCT conducted in adolescents with type 1 diabetes to date and the study has a number of important strengths, some of which have already been identified. Despite the strengths, limitations are inherent within the study. The following sections will address the strengths and weaknesses of the present study many of which are based on conclusions and recommendations from the Hampson et al. (2001) review. The conclusions drawn from this review are summarised in Table 26 and are not reported in any pre-determined order from the

review. The reporting of the study strengths and weaknesses are ordered according to the sequence within the table.

Table 26: Summary of conclusions from Hampson et al. (2001) review

i	Well designed RCTs of psychosocial interventions are required reporting results in a way to allow effect sizes to be calculated	**Page 30**
ii	There is a lack of clear description of the components of the studies	**Pages 15-17**
iii	Psychosocial interventions need to be theoretically guided	**Page 30**
iv	There is a need for longer term follow up and interventions should be evaluated that assess outcomes that the intervention specifically targets for change, at time points that reflect the impact of the intervention	**Page 28**
v	Intervention development should involve consultations with stake holders to increase validity	**Page 30**
vi	Interventions should target adolescents with poor metabolic control who are at risk of developing future complications	**Page 24**
vii	Outcome measures need to be valid and reliable to allow comparison of evidence across studies. Measures of HbA_{1c} was not considered the most appropriate outcome on which to assess the benefits of an intervention designed to directly influence behaviour. Assessing changes in psychosocial measures should be included and limited to avoid overburden	**Page 30**
viii	Patient preference arms should be included	**Page 30**
ix	Appraisals of psychosocial interventions need to include economic evaluation of the costs and benefits	**Page 25**
x	Interventions should provide evidence on the effective targeting of different age groups, disease stage and different management problems	**Page 30**

7:6:1 Strengths of the study

The strengths are considered in light of the conclusions from the review. In relation to point (**i**), the study is the first multi centre RCT conducted in adolescents with type 1

diabetes to date conducted within a robust design. The context and settings of intervention delivery were considered key strengths. In many of the studies of MI, the intervention has been introduced into a pre-existing healthcare relationship or as an adjunct to other interventions. In the present study there was no pre-existing relationship with the young people or other healthcare context for the relationship outside the research. In general, interventions based on MI reported in the literature tend to be relatively brief and clinic-based. Within the present study the young people were in charge of when and where they met with the interventionists and the autonomy to determine frequency and setting location was deemed important in terms of retention and adherence. Both interventionists were independent of the diabetes clinic and the contact was time - limited with a maximum of a year. Blinding of outcomes of clinic teams to randomisation was largely achieved throughout the duration of the intervention and at 24 month follow- up. Although the sample size was relatively small, the power was adequate to detect statistically significant outcomes.

Point (**ii**) of the review addressed the lack of description of key intervention components within studies, which relates to the issue of internal validity addressed by Burke et al. (2002). The scrutiny afforded to the internal validity of the MI intervention (through training, standardisation of the content and delivery of both interventions and attention to quality monitoring) was unique to this study and permitted evaluation of the key components, the training involved and degree of supervision necessary to facilitate outcomes. The interventions differed sufficiently in their components and 'spirit' to draw conclusions of their efficacy and make

comparisons with other studies. This discriminability provided valid control over threats to internal validity. Quality assurance procedures such as the monitoring of interventions through audiotapes and regular supervision were considered key strengths in identification of the key components and processes involved in facilitating outcomes. However, despite these measures to enhance 'intervention integrity', it remains difficult to determine whether the positive outcomes within the MI group were due to the power of the intervention, skills of the author, or therapist characteristics.

The principle components identified within both interventions were designed to meet the needs of the adolescents' emerging independence. Within both interventions, the psychosocial and emotional impact of diabetes was addressed, facilitating the young people involved to cope with the emotional, physical and mental challenges of their diabetes management. The autonomy afforded within both interventions reflected the young people's need for self decision making in diabetes management, whilst at the same time receiving additional support by the diabetes health care team. Motivational Interviewing has been considered a beneficial intervention for young people as it does not seek to impose specific outcomes (McCambridge and Strang, 2003; Lawendowski, 1998). Within the present study although key components of MI remained unchanged, there was a greater focus on identifying topics to talk about (through agenda setting) and exploration on the costs and benefits of change (pros and cons) than have been identified in the MI literature. The flexibility afforded within the sessions fostered less resistance than was anticipated and relatively low levels of resistance were encountered.

In reference to point (**iii**) within the review, both interventions were delivered within theoretically guided principles. The support counselling intervention was centred around problem solving, goal setting and self management principles with additional theoretically guided elements. Motivational interviewing has theoretical underpinnings from various social psychology theories and models of health behaviour, as well as personal centred counselling approaches. Development of the MI intervention was based on process developmental work within the MI field which had demonstrated efficacy and clinical applicability. Researchers have however argued that to date, MI lacks a theoretical framework for understanding process and efficacy (Markland et al. 2005).

The outcome measures used evaluated a range of psychosocial outcomes. The longitudinal design allowed the adolescents to be assessed prospectively and longer term follow up is preferable to identify development and persistence of clinical benefits and increase generalisability of the findings. This addressed the recommendation of point (**iv**).

The aim of the study was to replicate the pilot study of Channon et al. (2003) and although consultation with stakeholders was not carried out - point (**v**) - there was preliminary evidence of the efficacy of MI as clinically feasible in adolescents with diabetes.

A key strength not identified within the review was the advantage of using the central testing laboratory to ensure consistency in calibration of HbA_{1C} values. There has been increasing awareness of the variability of HbA_{1c} results assayed in different laboratories (Thomas, 2000) and to date there are over 30 different glycosylated haemoglobin testing methods available, hence the need for reliability and comparability of testing between centres (Hawkins, 2003).

7:6:2 Weaknesses of the study

The limitations inherent within the study are examined in light of the conclusions within the review along with other design considerations. In relation to point (**vi**), the limited exclusion criteria meant that many participants were recruited who already had good metabolic control for whom behaviour change may have been unrealistic. Within the present study, only 32% of participants had HbA_{1c} of 9.0 % or higher, although the mean HbA_{1c} values at baseline for MI and control groups were MI (9.21 SD 1.96) and Control, (9.12 SD 1.47), which is considered suboptimal and at risk of developing future complications according to ISPAD (2000) guidelines.

Although the sample sizes were small, participants within the poorly controlled MI group demonstrated marked reductions in HbA_{1c} over the study period compared to the control group. These findings provide initial support for the utility of implementing an MI intervention with poorly controlled adolescents and would address one of the key recommendations (point **iv**) from the review.

Despite recommendations from this review - point (**vii**) - that outcome measures should be limited to avoid overburden and to allow comparisons between studies, the present study assessed a high number of questionnaires with a mixed level of reliability. For example, some of the outcome measures (Child Health Locus of Control Scale, The Therapeutic Alliance Questionnaire, Impact of Diabetes Subscale on the PMDQ and the Diabetes Readiness to Change Questionnaire) either had poor internal consistency or were not subjected to piloting after modification, and their validity could not be guaranteed. Murphy, Rayman et al. (2006) argued it is essential that clinical and research organisations agree a common set of psychometrically sound outcome measures including measurement of HbA_{1c}, which include common reference methods, age validated questionnaires, service utilization and costs.

One of the key conclusions from the review was the importance of evaluation of psychosocial interventions in paediatric diabetes from patient-preference trials, point (**viii**). Excluding participant choice of treatment is considered a key weakness in behavioural trials (Stephenson and Imrie, 1998), and allocating participants randomly to treatment may have decreased motivation and enhanced the attrition rate. Furthermore, a recent study highlighted that participants within RCTs fail to understand information about randomisation and equipoise despite the provision of clear trial information (Robinson et al. 2005). The implementation of patient preferences through the use of comprehensive cohort design have been suggested (Brewin and Bradley, 1989) whereby patients are randomised to one of three groups:

a) No strong preferences and consent to randomisation

b) Preference for a treatment and consent to randomisation and

c) Refuse randomisation and opt for treatment of choice.

Although within patient preference trials, greater sample sizes are required and the uncertainty of unknown and uncontrolled confounders in the non randomised group exist (Torgerson and Sibbald, 1998), it has been argued such designs may enhance uptake of participation in studies in difficult to reach patients.

In relation to point (**ix**), no economic evaluation of the costs and benefits were undertaken of the interventions. The cost effectiveness of MI and evaluation of the potential barriers to implementation are still not known.

The review suggested that interventions should provide evidence on the effective targeting of different age groups, disease stage and different management problems, point (**x**). The present study did not provide evidence on these key factors relating to outcomes and early or late adolescence, duration of diabetes, self care activities, educational level or family cohesion and structure. These factors warrant further study.

Other specific design issues are addressed that have not been identified within the Hampson, Skinner et al. (2001) review. A key weakness within the design of MI intervention development included the integral and simultaneous method of interventionist training, intervention development and supervision. Implementing the early phases of the trial was challenging and resource intensive in terms of cost, travel and investment in time. The recruitment process, intervention development, training

and implementation of the intervention happened within a relatively short space of time, and often occurred simultaneously. Moreover it enhanced the possibility of a learning curve effect within the delivery of the MI intervention. This could have been addressed by a run in period before formal recruitment to ensure the intervention was delivered proficiently. A way to address this weakness in future studies which would be cost effective and yet enhance the generalisability of the findings would be to undertake preliminary work through exploratory and modelling experiments prior to the conduct of the RCT. A successful application of this design was implemented recently in an RCT by Byrne et al. (2006) in the development of a complex intervention for secondary prevention in coronary heart disease. This study conducted qualitative research through focus groups which yielded important data on the needs of the target population, key components of the intervention, training needs of the researchers, cost and time. The outcomes within a controlled design are currently being explored.

Loss of HbA_{1c} data at baseline and follow up occurred during the study with some blood samples having insufficient blood collection for sampling. Although every effort was made to ensure communication about insufficient/lost samples between the author and the designated person at the central laboratory this was not always achieved.

The same therapists in both MI and control groups implemented the interventions across sites and this was intensive of both time and cost. Since they were health care professionals (health psychologist and paediatric diabetes nurse), the applicability of

delivery of the interventions by non medical practitioners remains unexplored. No inferential subgroup analyses between centres were undertaken to explore interaction effects between the different centres, sample characteristics and differences in HbA_{1c} between centres. In addition, the sample was recruited within South and South East Wales, an economically deprived area with a homogenous group. This may have may have limited the generalisability of the results.

Due to the lack of blinding in both groups it is possible that the Hawthorne effect (Rosenthal, 1966) was in effect such as reactivity to assessment and intervention. This may have been enhanced within the MI group. Given that the author was present during recruitment, data collection (and sometimes completion) and also delivered the intervention, it is possible that the participants expected change to occur and this may have been implicit in further completion of data at 24 months. Social desirability as a reliability threat is difficult to evaluate as it was possibly operating in both directions. It has been argued that when evaluating intervention studies, researchers should introduce specific psychological and social variables that may have affected the outcome, but were not monitored during the intervention (Wickstrom and Bendix 2000).

7:7 Summary

Detailed scrutiny of the results reported in the previous chapter has been reported, along with considerations of the findings according to the existing literature. Discussion of the potential threats to validity has also been explored. This discussion sets the stage for conclusions to be drawn about the implications of the study for

future research and practice, along with considerations of how the study fits in accordance with government guidelines on paediatric diabetes care. These are explored in the final chapter (Chapter 12). The next chapter (Chapter 8) introduces the background literature to Study II. This study is an exploratory and retrospective analysis of the relationship between quality of life and metabolic control within a subset of the data obtained for this present study.

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8:1 Introduction

Chapter 1 highlighted the immense psychological and emotional burden of Type 1 diabetes in adolescents and it has been argued that psychosocial factors are implicated in nearly every aspect of the disease and self management (Garrett et al. 2002). Good metabolic control is determined by a combination of physiological and psychological factors with good self care being an important determinant in achieving optimal metabolic control and delaying the onset and progression of complications (DCCT, 1994). It has even been suggested that psychosocial factors are the most important influences affecting the care and management of diabetes (Swift, 2002).

Despite psychological factors playing an important role in diabetes management and optimal blood glucose control, not much is known about the effect of psychological well being on self care and metabolic control outcomes (Skinner and Hampson, 2001). Quality of life has been regarded as a key aspect of psychosocial functioning in adolescents due to the demands that diabetes poses on the young person's lifestyle such as the prescriptive routine of blood monitoring, adherence to insulin regimen, diet and exercise (Hoey et al. 2001). While it is generally accepted that adolescents with diabetes suffer a greater burden of psychosocial ill health and poor quality of life, there have been few studies demonstrating the longer term outcomes of quality of life in either children or adolescents (Cameron, 2003). Moreover the outcomes from studies are contradictory. Whilst some studies have shown that quality of life in adolescents with diabetes is poorer than the general population, other studies have

shown no difference (Laffell et al. 2003) and even better quality of life when compared to healthy counterparts (Upton et al. 2005; Wagner et al. 2005). Delamater (2000) argued that it has become increasingly important to study the effect of quality of life in adolescents not just because of increasing awareness of its impact on metabolic control, but also as central outcomes in health care interventions and policy.

To date the research in diabetes and teenagers has tended to focus more on the effects of family functioning and outcomes (Drotar, 1997) and adjustment and coping with illness (Grey et al.1991), rather than distinct psychosocial factors directly affecting metabolic control and self care. Whilst family factors and coping are recognized as important factors in well being, key psychosocial factors such as self efficacy, quality of life and health locus of control have also been identified within the literature as impacting upon adolescents management and subsequent control of diabetes (Rubin and Peyrot, 1999).With the link between poor control and longer term complications firmly established (DCCT, 1994), it is argued that is important to examine key psychological mechanisms that facilitate metabolic control indirectly through self care. Separate analysis of the DCCT (1994) data on the adolescent sub-sample (Madsen et al. 2002) showed that the intensively treated cohort experienced poorer quality of life regarding school satisfaction and greater psychological distress with their diabetes compared to their conventionally treated counterparts. These results raise the question about the association between glycaemic control and adolescent quality of life. Self efficacy has received positive support within the broad literature demonstrating its significant effect on health functioning among individuals with chronic illness. The literature regarding the role of self efficacy in adolescent diabetes

care however is sparse. Furthermore adolescents' beliefs about control of their diabetes would appear relevant to their ability to effectively control their glucose through positive self care. To date relatively little attention has been given to the central role of health perceptions regarding control of diabetes.

This chapter explores the background literature on quality of life, self efficacy and health locus of control and their relationship with metabolic control which provide the rationale for examination of the exploratory study. The following chapter (Chapter 9) describes the aims, hypotheses and methods which are followed by the results (Chapter 10).

8:2 The concept of quality of life

Although quality of life has received increased attention in recent years, no universally accepted definition exists (Aaronson, 1989). In 1948, the World Health Organisation (WHO) defined health from a new perspective, stating that health was defined not only by the absence of disease but also by the presence of physical, mental and social well being (Constitution of the WHO, 1952). More recently the World Health Organisation Quality of Life (WHOQOL) Group (1995: p.1404) defined quality of life as "*individuals' perceptions of their position in life ....in relation to their goals, expectations, standards and concerns*". Patrick and Erikson (1988) narrowed the scope of quality of life to include aspects of health functioning directly related to disease and /or medical treatment (health related quality of life or HRQoL). Quality of life in this context refers to health related problems, impact of

disease and well being. Polonsky (2000) argued however that HRQoL is ambiguous and poorly defined. Snoek (2000) suggested that one of the most intriguing findings in quality of life and diabetes research to date is the weak relationship between objective health and subjective health related quality of life, such that good health (such as good metabolic control) does not always guarantee good quality of life (such as happiness).

Within the literature, quality of life has been conceptualised as a multi dimensional construct which takes into consideration essentially four domains;

a) disease state and physical symptoms

b) emotional status

c) physiological functioning

d) social functioning and the patient's subjective evaluation of well being.

In addition, other quality of life domains that have relevance to adolescents with diabetes include academic achievement, neuropsychological functioning, social functioning and satisfaction with life (Speith and Harris, 1996). The major challenges relating to poor conceptualisation has led to difficulties with measurement and uniformity. Within the diabetes field in particular, this relates to confusion regarding the appropriateness of specific outcome measures. Diabetes coping and self efficacy are often targeted quality of life outcomes, and there is conceptual overlap between specific aspects of quality of life with other outcome measures such as distress, depression, and mood (Eiser and Morse, 2001). Moreover quality of life is a subjective evaluation that is specific to each individual and what is important to a treatment provider may not be so important for the adolescent.

8:3 Measurement of quality of life

Prior to 1990, generic measures or 'health scales' were developed although the outcomes of such scales were rooted in morbidity or mortality (Eiser and Morse, 2001). Children with different chronic diseases were combined together as a single sample and compared with 'healthy' subjects. Recent emphasis on care for children with chronic illness has changed from a shift in measurement of treatment and survival to taking into account the quality of life (Upton et al. 2005). Quality of life is traditionally measured via psychometric means such as instruments and evaluation tools that provide a score or reference norm of functioning. Two broad approaches to the measurement of quality of life in children and adolescents are evident; generic and disease specific. In order to gain a broader understanding of these measurement approaches the key generic scales and diabetes specific scales which have demonstrated robust psychometric properties will be discussed. To date there are few multidimensional approaches to measuring diabetes related quality of life which may yield a broader picture of overall functioning in young people (Delamater, 2000).

8:3:1 Generic

The generic approach involves measures which are applicable across different health and illness groups and compare quality of life in people with a disease with those without. The most widely used generic measure in adults with chronic illness is the Short Form General Health Survey (such as SF-36) [Ware and Sherbourne, 1992]. The SF-36 is a generic profile of functional health and well being which assesses

health outcomes in physical and mental health domains. Other generic measures of emotional status which have been used in studies with adolescents and adults with type 1 diabetes include the Well Being Questionnaire (Bradley, 1994) and the Symptom Checklist (SCL-90R) [Derogatis, 1994].

Health related quality of life (HRQoL) has been regarded as an important paediatric outcome although is not routinely measured in trials (Eiser et al. 2001). Recently, a newer modular approach to measuring this has been established. The PedsQL 4.0 Generic Core Scales (Varni et al. 2001) and the PedsQL 3.0 Type 1 Diabetes Module (Varni et al. 2003) were designed to be used together in an assessment of both generic- and disease-specific QOL. The PedsQL 4.0 has recently been revised in the UK by Upton et al. (2005) to form the UK Paediatric Quality of Life Inventory (PedsQL). The 23 item scale measures child and parent proxy reports on 4 point Likert series across four domains; emotional functioning, physical functioning, social functioning and school functioning. A total scale score is obtained for the scale whereby higher scores relate to better quality of life. The psychometric properties were tested with 1,399 children and 970 parents across a range of chronic disease and healthy conditions. The scale demonstrated good internal reliability (Cronbach's alpha for the child and proxy report total scales was 0.90) and evidence of discriminant validity between healthy and chronically ill conditions. In particular, children with asthma, irritable bowel disease and survivors of cancer scored lower on the domains than healthy children. Children with type 1 diabetes also scored lower than their healthy counterparts on domains of school and physical functioning, although scored

higher in domains of emotional and social functioning. The authors argued that these findings warrant further investigation.

8:3:2 Disease specific

Disease specific measures focus on specific aspects of an individual illness. A challenge regarding these measures relates to the similar methodological and conceptual challenges as the generic measures. Some researchers have even suggested that these tools provide limited information about the true quality of life of individuals (Bowling, 1997). The most recent and widely used measures are described below.

Diabetes Quality of Life (DQOL)

The most frequently used diabetes specific quality of life measure is the Diabetes Quality of Life Scale (DQOL) originally developed for use in the DCCT (Jacobson et al. 1988). Prior to the development of the DQOL there were no available diabetes specific quality of life measures. It is a multidimensional construct that assesses the patient's personal experience of diabetes care and treatment. Four separate domains are measured: satisfaction with treatment, impact of treatment, worry about the future effects of diabetes and social issues. There is also a single overall well being scale. The psychometric properties were tested with 192 adult patients with type 1 diabetes and the scale demonstrated good internal consistency (Cronbach's alpha coefficient between 0.66 and 0.92) and test-retest reliability (r = .78 to .92). Good convergent validity was established with relevant measures of psychiatric symptoms, general well being and adjustment to illness. Although the scale was developed for both the adult and adolescent sample within the DCCT, a revised version of the DQOL (Diabetes

Quality of Life for Youths [(DQOLY) Ingersoll and Marrero, 1991] was subsequently developed specifically for use with adolescents with diabetes. This scale has been described in section 5:11:2:6 (p. 186-187) and a brief summary is offered below.

Diabetes Quality of Life for Youths [(DQOLY) Ingersoll and Marrero, 1991]

The DQOLY is the most widely used measure in paediatric diabetes to evaluate quality of life. In summary, there are 52 items which are subdivided into three inter correlated scales; diabetes life satisfaction, disease impact, disease related life worry and one general health perception question. There is one health perception question which is scored from 1- 4, a low score indicating better quality of life. Lower scores overall indicate a higher quality of life. Criticisms of the DQOLY are levelled at the failure of its domains to capture adolescents' quality of life with respect to normal social and emotional development for comparison with healthy adolescents (Laffell et al. 2003). It has been described as clinically driven and prescriptive with the possibility that elements of quality of life for the adolescent maybe unknown to the treatment provider (Walker and Bradley, 2002).

ADDqol-Teen (McMillan et al. 2004)

A more recent measure that uses an individual person centred approach in measuring the perceived impact of diabetes on the quality of life of adolescents is the ADDqol-Teen (McMillan et al. 2004). The questionnaire is based on the original ADDqol (Bradley, Todd et al. 1999) although wording of questions is more specific and concrete than the broader concepts of the adult version. The questionnaire has 30 items covering 25 domains measuring specific areas such as school, holidays, family

and freedom to eat that reflect the adolescents' own perception of life rather than the researcher's opinions. Respondents are asked about the frequency with which diabetes impacts on each domain and how much it bothers them. The scores are multiplied to give a weighted score for each domain. Recent validation on 152 adolescents with mean age of 16.4 years, demonstrated that domains that most negatively impacted upon quality of life were interruption to social activities and concerns about the future regarding career and marriage. This is the first questionnaire that allows the child to state what aspects of diabetes matter to them personally.

The Schedule for the Evaluation of Individual Quality of Life Scale (SEIQoL)

The SEIQoL (O'Boyle, 1994) is an individualised interview approach that encompasses qualitative and quantitative methods. It defines quality of life according to domains that are important to the individual and recognises the importance of own experiences as well as subjective well being. Respondents choose five domains or aspects of quality of life which are important to them (such as family, school, pets and social) and rate each domain on scale ranging from 1 to 6 where 6 represents '*as good as it could possibly be*' and 1 represents '*as bad as it could possibly be*'. Although used mainly with adults, Walker and Bradley (2002) modified the original SEIQoL to include a diabetes domain and piloted the measure in fifteen adolescents with Type 1 diabetes ages between 12-17 years. The results demonstrated that the quality of life domains most important to adolescents were family, friends and school. Diabetes was rated as least important. A strength of this questionnaire is the ability for the adolescent to rate areas of their lives most important for their quality of life instead of imposed estimations from others within domains that may not be

appropriate. It has been suggested however that it is time consuming to complete (Association for Palliative Medicine Group, 2001).

8:4 Quality of life and metabolic control

Studies in adults with diabetes have demonstrated that patients suffering from long term complications such as retinopathy and neuropathy experience reduced quality of life (Lloyd et al. 1992). The relationship however between glycaemic control and quality of life is tenuous (Weinberger et al. 1994). Snoek (2000) suggested that because the effects of laboratory measures of HbA_{1c} cannot immediately be felt by the patient by way of physical wellness (except in extreme values) it is of no surprise that perceived quality of life is not associated with metabolic control. Testa, Simonson and Turner (1998) measured absolute, versus relative, quality of life ranges and compared with changes in glycaemic control in patients with type 2 diabetes. They found that decreases in HbA_{1c} by 1.5 % provided almost a 50% increase in relative quality of life perceptions emphasising the value of studying the relationship between quality of life and glycaemic control. The following sections will demonstrate the evidence of quality of life and metabolic control outcomes in the diabetes literature.

8:4:1 Quality of life and metabolic control (adults)

Within adult populations with type 1 diabetes, there have been many studies demonstrating a positive relationship between HbA_{1c} values and quality of life, particularly when measured with disease specific scales (Rubin and Peyrot, 1999). Most studies however are cross sectional in nature and causal mechanisms cannot be

assumed. The only double blind randomised controlled trial that has examined the effect of an intervention on quality of life and metabolic control was undertaken by the Testa and Simonson (1998). Five hundred and sixty nine participants with type 2 diabetes were randomised to receive diet and oral sulphonamides (glucose lowering drugs) or placebo over three months. All participants received a 3 week placebo washout period at baseline. Outcomes measures included HbA_{1c} values and a diabetes specific quality of life questionnaire which measured symptom distress and general perceived health. Although the direct relationship between quality of life and HbA_{1c} was not examined, the authors found that mean HbA_{1c} decreased in the intervention group and quality of life improved (assessed as improved health, less symptom distress, improved cognitive functioning, more vitality and enhanced sleep).

The evidence however is inconclusive and several other studies have shown no association (Weinberger et al. 1994; Bagne et al. 1995 and Aalto et al. 1997). The DCCT study (1993) showed no difference in quality of life between intensive and conventional treatment groups (combined adult and adolescent), although the intensive treatment group had fewer micro-vascular complications and reduced HbA_{1c} levels from baseline.

8:4:2 Quality of life and metabolic control (adolescents)

Despite the wide research on the relationship between quality of life and metabolic control in adults with diabetes, there is paucity of literature in adolescents. Results from studies within paediatric populations have been mixed with some studies suggesting a link between quality of life and metabolic control (Hoey et al. for

Hvidøre study group, 2001; Guttman-Bauman et al. 1998; Vanelli et al. 2003 and Hesketh et al. 2004), while others have found no association (Ingersoll and Marrero, 1991; Grey, Boland, Davidson et al. 1998). Most studies are cross sectional designs with only a few examining prospective changes over time. The key studies will be considered.

The Hvidøre Study Group on Childhood Diabetes (Mortensen et al. 2002; Hoey et al. 2001) is the largest international study to date supporting the relationship between metabolic control and quality of life in adolescents with type 1 diabetes. This cross sectional study already highlighted in Chapter 1 (section 1.7 p. 20-21), included 2,101 adolescents, aged between 10-18 years, from 21 centres within 17 countries from Europe, Asia, and North America. Quality of life was measured by the DQOLY (Ingersoll and Marrero, 1991). The study demonstrated that better metabolic control was associated with a better quality of life for adolescents. In particular, less satisfaction was significantly associated with higher HbA_{1c} and a lower impact score was significantly associated with lower HbA_{1c}. More worries and less satisfaction were evident with increasing age especially in girls.

Another study that has demonstrated the link between metabolic control and quality of life was by Guttman-Bauman et al. (1998). The authors examined the relationship between indices of metabolic control, negative acute events and quality of life (measured by the DQOLY). Metabolic control was measured at the time of out patient visits and examined retrospectively a year preceding the study. Sixty nine participants aged between 10-20 years with type 1 diabetes completed data. Acute events were

measured as hospital admissions due to diabetes related problems and visits to accident and emergency over 12 months. Adolescents with better metabolic control (over the long term and at the time of the visit) reported better quality of life. Lower HbA_{1c} values were related to better satisfaction scores while higher mean HbA_{1c} and more acute events (such as frequent hospitalisations) were related to negative impact and more worries about diabetes. The relationships between HbA_{1c} and quality of life were stronger when measured over the past year than versus a single HbA_{1c}. Increasing age at diagnosis and higher socioeconomic status were both predictors of lower HbA_{1c} levels.

A cross sectional study by Vanelli et al. (2003) also demonstrated the relationship between higher quality of life and achievement of good metabolic control. The authors examined whether the demands of an intensified insulin regime and favourable metabolic control levels influenced quality of life in adolescents. One hundred and fifty three adolescents completed the DQOLY during routine out patient clinics. Metabolic control was measured by HbA_{1c} at the time of visit. Increased worries, poorer satisfaction and poorer health perception were associated with higher HbA_{1c}. The authors suggested that enhancing quality of life is a positive way to achieve optimal glycaemic control.

A prospective cohort study by Hesketh et al. (2004) examined quality of life and the relationship with metabolic control in adolescents over a 2 year period. Eighty three adolescents with type 1 diabetes completed an adapted form of the Child Health Questionnaire (PF-80) [Waters et al. 2000] which measured domains comprising

physical, psychosocial, and family functioning. All items are based on a 4 week recall with one single item measuring change in the child's health over the past year. Poorer physical health (measured by self report body pain, subjective assessment of overall health and limitations of physical health on social activities and relationships) at baseline was related to poorer metabolic control at 2 years. The relationship was not evident for psychosocial health. The authors concluded that better physical health buffers against deteriorations in psychological well being and metabolic control.

Other findings within the literature are inconclusive with no demonstrated associations between metabolic control and quality of life. A study by Grey, Boland, Yu et al. (1998) examined the factors that influence quality of life in adolescents with diabetes and measured the relationship with HbA_{1c}. Fifty two adolescents aged between 13 and 20 years completed a range of scales including the DQOLY and Self Efficacy for Diabetes scale [(SED) Grossman et al. 1987]. Although the adolescents perceived their quality of life as good with high satisfaction, moderate impact of diabetes and low worries about complications, there was no significant relationship with metabolic control. Moreover there was variation among adolescents in their quality of life. Adolescents who reported that diabetes had a large impact on their quality of life (i.e. disease related worries) had lower self efficacy (confidence to manage their diabetes) and were more depressed. Conversely adolescents who were more satisfied with their quality of life reported higher self efficacy, less depressive symptoms and better coping. Girls tended to worry more about their diabetes than boys. Neither age nor duration of diabetes was associated with metabolic control. In contrast to other studies, family warmth and caring behaviours as measured by the

Family Adaptability and Cohesion Scale [(FACES II) Olson, 1986] was not related to quality of life, although associated with metabolic control. Depression was the strongest factor in relation to quality of life and to a lesser extent, difficulty coping with diabetes. The authors concluded that awareness of depression is important in adolescents with type 1 diabetes and that coping mechanisms, family involvement and diabetes management should be closely monitored to help adolescents maintain better metabolic control and quality of life.

Other studies have failed to demonstrate a link between metabolic control and quality of life. Within the DCCT (1994) study there were no significant differences in quality of life between adult and adolescents participants in the intensive management group and controls (although retrospective analyses within the adolescent sub-sample by Madsen et al. 2002 reported decreased school satisfaction and greater psychological distress within the intensive intervention group which are described in section 8:5). Ingersoll and Marrero (1991) examined the relationship between the DQOLY subscales and metabolic control with 74 adolescents with type 1 diabetes aged between 10.8 to 20.8 years. No relationship was found between satisfaction, perceived impact of diabetes, worries about diabetes and metabolic control. Other small scale studies (Faro, 1999; Faulkner, 2003) failed to demonstrate a link between quality of life and metabolic control. Absence of relationships has been linked to small sample sizes and insufficient sensitivity of measures to detect clinically meaningful increases or decreases in quality of life.

8:4:3 Intervention studies in adolescents with type 1 diabetes

Although there are a few studies that have implemented behavioural interventions to enhance quality of life and metabolic control in adults with diabetes (Snoek, van der Ven et al. 2001; Rubin, Peyrot and Saudek, 1989; Anderson, Funnell et al. 1995), there are fewer studies for adolescents. The two studies by Grey, Boland, Davidson et al. (1998); Grey et al. (2000), described in section 2:5:3 p. 65-68, demonstrated the positive effects of a behavioural coping skills training (CST) on better quality of life (lower impact of diabetes) in adolescents both in the short term and longer term. There were no relationships however between quality of life and follow up reductions in HbA_{1c}.

Another study by Grey, Boland, and Tamborlane (1999) studied the impact of the fast acting insulin analogue lispro on adolescents' quality of life and glycaemic control, versus a control group who received regular insulin. Lispro insulin has a more rapid onset than regular insulin and is administered immediately prior to eating meals giving flexibility with reduced risk of hypoglycaemia. The results at 12 months demonstrated that adolescents who received lispro insulin achieved similar levels of metabolic control to those in the control group without differences in total daily dose, insulin regimen, incidence of hypoglycemia or weight gain. Those taking lispro reported less negative impact of diabetes on quality of life and fewer worries about diabetes than controls. Both groups were equally satisfied with their diabetes treatment. The authors concluded that lispro insulin is a safe alternative for

adolescents on intensive regimens and may assist young people in coping with diabetes through enhanced quality of life.

8:5 Quality of life and psychosocial outcomes

Various studies have examined the relationship between diabetes quality of life and demographic, clinical and psychosocial factors (Delamater et al. 1999; Aalto et al. 1997). Although a detailed review is not warranted within this chapter, some of the key outcomes will be discussed.

Graue et al. (2003) compared diabetes quality of life measured by the DQOLY and general health status measured by the Child Health Questionnaire [(CHQ) Landgraf et al. 1996] with healthy controls in 130 adolescents with type 1 diabetes. The results demonstrated that adolescents with diabetes reported lower general health, than their healthy counterparts specifically in the areas of mental health, self esteem and family cohesion. Older female adolescents (those aged between 16-18 years) were more likely to have lower diabetes related life satisfaction, increased worries about complications and perceived that diabetes had a greater impact on their life. There were no relationships between health functioning, quality of life and glycaemic control.

Aalto et al. (2000) investigated the impact of psychosocial factors on quality of life in 385 adults with type 1 diabetes. The most important factors in patients' quality of life

were self efficacy, positive social support and high internal locus of control (associated with lower pain experience).

Delamater et al. (1999) studied the effect of quality of life (measured by the DQOLY) in adolescents with type 1 diabetes and associations with age, duration of diabetes and ethnicity. Significantly lower quality of life was reported in adolescent girls from single parent households, particularly amongst African-American households, compared to their Caucasian counterparts. Poorer quality of life was also associated with poor coping, diabetes related stress, greater behavioural problems and non supportive family behaviour. Lower socioeconomic status and higher diabetes stress were also associated with higher impact and worries scores. Age, diabetes duration and metabolic control as measured by HbA_{1c} were not related to quality of life.

Other studies have focused on various aspects of psychosocial functioning on metabolic control. Madsen et al. (2002) examined psychosocial outcomes within the adolescent cohort of the DCCT (1994) study. Psychosocial functioning (measured by the DQOLY and Symptom Checklist 90-revised) was studied at baseline, 1 year and 3 years following 224 adolescents' entry into the DCCT. Results demonstrated that the intensive regime implemented in the younger adolescents (those aged between 13-15 years) was associated with poor quality of life in relation to less satisfaction with school. Older adolescents (those aged between 16-18 years) reported elevated psychological distress. Other key findings within the psychosocial literature point to the relationship between family conflict, depression and poor coping on poorer metabolic control.

8:6 Overview of quality of life findings

Overall the research is conflicting with some studies reporting that better quality of life is related to lower metabolic control and others finding no relationship. The methodological weaknesses point to inconsistencies in defining studies that measure quality of life. Quality of life research has developed inductively with lack of theory guiding the development of research (Albrecht, 1994). Most criticisms are levelled against lack of uniformity in measures across studies and small sample sizes. A challenge with both the disease specific and generic measures relates to methodological and conceptual inconsistencies with lack of definition of quality of life (Eiser and Morse, 2001). Moreover it has been argued by Snoek (2000) that the validity of quality of life is difficult to determine as there is no 'gold standard' in its measurement. The increasing number of scales within the diabetes field has generated criticism that they are disparate, heterogeneous and contradictory in their approach (Testa, 2000). Despite its importance in outcome assessments, quality of life in adolescents with diabetes is still understudied (Delamater, 2000). The study by Hesketh et al. (2004) is regarded as a key study in the diabetes literature although quality of life is was measured via a generic child functioning scale and it is argued that it is difficult to generalise these findings in terms of adolescents specific diabetes related quality of life. Rubin and Peyrot (1999) suggested that psychosocial factors such as locus of control, self efficacy, coping, attitude and beliefs influence well being and health status, and that research needs to control for or consider the moderating effects of these factors in explaining outcomes in quality of life. Low self efficacy has

been identified as the strongest and most consistent barrier to self management (Glasgow et al. 2001) and several studies have demonstrated the significant impact of self efficacy on health functioning in self care. The utility of self efficacy beliefs in diabetes self management and outcomes will be considered in the next section.

8:7 Self Efficacy

8:7:1 The concept of self efficacy

Self efficacy is defined as a judgement of one's capability to perform a particular behaviour or task, which influences the choices a person makes, the effort applied to the task and how long a person will persist when confronted with obstacles or failures (Bandura, 1986). Social cognitive theory (Bandura, 1977, 1986, 1997) suggests that self efficacy is a set of beliefs about capabilities to produce desired behaviour. These beliefs can be developed and strengthened through performance accomplishments (e.g. such that successful accomplishment reinforces efficacy), vicarious experience (modelling on the successes of similar others), verbal persuasion (suggestions that one can cope) and teaching about the interpretation of physiological state (e.g. fatigue can be due to disease activity or exercise). Self efficacy operates through three main functions: a) self monitoring b) goal setting and c) self incentives for personal change (Bandura, 1997). It is the combined influence of efficacy beliefs and expected outcomes that have been reported to be the best predictors of human behaviour. For example, an individual is less likely to engage in a behaviour if they do not believe that a particular behaviour will lead to a particular outcome and if they do not believe they are capable of performing a particular behaviour (Bandura, 1997).

Self efficacy beliefs have been found to be powerful personal resources in coping with stress (Lazarus and Folkman, 1987), relapse in smoking cessation (Gulliver et al. 1995) and a strong predictor of health related behaviour (Connor and Norman, 1995; Schwarzer and Fuchs, 1995). It has been suggested that the stronger the individual's efficacy beliefs, the higher the goals they set for themselves and the firmer their commitment to engage in the intended behaviour even in the face of failures (Locke & Latham, 1990). Within self management of chronic illness, it has been argued that self efficacy is an essential contributor to developing self management capabilities (Holman and Lorig, 1992). The value of self efficacy in predicting outcomes in patients with diabetes is supported by several studies. Before considering the literature on the role of self efficacy beliefs in outcomes in diabetes, the measurement of self efficacy will be considered along with reference to specific diabetes related scales.

8:7:2 Measurement of self efficacy

There is a debate about the generality or specificity of the self efficacy construct (Schwarzer and Fuchs, 1995) and this is reflected in the scales developed within the health behaviour domain. One of the key weaknesses in the way that self efficacy is used in health research is related to conceptual challenges (Maibach and Murphy, 1995). Much of the research on self efficacy has focused on the role of task specific self efficacy as a predictor of behaviours, and as a consequence measurement of self efficacy has been adopted as part of most health behaviour theories (Connor and Norman, 1995). Ajzen (1988) however argued that rather than focus on the mastery experiences of specific behaviours, theorists should focus on consistent patterns of

behaviour over time. Within the diabetes field, measurement of self efficacy has primarily been by situation specific self management (such as blood glucose monitoring, specific diet related behaviours and ordering meals in a restaurant) rather than global measures of mastery. Previous research within diabetes self efficacy measurement indicates that specifically worded items are more predictive of specific behaviours (Anderson, Funnell et al. 2000). For purposes of brevity, the next section will identify the most widely used self efficacy scales that measure diabetes related behaviour in adults and adolescents.

8:7:2:1 Measurement and adults with diabetes

Diabetes related self efficacy has been assessed by several instruments in adult patients with type 1 and type 2 diabetes. The Confidence in Diabetes Self Care Scale (van der Ven, Weinger et al. 2003) was developed to measure diabetes specific self efficacy beliefs in day to day management. Self efficacy beliefs however are not the only determinant of behaviour change as a person can have high self efficacy without translating beliefs into behaviour. Within health behaviour models (e.g. the Theory of Planned Behaviour, Ajzen, 1988) self efficacy works in concert with social norms and attitudes to predict behaviour. One scale that has been developed that incorporates the role of social norms is the Diabetes Empowerment Scale (DES) by Anderson, Funnell et al. (2000). The measure includes items such as the role of social support, goal setting and coping with negative emotions in managing psychosocial aspects of diabetes. The DES incorporates 37 items within three subscales; managing the psychosocial aspects of diabetes, assessing readiness to change and setting/ achieving diabetes goals. Although only preliminary pilot data are available in support of the

DES, it represents the first diabetes self efficacy scale to incorporate psychosocial factors to predict behaviours.

8:7:2:2 Measurement and adolescents with type 1 diabetes

Instruments in diabetes measurement are far fewer for children and adolescents. The author is only aware of one validated scale [Self Efficacy Diabetes Scale (SED)] that measures adolescents' self efficacy regarding managing and controlling diabetes and related situations and is the scale used within Study I. It has been described in greater detail in section 5:11:2:7 (p. 187-188).

8:8 Self efficacy beliefs, quality of life and metabolic control

The concept of self efficacy has received extensive support demonstrating its significant effect on health functioning among individuals with chronic illness. Enhancing the self efficacy of people with diabetes has been viewed as a valued component of diabetes management since it is related to the willingness and ability of people to engage in preventative and disease management behaviours (Anderson, Funnell et al. 2000).

8:8:1 Relationship between self efficacy and quality of life

The literature demonstrates that self efficacy judgements have implications for appraisals of life satisfaction among individuals diagnosed with diabetes mellitus. Stronger beliefs in one's ability to carry out responsibilities of the regime may generate feelings of mastery, which in turn decrease potential of complications and

ultimately result in life satisfaction. Senecal et al. (2000) documented a significant relationship between higher self efficacy beliefs and greater life satisfaction in 638 adults diagnosed with diabetes. Similarly Grey, Boland, Yu et al. (1998) showed that higher diabetes self efficacy appraisals were associated with better life satisfaction as well as better coping and lower depression in adolescents with type 1 diabetes.

8:8:2 Relationship between self efficacy and metabolic control

Despite the theoretical support for self efficacy as an important predictor of self care and HbA_{1c}, little empirical evidence has been reported particularly in children and adolescents. The literature regarding self efficacy beliefs and adults is considered first. Anderson, Funnell et al. (1995) conducted a six week patient empowerment education programme in adults with type 1 and type 2 diabetes in order to enhance self efficacy and improve metabolic control. The education programme was delivered for 2 hours and offered weekly for six weeks. Self efficacy was measured by patient's perceived ability to perform specific behaviours such as identifying goals, managing stress, and receiving social support. The results demonstrated that the intervention group experienced greater gains in self efficacy than the control group and greater reductions in HbA_{1c}. Patient empowerment aimed at increasing self efficacy was consistent with gains in glycaemic control.

A study by Rose, Fliege et al. (2002) demonstrated the positive value of efficacy beliefs and active coping as the greater predictors for achieving good glucose control and better quality of life. Although studies have demonstrated the relationship between higher self efficacy beliefs and adherence to the diabetes regime (McCaul et

al. 1987; Williams and Bond, 2002; Kavanagh et al. 1993), the relationship between self efficacy and metabolic control among adolescents with type 1 diabetes has received far less attention.

The first study to examine the role of self efficacy and metabolic control in young people with type 1 diabetes both longitudinally and cross-sectionally was by Johnston-Brooks, Lewis and Garg (2002). One hundred and ten participants aged between 18-35 years, completed a measure of self efficacy (adapted by Kavanagh et al. 1993), the Summary of Diabetes Self Care Activities Scale [(SDSC) Toobert and Glasgow, 1994) and Self Esteem Scale (Rosenberg, 1965). The outcome measure was HbA_{1c} at 12 months. The results indicated that over a one year period higher self efficacy at baseline predicted reduced HbA_{1c} at 12 months and that this relationship was mediated by dietary self care behaviour both cross-sectionally and longitudinally. Within this study dietary self care was an important mechanism by which self efficacy facilitated reduced metabolic control in young people with type 1 diabetes. A drawback related to the measurement of self efficacy. Although the adapted measure by Kavanagh et al. (1993) was reported to demonstrate adequate reliability and validity, there is no detailed analysis within the study or literature demonstrating the psychometric properties of this scale within similar studies.

8:9 Self efficacy as a mediator variable

Despite the considerable research demonstrating the adaptive value of self efficacy, the specific mechanisms through which self efficacy operate remain unclear. Besides being identified in the literature as a predictor of health outcomes, self efficacy has also been shown to account for the relationship between independent and dependent variables as a mediator variable (Holmbeck, 1997). A mediator variable has been defined as "*the generative mechanism through which the focal independent variable is able to influence the dependent variable of interest*" (Baron and Kenny, 1986: p. 1173). There are however very few studies examining the role of self efficacy as a mediator within the diabetes literature. Ott et al. (2000) examined the mediating relationship of self efficacy between adolescents' personal responsibility for their diabetes care (i.e. mastery control), supportive/non supportive behaviour from parents and adherence to treatment in 143 adolescents with type 1 diabetes. The results demonstrated that self efficacy mediated the relationship between adolescents' personal responsibility for their diabetes care and adherence to treatment. Self efficacy however was not significant in mediating the relationship between supportive parental behaviour and adherence.

8:10 Overview of the self efficacy findings

Based on the research to date, there is support for the role of self efficacy beliefs in diabetes related self management behaviour in both adults and adolescents with type 1 diabetes. It has been argued however that low correlations between self efficacy and

diabetes self management limit the predictive value in studies (Glasgow et al. 2001). Although self efficacy may have a positive impact on diabetes related behaviour, physiological outcomes and emotional states, studies rarely examine the potential mediators (i.e. mechanisms) of self efficacy. It is argued that a greater understanding of the link between self efficacy with outcomes such as HbA_{1c} is important particularly since low self efficacy has been identified as a key psychosocial barrier to self care. The inconsistent results linking quality of life to metabolic control suggests that the relationship may be mediated by other psychosocial factors and a substantial amount of research on health behaviour has focused on the locus of control concept. The health locus of control construct, measurement, link with self efficacy and the evidence in adults and adolescents with diabetes is considered in sections 8.11- 8.18.

8:11 Locus of Control

8:11:1 The concept of locus of control

Health locus of control [(HLOC) Rotter, 1966; Wallston et al. 1976] is a type of control belief that has been extensively studied with health behaviours and has been reported to have explanatory power in explaining diabetes related health outcomes (Peyrot and Rubin, 1994; Stenstrom et al. 1998). According to Rotter's (1966) social learning theory, locus of control refers to an attribution of responsibility for outcome that has internal or external causality. Typically 'internal locus of control' indicates the perception of ability to control events in one's life whereas 'external locus of control' indicates the person believes his or her life is controlled by forces such as fate and luck. The term 'locus' refers to the location where control resides - either internal

(I) to the individual based on personality trait or external (E) to the individual based on chance or other forces.

The Multidimensional Health Locus of Control Construct (MHLC) was developed by Wallston et al. (1978) and later refined by Wallston (1989) to measure the role of beliefs in the context of health behaviour and health outcomes. Although originally (I) and (E) beliefs were represented on opposite ends of a continuum, Wallston and Wallston (1982) suggested that these two beliefs are independent of one another such that a person can hold (I) and (E) beliefs simultaneously. Subsequently other dimensions, Chance (C) and Powerful Others (PO) were added as distinct from the (E) dimension. While MHLC and HLOC are often used interchangeably within the literature, for purposes of this thesis, the term health locus of control will be referred to as HLOC. While Internal HLOC has been more often related to health behaviours and health outcomes, it is also said to be less powerful than self efficacy in reaching one's health goals (Wallston, 2005).

The following sections will examine the most widely used measures of HLOC, the link with self efficacy and the evidence of health locus of control beliefs with diabetes outcomes. The evidence relating to the potential moderating effect of the value for health on health locus of control is also considered. Since the HLOC construct is primarily measured within the literature by the corresponding MHLC scale (Wallston et al. 1978) this will be described in the next section. The other two scales included are the Diabetes Locus of Control scale ([(DLOC) Ferraro et al. 1987] and the Child

Health Locus of Control [(CHLC) Parcel and Meyer, 1978] the latter being the scale which has been measured within Study I.

8:12 Measurement of health locus of control

Multidimensional Health Locus of Control Measure (Wallston et al. 1978)

The MHLC measure is actually a set of interrelated scales which examine beliefs in areas of health and functioning. They are used extensively in health research as predictors of health behaviour. Forms A and B constitute a health focused scale that measures beliefs about control of one's health. Each form comprises 18 items that form 3 subscales. Respondents rate on a 6 point Likert scale ranging from 'strongly agree' to 'strongly disagree'. There are 6 items within each subscale that constitute *Internal Health Locus of Control* (IHLC), *Powerful Others* (PHLC) and *Chance* (CHL). Typical items include "If I get sick it is my own behaviour that determines my health" (IHLC) to "*No matter what I do if I am going to get I will get sick*" (CHL). *Powerful others* and *Chance* (which include the role of fate and luck) relate to external (E) locus of control. Form C comprise 18 items that measure locus of control beliefs regarding an existing medical condition which includes, *Doctors* (DLC) and *Other People* (OPLC). Further refinements include a *God Locus of Health Control* (GLHC) developed by Wallston et al. (1999). The MHLC scales can be administered together or alone. Inter- correlations between subscales are low although they are not mutually exclusive of one another and O'hea et al. (2005) has suggested that individuals can have simultaneous beliefs in different types of health locus of control. The interaction between different loci of beliefs has been explored very seldom in the

literature. Studies that have explored interactions have found associations between the combination of high Internal and high Chance HLOC and reductions in HbA_{1c} control in patients with diabetes (Stenstrom et al. 1998).

Diabetes Locus of Control Scale [(DLOC) Ferraro et al. 1987]

One measure used within the diabetes literature that examines diabetes specific locus of control is the DLOC. The DLOC consists of 18 items comprising three six-item subscales. The response format is a 6-point Likert scale with higher scores indicating a stronger control orientation. The *Internal Health Locus of Control* (IHLC) subscale, measuring patients' internal diabetes health control beliefs, consist of such items as "*If my diabetes goes out of control, it is my own behaviour which determines how soon I get back in control again*". The *Powerful Others* (PHLC) subscale measures beliefs in powerful others employing items such as "*Having regular contact with my doctor is the best way for me to keep my diabetes in control*". Finally, the *Chance Health Locus of Control* (CHLC) subscale measures beliefs in chance and fate using such items as "*Most things that affect my diabetes happen by accident*". The DLOC scale has been shown to possess adequate psychometric properties, both in a type 1 and 2 diabetes American sample and in a Swedish type 1 diabetes sample. Peyrot and Rubin (1994) examined the structure and correlates of scales measuring diabetes locus of control in 165 patients with type 1 and type 2 diabetes. The authors found that within the scales that measured internal diabetes locus of control there were two separate components, autonomy and self blame. Autonomy was related to positive self care, positive emotional well being and reduced glycaemic control, while self blame was related to negative outcomes. Chance diabetes locus of control was associated with emotional

dysfunction. The authors argued that the findings were important for educational interventions to target patients who believe health outcomes are related to self blame and chance, since these patients were at increased risk for health related problems.

The Child Health Locus of Control [(CHLC) Parcel and Meyer, 1978]

The CHLC (Parcel and Meyer, 1978) used in this present study is a 20-item binary (Agree/Disagree) response questionnaire addressing the degree of internality/externality of the child's locus of control in relation to health issues. The scale has been described in section 5:11:2:8 (p. 188-190).

8:13 Health locus of control and self efficacy: Conceptual considerations

Although the constructs locus of control and self efficacy are conceptually related, locus of control is contrasted to self efficacy in a number of ways. In contrast to Rotter's (1966) concept of locus of control, self efficacy focuses on the beliefs of individuals regarding his or her ability to cope with the demands of a specific task in a specific context and thus represents a belief in one's competence in dealing with challenge. Once an action has taken place, self efficacious individuals invest more effort than those with low self efficacy. The belief in one's competence represents a stable-internal attribution of successful action. Self efficacy is thus competence based, action related and has predictive utility which differs to the more global construct of locus of control.

Locus of control in contrast, refers to an attribution of responsibility for outcomes (internal-external causation) without referring to any prospective or subsequent action. It is thus the action-oriented aspect of self efficacy that contrasts it to locus of control construct. According to Bandura's theory however, locus of control plays a role in behaviour change and maintenance. Bandura (1997: p. 19) stated, "*behaviour is influenced by generalised expectations that outcomes are determined whether by one's actions or forces outside one's control*". Thus locus of control does not seem to operate alone to determine behaviour. An individual can have a strong internal belief that implementing a particular behaviour will lead to good health, although if that person fails to believe they can carry out the behaviour and that the desired behaviour will lead to positive health they are not likely to engage in the behaviour.

Although it has been demonstrated that self efficacy is a much stronger predictor of behaviour than locus of control, the effect of self efficacy beliefs on behaviour is modified by locus of control (Wallston, 1989) and it has been suggested that from a theoretical standpoint it is preferable to assess both self efficacy and locus of control beliefs along with the interactions among them to predict behaviour (Wallston, 2005). Furthermore Wallston (1989: p. 100) argued that "*one cannot be self efficacious without being somewhat internal, but one can be internal without being efficacious*". It is therefore more likely for an individual with an internal locus of control to have a higher self efficacy for health behaviours when compared to an individual with an external health locus of control.

8:14 Relationship between health locus of control and self efficacy

Although the relationship between health locus of control and self efficacy dimensions are related, the associations are often weak (Wallston, 2005). Within studies that have examined the interrelationships between general (rather than situation-specific) self efficacy and locus of control, a positive association has been found between the General Self Efficacy Scale [(GSE) Leganger et al. 2000) and the (IHLC) subscale of the MHLC inventory. People with high general self efficacy also tended to believe that they could influence their own health by personal action which was not the case for 'others' or 'chance' subscale.

Waller and Bates (1992) studied the relationship between multi dimensional health locus of control and self efficacy in 57 healthy elderly respondents. The authors found that participants most characterised by high internal health locus of control also demonstrated higher self efficacy and benefited more from a health education programme than those with an external locus of control and low self efficacy. Chambliss and Murray (1979) found that overweight individuals were most responsive to behavioural treatment where they had a high sense of efficacy and an internal locus of control. Other studies however have failed to demonstrate relationships between these two constructs. Paxton and Sculthorpe (1999) found no significant associations between internal health locus of control and high self efficacy beliefs to lose weight in an Australian sample.

The separate effects of self efficacy and locus of control on health outcomes have also been examined. Cross et al. (2006) examined the relationship between self efficacy and health locus of control in 303 individuals with rheumatoid and osteoarthritis. Higher self efficacy and internal locus of control were independently associated with better physical functioning with arthritis although internal locus of control influenced outcomes to a lesser extent. In a similar study by Gramstad et al. (2001) the role of self efficacy and health locus of control was examined on psychosocial functioning in 101 individuals with epilepsy. Self efficacy was highly correlated with psychosocial functioning (explaining 48% of the variance) although no significant relationship was found for health locus of control.

8:15 Health locus of control and psychosocial outcomes

Since people with diabetes need to modulate their self management to maintain blood glucose control as close to normal range as possible, their beliefs from a control standpoint would appear to be relevant to their ability to control their disease. Within studies in chronic illnesses, higher belief in internal locus of control has been found to predispose the individual to active coping (Härkäpää et al. 1991). The relationship however between HLOC and psychosocial outcomes in patients with diabetes mellitus, has been mixed. Studies with positive outcomes are considered first. High internal locus of control has been found to be associated with better adjustment to diabetes (Helgeson and Franzen, 1998) and improved adherence to diabetes self care regimes (Evans and Hughes, 1987). Aalto, Uutela et al. (1998) studied the psychosocial correlates of quality of life in 385 adults with type 1 diabetes and found

that stronger internal locus of control was related to physical improvement on pain scales, while reliance on the role of 'significant others' was related to poorer perception of diabetes related health. Other studies have found no link between internal health locus of control and psychosocial outcomes (Coates and Boore, 1998; Ruzicki 1984).

8:16 Health locus of control and metabolic control

The relationship between health locus of control and metabolic control has been examined although the evidence is inconsistent and there is paucity of studies with adolescents. Some of the key studies and their findings will be considered.

8:16:1 Health locus of control and metabolic control in adults

Health locus of control has been related to HbA_{1c} in adult patients with type 1 and type 2 diabetes. Reynaert et al. (1995) conducted a study to determine if there was a relationship between internal locus of control and metabolic control (measured by HbA_{1c} levels) in 61 patients with type 1 and type 2 diabetes. Health locus of control was measured by Wallston's (1978) MHLC scale. The results indicated that for individuals with type 1 diabetes, those with internal locus of control had significantly lower HbA_{1c} levels than those with an external locus of control. The results were not significant for those patients with type 2 diabetes. High internal locus of control has been found to be associated with lower HbA_{1c} in patients with type 2 diabetes following a group education programme (Trento et al. 2006). A similar study by Macrodimitris and Endler (2001) examined the relationship between perceived

control in diabetes (measured as perceived ability to control life events regarding diabetes) and HbA_{1c}. One hundred and fifteen patients with type 2 diabetes were assessed via the Event Perception Measure (Conway and Terry, 1992) adapted for individuals with diabetes. Higher perceived control was significantly related to decreased HbA_{1c} levels. The authors concluded that perception of control is a good indicator of whether someone will actually exhibit control over their condition.

Another study with similar findings was conducted by Surgenor et al. (2000). The authors investigated the relationship between sense of control and HbA_{1c} in 92 female patients with type 1 diabetes. Sense of control was operationalised as 'a person's view that he/she has control as well as the belief that he or she can gain control over health if desired'. Control was assessed using three components;

1) sense of control, or a person's perception that they had control,

2) mode of control, or the ways by which the individual attains and maintains sense of control,

3) motivation for control.

The results demonstrated that participants who had higher levels of sense of control in all three domains had significantly lower levels of HbA_{1c}.

8:16:2 Health locus of control and metabolic control in adolescents

The study of health locus of control and adolescents with diabetes is sparse. Adolescents with type 1 diabetes with high levels of self efficacy beliefs and who also believed they were instrumental (i.e. experienced higher internal HLOC) in managing their behaviour demonstrated low HbA_{1c} levels (Grossman et al. 1987). Gross et al.

(1985) studied both locus of control and health locus of control in addition to other factors in adolescents with type 1 diabetes and compared to healthy peers. The only differences found were in health locus of control domain. Adolescents with diabetes had higher internal locus of control beliefs than their peers. Negative findings between health locus of control and metabolic control have also been found. Moffat and Pless (1983) used the CHLC to measure the relationship between health locus of control and metabolic control in 444 children and adolescents with type 1 diabetes at a 3 week summer camp and reported no association between locus of control and HbA_{1c}. When another locus of control scale was administered (Norwicki Strickland Locus of Control Scale, Norwicki and Strickland, 1973), significant associations were found up to a year after attendance at the camp. Closer examination of this scale demonstrates that although it uses a binary (yes/no) answer format, participants are scored on perceptions of control around friendships, achievement, personal control and helplessness which may impact on diabetes health. This scale arguably represents a more holistic measurement of the health locus of control construct than the CHLC.

8:17 Value for health and health locus of control

The inconsistent relationship between health locus of control and health related behaviour has been attributed to lack of attention to the *value of health* that individuals place on their health (Wallston and Smith, 1994). A number of studies have demonstrated the importance of and the moderating impact of value for health in explaining health locus of control outcomes. It has been suggested that value for health is even more salient during adolescence since the different values that young

people place on their health will determine involvement in health reducing behaviours such as smoking, alcohol intake and other risk taking behaviour (Torres and Fernandez, 1995). Furthermore, the broader developmental tasks of adolescence, such as gaining autonomy and establishing intimate relationships with peers (Masten and Coatsworth, 1998) may be directly at odds with the somewhat intrusive nature the diabetes regimen potentially limiting the value of diabetes related health. A study by Costa et al. (1989) found that higher value for health in younger adolescents (between 12-14 years) correlated with more frequent physical exercise, regular teeth brushing, concern for eating habits and preference for healthy food although the relationship was not significant for older adolescents. Value for health has also been found to be associated with positive dental self care behaviours and adherence to the diabetes regimen in adults with type 1 diabetes (Knecht et al. 1999). The moderating effect of value for health has been demonstrated between chance locus of control and smoking status (Bennett et al. 1997). In another study however, value for health and health locus of control for alcohol consumption demonstrated little explanatory power (Bennett et al. 1998).

8:18 Interaction between health locus of control beliefs and outcomes

The strongest predictive value of health locus of control has been when it is measured as an interaction variable (Wallston, 2005). There is however paucity of research examining the interaction of locus of control beliefs to explain outcomes. O'hea et al. (2005) examined the interactions of health locus of control dimensions of chance, internal, external, powerful others, other people, god and doctors on adherence to

medication measured as HbA_{1c} in 119 patients with type 2 diabetes. Poorer HbA_{1c} was related to different combinations (interactions) of health locus of control beliefs. Specifically higher 'chance' and lower 'internal' health locus of control beliefs were related to poorer HbA_{1c}. Moreover poorer HbA_{1c} was related to low 'other people' and high 'chance' beliefs along with the interaction between 'god' locus of control beliefs and internal. The outcomes demonstrated the utility of measuring beliefs outside the 'internal-external dichotomy' and provide additional support for 'internal' locus of control beliefs as pivotal in predicting health behaviours. The authors argued that individuals may have competing beliefs in different domains of health locus of control and that examining the interaction of health locus of control beliefs may explain inconsistent results within the literature

8:19 Overview of the literature

Although health locus of control has been found to be of some value in explaining health outcomes, the results appear to be inconsistent. One key factor in the inconsistent findings may rest with the way health locus of control is measured. Although the MHLC remains the most widely used measure in general or disease specific studies, it has also attracted key criticisms. One weakness rests with the way MHLC scales are measured in a linear fashion. Wallston (1989: p.90) argued that "*the MHLC measure is not used wisely and suffers from the 'silver bullet complex' - the belief that a single measure from a single construct will magically explain the amount of variance in health behaviour*". Wallston (2004, cited in Luszczynska and Schwarzer, 2005) has even argued that the role of self efficacy is a more powerful

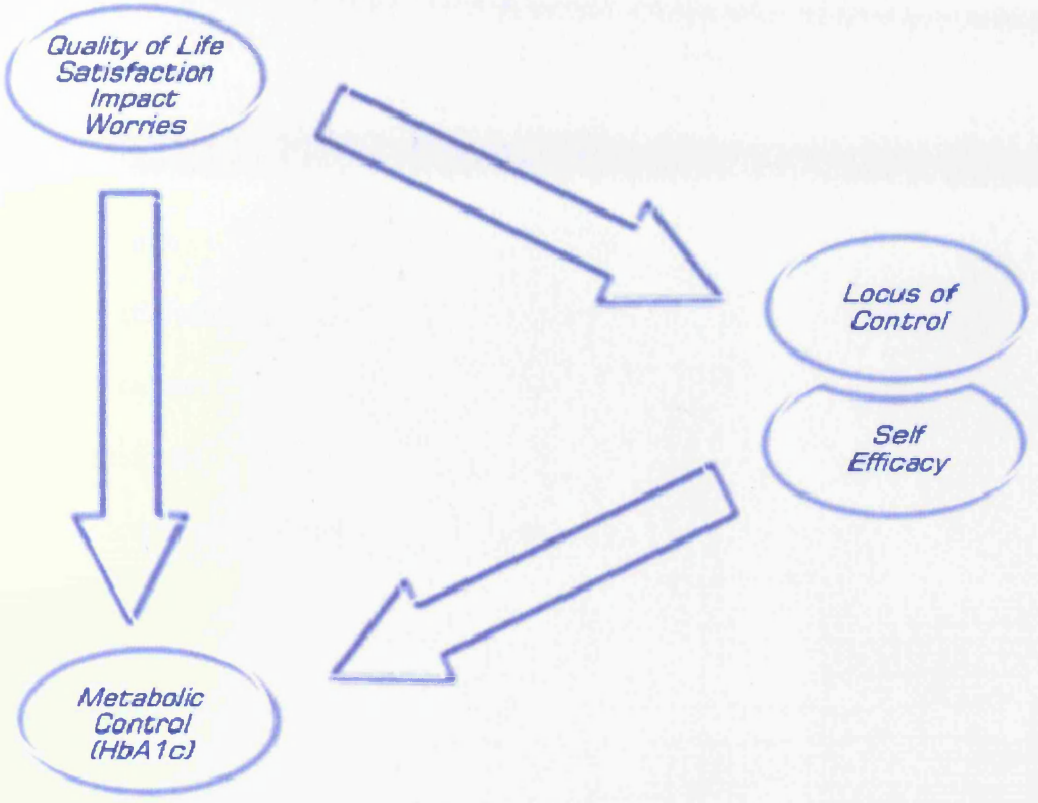
construct in predicting behaviour and suggested that locus of control is a necessary but not sufficient factor in promoting healthy behaviour. Furthermore there are very few studies that examine changes in HLOC over time and how these relate to disease outcomes.

8:20 Rationale for the present study

The rationale of this study is to examine the relationship between quality of life and HbA_{1c} in adolescents with type 1 diabetes, cross-sectionally and longitudinally within the context of Study I. Although a few studies have examined the relationships between these variables in adolescents cross-sectionally (Hoey et al. 2001; Vanelli et al. 2003) there are no documented studies that have examined the predictive value of quality of life on metabolic control, along with examining changes in quality of life over time. Most studies have examined the effect of metabolic control *on* quality of life, and reciprocal relationships may be in force. A positive relationship between quality of life and metabolic control may have clinical implications. It may be that adolescents with a better quality of life may be more able to deal with the psychological and physical demands of diabetes management and better quality of life may facilitate better metabolic control through improved self care as part of a positive reciprocal cycle. Studying quality of life at fixed time points (baseline, 12 and 24 months) does not allow for examination of *improvements* in quality of life over time which may translate to improved glycaemic control, and therefore examination of this relationship was warranted.

It is proposed that the relationship of quality of life to HbA_{1c} is mediated by other factors such as self efficacy and health locus of control. The literature suggests that high self efficacy is a significant variable in determining outcomes such as self care in patients with diabetes. Enhanced self efficacy may increase the adolescents' motivation for - and success with - behavioural efforts that are then translated into positive glycaemic control. Furthermore, adolescents' beliefs about control of their diabetes (health locus of control) would appear relevant to their ability to manage their glucose levels through positive self care. Relatively little attention has been given to the central role of health locus of control perceptions in diabetes. A model whereby self efficacy and locus of control act as a mediators on the effect of quality of life with HbA_{1c} may have greater predictive utility for patient's metabolic control than quality of life alone. Figure 14 describes the proposed model of relationships.

Figure 14: A proposed conceptual model of the variables quality of life, self efficacy and health locus of control and the outcome measure HbA_{1c}



The following chapter (Chapter 9) will discuss the aims, hypotheses and methods of the present study within a retrospective design of the data collected for Study I.

CONTENTS

CHAPTER 9: STUDY II - AIMS, HYPOTHESES AND METHOD

9:1 Introduction

This chapter describes the aims, hypotheses and methods involved in implementing Study II using the pre-existing data collected within Study I. The study is detailed according to item 18 within the CONSORT checklist for reporting sub-group analyses (Moher et al. for the CONSORT Group, 2001). This proposes that reporting of adjusted analyses should indicate which were specified *a priori* and which were exploratory. Outcomes research using analysis of pre-existing data is a relatively new field with the potential to improve the quality and effectiveness of health care, and may provide a useful complement to randomized studies (Canto et al. 1999). Methodological biases of retrospective data which involve the potential of selection bias, confounding and data dredging have been identified within observational epidemiological studies (Davey-Smith and Ebrahim, 2003). Methods used to overcome these potential biases in the present study are described. The structure of the chapter is as follows. Sections 9:2- 9:3 identify the study aims and hypotheses. Sections 9:4-9:7 describe the design, sample, measures used and the methods implemented. The final section, 9:8 concludes by outlining the method of analysis.

9:2 Aims

The aims of the study were three-fold:

1) To examine the relationships between quality of life and HbA_{1c} cross-sectionally at baseline and longitudinally at 3 time points; baseline, 12 and 24 months.

2) To examine the mediating relationships of self efficacy and health locus of control on quality of life and metabolic control.

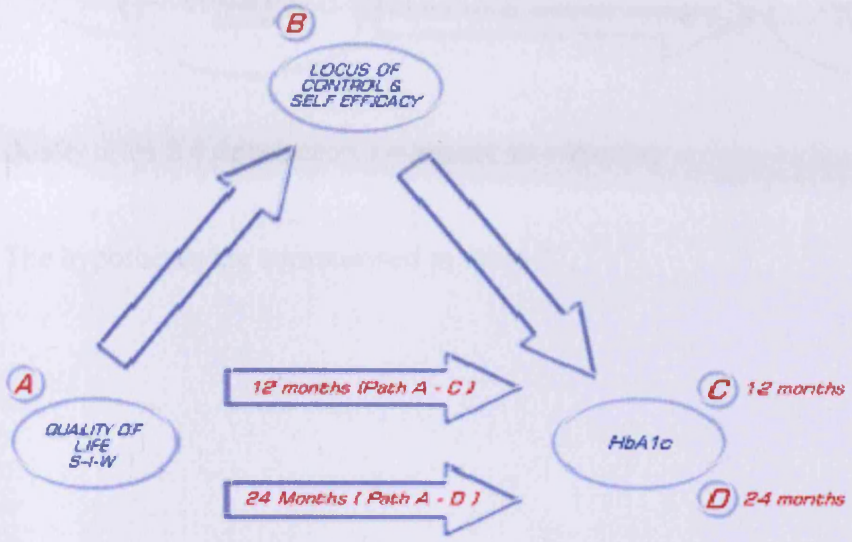
3) To examine the longitudinal relationships between changes in quality of life and changes in HbA_{1c} over the 2 year study period.

The model building approach of examining relationships between quality of life and HbA_{1c}, along with the mediating role of self efficacy, was specified *a priori* and prior to knowledge of Part I study outcomes. The additional mediating role of health locus of control was specified after analysis of the study to add explanatory power to the model.

9:3 Hypotheses

On the basis of the empirical literature, it was anticipated that baseline quality of life would be related to HbA_{1c} at 3 time points; baseline, 12 months (Path A-C) and 24 months (Path A-D). It was also anticipated that baseline self efficacy and locus of control would mediate the relationship between baseline quality of life subscales and HbA_{1c} at 12 months (Path A-B-C) months and 24 months (Path A-B-D). Figure 15 demonstrates the proposed relationships between quality of life, self efficacy, health locus of control and HbA_{1c}.

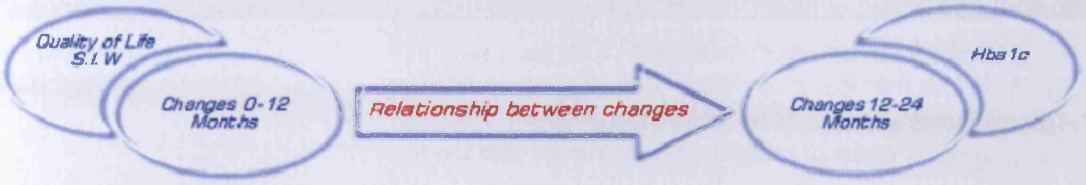
Figure 15: The proposed relationships between baseline quality of life, locus of control, self efficacy and HbA1c at 12 months and 24 months.



Quality of life S = Satisfaction, I = Impact, W = Worries

Given that quality of life is a dynamic construct (Allison et al. 1997), the adolescents' attitudes towards this may have improved over the course of the year whilst the intervention was delivered. This may have translated into clinical improvements in glycaemic control. It was anticipated that short term changes in quality of life would be associated with longer term changes in HbA_{1c}.as demonstrated in figure 16.

Figure 16: The proposed longitudinal relationships changes in HbA_{1c} between baseline and 12 months and changes in HbA_{1c} between 12 -24 months



Quality of life S = Satisfaction, I = Impact, W = Worries

The hypotheses are summarised in table 27.

Table 27: Hypotheses relating to model building approach to examine relationships between quality of life, self efficacy, health locus of control and HbA_{1c}	
Hypothesis 1:	
Cross sectional relationships	**1:1** There will be a relationship between quality of life subscales (satisfaction, impact and worries) and HbA_{1c} at baseline. Better quality of life on subscales Satisfaction, Impact and Worries will be related to lower HbA_{1c}.
Hypothesis 2:	
Longitudinal relationships	**2:1** There will be a direct relationship between baseline quality of life subscales (satisfaction, impact and worries) and HbA_{1c} at 12 months (PATH A-C)
	2:2 There will be a direct relationship between baseline quality of life subscales (satisfaction, impact and worries) and HbA_{1c} and at 24 months (Path A-D).
	2:3 Baseline quality of life subscales will predict HbA_{1c} at 12 months
	2:4 Baseline quality of life subscales will predict HbA_{1c} at 24 months
	2:5 Building on this model it is hypothesised that self efficacy (SES) and health locus of control (CHLC) will mediate the relationship between baseline quality of life subscales and HbA_{1c} at 12 (Path A-B-C) months
	2:6 Self efficacy (SES) and health locus of control (CHLC) will mediate the relationship between baseline quality of life subscales and HbA_{1c} at 24 (Path A-B-D) months.
Hypothesis 3:	
Model building examining longitudinal changes in quality of life and changes in HbA_{1c}.	**3:1** There will be significant relationships between changes in quality of life between 0 -12 months and changes in HbA_{1c} between 12 - 24 months. Better quality of life between baseline and 12 months will be related to better HbA_{1c} between 12 and 24 months.
	3:2 Building on this model, it is hypothesised that changes in quality of life between baseline - 12 months will predict better HbA_{1c} between 12 - 24 months.

9:4 Design

The study used a cross sectional and longitudinal design at 3 time points (baseline, 12 months and 24 months) based on pre- existing (retrospective) data collected within Study I which this thesis examines. Analysis is based on intention to treat as in Part I. Although the study is exploratory, *a priori* hypotheses had been formulated based on the empirical literature and prior to knowledge of outcomes in Study I.

9:5 Participants

Baseline data were analysed on the same number of participants that entered (n=66) the study. Follow up HbA_{1c} analyses were based on intention to treat. This included 60 participants who completed HbA_{1c} data at 12 months and 50 at 24 months. However, only completed data *across time points* were analysed.

9:6 Measures

The questionnaires used for this study have all been described within chapter 5 sections 5:11:2. They are; The Diabetes Quality of Life for Youths [(DQOLY) Ingersoll and Marrero, 1991]; Self Efficacy for Diabetes Scale [(SED) Grossman et al. 1987] and the Children's Health Locus of Control [(CHLC) Parcel and Meyer, 1978].

Metabolic control was analysed using the same HbA_{1c} data values within the main study data at time points; baseline, 12 months and 24 months.

9:7 Method

Data were analysed on a subset within the data set of Study I. The quality and accuracy of the questionnaire and HbA_{1c} data had been verified by two statisticians thereby reducing the likelihood of bias in the analysis. Potential methodological biases were avoided by the specification of *a priori* hypotheses and rationale for statistical methods and analyses. Because sub group analyses have less power to detect an effect from the main RCT under study (Assman et al. 2000) recommendations were established by the supervising statistician and the author for hypotheses generation and analysis. These were informed by guidelines within the existing literature (e.g. Brookes et al. 2001; Pocock et al. 2000) to avoid over interpretation of the outcomes.

9:8 Method of Analysis

A model building approach was used to examine relationships between quality of life subscales (satisfaction, impact and worries), self efficacy, health locus of control and HbA_{1c}. Missing data were excluded along each model building stage of the analyses and hypothesis testing. The significance level was set at $p<0.05$ for all analyses.

To test hypothesis 1:1, the analysis commenced with examination of the cross sectional relationships between the baseline measures of quality of life, self efficacy, locus of control and baseline HbA_{1c} using Pearsons correlations.

The next goal of building the best model to predict HbA_{1c} at 12 and 24 months was to determine which of the quality of life subscales were the most important predictors of HbA_{1c}. Hypothesis testing 2:1 and 2:2 involved examining the relationships between measures of quality of life and HbA_{1c} at 12 and 24 months using Pearsons correlations. To test hypothesis 2:3 and 2:4, hierarchical regression analyses were conducted to examine the predictive relationships between quality of life subscales satisfaction and impact and HbA_{1c} at 12 and 24 months. To assess assumption of no multi-collinearity within regression models (Field, 2005), collinearity statistics (VIF and Tolerance) were observed. The variables baseline HbA_{1c} and type of intervention group (MI or control group) were included as covariates in the model and a hierarchical blockwise entry approach was used to enter the variables. To test for the controlling variables, Pearson correlations were used for HbA_{1c} at baseline and 12 and 24 months and an independent *t* -test to observe for differences between the MI and control groups. Subscales that reached statistical significance at the univariate level were added into the model

The next stage in hypothesis testing 2:5 and 2:6 was to test for mediation. Three conditions need to be met by data before they are analysed for a mediating effect (Baron and Kenny, 1986). These conditions state that significant correlations should exist between a) the independent and dependent variables, b) the independent variable and the mediator, and c) the mediator and the dependent variable. The conditions were explored prior to analyses. Non significant correlations were excluded from the model.

Hypothesis testing 3:1 involved examining changes in quality of life and changes in HbA_{1c}. Firstly, change scores were calculated (i.e. the baseline values of quality of life subscales were subtracted from the values at 12 months and the same method applied for HbA_{1c} between 12 months and 24 months). The mean difference and standard deviation (SD) in change scores between time points were calculated for quality of life and HbA_{1c}. This was followed by examination of the relationships between quality of life and HbA_{1c} using univariate Pearsons correlations. Conditions for inclusion in a regression model to test hypothesis 3:2 were met if significant relationships existed. In order to examine the differences in means of quality of life subscales between baseline and 12 months, a paired sample *t*- test was carried out for each of the subscales.

The outcomes of the study are described in Chapter 10.

CONTENTS

CHAPTER 10: STUDY PART II - RESULTS

10:5 Hypothesis 3

10:5:1 *Hypothesis 3:1*

10:5:1:1 *Results*

10:5:2 *Hypothesis 3:2*

10:6 Summary statement

10.1 Introduction

This chapter presents the findings from Study II. Firstly, outcomes from data exploration are summarised. This is followed by descriptive outcomes of baseline questionnaire data, along with HbA_{1c} data over time points; baseline, 12 and 24 months. Inferential analyses are then presented for baseline questionnaire data to check for multicollinearity. Thereafter the results of hypothesis testing 1, 2 and 3 are structured as follows; hypothesis 1 (section 10:3), hypothesis 2 (section 10:4) and hypothesis 3 (section 10:5). Finally a summary statement of the data is presented to conclude the chapter.

10:1 Data screening

Prior to conducting the analysis, the data were screened to ensure they met the assumptions of hierarchical regression which included linearity, normality, homoscedascity and non-multicollinearity. Scatterplots of the data revealed no problems with linearity. The Child Health Locus of Control (CHLC) data (baseline and 12 months) had been transformed in Study I using reflection and square root transformation as recommended by Tabachnick and Fidell (1996).

10:1:2 Internal consistency of measures

Cronbach's alpha coefficients (α) for the baseline questionnaires are demonstrated in table 28 (as described in section 6:3 p. 208). The internal consistency for the scales

was satisfactory except for the CHLC scale which was considered below the acceptable social science cut off of α of 0.70 and above (Kline, 1986).

Table 28: Cronbach's alpha coefficients of the DQOLY, SED and CHLC questionnaires

Baseline	QOL Satisfaction	QOL Impact	QOL Worries	Self efficacy	Child Health Locus of control
Alpha coefficient	α=.918 17 items	α .869 23 items	α .839 11 items	α.871 35 items	α .605 20 items

DQOLY= Diabetes Quality of Life in Youths Questionnaire

SED = Self Efficacy for Diabetes Scale

CHLC = Child Health locus of Control Scale

10:2 Baseline outcomes

10:2:1 Descriptive analysis

Scores for the scales measuring the quality of life subscales, self efficacy and health locus of control were analysed at baseline. Glycosylated haemoglobin (HbA_{1c}) was measured at baseline, 12 months and 24 months. Means, standard deviations for all variables are shown in Table 29. The sample sizes for each time point (which excludes missing values) are demonstrated in the results.

Table 29 (a) : The means and standard deviations of questionnaires at baseline and HbA_{1c} at baseline, 12 and 24 months.

Time	Questionnaire		Mean	Standard deviation (SD)
Baseline	Diabetes Quality of Life Measure for Youths	Satisfaction	36.49 n=60	12.01
		Impact	51.61 n=60	12.99
		Worries	18.45 n=60	9.08
Baseline	Children's Health Locus of Control		11.14 n=63	2.60
Baseline	Self Efficacy for Diabetes Scale		163.52 n=61	22.26

Table 29 (b) : The means and standard deviations of HbA_{1c} at baseline, 12 and 24 months.

Time	Mean	Standard deviation (SD)
Baseline	9.17 n=63	1.75
12 months	8.94 n=50	1.77
24 months	8.72 n=46	1.81

10:2:2 Inferential analysis

Univariate correlational analyses were conducted between the DQOLY, SES and CHLOC at baseline to observe for multicollinearity.

There were significant associations between quality of life satisfaction, quality of life impact, quality of life worries and self efficacy (r=-0.461 p=0.001; r=-0.372 p=0.006 and -0.297 p=0.029 respectively). Greater satisfaction, less impact of diabetes on

quality of life, and fewer worries about diabetes were associated with higher self efficacy. Quality of life subscales and self efficacy were not related to health locus of control. Although the baseline quality of life subscales were moderately inter-correlated with self efficacy, the relationships were not so high to preclude examining them together in statistical analysis.

10:3 Hypothesis 1

Data were analysed on 54 participants with completed data.

Hypothesis 1 revisited from section 9:3	
	1:1 There will be a relationship between quality of life subscales (satisfaction, impact and worries) and HbA_{1c} at baseline. Better quality of life on subscales Satisfaction, Impact and Worries will be related to lower HbA_{1c}.

10:3:1 Results

There were no significant relationships between baseline quality of life satisfaction, impact and worries and baseline HbA_{1c} ($r=0.170$ $p>0.05$, $r=0.224$ $p>0.05$ and $r=0.130$ $p>0.05$ respectively). There were no significant relationships between baseline self efficacy, locus of control and baseline HbA_{1c} ($r=-0.169$ $p>0.05$ and -0.078, $p>0.05$ respectively).

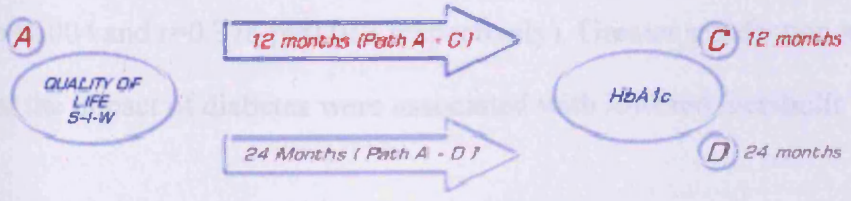
10:4 Hypothesis 2

Hypotheses 2 revisited from section 9:3	
Longitudinal relationships	**2:1** There will be a direct relationship between baseline quality of life subscales (satisfaction, impact and worries) and HbA_{1c} at 12 months (PATH A-C)
	2:2 There will be a direct relationship between baseline quality of life subscales (satisfaction, impact and worries) and HbA_{1c} at 24 months (Path A -D).
	2:3 Baseline quality of life subscales will predict HbA_{1c} at 12 months
	2:4 Baseline quality of life subscales will predict HbA_{1c} at 24 months
	2:5 Building on this model it is hypothesised that self efficacy (SES) and health locus of control (CHLOC) will mediate the relationship between baseline quality of life subscales and HbA_{1c} at 12 (Path A-B-C) months
	2:6 Self efficacy (SES) and health locus of control (CHLOC) will mediate the relationship between baseline quality of life subscales and HbA_{1c} at 24 (Path A-B-D) months.

10:4:1 Hypothesis 2:1

Data were analysed on n=51 participants with completed data. Pearson correlations were examined between baseline quality of life subscales and HbA_{1c} at 12 months (Path A-C).

Figure 17: Proposed relationships between quality of life subscales and HbA_{1c} at 12 months (PATH A-C)



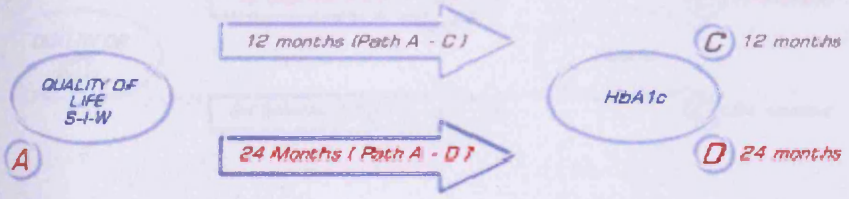
10:4:1:1 Results

The hypothesis was not supported. Correlational analysis between baseline quality of life subscales (satisfaction, impact and worries) and HbA_{1c} at 12 months demonstrated no significant relationships (Satisfaction = -0.120 $p>0.05$, Impact = r -0.095 $p>0.05$ and Worries = r -0.023 $p>0.05$) respectively.

10:4:2 Hypothesis 2:2

Data were analysed on n=51 participants with completed data. Pearson correlations were examined between baseline quality of life subscales and HbA_{1c} at 24 months (Path A-D).

Figure 18: Proposed relationships between quality of life subscales and HbA_{1c} at 24 months (PATH A-D)



10:4:2:1 Results

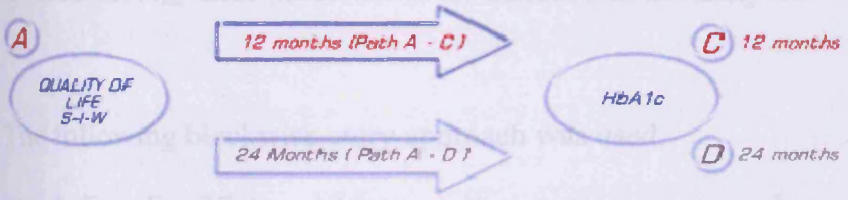
The hypothesis was supported. Significant relationships existed between satisfaction with quality of life and impact of diabetes with reduced HbA_{1c} levels ($r= 0.426$ $p=0.004$ and $r=0.378$ $p=0.013$ respectively). Greater satisfaction and lower perception of the impact of diabetes were associated with lowered metabolic control at 24

months. There was no significant relationship between worries about diabetes and HbA_{1c} (r=.288, p=0.082).

10:4:3 Hypothesis 2:3

To test the hypothesis that quality of life subscales will predict reduced HbA_{1c} levels at 12 months (Path A-C), conditions of regression analysis were tested which determine that significant relationships exist at the univariate correlational level between baseline quality of life scales and HbA_{1c} at 12 months.

Figure 19: The proposed predictive relationships between quality of life subscales and HbA_{1c} at 12 months (PATH A-C)



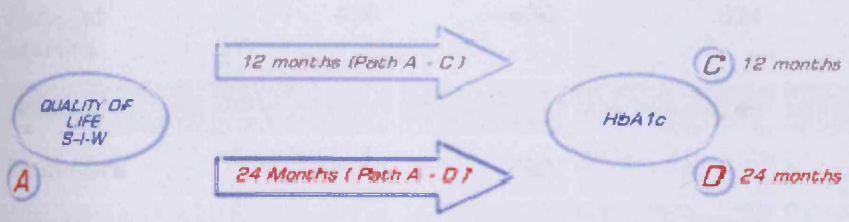
10:4:3:1 Results

The conditions were for testing Path A-C using regression analysis were not met. There were no significant relationships at the univariate correlational level between the baseline quality of life subscales and HbA_{1c} at 12 months. The hypothesis that baseline quality of life subscales would predict reduced HbA_{1c} levels at 12 months was therefore not tested.

10:4:4 Hypothesis 2:4

To test the hypothesis that quality of life subscales will predict reduced HbA_{1c} levels at 24 months (Path A-D), the conditions for regression were explored.

Figure 20: The proposed predictive relationships between quality of life subscales and HbA_{1c} 24 months (Path A-D)



Since there were significant relationships between Satisfaction and Impact and 24 months HbA_{1c}, these predictors were included in the analyses.

The following blockwise entry approach was used.

Step1: Baseline HbA_{1c} and Intervention group were entered as covariates.

Step 2: Satisfaction and Impact were entered into model simultaneously.

10:4:4:1 Results

Data based on 46 participants with completed data.

Table 30: Hierarchical regression analysis assessing baseline quality of life scales Satisfaction and Impact and HbA_{1c} at 24 months

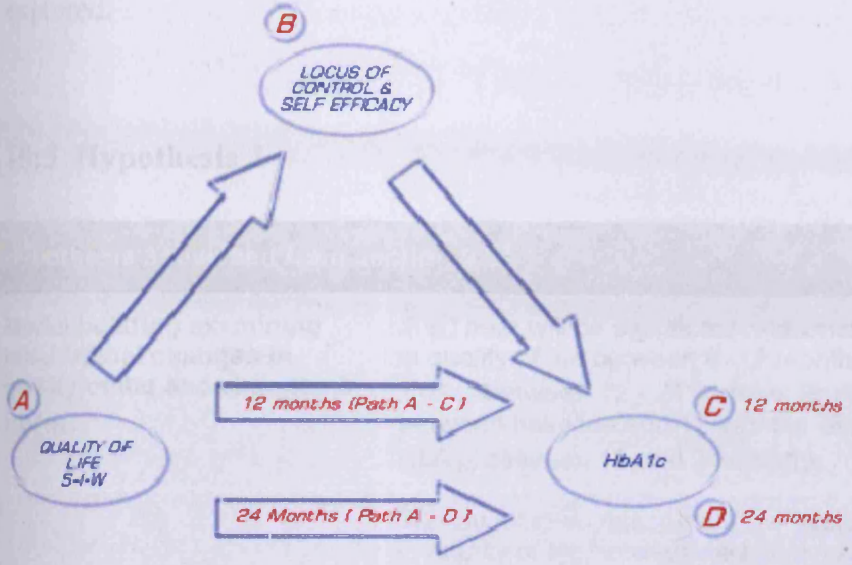
			Model R^2 = .522 $F(4,45)$ =11.201 p=0.001		
	R2	ΔR^2 change	β	SEβ	Significance
Covariate: HbA_{1c} at baseline	.430	.430	.624	.111	p=0.001
Group			-.140	.410	p>0.05
Predictors	.522	.092			
Satisfaction			.237	.028	p>0.05
Impact			.140	.023	p>0.05

The hypothesis was supported. The regression model demonstrated a good fit R^2= .522 and the relationship between quality of life and HbA_{1c} at 24 months was significant [F (4,54) = 11.201 p<0.001]. After controlling for intervention group and baseline HbA_{1c}, quality of life satisfaction and impact made a significant contribution adding 9.2 % of the variance to the model. The individual contributions of satisfaction and impact however did not produce any unique variance to the model.

10:4:5 Hypothesis 2:5 and 2:6

Prior to testing the following paths A -B, B-C, A-C and A-D (see figure 21 below), the conditions for mediation were explored identified within method of analysis section.

Figure 21: Proposed mediating relationships between paths A-B-C and A-B-D.



Quality of life S = Satisfaction, I = Impact, W = Worries

10:4:5:1 Results of hypothesis 2:5

Path A-B-C

Since there were no significant relationships between quality of life subscales, self efficacy and health locus of control and HbA_{1c} at 12 months, the conditions for mediation were not met.

10:4:5:2 Results of hypothesis 2:6

Path A-B-D

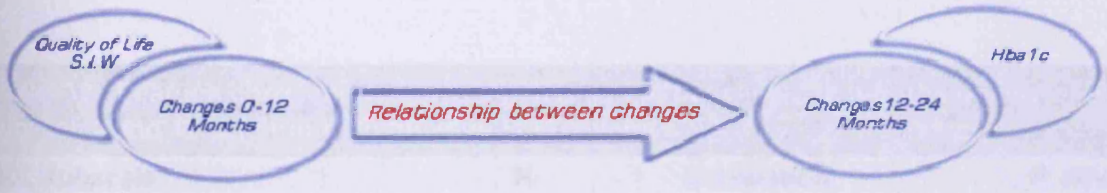
Based on the conditions for mediation (described in section 9:8 p: 372), the following variables did not meet statistical significance at the 0.05 level; (1) self efficacy and 24 month HbA_{1c} ($r= -0.179$ $p>0.05$) (2) baseline quality of life subscales and locus of

control (Satisfaction = r-.191 p>0.05; Impact r=-0.118 p>0.05 and Worries 0.076 p>0.05). The conditions for mediation were not fully met and the model was not explored.

10:5 Hypothesis 3

Hypothesis 3 revisited from section 9:3	
Model building examining longitudinal changes in quality of life and changes in HbA_{1c}.	**3:1** There will be significant relationships between changes in quality of life between 0 -12 months and changes in HbA_{1c} between 12 - 24 months. Better quality of life between baseline and 12 months will be related to better HbA_{1c} between 12 and 24 months.
	3:2 Building on this model, it is hypothesised that changes in quality of life between baseline - 12 months will predict better HbA_{1c} between 12 - 24 months.

The proposed relationships between changes in quality of life subscales and changes in HbA_{1c} revisited (Figure 16).



S=Satisfaction I = Impact and W =Worries

10:5:1 Hypothesis 3:1

To test the hypothesis that changes in quality of life subscales between 0 - 12 months will be related to improvements in changes in HbA_{1c} between 12 - 24 months, Pearson correlations were carried out with significance level set at $p<0.05$.

10:5:1:1 Results

The descriptive analyses are demonstrated in Table 31. Negative differences on quality of life indicate improvement, while a negative difference in HbA_{1c} represents decrements. Changes in quality of life are calculated from baseline values on a 5 point scale whereby 1 = better quality of life and 5 = worst.

Data were analysed on 42 participants and excludes missing data.

Table 31: The minimum, maximum, mean difference and standard deviation in changes scores on quality of life subscales between baseline and 12 months and change scores in HbA_{1c} between 12 - 24 months

Variable	N	Minimum	Maximum	Mean difference	SD
Satisfaction	42	-41.00	31.69	*-1.18	14.80
impact	42	-40.00	46.79	1.55	18.34
worries	42	-27.30	29.00	1.75	12.43
HbA_{1c} 12 - 24 months	42	-4.60	6.30	-.114	1.96

*negative - mean difference represents improvement

Table 32 describes the relationships between changes in quality of life between baseline and 12 months and changes in HbA_{1c} between 12 – 24 months.

Table 32: Pearson correlations between changes in baseline - 12 months quality of life subscales and 12- 24 month changes in HbA_{1c} values

QOL subscale	N	Correlation	P value
Satisfaction	42	-.264	p>0.05
Impact	42	.016	p>0.05
Worries	42	-.150	p>0.05

The hypothesis was not supported. Although the mean quality of life with satisfaction improved over the course of the intervention (mean difference -1.18), there were no significant relationships between changes in the quality of life subscales and changes in HbA_{1c} between 12 - 24 months. When the differences in means were explored

between the baseline quality of life subscales and 12 months, there were no significant differences between the two time points (satisfaction t=.582 p>0.05; impact t=-.592 p>0.05 and worries t=.257 p>0.05) respectively.

Table 33 demonstrates the inter-correlations between baseline QOLY, SES and CHLOC, HbA_{1c} at baseline, 12 and 24 months and changes in quality of life between 0-12 months and changes in HbA_{1c} between 12 -24 months

able 33: The inter-correlations between baseline QOLY, SES and CHLOC, HbA_{1c} at baseline, 12 and 24 onths and changes in quality of life between 0-12 months and changes in HbA_{1c} between 12 -24 months

ariable	Baseline SED	Baseline CHLOC	Baseline Satisfaction	Baseline Impact	Baseline Worries	Changes in Satisfaction 0-12 months	Changes in Impact 0-12 months	Changes in Worries 0-12 months
aseline ED		.245 (n=54)	-.461** (n=54)	-0.372** (n=54)	-0.297 (n=54)			
aseline HLOC	.245 (n=54)		-.191 (n=54)	-0.118 (n=54)	-0.076 (n=54)			
aseline atisfaction	-.461** (n=54)	-.191 (n=54)		0.738** (n=54)	0.589** (n=54)			
aseline npact	-.372** (n=54)	-.118 (n=54)	.738** (n=54)		0.738** (n=54)			
aseline Vorries	-.297* (n=54)	-.076 (n=54)	.589** (n=54)	0.738** (n=54)				
bA1c aseline	-.169 (n=54)	-.078 (n=54)	.170 (n=54)	.224 (n=54)	0.130 (n=54)			
bA1c 2months	-.021 (n=51)	-0.086 (n=51)	-0.120 (n=51)	-0.095 (n=51)	-0.023 (n=51)			
bA1c 4months	-.179 (n=43)	-.375 * (n=43)	.426** (n=43)	.378** (n=43)	.268 (n=43)			
hanges in bA1c 12-4 months						-.264 (n=42)	.016 (n=39)	-.150 (n=40)

)<0.05 ** p<0.005

Sample size for each data point is in brackets. Data represented are for completed data only.

10:5:2 Hypothesis 3:2

The conditions for testing the hypothesis within a regression model were not met due to lack of significant relationships at the univariate correlation level.

10:6 Summary statement

The results provided preliminary evidence of the association between better quality of life at baseline and reductions in HbA_{1c} longer term. Satisfaction and Impact subscales of quality of life were associated with reductions in $HbA1_c$ at 24 months and predicted reductions in HbA_{1c}, although the amount of variance explained was very small (0.9%). Although there were improvements in satisfaction with quality of life over the intervention period (baseline to 12 months), these did not translate into improvements in HbA_{1c} longer term (12 -24 months). The results need to be interpreted with caution due to the small sample sizes and exploratory nature of the analysis. The following chapter (Chapter 11) discusses these findings in relation to the aims, hypotheses and current literature.

CONTENTS

CHAPTER 11: STUDY PART II - DISCUSSION

11.1 Introduction

The aims of this study were to explore relationships between quality of life and HbA_{1c} cross-sectionally and longitudinally, along with the mediating relationship of self efficacy and health locus of control on HbA_{1c}. It was also proposed that changes in quality of life between baseline and 12 months would predict improvements in changes in HbA_{1c} between 12 and 24 months. The association was strongest for quality of life satisfaction and impact, such that greater satisfaction and reduced perceptions of negative impact with quality of life predicted better metabolic control over the longer term, after adjusting for intervention group and baseline HbA_{1c}. When changes in quality of life and HbA_{1c} were assessed over time, contrary to expectation, a decrease in HbA_{1c} was not associated with concomitant gains in quality of life. The results of the study are discussed in the next section and the findings discussed in relation to the aims, hypotheses and relevant literature.

11:2 Outcomes from hypothesis 1

Hypothesis 1:	
Longitudinal relationships	**1:1** There will be a relationship between quality of life subscales (satisfaction, impact and worries) and HbA_{1c} at baseline. Better quality of life on subscales Satisfaction, Impact and Worries will be related to lower HbA_{1c}

The results demonstrated no significant relationships between baseline quality of life subscales, self efficacy, locus of control and HbA_{1c}. These outcomes will be considered.

Although there were no significant relationships between the quality of life subscales and HbA_{1c} the size of the correlation coefficient is considered. The coefficients for satisfaction and impact were 0.17 and 0.22 respectively. When compared to Cohen's (1988) convention for the magnitude of association, these represent small-medium associations. Given a larger sample size and greater power, these findings may have been significant.

The lack of significant findings are consistent with the cross sectional outcomes of Ingersoll and Marrero (1991); Grey, Boland, Bolyai et al. (1998) and the DCCT study group (1994). They are however in direct contrast to the cross sectional findings of Hoey et al. (2001) which demonstrated the association between lower HbA_{1c} levels and better adolescent quality of life as measured by the DQOLY subscales. Within this study however, even with a large sample (2,101 children and adolescents), the worries subscale only just reached statistical significance in the relationship with HbA_{1c}. Additionally, despite the better quality of life, 38% of the adolescents on 3 injections or more of insulin still maintained a mean HbA_{1c} between 9-9.5%. This is considered high according to ISPAD (2000) guidelines which recommended a treatment target of 7.5 % and less to prevent future micro-vascular complications.

In order to understand the relationships between quality of life, self efficacy, health locus of control and HbA_{1c} cross sectionally, it may be important to examine the role of general psychosocial factors (that may buffer the stress of diabetes) such as depression, social support and self care. Furthermore, within this study cultural,

socioeconomic and self care factors were not examined which may have also influenced how adolescents perceived their quality of life, self efficacy and health locus of control at baseline.

11:3 Outcomes from hypothesis 2

The goal of building the best model to predict HbA_{1c} at 12 and 24 months was to determine which of the quality of life subscales were the most important predictors of HbA_{1c}. The outcomes of each hypothesis are explored.

11:3:1 Hypothesis 2:1 and 2:2

Hypothesis 2:	
Longitudinal relationships	**2:1** There will be a direct relationship between baseline quality of life subscales (satisfaction, impact and worries) and HbA_{1c} at 12 months (PATH A-C)
	2:2 There will be a direct relationship between baseline quality of life subscales (satisfaction, impact and worries) and HbA_{1c} at 24 months (Path A-D)

The results indicated that quality of life subscales were associated with HbA_{1c} at 24 months, although not at 12 months. Despite the lack of statistical significance, the correlation coefficient between quality of life satisfaction and HbA_{1c} at 12 months was r= 0.23. It would be expected that this marginal association would yield significant association, given a larger sample size and enhanced statistical power.

At 24 months the amount of variance explained by quality of life subscales satisfaction and impact were (r=0.426, p=0.004 and r=0.378, p=0.013 respectively).

The correlation between worries about diabetes and HbA_{1c} at 24 months was much smaller (r= 0.286, p>0.05). The size of these correlation coefficients are defined as medium to high (0.3 – 0.5) according to Cohen's (1988) conventions.

11:3:2 Hypothesis 2:3 and 2:4

Hypothesis 2:	
Longitudinal relationships	**2:3** Baseline quality of life subscales will predict HbA_{1c} at 12 months
	2:4 Baseline quality of life subscales will predict HbA_{1c} at 24 months

The results indicated that although the quality of life subscales satisfaction and impact significantly predicted HbA_{1c} levels at 24 months, conditions for regression were not met at 12 months. Although the amount of variance explained was small (R^2=0.09), the findings provide some support not only for the utility in measuring quality of life but also to facilitate better psychosocial functioning with the potential to improve long term glycaemic control. Pouwer, Snoek et al. (2001) found that a psychological intervention delivered to adults with diabetes in routine out patient clinics, improved mood and general well being compared with standard care, although had no effect on reducing HbA_{1c}. Monitoring of psychological health may also help improve patient-reported outcomes as part of ongoing diabetes care (Skovlund, Peyrot et al. 2005; Pouwer, Snoek et al. 2001).

Although the quality of life subscales satisfaction and impact significantly predicted HbA_{1c} levels at 24 months, they did not add any unique variance to the model and

individually were not significant. Baseline HbA_{1c} and group (MI versus control) accounted for most of the variance in follow up HbA_{1c} (43%) with quality of life adding an additional 9.2% of the variance to the model. A likely explanation for the small variance was the result of collinearity between the subscales. The baseline quality of life subscales were highly inter-correlated (satisfaction and impact r=.738; impact and worries r=.738 and worries and satisfaction r=.589). Collinearity statistics demonstrated the following Tolerance statistics; Satisfaction = .325; Impact= .179 and Worries= .401. Menard (1995) proposed that a Tolerance value of <0.2 indicates a potential problem in bias of the model. Indeed when examining the variance proportions across the small eigenvalues (Field, 2005), satisfaction and impact explained the highest variance proportions attributable to each eigenvalue (satisfaction =.68 and impact =.98). Thus although quality of life significantly predicted HbA_{1c} at 24 months, the results need to be interpreted with caution due to the bias within the model.

11:3:3 Hypothesis 2:5 and 2:6

Hypothesis 2:	
Longitudinal relationships	**2:5** Building on this model it is hypothesised that self efficacy (SES) and health locus of control (CHLC) will mediate the relationship between baseline quality of life subscales and HbA_{1c} at 12 (Path A-B-C) months
	2:6 Self efficacy (SES) and health locus of control (CHLC) will mediate the relationship between baseline quality of life subscales and HbA_{1c} at 24 (Path A-B-D) months

The potential influence of self efficacy and health locus of control on HbA_{1c} was explored to elicit potential insight into the way in which psychosocial factors

indirectly influence self care through HbA_{1c} values. The conditions for mediation were not fully met at the $p<0.05$ level for 12 or 24 months, and thus the relationships were not explored. The lack of relationships may have been due to low sample size and lack of power to detect statistically significant relationships. These specific constructs will be considered in turn.

11:3:3:1 Relationships between self efficacy and HbA_{1c}

The results demonstrated no significant relationship between self efficacy and HbA_{1c} at baseline, 12 months or 24 months. These are in contrast to the cross sectional findings of Talbot et al. (1997) who found low levels of self efficacy were related to high HbA_{1c} values (Pearson's correlation $r= -0.28$) However, the study examined the self efficacy in adults with type 2 diabetes and the results may not generalise to an adolescent sample with type 1 diabetes. When the role of self efficacy and HbA_{1c} was studied cross sectionally and longitudinally in adolescents with type 1 diabetes (Johnston – Brooks et al. 2002), self efficacy significantly predicted lower HbA_{1c} both at baseline and at 2 years, although the amount of variance explained was very small ($R^2= 0.07$ cross sectionally and longitudinally).

The factors influencing glycaemic control are complex and it is possible that the Self Efficacy for Diabetes Scale (SED) failed to capture the level, strength and generality of self efficacy as identified by Maibach and Murphy (1995). Anderson, Funnell et al. (2000) suggested that for self efficacy scores to have predictive value, the items must be specific. Although the items within the SED measure perceived ability to carry out situation specific self efficacy behaviours relating to the diabetes regimen, the items

are not worded in specific terms. For example, item 4 on the SED ' *I can keep check of my blood sugar levels*' is worded with greater specificity ' *I believe I can detect a low glucose reading in time to correct*' within the Confidence In Diabetes Self-Care Scale [(CIDS), van der Ven, Weinger et al. 2003]. Furthermore, Schwartzer and Fuchs (1995) suggested three major cognitions operate to determine health behaviour; risk perception [e.g. "*my risk of getting hypos are...*"], outcome expectancies [i.e. the "*If* (behaviour), *then* (consequences)"] and perceived (confidence) self efficacy to carry out the behaviour. Within the SED, only the latter cognition is measured. Moreover barriers to self management are not measured [e.g. "*I am confident that I can* ... (perform something), *even if* ... (barrier)"] and barriers to self care activities are identified as a major factor in adherence (Glasgow et al. 2001). Further limitations of the SED were explored in greater detail within section 7:3:5 (p. 266-267).

Examining self efficacy and its relationship with HbA_{1c} has clinical implications. Diabetes related self-efficacy can be modified through education and psychosocial interventions more readily than general psychosocial factors (such as quality of life) (Aalto, Uutela et al. 1997). The authors argued for the importance of supporting and developing self efficacy through diabetes education and counselling to enhance glycaemic control and quality of life.

11:3:3:2 Relationships between health locus of control and HbA_{1c}

The lack of association between baseline health locus of control and quality of life subscales and between health locus of control and 12 months HbA_{1c} may be partially

explained by the low internal consistency of the CHLC scale (α = .605). The limitations of the CHLC were discussed in greater detail in section 7:3:6 (p. 268-270). There was however a positive association between baseline locus of control and HbA_{1c} at 24 months demonstrating the potential benefit of higher internality of beliefs and better metabolic control longer term. High internal locus of control has been shown to facilitate active coping in adults experiencing low back pain (Härkäpää, Järvikoski et al. 1991) and active coping has been found to be significantly related to reduced HbA_{1c} in adolescents with diabetes (Graue, Wentzel-Larsen et al. 2004). Adolescent's perceptions of competence in being able to control aspects of their regimen and HbA_{1c}, maybe important, particularly in coping with the daily demands of diabetes self care and uncertainty over glycaemic control during puberty.

11:4 Outcomes from hypothesis 3

Hypothesis 3:	
Model building examining longitudinal changes in quality of life and changes in HbA_{1c}.	**3:1** There will be significant relationships between changes in quality of life between 0 -12 months and changes in HbA_{1c} between 12 - 24 months. Better quality of life between baseline and 12 months will be related to better HbA_{1c} between 12 and 24 months
	3:2 Building on this model, it is hypothesised that changes in quality of life between baseline - 12 months will predict better HbA_{1c} between 12 - 24 months

Monitoring change scores in quality of life from baseline to 12 months enabled exploration of the relationship with concomitant changes in HbA_{1c}. The absence of relationships between improvements in the quality of life subscales and follow up

improvements in HbA_{1c} corroborate the findings by Lau et al. (2004) who found no associations between changes in quality of life measured by the SF-36 physical scale following reduction in changes in HbA_{1c}. It is possible that the non significant relationships may be due to the lack of responsiveness of the DQOLY. Although the measure demonstrated good internal consistency (α = .918, .869 and .839 for satisfaction, impact and worries respectively), it has not been used previously to evaluate changes in quality of life (Garrett et al. 2002). Thus it may have lacked sensitivity to detect important changes in adolescent's perceptions of quality of life related to their diabetes. It would have been interesting to explore change scores that had been calibrated on the adolescent's appraisal of quality of life change from baseline to 12 months. Fisher et al. (1999) found greater sensitivity and accuracy to quality of life change when the construct was measured as retrospective appraisals over time. There is however no gold standard of investigating patients response to change in health within the literature (Stratford and Riddle, 2005).

The magnitude of difference in changes over 12 months in quality of life is considered. The mean difference in changes in satisfaction with quality of life from baseline to 12 months was -1.18 (SE 2.03). Some investigations suggest that differences of approximately 0.5 represent small but important changes while large improvements correspond to a difference in score of greater than 1.0 (Juniper et al. 1994). Based on this information, the mean difference in satisfaction falls into the category of small but important change (albeit non significant). In terms of assessing the magnitude of change in the DQOLY over time, it is still not known what constitutes change as clinically important (such as worsening, moderately worsening,

mild improvement or substantial improvement) to make a difference to the patients' and their families lives. Testa (2000) argued that quality of life measures should establish what are termed Meaningful Category Indicators or MCI's. These represent reference measures by which intervals correspond to a change that allows categorisation of quality of life changes. Calibration of changes in the quality of life scores within this study would have added meaningful outcome categories such as the degree and strength of the change.

11:5 Design considerations

11:5:1 Design

The study was analysed using pre-existing data collected within the study data set in Part I. A strength of this approach is that it allowed data that was readily accessible and had been subjected to rigorous quality monitoring and accuracy standards. Although the RCT is the best study design to compare treatment effectiveness, it cannot address every question (Canto et al. 1999). Indeed it as been argued by Berg and Vickrey (1994) that the field of outcome research should include exploratory research to improve the ability of the RCT to measure outcomes most relevant to patients. Potential problems of bias were avoided by specifying *a priori* hypotheses before the results of the main RCT trial were analysed, with prior specification of the design protocol and hypotheses generated by theoretical literature (with the exception of health locus of control). The testing of outcomes of the questionnaires within the pre existing data still rendered the problem of multiple testing and the potential for spurious results and observed outcomes by chance through inflation and a type 1 error. Since this was an exploratory study and was designed to provide corroborative

clinical outcome results within the study, and not merely replace the key primary and secondary findings, no statistical test (such as Bonferroni correction factor) for correction of multiple testing was warranted.

11:5:2 Sample size

The sample sizes were reduced along each model building exercise since only data that were complete across time points were analysed. Thus the sample sizes were relatively small (n= 54 at baseline; n= 51 when examining baseline to 12 months; n= 46 when examining baseline to 24 months and n= 46 when examining changes between baseline and 24 months). It is possible that the relatively small sample sizes within the model failed to detect associations that were present and hence led to type 2 error (false acceptance of the null hypothesis when an effect exists). Tabachnick and Fidell (1996) suggested that the minimum number of subjects for predictors in a regression analysis should be 5-to-1. Meanwhile, Nunnally (1978) suggested a minimum subject-to-predictor ratio of 100 subjects per 2 or 3 independent variables.

It has been argued that in determining sample sizes for regression analysis, researchers should use methods that include effect size since traditional simplistic rules-of-thumb often lead to designs that lack sufficient power (Green, 1991). The method that Green (1991) proposed is based on the formula $N \geq L / f^2$ where N=sample size; L=number of predictors and f^2 is the effect size (measured as $R^2 / (1-R^2)$. For example, according to Cohen's calculations (1988, cited in Green, 1991), the minimum sample size required within this present study to test the hypothesis that the population multiple correlation equals zero with a power of .80 (alpha =0.5), effect

size of .13 (medium) with 3 predictors (i.e. quality of life subscales) is n=73. This is well above the sample size on which the data were analysed.

11:5:3 Sampling

The study had few exclusion criteria and some adolescents were recruited who already had good metabolic control. In order to generalise findings to wider population of adolescents with diabetes, it would have been appropriate to examine the effects of psychosocial factors on poorly controlled subjects (i.e. those with HbA_{1c} of $\geq 9.0\%$). Young people with high baseline HbA_{1c} levels may have experienced poorer quality of life and had the potential to experience greater improvements in quality of life than those with lower HbA_{1c} levels. This is a stimulus for future research.

11:5:4 DQOLY scale

The response limitations of the DQOLY and collinearity have been addressed. The DQOLY has recently been modified by an international team for the Hviødre study group (Skinner et al. 2006) to form the DQOLY-SF. The researchers examined the construct validity and internal consistency in 2,077 adolescents with type 1 diabetes in 18 countries. Using exploratory and confirmatory factor analysis, a 6 factor solution was found comprising domains of impact, future worries, parental control, impact on symptoms and impact on activities. There were many redundant items within the DQOLY on the Impact and Worries subscale. Within the modified scale, the domains symptoms, impact, future worries, and impact on activities all predicted HbA_{1c} and were sensitive to scores from participants across age groups. All the

domains reached satisfactory reliability coefficients. The authors concluded that the DQOLY-SF demonstrates satisfactory construct validity and internal consistency and is brief enough to be used within routine care. The scale may address some of the limitations in measuring quality of life within this present study.

11:6 Statistical considerations

11:6:1 Baseline imbalances

The imbalance of scores on quality of life subscales between the MI and control groups at baseline is considered. Analysing change scores does not control for baseline imbalance because of regression to the mean (Vickers and Altman, 2001). However because this study analysed relationships within the whole sample, and did not analyse outcome according to intervention group, there was no requirement to fit an analysis of covariance as recommended by Senn (1991).

11:6:2 Collinearity

The literature provides little information about how to deal with collinearity within data. One potential method in dealing with the collinearity in quality of life subscales would have been to run a factor analysis on the three subscales and use the resulting factor scores as the predictor. Others (e.g. Bowerman and O'Connell, 1990) advocate collection of more data, which was not practical within this study given that analysis was determined on pre-existing data.

11:6:3 Unmeasured factors

The lack of significant relationships between quality of life, self efficacy and health locus of control and HbA_{1c} may be due to 'unmeasured factors' particularly since little is known of the psychological effects of patient's behaviour on health in diabetes self management (Peyrot, 1999). Diabetes related stress (Ellis, Frey et al. 2005), coping styles (Grau et al. 2004) and depression (Massengale, 2005) are all known to affect the way adolescents deal with their diabetes and these factors were not measured within Study I or Study II.

11:7 Overview of the findings

The study provided preliminary support for the predictive relationship between quality of life and metabolic control. The association was strongest for quality of life satisfaction and impact such that greater satisfaction and lower perceived negative impact with quality of life predicted better metabolic control over the longer term, after adjusting for intervention group and baseline HbA_{1c}. Cause and affect cannot be assumed because of the low sample sizes and the high amount of variance explained by baseline HbA_{1c} within the regression model in examining outcomes in metabolic control. The link however between better baseline quality of life and reductions in metabolic control over the longer term may have important implications clinically. The maintenance of healthy self management behaviour for minimising long term complications is well established (DCCT study, 1994). As such, the study provides initial support for the role of quality of life in exerting indirect effects through metabolic control. The findings justify efforts to assess quality of life perception in

adolescents at baseline in order to facilitate achievement of better metabolic control through individual strategies. Such strategies may include attention to preferred communication styles, focus on the barriers to self management, improvement of adolescent/parent satisfaction with care or increased involvement of the adolescent and family in decision-making. By motivating an adolescent to achieve adequate metabolic control through enhancing quality of life, this may offset the burden of complex treatment regimen or increased incidence of hypoglycaemia induced by tight metabolic control. Although monitoring of quality of life in clinical practice is proposed (Varni et al. 2005; Hesketh et al. 2004), there is little research to guide effective interventions to facilitate quality of life and well being.

The preliminary nature of these findings is reinforced. The relationship between quality of life and glycaemic control is complex and the outcomes from previous studies by which to compare the present findings are limited by their design. The impressive cross sectional findings of Hoey et al. (2001) for instance are limited by the cross-sectional and correlational nature of the data limiting causal effects to be established. The longitudinal studies that have demonstrated positive relationships between metabolic control and quality of life such as the work of Grey et al. (1998; 2000) examined the effects of an intervention (such as effectiveness of coping skills training and sulphonylurea medication) on outcomes and as such represent a different design to the present study. A prospective study of quality of life in adolescents with type 1 diabetes study is currently being explored at the Vrije University Medical Centre, EMGO Institute, The Netherlands (de Wit et al. work in progress). The investigators are measuring a computerised assessment of diabetes related quality of

life taken during out patient clinics and are implementing tailored care according to the psychosocial needs of the adolescents. The effects of this intervention at 3, 6 and 9 months are explored on psychosocial and clinical outcomes at 12 months. This study aims to provide valuable insight into the utility of monitoring quality of life in a clinical setting and how to implement psychosocial care to enhance quality of life functioning.

11:8 Goals for future research

Although the analytic techniques used within the present study enhanced statistical power, further insights from statistical approaches such as structural equation modelling [(SEM) Tabachnick and Fidell, 1996] could be used to determine causality of relationships (such as examining clinical changes in quality of life on metabolic control). Such methods will also allow examination of the mechanisms through which interventions such as MI or cognitive behavioural therapy (CBT) exert their effects.

Recognising the importance of quality of life measurement for children and adolescents, Varni et al. (2005: p. 6) recommended that screening alone is insufficient to facilitate quality of life outcomes and proposed "*intervention studies that provide physicians with targeted recommendations linked to health quality of life data are especially needed*". More prospective studies such as the one currently undertaken in The Netherlands are required, and the application of computer assisted methods may enhance uptake to ease the burden of time and cost in clinical practice associated with traditional survey methods. Utilising information technology is becoming more prominent in diabetes practice [e.g. negotiated telephone support, (Howells et al.

2002); telemedicine (Leisenfeld et al. 2000) and '*Sweet Talk*' (Franklin et al. 2006)]. D'Alessandro and Dosa (2001) argued that information sharing technologies, such as the user centred designs as above, serve to empower the child and their family through collaboration and shared decision making in their health.

CONTENTS

12:1 Introduction

The outcomes from the study demonstrated that MI can be an effective method of working with adolescents with type 1 diabetes, producing long-term reductions in glycaemic control and gains in psychological well-being, quality of life and personal models of diabetes. This study delivered was a robust design with high quality intervention delivery, closely monitored to ensure adherence to the documented 'approaches'.

Since the commencement of the study, there have been a number of developments in government policy guiding diabetes research, along with further reviews and meta-analysis in the paediatric diabetes and motivational interviewing field. This concluding chapter discusses these recent developments in relation to care of children and adolescents with type 1 diabetes, along with the most recent systematic reviews and meta analyses. Recent research and clinical developments in MI are also addressed. The chapter concludes with considerations for future research in young people with diabetes.

12:2 Recent national guidelines on service provision

Recent government guidelines have addressed the need to provide consistent high quality care to young people with diabetes and their families to facilitate well being. In 2002, the National Standards Framework (NSF) brought the issue of diabetes care to the fore by launching the 'NSF for diabetes: Standards' (Department of Health, 2002). The aim of this document was to improve the care of people with diabetes 'by

offering care that is structured and proactive and providing people with the support they need to manage their own condition'.

One unique feature of the NSF was the emphasis on putting the young person living with diabetes at the centre of care. Standard 3 of the NSF, entitled 'Empowering People with Diabetes,' proposed that '*all children, young people and adults with diabetes will receive a service which encourages partnership in decision making, supports them in managing their diabetes and helps them adopt and maintain a healthy lifestyle*'. Furthermore, Standard 5 emphasised the clinical care of young people and recommended that, '*all children and young people with diabetes will receive consistently high quality care and they will be supported to optimise the control of blood glucose and their physical, psychological, intellectual, educational and social development*'.

Diabetes care for young people was further highlighted with the launch of the National Institute of Clinical Excellence (NICE) guidelines in July 2004. This document '*Type 1 Diabetes: Diagnosis, treatment and management of type 1 diabetes in children and adults*' specified a number of research recommendations which included the need to evaluate the effectiveness of structured education programmes for children, young people and their families. It also stressed the need to provide psychosocial care in service provision, along with targets of glycaemic control to less than 7.5% to prevent micro-vascular complications. In addition, the Department of Health (2004) National Service Framework for the care of children, young people and

maternity services aimed to actively promote the physical and mental well being of children with or without disability and chronic illness.

Despite these reports it is evident that deficiencies remain in the delivery of care in young people with diabetes. A Department of Health NSF for diabetes follow up report called, '*Turning the Corner: Improving Diabetes Care*' (DOH, 2005a) highlighted that despite psychological interventions being considered an important part of multi-disciplinary care necessary to improve outcomes, there remain a significant delay in implementing psychosocial care in children's services. These deficiencies were further apparent in a recent Diabetes UK report. This report (Diabetes UK, 2005: *Diabetes: State of the Nations*) indicated that currently 85% of young people with diabetes in England are not meeting recommended blood glucose levels and qualitative reports from young people and their families highlighted lack of satisfaction with psychological and emotional support available. The recently published National Diabetes Audit Report (2006) outlined in Chapter 1, corroborated the evidence above and demonstrated that only 15.9% of children and adolescents under 16 years achieved HbA_{1c} targets of less than 7.5% as recommended by the NICE guidelines. These reports demonstrate the discrepancies between what should be achieved and what is actually delivered (Hindmarsh, 2006).

The evidence from the present study suggested that MI is an intervention that shows promise in reducing HbA_{1c} and enhancing psychological functioning. Moreover given the emphasis on autonomy in decision making, enhancing personal resources through improving self efficacy within a collaborative relationship, it is an intervention that

can assist diabetes practitioners to reach the NSF standards 3 and 5 by the target year 2013.

12:3 Recent reviews and meta analysis

12:3:1 Psychosocial interventions and type 1 diabetes

Since the systematic review by Hampson et al. (2001), two recent reviews have been conducted on the effectiveness of psychosocial interventions in type 1 diabetes. A review and meta analysis by Winkley et al. (2006) examined the effectiveness of RCTs conducting psychological interventions on metabolic control and psychological distress in adults and children (including adolescents) with type 1 diabetes. Psychological studies were operationalised into three domains; support counselling, cognitive behavioural therapy and psychoanalytic therapies. Motivational interviewing was categorised as support counselling, although no studies in MI were eligible for analysis due to lack of controlled studies. Ten studies in children and adolescents were examined comprising 543 participants. The results demonstrated standardised effect sizes of -0.35 (95% confidence interval -0.04 to -0.66 p=0.03) representing a 0.5% absolute reduction in HbA_{1c}. The effects on psychological distress in children and adolescents were greater on metabolic control with a standardised effect size of -0.46 (confidence interval -0.25 to -0.51 p=0.059). The authors concluded that despite reductions in HbA_{1c} and psychological distress, the methodological quality of the studies was moderate to poor and that the evidence for effectiveness in children and adolescents weak.

A follow up review of psycho-educational interventions for children and young people with type 1 diabetes, based on the systematic review of Hampson et al. (2001), has recently been undertaken by Murphy, Rayman and Skinner (2006). Psycho-educational interventions included those which involved any form of psychosocial training, individual or family counselling and diabetes knowledge and skill. Out of the studies reviewed 13 of 24 (54%) were controlled studies which compared favourably with the earlier review where only 40% were RCTs, although only one RCT was conducted within the UK. The number of family interventions increased from 10% in the Hampson et al. (2001) review to 30%. The assessment of psychosocial factors such as self efficacy, quality of life and family behaviour have increased to 79% from just 33% previously, while HbA_{1c} was still the most common primary outcome measure (used in 79% of the studies).

Murphy et al. (2006) concluded that although there have been significant improvements in the quality and quantity of educational interventions since the previous review, the effects on glycaemic control were limited and the effect sizes in outcomes had not increased significantly. The median effect size for glycaemic control was 0.18 (compared to 0.17 in 2000) which is comparable to change in 0.3% in HbA_{1c}. The authors suggested this represents a small change in improvements in glycaemic control. The median effect size for psychosocial outcomes remained the same (ES 0.35 current to 0.36 in Hampson et al. 2001 review). Although specific studies within the review (e.g. Grey et al. 1998; Grey et al. 2000) demonstrated relatively large gains in glycaemic control and psychosocial functioning and were methodologically robust, there was still insufficient evidence to recommend adoption

of a particular intervention and no intervention has been proven effective in randomised studies for those with poor glycaemic control. Furthermore the reviewers argued that most studies compared the intervention with routine care rather than a control group, and it remains to be explored what theoretical method is superior in facilitating change. Studies have yet to compare the psychosocial benefits with or without intensive insulin therapy to improve glycaemic control (Murphy et al. 2006).

The evidence from the two reviews suggest that although psychosocial interventions appear to be efficacious in facilitating adolescents to achieve better metabolic control and psychosocial functioning, the evidence is modest. The authors reported the greatest weaknesses related to poor methodological quality, small sample sizes, lack of theoretically driven studies and poor reporting of trials according to CONSORT (2001) guidelines.

12:3:2 Motivational Interviewing

Since the commencement of the present study, there have been no reviews examining MI in diabetes care *per se*. Included here are the most recent reviews and meta analyses in MI that have targeted a range of health outcomes.

The most recent systematic review and meta-analysis of MI interventions was conducted by Rubak et al. (2005). Seventy two randomised controlled trials were evaluated on the effectiveness of MI in disease areas including asthma, diabetes and lifestyle change in smoking cessation, weight loss and addiction problems. Motivational Interviewing was found to be effective in improving the combined effect

of body mass index (BMI), blood cholesterol concentration, systolic and blood pressure and mediated lifestyle change in areas of weight loss and smoking. MI had a significant and clinical effect on three out of four studies with equal effects on physiological (72%) and psychological (75%) areas. The authors concluded that MI was effective even in relatively short consultations (15 minutes) and the effects were stronger with more frequent sessions. Although MI was found to be superior to traditional advice-giving in facilitating patient behaviour change, there were often varying degrees of effectiveness depending on who was delivering the intervention. Motivational Interviewing consultations with doctors and psychologists were more effective (effect in approximately 80% of studies) than those with other healthcare practitioners (46% of studies). The level of MI training necessary to facilitate change, and the key components of the intervention that were efficacious, were both unexplored within the review.

Two further meta-analyses (Hettema et al. 2005 and Burke et al. 2003) have been conducted. The most recent by Hettema et al. (2005) was conducted on 72 randomised controlled trials on outcomes of a range of target behaviours. The analysis demonstrated that there was a high level of variability across MI populations, target problems and settings. The strongest effect for MI was found in reducing substance misuse (ES 0.41) although there was no effect in studies of smoking cessation. Motivational interviewing was also effective in health promoting behaviours of HIV risk reduction (ES=0.53), adoption of water purification in rural African villages (ES=0.30) and diet and exercise behaviours (ES=0.78). Some interesting findings indicated that the effect sizes for MI reduced over time (ES 0.39 at baseline - 1 month

to ES 0.11 for 12 months and longer) and that effect sizes were smaller when practitioners adhered to a manualised guided practice. The effects were strongest in ethnic minority populations and for participants who were more resistant to change their behaviour. The latter findings are consistent with the findings of Project MATCH (1997). The largest effects for MI were when compared to no treatment, standard education and when added to another standard treatment. The authors concluded that MI produced small to medium effects on health outcomes and that the effect size is increased when added at the outset of treatment thought to be due to a synergistic effect on treatment adherence. The results for the manualised guided practice were thought to be decreased because of the practice towards a less patient centred style.

Burke et al. (2003) conducted a meta-analysis of thirty controlled trials of adapted MI interventions (AMIs). The authors evaluated evidence across five target problem areas; alcohol and drug misuse, smoking, diet and exercise, HIV risk behaviours and treatment adherence. The evidence was examined on efficacy of AMIs compared to no treatment, control group or active treatment, sustained efficacy over time and the practical usefulness for patients. The authors found that compared to no treatment, AMIs displayed moderate effect sizes for interventions targeted at drug abuse, alcohol misuse, diet and exercise. AMIs were equivalent to other active treatments, although the comparison treatments tended to be longer in duration than AMIs. There was no support for the efficacy of studies in the areas of smoking cessation or HIV risk behaviours. In terms of the clinical impact, 51% of people who received AMI treatment sustained improvements at follow up compared to 37% of those receiving

no treatment or treatment as usual. The authors concluded that future research should pay attention to enhancement of internal validity through detailed descriptions of the AMI under study, assessment of treatment fidelity and integrity and greater uniformity and comparability of AMI treatments across studies.

12:4 Clinical developments in Motivational Interviewing

12:4:1 Training developments

Little detail of the training programs provided to practitioners is given in most studies of MI making it difficult to establish the effects of training duration, content and format on the skill level of practitioners (Dunn et al. 2001; Burke et al. 2002). One recent study that has examined the effectiveness of training methods on MI skill acquisition is the Evaluating Methods for Motivational Enhancement Education (EMMEE) project conducted by Miller, Yahne et al. (2004). This controlled trial investigated the effects of five different training methods on the acquisition of skills in MI. Practitioners working in substance misuse were randomised to:

- two day workshop
- workshop and feedback
- workshop and coaching
- workshop and feedback with coaching
- waiting list group which comprised 6 month self guided training of a manual and training videos.

The trainers emphasised that workshops were the 'starting point' and that it would take time to develop MI proficiency in clinical practice. The four groups that received

workshop training demonstrated significantly greater skill acquisition in MI in comparison to controls who received a therapist manual and video-tapes. Furthermore, the advantage of the workshop and combined feedback with coaching was the increase in client commitment to change speech ('change talk') from baseline to 4 months post training. The results at 12 month follow up post training showed a reduction in skill level if participants did not receive either coaching or feedback, and the authors recommended that further feedback and/or coaching after training workshops is necessary to maintain and improve the skills learned over time.

Further developments in the training and measurement in behaviour change counselling (BCC) continue. As previously identified in section 4:4:1 (p:120), Lane et al. (work in progress) demonstrated that a two day workshop in BCC produced mean improvements of two to five points in a practitioner's total score across items on the BECCI (Lane, Huws-Thomas et al. 2005) measure. There were no differences in practitioner skill efficacy whether simulated patients were used or role play was with trainers.

The results from these practitioner training workshops are encouraging in the development of MI skill acquisition. What is lacking is a description of the level of competence that needs to be attained before a practitioner is considered to be delivering MI to an identified 'high' standard.

12:4:2 Process analysis

Significant developments in the internal validity of MI studies have taken place since the commencement of the present study. A flexible menu driven approach for intervening with young drug users has been identified by McCambridge and Strang (2003) which is the first published MI intervention to be described in detail. This topic based intervention has been adapted from the approach used by Rollnick et al. (1992) with additional components added and a longer intervention time (one hour versus 40 minutes in earlier studies). A number of key strategies were similar to the menu driven approach used within this present study ('*Typical Day*' '*Pros and Cons*', '*Exploring Concerns*' and '*Decisional Balance*') although were sufficiently diverse to meet the needs of young people with very different target problems. The utility of the intervention was examined by McCambridge and Strang (2004) against an 'education as usual' control group in a cluster RCT with 200 young multiple drug users. A striking feature of the results were improvements in the intervention group (ES 0.37) across multiple drug using behaviours (smoking, alcohol use and cannabis), although changes in perceptions of risk and harm were not as marked as changes in observed drug behaviours. The study demonstrated the positive benefits of a 1 hour intervention using a topic driven menu approach with young people. As with the present study, those components which facilitated greatest change in behaviours remains unanswered.

A study by Tappin et al. (2005) also demonstrated the emerging growth in attention to internal validity within MI studies. The authors examined the effects of an MI

intervention compared to education in pregnant smokers within a socially deprived area of Glasgow. The MI intervention did not significantly increase smoking cessation among heavy smokers. A salient aspect of this study is the degree of training and supervision offered to the community midwives delivering the intervention (eight day intensive training followed by one day per month of booster sessions to aid competence). All interviews were audio-recorded and analysed by experienced MI trainers using the MISC [(Version 1.0) Miller, 2000] independent of the study. A high level of MI skill proficiency was reported. This study shows that these women did not significantly decrease their smoking, despite receiving an intervention that was reflective of MI. Questions regarding the integrity of this intervention can be ruled out in the light of these findings, so other questions are raised regarding the suitability of this type of intervention for this group of clients. The studies by McCambridge and Strang (2003; 2004) and Tappin et al. (2005) highlighted how the description of the intervention used and quality control were useful in the evaluation of the findings of those studies.

12:4:3 Measurement of Motivational Interviewing

Recent developments in the measurement of MI have developed via process measurement tools with added sensitivity to evaluate improvements in clinician skill proficiency. Moyers, Martin et al. (2005) have adapted the MISC (Version 1.0) skill code to form a shorter version Motivational Interviewing Treatment Integrity (MITI) scale. An advantage of the revised scale is the shorter length, reduced complexity and sensitivity to measurement of person centred competence such as the spirit of MI. Due to it's recent development the scale has not been tested in MI training practice to

observe norms in clinician progress. Although benchmarks have been set which describe whether the practitioner has conducted MI to a minimal, intermediate or high extent, these have yet to be tested clinically.

Another development by Moyers, Miller et al. (2005) has been in the identification of therapist interpersonal skill on client involvement within MI interviews. The authors analysed 103 audio-taped interviews conducted within the EMMEE project (Miller et al. 2004) using MISC (Version 1.0) skills code. Therapists were evaluated on measures of interaction that adhered to the 'spirit' of MI such as empathy, egalitarianism, warmth and genuineness as well as specific behaviours such as MI consistent responses (affirmations, reflections, open questions and support). Using a structural model design, the authors found that the relationship between clinician interpersonal skills accounted for as much as 70% of the variance in client co-operation and collaboration, particularly when MI consistent responses were added to the model. These findings add support to Miller and Rollnick's (2002) emphasis on the spirit of MI rather than the specific techniques for implementing change. They also contribute to the work on therapist characteristics and the therapeutic alliance regardless of intervention used. An interesting finding was that MI inconsistent responses (i.e. confronting, denying, giving advice) increased client involvement when they were examined with interpersonal skills. The authors argued that despite the inconsistent responses, therapists who demonstrated genuineness and honesty were accepted by the clients which in turn elicited cooperation. The recent developments described in this chapter have demonstrated the commitment to

enhancing internal validity of studies in MI along with the links between in session interactions and client's responses.

12:5 Implications for future research

The emerging evidence from studies, government policy and audit is that routine clinical care is inadequate for optimal blood glucose control and well being in children and adolescents with type 1 diabetes. Such messages provide the incentive needed for health professionals to challenge current models of care delivery around self management with adolescents. Clark (2005) argued that we need to access the individual's 'personal model' of diabetes (i.e. preferred communication styles, cognitive representations and coping strategies) to enhance self management. Moving towards person-centred care however demands changes in attitudes and behaviour by health professionals and patients alike. A recent qualitative study examining the attitudes of patients with diabetes towards health care professional communication styles, demonstrated that despite the high value placed on patient centred interactions by health care professionals, patients perceived them as having a judgemental approach and requested greater participation in self care decision making (Richards et al. 2006). Training practitioners in interpersonal styles of working do not always change practitioners' behaviour (Pill, Rees et al. 1999), although a recent study by Parkin et al. (2006) demonstrated that professional centred training of diabetes specialist practitioners, facilitated improvement in patients perceptions of autonomy with decision making within the consultations.

Although the present study placed high emphasis on internal validity to rule out alternative explanations, it remains unanswered what components of the MI intervention influenced reductions in HbA_{1c} and enhancements in psychological functioning. Isolation of the potential active ingredients within the MI intervention is worthy of further study. The study this far has provided important explanatory information about the efficacy of an MI intervention, the context of the training and skill acquisition, and key components within the intervention. Although implemented as a definitive RCT study, a goal for future intervention research with young people would be to apply the Medical Research Council (MRC, 2000) framework in harnessing the information relating to design, process and outcomes beyond the quantitative level. Required now is further implementation of modelling and exploratory phases (such as the utility of modelling experiments as identified in section 7:5:2:1) and qualitative methods to affirm the principles on which developing the intervention, training and delivery of MI were based. This process analysis involves what industrialists call "evolutionary operations" – rolling analyses over time and integrating quantitative and qualitative findings to optimise the production process (Box and Draper, 1998; Bradley, Wiles et al. 1999). Indeed a phased approach has been identified as a suitable approach in diabetes care to address the complexity inherent in delineating self management, education and psychological programmes (Mühlhauser and Bergen, 2002).

It is possible that a potentially intensive intervention such as MI may not be necessary for facilitating improvements in self care and the utility of an adaptation of MI as an intervention for young people with diabetes is currently being examined at the

Departments of General Practice and Child Health, Cardiff University. The Development and Evaluation of a Psychosocial Intervention for Children and Teenagers Experiencing Diabetes (DEPICTED) Study, (Gregory, Robling et al. work in progress) is a large scale randomised controlled study that commenced in 2005. In the first phase, new psychosocial interventions are being developed to explore how best to discuss the relevant aspects of lifestyle change with adolescents in order to prevent long term complications. Although the intervention has yet to be developed, it is anticipated it will contain principles adapted from MI, BCC and education/self management models (Personal communication, Hood 2006). The training needs of health care practitioners are being identified through focus groups involving patients, practitioners and significant others to match the needs and preferences of diabetes staff (doctors, specialist nurses and dieticians). Phase 2 involves evaluation of a training package for clinicians to facilitate behaviour change in their patients. This is being carried out in approximately 24 clinics in England and Wales on the effect of blood sugars levels and quality of life in 700 young people with diabetes. If such interventions are successful, it increases the capacity for multidisciplinary working to facilitate working towards lifestyle changes in young people.

Further examination of therapeutic processes occurring within sessions and how they relate with HbA_{1c} and psychological outcomes is also required. A recent systematic review of interventions aimed at changing the interactions between practitioners and patients, found that almost one half of those interventions delivered through training in counselling skills and behaviour change were associated with at least one worse health outcome for patients compared to the comparison group (Griffin, Kinmonth et

al. 2004). Conversely interventions that aimed directly at improving outcomes through pre consultation clinical interviews, knowledge building, activation in decision making and negotiation showed a 75% effect in improvement compared to no intervention. The authors argued these findings reinforced the difficulties of consistently altering practitioner behaviour within the consultation. Although training in psychosocial interventions may be an integral part of improving care, it is argued that training practitioners may not effective if practitioners are not able, or willing, to transfer those skills into their daily clinical work (Lane et al. work in progress). Skinner (2006) suggested there is still a large gap between diabetes practitioners' research knowledge on patient-provider interactions and the translation of patient centred models of care in practice.

The potential of mediating and moderating factors within MI outcomes are largely unexplored. Given that there is little direct evidence to suggest that MI works by enhancing motivation or readiness to change (Burke et al. 2003), it would be beneficial to elucidate the potential influencing factors on diabetes outcomes such as the interacting influences of demographic factors and psychological factors (e.g. coping, self efficacy and depression). Given that psychological processes do not work alone, it would be interesting to examine the complex interaction between physiological and psychological factors that influence diabetes outcomes. Furthermore it is increasingly recognised that qualitative research is required that determine health behaviour, such as the cultural context, values, beliefs about health, barriers to self care and community norms (Pope and Mays, 1995). Such information may reveal insights about how beliefs and perceptions translate into lifestyle

behaviour change such as changes in injecting practice, dietary behaviours and blood glucose monitoring. Exploring barriers to key aspects of the regimen through interviews, observations and the young people's narratives would be helpful in designing interventions particularly for those with poor metabolic control. Despite extensive research on diabetes self care, very little is known how adolescents with poor metabolic control care for their diabetes (Frey et al. 2004). As Bradley, Wiles et al. (1999, p.715) concluded in their review of complex health interventions " *an integrated quantitative and qualitative approach to developing and evaluating complex interventions in health service research is both efficient and generalisable.....It helps interpret quantitative findings and questions underlying theory and assumptions to better inform future hypotheses and intervention designs.*"

12:6 Implications for clinical practice

This study has confirmed the importance of providing a psychological intervention for young people with diabetes. If glycaemic control of young people is to be reduced to under the 7.6% level which is the threshold at which micro-vascular complications are reduced (ISPAD, 2000; DCCT, 1994), then evidence based psychological support is warranted to assist young people to cope with the burden of diabetes. The long term implications and life threatening nature of type 1 diabetes makes the psychosocial challenges complex among children and adolescents (Department of Health, 2005b) and dissemination of interventions with demonstrated efficacy remains slow to develop in diabetes practice (Snoek, 2006). Although resource implications have been identified as the major barrier (Hindmarsh, 2006), there is also an evident shortfall in effective communication between patient-provider in diabetes care.

The Hampson review (HTA, 2001) highlighted the need for psychosocial interventions to target adolescents with poorer metabolic control, and sub analyses within the present study demonstrated the significant decreases in metabolic control within the MI group albeit with a small sample size. Snoek (2006) argued that the major question in psychosocial research in diabetes is not whether psychological counselling is effective to reduce HbA_{1c} *per se* but whether psychological counselling helps to improve control in poorly controlled patients (Ismail, 2006; Snoek, 2006). There are few studies to date that have examined the effectiveness of interventions that target poorly controlled adolescents, and the determinants of poor metabolic control remain unexplained.

The study points to a possible new intervention that can be implemented as part of routine care in diabetes clinics that is consistent with the high quality care specified by the NSF and NICE (2004). Despite the published guidelines (in particular clinical guideline 15 NICE, 2004) highlighting the importance of psychological issues in the care of patients with diabetes, deficiencies remain in accessing appropriate services. Psychological referral services in UK diabetes clinical remains poor (Skinner, 2004) and a recent UK survey of paediatric diabetes services (Edge et al. 2005) demonstrated the scarcity of health psychologists and mental health professionals in children's centres. The MI approach delivered within the present study has clinical applicability and has training implications for diabetes professionals.

The intervention actively mobilises the young person to make their own decisions for their health and reflects an emerging independence from clinic and parents. Service provision for children and adolescents with diabetes has improved in the UK but still lags behind our European colleagues and remains medically oriented despite clear evidence that this approach is less than helpful (Hindmarsh, 2006; Jefferson et al. 2003; Danne et al. 2001). It remains to be explored which components are the most helpful for young people and at what stage of their disease these components would be helpful in assisting them to overcome their barriers with the regimen. Specific direction is required as to how the intervention may be incorporated into diabetes services for children and young people.

12:7 Conclusion

The outcomes from the present study have demonstrated an adequately powered multi centre RCT that has confirmed the feasibility, effectiveness and consistency of MI in adolescents with type 1 diabetes. In the years since the release of the DCCT study (1994) findings, clinicians have struggled to help adolescents achieve optimal glycaemic control as close as possible to normal range. Although strict metabolic control can be achieved by intensive regimes (de Beaufort and Swift, 2006), there is great concern that such complicated regimens cannot be accomplished without sacrificing quality of life (Grey, Davidson et al. 2000).

The present study has produced some positive findings to facilitate the health of young people with type 1 diabetes. The study has adhered to the CONSORT (2001) guidelines and paid close attention to internal validity to rule out alternative

explanations for the outcomes. This is the first randomised controlled study in the adolescent diabetes field to specify clearly the independent variable under study – MI and compare to an active control condition over a longitudinal period. The findings demonstrated significant decreases in HbA_{1c} in the MI intervention group at 12 and 24 months and these changes were not linked to the changes of insulin therapy. Furthermore the results were enduring in the absence of 'booster' sessions of MI or stepped care. Given the potential benefit of enhanced glycaemic control on the future risks of developing micro vascular complications of diabetes, the results suggested that MI may be of value in addition to pharmacological developments in reducing the longer term adverse consequences of diabetes.

The gains in quality of life, some aspects of well being and personal models of diabetes are also promising. Given that diabetes places considerable demands which interfere with adolescent's psychological development and developmental tasks, then the outcomes in this intervention of enhanced psychological functioning at 12 months and the maintenance in some psychosocial areas are important findings. It is possible that enhancements in well being and quality of life may render the adolescent more able to deal with the psychological and physical demands of diabetes management through improved self care as part of a positive reciprocal cycle.

Improving quality of life represents an important clinical and behavioural outcome in the lives of adolescents with diabetes (Delamater, 2000) and the results demonstrating the predictive impact of favourable baseline quality of life and decreased metabolic control at 24 months are promising. There is a call for the routine screening of

psychological well being in diabetes clinics (Clark, 2005), which will identify those young people at risk of poor metabolic control, diabetes management and depression.

This study confirms the utility of MI as a valid intervention in young people with diabetes as an important extension to the evidence base. The flexible menu driven approach delivered has been found to be efficacious in other studies with young people experiencing illicit drug use (McCambridge and Strang, 2003) and replication of the present study is required. This will add to the growing optimism about the potential of MI, particularly with public policy concern around the need to address poorly controlled young people and the shortfall in translation of evidence in effective diabetes care delivery into practice.

Despite advances in treatment technology, the evidence suggests that psychological and emotional well being is the foundation upon which all other aspects of the treatment regimen rest. Psychosocial interventions, such as the one delivered within this study, which continue to explore the needs and experiences of young people with diabetes within a climate of collaboration, are necessary to facilitate the well being of this vulnerable population.

CHAPTER 13: REFERENCES

Aalto, A. M; Uutela, A and Aro, A. R. (2000) Disease-related distress among insulin-treated diabetic patients – Associations with health status, psychosocial factors and self-care practices. *European Journal of Public Health,* 10(1), 68–74.

Aalto, A.M; Uutela, A. and Kangas, T. (1998) Health behaviour, social integration, perceived health and dysfunction. A comparison between type I and type II diabetes and controls. *Scandinavian Journal of Social Science and Medicine, 24, 272-281.*

Aalto, A.M; Uutela, A. and Aro, A.R. (1997) Health related quality of life among insulin dependent diabetes related and psychosocial correlates. *Patient Education and Counselling,* 30, 215-225.

Aaronson, N.K. (1989) Quality of life assessment in clinical trials: Methodological issues. *Controlled Clinical Trials*, 10, 195S-208S.

Ackerman, S.J and Hilsenroth, M.J. (2003) A review of therapist characteristics and techniques positively impacting the therapeutic alliance. *Clinical Psychology Review,* 23, 1-33.

Ajzen, I. (1988) *Attitudes, Personality and Behaviour.* Milton Keynes, CA: Open University.

Albrecht, G.L. (1994) Subjective health assessment: In Jenkinson, C. (Ed). *Measuring Health and Medical Outcomes (*pp: 129-149). London: UCL.

Allison, P.J; Locker, D and Feine, J.S. (1997) Quality of life: a dynamic construct. *Social Science and Medicine,* 45(**2**), 221-30.

Altman, D.G and Schulz, K.F. (2001) Concealing treatment allocation in randomised trials. *British Medical Journal*, 323, 446-447.

Altman, D.G and Dore, C.J. (1990) Randomisation and baseline comparisons in clinical trials. *Lancet.* 335. 149-152.

American Diabetes Association. (2003) Standards of medical care for patients with diabetes mellitus. *Diabetes Care*, 26, S33–S50.

Amrhein, P.C; Miller, W.R; Yahne, C.E; Palmer, M and Fulcher, L. (2003) Client commitment language during motivational interviewing predicts drug use outcomes. *Journal of Consulting and Clinical Psychology,* 71, 862-878.

Anderson, B. J; Brackett, J; Ho, J and Laffel, L. M. (1999). An office-based intervention to maintain parent-adolescent teamwork in diabetes management: Impact on parent involvement, family conflict, and subsequent glycaemic control. *Diabetes Care,* 22, 713–721.

Anderson, B; Ho, J; Brackett, J; Finkelstein, D and Laffel, L. (1997) Parental involvement in diabetes management tasks: Relationships to blood glucose monitoring adherence and metabolic control in young adolescents with insulin-dependent diabetes mellitus. *Journal of Paediatrics,* 130, 257-265.

Anderson, B. A., Auslander, W. F; Jung, K. C; Miller, J. P, and Santiago, J. V. (1990) Assessing family sharing of diabetes responsibilities. *Journal of Paediatric Psychology*, 15, 477-492.

Anderson, B. J; Wolf, F. M; Burkhart, M. T; Cornell, R. G and Bacon, G. E. (1989) Effects of peer-group intervention on metabolic control of adolescents with IDDM: Randomized out-patient study. *Diabetes Care,* 12, 179-183.

Anderson, R.M; Funnell, M. M; Fitzgerald, J. T and Marrero, D. G. (2000) The Diabetes Empowerment Scale – A measure of psychosocial self-efficacy. *Diabetes Care,* 23(**6**), 739–743.

Anderson, R.M; Funnell, M.M; Butler, P.M; Arnold, M.S; Fitzgerald, J.T and Feste, C. (1995) Patient empowerment: results of a randomized controlled trial. *Diabetes Care* 18, 943–949.

Anderson, R.J; Freedland, K.E; Clouse, R.E and Lustman, P.J. (2001) The prevalence of co-morbid depression in adults with diabetes: a meta-analysis. *Diabetes Care*, 24(**6**), 1069-1078.

Assmann, S.F; Pocock, S.J; Enos, L.E and Kasten, L.E. (2000) Subgroup analysis and other misuses of baseline data in clinical trials. *Lancet,* 25(**355**), 1064-9.

Association for Palliative Medicine Group. (2001) THE 'WHICH TOOL' GUIDE: *Preliminary review of tools to measure clinical effectiveness in palliative care. Clinical Governance and Clinical Effectiveness Group.* Accessed online 19th November 2006: http://www.palliative-medicine.org.

Atkinson, M.A and Eisenbarth, G.S. (2001) Type 1 diabetes: new perspectives on disease pathogenesis and treatment. *Lancet.* 358(**9277**), 221-229.

Auerbach, S.M; Clore, J.N; Kiesler, D.J; Orr, T; Pegg, P.O; Quick, B.G and Wagner C. (2002) Relation of diabetic patients' health-related control appraisals and physician-patient interpersonal impacts to patients' metabolic control and satisfaction with treatment. *Journal of Behavioural Medicine,* 25(**1**), 17-31.

Baer, J and Peterson, P.L. (2002) Motivational interviewing with adolescents and young adults. In. Miller, W.R and Rollnick, S. (Eds) *Motivational Interviewing: Preparing people for change.* (2nd Edition pp: 320-332). New York: The Guildford Press.

Bagne, C.A; Luscombe. F.A; Damiano, A. (1995) Relationships between glycaemic control, diabetes-related symptoms and SF-36 scale scores in patients with non-insulin dependent diabetes mellitus. *Quality of Life Research,* 4, 392-3.

Bagozzi, R. P. and Edwards, E.A. (2000) Goal-striving and the implementation of goal intentions in the regulation of body weight. *Psychology and Health,* 15, 255-270.

Baker, A; Kochan, N; Dixon, J; Heather, N and Wodak, A. (1994) Controlled evaluation of a bried intervention for HIV prevention among injecting drug users. *AIDS Care,* 6(**5**), 559-570.

Baker, A; Heather, N; Wodak, A; Dixon, J and Holt, P. (1993) Evaluation of a cognitive-behavioural intervention for HIV prevention among injecting drug users. *AIDS,* 7, 247-256.

Bandura, A. (1997) *Self-Efficacy: The Exercise of Control.* New York: W.H. Freeman.

Bandura, A. (1986) *Social Foundations of Thought and Action.* New Jersey: Prentice Hall.

Bandura, A. (1977). Self-efficacy: Toward a unifying theory of behavioural change. *Psychological Review,* 84, 191-215.

Bandura, A. (1969) *Principles of Behaviour Modification.* London: Hope, Rinehard and Winston.

Barlow, J. H; Shaw, K. L and Southwood, T. R. (1998) Do psychosocial interventions have a role to play in paediatric rheumatology? *British Journal of Rheumatology*, 37, 573–578.

Baron, R.M and Kenny, D.A. (1986) The moderator-mediator variable distinction in social psychological research: conceptual, strategic, and statistical considerations. *Journal of Personality and Social Psychology,* 51, 1173–82.

Barber, C.J and Lowes, L. (1998) Eating disorders and adolescent diabetes: is there a link? *British Journal of Nursing,* 7(7), 398-402.

Bases, H and Schonfeld, D.J. (2002) Measurement methodology in children's health locus of control. *Journal of Developmental and Behavioural Paediatrics,* 23(3), 163-165.

Battaglia, M. R; Alemzadeh, R; Katte, H; Hall, P. L and Perlmuter, L. C. (2006). Brief Report: Disordered eating and psychosocial factors in adolescent females with type 1 diabetes mellitus. *Journal of Paediatric Psychology*, 31, 552-556.

Bauman, L.J; Drotar, D; Leventhal, J.M; Perrin, E.C and Pless, I.B. (1997) Psychosocial interventions for children with chronic health conditions. *Pediatrics*, 100(2), 244-251.

Baumer, J. H; Hunt, L.P and Shield, J.P.H (1998). Social disadvantage, family composition, and diabetes mellitus: prevalence and outcome. *Archives of Disease in Childhood*, 79(5), 427-430.

BBC News. (2004) *Wales on child poverty map.* Monday 13th December 2004. Accessed online 30th October 2006: http://www.bbc.co.uk.

Beale, I. L. (2006) Scholarly literature review: Efficacy of psychological interventions for paediatric chronic illness. *Journal of Paediatric Psychology*, 31(**5**), 437-451.

Beeney L.J; Dunn S.M and Welch G. (1994) Measurement of diabetes knowledge — the development of the DKN scales. In. Bradley, C (Ed). *Handbook of Psychology and Diabetes: A Guide to Psychological Measurement in Diabetes Research and Practice* (pp: 159-189). Chur, Switzerland: Harwood Academic.

Benjamin, E. M. (2002) Self-monitoring of blood glucose: The basics. *Clinical Diabetes* 20, 45-47.

Bennett, P; Norman, P; Murphy, S; Moore, L and Tudor-Smith, C. (1998) Beliefs about alcohol, health locus of control, value for health and reported consumption in a representative population sample. *Health Education Research.* 13(**1**), 25-32.

Bennett, P; Norman, P; Moore, L; Murphy, S and Tudor-Smith, C. (1997) Health locus of control and value for health in smokers and non-smokers. *Health Psychology*, 16(**2**), 179-182.

Berg, A.T and Vickrey, B.G. (1994) Outcomes research. *Science,* 264(**5160**), 757-8.

Berg-Smith, D.E; Heckemeyer, C.M; Kratt, P.P and Mason, D.E. (1997) Motivational interviewing to improve adherence to a behavioural weight control program for older obese women with NIIDDM. A pilot study. *Diabetes Care*, 20(**1**), 53-54.

Bergenstal, R; Callahan, P; Johnson, M, Upham, P; Hollander, P; Spencer, M and Castle, G. (1996) Management principles that most influence glycaemic control: a follow up study of former DCCT participants. *Diabetes,* 45 (Supplement 2). 124A. (Abstract).

Berkovitch, M; Papadouris, D; Shaw, D; Onuaha, N; Dias, C and Olivieri, N. F. (1998). Trying to improve compliance with prophylactic penicillin therapy in children with sickle cell disease. *British Journal of Clinical Pharmacology*, 45, 605-607.

Betts, P.R and Swift, P.G.F. (2003) Doctor, who will be looking after my child's diabetes? *Archives of Disease in Childhood*, 88, 6-7.

Blake, K.D; Gusella, J; Greaven, S and Wakefield, S. (2006) The risks and benefits of being a young female adolescent standardized patient. *Medical Education,* 40, 26-35.

Blake, K.D; Mann, K; Kaufman, D and Kappleman, M. (2000) Learning adolescent psychosocial interviewing using simulated patients. *Academic Medicine,* 75(**10**), 556–558.

Bland, M. (2002) *An Introduction to Medical Statistics*, 3rd Edition. Oxford: Oxford University Press.

Boardway, R. H; Delamater, A. M; Tomakowsky, J and Gutai, J. P. (1993). Stress management training for adolescents with diabetes. *Journal of Paediatric Psychology*, 18, 29-45.

Boland, E.A; Grey, M; Oesterle, A; Fredickson, L; Tamborlane, W.V. (1999) Continuous subcutaneous insulin infusion: a new way to lower risk of severe hypoglycaemia, improve metabolic control, and enhance coping in adolescents with type 1 diabetes. *Diabetes Care*, 22, 1779-1784.

Bond, G. G; Aiken, L. S and Somerville, S. C. (1992) The Health Belief Model and adolescents with insulin-dependent diabetes mellitus. *Health Psychology,* 11(**3**), 190–198.

Bonetti, D; Eccles, M; Johnston, M; Steen, N; Grimshaw, J; Baker, R; Walker, A and Pitts, N. (2005) Guiding the design and selection of interventions to influence the implementation of evidence based practice: An experimental simulation of a complex intervention trial. *Social Science and Medicine*, 60, 2135-2147.

Borch-Johnsen, K; Kreiner, S and Deckert, T. (1986) Mortality of type 1 (insulin-dependent) diabetes mellitus in Denmark: a study of relative mortality in 2930 Danish type 1 diabetic patients diagnosed from 1933 to 1972. *Diabetologia,* 29(**11**), 767-72.

Bowerman, B.L and O'Connell, R.T (1990) *Linear Statistical Models: an applied approach,* 2nd Edition. Belmont, California: Duxbury.

Bowling, A. (2005) Just one question: If one question works why ask several? *Journal of Epidemiology and Community Health,* 59, 342-345.

Bowling. A. (1997) *Measuring Health: A Review of Quality of Life Measurement Scales*, 2nd Edition. Buckingham: Open University.

Box, G.E.P and Draper, N.R (1998) *Evolutionary Operation: a statistical method for process measurement.* New York: Wiley.

Bradburn, N. (1969) *The Structure of Psychological Well-Being.* Chicago: Aldine Publishing.

Bradley, C. (1994). *Handbook of Psychology and Diabetes: A Guide to Psychological Measurement in Diabetes Research and Practice.* Chur, Switzerland: Harwood Academic.

Bradley, C and Gamsu, D.S. (1994) Guidelines for encouraging psychological well being: Report of a working group of the World Health Organization Regional Office for Europe and International Diabetes Federation European Region St Vincent Declaration Action Programme for Diabetes, *Diabetic Medicine,* 11, 510–516.

Bradley, C; Todd C; Gorton T; Symonds, E; Martin, A and Plowright, R. (1999) The development of an individualized questionnaire measure of perceived impact of diabetes on quality of life: the ADDQoL. *Quality of Life Research,* 99(**8**), 79-91.

Bradley, C and Lewis, K.S. (1990) Measures of psychological well-being and treatment satisfaction developed from the responses of people with tablet-treated diabetes. *Diabetic Medicine*, 7(**5**), 445-51.

Bradley, F; Wiles, R; Kinmonth, A-L; Mant, D and Gantley, M. (1999) Development and evaluation of complex interventions in health services research: Case study of the Southampton heart integrated care project (SHIP). *British Medical Journal,* 318, 711-715.

Brewin, C.R and Bradley, C. (1989) Patient preferences and randomised controlled trials. *British Medical Journal,* 299, 313-315.

Brink, S. J. (1995) Presentation and ketoacidosis. In Kelnar, C.J.H. (Ed). *Childhood and Adolescent Diabetes* (pp: 213-240). London: Chapman and Hall Medical.

Brookes, S.T; Whitley, E; Peters, T.J; Mulheran, P.A; Egger, M and Davey-Smith, G. (2001) Sub-group analyses in randomised controlled trials: quantifying the risks of false-positives and false-negatives. *Health Technology Assessment*, 5(**3**), 1-56. HTA.

Brown, R.A; Ramsey, S.E; Strong, D.R; Myers, M.G; Kahler, C.W; Lejuez, C.W Niaura, R; Pallonen, U.E Kazura, A.N; Goldstein, M.G and Abrams, D.B. (2003) Effects of motivational interviewing on smoking cessation in adolescents with psychiatric disorders. *Tobacco Control*, 12 (Supplement 4:IV3-10).

Brown, S. J. (1999) Patient centred communication. *Annual Review of Nursing Research*, 17, 85-104.

Brown, S.A. (1992) Meta analysis of diabetes patient education research: Variations in interventions across studies. *Research in Nursing and Health*, 15, 409-419.

Brown, S.A. (1990). Effects of educational interventions in diabetes care: A meta-analysis of findings. *Nursing Research*, 37(**4**), 223-230.

Bryden, K.S; Dunger, D.B; Mayou, R.A; , Peveler, R.C and Neil, H.A. (2003) Poor prognosis of young adults with type 1 diabetes: a longitudinal study. *Diabetes Care* 26, 1052–1057.

Bryden, K.S; Peveler, R.C; Stein, A; Neil, A; Mayou, R.A and Dunger, D.B. (2001) Clinical and psychological course of diabetes from adolescence to young adulthood: a longitudinal cohort study. *Diabetes Care* 24(**9**), 1536–1540.

Burke, B. L; Dunn, C. W; Atkins, D and Phelps, J. S. (2004) The emerging evidence base for motivational interviewing: A meta-analytic and qualitative inquiry. *Journal of Cognitive Psychotherapy*, 18, 309-322.

Burke, B. L; Arkowitz, H and Menchola, M. (2003) The efficacy of motivational interviewing: a meta-analysis of controlled clinical trials. *Journal of Consulting and Clinical Psychology.* 71, 843–861.

Burke, B. L; Arkowitz, H and Dunn, C. (2002) The efficacy of motivational interviewing. In. Miller, W.R and Rollnick, S. (Eds), *Motivational Interviewing: Preparing people for change* (2nd Edition, pp: 217-250). New York: The Guilford Press.

Burroughs, T. E; Harris, M. A; Pontious, S. L and Santiago, J. V. (1997). Research on social support in adolescents with IDDM: A critical review. *Diabetes Educator*, 23, 438-448.

Butler, C.C; Rollnick, S; Cohen, D; Bachman, M Russell, I and Stott, N. (1999) Motivational Interviewing versus brief advice for smokers in general practice: a randomised trial. *British Journal of General Practice.* 49(**445**), 611-616.

Byrne, M; Cupples, M.E; Smith, S.M; Leathem, C; Corrigan, M; Byrne, M.C and Murphy, A.W. (2006) Development of a complex intervention for secondary prevention of coronary heart disease in primary care using the UK Medical Research Council Framework. *The American Journal of Managed Care,* 12(**5**) 261-266.

Cameron, F.J. (2003) The impact of diabetes on health-related quality of life in children and adolescents. *Paediatric Diabetes,* 4(**3**), 132- 136.

Canto, J.G; Kiefe, C.I; Williams, D; Barron, H.V and Rogers, W.J. (1999) Comparison of outcomes research with clinical trials using pre-existing data. *The American Journal of Cardiology,* 84, 15 923-927.

Cecero, J.J; Fenton, L.R; Frankforter, T.L; Nich, C and Carroll, K.M. (2001) Focus on therapeutic alliance: The psychometric properties of six measures across three treatments. *Psychotherapy*, 38(**1**), 1-11.

Chambless, D. L and Ollendick, T. H. (2001). Empirically supported psychological interventions: Controversies and evidence. *Annual Review of Psychology*, 52, 685-716.

Chambliss, C.A and. Murray, E.J. (1979) Efficacy attribution, locus of control, and weight loss. *Cognitive Therapy and Research,* 3(**4**), 349-353.

Channon, S; Huws-Thomas, M.V; Gregory, J.W and Rollnick, S. (2005) Motivational interviewing with teenagers with diabetes. *Clinical Child Psychology and Psychiatry*, 10(**1**), 43-51.

Channon, S; Smith, V and Gregory, J. (2003) A pilot study of motivational interviewing in adolescents with diabetes. *Archives of Disease in Childhood*, 88, 680-683.

Clay, D.L. (2000) Commentary: Rethinking our interventions in paediatric chronic pain and treatment research. *Journal of Paediatric Psychology,* 25(**1**), 53-55.

Clark. M. (2005) 'The long and winding road'...The 2005 Mary MacKinnon Lecture. *Practical Diabetes International*, 23(**2**), 69-74.

Clark, M and Hampson, S.E. (2001) Implementing a psychological intervention to improve lifestyle self-management in patients with type 2 diabetes. *Patient Education and Counselling*, 42(**3**), 247-256.

Coates, V. E and Boore, J. R. P. (1998) The influence of psychological factors on the self-management of insulin-dependent diabetes mellitus. *Journal of Advanced Nursing*, 27(**3**), 528–537.

Cohen, M.Z; Tripp-Reimer T, Smith, C; Sorofman, B and Lively, S. (1994) Explanatory models of diabetes: patient practitioner variation. *Social Science and Medicine,* 38, 59–66.

Cohen, J. (1988) *Statistical power analysis for the behavioural sciences,* 2nd edition. Hillsdale, NJ: Lawrence Erlbaum.

Colby, S.M; Monti, P.M; Barnett N, P; Rohsenow, D.J; Weissman, K; Spirito, A; Woolard, R.H and Lewander W.J. (1998) Brief motivational interviewing in a hospital setting for adolescent smoking: a preliminary study. *Journal of Consulting and Clinical Psychology*, 66(**3**), 574-8.

Connis, R.T; Taylor, T.R; Gordon, M.J; Mecklenburg, R.S; Liljenquist, J.E; Stephens, J.W and Baker, M.S. (1989) Changes in cognitive and social functioning of diabetic patients following initiation of insulin infusion therapy. *Experimental Ageing Research*, 15, 51–60.

Connor, M and Norman, P. (1995) *Predicting Health Behaviour: Research and Practice with Social Cognition Models.* Buckingham: Open University.

Consititution of the World Health Organisation (1952) Handbook of Basic Documents, *World Health Organisation*, 5th Edition. Geneva: Palais des Nations.

Conway, V. J and Terry, D.J (1992) Appraised controllability as a moderator of the effectiveness of different coping strategies. A test of the goodness of fit hypothesis. *Australian Journal of Psychology,* 44, 1-7.

Cook, S; Herold, K; Edidin, D.V; Briars R. (2002) Increasing problem solving in adolescents with type 1 diabetes: the choices diabetes program. *Diabetes Educator,* 28, 115-24.

Cooper, Z and Fairburn, C (1987) The eating disorder examination: A semi-structured interview for the assessment of the specific psychopathology of eating disorders. *International Journal of Eating Disorders*, 6(**1**), 1-8.

Costa, F. M; Jessor, R. and Donovan, J. E. (1989) Value on health and adolescent conventionality: A construct validation of a new measure in Problem-Behaviour Theory. *Journal of Applied Social Psychology*, 19, 841-861.

Couper, J.J; Taylor, J, Fotheringham, M.J; Sawyer M. (1999) Failure to maintain the benefits of home-based intervention in adolescents with poorly controlled type 1 diabetes. *Diabetes Care*, 22, 1933-7.

Cox, D.J; Gonder-Frederick, L.A; Polonsky, W, Schlundt, D; Julian, D and Clarke W. (1995) A multi centre evaluation of Blood Glucose Awareness Training-II. *Diabetes Care* 18, 523 –528.

Cradock, S. (2004) Helping patients to improve self management of diabetes. *Heart Online,* Volume 90, iv 36. Accessed online 20th October 2006: http://heart.bmj.com/cgi/content/full/90/supp:l_4/iv36

Cronbach L.J. (1951) Coefficient alpha and the internal structure of tests. *Psychometrika*, 16, 297–334.

Cross, M.J; March, L.M; Lapsley, H.M; Byrne, E and Brooks, P.M. (2006) Patient self-efficacy and health locus of control: relationships with health status and arthritis-related expenditure. *Rheumatology,* 45(**1**), 92-99.

D'Alessandro, D.M and Dosa, N.P. (2001) Empowering children and families with information technology. *Archives of Paediatric and Adolescent Medicine*, 155, 1131-1136.

Dabadghoa, P; Vidmar, S and Cameron, F.J. (2001) Deteriorating diabetic control through adolescence - do the origins lie in childhood? *Diabetic Medicine,* 18, 889-894.

Dahl-Jørgensen, K; Swift, P; Kida, K and Hanas, R. (2002) *Global standardisation and harmonisation of* HbA_{1c}. International Society for Paediatric and Adolescent Diabetes (ISPAD). Accessed online August 2003: http://www.ispad.org

Dahlquist, G and Källén, B. (2005) Mortality in childhood-onset type 1 diabetes A population-based study. *Diabetes Care,* 28, 2384-2387.

Danne, T; Mortensen, H.K; Hougaard, P for the Hvidøre study group (2001) Persistent differences among centres in glycaemic control and hypoglycaemia in a study of 3,805 children and adolescents with type 1 diabetes from the Hvidøre study group. *Diabetes Care*, 24, 1342-1347.

Daneman, D. (2006) Type 1 diabetes. *Lancet,* 367(**9513**), 847-858.

Daneman, D. (2005) Early diabetes-related complications in adolescents. *Hormone Research,* 63, 75-85.

Daneman, D; Olmsted, M; Rydall, A; Maharaj, S and Rodin, G. (1998) Eating disorders in young women with type 1 diabetes: Prevalence, problems and prevention. *Hormone Research*, 50, 79-86.

Davey - Smith, G and Ebrahim, S. (2003) 'Mendelian randomization': can genetic epidemiology contribute to understanding environmental determinants of disease? *International Journal of Epidemiology,* 32, 1-22.

Davis, W.K; Hess, G.E and Hiss, R.G. (1988) psychosocial correlates of survival in diabetes. *Diabetes Care*, 11(7), 538-545.

Daviss, WB, Coon, H, Whitehead, P, Ryan, K, Burkley, M, McMahon, W (1995) Predicting diabetic control from competence, adherence, adjustment, and psychopathology. *Journal of the American Academy of Child and Adolescent Psychiatry,* 34, 1629-1636.

DCCT Research Group (1995) The relationship of glycaemic exposure (HbA_{1c}) to the risk of development and progression of retinopathy in the diabetes control and complications trial. *Diabetes,* 44, 968-983.

DCCT Research Group (1994). Effect of intensive diabetes treatment on the development and progression of long-term complications in adolescents with insulin-dependent diabetes mellitus: Diabetes Control and Complications Trial. *Journal of Paediatrics,* 125, 177 –188.

DCCT Research Group (1993). Diabetes Control and Complications Trial (DCCT): The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. *New England Journal of Medicine*, 329, 977-986.

DCCT Research Group (1988) Reliability and validity of a diabetes quality-of-life measure for the Diabetes Control and Complications Trial (DCCT). *Diabetes Care*, 11, 723-732.

Deakin, T; McShane, C.E; Cade, J.E; Williams, R.D.R.R. (2005) Group based training for self-management strategies in people with type 2 diabetes mellitus. *The Cochrane Database of Systematic Reviews* 2007. Issue 1. The Cochrane Collaboration: John Wiley and Sons.

de Beaufort, C and Swift, P. (2006) Support for young people with diabetes. Reducing psychological distress may improve metabolic control. *British Medical Journal,* 333, 55-56.

Deci, E.L and Ryan, R.M. (1985) *Intrinsic motivation and self determination in human behaviour.* New York: Plenum Press.
Delamater, A.M; Jacobson, A.M; Anderson, B; Cox, D; Fisher, L; Lustman, P; Rubin, R and Wysocki, T. (2001) Psychosocial therapies in diabetes. *Diabetes Care,* 24, 1286-1292.

Delamater A. M. (2000) Quality of life in youths with diabetes. *Diabetes Spectrum,* 13, 23-27.

Delamater, A. M; Shaw, K; Applegate, B; Pratt, I; Eidson, M; Lancelotta, G; Gonzalez-Mendoza, L and Richton, S. (1999) Risk for metabolic control problems in minority youths with diabetes. *Diabetes Care,* 22(**5**), 700-705

Department of Health (2005a) *Turning the Corner: Improving Diabetes Care*: Report from Dr Sue Roberts National Clinical Director for Diabetes to the Secretary of State for Health. Accessed online 26th August 2006:

Department of Health (2005b) *Improving Diabetes Services – The NSF two years on.* Accessed online 1st October 2006: http://www.dh.gov.uk/PublicationsAndStatistics http://www.dh.gov.uk/PublicationsAndStatistics/Publications

Department of Health (2004) *National Service Framework for Children, Young People and Maternity Services.* National Standards Framework: Accessed online 20th November 2006: http://www.dh.gov.uk/PublicationsAndStatistics

Department of Health (2002) *National Service Framework for Diabetes: standards.* National Standards Framework: Accessed online 20th November 2006: http://www.dh.gov.uk/PublicationsAndStatistics

DERI Mortality Study Group; Tuomilehto, J; Lounamaa, R; Lounamaa, P and Tuomilehto-Wolf, E. (1991) International evaluation of cause-specific mortality and IDDM. *Diabetes Care,* 14, 55-60.

Derogatis, L. R. (1994) Symptom Checklist 90-R: *Administration, Scoring and Procedures.* Minneapolis: National Computer Systems.

Derogatis, L.R. (1986) The psychosocial adjustment to illness scale (PAIS). *Journal of Psychosomatic Research.* 30(**1**), 77-91.

Devendra, D; Liu, E and Eisenbarth, G.S. (2004) Type 1 diabetes: recent developments. *British Medical Journal,* 328, 750-754.

DeVries, J.H; Snoek, F.J and Heine, R.J. (2004) Persistent poor glycaemic control in adult type 1 diabetes. A closer look at the problem. *Diabetic Medicine*, 21(**12**), 1263-1268.

de Wit, M et al. (work in progress) *Monitoring Health-Related Quality of Life In Adolescents With Type 1 Diabetes Prior To Periodic Outpatient Consultation: Impact On Psychosocial Adaptation, Satisfaction With Care and Glycaemic Control. A Randomised Controlled Cross-Over Study.* VU University Medical Center, EMGO-Institute. Accessed online from the Netherlands Trial Register: Accessed online 29th November 2006:http://www.trialregister.nl/trialreg/admin/rctview.

DIABAUD 2: Scottish Study Group For the Care of the Young Diabetic (2001) Factors influencing glycaemic control in young people with type 1 diabetes in Scotland: A population based study (DIABAUD2). *Diabetes Care*, 24(**2**), 239-244.

Diabetes UK report (2005) *Diabetes: State of the Nations.* Progress made in delivering the National Service Frameworks. A report from Diabetes UK. All Party Parliamentary Group for Diabetes: Hansard Society. Accessed online 1st December 2006: http://www.diabetes.nhs.uk/downloads/StateOfNations.pdf

Dickinson, J.K and O'Reilly, M.M. (2004) The lived experience of adolescent females with type 1 diabetes. *The Diabetes Educator*, 30(**1**), 99-107.

DiClemente, C.C and Velasquez, M.M. (2002) Motivational interviewing and the stages of change. In Miller, W.R and Rollnick, S. (Eds.) *Motivational Interviewing, Second Edition: Preparing People for Change.* (2nd Edition pp: 201- 216). New York: The Guilford Press.

Domargard, A; Sarnblad, S; Kroon, M; Karlsson, I; Skeppner, G and Aman, J. (1999) Increased prevalence of overweight in adolescent girls with type 1 diabetes mellitus. *Acta Paediatrica*, 88, 1223-1228.

Dorchy, H. (2000) Insulin regimens and insulin adjustments in diabetic children, adolescents and young adults: personal experience. *Diabetes and Metabolism*, 26(**6**), 500-507.

Dorchy, H; Roggemans, M.P and Willems, D. (1997) Glycated haemoglobin and related factors in diabetic children and adolescents under 18 years of age: a Belgian experience. *Diabetes Care,* 20, 2–6.

Dorman, J.S; Laporte, R.E; Kuller, L.H; Cruickshanks, K.J; Orchard, T.J; Wagener, D.K; Becker, D.J; Cavender, D.E and Drash, A.L. (1984) The Pittsburgh insulin-dependent diabetes mellitus (IDDM) morbidity and mortality study. Mortality results. *Diabetes,* 33(**3**), 271-276.

Draycott, S and Dabbs, A. (1998) Cognitive dissonance 2: A theoretical grounding of motivational interviewing. *British Journal of Clinical Psychology*, 37(**3**), 355-36

Drotar, D. (2006) Commentary: Revising behavioural family systems therapy to enhance treatment adherence. *Journal of Paediatric Psychology*, 3(**9**), 939-944.

Drotar, D. (1997) Relating parent and family functioning to the psychological adjustment of children with chronic health conditions: What have we learned? What do we need to know? *Journal of Paediatric Psychology* 22(**2**), 149-165.

Dunger, D.B. (1992) Diabetes in puberty. *Archives of Disease in Childhood.* 67, 569–570.

Dunn, C; Deroo, L, and Rivara, F. (2001) The use of brief interventions adapted from motivational interviewing across behavioural domains: A systematic review. *Addiction*, 96, 1725-1742.

Dunn, S.M; Beeney, L.Y; Hoskins, P.L and Turtle, J.R. (1990) Knowledge and attitude change as predictors of metabolic improvement in diabetes education. *Social Science and Medicine*, 31(**10**), 1135-1141.

Dunn, S.M; Bryson, J.M; Hoskins, P.L; Alford, J.B; Handelsman, D.J; Turtle, J.R (1984) Development of the Diabetes Knowledge (DKN) Scales: forms DKNA, DKNB and DKNC. *Diabetes Care,* 7(**1**), 36-41.

Dworetsky, J.P. (1995) *Human development: A life span approach*, 2nd Edition. New York: West.

Dyrløv, K; Povlsen,L; Solvkær, L; Marinelli, K; Olsen, B; Hougaard P and Mortensen, H.B. (2000) Improving the outcome for children and adolescents with type 1 diabetes: results of a changing service in Copenhagen. *Practical Diabetes International*, 17, 17-25.

Edgar, K.A and Skinner, T.C. (2003) Illness representations and coping as predictors of well being in adolescents with type 1 diabetes. *Journal of Paediatric Psychology,* 28(7), 485-493.

Edge, J.A; Swift. P.G.F; Anderson, W; Turner, B on behalf of the Youth and Family Advisory Committee of Diabetes UK (2005) Diabetes services in the UK: fourth national survey; are we meeting NSF standards and NICE guidelines? *Archives of Disease in Childhood,* 90, 1005-1009.

EDIC Research Group. (2003) The Writing Team for the Diabetes Control and Complications Trial/Epidemiology of Diabetes Interventions and Complications Research Group. Sustained effect of intensive treatment of type 1 diabetes mellitus on development and progression of diabetic nephropathy. The Epidemiology of Diabetes Interventions and Complications (EDIC) Study. *Journal of the American Medical Association,* 290, 2159-67.

Edwards, P; Cooper, R; Roberts, I and Frost, C. (2005) Meta analysis of randomised trials of monetary incentives and response to mailed questionnaires. *Journal of Epidemiology and Community Health*, 59, 987-999.

Eiser, C and Morse, R. (2001) Quality of life measures in chronic diseases of childhood. *Health Technology Assessment,* 5(**4**), HTA: HMSO.

Eiser, C. (1990) Psychological effects of chronic disease. *Journal of Clinical Nursing,* 9(**4**), 549-556.

Ellis, D.A; Frey, M.A; Naar-King, S; Templin, T; Cunningham, P.B and Cakan, N. (2005) The effects of multi-systemic therapy on diabetes stress among adolescents with chronically poorly controlled type 1 diabetes: Findings from a randomized, controlled trial. *Paediatrics,* 116(**6**), 826-832.

Ellis, S.E; Speroff, T; Dittus, R.S; Brown, A; Pichert, J.W and Elasy, T.A. (2004) Diabetes patient education: a meta-analysis and meta-regression. *Evidence Based Nursing,* 52(**1**), 97-105.

Etter, J.F and Sutton, S. (2002) Assessing 'stage of change' in current and former smokers. *Addiction,* 97, 1171-1182.

EURODIAB ACE study group (2000) Variation and trends in incidence of childhood diabetes in Europe. *Lancet*, 355, 873-876.

Evans, C.L and Hughes, I.A. (1987) The relationship between diabetic control and individual and family characteristics. Journal of Psychosomatic Research. 31(**3**), 367-374.

Fairburn, C.G; Peveler, R.C; Davies, B; Mann, J.I and Mayou, R.A. (1991) Eating disorders in young adults with insulin dependent diabetes mellitus: a controlled study. *British Medical Journal,* 303, 17–20.

Fan, X; Miller, B.C; Park, K.E; Winward, B.W; Christensen, M; Grotevant, H.D and Tai, R.H.g (2006) An exploratory study about inaccuracy and invalidity in adolescent self-report surveys. *Field Methods,* 18(**3**), 223-244.

Faulkner, M.S. (2003) Quality of life for adolescents with type 1 diabetes: Parental and youth perspectives. *Paediatric Nursing,* 29(**5**), 362-368.

Faro, B. (1999) The effects of diabetes on adolescents' quality of life. *Paediatric Nursing*, 25(**3**), 247-254.

Feltbower, R.G; McKinney, P.A; Parslow, R.C; Stephenson, C.R and Bodansky, H.J. (2003) Type 1 diabetes in Yorkshire, UK: time trends in 0-14 and 15-29 year olds, age at onset and age-period-cohort modelling. *Diabetic Medicine*, 20, 437-441.

Ferraro, L. A; Price, J. H; Desmond, S. M and Roberts, S. M. (1987) Development of a Diabetes Locus of Control Scale. *Psychological Reports,* 61, 763–770.

Field, A. P. (2005) *Discovering Statistics using SPSS*, 2nd Edition, London: Sage.

Field, L.L. (2002) Genetic linkage and association studies of type I diabetes: challenges and rewards. *Diabetologia,* 45, 21-35.

Fielding, D and Duff, A. (1999) Compliance with treatment protocols: interventions for children with chronic illness. *Archives of Disease in Childhood,* 80, 196-200.

Fisher, D; Stewart, A.L; Bloch, D.A; Lorig, K; Laurent, D and Holman, H. (1999) Capturing the patient's view of change as a clinical outcome measure. *Journal of the American Medical Association,* 12(**282**), 1157-1162.

Fox, L.A; Buckloh, L.M; Smith, S.D; Wysocki, T and Mauras, N. (2005) A randomized controlled trial of insulin pump therapy in young children with type 1 diabetes. *Diabetes Care,* 28, 1277-1281.

Franklin, V.L; Waller, Pagliari, A.C and Greene, S.A. (2006) A randomized controlled trial of Sweet Talk, a text-messaging system to support young people with diabetes. *Diabetic Medicine*, 23(**12**), 1332–1338.
Accessed online 25th November 2006: doi:10.1111/j.1464-5491.2006.01989.x

Frey, M.A; Ellis, D; Naar-King, S and Greger, N. (2004) Diabetes management in adolescents in poor metabolic control. *The Diabetes Educator,* 30(**4**), 647 - 657.

Garcia, A.A; Villagomez, E.T; Brown, S.A; Kouzekanani, K and Hanis, C.L. (2001) The Starr County Diabetes Education Study: Development of the Spanish-language diabetes knowledge questionnaire. *Diabetes Care,* 24, 16-21.

Garrett, A.M; Schmidt, L and Fitzpatrick, R. (2002) Patient assessed health outcome measures for diabetes: a structured review. *Diabetic Medicine,* 19, 1-11.

Glasgow R.E; Toobert, D.J and Gillette, R.D. (2001) Psychosocial barriers to diabetes Self management and quality of life. *Diabetes Spectrum*, 14(**1**), 33-41.

Glasgow, R.E and Anderson, R.M. (1999) In diabetes care, moving from compliance to adherence is not enough: Something entirely different is needed (Letter). *Diabetes Care,* 22(**12**), 2090 -2092.

Glasgow, R.E; Vogt, T.M and Boles, S.M. (1999) Evaluating the public health impact of health promotion interventions: the RE-AIM framework. *American Journal of Public Health*, 89(**9**), 1322–1327.

Glasgow, R. E; Strycker, L. A; Hampson, S. E Ruggiero, L. (1997). Personal-model beliefs and social environmental barriers related to diabetes self-management. *Diabetes Care,* 20(**4**), 556–561.

Glasgow, R.E and Anderson, B.J. (1995) Future directions for research on paediatric chronic disease management: Lessons from diabetes. *Journal of Paediatric Psychology*, 20(**4**), 389-402.

Glasgow, R.E Osteen, V.L. (1992) Evaluating diabetes education. Are we measuring the most important outcomes? *Diabetes Care,* 15(**10**), 1423–1432.

Glasgow, R.E; Toobert, D.J and Hampson, S.E. (1991) Participation in outpatient diabetes education programs: How many patients take part and how representative are they? *Diabetes Educator,* 17, 376-380.

Gollwitzer, P.M; and Branstätter, V. (1997) Implementation intentions and effective goal pursuit. *Journal of Personality and Social Psychology,* 73, 186-199.

Goran, M.I and. Gower, B.A. (2001) Longitudinal study on pubertal insulin resistance *Diabetes,* 50, 2444-2450.

Gramstad, A; Iversen, E and Berna, A.E. (2001) The impact of affectivity dispositions, self efficacy and locus of control on psychosocial adjustment in patients with epilepsy. *Epilepsy Research,* 46, 53–61.

Graue, M; Wentzel-Larsen, T; Bru, E; Hanestad, B.R and Sovik, O. (2004) The coping styles of adolescents with type 1 diabetes are associated with degree of metabolic control. *Diabetes Care,* 27, 1313 -1317.

Graue, M; Wentzel-Larsen, T; Hanestad, B.R; Båtsvik, B and Søvik, O. (2003) Measuring self-reported, health-related, quality of life in adolescents with type 1 diabetes using both generic and disease-specific instruments *Acta Paediatrica,* 92, (**10**), 1190-1196.

Gray, A; Fenn, P and McGuire, A. (1993) The cost of insulin-dependent diabetes mellitus (IDDM) in England and Wales. *Diabetic Medicine*, 12, 1068–1076.

Greco, P; Shroff Pendley, J; McDonell, K; Reeves, G. (2001) Peer group intervention for adolescents with type 1 diabetes and their best friends. *Journal of Paediatric Psychology*, 26(**8**), 485-490.

Green S.B. (1991) How many subjects does it take to do a regression analysis? *Multivariate Behavioural Research*, 26(**3**), 499-510.

Greene, S.A. on behalf of the Scottish Study Group for the Care of Diabetes in the Young (2006) A longitudinal observational study of insulin therapy and glycaemic control across the population of Scottish children with type 1 diabetes: DIABAUD 3. *Diabetic Medicine,* 23, 834-838.

Greening, L; Stoppelbein, L and Reeves, C.B. (2006) A model for promoting adolescents' adherence to treatment for type 1 diabetes mellitus. *Children's Health Care,* 35(**3**), 247-267.

Gregory, J.W; Robling, M; Rollnick, S; Hood, Channon, C; K; Lowes, L et al. (work in progress) *Development and evaluation of a psychosocial intervention for children and teenagers experiencing diabetes* (The DEPICTED Study). Wales College of Medicine, Cardiff University. Accessed online 20th November 2006: http://www.ncchta.org

Grey, M; Davidson, M; Boland, E.A and Tamborlane, W.V. (2001) Clinical and psychosocial factors associated with achievement of treatment goals in adolescents with diabetes mellitus. *Journal of Adolescent Health,* 28(**5**), 377-385.

Grey, M; Boland, E.A; Davidson, M; Li, J and Tamborlane, W.V. (2000) Coping skills training for youth with diabetes mellitus has long lasting effects on metabolic control and quality of life. *Journal of Paediatrics,* 137, 107-113.

Grey, M; Boland, E.A and Tamborlane, W.V. (1999) Use of Lispro insulin and quality of life in adolescents on intensive therapy. *The Diabetes Educator,* 25(**6**), 934-941.

Grey, M; Boland, E.A; Davidson, M; Yu, C; Sullivan-Bolyai, S and Tamborlane, W.V. (1998) Short term effects of coping skills training as adjunct to intensive therapy in adolescents. *Diabetes Care*, 21(**6**), 902-908.

Grey M, Boland E. A, Yu, C, Sullivan-Bolyai, S, and Tamborlane, W.V. (1998) Personal and family factors associated with quality of life in adolescents with diabetes. *Diabetes Care,* 21(**6**), 909-14.

Grey, M; Cameron, M. E and Thurber, F. W. (1991) Coping and adaptation in children with diabetes. *Nursing Research,* 40, 144 –149.

Griffin, S.J; Kinmonth, A.L; Marijcke, W.M; Gillard, S; Grant, J and Stewart, M. (2004) Effect on health related outcomes of interventions to alter the interactions between patients and practitioners: A systematic review of trials. *Annals of Family Medicine*, 2, 595-608.

Griffin, S.J; Kinmonth, A.L; Skinner, C and Kelly, J. (1999) *Educational and psychosocial interventions for adults with diabetes. A survey of the range and types of interventions, the extent to which they have been evaluated in controlled trials and a description of their relative effectiveness as reported in existing reviews.* London: British Diabetic Association, 1998. Accessed online July 2005: http://www.diabetes.org.

Gross, A.M; Deicher, H.K Snitzer, J; Bianchi, B and Epstein, S. (1985) Personality variables and metabolic control in children with diabetes. *Journal of Genetics and Psychology,* 146(**1**), 19-26.

Gross, A. M; Heimann, L; Shapiro, R and Schultz, R. M. (1983) Children with diabetes: Social skills training and haemoglobin A1c levels. *Behaviour Modification,* 7, 151-164.

Grossman, H.Y; Brink, S and Hauser, S.T. (1987) Self Efficacy in adolescent girls and boys with insulin dependent diabetes mellitus. *Diabetes Care,* 10, 324-329.

Gulliver, S.B; Hughes, J.R; Solomon, L.J and Dey, A.N. (1995) An investigation of self-efficacy, partner support and daily stresses as predictors of relapse to smoking in self-quitters. *Addiction,* 90(**6**), 767- 772.

Gutgesell, M and Payne, N. (2004) Issues of adolescent psychological development in the 21st Century. *Paediatrics in Review*, 25, 79-85.

Guthrie, D.W; Bartsocas, C; Jarosz-Chabot, P and Konstantinova, M. (2003) Psychosocial issues for children and adolescents with diabetes: Overview and recommendations. *Diabetes Spectrum* 16, 7-12.

Guttmann-Bauman, I; Flaherty B,P; Strugger M and McEvoy, R,C. (1998) Metabolic control and quality of life assessment in adolescents with IDDM. *Diabetes Care,* 21, 915-18.

Hains, A.A; Berlin, K.S; Hobart Davies, M.S.W; Parton, E.A and Alemzadeh, R. (2006). Attributions of adolescents with type 1 diabetes in social situations: Relationship with expected adherence, diabetes stress, and metabolic control. *Diabetes Care,* 29, 818-822.

Haire-Joshu, D; Glasgow, R.E and Tibbs, T.L. (1999) Smoking and diabetes. *Diabetes Care*, 22(11), 1887-1898.

Hamilton, J and Daneman, D. (2002) Deteriorating diabetes control during adolescence: physiological or psychosocial? *Journal of Paediatric Endocrinology and Metabolism*, 15(**2**), 115-26.

Hampson, S.E; Skinner, T.C; Hart, J; Storey, L; Gage, H; Foxcroft, D; Kimber, A; Shaw, K and Walker, J. (2001) Effects of educational and psychosocial interventions for adolescents with diabetes mellitus: a systematic review. *Health Technology Assessment,* 5(**10**). HTA.

Hampson, S.E; Glasgow, R.E and Foster, L.S. (1995) Personal models of diabetes among older adults: relationship to self-management and other variables. *Diabetes Education* 21, 300–307.

Hampson S.E; Glasgow R. E and Toobert, D.J. (1990) Personal models of diabetes and their relations to self-care activities. *Health Psychology,* 9, 632–646.

Hanna K.M and Guthrie D.W. (2000) Adolescents' perceived benefits and barriers related to diabetes self-management: Part 1. *Issues in Comprehensive Paediatric Nursing,* 23, 165–174.

Hanson, C.L; Cigrang, J.A; Harris, M.A; Carle, D.L; Relyea, G and Burghen, G.A. (1989) Coping styles in youths with insulin-dependent diabetes mellitus. *Journal of Consulting and Clinical Psychology*, 57(**5**), 644-51.

Harbeck-Weber, C and McKee, D.H. (1995) Prevention of emotional and behavioural distress in children experiencing hospitalization and chronic illness. In. Roberts, M.C (Ed). *Handbook of Paediatric Psychology*, (pp: 167–184). New York: Guildford Press.

Härkäpää; K; Järvikoski, A; Mellin, G; Hurri, H and Luoma J (1991) Health locus of control beliefs and psychosocial distress as predictors for treatment outcomes in low back pain patients: results of a 3 month follow-up of a controlled intervention study. *Pain*, 46, 35-41.

Harland, J; White, M; Drinkwater, C; Chinn, D; Farr, L and Howel, D. (1999) The Newcastle exercise project: a randomised controlled trial of methods to promote physical activity in primary care. *British Medical Journal*, 319, 828-832.

Harris, M and Mertlich, D. (2003) Piloting home-based behavioural family systems therapy for adolescents with poorly controlled diabetes. *Children's Health Care*, 32, 65–79.

Harrison, L. (1995) The validity of self report data on drug use. *Journal of Drug Issues*, 25, 91-111.

Hauser, S.G; Jacobson, A.M; Benes, K.A and Anderson, B.J. (1997) Psychological aspects of diabetes mellitus in children and adolescents: Implications and interventions. In: Alessi, N.E (Ed). *Handbook of Child and Adolescent Psychiatry* (pp: 340–354).Vol. 4. New York: Wiley.

Hauser, S. T; Jacobson, A. M; Lavori, P; Wolfsdorf, J. I; Herskowitz, R. D; Milley, J. E. (1990) Adherence among children and adolescents with insulin-dependent diabetes mellitus over a four-year longitudinal follow-up. II. Immediate and long-term linkages with the family milieu. *Diabetes Spectrum*, 4, 282–292

Hawkins, R.C. (2003) Comparison of four point-of-care HbA1c analytical systems against central laboratory analysis. *Singapore Medical Journal,* 44(**1**), 008-011.

Helgeson, V.S and Franzen, P.L. (1998) The role of perceived control in adjustment to diabetes. *Anxiety, Stress, and Coping*, 11(**2**), 113-136.

Hesketh, K.D; Wake, M.A. and Cameron, F.J. (2004) Health related quality of life and metabolic control in children with type 1 diabetes. *Diabetes Care,* 27(**2**), 415-420.

Hettema, J; Steele, J and Miller, W. R. (2005) Motivational interviewing. *Annual Review of Clinical Psychology*, 1, 91–111.

Heritier, S.R; Gebski, V.J and Keech, A.C. (2003) Inclusion of patients in clinical trial analysis: the intention-to- treat principle. *The Medical Journal of Australia,* 179, 438-440.

Hinde, F.R.J; Standen, P.J; Mann, N.P and Johnston, D.I. (1989) Seasonal variation of haemoglobin A1 in children with insulin-dependent diabetes mellitus. *European Journal of Paediatrics* 148(**7**), 597-599.

Hindmarsh, P.C. (2006) *First steps in crossing the quality chasm - diabetes care delivery for children and adolescents.* Accessed online 20th October 2006: www.diabetes.nhs.uk/downloads

Hoey, H; Aanstoot, H.J; Chiarelli, F; Daneman, D; Danne, T; Dorchy, H; Fitzgerald M, Garandeau, P; Greene, S; Holl, R; Hougaard, P; Kaprio, E; Kocova, M; Lynggaard, H; Martul, P; Matsuura, N; McGee, H.M; Mortensen, H.B; Robertson, K; Schoenle, E; Sovik, O; Swift, P; Tsou, R.M; Vanelli, M and Aman, J. (2001) Good metabolic control is associated with better quality of life in 2,101 adolescents with type 1 diabetes. *Diabetes Care,* 24(**11**), 1923–1928.

Hoey, H; Mortensen, H; McGee, H and Fitzgerald, M. for the Hvidøre Study Group (1999) Is metabolic control related to quality of life? A study of 2,103 children and adolescents with IDDM from 17 countries. *Diabetes Research and Clinical Practice,* 44 (Supplement 3).

Holl, R.W; Lang, G.E; Grabert, M; Heinze, E; Lang, G.K; Debatin, K.M. (1998) Diabetic retinopathy in paediatric patients with type 1 diabetes: effect of diabetes duration, pre-pubertal and pubertal onset of diabetes and metabolic control. *Journal of Paediatrics,* 132(**5**), 790-794.

Holman, H.R and Lorig, K. (1992) Perceived self efficacy in the self management of chronic disease. In: Schwarzer, R. (Ed) *Self Efficacy: thought control of action* (pp: 305-323). Washington D.C: Hemisphere Publishing.

Holmbeck, G. N; Bruno, E.F. and Jandasek, B (2006) Longitudinal research in paediatric psychology: An introduction to the special issue. *Journal of Paediatric Psychology,* 31(**10**), 995-1001.

Holmbeck. G.N. (2002) A developmental perspective on adolescent health and illness: An introduction to the special issues. *Journal of Paediatric Psychology,* 27(**5**), 409-416.

Holmbeck, G. N. (1997) Towards terminological, conceptual and statistical clarity in the study of mediators and moderators: examples from the child-clinical and paediatric psychology literatures. *Journal of Consulting and Clinical Psychology*, 65, 599–610.

Holmes, C.S; Chen, R; Streisand, R; Marschall, D.E; Souter, S; Swift, E.E; and. Peterson, C.C. (2006) Predictors of youth diabetes care behaviours and metabolic control: A structural equation modelling approach. *Journal of Paediatric Psychology* 31(**8**), 770-784.

Hood, K.K; Huestis, S; Maher, A; Butler, D; Volkening, L and. Laffel, L.M.B. (2006) Depressive symptoms in children and adolescents with type 1 diabetes: Association with diabetes-specific characteristics. *Diabetes Care*, 29(**6**), 1389-1391.

Horvath, O and Greenberg, L.S. (1994) *The Working alliance: Theory, research and practice*. New York: Wiley.

Horvath, A.O and Greenberg, L.S. (1989) Development and validation of the Working Alliance Inventory. *Journal of Counselling Psychology,* 36, 223-233.

Horvath, A.O. (1994) Empirical validation of Bordin's pantheoretical model of the alliance: The working Alliance Inventory perspective. In Horvath, A.O and Greenberg, L.S (Eds) *The Working Alliance: Theory, Research and Practice* (pp: 109-139). New York: Wiley.

Hovarth, A.O. (2001) The therapeutic alliance: concepts, research and training. *Australian Psychologist*, 26, 170-176.

Howells, L; Wilson, A.C; Skinner, T.C; Newton, R; Morris, A.D and Greene, S.A. (2002) A randomised control trial of the effect of negotiated telephone support on glycaemic control in young people with type 1 diabetes. *Diabetic Medicine,* 19(**8**), 643-648.

Hunter, C.P; Frelick, R.W; Feldman, A.R; Bavier, A.R; Dunlap, W.H; Ford L, Henson D, Macfarlane D, Smart, C.R; Yancik, R. et al. (1987) Selection factors in clinical trials: results from the Community Clinical Oncology Program Physician's Patient Log. *Cancer Treatment Reports,* 71(**6**), 559-65.

Ingersoll, G.M; Orr, D.P; Herrold, A; and Golden, M.P. (1998) Cognitive maturity and self management among adolescents with type 1 diabetes. *Behavioural Paediatrics*, 108(**4**), 620-623.

Ingersoll, G.M and Marrero, D.G. (1991) A modified quality-of-life measure for youths: psychometric properties. *Diabetes Educator,* 7(**4**), 4–118.

Ismail. K. (2006) What works for whom and why? *British Medical Journal.* Accessed online 28th August 2006: http://www.bmj.com/doi 10.113/bmj.38874.652569.55

ISPAD Consensus Guidelines. (2000) *Consensus guidelines for the management of type 1 diabetes mellitus in children and adolescents.* International Society of Paediatric and Adolescent Diabetes (ISPAD). Accessed online 4th March 2006: http://www.d4pro.com/diabetesguidelines/ispad.

Jacobson, A; Hauser, S.T; Willett, J; Wolfsdorf, J.I; Herman, L and de Groot, M. (1997) Psychological adjustment to IDDM: 10-year follow-up of an onset cohort of child and adolescent patients. *Diabetes Care* 20, 811–818.

Jacobson A; Hauser, S.T; Lavori, P; Wolfsdorf, J.I; Herskowitz, R..D; Milley, J.E; Bliss, R; Gelfand, E; Wertlieb, D and Stein, J. (1990) Adherence among children and adolescents with insulin-dependent diabetes mellitus over a four-year longitudinal follow-up: the influence of patient coping and adjustment. *Journal of Paediatric Psychology*, 15, 511–526.

Jacobson, A; Barofsky, I; Cleary, P and Rand, L. (1988) Reliability and validity of a diabetes quality-of-life measure for the diabetes control and complications trial (DCCT). *Diabetes Care,* 11, 725-732.

Jefferson, I.G; Swift, P.G.F; Skinner, T.C; Hood, G.K (2003) Diabetes Services in the U.K: Third national survey confirms continuing deficiencies. *Archives of Disease in Childhood.* 88, 53-56.

Johnson, S.B. (1993) Chronic diseases of childhood: assessing compliance with complex medical regimens. In. Krasnegor, N.A; Epstein, L; Johnson, S.B and Jaffe, S.J. (Eds) *Developmental aspects of health compliance behaviour* (pp: 157-184). New Jersey: Lawrence Erlbaum.

Johnston, B.D; Rivara, F.P; Droesch, R.M; Dunn, C and Copass, M.K. (2002) Behaviour change counselling in the emergency department to reduce injury risk: A randomized, controlled trial. *Pediatrics,* 110(**2**), 267-274.

Johnston-Brooks C. H; Lewis, M.A and Garg, S. (2002) Self Efficacy impacts self care and HbA_{1c} in young adults with type 1 diabetes. *Psychosomatic Medicine* 64, 43-51.

Jones, J.M; Lawson, M; Daneman, D; Olmsted, M.P and Rodin, G. (2000) Eating disorders in adolescent females with and without type 1 diabetes: cross sectional study. *British Medical Journal,* 320, 1563-1566.

Juniper, E.F; Guyatt, G.H; Willan, A and Griffith, L.E. (1994) Determining a minimal important change in a disease-specific quality of life questionnaire. *Journal of Clinical Epidemiology,* 47, 81-87.

Kadohiro, J.K. (2000) Diabetes and adolescents: From research to reality. *Diabetes Spectrum*, 13(**2**), 81-83.

Kamps, J.L; Roberts, M.C and Vareia, R.E. (2006) Development of a new fear of hypoglycaemia scale: preliminary results. *Journal of Paediatric Psychology*, 30(**3**), 287-291.

Kaplan, R. M; Chadwick, M. W and Schimmel, L. E. (1985) Social learning intervention to promote metabolic control in type 1 diabetes mellitus: Pilot experiment results. *Diabetes Care,* 8, 152-155.

Karoly, P. (1999) A goal systems-self-regulatory perspective on personality, psychopathology, and change. *Review of General Psychology*, 3, 264–291.

Kavanagh, D.J; Gooley, S and Wilson, P.H. (1993) Prediction of adherence and control in diabetes. *Journal of Behavioural Medicine*, 16, 509–522.

Kazak, A. E; Simms, S; Barakat, L; Hobbie, W; Foley, B; Golomb, V and Best, M. (1999). Surviving cancer competently intervention program (SCCIP): A cognitive-behavioural and family therapy intervention for adolescent survivors of childhood cancer and their families. *Family Process,* 38, 175-191.

Kazdin, A.E; Bass, D; Ayers, W.A and Rodgers, A. (1990). Empirical and clinical focus of child and adolescent psychotherapy research. *Journal of Consulting and Clinical Psychology,* 58, 729-740.

Keenan, H.T; Foster, C.M and Bratton, S.L. (2002) Social factors associated with prolonged hospitalization among diabetic children. *Paediatrics*, 109, 40 –44.

Kerr, D; Nicholls, H and Cavan, D.A. (2002) The lost tribes in diabetes. *Diabetic Medicine*, 19(**8**), 703.

Kibby, M.Y; Tyc, V.L and Mulhern, R.K. (1998) Effectiveness of psychological intervention for children and adolescents with chronic medical illness: a meta-analysis. *Clinical Psychology Review*, 18(**1**), 103-17.

Kilpatrick, E.S. (2004) HbA1c measurement. *Journal of Clinical Pathology*, 57, 344-345.

Kline, P. (2000) *The Handbook of Psychological Testing*, 2nd Edition. London: Routledge.

Kneckt, M.C; Syrjälä, A.M.H and Knuuttila, M.L.E. (1999) Locus of control beliefs predicting oral and diabetes health behaviour and health status. *Acta Odontologica Scandinavica,* 57(**3**), 127-131.

Knowles, M. (1990) *The Adult Learner: A Neglected Species.* 4th Edition. Houston: Gulf Publishing.

Kokkonen, K. and Kokkonen, E.R. (1995) Mental health and social adaptation in young adults with juvenile-onset diabetes. *Nordic Journal of Psychiatry,* 49, 175-181.

Kordonouri, O; Lauterborn, R and Deiss, D. (2002) Lipohypertrophy in young patients with type 1 diabetes (Letter). *Diabetes Care*, 25, 634.

Kovacs M; Goldston, D; Obrosky, D.S and Bonar, L.K. (1997) Psychiatric disorders in youth with IDDM. Rates and risk factors. *Diabetes Care*, 20, 36–44.

Krahn, L.E; Bostwick, J.M; Sutor, B and Olsen, M.W. (2002). The challenge of empathy: A pilot study of the use of standardized patients to teach introductory psychopathology to medical students. *Academic Psychiatry,* 26, 26-30.

Kruijver, I.P; Kerkstra, A; Kerssens, J.J; Holtkamp, C.C; Bensing, J.M and van de Wiel, H.B. (2001) Communication between nurses and simulated patients with cancer: evaluation of a communication training programme. *European Journal of Oncology Nursing*, 5(**3**),140-50.

Kuchipudi, V; Hobein, K; Flickinger, A. and Iber, F. L. (1990) Failure of a 2-hour motivational intervention to alter recurrent drinking behaviour in alcoholics with gastrointestinal disease. *Journal of Studies on Alcohol,* 51, 356–360.

Kurtz, S.M; Silverman, J and Draper, J. (2005) *Teaching and Learning Communication Skills in Medicine,* 2nd Edition. Oxford: Radcliffe Medical Press.

Kyngäs, H.A and Rissanen, M. (2001) Support as a crucial predictor of good compliance of adolescents with a chronic disease. *Journal of Clinical Nursing,* 10, 767-774.

Kyngäs, H. A. (1999) Compliance of adolescents with asthma. *Nursing and Health Sciences*, 1(**3**), 195–202.

Kyngäs, H.A; Hentinen M, and Barlow J.H. (1998) Adolescents' perceptions of physicians, nurses, parents and friends: help or hindrance in compliance with diabetes self-care? *Journal of Advanced Nursing,* 27(**4**), 760-769.

Laffel, L.M.B; Connell, A; Vangsness, L; Goebel-Fabbri, A; Mansfield, A and Anderson, B.J. (2003) General quality of life in youth with type 1 diabetes: Relationship to patient management and diabetes-specific family conflict. *Diabetes Care,* 26, 3067-3073.

Laffel, L.M.B; Vangsness, L, Connell, A,; Goebel-Fabbri, A; Butler, D and Anderson, B.J. (2003) Impact of ambulatory, family-focused teamwork intervention on glycaemic control in youth with type 1 diabetes. *The Journal of Paediatrics*, 142(**4**), 409-416.

La Greca, A.M; Bearman, K.J and Moore, H. (2002). Peer relations of youths with paediatric conditions and health risks: promoting social support and healthy lifestyles. *Journal of Developmental and Behavioural Paediatrics*, 23, 271-280.

La Greca, A.M and Bearman, K.J. (2000) Children with paediatric conditions: can peers' impressions be managed? And what about their friends? [Commentary]. *Journal of Paediatric Psychology*, 25, 147–149.

La Greca, A. M; Auslander, W.F; Greco, P; Spetter, D; Fisher, E.B and Santiago, J. V. (1995). I get by with a little help from my family and friends: Adolescents' support for diabetes care. *Journal of Paediatric Psychology*, 20, 449-476.

Laing, S.P; Jones, M.E; Swerdlow, A.J; Burden, A.C and Gatling, W. (2005) Psychosocial and socioeconomic risk factors for premature death in young people with type 1 diabetes. *Diabetes Care* 28, 1618-1623.

Laing, S.P; Swerdlow, A.J; Slater, S.D; Botha, J.L; Burden., A.C; Waugh, N.R; Smith, A.W.M; Hill, R.D; Bingley, P.J; Patterson, C.C; Qiao, Z and Keen, H.(1999[a]) The British Diabetic Association Cohort Study, I: all-cause mortality in patients with insulin-treated diabetes mellitus. *Diabetic Medicine*. 16(**6**), 459-465.

Laing, S.P; Swerdlow, A.J; Slater, S.D; Botha, J.L; Burden., A.C; Waugh, N.R; Smith, A.W.M; Hill, R.D; Bingley, P.J; Patterson, C.C; Qiao, Z and Keen, H. (1999[b]) The British Diabetic Association Cohort Study, II: cause-specific mortality in patients with insulin-treated diabetes mellitus. *Diabetic Medicine,* 16(**6**), 466 – 471.

Lamb, W.H and Laing, T. (2004) The 730+ Club: Children as an agent for change in the delivery of a paediatric diabetes service. Oral presentation at the ISPAD conference, Cambridge: UK. 2006. *Paediatric Diabetes,* 7(Supplement 5), 58.

Landgraf, J.M; Abetz, L and Ware, J.E. (1996) *The Child Health Questionnaire (CHQ): A user's manual.* The Health Institute, New England Medical Centre: Boston.

Lane, C; Hood, K and Rollnick, S. (work in progress) *Teaching motivational interviewing skills to experienced healthcare practitioners: Does the use of simulated patients in a training workshop enhance skill acquisition in comparison to role-plays with fellow trainees*? Centre for Nursing Research, Cardiff School of Nursing Studies, Cardiff University. UK.

Lane, C; Huws-Thomas, M.V; Hood, K; Rollnick, S; Edwards, K and Robling, M. (2005) Measuring adaptations of motivational interviewing: The development and validation of the Behavior Change Counselling Index. *Patient Education and Counselling*, 56, 166-73.

Larson, R and Richards, M.H. (1994) *Divergent realities. The emotional lives of mothers, fathers and adolescents.* New Your: Basic Books.

Lau, C; Qureshi, A.K and Scott S.G. (2004) Association between glycaemic control and quality of life in diabetes mellitus. *Journal of Postgraduate Medicine*, 50, 189-194.

Lawendowski L.A. (1998) A motivational intervention for adolescent smokers. *Preventive Medicine,* 27(**5**), A39-A46(8).

Lawson, V; Lyne, P.A; Harvey, J.N and Bundy, C.E. (2005) Understanding why people with type 1 diabetes do not attend for specialist advice: A qualitative analysis of the views of people with insulin dependent diabetes who do not attend diabetes clinic. *Journal of Health Psychology,* 10(**3**), 409-423.

Lazarus, R. S and Folkman, S. (1987) Transactional theory and research on emotions and coping. *European Journal of Personality*, 1, 141-170.

Leganger, A; Kraft, P and Røysamb, E. (2000) Perceived self efficacy in health behaviour research: Conceptualisation, measurement and correlates. *Psychology and Health*, 15, 51-69.

Lemanek, K. (1990) Adherence issues in the medical management of asthma. *Journal of Paediatric Psychology* 15(**4**), 437-458.

Leonard, J. (2003) Biopsychosocial factors affecting metabolic control among female adolescents with type 1 diabetes, *Diabetes Spectrum* 16, 154-159.
Leonard, B.J; Jang, Y.P; Savik, K; Plumbo, P.M and Christensen, R. (2002) Psychosocial factors associated with levels of metabolic control in youth with type 1 diabetes. *Journal of Paediatric Nursing,* 17, 28 –37.

Lernmark, B; Persson, B; Fisher, L and Rydelius, F-A. (1999). Symptoms of depression are important to psychological adaptation and metabolic control in children with diabetes mellitus. *Diabetic Medicine,* 16, 14- 22.

Leventhal, H; Benyamini, Y; Brownlee, S; Diefenbach, M; Leventhal, E.A and. Patrick-Miller, L and Robitaille, C. (1997) Illness representations: Theoretical foundations. In. Petrie, K.J and Weinman, J.A. (Eds) *Perceptions of Health and Illness: Current research and applications* (pp: 19–45) Amsterdam, NL: Harwood Academic.

Leventhal, H; Diefenbach, M and Leventhal, E.A. (1992) Illness cognition: Using common sense to understand treatment adherence and affect cognition. *Cognitive Therapy and Research,* 16, 143–163.

Liesenfeld, B; Renner, R; Neese, M and Hepp, K.D. (2000) Telemedical care reduces hypoglycaemias and improves glycaemic control in children and adolescents with type 1 diabetes. *Diabetes Technology and Therapeutics*, 2, 561-7.

Lewin, A.B; Heiderken, A.D; Geffken, G.R; Williams, L.B; Storch, E.A; Gelfand, K.M and Silverstein, J.H. (2006) The relation between family factors and metabolic control: The role of diabetes adherence. *Journal of Paediatric Psychology,* 31(2), 174-183.

Liesenfeld, B; Renner, R; Neese, M; Hepp, K.D. (2000) Tele-medical care reduces hypoglycemia and improves glycaemic control in children and adolescents with type 1 diabetes. *Diabetes Technology and Therapeutics*, 2(**4**), 561-567.

Lloyd, C.E; Matthews, K.A; Wing, R.R and Orchard, T.J. (1992) Psychosocial factors and complications of IDDM. The Pittsburgh Epidemiology of Diabetes Complications Study. VIII. *Diabetes Care*, 15(**2**), 166-172.

Locke, E.A and Latham, G.P. (1990) Work motivation and satisfaction: Light at the end of the tunnel. *Psychological Science,* 1(**4**), 240–246.

Lowes, L. (1996) Paediatric nursing and children's autonomy. *Journal of Clinical Nursing,* 5, 367–372.

Lowes, L and Barber, C.J. (1998) Eating disorders and the adolescent with diabetes: Is there a link? *British Journal of Nursing*, 7(**7**), 398-402.

Lowes, L and Gregory, J.W. (2004) Management of newly diagnosed diabetes: home or hospital? *Archives of Disease in Childhood,* 89, 934-937.

Luborsky, L; Diguer, L; Seligman, D.A; Rosenthal, R; Krause, E.D; Johnson, S; Halperin, G; Bishop, M; Berman, J.S and Schweizer, E. (1999) The researchers own therapy allegiances: A "wild card" in comparisons of treatment efficacy. *Clinical Psychology: Science and Practice*. 6(**1**), 95-106.

Lustman, P.J and Clouse, R.E. (2005) Depression in diabetic patients: The relationship between mood and glycaemic control. *Journal of Diabetes and its Complications*, 19(**2**), 113-122.

Luszczynska, A and Schwarzer, R. (2005) Multidimensional health locus of control: Comments on the construct and its measurement. *Journal of Health Psychology,* 10(**5**), 633-642.

Machin, D; Campbell, M.J; Fayers, P and Pinol, A. (1987) *Sample Size Tables for Clinical Studies.* Oxford, UK: Blackwell Science.

Mackner, L.M and Crandall, W.V. (2006) Brief report: psychosocial adjustment in adolescents with inflammatory bowel disease. *Journal of Paediatric Psychology*, 31(**3**), 281-5.

Macrodimitris, S.D and Endler, N.S (2001) Coping, control and adjustment in type 2 diabetes. *Health Psychology*, 20, 208-216.

Madsen, S; Roisman, G.I and Collins, W.A. (2002) The intersection of adolescent development and intensive intervention: Age-related psychosocial correlates of treatment regimens in the Diabetes Control and Complications Trial. *Journal of Paediatric Psychology*, 27(**5**), 451-459.

Maharaj, S; Daneman, D; Olmsted, M and Rodin, G. (2004) Metabolic control in adolescent girls: Links to relationality and the female sense of self. *Diabetes Care* 27, 709-715.

Maibach, E and Murphy D.A. (1995) Self efficacy in health promoting research and practice: Conceptualisation and measurement. *Health Education Research,* 10(**1**), 37-50.

Mandrup-Poulson, T and Nerup, J. (1995) Pathogenesis of childhood diabetes. In. Kelnar, C. J. H. (Ed) *Childhood and Adolescent Diabetes* (pp: 183-189). London: Chapman and Hall Medical.

Markland, D; Ryan, R.M; Tobin, V.J and Rollnick, S. (2005) Motivational interviewing and self determination theory. *Journal of Social and Clinical Psychology*, 24(**6**), 811-831.

Marlatt, G.A; Baer, J.S; Kivlahan, D.R; Dimeff, L.A; Larimer, M.E; Quigley, L.A; Somers, J.M and Williams, E. (1998) Screening and brief intervention for high-risk college student drinkers: results from a 2-year follow up assessment. *Journal of Consulting and Clinical Psychology,* 66, 604-615.

Martin, D.J; Garske, J.P and Davis, M.K. (2000) Relation of the therapeutic alliance with outcome and other variables: A meta-analytic review. *Journal of Consulting and Clinical Psychology*, 68(**3**), 438-450.

Martino, S; Carroll, K.M; O'Malley, S.S and Rounsaville, B.J. (2000) Motivational interviewing with psychiatrically ill substance abusing patients. *American Journal on Addictions*, 9(**1**), 88-91.

Massengale, J. (2005) Depression and the adolescent with type 1 diabetes: the covert comorbidity. *Issues in Mental Health Nursing,* 26(**2**), 137-148.

Masten, A. S and Coatsworth, J. D. (1998) The development of competence in favourable and unfavourable environments: Lessons from research on successful children. *American Psychologist*, 53(**2**), 205-220.

Matthews, A.M; Gelder, N.G and Johnston, D.W. (1981) *Agoraphobia – Nature and Treatment.* London: Tavistock.
Mazze, R.S; Lucido, D, and Shamoon, H. (1984) Psychological and social correlates of glycaemic control. *Diabetes Care*, 7, 360-366.

McCambridge, J and Strang, J. (2004) The efficacy of single-session motivational interviewing in reducing drug consumption and perceptions of drug-related risk and harm among young people: results from a multi-site cluster randomised trial. *Addiction,* 99, 39-52.

McCambridge, J and Strang, J. (2003) Development of a generic drug intervention model for public health purposes: A brief application of motivational interviewing with young people. *Drug and Alcohol Review*, 22, 391-99.

McCaul, K.D; Glasgow, R.E and Schafer, L.C. (1987) Diabetes regimen behaviours. Predicting adherence. *Medical Care,* 25(**9**), 868-871.

McKelvey, J; Waller, D. A; North, A. J; Marks, J. F; Schreiner, B; Travis, L.B and Murphy, J.N. (1993). Reliability and validity of the diabetes family behaviour scale. *Diabetes Educator,* 19, 125–132.

McMillan, C.V; Honeyford, R; Datta, J; Madge, N.J.H and Bradley, C. (2004) The development of a new measure of quality of life for young people with diabetes mellitus: the ADDQoL-Teen. *Health and Quality of Life Outcomes.* Volume 2(**61**). Accessed online 3rd June 2006: http://www.hqlo.com/content/2/1/61 /doi:10.1186/1477-7525-2-61

Medical Research Council (2000) *A framework for the development and evaluation of RCTs for complex interventions to improve health.* Accessed online January 3rd 2002: http://www.mrc.ac.uk

Menard, S. (1995) *Applied logistic regression analysis.* Sage University paper series on quantitative applications in the social sciences, 07-106. Thousand Oaks. CA: Sage.

Mendez, F. J and Belendez, M. (1997) Effects of a behavioural intervention on treatment adherence and stress management in adolescents with IDDM. *Diabetes Care,* 20(**9**), 1370-1375.

Menarini, A diagnostics (2006) *HbA_{1c} Calibrator.* Accessed online 24th November 2006: www.menarinidiag.co.uk.

Mhurchu, C.N; Margetts, B.M and Speller, V. (1998) Randomized clinical trial comparing the effectiveness of two dietary interventions for patients with hyperlipidaemia. *Clinical Science*, 95, 479–487.

Miller, W.R. (2005) Are alcoholism treatments effective? The Project MATCH data: Response. *BMC Public Health,* 5(**76**). Accessed online 16th September 2006: http://www.pubmedcentral.nih.gov.

Miller, W.R and Rollnick, S. (2005) Talking oneself into change: Motivational interviewing, stages of change and therapeutic process. *Journal of Cognitive Psychotherapy*, 18, 299-308.

Miller, W.R; Yahne, C.E; Moyers, T.B; Martinez, J and Pirritano, M. (2004) A randomised controlled trial of methods to help clinicians learn motivational interviewing. *Journal of Consulting and Clinical Psychology*, 72, 1050-1062.

Miller, W.R; Moyers, T.B; Ernst, D and Amrhein, P (2003) Manual for the Motivational Interviewing Skill Code (MISC version 2.0). Accessed online 15th October 2004: http://casaa.unm.edu/codinginst.html

Miller, W. R. and Rollnick, S. (2002) *Motivational Interviewing: Preparing People for Change*, 2nd edition. New York: Guildford Press.

Miller, W.R. (2001) When is it Motivational Interviewing? Comments on Dunn et al.'s "The use of brief interventions adapted from motivational interviewing across behavioural domains: a systematic review" *Addiction,* 96(**12**) 1770-1772.

Miller, W.R. (2000) *Manual for the motivational interviewing skill code* (MISC version 1.0): A coder's manual. Accessed online October 2006 from http//casaa.unm.edu./download/misc1.pdf.

Miller, W. R. and Rollnick, S. (1991) *Motivational Interviewing: Preparing People to Change Addictive Behaviour*. New York: Guilford Press.

Miller, W.R and Sovereign, R.G. (1989) The check-up: a model for early intervention in addictive behaviours. In. Loberg T; Miller, W.R; Nathan, P.A and Marlatt, G.A. (Eds) *Addictive behaviours: prevention and early intervention* (pp: 219-231) Amsterdam: Swets and Zeitlinger.

Miller, W. R; Sovereign, R. G. and Krege, B. (1988) Motivational interviewing with problem drinkers: II The Drinker's Check-Up as a preventive intervention. *Behavioural Psychotherapy* 16, 251–268.

Miller, W. R. (1983) Motivational interviewing with problem drinkers. *Behavioural and Cognitive Psychotherapy* 11, 147–172.

Millstein, S. (1989) Adolescent health: Challenges for behavioural scientists. *American Psychologist,* 44, 837-842.

Milton, B; Holland, P and Whitehead, M. (2006) The social and economic consequences of childhood-onset Type 1 diabetes mellitus across the life course: a systematic review. *Diabetic Medicine,* 23(**8**), 821-829.

Misuraca, A; Di Gennaro, M; Lionello, M; Duval, M; Aloi, G. (1996) Summer camps for diabetic children: an experience in Campania, Italy. *Diabetes Research and Clinical Practice,* 32, 91–96.

Modi, A.C and Quittner, A.L. (2006) Barriers to treatment adherence for children with cystic fibrosis and asthma: What gets in the way? *Journal of Paediatric Psychology*, 31, 846 - 858

Moffatt, M.E and Pless, I.B. (1983) Locus of control in juvenile diabetic campers: changes during camp, and relationship to camp staff assessments. *Journal of Paediatrics*, 103(**1**), 146-50.

Moher, D; Schultz, K.F; Altman, D for the CONSORT Group (2001) CONSORT Statement: Revised recommendations for improving the quality of reports of parallel-group randomized trials. *Journal of the American Medical Association*, 285, 1987-1991.

Mollema, E.D; Snoek, F.J; Adèrc, H.J; Heine R.J and van der Ploeg, H.M. (2001) Insulin-treated diabetes patients with fear of self-injecting or fear of self-testing: Psychological co-morbidity and general well-being. *Journal of Psychosomatic Research*, 51(**5**), 665-672.

Montague, C.T; Farouqi, I.S and Whitehead, J.P. (1997) Congenital leptin deficiency with insulin-dependent diabetes mellitus in relation to metabolic control and body mass index. *European Journal of Endocrinology,* 138, 501–509.

Monti, M; Colby, S. M; Barnett, N. P; Spirito, A and Rohsenow, D.J. (1999) Brief intervention for harm reduction with alcohol positive older adolescents in a hospital emergency department. *Journal of Consulting and Clinical Psychology* 67(**6**), 989–994.

Moran, A; Jacobs, D.R; Steinberger, J; Hong, C.P; Prineas, R; Luepker, R and Sinaiko, A.R. (1999). Insulin resistance during puberty: results from clamp studies in 357 children. *Diabetes,* 48(**10**), 2444-2450.

Moran, A; Jacobs D, R; Steinberger, J; Cohen, P; Hong, C.P; Prineas, R and Sinaiko, A.R. (2002) Association between the insulin resistance of puberty and the insulin-like growth factor-I/growth hormone axis. *Journal of Clinical Endocrinology and Metabolism*, 87, 4817–20.

Moran, A; Jacobs, D.R; Steinberger, J; Hong, C.P; Prineas, R; Luepker, R and Sinaiko, A.R. (1999) Insulin resistance during puberty: results from clamp studies in 357 children. *Diabetes*, 48(**10**), 2039-2044.

Morris, A.D; Boyle, D.I; McMahon, A.D; Greene, S.D; MacDonald, T.M; Newton, R.W. (1998) Adherance to insulin treatment, glycaemic control and ketoacidosis in insulin dependent diabetes mellitus: The DARTS/MEMO Collaboration. Diabetes Audit and Research in Tayside Scotland. Medicines Monitoring Unit. *Lancet.* 98(**22**), 1505-1510.

Mortensen H.B on behalf of the Hvidøre Study group on Childhood Diabetes. (2002) Findings from the Hvidøre study group on childhood diabetes: Metabolic control and quality of life. *Hormone Research*, 57(Supplement: 1), 117-120.

Mortensen H.B; Robertson K.J; Aanstoot H, J; Danne, T; Holl, R.W; Hougaard, P; Atchison, J.A; Chiarelli, F; Daneman, D; Dinesen, B; Dorchy, H; Garandeau, P; Greene, S; Hoey, H; Kaprio, E. A; Kocova, M; Martul, P; Matsuura, N; Schoenle E.J; Sovik, O; Swift, P.G; Tsou, R.M; Vanelli, M and Aman, J. (1998) Insulin management and metabolic control of type 1 diabetes mellitus in childhood and adolescence in 18 countries. Hvidøre Study Group on Childhood Diabetes. *Diabetic Medicine,* 15(**9**), 752–759.

Mortensen, H.B and Hougaard, P. (1997) Comparison of metabolic control in a cross-sectional study of 2,873 children and adolescents with IDDM from 18 countries. For the Hvidøre Study Group on Childhood Diabetes. *Diabetes Care*, 20(**5**), 714-720.

Mortensen. H.B (1998) Practical aspects of managing diabetes in adolescents. *Acta Paediatrica,* 87, (Supplement 425), 72-76.

Moy, C.S; LaPorte, R.E; Dorman, J.S; Songer, T.J; Orchard, T.J; Kuller, L.H; Becker, D.J and Drash, A.L. (1990) Insulin-dependent diabetes mellitus mortality. The risk of cigarette smoking. *Circulation*, 82, 37-43,

Moyers, T.B; Martin, T; Manuel, J.K; Hendrickson, S.M.L and Miller. W. R (2005) Assessing competence in the use of motivational interviewing. *Journal of Substance Abuse Treatment,* 28, 19-26.

Moyers, T.B; Miller, W.R, and Hendrickson, S.M.L. (2005) How does motivational interviewing work? Therapist interpersonal skill predicts client involvement within motivational interviewing sessions. *Journal of Consulting and Clinical Psychology*, 73(**4**), 590-598.

Műhlhauser I and Bergen, M. (2002) Patient education – Evaluation of a complex intervention. *Diabetologia,* 45(**12**), 1723-1733.

Murphy, H. R; Rayman, G and Skinner, T. C. (2006) Psycho-educational interventions for children and young people with type 1 diabetes. *Diabetic Medicine*, 23(**9**), 935-943.

Murphy, H.R; Wadham, C; Rayman, G and Skinner, Chas, T. (2006) Integrating paediatric diabetes education into routine clinical care: The families, adolescents and children's teamwork study (FACTS) [Letter]. *Diabetes Care,* 29, 1177.

Naess, S; Midthjell, K; Moum T; Sorensen, T and Tambs, K. (1995) Diabetes mellitus and psychological well-being. Results of the Nord-Trondelag health survey. *Scandinavian Journal of Social Medicine,* 23(**3**),179-88.

National Diabetes Audit Report (2006) *Key findings about the quality of care for children and young people with diabetes in England, incorporating registrations from Wales*. NHS: The information Centre. Accessed online 15th January 2007: http://www.icservices.nhs.uk

National Diabetes Support Team (2005) Diabetes care for children and young people. *Diabetes UK*: NHS. Accessed online 21st August 2006: http://www.diabetes.nhs.uk/.

National Institute for Health and Clinical Excellence (2004) *CG15 Type 1 Diabetes in Children, Young People and Adults: NICE Guideline*. Accessed online 15th September 2006: http://www.nice.org.uk

National Standards for Diabetes Self-Management Education Task Force (2000) National Standards for Diabetes Self-Management Education. *Diabetes Care,* 23(**5**), 681-689.

Nerenz, D.R; Repasky, D.P; Whitehouse, F.W and Kahkonen, D.M (1992) Ongoing assessment of health status in patients with diabetes mellitus. *Medical Care*, 30(**5**) (5 Supplement). MS 112-124.

Noonan, W and Moyers, T. (1997) Motivational Interviewing: A review. *Journal of Substance Misuse*, 2, 8-16.

Norris, S.L; Nichols, P; Caspersen, C; Glasgow, R; Engelgau, M.M; Jack, L; Snyder, S; Carande-Kulis, V; Isham, G and. Garfield, S. (2001) Increasing diabetes self-management education in community settings: A systematic review. *American Journal of Preventive Medicine*, 22(**4**), 39-66.

Norris, S.L; Lau, J; Smith, S.J; Schmid, C.H and Engelgau, M.M. (2002) Self - management education for adults with type 2 diabetes: A meta-analysis of the effect on glycaemic control. *Diabetes Care*, 25(**7**), 1159-1171.

Nordfeldt, S and Ludvigsson J. (2000) Seasonal variation of HbA1c in intensive treatment of children with type 1 diabetes. *Journal of Paediatric Endocrinology and Metabolism*, 13(**5**), 529-35.

Northam, E.A; Todd, S and Cameron, F.J. (2005) Interventions to promote optimal health outcomes in children with type 1 diabetes - are they effective? *Diabetic Medicine* 23, 113-121.

Northam, E. A.; Matthews, L. K; Anderson, P. J; Cameron, F. J and Werther, G. A. (2003) Psychiatric morbidity and health outcome in type 1 diabetes – perspectives from a prospective longitudinal study. *Diabetic Medicine*, 22(**2**), 152-157.

Norwicki, S and Strickland, B.R. (1973) A locus of control scale for children. *Journal of Consulting and Clinical Psychology*, 40, 148-155. Accessed online 2nd September 2006: www.garfield.library.upenn.edu/Classics1991/A1991FP633000001.

Notkins, A.L. (2002) Immunologic and genetic factors in type 1 diabetes. *The Journal of Biological Chemistry*, 277(**46**), 43545-43548.

Notkins, A.L and Lernmark, A. (2001) Autoimmune type 1 diabetes: Resolved and unresolved issues. *Journal of Clinical Investigation,* 1247-1252.

Nunnally, J.C. (1978) *Psychometric Theory*, 2nd Edition. New York: McGraw Hill.

O'Boyle, C. A. (1994) The schedule for the evaluation of individual quality of life (SEIQoL). *International Journal of Mental Health*, 23, 3-23.

O'Brien, R.W; Bush, P.J and Parcel, G.S. (1989) Stability in a measure of children's health locus of control. Journal of School Health, 59(**4**), 161-4.

Offer, D and Sabshin, M. (1984) *Normality of the life cycle: A critical integration.* New York: Basic Books.

O'hea, E.L; Grothe, K.B; Bodenlos, J.S; Boudreaux, E.D; White, M.A and Brantley, P.J. (2005) Predicting medical regimen adherence: The interactions of health locus of control beliefs. *Journal of Health Psychology*, 10(**5**), 705-717.

Olson, D.H. (1986) Circumplex model VII: Validation studies and FACES III. *Family Process*; 25(**3**), 337-351.

Olsen, B.S; Johannesen, J; Sjølie,A.K; Borch-Johnsen, K; Hougaard, P; Thorsteinsson, B; Pramming, S; Marinelli, K; Mortensen, H.B and the Danish Study Group of Diabetes in Childhood. (1999) Metabolic control and prevalence of micro-vascular complications in young Danish patients with type 1 diabetes mellitus. *Diabetic Medicine,* 16, 79-85.

Onkamo, P; Vaananen, S; Karvonen, M and Tuomilehto, J. (1999) Worldwide increase in incidence of type I diabetes—the analysis of the data on published incidence trends. *Diabetologia,* 42, 1395-403.

Oort, F. J. (2005) Using structural equation modelling to detect response shifts and true change. *Quality of Life Research,* 14, 587-598.

Orr, D. P; Golden, M. P; Myers, G and Marrero, S. D. (1983). Characteristics of adolescents with poorly controlled diabetes referred to a tertiary care centre. *Diabetes Care,* 6(**2**), 170–175.

Ott, J; Greening, L, Palardy, N; Holderby, A and Debell, W.K. (2000) Self efficacy as a mediator variable for adolescents adherence to treatment for insulin dependent diabetes mellitus. *Children's Health Care.* 29, 47-63.

Overstreet, S; Holmes, C; Dunlap, W and Frentz, J. (1997) Socio-demographic risk factors to disease control in children with diabetes. *Diabetic Medicine*, 14, 153–157.

Ozolins, A.R and Stenstrom, U. (2003) Validation of health locus of control patterns in Swedish adolescents. *Adolescence,* 38(**152**), 651-657.

Parcel, G.S and Meyer, M.P. (1978) Development of an instrument to measure children's health locus of control. *Health Education Monographs*, 6(**2**), 149-59.

Parkin, T; Barnard, K; Cradock, S; Pettman, P; Skinner, T.C. (2006) Does proffessional-centred training improve consultation outcomes? *Practical Diabetes International*, 23(**6**), 253 – 256.

Parkin, T and Skinner, T.C. (2002) Does patient perception of consultation concord with professional perception of consultation? *Diabetic Medicine,* 19 (Supplement 2). A14.

Parkerson, G.R; Connis, R.T; Broadhead, W.E; Patrick D.L; Taylor, T.R and Chiu-Kit J.T. (1993) Disease specific versus generic measurement of health related quality of life in insulin dependent diabetic patients. *Medical Care,* 7, 629-639.

Patenaude A. F. and Kupst M. J. (2005) Psychosocial functioning in paediatric cancer. *Journal of Paediatric Psychology* 30, 9–27.

Patrick, D.L and Erikson, P. (1988) *Assessing Health Related Quality of Life in General Population Surveys.* Series 2: Report from the National Centre for Health Statistics. Hyatsville: NCHS.

Paxton, S.J and Sculthorpe, A. (1999) Weight and locus of control beliefs in an Australian community sample. *Psychology and Health,* 14, 417-431.

Pendley, J. S; Kasmen, L; Miller, D; Donze, J; Swenson, C and Reeves, G. (2002) Peer and family support in children and adolescents with type 1 diabetes. *Journal of Paediatric Psychology,* 27, 429–438.

Perrin, J. M; MacLean, W. E; Gortmaker, S. L and Asher, K. N. (1992) Improving the psychological status of children with asthma: A randomized controlled trial. *Developmental and Behavioural Paediatrics,* 13, 241-24.

Peterson, T; Lee, P; Hollis, S; Young, B; Newton, P and Dorman, T. (1998) Well being and treatment satisfaction in older people with diabetes. *Diabetes Care,* 21, 930-935.

Petterson, T; Lee, P; Hollis, S; Young, B; Newton, P and Dornan, T. (1998) Well-being and treatment satisfaction in older people with diabetes. *Diabetes Care,* 21(**6**), 930-935

Peveler, R.C; Bryden, K.S; H; Neil, A.W; Fairburn, C.G; Mayou, R.A; Dunger, D.B and Turner, H.M. (2005) The relationship of disordered eating habits and attitudes to clinical outcomes in young adult females with type 1 diabetes. *Diabetes Care,* 28, 84-88.

Peyrot, M. (1999) Behaviour change in diabetes education. *The Diabetes Educator,* 25(Supplement 6) 62-73.

Peyrot, M; Rubin, R.R; Lauritzen, T; Skovlund, S.E; Snoek, F.J; Matthews, D.R and Landgraf, R, the International DAWN Advisory Panel (2006) Patient and provider perceptions of care for diabetes: results of the cross-national DAWN study. *Diabetologia,* 49, 279-288.

Peyrot, M and Rubin, R.R. (1994) Structure and correlates of diabetes-specific locus of control. *Diabetes Care,* 17(**9**), 994-1001.

Piaget, J and Inhelder, B. (1969) *The Psychology of the Child.* New York: Basic Books.

Pickup, J; Mattock, M; and Kerry, S. (2002) Glycaemic control with continuous subcutaneous insulin infusion compared with intensive insulin injections in patients with type 1 diabetes: meta-analysis of randomised controlled trials. *British Medical Journal*, 324, 705-708.

Pill, R.M; Rees, M.E; Stott, N.C.H and Rollnick, S. (1999) Can nurses learn to let go? Issues arising from an intervention designed to improve patients' involvement in their own care. *Journal of Advanced Nursing,* 29(**6**), 1492-1499.

Pill, R.M; Stott N.C.H; Rollnick, S and Rees M. (1998) A randomized controlled trial of an intervention designed to improve the care given in general practice to type II diabetic patients: patient outcomes and professional ability to change behaviour. *Family Practice,* 15(**3**), 229-235.

Plante, W.A; Lobato, D and Engel, R. (2001) Review of group interventions for paediatric chronic conditions. *Journal of Paediatric Psychology*, 26(7), 435-453.

Pocock, S.J; Assmann, S.E; Enos, L.E and Kasten, L.E. (2000) Sub-group analysis, covariate adjustment and baseline comparisons in clinical trial reporting. *Statistical Medicine,* 21, 2917-2930.

Polonsky, W.H. (2000) Understanding and assessing diabetes: Specific quality of life. *Diabetes Spectrum*, 13, 36 - 41.

Pope, C and Mays, N. (1995) Reaching them parts other methods cannot reach: An introduction to qualitative research methods in health and health services research. *British Medical Journal*, 311, 42-45.

Pouwer; F; Snoek, F.J; van der Ploeg, H.M; Adèr, H.J and Robert J. Heine, R.J. (2001) Monitoring of psychological well-being in out-patients with diabetes Effects on mood, HbA1c, and the patient's evaluation of the quality of diabetes care: a randomized controlled trial. *Diabetes Care,* 24, 1929-1935.

Pouwer, F; van der Ploeg, H.M; Ader, H.J; Heine, R.J and Snoek, F.J. (1999). The 12 item Well-Being Questionnaire. An evaluation of its validity and reliability in people with diabetes. *Diabetes Care,* 22(**12**), 2004-2010.

Prochaska, J and DiClemente, C. (1984) *The transtheoretical approach: Crossing traditional boundaries of therapy.* Illinois: Dow-Jones-Irwin.

Project MATCH Research Group (1997) Matching alcoholism treatments to client heterogeneity: Project MATCH post treatment outcomes. *Journal of Studies on Alcohol,* 58, 7-29.

Project MATCH Research Group (1998) Matching alcoholism treatments to patient heterogeneity: Project MATCH three-year drinking outcomes. *Alcohol Clinical Experimental Research*, 22, 1300–1311.

Rapkin, B.D and Schwartz, C.E. (2004) Toward a theoretical model of quality -of -life appraisal: Implications of findings from studies of response shift. *Health and Quality of Life Outcomes*, 2(**14**). Accessed online August 21st 2006: http://www.biomedcentral.com/content/pdf/1477-7525-2-14.pdf

Rapoff, M.A. (1999) *Adherence to paediatric medical regimens.* New York: Kluwer Academic.

Rapoff, M.A. (2001) Commentary: Pushing the envelope: Furthering research on improving adherence to chronic paediatric disease regimens. *Journal of Paediatric Psychology*, 26(**5**), 277-278.

Reynaert, C; Janne, P; Donckier, J; Buysschaert, M; Zdanowicz, N and Lejeune, D. (1995) Locus of control and metabolic control. *Diabetes Metabolism,* 21, 180-187.

Richards, G; Morris, M; Booker, S and Johnson, A. (2006) What do people with type 1 diabetes find helpful? Results from a focus group study. *Practical Diabetes International*, 23(**6**), 249-252.

Richmond, R; Heather, A. W; Kehoe, L and Webster, I. (1995) Controlled evaluation of a general practice-based brief intervention for excessive drinking. *Addiction*, 90, 119-132.

Roberts, S. (2006) *Turning the corner: Improving diabetes care*. Department of Health. Accessed online 2nd November 2006: http://www.dh.gov.uk/PublicationsandStatistics

Roberts, C and Torgerson, D. J. (1999) Understanding controlled trials: Baseline imbalance in randomised controlled trials: *British Medical Journal*, 319, 185-185.

Robinson, E.J; Kerr, C.E.P; Stevens, A.J; Lilford, R.J; Braunholtz, D.A; Edwards, S.J; Beck, S.R and Rowley, M.G. (2005) Lay public's understanding of equipoise and randomisation in randomised controlled trials. *Health Technology Assessment*, 9(**8**), 1–192: HTA.

Robinson, N; Lloyd, C.E and Stevens, L.K. (1998) Social deprivation and mortality in patients with diabetes mellitus. *Diabetic Medicine,* 15, 205–212.

Rogers, C.R. (1967) *The therapeutic relationship and its impact: A study of psychotherapy with schizophrenics*. Madison: University of Wisconsin Press.

Rohlfing C.L; Wiedmeyer H, M, and Little, R.R. (2005) Defining the relationship between plasma glucose and HbA_{1c}: Analysis of glucose profiles and HbA_{1c} in the Diabetes Control and Complications Trial. *Diabetes Care*, 25, 275-278.

Rollnick, S; Allison, J; Ballasiotes, S; Barth, T; Butler, C.C; Rose, G and Rosengren, D.B. (2002) Variations on a theme: Motivational Interviewing and its adaptations. In. Miller, W.R and Rollnick, S. (Eds) *Motivational Interviewing: Preparing people for change.* (2nd Edition pp: 270-283). New York: The Guildford Press.

Rollnick, S. (2001) Enthusiasm, quick fixes and premature controlled trials. Commentaries on Dunn et al's 'the use of brief interventions adapted from motivational interviewing across behavioural domains: a systematic review'. *Addiction*, 96, 1769-1770.

Rollnick, S; Mason, P and Butler, C. (1999) *Health Behaviour Change: A guide for practitioners*. London: Churchill Livingstone.

Rollnick, S; Butler, C.C and Stott, N.C.H. (1997) Helping smokers make decisions: the enhancement of a brief intervention for general medical practice. *Patient Education and Counselling,* 31, 191-203.

Rollnick, S and Miller, W.R. (1995) What is motivational interviewing? *Behavioural and Cognitive Psychology,* 21, 95-103.

Rollnick, S; Heather, N and Bell, A. (1992) Negotiating behaviour change in medical settings: The development of brief motivational interviewing. *Journal of Mental Health*, 1, 25-37.

Rose, M; Fliege, H; Hilderbrandt, M; Schrop, T and Klapp, B.F. (2002) The network of psychological variables in patients with diabetes and their importance for quality of life and metabolic control. *Diabetes Care,* 25(**1**), 35-42.

Rosen, C.S. (2000) Is the sequencing of change processes by stage consistent across health problems? A meta-analysis. *Health Psychology,* 19, 593-604.

Rosenberg, M. (1965) *Society and The Adolescent Self-Image*. Princeton, New Jersey: Princeton University Press.

Rosengren, D.B. (2003) Personal communication: *Analysis of audiotapes of MI during Wales College of Medicine RCT.* Alcohol and Drug Abuse Institute: University of Washington.

Rosenthal, R. (1966) *Experimenter effects in behavioural research.* New York. Appleton.

Rotter, J. B. (1966) Generalized expectancies for internal versus external control of reinforcement. *Psychological Monographs*, 80. Number: 609.

Rubak, S; Sandboek, A; Lauritzen, T and Christensen, B. (2005) Motivational interviewing: A systematic review and meta-analysis. *British Journal of General Practice*, 55, 305-12.

Rubin, R.R. (2001) Facilitating self care in people with diabetes. *Diabetes Spectrum*, 14, 55-57.

Rubin, R.R and Peyrot, M. (1999) Quality of life and diabetes. *Diabetes Metabolism Research and Reviews*, 15, 205-218.

Rubin, R.R; Peyrot, M and Saudek C.D. (1993) The effect of a diabetes education program incorporating coping skills training on emotional well-being and diabetes self-efficacy. *Diabetes Educator,* 19, 210–214.

Rubin R, R; Walen, S.R and Ellis, A. (1990) Living with diabetes. *Journal of Rational-Emotive Cognitive Behavioural Therapy,* 1, 21-39.

Rubin, R.R; Peyrot, M and Saudek, C. D. (1989) Effect of diabetes education on self care, metabolic control and emotional well being. *Diabetes Care,* 12, 673-679.

Ruzicki, D.A. (1984) Relationship of participation preference and health locus of control in diabetes education. Diabetes Care, 7(**4**), 372-377.

Sackett, D.L. (2000) Why randomized controlled trials fail but needn't: 1. Failure to gain "coal-face" commitment and to use the uncertainty principle. *Canadian Medical Association Journal,* 162(**9**), 1311-4.

Salerno, M; Argenziano, A; Di Maio, S; Gasparini, N; Formicola, S; DeFilippo, G and Tenore, A. (1997) Pubertal growth, sexual maturation, and final height in children with IDDM: effects of age at onset and metabolic control. *Diabetes Care,* 20, 721–724.

Salomon, J; Tandon, A and Murray, C.J.L. (2004) Comparability of self report health: Cross cultural survey using anchoring vignettes. *BMJ.com.* 328 (7434). Accessed online 2nd November 2006: http://www.bmj.com doi:10.1136/bmj.37963.691632.44

Sanchez, C.D; Newby, K.L; McGuire, D.K; Hasselblad, V; Feinglos, M.N and Magnus-Onman, E. (2005) Diabetes-related knowledge, atherosclerotic risk factor control and outcomes in acute coronary syndromes. *The American Journal of Cardiology*, 95(**11**), 1290-1294.

Saunders, B; Wilkinson, C and Philips, M. (1995) The impact of a brief motivational intervention with opiate users attending a methadone programme. *Addiction*, 90(**3**), 415-424.

Satin, W; La Greca, A. M; Zigo, M and Skyler, J. (1989) Diabetes in adolescents: Effects of multi-family group intervention and parent simulation of diabetes. *Journal of Paediatric Psychology*, 14, 259-275.

Sawyer, M.G; Couper, J.J; Kennedy, J.D and Martin, A.J. (2003) Chronic illness in adolescents. *Medical Journal of Australia*, 179(**5**), 237.

Schafer, L. C; McCaul, K. D and Glasgow, R. E. (1986) Supportive and non-supportive family behaviours: Relationships to adherence and metabolic control in persons with type 1 diabetes. *Diabetes Care*, 9, 179–185.

Schaefer, C. E. (1999) Preface. In. Schaefer, C.E. (Ed) *Short-term psychotherapy groups for children: Adapting group processes for specific problems* (pp. vii-xii). Northvale, New Jersey: Jason Aronson.

Schilling, L.S; Grey, M and Knafl, K.A. (2002) The concept of self-management of type 1 diabetes in children and adolescents: an evolutionary concept analysis. *Journal of Advanced Nursing.* 37(**1**), 87-99.

Schultz, C. J; Konopelska-Bahu, T; Dalton, R.N; Carroll, T.A; Stratton, I; Gale, E.A; Neil, A and Dunger, D.B. (1999) Micro-albuminuria prevalence varies with age, sex, and puberty in children with type 1 diabetes followed from diagnosis in a longitudinal study. Oxford Regional Prospective Study Group. *Diabetes Care,* 22(**3**), 495-502.

Schwartz, C.E Feinberg, R.G; Jilinskaia, E and Applegate, J.C. (1999) An evaluation of a psychosocial intervention for survivors of childhood cancer: Paradoxical effects of response shift over time. *Psycho-Oncology*, 8(**4**), 344–354.

Schwarzer, R and Fuchs, R. (1995) Self efficacy and health related behaviours. In. Connor, M and Norman, P. (Eds) *Predicting Health Behaviour* (pp: 163-196). Buckingham: Open University.

Schwarzer, R and Jerusalem, M. (1995) Generalized Self-Efficacy Scale. In. M Johnston, M; Wright, S.C and Weinman, J. (Eds) *Measures in Health Psychology: A User's Portfolio, Causal and Control Beliefs* (pp: 35-37). Windsor England: NFER-NELSON.

Schwarzer, R. (1992) *Self-efficacy: Thought control of action.* Washington, DC: Hemisphere.

Scott, A and Donnelly, R. (2001) Improving outcomes for young people with diabetes. *Diabetic Medicine*, 18, 861-863.

Seiffge-Krenke, I and Stemmler, M. (2003) Coping with everyday stress and links to medical and psychosocial adaptation in diabetic adolescents. *Journal of Adolescent Health,* 33(**3**), 180-188.

Semiz, S; Özarslan Ü; Bundak, B.R and Bircan, I. (2000) Summer camps for diabetic children: an experience in Antalya, Turkey. *Acta Diabetologica,* 37(**4**), 197-200.

Senecal, C; Nouwen, A and White, A. (2000) Motivation and dietary self care in adults with diabetes: Are self efficacy and autonomous self regulation complementary or competing constructs? *Health Psychology*, 19(**5**), 452-457.

Senft, R. A; Polen, M. R; Freeborn, D. K and Hollis, J. F. (1997) Brief intervention in a primary care setting for hazardous drinkers. *American Journal of Preventive Medicine*, 13(**6**), 464-70.

Senn, S. (1991) Baseline comparisons in randomised controlled trials. *Statistics in Medicine*, 10, 1157-1159.

Shadish, W.R; Cook, D.T and Campbell, D.T. (2002). *Experimental and Quasi-Experimental Designs for Generalized Causal Inference.* Boston: Houghton-Mifflin.

Skinner, T.C; Hoey, H; McGee, M; Skovlund, S.E for the Hvidøre Study Group on Childhood Diabetes (2006) Diabetes quality of life for youth – short form (DQOLY-SF). Exploratory and confirmatory analysis in a sample of 2,077 young people with type 1 diabetes mellitus. *Diabetologia*, 49, 621-628.

Skinner, T.C. (2006) Commentary: When will people with diabetes receive the respect and empathy they deserve? *Practical Diabetes International.* 23(**6**), 247.

Skinner, T.C; Murphy, H and Huws-Thomas, M.V. (2005) Diabetes in Adolescents. In. Snoek, F.J and Skinner, T.Chas (Eds). *Psychology and Diabetes Care (Practical Diabetes),* 2nd Edition.(pp:27-51). Chichester: John Wiley.

Skinner, T.C. (2004) Psychological barriers. *European Journal of Endocrinology,* 151, T13-T17.

Skinner, T.C and Cradock, S. (2001) Managing type 2 diabetes: A dynamic approach. *Nursing Times*, 97(7), 42-43.

Skinner, T. C and Hampson, S. E. (2001) Personal models of diabetes in relation to self-care, well-being, and glycaemic control: A prospective study in adolescence. *Diabetes Care,* 24, 828 –833.

Skinner, T. C; John, M and Hampson, S. E. (2000) Social support and personal models of diabetes as predictors of self-care and well-being: A longitudinal study of adolescents with diabetes. *Journal of Paediatric Psychology,* 25, 257 –268.

Skinner, T.C; Copp, C and Hampson, S.E. (1998) Adherence and quality of life in adolescence: associations with personal models (Abstract). *Diabetic Medicine,* 15, 119.

Skinner, T. C and Hampson, S. E. (1998) Social support and personal models of diabetes in relation to self-care and well-being in adolescents with type I diabetes mellitus. *Journal of Adolescence,* 21, 703 –715.

Skovlund, S.E; Peyrot, M. on behalf of the DAWN International Advisory Panel. (2005) The Diabetes Attitudes, Wishes, and Needs (DAWN) Program: A new approach to improving outcomes of diabetes care. *Diabetes Spectrum,* 18, 136-142.

Smith, C.P; Firth, D; Bennett, S; Howard, C and Chisholm, P. (1998) Ketoacidosis occurring in newly diagnosed and established diabetic children. *Acta Paediatrica,* 87(**5**), 537-541.

Snoek, F.J. (2006) Diabetes and psychological well being: crossing borders to achieve optimum care. *Practical Diabetes International*, 23(**6**), 241-242.

Snoek, F.J. (2006) Not the magic bullet: Letter in response to Winkley et al. (2006). *British Medical Journal*. Accessed online 28th August 2006: BMJ/doi 10.113/bmj.38874.652569.55

Snoek, F.J and Skinner, T.C. (2002) Psychological counselling in problematic diabetes. *Diabetic Medicine*, 19, 265-273.

Snoek, F.J; van der Ven, N.C.W; Lubach, C.H.C; Chatrou, M; Ader, H.J; Heine, R.J and Jacobson, A.M. (2001) Effects of cognitive behavioural group training (CBGT) in adult patients with poorly controlled insulin-dependent (type 1) diabetes: a pilot study. *Patient Education and Counselling*, 45(**2**), 143–148.

Snoek, F.J. (2000) Quality of life: A closer look at measuring well being. *Diabetes Spectrum,* 13(**1**), 24-28.

Sprangers, M.A.G and Schwartz, C.E. (1999) Integrating response shift into health related quality of life research: A theoretical model. *Social Science and Medicine,* 48, 1507-1515.

Speith, L. E and Harris, C. V. (1996) Assessment of health-related quality of life in children and adolescents: An integrative review. *Journal of Paediatric Psychology*, 21(**2**), 175-193.

Spencer, J and Dales, J. (2006) Meeting the needs of simulated patients and caring for the person behind them? *Medical Education* 40(**1**), 3–5.

Stark, L.J; Janicke, D, M; McGrath, A.M; Mackner, L.M; Hommel, K.A and Lovell, D. (2005) Prevention of osteoporosis: A randomized clinical trial to increase calcium intake in children with juvenile rheumatoid arthritis. *Journal of Paediatric Psychology*, 30(**5**), 377 - 386.

Stark, L. J; Mackner, L. M; Kessler, J. H; Opipari, L. C and Quittner, A. L. (2002). Preliminary findings for calcium intake in children with cystic fibrosis following behavioural intervention for caloric intake. *Children's Health Care*, 32, 107–118.

Steed, L; Cooke, D and Newman, S. (2003) A systematic review of psychosocial outcomes following education, self-management and psychological interventions in diabetes mellitus. *Patient Education and Counselling*, 51(**1**), 5-15.

Steinberg, L. (2006) Cognitive and effective development in adolescence. *TRENDS in Cognitive Science,* 9(**2**), 69-74.

Steinberg, L. (1990) Autonomy, conflict, and harmony in the family relationship. In Feldman, N.S and Elliot, G (Eds.) *At the Threshold: The Developing Adolescent* (pp: 255–276). Cambridge, MA: Harvard University Press.

Stenstrom, U; Wikby, A; Andersson, P-O and Ryden, O. (1998) Relationship between locus of control beliefs and metabolic control in insulin-dependent diabetes mellitus, *British Journal of Health Psychology*, 3(**1**), 15-25.

Stephens, R.S; Roffman, R.A and Curtin, L. (2000) Comparison of extended versus brief treatments for marijuana use. *Journal of Consulting and Clinical Psychology*, 68(**5**), 898-908.

Stephenson, J and Imrie, J. (1998) Why do we need randomised controlled trials to assess behavioural interventions? *British Medical Journal,* 316, 611-613.

Stewart, S.M; Rao, U; Emslie, G.J; Klein, D and White, P.C. (2005) Depressive symptoms predict hospitalization for adolescents with type 1 diabetes mellitus. *Paediatrics,* 115(**5**), 1315-1319.

Stratford, P and Riddle, D.L. (2005) Assessing sensitivity to change: choosing the appropriate change coefficient. *Health and Quality of Life Outcomes*, 3(**23**) 1-7. Accessed online 30th September 2006: http:www.hqlo.com/ doi: 10.1186/1477-7525-3-23.

Stott. N; Rees, M; Rollnick, S; Pill, R.M and Hackett, P. (1996) Professional responses to innovation in clinical method: diabetes care and negotiating skills. *Patient Education and Counselling*, 29, 67-73.

Stott, N; Rollnick, S; Rees, M and Pill, R.M. (1995) Innovation in clinical method: diabetes care and negotiating skills. *Family Practice,* 12(**4**), 413-418.

Surgenor, L.J; Horn, J; Hudson, S.M; Lunt, H and Tennent, J. (2000) Metabolic control and psychological sense of control in women with diabetes mellitus. Alternative considerations of the relationship. *Journal of Psychosomatic Research*, 49, 267-273.

Suris, J-C; Michaud, P-A, and Viner, R. (2004) The adolescent with a chronic condition. Part I: developmental issues. *Archives of Disease in Childhood*, 89, 938–942.

Surwit, R.S and Schneider, M.S. (1993) Role of stress in the aetiology and treatment of diabetes mellitus. *Psychosomatic Medicine*, 55, 380–393.

Svoren, B.M; Butler, D; Levine, B.S; Anderson, B.J and Laffel, L.M.B. (2003) Reading adverse outcomes in youths with type 1 diabetes: A randomised controlled trial. *Paediatrics,* 112, 914-922.

Swanson, A.J; Pantalon, M.V and Cohen, K.R. (1999) Motivational interviewing and treatment adherence among dually-diagnosed patients. *Journal of Nervous and Mental Disease*, 187(**10**), 630-635.

Swift, P.G.F. (2002) Diabetes guidelines for kids. *Diabetes Voice,* 47(**1**), 1-25. Accessed online: August 24th 2006. http://www.diabetesvoice.org/issues/2002-03/Diabetes_guidelines_for_kids.pdf

Swift, P.G.F. (2000) International Society for Paediatric and Adolescent Diabetes (ISPAD). *Consensus guidelines 2000. ISPAD consensus guidelines for management of type 1 diabetes mellitus in children and adolescents.* Zeist: Medical Forum International.

Swift, P.G.F. (1997) Optimization of insulin treatment in children. *Annals of Medicine,* 29(**5**), 419-24.

Swift, P.G.F; Hearnshaw, J.R; Botha, J.L; Wright, G; Raymond, N.T and Jamieson K. F. (1993) A decade of diabetes: keeping children out of hospital. *British Medical Journal,* 10, 307, 96-98.

Swift. P.G.F. (1995) Insulin types and regimens. In. Kelnar C. J. H. (Ed) *Childhood and Adolescent Diabetes* (pp: 253-270). London: Chapman and Hall Medical.

Tabachnick, B. G and Fidell, L. S. (1996) *Using Multivariate Statistics,* 3rd Edition. New York: Harper Collins.

Talbot, F and Nouwen, A. (2000) A review of the relationship between depression and diabetes in adults: is there a link? *Diabetes Care,* 23(**10**), 1556-1562.

Talbot, F; Nouwen, A; Gingras, J; Gosselin, M and Audet, J. (1997) The assessment of diabetes related cognitive and social factors: the multidimensional diabetes questionnaire, *Journal of Behavioural Medicine,* 20(**3**), 291-312.

Tamborlane, W.V; Bonfig, W and Boland, E. (2001) Recent advances in treatment of youth with type 1 diabetes: better care through technology. *Diabetic Medicine,* 18 (**11**), 864–870.

Tappin, D.M; Lumsden, M.A; Crawford, F; McIntyre, D; Stone, D.H; Webber, R; MacIndoe, S and Mohammed, E. (2005) A randomised controlled trial of home based motivational interviewing by midwives to help pregnant smokers quit or cut down. *British Medical Journal,* 331, 373-377.

Tattersall, R.B and Gill, G.V. (1991) Unexplained deaths of type 1 diabetic patients. *Diabetic Medicine,* 8, 49–58.

Tattersall, R.B. (1987) Psychological aspects of diabetes in childhood and adolescence. *Paediatric Annals*, 16, 728-740.

Testa, M. (2000) Quality of life assessment in diabetes research: Interpreting the magnitude and meaning of treatment effects. *Diabetes Spectrum*, 13, 36-41.

Testa, M and Simonson, D.C. (1998) Health economic benefits and quality of life during improved glycaemic control in patients with type 2 diabetes mellitus: A randomised controlled double-blind trial. *Journal of American Medical Association,* 280(**17**), 1490-1496.

Testa, M; Simonson, D.C and Turner, R.R. (1998) Valuing quality of life and improvements in glycaemic control in people with type 2 diabetes. *Diabetes Care,* 21(**3**), Supplement 3: C44-52.

Thomas, A. (2000) Standardization of HbA1c measurement - the issues. *Diabetic Medicine,* 17(**1**), 2–4.

Thomas, A. M; Peterson, L and Goldstein, D. (1997) Problem solving and diabetes regimen adherence by children and adolescents with IDDM in social pressure situations: A reflection of normal development. *Journal of Paediatric Psychology*, 22, 541-561.

Thomson O'Brien, M; Freemantle, N; Oxman, A; Wolf, F; Davis, D and Herrin, J. (2001) Continuing education meetings and workshops: Effects on professional practice and health care outcomes (Review). *Cochrane Database of Systematic Reviews. Issue 1.*

Todd, C and Bradley, C. (1994) Evaluating the design and development of psychological scales. In: Bradley, C. (Ed). *Handbook of Psychology and Diabetes: A Guide to Psychological Measurement in Diabetes Research and Practice* (pp: 15-42). Chur, Switzerland: Harwood Academic.

Torgerson, D and Sibbald, B. (1998) Understanding controlled trials: What is a patient preference trial? *British Medical Journal,* 316, 260. Accessed online 23rd September 2006: http://www.bmj.com/cgi/content/full/316/7128/360

Torrance, T; Franklin, V and Greene, S. (2003) Insulin pumps: A growing option in the UK for children and young adults with type 1 diabetes. *Archives of Disease in Childhood*, 88, 949-953.

Torres, R and Fernandez, F. (1995) Self esteem and value of health as determinants of adolescent health behaviour. *Journal of Adolescent Health,* 16(**1**), 60-63.

Trento, M; Passera, P; Miselli, V; Bajardi, M; Borgo, E; Tomelini, M; Tomalino, M; Cavallo, F and Porta, M. (2006) Evaluation of the locus of control in patients with type 2 diabetes after long-term management by group care. *Diabetes Metabolism.* 32(**1**), 77-81.

Trief, P. M; Grant, W and Elbert, K. (1998) Family environment, glycaemic control, and the psychosocial adaptation of adults with diabetes. *Diabetes Care,* 21, 241-245.

Trigwell, P; Grant, P.J and House, A. (1997) Motivation and glycaemic control in diabetes mellitus. *Journal of Psychosomatic Research,* 43(**3**), 307-315.

Toobert, D. J and Glasgow, R. E. (1994) Assessing diabetes self-management: The Summary of Diabetes Self-Care Activities Questionnaire. In. Bradley, C. (Ed), *Handbook of Psychology and Diabetes* (pp: 351-375). Chur, Switzerland: Harwood Academic.

UK Prospective Diabetes Study (UKPDS) Group (1998) Intensive blood glucose control with sulphonylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes. *Lancet,* 352, 837-853.

Unite for Diabetes (2006) United Nations Resolution for Diabetes. Accessed online October 21st 2006: http://www.unitefordiabetes.org/.

Upton, P; Eiser, I; Cheung, I; Hutchings, H.A; Jenney, M; Maddocks, A; Russell, I.T and Williams, J.G. (2005) Measurement properties of the UK-English version of the Paediatric Quality of Life Inventory™ 4.0 (PedsQL™) generic core scales. *Health and Quality of Life Outcomes*, 3:22. Accessed online: 23rd May 2006. http://www.hqlo.com/content/pdf/1477-7525-3-22.pdf

van der Ven, N. C.W; Weinger, K; Yi, J; Pouwer, F; Adèr, H; van der Ploeg, H..K and Snoek, F.J. (2003) The Confidence in Diabetes Self-Care Scale: Psychometric properties of a new measure of diabetes-specific self-efficacy in Dutch and U.S. patients with type 1 diabetes. *Diabetes Care,* 26, 713-718.

van der Ven, N. (2003) Psychosocial group interventions in diabetes care. *Diabetes Spectrum,* 16, 88-95.

Vanelli, M; Chiarelli, F; Chiari, G and Tumini, S. (2003) Relationship between metabolic control and quality of life in adolescents with type 1 diabetes. *Acta Bio Medica,* 74(**1**), 13-17.

Varni, J.W; Burwinkle, T.M and Lane, M.M. (2005) Health-related quality of life measurement in paediatric clinical practice: An appraisal and precept for future research and application. *Health and Quality of Life Outcomes,* 3(**34**). Accessed online August 2006: http://www.hqlo.com/content/3/1/34/ doi:10.1186/1477-7525-3-34

Varni, J.W; Burwinkle, T.M; Jacobs, J.R; Gottschalk, M; Kaufman, F and Jones, K.L (2003) The PedsQL in type 1 and type 2 diabetes. Reliability and validity of the Paediatric Quality of Life Inventory Generic Core Scales and type 1 diabetes. *Diabetes Care,* 26(**3**), 631-637.

Varni, J.W; Seid, M and Kurtin, P. (2001) The PedsQL™ 4.0: Reliability and validity of the Paediatric Quality of Life Inventory™ Version 4.0 Generic Core Scales in healthy and patient populations. *Medical Care*, 39(**8**), 800-812.

Vermeire, E; Wens, J; Van Royen, P; Biot, Y; Hearnshaw, H and Lindenmeyer, A. (2005) Interventions for improving adherence to treatment recommendations in people with type 2 diabetes mellitus. *The Cochrane Database of Systematic Reviews* 2007, Issue 1. The Cochrane Collaboration: John Wiley and Sons.

Vickers, A.J and Altman, D.G. (2001) Analysing controlled trials with baseline and follow up measurements. *British Medical Journal,* 323, 1123-1124.

Vila, G; Roberts, J.J; Clemencon, C.N; Vera, L.; Crosnier, H; Rault, G; Jos, J and Mouren-Simeoni, M.C. (1995) Eating and emotional disorders in adolescent girls with insulin-dependent diabetes mellitus. *European Child and Adolescent Psychiatry*, 4, 270-279.

Vincent, D; Clark, L; Marquez- Zimmer, L and Sanchez, J. (2006) Using focus groups to develop a culturally competent diabetes self-management program for Mexican Americans. *The Diabetes Educator,* 32(**1**), 89-97.

Viner, R.M; Christie, D; Taylor, V and Hey, S. (2003) Motivational/solution focused interventions improves HbA_{1c} in adolescents with type 1 diabetes: a pilot study. *Diabetic Medicine*, 20, 739-742.

Wagner, J.A. (2005) Response shift and glycaemic control in children with diabetes. *Health and Quality of Life Outcomes*, 3:38. Accessed online: 28th September 2006 http://www.hqlo.com/content/3/1/38

Wagner, J; Malchoff, C and Abbott, G. (2005) Invasiveness as a barrier to self-monitoring of blood glucose in diabetes. *Diabetes Technology and Therapeutics,* 7(**4**), 612 -619.

Waldron, S. (2005) Dietary education and outcomes for young people with type 1 diabetes. *Canadian Journal of Diabetes*, 29(**2**), 133-141.

Walker, J and Bradley, C. (2002) Assessing the quality of life of adolescents with diabetes: using the SEIQoL, DQoL, patient and diabetes specialist nurse ratings. *Practical Diabetes International,* 19, 141- 144.

Wallach, P.M; Elnick, M; Bognar, B and Kovach, R; Papadakis, M; Zucker, S and Speer A. (2001) Standardized patients' perceptions about their own health care. *Teaching and Learning in Medicine*, 13, 227–231.

Wallander J. L. and Varni J. W. (1998) Effects of paediatric chronic physical disorders on child and family adjustment. *Journal of Child Psychology and Psychiatry* 39, 29–46.

Waller, K.V and Bates, R.C. (1992) Health locus of control and self-efficacy beliefs in a healthy elderly sample. *American Journal of Health Promotion.* 6(**4**), 302-309.

Wallston, K. (2005) Overview of the special issue on research with the Multidimensional Health Locus of Control (MHLC) scales. *Journal of Health Psychology,* 10(**5**), 619-621.

Wallston, K.A; Malcarne, V.L; Flores, L; Hansdottir, I; Smith, C.A; Stein, M.J;. Weisman, M.H and Clements, P.J. (1999) Does God determine your health? The God Locus of Health Control Scale. *Cognitive Therapy and Research.* 23(**2**), 131-142.

Wallston, K. A. and Smith, M. S. (1994) Issues of control and health: the action is in the interaction. In. Penny, G; Bennett, P and Herbert, M. (Eds) *Health Psychology*: *A Lifespan Perspective* (pp: 153-168). London: Harwood.

Wallston, K.A (1989) Assessment of control in health-care settings. In. Steptoe, A and Appels, A. (Eds) *Stress, Personal Control and Health* (pp: 85-105). Brussels: John Wiley.

Wallston, K.A., Wallston, B.S. (1982) Who is responsible for your health? The construct of locus of control. In Sanders, G.S and Suls, J. (Eds) *Social Psychology of Health and Behaviour,* (pp: 65-95). New Jersey: Erlbaum.

Wallston, K.A; Wallston, B.S and DeVellis, R. (1978) Development of the Multidimensional Health Locus of Control (MHLC) Scales. *Health Education Monographs*, 6, 160-170.

Wallston, B.S; Wallston, K.A., Kaplan, G.D. and Maides, S.A. (1976). Development and validation of the Health Locus of Control (HLC) Scale. *Journal of the Consulting Clinical Psychologist*, 44, 580-585.

Wampold, B.E. (2001) *The Great Psychotherapy Debate: Models, Methods and Findings*. Mahwah, New Jersey: Erlbaum.

Ware, J.E and Sherbourne, C.D. (1992) The 36 item short form health survey (SF-36). I. Conceptual framework and item selection. *Medical Care,* 30, 473-483.

Waters, E; Salmon, L; Wake, M; Hesketh, K and Wright, M. (2000) The Child Health Questionnaire in Australia: reliability, validity and population means. *Australian and New Zealand Journal of Public Health*, 24, 207–210.

Weinberger, M; Kirkman, M.S; Samsa, G.P; Cowper, P.A; Shortliffe, E.A; Simel, D, et al. (1994) The relationship between glycaemic control and health-related quality of life in patients with non-insulin-dependent diabetes mellitus. *Medical Care 32*, 1173-1181.

Weinger, K; Butler, H.A; Welch, G.A; and La Greca, A.M. (2005) Measuring diabetes self-care: A psychometric analysis of the self-care inventory-revised with adults. *Diabetes Care,* 28(**6**), 1346–1352.

Weinger, K; O'Donnell, K.A and Ritholz, M.D. (2001) Adolescent views of diabetes-related parent conflict and support: A focus group analysis. *Journal of Adolescent Health*, 29(**5**), 330–336.

Weissberg-Benchell, J; Antisdel-Lomaglio, J and Seshadri, R. (2003) Insulin pump therapy: A meta-analysis. *Diabetes Care*, 26, 1079-1087.

Weissberg-Benchell, J; Glasgow, A.M; Tynan, W.D; Wirtz, P; Turek, J and Ward, J. (1995) Adolescent diabetes management and mismanagement. *Diabetes Care*, 18(**1**), 77-82.

Welch, G; Rose, G and Ernst, D. (2006) Motivational Interviewing: What is it, How is it used and Does it work? *Diabetes Spectrum,* 19(**1**), 5-11.

Welch, G; Jacobson A and Polosnky, W. (1997) The Problem Areas in Diabetes Scale: an evaluation of its clinical utility. *Diabetes Care,* Diabetes Care, 20(**5**), 760-766.

Whittemore, R; Kanner, S; Singleton, S; Hamrin, V; Chiu, J and Grey, M. (2002) Correlates of depressive symptoms in adolescents with type 1 diabetes. *Paediatric Diabetes,* 3, 135–143.

WHOQOL Group. (1995) The World Health Organisation Quality of Life Assessment (WHOQOL). Position paper from the Word Health Organisation. *Social Science and Medicine,* 41, 1403-1409.

Wikblad, K; Leksell, J; Wibell, L (1996) Health-related quality of life in relation to metabolic control and late complications in patients with insulin dependent diabetes mellitus. *Quality of Life Research,* 5, 123-30.

Wikstrom, G and Bendix, T (2000) The "Hawthorne Effect" – what did the original Hawthorne studies actually show? *Scandinavian Journal of Work and Environmental Health,* 26(**4**), 363-367.

Willett J. B., Singer J. D., Martin N. C. (1998) The design and analysis of longitudinal studies of development and psychopathology in context: Statistical models and methodological recommendations. *Development and Psychopathology*, 10, 395-426.

Williams, G, C; McGregor, H.A; Sharp, D; Levesque, C; Kouides, R.W; Ryan, R.M and Deci, E.L. (2006) Testing a self-determination theory intervention for motivating tobacco cessation: supporting autonomy and competence in a clinical trial. *Health Psychology*, 25(**1**), 91–101.

Williams, G.C; McGregor, H.A; Zeldman, A; Freedman, Z.R; Deci, E.L. (2004) Testing a self determination theory process model for promoting glycaemic control through diabetes self management. *Health Psychology,* 23(**1**), 58-66.

Williams, G. C and Deci, E. L. (2001) Activating patients for smoking cessation through physician autonomy support. *Medical Care,* 39, 813-823

Williams, G. C; Cox, E. M; Kouides, R and Deci, E. L. (1999) Presenting the facts about smoking to adolescents: The effects of an autonomy supportive style. *Archives of Paediatrics and Adolescent Medicine*, 153, 959-964.

Williams, G. C; Freedman, Z. R and Deci, E. L. (1998) Supporting autonomy to motivate glucose control in patients with diabetes. *Diabetes Care,* 21, 1644-1651.

Williams, G.C; Grow, V.M; Freedman, Z.R; Ryan, R.M and Deci, E.L. (1996) Motivational predictors of weight loss and weight-loss maintenance. *Journal of Personality and Social Psychology,* 70, 115-126.

Williams, K.E and Bond, M.J. (2002) The roles of self-efficacy, outcome expectancies and social support in the self-care behaviours of diabetics. *Psychology, Health, and Medicine,* 7, 127–141.

Williams, R.M and Dunger, D.B. (2004) Insulin treatment in children and adolescents. *Acta Paediatrica,* 93, 440-446.

Winkley, K; Landau, S; Eisler, I and Ismail, K. (2006) Psychological interventions to improve glycaemic control in patients with type 1 diabetes: systematic review and meta – analysis of randomised controlled trials. *British Medical Journal,* 333(**7558**) Accessed online 28th August 2006: BMJ/doi 10.113/bmj.38874.652569.55

Wolfsdorf. J.I. (1999) Improving diabetes control in adolescents. *Diabetes Care,* 22, 1767-1768.

Wood-Dauphinee, S. (1999) Assessing quality of life in clinical research: From where have we come and where are we going? *Journal of Clinical Epidemiology,* 52(**4**), 355-363.

Woollard, J; Beilin, L; Lord, T; Puddey, I; MacAdam, D and Rouse, I. (1995) A controlled trial of nurse counselling on lifestyle change for hypertensives treated in general practice: preliminary results. *Clinical and Experimental Pharmacology and Physiology*, 22(**6-7**), 466-468.

World Health Organisation (2001) *International classification of functioning, disability and health (ICF).* Geneva, Switzerland: World Health Organisation.

Wredling, R; Stalhammer, J; Adamson, U; Berne, C; Larsson, Y; Ostman, J (1995) Well being and treatment satisfaction in adults with diabetes: A Swedish population based study. *Quality of Life Research*, 4, 515-522.

Wysocki, T; Harris, M.A;. Buckloh, L.M; Mertlich, D; Sobel-Lochrie, A; Taylor, A: Sadler, M; Mauras, N and White, N.H. (2006) Effects of behavioural family systems therapy for diabetes on adolescents' family relationships, treatment adherence, and metabolic control. *Journal of Paediatric Psychology*, 31(**9**), 928-938.

Wysocki, T. (2002) Parents, teens and diabetes. *Diabetes Spectrum,* 15, 6-8.

Wysocki T; Harris M.A; Greco P; Bubb J; Danda C.E; Harvey L.M; McDonell K; Taylor A; White, N. H. (2000) Randomized controlled trial of behaviour therapy for families of adolescents with insulin-dependent diabetes mellitus. *Journal of Paediatric Psychology*, 25(**1**), 23-33.

Wysocki, T; Miller, K. M; Greco, P; Harris, M. A; Harvey, L. M; Taylor, A; Danda, C. E; McDonell, K and White, N. H. (1999) Behaviour therapy for families of adolescents with diabetes: Effects on directly observed family interactions. *Behaviour Therapy*, 30, 507-525.

Wysocki, T; Taylor, A; Hough, B.S; Linscheid, T.R; Yeates, K.O and Naglieri J. A. (1996) Deviation from developmentally appropriate self–care autonomy: Association with diabetes outcomes. *Diabetes Care*, 19, 119–125.

Appendix 1

APPENDIX 1

Setting the scene strategy

The key elements within this task involved explaining the nature of the tasks involved, details of the session and duration, confidentiality issues, and providing reassurance to ask questions and stop at any time. The role of the interventionist as a mentor or coach was emphasised to promote autonomy.

"Thank you for agreeing to see me today. My name is .....and my aim is to inform you of what the sessions involve, how long they take, and my role. Please feel free to stop me and ask questions at any time. The session today should take around 45 minutes, and certainly no more than an hour. I will ask you some questions about yourself, such as your diabetes, hobbies and other things that are important to you. My role during the course of the study is to be a 'coach' rather than someone who tells you what to do. This will involve us talking about your health, talking about behaviour change and working through things together..... You are free to drop out at any time. How does this sound? (Counsellor awaits response). Do you have any questions about this?"

Appendix 2

APPENDIX 2

The agenda setting task

This took the form of:

- Using an agenda setting template (a pre-completed agenda setting chart) as a source of reference.
- The actor/'patient' drawing their self selected items on a sheet of A3 paper in collaboration with the therapist.

An example of the agenda setting task is as follows:

1: Introduce the task

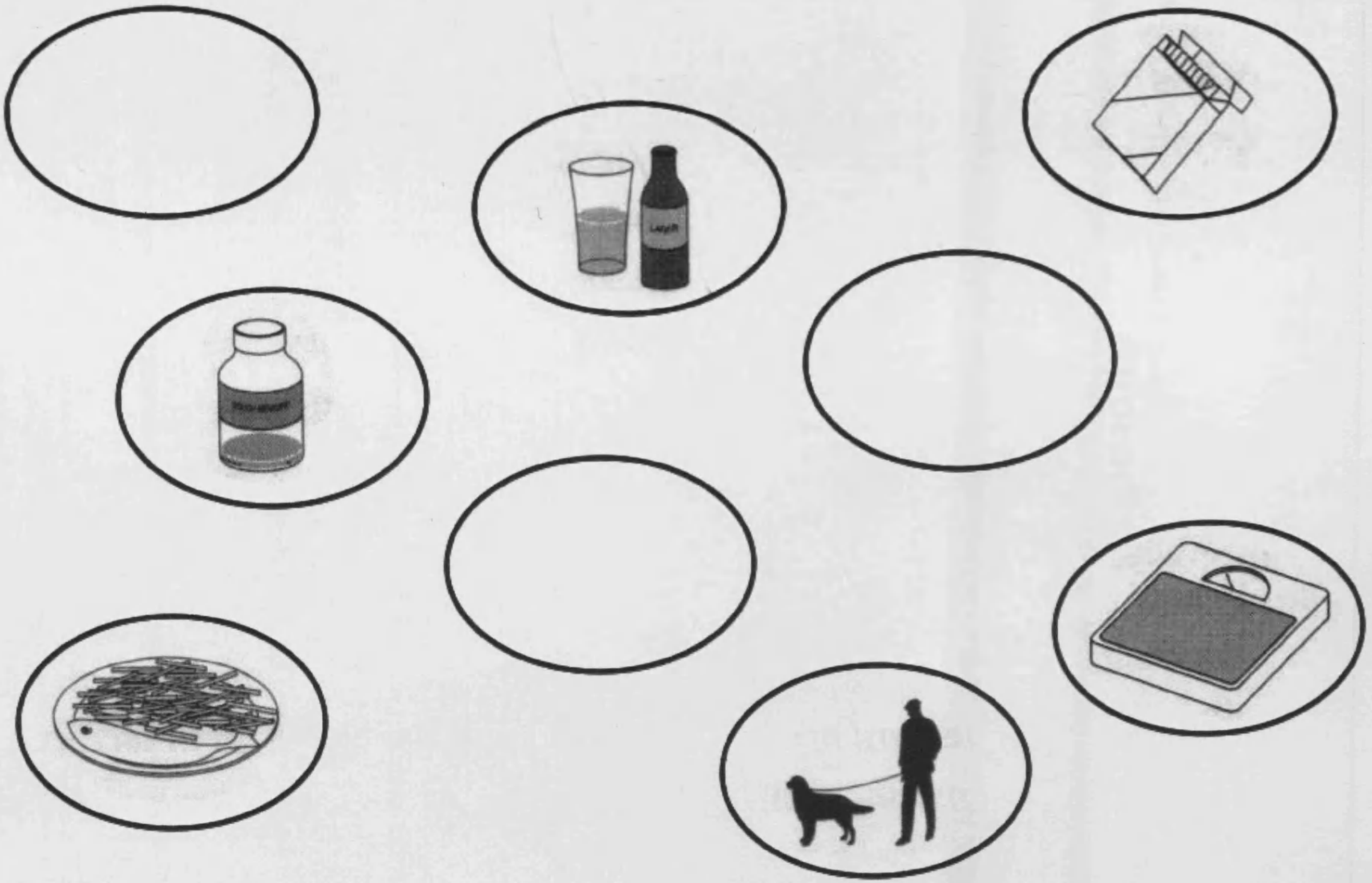
"What I would like to do now is get some idea of how you are doing with your diabetes and how it might fit, or not, with other things in your life. Sometimes it can be hard to explain how your diabetes management is going because there are so many bits to it. Some things may be fine, while other things may cause problems sometimes. Also, there are going to be many other things going on in your life that might not be to do with diabetes, but they are important to you.

2: Introduce the chart.

You'll see here an example of a map with completed circles. Although it doesn't relate directly to diabetes, there may be things on there that you would

like to talk about. You may want to put things like blood sugar testing, injections, diet, exercise ad clinic on it. They may affect your diabetes, or they may not. For now, what I would like you to do is to take some time to think about any areas that are concerning you/ hassling you/ or are important to you and draw them on the blank sheet in front of you. I will help you along with this and please feel free to stop and ask questions if you wish.

How does this sound? Is it OK to proceed?



Appendix 3

APPENDIX 3

Agenda setting task refined

1. Introduction to the task was as follows:

"What I would like to do now is get some idea of how you are doing with your diabetes and how it might fit, or not with other things in your life. Sometimes it can be hard to explain how your diabetes management is going because there are so many bits to it. Some things may be fine, while other things may cause problems sometimes. Also, there are going to be many other things going on in your life that might not be to do with diabetes, but they are important to you".

2: Introduce the chart:

"The way I do this is by drawing it out. You'll see here a kind of map, with all the diabetes bits on it. As you can see its got blood sugar testing, injections, diet, exercise and clinic on it. It's also got a section on independence where we can look how you are doing in terms of managing it yourself and what your parents might want to help you with. Around that, we can put other things that are important now. They may affect your diabetes, or they may not. Some people get confused when I show them this, so I've got an example done by another teenager which might give you a better idea what I'm on about"

Does that make sense? Shall we have a go at yours?

OK, so what do you think would be some of the things that would go on your chart? In the diabetes bits, which area would you start with?

If the author was met with silence, then the area of least likelihood or desirability of change was addressed enabling rapport to be enhanced. The opening question typically followed:

"I know sometimes it's hard to know where to start. What about clinic- do you usually manage every three months? What is getting your HbA_{1c} like?"
OK, so what do you think would be some of the things that would go on your chart? In the diabetes bits, which area would you start with?"

Once the agenda setting task was introduced, a topic was selected by the young person. If the patient remained silent then the interventionist introduced "the easiest" topic that came to mind (e.g. ' the clinic'). A typical open ended question to elicit response was;

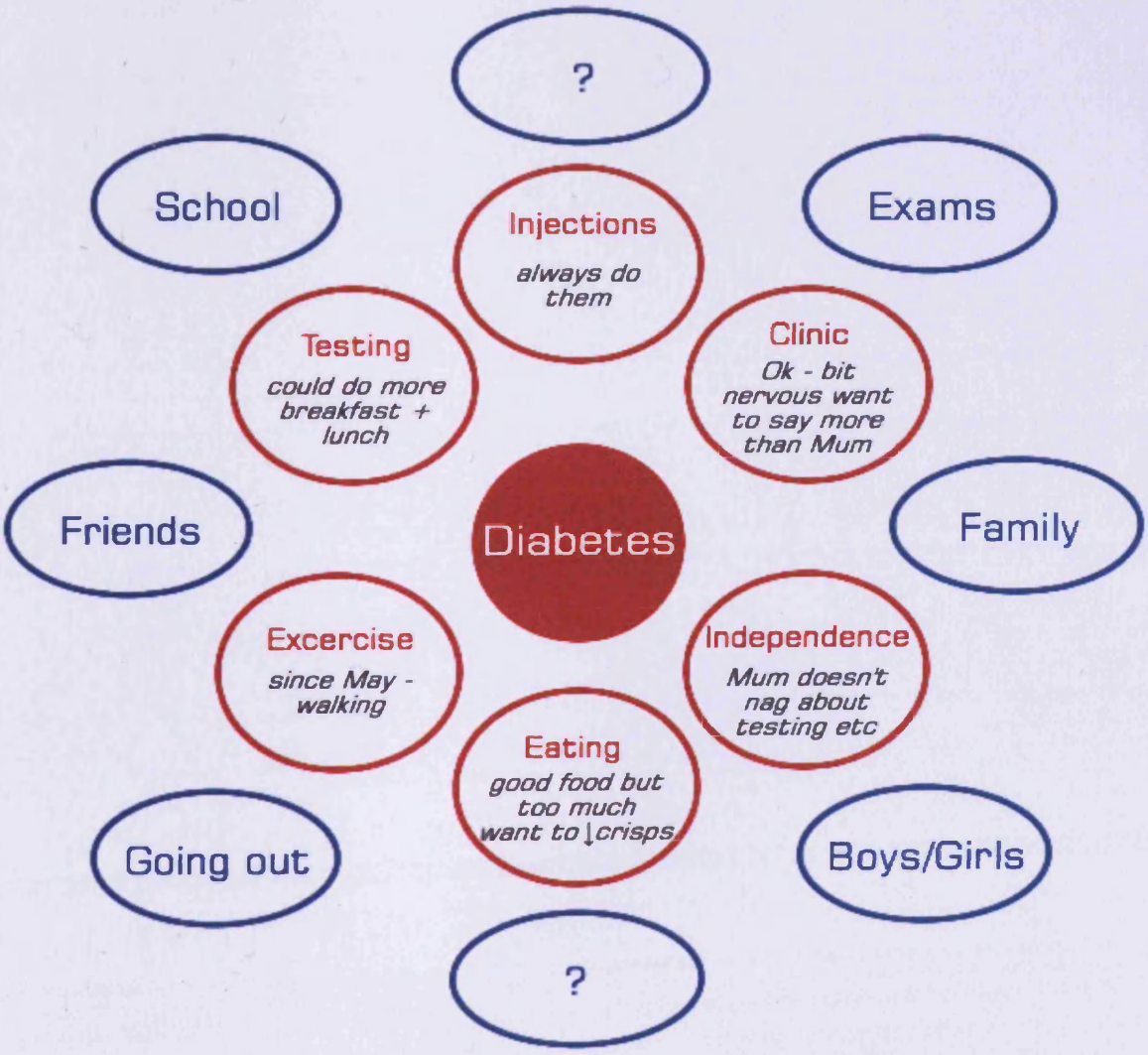
"I know sometimes it's hard to start, what about the clinic? What is getting your HbA_{1c} reading like?

In order to enhance collaboration and autonomy, it was important to elicit confirmation that the wording meets the person's agreement. Upon agreement from the patient another topic was introduced until the chart was complete, or the patient decided otherwise. Blank circles were addressed and the opportunity given to explore

these at a later date. During the task, at key moments the situation was summarised and the patient's response elicited.

Due to the practical nature of the task, the author was careful to not over focus on feelings. Emotive problems identified such as risk taking behaviours were dealt with sensitively once rapport had been established and permission sought to explore these behaviours.

Example of chart:



Appendix 4

APPENDIX 4

CONSENT TO AUDIOTAPE

"A randomised controlled trial of motivational interviewing with adolescents with diabetes"

I give my permission to have me meetings audio-taped with the research worker. I understand that the contents of the tape will be anonymous, confidential, and will not be used outside the research project. The tapes will be destroyed after use.

Participants signature Date

Research workers signature Date

Appendix 5

APPENDIX 5

Example of a goal setting plan

My problems are:

- High blood sugar readings
- Not testing as frequently as I would like.
- Reaching out for sugary foods when I am bored.
- Fear of how my sugars interfere with my sports
- Fear of what clinic may say.

I would like to achieve:

- Test my sugars more frequently.
- Not be afraid of what clinic may say about my readings/frequency of testing.
- Avoid reaching out for foods high in sugar/ starch when I am bored.
- Maintain stable readings.

What is likely to get in my way:

- Not bothering to test. Thinking to myself 'what the heck'.
- Boredom
- Fear of result.
- Location – such as being at school.
- Avoid doing injections

- Eating too much when bored - " snacking and forgetting".

How I will overcome this:

THINGS I CAN DO / MY PLAN

When I reach for bad stuff in cupboard, imagine myself maintaining the high sugars that I have now. Imagine the fear of going to clinic with these readings.
Set aside a time each day to test sugars. This will be around 18:00 before evening meal.
Think of the positive aspects when I achieve my goal.

Ensure that I have privacy and time to TEST and do injection so I don' t get 'caught out' . Plan the day first thing in the morning.

E mail therapist/ or Text for a bit of encouragement
Say to yourself" I know I can do it, even if I have a set back. One failure does not mean TOTAL failure"

Appendix 6

MANUAL FOR THE CONTROL GROUP
PATIENT CENTRED SUPPORT COUNSELLING

Aim

The aim of the control intervention is to provide support, information and education in a patient centred style in teenagers with diabetes. It is based on facilitating the young person to manage their diabetes effectively through advising, provision of information, agreement of goals and assisting with problem solving.

The manual

The manual is designed to help the researcher reach his or her patients in an efficient, supportive, and patient centred way. Every home session with the young person in the control arm will be an opportunity for education and to facilitate the young people in his or her self care to enhance well-being. The manual provides a cross-reference point and aid memoir during the study. The communication between the researcher and the young person needs to take into consideration developmental needs such as cognitive maturity, family circumstances, self identity and diabetes self management

How will this manual help?

It is intended to combine theory, with the researcher's practical skills in order for the researcher to deliver the control intervention. Once the researcher has completed the manual training sessions with the Clinical Psychologist, there will be a list of references to look up the research evidence of the skills undertaken.

The intervention will work within a set of goals and these will be considered in turn.

Goal 1: To establish a therapeutic relationship

The researcher will use effective communication skills to establish a therapeutic relationship with the young person and establish 'ground rules' such as time, roles, confidentiality, and expectations. This will involve:

❖ Setting the Scene

The environment needs to be conducive to effective communication. Therefore, it needs to be private, free from physical barriers such as sitting behind a table, and free from interruption. The time limit of the sessions needs to be specified and discussed at the outset of each session. Additionally the frequency of sessions needs to be addressed. Roles and expectations during the research project need to be clarified and discussed with the young person.

❖ Communication skills.

Conveying interest. The researcher needs to demonstrate that he or she is listening to the young person. Leaning the body slightly towards the patient, maintaining eye contact without staring will convey this.

Open and relaxed posture. Ideally, arms and legs should not be crossed and there should be no barriers between the researcher and the young person (such as notes or bags). Looking too relaxed can be counterproductive.

Monitoring non-verbal communication. It is important for the researcher to monitor the young person's non-verbal communication through the sessions. The feedback will tell the researcher how the young person is feeling and how the sessions are proceeding. The information can be used to maintain an interactive dialogue where both researcher and young person are working toward a common goal. Indicators of boredom or ambivalence include crossed arms/ legs and a closed posture.

Alternatively, a young person looking elsewhere and appearing distracted may indicate depression and unwillingness to talk at that moment.

Active listening. Active listening involves listening to the person's emotions, behaviours, and speech. The researcher needs to communicate understanding back to the young person as well as combining words, with body language cues. The use of *encouragers* are necessary to facilitate the conversation on. 'Encouragers' include, "go on"; "I see".

Therapeutic use of silence. The use of silence is therapeutic since it allows the young person to think about what he or she has said and what is being discussed. It gives the researcher the opportunity to attend to, and observe the young person. It is one of the greatest aspects of good listening.

Communicating Understanding. This seeks to clarify what is being said and clears any misunderstood information. Typical clarifying questions may be, " I'm not sure I fully understand. Can you explain that again"? This will enable the young person to feel they are being heard and understood.

Goal 2: Establishing the needs of the young person

The support counselling intervention is a non-directive, patient centred form of support. However this doesn't mean that the form of helping is purposeless. The action orientation method of support counselling provides the young person with goals that focus on results, outcomes and accomplishments.

Once rapport has been established then it is important to elicit information from the young person such as:

- Elicitation of history (duration of diabetes/ family history)
- Regimen (type of insulin/ how often injects/ diabetes control)
- Support mechanisms (peers/ siblings/ family/ extended family)
- Likes and dislikes
- Pets
- School work
- Aspirations and dreams
- Hobbies and talents (sport/ musical/ creativity)

Due to the non-directive stance, it will be the young person's decision what they talk about during these sessions, although they will be advised that they will be required to talk about their diabetes periodically. It is reasonable for the researcher to elicit *what priorities* the young person has and the researcher may wish to come back to these identified priorities during the course of the sessions.

Goal 3: Information giving

This is an essential part of the control intervention's core goals. The aim is not to bombard the young person with information that the researcher thinks is important for them to know, or to confuse them with information that the person feels is irrelevant, but to present information that is reliable and accurate *when the young person wants it*. The young person may have already been subjected to a wealth of information from the media, their diabetes nurse specialist, their GP, and so on. This may also lead to conflicting information which can be bewildering. It is thus important to elicit what they already know. Listening to the young person express, their knowledge can form a building block for future sessions and enables the researcher to gauge how to convey new information when it arises.

What information will the researcher need to provide?

The type of information to give will depend upon the needs and cognitive ability of the young person. Information is only useful if it leads to understanding and it is important to provide basic principles (assisted by drawings) rather than detailed information. Diabetes control is highly variable and there will be no right or wrong answers to many questions around regimens, insulin requirements and frequency of glucose testing. It is important to remember that the researcher will not take direct responsibility for treatment decisions and the final responsibility of the regimen lies with the consultant paediatrician and the diabetes nurse specialist. Therefore, wherever questions arise pertaining to the regimen and insulin adjustment then the young person will be advised to seek the help of their diabetes nurse specialist.

Has information been understood?

Once information has been provided then the researcher needs to check that the young person has heard, remembered, and understood the information. It also helps them to develop greater understanding and insight to change their outcomes.

Goal 4: Developing Practical Problem Solving

Exploring problems

Old habits die-hard and it may be a difficult process for the young person to verbalise any problems. A first step is to ask the young person what they would like to accomplish (in an ideal world), brainstorming solutions, and then set about setting goals. It is the young person who identifies the problems, sets the goals and solutions.

It is important to clarify how the young person feels about the goals and it will be beneficial to cast goals into two areas:

1. Goals relating to HbA_{1c} and insulin regimen over which the young person has limited control.
2. Goals which are achievable in the short term such as commencement of exercise, cutting down on sugary/fatty foods, small amounts of weight loss, adherence to medication, and frequency of blood sugar testing.

The young person can be helped in the problem solving process by encouraging them to:

- Define the problem in specific terms. Stating they would like to lose weight/ 'do' exercise is unspecific. Thus, they need to state how much they would like to lose/ what form of exercise they would like to take - taking into account their metabolic control.
- Setting a realistic weight loss plan / exercise plan/ medication adherence. Setting a time and place for the behaviour (setting an implementation intention, Gollwitzer and Branstätter 1997).
- Provision of 'mental mapping'. Assist the young person in visualization of goals and achieving those goals. For example; running around the rugby pitch/ playing netball with others/ swimming in the pool.

If the prospect of identifying problems is too daunting, then a menu of a list of solutions may be presented (based on what other young people have described in the clinical setting) such as:

- Do school work for an 1 hour every night
- Eat more at lunchtime to prevent hypo
- Have sandwiches with less fat
- Have 5 portions of fruit a day

- ❖ Check blood glucose more regularly
- ❖ Pick up insulin from GP on time
- ❖ Eat snacks when I should
- ❖ Help mum around the house more
- ❖ Not get so cross at home

Follow up

Ask the young person to evaluate their efforts and assist the young person to reflect on their goals. Typical questions may include, "*You lost 2 lbs last month, how do you feel about that?*" or "*How do you feel in yourself now that you eat your snacks more regularly?*". It is important to reaffirm any progress the young person has made.

What not to do.

- ❖ Solve, or try to solve the problem for the young person.
- ❖ Question what the patient has said.
- ❖ Place own value judgements on behaviour.
- ❖ Judge the young person.
- ❖ Threaten ("*if you don't do.....(*behaviour)*.....then you will get complications later*").
- ❖ Devalue efforts (however small- they will be big to the young person).

Goal 5: Facilitating support in the handover of responsibility from parents.

Adolescence and the transition into adulthood can be stressful for both parents and the young person. Parents may need help in accepting a decrease in the extent of control over their child's life. Both knowledge of the condition and control of the regimen maybe gradually shifted from parent to teenager during the time of the intervention. It is possible that some parents will need encouragement to allow their child physical

and emotional freedom. Ingersoll et al. (1998) argued that adolescents should assume as much responsibility as possible. Indeed, there are societal, as well as parental expectations, that adolescents become self-reliant and assume responsibility for their behaviours.

Each transition will depend on an appraisal of the young person's needs and degree of family support. When addressing the handover of responsibility two factors need to be addressed:

- *Cognitive and emotional*
- *Motivational*

Cognitive and Emotional

The researcher will reinforce parental strategies of planning self-care activities with the young person. Treatment and illness knowledge, which influences ability to manage adverse symptoms, will need to be clarified with the young person during the handover of responsibility. Thus any support and information given needs to be structured, concrete, and supportive with the provision of factual information. Parental participation must not be discouraged and indeed positive coping skills, support and actions of siblings need to be affirmed.

Motivational

The young person is an active participant in his or her care and positive managerial skills and attitudes need to be reinforced. It is important to remember that diabetes is *only one part* of the young person's life and the process of development in adolescence is transactional – depending heavily on contextual and situational factors.

Goal 6: To investigate physical and psychological aspects of problems

Management of diabetes requires the young person to implement, monitor, and regulate a complex regimen. Sometimes, young people have difficulty in consistently meeting the expectations of their health care professionals and fulfilling self-management responsibilities. If a young person describes challenges around omitting insulin, blood sugar testing, and/or diet then the pejorative term *compliance* should be avoided since this may engender resistance. Instead, the researcher will:

- Focus and encourage exploration of the amount, precision, and regularity of behaviour(s) rather than the degree to which the behaviour conforms to the prescribed ideals.
- Emphasis confidentiality to foster trust.

Psychological needs

If the nature of the problem is psychological then the young person will be encouraged to vent their feelings and an appraisal of the person's emotional well being will be undertaken. It may be that the young person feels they are not coping with their diabetes and if so, then the young person's coping mechanisms will be explored. The researcher will recognize that diabetes is a chronic illness and will encourage verbalization of everyday stressors as appropriate.

Medical Emergencies

If the young person presents with medical or psychological problems that needs attention then they will be referred to their consultant paediatrician and diabetes nurse specialist. Acute medical emergencies such as the presentation of hypoglycaemic coma or diabetic ketoacidosis will be treated as a medical emergency.

Goal 7: Blood glucose awareness training

Altered awareness of hypoglycaemia becomes increasingly common with the progression and duration of diabetes and is associated with an increased risk of severe hypoglycaemia. The cause is yet unknown, but is hypothesized to be associated with a reduction in somatic autonomic symptoms. The literature increasingly highlights the importance of providing training in the clinical setting. This is based on the intervention developed by Cox et al. (1995). This involves observing and recording any blood glucose–relevant cues, estimation of blood glucose level based on these cues, comparing estimate to the current self-monitoring of blood glucose reading and evaluating the accuracy of estimated reading. The young person is also taught to can recognize and interpret symptoms of extreme blood glucose to improve detection of these events. The emphasis is on improving the young person's ability to identify mismatches in estimation and actual reading thereby improving diabetes management.

Appendix 7

Wales College of Medicine
Department of Child Health
Professor Sailesh Kotecha
Professor of Child Health and Head of Department
Professor John Gregory
Professor of Paediatric Endocrinology

Coleg Meddygaeth Cymru
Adran Iechyd Plant
***Yr Athro* Sailesh Kotecha**
Athro Iechyd Plant a Phennaeth Adran
Yr Athro John Gregory
Athro Endocrinoleg Pediatrig

CARDIFF UNIVERSITY
PRIFYSGOL CAERDYDD

Cardiff University
Heath Park
Cardiff CF14 4XN
Tel *Ffôn* +44(0)29 2074 3375
Fax *Ffacs* +44(0)29 2074 4283
Prifysgol Caerdydd
Mynydd Bychan
Caerdydd CF14 4XN

PATIENT INFORMATION ON A RESEARCH STUDY IN THE DIABETES CLINIC

"A multi-centre, randomised, controlled trial of motivational interviewing with adolescents with diabetes"

Thank you for reading this leaflet. It explains what the study is, why the doctors in your diabetes clinic have agreed to contact you and what would happen if you took part. If you are willing to be contacted to discuss taking part, there is a consent form for you to sign and return it to us.

INTRODUCTION

The Department of Child Health, University of Wales College of Medicine in Cardiff has been given funding by Diabetes UK for this research project. We will be offering two types of counselling to young people with diabetes who attend clinics in South Wales. One is called motivational interviewing and the second is support counselling. The research study is to find out if either or both of these services are helpful for young people with diabetes. "Randomised" and "controlled" mean that the young people who volunteer will take part in either motivational interviewing or support counselling but they will not have the choice which.

By law, we are not allowed to have your name and address without you agreeing to it. That is why we have asked the clinics to send out this information for us.

WHY IS THIS STUDY BEING DONE?

We are looking for ways to try to improve the quality of care and support provided to young people with diabetes. We do not know whether either or both of these types of counselling will help, but the aim of the study is to find out. If they are helpful then we would want to try and find a way in which they can be offered to more young people with diabetes in the future.

WHY HAVE I BEEN SELECTED?
We are asking five diabetes clinics across South Wales to contact the young people who attend their clinic, who are between 14 and 17 years old, have been diagnosed for a year or more and who clinic staff think would be able to take part.

WHAT ARE WE ASKING YOU TO DO?
All you have to do now is decide if you **might** want to take part. You then fill in the form below and send it back in the envelope provided. Michelle Huws-Thomas, the researcher, will contact you to arrange a time to meet to give you more details. If you have any questions you want to ask before you sign the form, then you can contact Michelle on 029 20 744445 and she will be happy to answer them. After you have met with her you can decide if you would like to take part or not. We may not ask everyone who agrees to participate. Sending back this form does not mean you have to carry on with the study. It just gives us permission to contact you.

WHAT SHOULD I TELL MY DOCTOR IN CLINIC?
You will not need to tell your doctor in clinic whether you have decided to take part or not. All the clinic consultants have agreed that the young people can be approached with this letter but after that the contact is just between the researcher and you. Taking part or not taking part will not affect your routine clinics or your contact with the diabetes team in any way. The clinic staff will not ask you about the research and they will not be told who is taking part.

WILL MY GP BE TOLD?
If you decide to participate in the study we will also ask you if it is OK for your GP to know that you are taking part. If you consent, then your GP will be sent this information sheet and told of your participation. They will not be given any further information about your involvement. If you do not want your GP to know, then you can still take part in the study and we will keep your participation confidential.

DO I NEED TO TAKE PART?
No. You are in charge of deciding whether to take part. If you are under 16 we will also need your parent's consent. However if they think it is a good idea but you do not, then we will act on your wishes and will not contact you.

WHAT MIGHT HAPPEN TO ME?
If you do decide to take part, you will meet with Michelle or another member of the research team at a time and place of your choice. You will be asked to fill in some questionnaires during your first and last appointment whilst taking part in the study. In the other meetings you will be given the opportunity to talk about diabetes, your self-care and any other things in your life which might affect it. This support will be available, with the same person, for up to a year, depending on when you start and how long you wish to continue. If you would prefer discussion to be through the medium of Welsh, every effort will be made to accommodate this.

We will ask some people if they would be prepared for the researcher to audiotape the meetings. This is to help the researcher record what types of things get discussed and to improve their skills. If you are happy to take part but do not want the tape then this will be OK. There is a

separate consent form for the taping and all tapes will be destroyed after use. We will also ask that you have an HbA1c checked every 6 months. This will involve taking a small sample (less than a teaspoon) of blood, usually at the same time as your routine HbA1c in clinic so no additional needles are required.

WHAT HAPPENS IF I WANT TO STOP?

If at any point you decide that you do not want to carry on meeting you can stop. There will be no problem with doing this.

WHO WILL SEE ALL THE INFORMATION ABOUT ME?

The only person to see all the information will be the researcher who you meet with. They will remove your name from any information that is seen by anyone else. At the end when all the information has been collected there will be no identification of the people involved and the clinic staff will still not know who took part.

Thank-you for reading this information.

Sue Channon (Research lead)
Dr John Gregory
Dr Steve Rollnick

Appendix 8

Wales College of Medicine
Department of Child Health
Professor Sailesh Kotecha
Professor of Child Health and Head of Department
Professor John Gregory
Professor of Paediatric Endocrinology

Coleg Meddygaeth Cymru
Adran Iechyd Plant
***Yr Athro* Sailesh Kotecha**
Athro Iechyd Plant a Phennaeth Adran
Yr Athro John Gregory
Athro Endocrinoleg Pediatrig

CARDIFF UNIVERSITY
PRIFYSGOL CAERDYDD

Cardiff University
Heath Park
Cardiff CF14 4XN
Tel *Ffôn* +44(0)29 2074 3375
Fax *Ffacs* +44(0)29 2074 4283
Prifysgol Caerdydd
Mynydd Bychan
Caerdydd CF14 4XN

CONSENT FORM

"A randomised, controlled trial of motivational interviewing with adolescents with diabetes"

I have read the information sheet and I have discussed the study with Michelle Huws-Thomas, Research Worker. I understand that my treatment by the diabetes team will not be affected if I take part or do not take part. I know that I can decide to leave the study at any time.
(Please tick appropriate box/boxes)

I confirm that *I am happy to take part in this study

*My GP can be informed of my participation

Name:

Signature:

Date:

Research Worker's signature:

Date:

Appendix 9

Wales College of Medicine
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Mynydd Bychan
Caerdydd CF14 4XN

PATIENT CONSENT TO CONTACT FORM

"A randomised controlled trial of motivational interviewing with adolescents with diabetes"

Name:

Address:

Phone Number: Home:

Mobile:

Hospital where I attend diabetes clinic:

I have read the information sheet and I am happy for the researcher to contact me via telephone regarding the research study. This does not commit me to taking part in the study.

Signature:

Please now return this form to Michelle or send via the stamped, addressed envelope provided to:

Michelle Huws-Thomas, Researcher, Academic Corridor, Dept of Child Health, University Wales College of Medicine, Heath Park, Cardiff CF14 4XN.

Appendix 10

Wales College of Medicine
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PARENT/GUARDIAN CONSENT FORM

"A randomised, controlled trial of motivational interviewing with adolescents with diabetes"

I have read the information sheet and I have discussed the study with Michelle Huws-Thomas, Research Worker. I understand that .. .(name of child).....treatment by the diabetes team will not be affected if they take part or do not take part. I know that they can decide to leave the study at any time.

(Please tick appropriate box/boxes)

I confirm that *I am happy for .....to take part in this study.

*their GP can be informed of their participation

Name of Child:

Parent/Guardian's name:

Signature:
Date:

Research Worker's signature:
Date:

Appendix 11

Wales College of Medicine
Department of Child Health
Professor Sailesh Kotecha
Professor of Child Health and Head of Department
Professor John Gregory
Professor of Paediatric Endocrinology

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PRIFYSGOL CAERDYDD

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Cardiff CF14 4XN
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Fax *Ffacs* +44(0)29 2074 4283
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Mynydd Bychan
Caerdydd CF14 4XN

Dear (participant)

Re: research study – "a multi-centre, randomised controlled trial of motivational interviewing with adolescents with diabetes"

I am enclosing information on a research study that the diabetes clinic is taking part in. The research is including five diabetes clinics across South Wales and the researchers are looking for volunteers to take part. We decided to join the study because we thought it might be helpful for the young people who attend our clinic and may suggest ways in which we can improve our service in the future.

It is up to you whether you want to take part. Because you are over 16 we do not need permission to participate from your parent or guardian. The research will be completely separate to the clinic. Your visits to clinic and your contact with the diabetes staff will not be affected whether you take part or decide not to. We will not ask about or be told of your decision and no information will be given to us.

If you have any questions about the project, you can contact Michelle Huws-Thomas the researcher on 029 20744445 or Dr Gregory, the Consultant involved with the project on 02920 742274. They are both based at the Wales College of Medicine in Cardiff and I am sure they will be happy to help you.

Yours sincerely

Dr (Name of Consultant)

Consultant Paediatrician

Appendix 12

Wales College of Medicine
Department of Child Health
Professor Sailesh Kotecha
Professor of Child Health and Head of Department
Professor John Gregory
Professor of Paediatric Endocrinology

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Cardiff CF14 4XN
Tel *Ffôn* +44(0)29 2074 3375
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Prifysgol Caerdydd
Mynydd Bychan
Caerdydd CF14 4XN

Letter from Consultant to Parent/Guardian

Dear (parent or guardian)

Re: research study – "a multi-centre, randomised controlled trial of motivational interviewing with adolescents with diabetes"

I am enclosing information on a research study that this clinic is taking part in. The research includes five diabetes clinics across South Wales and the researchers are looking for volunteers to take part. We decided to join the study because we thought it might be helpful for the young people who attend our clinic, and may suggest ways in which we can improve our service in the future.

This information has been sent to (name of child). It is up to (child) whether he or she wants to take part, but because (child) is under 16, we will also need your permission. The research is completely separate to the clinic. (The child's) visits to clinic and contact with the diabetes staff will not change if he or she does take part (or decides not to). We will not ask about, or be told of (the child's) decision and no information will be given to us.

If you have any questions about the project, you can contact Michelle Huws-Thomas the researcher on 029 20744445 or Dr John Gregory, the Consultant involved with the project on 02920 742274. They are both based at the Wales College of Medicine in Cardiff and I am sure they will be happy to help you.

Yours sincerely

Dr .....(Consultant)

Consultant Paediatrician

Appendix 13

Name.....

WELL BEING QUESTIONNAIRE

Please circle a number on each of the following scales to indicate how often you feel each phrase has applied to you in the past few weeks

	All the time	Some of the time	Not much of the time	Not at all
Q1: I feel I am useful and needed	3	2	1	0
Q2: I have crying spells or feel like it	3	2	1	0
Q3: I find I can think quite clearly	3	2	1	0
Q4: My life is pretty full	3	2	1	0
Q5: I feel downhearted and blue	3	2	1	0
Q6: I enjoy the things I do	3	2	1	0
Q7: I feel nervous and anxious	3	2	1	0
Q8: I feel afraid and upset for no reason	3	2	1	0
Q9: I get upset easily or feel panicky	3	2	1	0
Q10: I feel like I am falling apart and going to pieces	3	2	1	0
Q11: I feel calm and can sit easily	3	2	1	0
Q12: I fall asleep easily and get a good night's rest	3	2	1	0
Q13: I feel energetic, active or vigorous	3	2	1	0
Q14: I feel dull or sluggish	3	2	1	0
Q15: I feel tired, worn out, used up or exhausted	3	2	1	0
Q16: I have been waking up feeling fresh and rested	3	2	1	0
Q17: I have been happy, satisfied or pleased with my personal life	3	2	1	0
Q18: I have felt well adjusted to my life situation	3	2	1	0
Q19: I have lived the kind of life I wanted to	3	2	1	0
Q20: I have felt eager to tackle my daily tasks or make new decisions	3	2	1	0
Q21: I have felt I could handle or cope with any serious problem or major change in my life	3	2	1	0
Q22: My daily life has been full of things that were interesting to me	3	2	1	0

Please ensure you have completed each of the 22 statements and have circled a number on each of the 22 scales.

Appendix 14

NAME _____

DKN SCALE FORM A

INSTRUCTIONS: This is a short quiz to find out how much you know about diabetes. There are 15 questions and each one has several possible answers. For questions 1 to 12 only one answer is correct. If you know the right answer, circle the letter in front of it. If you don't know the answer, circle the letter in front of "I don't know". Notice that questions 13, 14, and 15 have more than one correct answer, so you should circle all the answers you think are right.

1. In uncontrolled diabetes the blood sugar is:

A Normal
B Increased
C Decreased
D I don't know

2. Which one of the following is true?

A It does not matter if your diabetes is not fully controlled as long as you do not have a coma
B It is best to have some sugar in the urine in order to avoid hypoglycaemia
C Poor control of diabetes could result in a greater chance of complications later
D I don't know

3. The NORMAL range for blood glucose is:

A 4.8 mmol/l
B 7-15 mmol/l
C 2-10 mmol/l
D I don't know

4. Butter is mainly:

A Protein
B Carbohydrate
C Fat
D Mineral and vitamin
E I don't know

5. Rice is mainly:

A Protein
B Carbohydrate
C Mineral and vitamin
E I don't know

6. The presence of keytones in the urine is:

A A good sign
B A bad sign
C A usual finding in diabetes
D I don't know

7. Which of the following possible complications is usually not associated with diabetes?

A Changes in vision
B Changes in the kidney
C Changes in the lung
D I don't know

8. If a person on insulin has a high blood or urine sugar level and ketones were present they should:

A Increase insulin
B Decrease insulin
C Keep insulin and diet the same and test blood/urine later
D I don't know

9. When people with diabetes on insulin become ill and unable to eat the prescribed diet:

A They should immediately stop taking insulin
B They must continue taking insulin
C They should use diabetic tablets instead of insulin
D I don't know

10. If you feel the beginnings of hypoglycaemia you should:

A Immediately take some insulin or tablets
B Immediately lie down and rest
C Immediately eat or drink something sweet
D I don't know

11. You can eat as much as you like of the following foods:

A Apples
B Celery
C Meat
D Honey
E I don't know

12. Hypoglycaemia is caused by:

A Too much insulin
B Too little insulin
C Too little exercise
D I don't know

IN THESE LAST THREE QUESTIONS THERE WILL BE MORE THAN ONE CORRECT ANSWER. PLEASE CIRCLE THE LETTERS IN FRONT OF ALL THE ANSWERS YOU THINK ARE CORRECT.

13. A kilogram is:

A A metric unit of weight
B Equal to 10 pounds
C A metric unit of energy
D A little more than two pounds
E I don't know

14. Two of the following substitutions are right:

A One portion (1oz) bread = 4 cracker biscuits (e.g. Sao biscuits)
B One egg = one portion of mince
C 5oz milk = 5oz orange juice
D 3/4 cup cornflakes = 3/4 cup porridge
E I don't know

15. If I don't feel like the egg allowed on my diet for breakfast I can:

A Have extra toast
B Substitute one small lamb cutlet
C Have an ounce of cheese instead
D Forget about it
E I don't know

Appendix 15

NAME _____

DIABETES FAMILY BEHAVIOUR SCALE

	All the time	Most of the time	Sometimes	Hardly ever	Never
1. My parent(s) watches while I test for sugar.	1	2	3	4	5
2. When there is a problem about the diabetes, we call the doctor.	1	2	3	4	5
3. My mother decides what I'm going to eat.	1	2	3	4	5
4. My parent(s) understands how I feel about having diabetes.	1	2	3	4	5
5. I ask my parent(s) for advice about diabetes.	1	2	3	4	5
6. My parent(s) talk about my diabetes.	1	2	3	4	5
7. We know when there are problems with my diabetes.	1	2	3	4	5
8. My parent(s) does things for me that I could do for myself in taking care of my diabetes.	1	2	3	4	5
9. My parent(s) read books about diabetes.	1	2	3	4	5
10. My parent(s) reminds me to test for sugar.	1	2	3	4	5
11. My parent(s) encourages me to get some exercise everyday.	1	2	3	4	5
12. My parent(s) buys sweet snacks for the family.	1	2	3	4	5
13. My parent(s) gives me rewards for taking care of my diabetes.	1	2	3	4	5
14. At home, my family eats food that is not on my diabetic diet.	1	2	3	4	5
15. My diabetes makes my parent(s) real nervous.	1	2	3	4	5
16. My parent(s) tests my sugar.	1	2	3	4	5
17. When my sugar runs high for several days, we wait and and don't make any changes until my next scheduled doctor's appointment.	1	2	3	4	5
18. We wait to call the doctor until I'm very sick with diabetes.	1	2	3	4	5
19. I take care of My diabetes myself.	1	2	3	4	5
20. My parent(s) makes sure that I don't run out of insulin.	1	2	3	4	5
21. My parent(s) writes down the sugar tests.	1	2	3	4	5
22. My parent(s) listens to my ideas about taking care of my diabetes.	1	2	3	4	5
23. If we're not sure what to do we call for help.	1	2	3	4	5
24. My parent(s) and I argue about whether I'm sticking to my diabetes diet.	1	2	3	4	5
25. My family has regular meal times.	1	2	3	4	5
26. My parent(s) seems embarrassed that I have diabetes.	1	2	3	4	5

My parent(s) listens to my problems about having diabetes.	1	2	3	4	5
My parent(s) make my snacks.	1	2	3	4	5
My parent(s) fill the insulin syringe.	1	2	3	4	5
My parent(s) makes me feel good about taking care of my diabetes.	1	2	3	4	5
My parent(s) give me my insulin shots.	1	2	3	4	5
My family embarrasses me by talking about my diabetes with other people.	1	2	3	4	5
When we go out to eat, I choose things from the menu in line with my exchange diet.	1	2	3	4	5
Other family members eat sweets in front of me.	1	2	3	4	5
I feel all alone with my diabetes.	1	2	3	4	5
My parent(s) encourages (wants) me to do the kinds of things other kids do.	1	2	3	4	5
My parent(s) believes (feels) that testing sugar is up to me.	1	2	3	4	5
My parent(s) is always ready to help me with my diabetes if I need it.	1	2	3	4	5
My parent(s) tells me to stop acting as if I'm sick.	1	2	3	4	5
My parent's remind me to give my insulin shots.	1	2	3	4	5
I don't worry about what my sugar test shows unless I start feeling back.	1	2	3	4	5
My parent(s) know how well I am taking care of my diabetes.	1	2	3	4	5
I have someone in my family to talk to about my diabetes.	1	2	3	4	5
My parent(s) gets angry with me when I make a slip in taking care of my diabetes (don't take care of my diabetes).	1	2	3	4	5
If my sugar test is too high, we check for acetone.	1	2	3	4	5
My family talks about diabetes.	1	2	3	4	5
My parent(s) is afraid to give me insulin shots.	1	2	3	4	5

Appendix 16

DRCQ

NAME _____

We would like to know your views about how you manage your diabetes at the moment. For each question, please put a tick next to the statement which best describes your situation. Please tick **ONE** statement for each question.

1) Do you always check your blood sugar in the way you have been advised to?

- ☐ Yes I have been for more than 6 months
- ☐ Yes I have been for less than 6 months
- ☐ No but I have been trying to recently
- ☐ No but I plan to soon
- ☐ No but I would like to in the next 6 months
- ☐ No and I do not plan to in the next 6 months

2) Do you always do the amount of exercise you have been advised to?

- ☐ Yes I have been for more than 6 months
- ☐ Yes I have been for less than 6 months
- ☐ No but I have been trying to recently
- ☐ No but I plan to soon
- ☐ No but I would like to in the next 6 months
- ☐ No and I do not plan to in the next 6 months

3) Do you always do your injections as often as you have been told to?

- ☐ Yes I have been for more than 6 months
- ☐ Yes I have been for less than 6 months
- ☐ No but I have been trying to recently
- ☐ No but I plan to soon
- ☐ No but I would like to in the next 6 months
- ☐ No and I do not plan to in the next 6 months

4) Do you follow your diet (including alcohol consumption) in the way you have been advised to?

- ☐ Yes I have been for more than 6 months
- ☐ Yes I have been for less than 6 months
- ☐ No but I have been trying to recently
- ☐ No but I plan to soon
- ☐ No but I would like to in the next 6 months
- ☐ No and I do not plan to in the next 6 months

5) Do you want to improve your HbA1c?

- ☐ Yes I have been trying to for more than 6 months
- ☐ Yes I have been trying to for less than 6 months
- ☐ Yes and I plan to soon
- ☐ Yes and I would like to in the next 6 months
- ☐ No and I do not plan to in the next 6 months

6) Do you want to do more to manage your diabetes yourself rather than having someone else
(e.g., your parent) manage it for you e.g., doing all your injections, blood tests, deciding what to eat etc?

- ☐ I have been managing my diabetes mostly on my own for more than 6 months
- ☐ I have been managing my diabetes mostly on my own for less than 6 months
- ☐ I have been trying to recently
- ☐ I plan to try soon
- ☐ I would like to in the next 6 months
- ☐ I do not plan to in the next 6 months

7) Do you smoke?

- ☐ No
- ☐ Yes

If no go on to question 8

If yes, do you want to cut down or give up smoking?

- ☐ Yes I have been trying to for more than 6 months
- ☐ Yes I have been trying to for less than 6 months
- ☐ Yes and I plan to soon
- ☐ Yes I would like to in the next 6 months
- ☐ No and I do not plan to in the next 6 months

8) Do the staff at the diabetes clinic say you need to try and lose weight?

- ☐ No
- ☐ Yes

Do you think you need to lose weight?

- ☐ No
- ☐ Yes

If you have answered yes to either or both parts of question 8, please answer the following

Do you want to lose weight?

- ☐ Yes I have been trying to for more than 6 months
- ☐ Yes I have been trying to for less than 6 months
- ☐ Yes and I plan to soon
- ☐ Yes I would like to in the next 6 months
- ☐ No and I do not plan to in the next 6 months

Thank you for filling this in. Can you please make sure you have put your name on the top and then send it back in the pre-paid envelope provided.

Appendix 17

HEALTH CARE CLIMATE (HCCQ) QUESTIONNAIRE

Motivational Interviewing (MI) Study- Department of Child Health, University Hospital of Wales

This questionnaire is designed to find out how you feel about the care you receive in your local diabetes clinic. Your responses are confidential and will only be seen by **the independent researcher within the research study**. The questionnaire will placed in a locked drawer once you have completed.

What is your name?.....
What is your address?.....

Which clinic do you attend? .....

Please tick the number to each question that applies.

1: I feel that my doctor/nurse has provided me with choices and information

Not at all true			Somewhat true			Very true
1	2	3	4	5	6	7

2: I feel understood by my doctor/ nurse

Not at all true			Somewhat true			Very true
1	2	3	4	5	6	7

3: I am able to be open with my doctor/nurse at our meetings

Not at all true			Somewhat true			Very true
1	2	3	4	5	6	7

4: My doctor/nurse conveys confidence in my ability to make changes

Not at all true			Somewhat true			Very true
1	2	3	4	5	6	7

5: I feel that my doctor/nurse accepts me

Not at all true			Somewhat true			Very true
1	2	3	4	5	6	7

6: My doctor/nurse has made sure that I understand my condition and what I need to do

Not at all true			Somewhat true			Very true
1	2	3	4	5	6	7

7: My doctor/nurse encourages me to ask questions

Not at all true			Somewhat true			Very true
1	2	3	4	5	6	7

8: I feel a lot of trust in my doctor/nurse

Not at all true			Somewhat true			Very true
1	2	3	4	5	6	7

9: My doctor/nurse answers my questions carefully and fully

Not at all true			Somewhat true			Very true
1	2	3	4	5	6	7

10: My doctor/nurse listens to how I would like to do things

Not at all true			Somewhat true			Very true
1	2	3	4	5	6	7

11: My doctor/nurse handles people's emotions really well

Not at all true			Somewhat true			Very true
1	2	3	4	5	6	7

12: I feel that my doctor/nurse cares about me as a person

Not at all true			Somewhat true			Very true
1	2	3	4	5	6	7

14: My doctor/nurse tries to understand how I see things before they suggest new things

Not at all true			Somewhat true			Very true
1	2	3	4	5	6	7

15: I am able to share things with my doctor/nurse

Not at all true			Somewhat true			Very true
1	2	3	4	5	6	7

Thank you for completing this questionnaire.

Appendix 18

Diabetes Quality of Life for Youths Questionnaire

DIABETES QUALITY OF LIFE IN YOUTHS QUESTIONNAIRE

NAME_____

Please answer each question by filling in the blanks or by circling the answer that best reflects your choice. All the answers are confidential and will placed in a locked drawer.

What is your sex? [M] Male [F] Female

How old are you? Years..... Months.....

How old were you when were diagnosed with diabetes?_____

In what year are you in at school? _____

How many days of school did you miss in the last year because of your diabetes? _____

DIABETES QUALITY OF LIFE QUESTIONNAIRE: YOUTHS

A: **DIRECTIONS:** Read each statement carefully. Please indicate how satisfied or dissatisfied you currently are with the aspect of your life described in the statement. Mark [X] the box that matches how satisfied or dissatisfied you feel: 1 = Very Satisfied, 2 = Moderately Satisfied, 3 = Neither Satisfied nor Dissatisfied, 4 = Moderately Dissatisfied, 5 = Very Dissatisfied. There are no right or wrong answers to these questions. All responses are confidential.

		Very satisfied				**Very dissatisfied**
A1:	How satisfied are you with the amount of time it takes to manage your diabetes?	[1]	[2]	[3]	[4]	[5]
A2:	How satisfied are you with the amount of time you spend getting checkups?	[1]	[2]	[3]	[4]	[5]
A3:	How satisfied are you with the time it takes to determine your blood sugar?	[1]	[2]	[3]	[4]	[5]
A4:	How satisfied are you with your current treatment?	[1]	[2]	[3]	[4]	[5]
A5:	How satisfied are you with the flexibility you have with your diet?	[1]	[2]	[3]	[4]	[5]
A6:	How satisfied are you with the burden your diabetes is placing on your family?	[1]	[2]	[3]	[4]	[5]
A7:	How satisfied are you with your knowledge about your diabetes?	[1]	[2]	[3]	[4]	[5]

SPEAKING GENERALLY:

A8:	How satisfied are you with your sleep?	[1]	[2]	[3]	[4]	[5]
A9:	How satisfied are you with your friendships?	[1]	[2]	[3]	[4]	[5]

Diabetes Quality of Life for Youths Questionnaire

		Very satisfied				Very disatisfied
A10:	How satisfied are you with the your work, school, and household activities?	[1]	[2]	[3]	[4]	[5]
A11:	How satisfied are you with the appearance of your body?	[1]	[2]	[3]	[4]	[5]
A12:	How satisfied are you with the time you spend exercising?	[1]	[2]	[3]	[4]	[5]
A13:	How satisfied are you with your leisure time?	[1]	[2]	[3]	[4]	[5]
A14:	How satisfied are you with life in general?	[1]	[2]	[3]	[4]	[5]
A15:	How satisfied are you with performance in school?	[1]	[2]	[3]	[4]	[5]
A16:	How satisfied are you with how your classmates treat you?	[1]	[2]	[3]	[4]	[5]
A17:	How satisfied are you with your attendance at school?	[1]	[2]	[3]	[4]	[5]

Compared with others your age, would you say your health is:

- 9 Excellent
- 9 Good
- 9 Fair
- 9 Poor

Diabetes Quality of Life for Youths Questionnaire

DIRECTIONS: Read each statement carefully. Please indicate How Often the following events happen to you. Mark [X] the box that matches how satisfied or dissatisfied you feel: 1 = Never, 2 = Very Seldom, 3 = Sometimes, 4 = Very Often, 5 = All the time. There are no right or wrong answers to these questions. We are interested in your honest opinion.

		Never				**All the time**
B1:	How often do you feel pain associated with the treatment of your diabetes?	[1]	[2]	[3]	[4]	[5]
B2:	How often are you embarrassed by having to deal with your diabetes in public?	[1]	[2]	[3]	[4]	[5]
B3:	How often do you feel physically ill?	[1]	[2]	[3]	[4]	[5]
B4:	How often does your diabetes interfere with your family life?	[1]	[2]	[3]	[4]	[5]
B5:	How often do you have a bad night's sleep?	[1]	[2]	[3]	[4]	[5]
B6:	How often do you find your diabetes limiting your social relationships and friendships?	[1]	[2]	[3]	[4]	[5]
B7:	How often do you feel good about yourself?	[1]	[2]	[3]	[4]	[5]
B8:	How often do you feel restricted by your diet?	[1]	[2]	[3]	[4]	[5]
B9:	How often does your diabetes keep you from driving a car?	[1]	[2]	[3]	[4]	[5]
B10:	How often does your diabetes interfere with your exercising?	[1]	[2]	[3]	[4]	[5]
B11:	How often do you miss work, school or household duties because of your diabetes?	[1]	[2]	[3]	[4]	[5]
B12:	How often do you find yourself explaining what it means to have diabetes?	[1]	[2]	[3]	[4]	[5]

Diabetes Quality of Life for Youths Questionnaire

		Never				All the time
B13:	How often do you find that your diabetes interrupts your leisure time activities?	[1]	[2]	[3]	[4]	[5]
B14:	How often are you teased because you have diabetes?	[1]	[2]	[3]	[4]	[5]
B15:	How often do you feel that because of your diabetes you go to the bathroom more than others?	[1]	[2]	[3]	[4]	[5]
B16:	How often do you find you eat something you shouldn't rather than tell someone that you have diabetes?	[1]	[2]	[3]	[4]	[5]
B17:	How often do you hide from others the fact that you are having an insulin reaction?	[1]	[2]	[3]	[4]	[5]
B18:	How often do you find that your diabetes prevents you from participating in school activities (for example, a school play, playing a sport).	[1]	[2]	[3]	[4]	[5]
B19:	How often do you find that your diabetes prevents you from going out to eat with your friends?	[1]	[2]	[3]	[4]	[5]
B20:	How often do you feel that your diabetes will limit what job you will have in the future?	[1]	[2]	[3]	[4]	[5]
B21:	How often do you find that your parents are too protective of you?	[1]	[2]	[3]	[4]	[5]
B22:	How often do you find that your parents worry too much about your diabetes	[1]	[2]	[3]	[4]	[5]
B23:	How often do you find that your parents act like diabetes is their disease, not yours?	[1]	[2]	[3]	[4]	[5]

Diabetes Quality of Life for Youths Questionnaire

DIRECTIONS: Read each statement carefully. Please indicate how often the following events happen to you. Check [X] the appropriate box. There are no right or wrong answers to these questions. If the question is not relevant to you, check "Does not apply".

		Does Not Apply					**All the time**
C1:	How often do you worry about whether you will get married?	[0]	[1]	[2]	[3]	[4]	[5]
C2:	How often do you worry about whether you will have children?	[0]	[1]	[2]	[3]	[4]	[5]
C3:	How often do you worry about whether you will not get a job you want?	[0]	[1]	[2]	[3]	[4]	[5]
C4:	How often do you worry about whether you will pass out?	[0]	[1]	[2]	[3]	[4]	[5]
C5:	How often do you worry about whether you will be able to complete your education?	[0]	[1]	[2]	[3]	[4]	[5]
C6:	How often do you worry that your body looks different because you have diabetes?	[0]	[1]	[2]	[3]	[4]	[5]
C7:	How often do you worry that you will get complications from your diabetes?	[0]	[1]	[2]	[3]	[4]	[5]
C8:	How often do you worry whether someone will not go out with you because you have diabetes?	[0]	[1]	[2]	[3]	[4]	[5]
C9:	How often do you worry that teachers treat you differently because of your diabetes?	[0]	[1]	[2]	[3]	[4]	[5]
C10:	How often do you worry that your diabetes will interfere with things that you do in school (sports, music, drama)?	[0]	[1]	[2]	[3]	[4]	[5]
C11:	How often do you worry that your diabetes causes you to do things with friends like going on dates or going to parties?	[0]	[1]	[2]	[3]	[4]	[5]

Appendix 19

SELF EFFICACY FOR DIABETES SCALE

Instruction: Please read the following questions. After each question, please make a check in the circle how much you believe you can or cannot do what is asked *now*.

Name:
Clinic attended:

Question					
: Be the one in charge of iving my insulin injection	Very sure I can't	Sure I can't	Not sure	Sure I can	Very sure I can
: Figure out my own meals nd snacks at home	Very sure I can't	Sure I can't	Not sure	Sure I can	Very sure I can
: Figure what foods to eat hen I am away from home	Very sure I can't	Sure I can't	Not sure	Sure I can	Very sure I can
: keep a track of my blood ugars regularly	Very sure I can't	Sure I can't	Not sure	Sure I can	Very sure I can
:Watch my own blood ugars in my urine	Very sure I can't	Sure I can't	Not sure	Sure I can	Very sure I can
: Change the amount of me I get insulin when I get a t of exercise	Very sure I can't	Sure I can't	Not sure	Sure I can	Very sure I can
: Judge the amount of food I hould eat before activities	Very sure I can't	Sure I can't	Not sure	Sure I can	Very sure I can
: Figure how much insulin give myself when I am sick bed	Very sure I can't	Sure I can't	Not sure	Sure I can	Very sure I can
: Prevent having reactions	Very sure I can't	Sure I can't	Not sure	Sure I can	Very sure I can
0:Avoid or get rid of dents, welling, or redness in my kin when I get my shot	Very sure I can't	Sure I can't	Not sure	Sure I can	Very sure I can
1: Talk to my doctor myself ask for things	Very sure I can't	Sure I can't	Not sure	Sure I can	Very sure I can
2: Suggest to my parents hanges in my insulin dose	Very sure I can't	Sure I can't	Not sure	Sure I can	Very sure I can
3: Sleep away from home on class trip, at a friend's ouse where no-one knows bout my diabetes	Very sure I can't	Sure I can't	Not sure	Sure I can	Very sure I can
4: keep myself free of blood ugars	Very sure I can't	Sure I can't	Not sure	Sure I can	Very sure I can
5: Know how to make my rine tests look better or orse than they are	Very sure I can't	Sure I can't	Not sure	Sure I can	Very sure I can
6: Avoid having acetones	Very sure I can't	Sure I can't	Not sure	Sure I can	Very sure I can
7: Change my doctor if I on't like him/her	Very sure I can't	Sure I can't	Not sure	Sure I can	Very sure I can

Self Efficacy for Diabetes Scale

8: Feel able to stop a eaction when I am having ne	Very sure I can't	Sure I can't	Not sure	Sure I can	Very sure I can
9: Ask for hep I need from ther people when I feel sick	Very sure I can't	Sure I can't	Not sure	Sure I can	Very sure I can
0: Tell a friend I have iabetes	Very sure I can't	Sure I can't	Not sure	Sure I can	Very sure I can
1: Play baseball or other ports that take a lot of nergy	Very sure I can't	Sure I can't	Not sure	Sure I can	Very sure I can
2: Argue with my doctor if I elt he/she were not being fair	Very sure I can't	Sure I can't	Not sure	Sure I can	Very sure I can
3: Prevent blindness and ther complications from my iabetes	Very sure I can't	Sure I can't	Not sure	Sure I can	Very sure I can
4: Tell my boy/girlfriend I ave diabetes	Very sure I can't	Sure I can't	Not sure	Sure I can	Very sure I can
5: Do things I have been old not to do when I really ant to do them	Very sure I can't	Sure I can't	Not sure	Sure I can	Very sure I can
6: Get as much attention rom others when my iabetes is under control as hen it isn't	Very sure I can't	Sure I can't	Not sure	Sure I can	Very sure I can
7: Easily talk to a group of eople at a party when I on't know them.	Very sure I can't	Sure I can't	Not sure	Sure I can	Very sure I can
8: Make my teacher see my oint of view	Very sure I can't	Sure I can't	Not sure	Sure I can	Very sure I can
9: Show my anger to a riend when he/she has done omething to upset me	Very sure I can't	Sure I can't	Not sure	Sure I can	Very sure I can
0: Take responsibility for etting my homework & hores done	Very sure I can't	Sure I can't	Not sure	Sure I can	Very sure I can
1: Regularly wear a medical lert/tag or bracelet which ays I have diabetes	Very sure I can't	Sure I can't	Not sure	Sure I can	Very sure I can
2: Snack food not on my iet without getting caught	Very sure I can't	Sure I can't	Not sure	Sure I can	Very sure I can
3: believe I have the ability o take control over my iabetes	Very sure I can't	Sure I can't	Not sure	Sure I can	Very sure I can
4: Follow my doctor's rders for taking control of ny diabetes	Very sure I can't	Sure I can't	Not sure	Sure I can	Very sure I can
5: Run my life the same as I ould if I didn't have iabetes	Very sure I can't	Sure I can't	Not sure	Sure I can	Very sure I can

Appendix 20

CHILDREN'S HEALTH LOCUS OF CONTROL SCALE

Name: .....

Date: ..... Record Number: .....

We would like to learn about different ways children look at their health. Here are some statements about health or illness (sickness). Some of them you will think are true and so you will circle the YES. Some of them you will think are **not** true and so you will circle the NO. Even if it is very hard to decide, be sure to circle YES or NO for **every** statement. **Never** circle both YES and NO for one statement. There are no right or wrong answers. Be sure to answer the way **you** really feel and **not** the way other people might feel.

PRACTICE: Try the statement below.

a. Children can get sick.
If you think this is true, circle ..... YES
If you think this is not true, circle ..... NO

b. Children never get sick.
If you think this is true, circle ..... YES
If you think this is not true, circle ..... NO

Try one more statement for practice.

c. When I am not sick, I am healthy ..... YES NO

NOW DO THE REST OF THE STATEMENTS THE SAME WAY YOU PRACTISED.

1. Good health comes from being healthy. ..... YES NO
2. I can do things to keep from getting sick ..... YES NO
3. Bad luck makes people sick. ..... YES NO
4. I can only do what the doctor tells me to do. ..... YES NO
5. If I get sick, it is because getting sick just happens. ..... YES NO
6. People who never get sick are just plain lucky. ..... YES NO
7. My mother must tell me how to keep from getting sick. ..... YES NO
8. Only a doctor or a nurse keeps me from getting sick. ..... YES NO
9. When I am sick, I can do things to get better. ..... YES NO
10. If I get hurt it is because accidents just happen ..... YES NO
11. I can do many things to fight illness. ..... YES NO
12. Only the dentist can take care of my teeth ..... YES NO
13. Other people must tell me how to stay healthy. ..... YES NO
14. I always go to the nurse right away if I get hurt at school ..... YES NO
15. The teacher must tell me how to keep from having accidents at school YES NO
16. I can make many choices about my health. ..... YES NO
17. Other people must tell me what to do when I feel sick. ..... YES NO
18. Whenever I feel sick I go to see the school nurse right away. ..... YES NO
19. There are things I can do to have healthy teeth ..... YES NO
20. I can do many things to prevent accidents. ..... YES NO

Appendix 21

THERAPEUTIC ALLIANCE QUESTIONNAIRE

Motivational Interviewing (MI) Study- Department of Child Health, University Hospital of Wales

This questionnaire is to give the research team an idea of how helpful you find the interviews within the study. Your responses will not be seen by Michelle or Carol, the counsellors. The questionnaire is confidential and will placed in a locked drawer once you have completed

What is your name?.....
What is your address?.....
Which group are you in? Motivational Interviewing*/ Counselling*? Delete as appropriate*

Please tick the column that applies

	Strongly Disagree	Disagree	Don't Know	Agree	Strongly Agree
BOND					
el comfortable talking with my nsellor (Michelle/Carol)* delete	1	2	3	4	5
el my counsellor understands me	1	2	3	4	5
lieve my counsellor likes me	1	2	3	4	5
counsellor disagrees with me on e things, but not in an offensive y	1	2	3	4	5
counsellor is judgemental of me	1	2	3	4	5
el that my counsellor listens to what ve to say	1	2	3	4	5
el that my counsellor respects my ings	1	2	3	4	5
el that my counsellor is not always est about her feelings towards me	1	2	3	4	5
TASK					
at I do in the research project gives a new way of looking at my betes	1	2	3	4	5
s experience helps me see the pros cons of what I'm doing with my betes	1	2	3	4	5
counsellor helps me believe I can nge my diabetes care *if I want to*	1	2	3	4	5
don't want to talk about my betes, it is OK to say so	1	2	3	4	5
far, I don't feel I am learning thing by participating in this study	1	2	3	4	5
far, my participation is personally ful	1	2	3	4	5
el my counsellor has an hidden pose	1	2	3	4	5
el my meetings with my counsellor a waste of time	1	2	3	4	5
counsellor tries to convince me to nge what I am doing with my betes	1	2	3	4	5
GOALS					
not interested in setting any goals changing my diabetes care	1	2	3	4	5
some goals for changing my betes care *only because* my sellor want me to	1	2	3	4	5
counsellor makes me feel that it is *me* what I do about my diabetes	1	2	3	4	5
counsellor comes up with a useful regarding my diabetes self care	1	2	3	4	5

Thank you for completing this questionnaire.

Appendix 22

NAME _____

PMDQ

For the next few questions, say what you believe is important for controlling your diabetes, which may be different from what is true for other people, or what you think your health care team may say. Take your own situation into account. Tick the box that best describes you feelings.

How **IMPORTANT** is each of the following for controlling your diabetes?

	NOT IMPORTANT	SLIGHTLY	FAIRLY	VERY	EXTREMELY IMPORTANT
Exercising regularly?	☐	☐	☐	☐	☐
Not smoking?	☐	☐	☐	☐	☐
Testing your blood glucose regularly?	☐	☐	☐	☐	☐
Recording your blood glucose results regularly?	☐	☐	☐	☐	☐
Following your eating plan?	☐	☐	☐	☐	☐
Not eating many sweets?	☐	☐	☐	☐	☐
Drinking little or no alcohol?	☐	☐	☐	☐	☐
Managing days when you are ill as recommended?	☐	☐	☐	☐	☐

For the next few questions, say what you believe is likely to be helpful for preventing the complications of your diabetes. This may be different from what is true for other people, or what you think your health care team may say. Take your own situation into account. Tick the box that best describes your feelings.

How **LIKELY** is each of the following to help prevent future complications of your diabetes (such as blindness and heart disease)?

	NOT LIKELY TO HELP	SLIGHTLY	FAIRLY	VERY	EXTREMELY LIKELY TO HELP
Exercising regularly?	☐	☐	☐	☐	☐
Not smoking?	☐	☐	☐	☐	☐
Testing your blood glucose regularly?	☐	☐	☐	☐	☐
Recording your blood glucose results regularly?	☐	☐	☐	☐	☐
Checking your feet regularly?	☐	☐	☐	☐	☐
Following your eating plan?	☐	☐	☐	☐	☐
Not eating many sweets?	☐	☐	☐	☐	☐
Drinking little or no alcohol?	☐	☐	☐	☐	☐
Managing days when you are ill as recommended?	☐	☐	☐	☐	☐
Making sure you get regular medical tests for diabetes-related problems (e.g., eye exams, blood pressure)	☐	☐	☐	☐	☐

Below is a list of concerns people with diabetes sometimes have. Please read each item carefully (do not skip any). Please tick the box on the right that best describes how often you **WORRY** about each item because of low blood sugar.

	NEVER	RARELY	SOMETIMES	OFTEN	ALWAYS
I worry about.....					
Not recognising I am having low blood sugar (hypo)	☐	☐	☐	☐	☐
Not having food, fruit or juice with me	☐	☐	☐	☐	☐
Passing out in public	☐	☐	☐	☐	☐
Embarrassing myself or friends in a social situation	☐	☐	☐	☐	☐
Having a low blood sugar (hypo) reaction while alone	☐	☐	☐	☐	☐
Appearing stupid or drunk	☐	☐	☐	☐	☐
Losing control	☐	☐	☐	☐	☐
No one being around to help me during a low sugar reaction (hypo)	☐	☐	☐	☐	☐
Making a mistake or having an accident	☐	☐	☐	☐	☐
Getting a bad report ☐ or being criticised		☐	☐	☐	☐
Feeling light-headed or dizzy	☐	☐	☐	☐	☐

For the following questions, please tick the box that best describes how much you **DISAGREE** or **AGREE** with the following statements.

	STRONGLY AGREE	AGREE	NEITHER AGREE OR DISAGREE	DISAGREE	STRONGLY DISAGREE
My diabetes is a serious condition	☐	☐	☐	☐	☐
My diabetes has become easier to live with	☐	☐	☐	☐	☐
I worry about getting the complications of diabetes	☐	☐	☐	☐	☐
My diabetes has not had much effect on my life	☐	☐	☐	☐	☐
My diabetes has strongly affected the way others see me	☐	☐	☐	☐	☐
My diabetes costs a lot of money to manage	☐	☐	☐	☐	☐
My diabetes has strongly affected the way I see myself as a person	☐	☐	☐	☐	☐
My diabetes means I have less independence	☐	☐	☐	☐	☐
My diabetes has strongly affected my family	☐	☐	☐	☐	☐
I will probably get diabetes complications	☐	☐	☐	☐	☐
My diabetes has changed my daily activities (friends, school and hobbies)	☐	☐	☐	☐	☐

Appendix 23

DEMOGRAPHIC QUESTIONNAIRE

Motivational Interviewing (MI) Study- Department of Child Health, University Hospital of Wales.

This questionnaire is to give the research team an idea of your living, educational and family status. It is confidential and will placed in a locked drawer once you have completed

Please tick next to the answer that applies.

Your name.....

Q 1: What is your gender? Male Female
Q 2: What is your age? In years .... months.....

Q 3: Please enter our address and postcode

Line 1:.....
Line 2.....
Town/City .....
Postcode.....

Q 4: What year are you in at school?.....

Q 5: At which level are you studying? Please tick that applies.

- SATS
- GCSEs
- GNVQ
- AS levels
- A levels
- Not studying at present

Q 6: What do you *expect* to obtain (or have already obtained) in your grades at school?

- Below 5 GCSEs
- 5 and above GCSEs
- 2 or more AS levels
- 2 or more A levels
- GNVQ
- None of the above

Q 7: Who do you live with?

- Both parents (or step parents/guardian)
- Father only
- Mother only
- Other members of family (e.g. nan)
- Live alone
- Other (please state).....

Q 8: What is the occupation of the person who looks after you?

- Professional (e.g. teacher, doctor, solicitor, nurse, lecturer, dentist, vet)
- Semi professional
- Manual worker (e.g. builder, carpenter, electrician)
- Non manual worker (e.g. taxi driver, shop worker)
- Self employed business
- Not working through disability/sickness
- Unemployed
- Retired
- Other (please state).....

Q 9: How would you describe your living arrangements?

- A home we own (or have a mortgage)
- A home we rent from the council or landlord
- A home we rent from the housing association
- Hostel
- Other (please state).....

Q 10: How may siblings (brothers & sisters, including step siblings) live with you?

Number.....

Q 11: How long have you had diabetes?

In years .....
In months.....

Q 12: Who manages your diabetes?

- Yourself on your own
- You and your mum/dad/guardian
- Someone else (please state).....

Thank you for completing this questionnaire. If you have any questions, please do not hesitate to contact Michelle or Carol at the Diabetes Research Team.

Appendix 24

Wales College of Medicine
Department of Child Health
Professor Sailesh Kotecha
Professor of Child Health and Head of Department
Professor John Gregory
Professor of Paediatric Endocrinology

Coleg Meddygaeth Cymru
Adran Iechyd Plant
Yr Athro Sailesh Kotecha
Athro Iechyd Plant a Phennaeth Adran
Yr Athro John Gregory
Athro Endocrinoleg Pediatrig

CARDIFF UNIVERSITY
PRIFYSGOL CAERDYDD

Cardiff University
Heath Park
Cardiff CF14 4XN
Tel *Ffôn* +44(0)29 2074 3375
Fax *Ffacs* +44(0)29 2074 4283
Prifysgol Caerdydd
Mynydd Bychan
Caerdydd CF14 4XN

Follow up data letter

Dear participant

Motivational Interviewing Diabetes study

Firstly thank you for participating in the study and we have appreciated your time and commitment. The diabetes research team hope you have had a good year since we last met. We are writing to let you know we are now reaching the end of the study. You may (or may not!) remember Michelle or Carol telling you that you would need to give one final HbA1C sample at the end. We are in the process of collecting these samples and will be doing this over the next few months during your routine clinic outpatient appointment. Our research student, Jessica will approach you for this in clinic, and we will ask the clinic staff to take a sample which shouldn't take longer than a few minutes. You will be pleased to know that we no longer require you to fill in *all* the questionnaires that you completed at the beginning of the study. Jessica will ask you however to fill in two short questionnaires whilst you are waiting to see your doctor or nurse will shouldn't take longer than 20 minutes to complete.

The study has produced some interesting results and once the final samples and questionnaires are completed, we will let you know the outcome of the study.

If you have any queries regarding this, please do not hesitate to contact Michelle Huws-Thomas on 02920 744445.

Thank you and good luck!

Dr Sue Channon Consultant psychologist
Dr John Gregory Consultant in Paediatric Endocrinology
Dr Steve Rollnick Senior Lecturer