A systematic review of psychological therapies for treatment resistant depression and an investigation into the utility of family liaison meetings within an adult mental health rehabilitation and recovery setting

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July 2017

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Thesis submitted in partial fulfilment of the requirement for the degree of Doctorate of Clinical Psychology at Cardiff University and South Wales Doctoral Programme of Clinical Psychology

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Total word count: 21, 356 (excluding tables, figures and references)

Declaration

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other award.
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Thesis Summary

This thesis has been written in the format of three papers: a systematic review, an empirical paper and a critical reflection paper. Paper one presents a systematic review into the effectiveness of psychological treatments for treatment resistant depression in adults.

Paper two presents a qualitative study aimed to explore utility of family liaison meetings in an adult mental health rehabilitation and recovery unit.

Paper three presents a critical reflection on the process of conducting the research contained in this thesis and as such is not intended for publication. The implications of the research for clinical practice and the relevance for clinical psychology, and adult psychiatric care are discussed. Reflections on personal and professional development are also explored.

Acknowledgements

I would like to thank my supervisors for their knowledge and guidance. In particular I would like to thank Dr Andrea Davies for providing the opportunity to work on this project and for her invaluable support, time and commitment in helping me during this process.

I wish to thank the staff members at Cefn Yr Afon who graciously gave up their valuable time to take part in this research.

I would also like to thank my professional mentor Dr Ruth Bagshaw for her frank no-nonsense discussions and providing me with the impetus and spurring me on to complete the thesis. Additionally I would like to thank my elective clinical placement supervisor Dr Sara Morgan for helping to manage my work stress levels and providing me with the workplace flexibility needed to undertake this research.

Finally I want to thank my family for their support and sense of humour which has helped me throughout my clinical training.

Paper One: Systematic Review

The Effectiveness of Psychological Treatments for Treatment Resistant

Depression in Adults: A Systematic Review

Brian Pert and Dr Dougal Hare

South Wales Doctoral of Clinical Psychology, Cardiff University

Paper One has been prepared for submission to Journal of Affective Disorders (See appendix 1 for submission guidelines). For ease of reading, as per journal guidelines figures have been included in the text rather than in appendices.

Word Count = 5644

(excluding tables, figures and references)

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Abstract

Aims

To evaluate the effectiveness of psychological interventions for the treatment of adults with a diagnosis of major depressive disorder who have not responded to at least one course of antidepressant medication.

Method

A literature review of random controlled trials of psychological interventions for adults with treatment resistant depression was conducted. CENTRAL, EMBASE, MEDLINE and PsycINFO databases were systematically searched for relevant papers. In addition to this, hand searching of reference lists was conducted to identify any additional papers missed during the computer search process. RCTs and cluster RCTs as well as trials using a crossover design were included if they were published in a peer-reviewed journal, written in English and participants were adults with a primary diagnosis of unipolar depression that had not responded to a minimum of four weeks of antidepressant medication. Due to the heterogeneity in study designs estimated effect sizes were not calculated. Studies were critically analysed and a narrative synthesis was conducted.

Results

Of 3052 original titles, 10 articles evaluating treatment comparisons were included. Psychotherapy was examined as an augmentation to antidepressants in 8 studies and as a substitution treatment in 3 studies. A total of 884 patients were evaluated (mean age \sim 40y; females = 56-85%)

Limitation

The evidence base for the use of psychotherapy in addressing treatment resistant depression is sparse. Few RCTs exist that adequately explore this area and those that are available are of mixed quality. The evidence base is compromised due to significant heterogeneity in the definition of treatment resistant depression as well as heterogeneity in study designs and patient populations.

Conclusion

The evidence base is sparse and results are mixed for the use of psychotherapy as a treatment for managing treatment resistant depression. The present results reflect small effect sizes or non-significant findings. There is a need for a consensus on the definition of treatment resistant depression allowing for more rigorous clinical trials to be conducted from which findings can be used to produce practice guidelines.

Keywords: systematic review; treatment resistant depression; treatment refractory depression; treatment effectiveness; psychotherapy.

Introduction

The majority of people with clinical depression recover well with first-line treatments such as antidepressant medication and/or psychotherapy in primary care settings (Cleare et al., 2015). Only a relatively small proportion of depressed patients in the UK are referred to psychiatrists for more specialist management. The reason for such referrals may include the patient being considered to be of increased risk, such as heightened suicidality, as a result of their depression, the potential for comorbidity, or they have failed to respond to first-line treatments and as such may be considered to be treatment resistant. Approximately 30% of patients with major depressive disorder (MDD) show a failure to respond to antidepressant medication or psychotherapy and will remain clinically symptomatic (Hollon et al., 2014; Rush et al., 2006) and as such are referred to as having treatment resistant depression (TRD) (Trevino et al., 2014). The reasons for a patient's nonresponse to treatment may be due to an intolerance of their prescribed medication or nonadherence to the treatment regime. However it may also be the result of TRD which may occur despite the patient receiving both an adequate dose and duration of treatment.

Compared to other patients with MDD those with TRD have lower productivity, higher medical comorbidity and increased rate of suicides and poor social functioning (Bennabi et al., 2015). TRD can result in a 40-50% increase in direct and indirect costs when compared to non-resistant depression (Gibson et al., 2010; Petersen et al., 2005; Russell et al., 2004).

Despite such concerns around TRD there remains a lack of consensus as to what constitutes TRD. There are more than 10 disparate definitions for TRD within the research literature (Berlim & Turecki, 2007). Currently there is an absence of reliable and clinically relevant biomarkers for detecting TRD (Kapur et al., 2012). Instead the condition is assessed based on clinical presentation. The term has typically been applied to depressive disorders in which antidepressant medication, as opposed to psychotherapy, has failed (Cleare et al., 2015; Berlim & Turecki, 2007; Ruhe et al., 2012). However, there remains disagreement around what constitutes 'failed' treatment. Clinical studies of antidepressant medication efficacy tend to define responsiveness as a minimum decrease of 50% on a standardised depression rating scale such as the Hamilton Rating Scale for Depression (HRSD, also known as HAM-D) or the Beck Depression Inventory (BDI) (Fagiolini & Kupfer, 2003).

It is imperative that a clear understanding of potential interventions that may be effective for TRD are established due to the condition's debilitating effects. The World Health Organisation claims that MDD is the leading cause of disability in the developed world (WHO, 2009). Currently healthcare providers utilise a range of treatment options such as antidepressant medication (Kennedy et al., 2009;

Barbui et al., 2008; Cipriani et al., 2006) and psychotherapeutic interventions (Bortolotti et al., 2008; Butler et al., 2006). A combination of medication and psychotherapy has been found to be the most effective form of treatment for MDD (Michalak & Lam, 2002). Although there remains a lack of guidance on effective treatments when depression fails to remit with first-line medication (MacQueen et al., 2017; Malhi et al., 2009), the most common intervention remains a change in medication rather than commencement of psychotherapy (Markowitz, 2008).

Previous systematic review of RCTs for pharmacological and psychological therapies for TRD found no strong evidence to guide the management of such people (Stimpson, 2002). This review is out of date and a number of relevant RCTs have subsequently been published. Similarly McPherson et al. (2005) summarised the evidence for psychological therapies from both controlled and uncontrolled studies into the treatment of TRD up to October 2002. The absence of a significant number of randomly controlled studies in McPherson's review is a major methodological shortcoming. Outcome studies of psychotherapy for depressive illness should include random control groups in order to control for self recovery and the fluctuating nature of depression. Without controls in place it is not possible to conclude if post-treatment change occurred as a result of the treatment itself or by other unknown factors associated with the condition. As a result of these issues there is a need for a more up to date review of the evidence base with a focus solely on controlled studies.

Aims of the Study

The aim of this systematic review is to provide an update of research evidence into the effectiveness of psychological therapies in the treatment of TRD in adults by focusing on random controlled trials (RCTs).

Method

An initial search of the Database of Abstracts of Reviews of Effects (DARE) and the Cochrane Database of Systematic Reviews (CDSR) as well as the National Institute for Health and Clinical Excellence (NICE) was conducted to establish if the need for a new review into the effectiveness of psychological treatments for TRD in adults was justified. From this search it was established that previous systematic reviews had been conducted by Stimpson et al. (2002) and McPherson et al. (2005). In addition to this a protocol for conducting a similar systematic review exists in the Cochrane Library (Wiles et al., 2013). However there is no evidence that this protocol resulted in a systematic review being produced. As such it was deemed there was a need for a new review in this area given that the last time the evidence base had been systematically reviewed was in 2002 (McPherson et al.,

2005). The current systematic review followed the Wiles et al. (2013) protocol from the Cochrane Library.

Search Strategy

Randomised controlled trials (RCTs) for psychological interventions for the treatment of adults with TRD were identified from four bibliographic databases (CENTRAL, EMBASE, MEDLINE, PsycINFO). The database search was conducted in June 2017 and restricted to English language papers or papers with an abstract in English (full details of the search strategy can be found in appendix 2).

Selection Criteria

RCTs and cluster RCTs (a type of randomised controlled trial in which groups of subjects, as opposed to individual subjects, are randomised) were considered for inclusion in this study as well as trials using a crossover design, however only data from the first treatment phase of crossover trials would be included. Participants from the included studies had to be aged between 18 and 74. If a study included participants either under the age of 18 or over the age of 74, they were included if the mean age of participants in the study was over 18 or under 74 years of age.

Only studies whereby the participants had a primary diagnosis of unipolar depression that had not responded to a minimum of four weeks of antidepressant medication were included. Studies had to state the use of a standardised diagnostic criteria to diagnose unipolar depression.

Only studies with experimental interventions that were psychological therapy as monotherapy (whereby the intervention comprises solely of psychological therapy) or psychological therapy as an adjunct to antidepressant therapy (whereby the psychological intervention had been administered in addition to antidepressant medication) were included in this study.

Screening

Titles and abstracts were initially examined to remove obviously irrelevant articles. The remaining study abstracts were screened against a standardised abstract screening form to determine if the study is suitable for inclusion within the review. A second reviewer also screened these studies for inclusion or exclusion from the review. The study selection process is outlined using Preferred Reporting Items for System Reviews and Meta-Analysis (PRISMA) flow diagram (See Figure 1).

Data Extraction

Data was extracted in relation to participants, interventions and their comparators, treatment effects as well as methodological details and potential biases. Data was entered into a standardised data extraction table (See appendix 3).

Risk of Bias

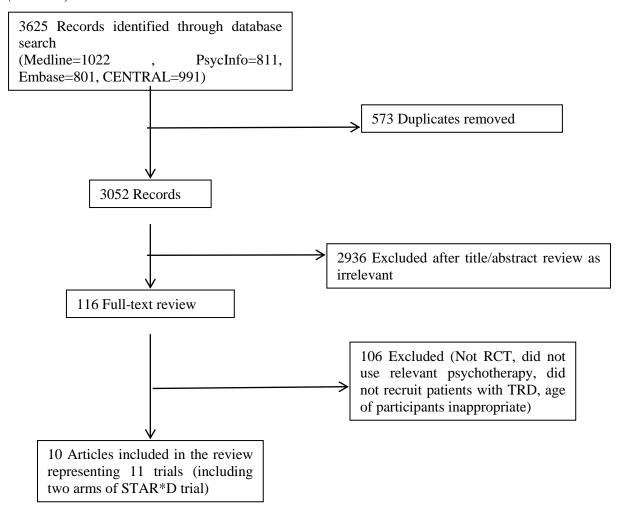
Included studies were assessed for risk of bias using the Cochrane collaboration's risk of bias tool (Higgins et al., 2011). This consisted of assessing included studies against the following criteria:

- Sequence generation: was the allocation sequence adequately generated?
- Allocation concealment: was allocation adequately concealed?
- Blinding of participants, study personnel and outcome assessors for each outcome: was knowledge of the allocated treatment adequately prevented during the study?
- Incomplete outcome data for each main outcome or class of outcomes: were incomplete outcome data adequately addressed?
- Selective outcome reporting: reports of the study free of suggestions of selective outcome reporting?
- Other sources of bias: was the study apparently free of other problems that could put it at a high risk of bias?

Results

The results of the search are shown in Figure 1. Of the 116 papers where full-text articles were reviewed, a total of 106 articles were excluded. Therefore data was obtained from 10 papers representing 11 studies, that met the eligibility criteria.

Figure 1: Preferred Reporting Items for System Reviews and Meta-Analysis (PRISMA)



Sample Characteristics

A total of 884 patients were evaluated. They were recruited from a range of settings including tertiary care, mental health and primary care clinics, general medical clinics, as well as the general population. Three studies were conducted in the United States, four in the United Kingdom, one in Canada, one in Italy and one in Brazil. Sample sizes ranged from 24 to 173 participants. The average age was approximately 40 years. Females comprised 56-85% of the studies' participants and at least 73% were Caucasian in the six studies that reported race. The average length of participants' current depressive episodes ranged from 29 to 366 weeks with the average number of lifetime depressive episodes ranging from 2.4 to 8.7. Depression severity was primarily measured using the Hamilton Rating Scale for Depression (HAM-D, sometimes abbreviated as HRSD) and self-report measures (Beck Depression Inventory (BDI), Patient Health Questionnaire (PHQ), Quick Inventory of Depressive

Symptomatology Self-Report (QIDS-SR)). The sample characteristics are summarised in Table 1 and so significant heterogeneity in the demographics, depression severity and chronicity.

Table 1: Sample Characteristics

		Samp	le Characteris	tics		
Study	Sample size, n Psychotherapy	Age, y (M ±SD)	Female, n (%) Psychotherapy	Caucasian, n	Duration of current	Number of prior MMD
	Comparator	Psychotherapy	Comparator	Psychotherapy	episode, wks	episode, (M
	Comparator	Comparator	Comparator	Comparator	(M ±SD)	±SD)
		Comparator		Comparator	Psychotherapy	Psychotherapy
					Comparator	Comparator
Town et al.,	30	38.9±11.8	17 (56%)	30 (100%)	104	Not reported
2017	30	44.2±12.2	21 (70%)	28 (93.3%)	156	Not reported
2017	30	++ .2 <u>+</u> 12.2	21 (7070)	20 (73.370)	130	
Souza et al.,	17	49.3±12.3	15 (88.2%)	Not reported	145.5	2.4
2016	23	49.18±12.5	19 (82.6%)		126	2.57
Eisendrath et	87	47.1 ±13.4	66 (75.9%)	69 (80%)	366	3.8
al., 2016	86	45.2 ±11.1	58 (76.7%)	68(79.5%)	341	3.5
Chiesa et al.,	26	50.9±11.4	18 (70%)	Not reported	93.86	Not reported
2015	24	46.7±10.8	18 (75%)		129.37	
Fonagy et al.,	67	42.7±10.4	44 (66.7%)	Not reported	192±177	3.5±1.4
2015	62	46.7±9.9	40(66.1%)		198±135	3.9±1.8
Watkins et al	21	43.0±11.0	14 (67%)	20 (95%)	Not reported	5.43±2.93
2011	21	45.2±9.3	10 (48%)	20 (95%)		4.84 ± 3.02
Harley et al.,	13	41.8	18 (75 %)	20 (83%)	28.7±18.8	Not reported
2008	11				41.8±53.6	
Wiles et al.,	14	45.5±12.8	12 (85.7%)	Not reported	86%>1yr	Not reported
2008	11	45.1±11.1	9 (81.8%)		82%>1yr	
Thase et al.,	65	40.6±11.5	41 (63%)	52 (80%)	129±214	7.3±14.1
2007	117	39.7±13.5	78 (67%)	99 (85%)	87±206	4.6±5.4
(Augmentation)						
Thase et al.,	36	43.4±14.7	22 (61%)	28 (78%)	76±135	8.7±18.8
2007	86	41.5±13.3	53 (62%)	63 (73%)	115±234	8.4±16.0

Blackburn &	17	37.8±13.1	17 (77%)	Not reported	30.4±6.1	4.1±3.4.
Moore, 1997	20	40.1±12.7	17 (65%)		29.9±5.6	3.2 ± 2.2
Study	Baseline	Baseline self-	Setting			
	HAM-D	reports	Location			
	Psychotherapy	Psychotherapy				
	Comparator	Comparator				
Town et al.,	23.5±5.3	PHQ-9	Mental Health			
2017	24.0±5.1	19.1±4.6	Clinic			
		20.3±4.8	Canada			
Souza et al.,	19.8±5.0	BDI	Tertiary Care			
2016	18.4±5.2	31.4±11.6	Brazil			
		28.8±8.0				
Eisendrath et	18.3±3.3	Not	Mental Health			
al., 2016	17.4±3.4	administered	Clinic &			
			General			
			Health Clinics			
			USA			
Chiesa et al.,	17.0±5.5	BDI	General			
2015	15.7±5.4	23.9±13.2	Community &			
		20.6±9.7	Mental Health			
			Clinic			
			Italy			
Fonagy et al.,	19.8±5.1	BDI	Primary Care			
2015	20.4±4.9	23.9±13.2	England			
		20.6±9.7				
Watkins et al	13.2±3.3	BDI	Primary Care			
2011	12.1±2.8	30.7±8.1	England			
		28.2±9.7	3 ·· ··			
Hawley of al	16 2+4 5	BDI	Mental Health			
Harley et al., 2008	16.2±4.5 18.6±4.7		Clinic			
4000	10.0±4./	27.3±8.8 27.4±11.7	USA			
		∠1. 7 ±11./	USA			
Wiles et al.,	Not	BDI	Primary Care			
2008	administered	31.1±8.5	England			
		26.8±6.8				
Thase et al.,	17.8±5.7	QIDS-SR	Mental Health			
,		-	17			

2007	16.0±6.7	11.9±4.3	Clinic
(Augmentation)		12.0±4.6	& Primary
			Care
			USA
Thase et al.,	16.4±6.2	QIDS-SR	Mental Health
2007	16.0±6.7	11.2±4.3	Clinic
(Substitute)		12.1±4.6	& Primary
			Care
			USA
Blackburn &	11.8±6.3.	BDI	Mental Health
Moore, 1997	10.6±6.8	20.4±11.1	Clinic
		19.7±14.2	Scotland

Identified studies utilise different criteria for determining treatment resistant depression (Table 2). While this led to heterogeneity between studies, they primarily utilised a similar methodology consisting of a baseline diagnosis of MDD, patients being administered antidepressants medication at an adequate dose, patients still presenting with residual symptoms of MDD as measured using a validated psychometric.

Table 2: Criteria to Determine Treatment Resistant Depression

	Criteria to Determine Treatment Resistant Depression									
Study	Criteria for initial	1 st step	1st step treatment	Was 1st step	Criteria to					
	MDD diagnosis	antidepressant	duration	antidepressant	determine					
		treatment: Type		treatment	persistence					
		and dosage		provided in the	following 1st step					
				study?	antidepressant					
					treatment					
Town et al., 2017	History of MDD	Antidepressant	>6 weeks	No	HAM-D>16					
	meeting DSM-IV	medication at								
	as measured by	adequate dosage								
	Mini-International									
	Neuropsychiatric									
	Interview									
	and SCID									
Souza et al., 2016	History of MDD	Equivalent to	>4 weeks	No	Criteria for failure					
	meeting DSM-IV	75mg			to respond to					
	as measured by	amitriptyline			medication not					
	Mini-International				reported					
	Neuropsychiatric									

	Interview				
Eisendrath et al., 2016	Unipolar MMD using SCID for DSM-IV	Antidepressant medication at adequate dosage.	Not stated but must have had 2 failed treatment of antidepressant medication	No	HAM-D>14
Chiesa et al., 2015	History of MDD meeting DSM-IV as measured by Mini-International Neuropsychiatric Interview	Antidepressant medication at adequate dosage.	>8 weeks	No	HAM-D>8
Fonagy et al., 2015	History of MDD meeting DSM-IV criteria HAM- D>14 and BDI>21	Antidepressant medication at adequate dosage.	Not stated but must have had 2 failed treatment one of which must be antidepressant medication	No	MDD on SCID-I
Watkins et al 2011	History of MDD meeting DSM-IV criteria HAM-D>8 and BDI>9	Equivalent to 125mg amitriptyline	>8 weeks	No	MDD on SCID-I
Harley et al., 2008	Not reported	As prescribed by non-study psychiatrist	>6 weeks	No	MDD on SCID-I
Wiles et al., 2008	Current antidepressant use. BDI>15 and adherent with medication treatment.	As prescribed by GP	>6 weeks	No	ICD-10 diagnosis of MDD
Thase et al., 2007	History of MDD HAM-D>14	Citalopram 20mg/day titrated to 40mg by week 4 if needed. Max. 60mg/day by week 6.	14 weeks	Yes	HAM-D>14
Blackburn & Moore, 1997	Unipolar MMD using SADS HAM-D>16	Equivalent to 100mg amitriptyline or 45mg phenelzine or 20mg sertraline	16 weeks	No	Moderate symptoms on BSI and HAM-D>11

Quality

The current systematic review used Cochrane collaboration's risk of bias tool (Higgins et al., 2011) in combination with reviewing additional methodological issues that may impact on quality (See Table 3). Studies' quality was rated as 'good', 'fair' or 'poor'. This tool was chosen as it fits with the methodology of the review. Studies were assessed for quality by a second independent rater. While historically it has been suggested that quality should be assessed under blind conditions to reduce selection bias (Chalmers et al., 1981), there is a lack of empirical evidence to support this practice (Irwig et al., 1994; Fisher et al., 1994). Due to this reason and in addition to blinding being a time-consuming process which is considered to be unlikely to alter the results of the review (Berlin, 1997) quality assessment in the current review was not conducted under blind conditions. The ratings are to some extent based on subjective judgements based on an interpretation as to the degree that a bias will have impacted on the overall quality of the study. As such no one bias domain is more important than another, nor are the number of domains met proportional to the overall quality rating. Instead the qualitative interpretation of the bias in the study influenced the overall interpretation.

Two of the included studies were rated as good in quality, four as fair and four as poor.

Table 3: Risk of Bias

	Risk of Bias									
	Randomization adequate?	Allocation concealment adequate?	Baseline comparability?	Subject/providers blind?	Outcomes assessed blind?	Dropout rate < 30%?	Differential dropout rate < 10%?:	Incomplete data addressed adequately?	Conflict of interest?	Overall quality rating
Town et al., 2017	+	+	+	-	+	+	-	+	+	Fair
Souza et al., 2016	+	+	+	-	+	+	-	+	+	Fair
Eisendrath et al., 2016	+	+	+	+	+	+	+	+	+	Good
Chiesa et al., 2015	+	+	+	?	?	+	+	+	+	Poor
Fonagy et al., 2015	+	+	+	+	?	+	+	+	+	Fair
Watkins et al., 2011	+	+	+	+	?	+	+	+	+	Poor

Harley et al., 2008	+	+	+	+	-	?	+	+	+	Fair
Wiles et al., 2008	+	?	+	-	-	+	-	+	+	Poor
Thase et al., 2007	+	+	+	+	+	+	+	+	-	Good
Blackburn & Moore, 1997	+	+	+	+	ı	ı	1	-	+	Poor

Of the two good-quality studies included in this review, the study by Eisendrath et al. (2016) was methodologically strong as a result of the study monitoring therapy fidelity. This ensured that participants were receiving a true and accurate reflection of what the therapy under investigation was supposed to be. Participants were not blind to the intervention they received (as was the case with all studies in this review) and this approach could have introduced an expectation bias. Similarly patients' treatment preferences were not monitored before randomisation and this may also have impacted on outcomes. While the study did not limit changes in medication during treatment, which may potentially have led to variances within the sample, a potential strength of this is that findings would represent real-world practice. The study by Thase et al. (2007), was funded by multiple pharmaceutical companies which may have resulted in potential conflicts of interests. This study used an equipoise randomisation with only one third of patients considering psychotherapy to be acceptable. This characteristic of the sample is not representative of real-world patients where psychotherapy is generally deemed to be an acceptable treatment option. One of the strengths of the methodology of this study was the ability to have patients switch from pharmacotherapy to psychotherapy and measure the subsequent effect.

Of the four studies rated as methodologically fair, the study by Town et al (2017) was based in a single study centre and as such it is not possible to determine if findings are generalisable to different geographical locations and populations. In addition the project was conducted by proponents of experimental treatment which increases the likelihood of allegiance effect. Also therapist adherents to the therapy intervention was not measured and as such it is possible that they deviated from standard therapy protocol. Souza et al (2016) study had a small sample which limits its ability to detect differences between treatments. The therapists were not fully qualified which may have reduced quality of psychotherapy. Due to the pragmatic design medication was clinicians' free choice which could favour a bias between groups. Although it is important to note that the pragmatic design also helps clinicians decide whether or not to add IPT to TAU. Similarly there were no restrictions to the

TAU group in the study by Fonagy et al. (2015). Harley et al. (2008) study also used a small sample size limiting its power. Additionally, there was limited information provided on samples' baseline characteristics which may have influenced the outcomes of therapy.

The four studies that were rated as poorest in quality all suffered from a range of methodological flaws including: a lack of adequate controls, small sample size resulting in a lack of power to detect change, a lack of detail about the treatments provided, including a lack of detail around monitoring the quality and adherence to the delivery of the therapeutic intervention.

Study Design and Interventions

Table 4 summarises the design and interventions of all the included studies.

Table 4: Study Design and Interventions

Study Design and Interventions							
Study	Duration	Study design	Augmentation	Psychotherapy	Number	Comparator	Power
-	of Follow		or Substitute	intervention	of		Calculation
	up, wks				sessions		
Town et al.,	26	RCT	Substitute	Intensive short	20	Continue	Yes
2017				term dynamic		antidepressant	
				psychotherapy		medication	
Souza et	24	Pragmatic RCT	Augmentation	IPT	16	Continue	Yes
al., 2016						antidepressant	
						medication	
Eisendrath	8	RCT	Augmentation	Group MBCT	8	Health	No
et al., 2016						Enhancement	
						Program	
Chiesa et	26	Equipoise	Augmentation	Group MBCT	8	Psychoeducation	No
al., 2015		Stratified					
		Randomisation					
Fonagy et	182	Pragmatic RCT	Augmentation	Long term	60	TAU, may	Yes
al., 2015				psychoanalytic		include any	
				psychotherapy		psychotherapy	
						other than	
						psychoanalytic	
Watkins et	12	RCT	Augmentation	Rumination	12	Continue	Yes
al 2011				Focused CBT		antidepressant	
						medication	
Harley et	16	RCT	Augmentation	Group DBT	16	Continue	No
al., 2008						antidepressant	
						medication	
Wiles et al.,	16	RCT	Augmentation	Cognitive	9.5	Continue	No
2008				therapy		antidepressant	
						medication	
Thase et	14	Equipoise	Augmentation	Cognitive	24	Antidepressant	Yes

al., 2007		Stratified		therapy		augmentation	
(Augmenta		Randomisation					
tion)							
Thase et	14	Equipoise	Substitute	Cognitive	24	Antidepressant	Yes
al., 2007		Stratified		therapy		substitute	
(Substitute)		Randomisation					
Blackburn	104	RCT	Substitute	Cognitive	27	Continue	No
& Moore,				therapy		antidepressant	
1997						medication	

Table abbreviations: RCT – Randomised Control Trial, IPT – Interpersonal psychotherapy, MBCT – Mindfulness Based Cognitive Therapy, CBT – Cognitive Behavioural Therapy, DBT – Dialectical Behavioural Therapy, TAU – Treatment as usual

Defining Treatment Resistance

Studies included in this review varied in their method of establishing TRD. Five of the included studies specified a diagnosis of MMD with results on psychometrics (mainly HAM-D) above an arbitrary score. However the scores on these psychometrics for a diagnosis of MMD varied significantly with one study considering scores >8 on HAM-D (Watkins et al., 2011) in comparison to another study considering scores >16 on HAM-D (Blackburn & Moore, 1997). This variance of MMD scores would suggest significant heterogeneity between studies in the severity of depression of participants. Four of the included studies specified the type and dosage of antidepressant medication as first line treatment which must have failed. However there was a large variance between the dosage of antidepressant medication ranging from 75 mg of amitriptyline in one study to 125 mg in another study. The remaining studies stated the use of antidepressant medication at adequate dose. While all the studies included were investigating drug resistant unipolar depression, subjects represented a significant heterogeneous group in respect to the medication they received. As a result it is possible that differences in medication may have affected the observed therapeutic outcomes.

Treatments and Treatment Duration

Both Chiesa et al. (2015) and the two arms of STAR*D (Thase et al., 2007) used an equipoise stratified randomisation design whereby participants could refuse randomisation to a nonpreferred treatment. Pragmatic random controlled trials were used in two studies (Souza et al., 2016; Fonagy et al., 2015). The aim of pragmatic randomised controlled trials are to reflect the heterogeneity of patients encountered in clinical practice and as such they aim to keep exclusion criteria to a minimum (Hotopf, 2002). The remaining six trials in this review used true randomisation.

Psychotherapy was examined as an augmentation strategy in eight studies and a substitution in three studies. Studies varied in their use of treatment interventions, with seven distinct therapeutic interventions included in this review. Three of the included studies used Cognitive Therapy (CT), two used Mindfulness Based Cognitive Therapy (MBCT), one used Rumination Focused Cognitive Behavioural Therapy (RFCBT), one used Dialectical Behavioural Therapy (DBT), one using Interpersonal Psychotherapy (IPT), one used Long-Term Psychoanalytic Psychotherapy (LTPP) and another study used Intensive Short-Term Dynamic Psychotherapy (ISTDP). The duration of therapy ranged between 8 and 60 sessions. The follow-up durations ranged between 8 and 182 weeks.

Sample Sizes

The majority of studies included in this review had relatively small sample sizes. The retention rates ranged from 25% to 100%. This results in low statistical power and as such investigations struggle to detect differences between the experimental group and the control group. Furthermore, the small sample sizes limit the generalisability of findings to the wider population.

Psychotherapy as Step 2 Treatment Outcomes

Table 5 summarises the primary outcomes of all included studies.

Table 5: Results of the Psychotherapy Intervention

Results of Psychotherapy Intervention					
Study	Retention rate,	Post-treatment HAM-D	Post-treatment BDI Score		
	Psychotherapy	(M ±SD)	(M ±SD)		
		Psychotherapy	Psychotherapy		
	Comparator	Comparator	Comparator		
		Effect Size	Effect Size		
Town et al.,	23(76.6%)	Remission:	PHQ-9 Remission:		
2017		36.0%	32.0%		
	27(90%)	3.7%	4.3%		
		d=.748	d=.835		
Souza et al.,	16(94%)	14.0±1.6	23.4±2.9		
2016		13.9±1.4	22.6±2.5		
	18(78%)	Non-Sig	Non-Sig		
Eisendrath et	67 (87.3%)	Remission:	Scores not reported		
al., 2016		22.4%			
	64 (83.7%)	13.8%			
		Non-Sig.			
Chiesa et al.,	24(92.3%)	Week 8 (sort term)	Week 8 (sort term)		
2015		9.82±7.35	14.18±15.10		

	21(87.5%)	13.80±7.32	17.23±7.61
		Non-Sig	d=.45
		Week 26 (long term)	Week 26 (long term)
		8.04±6.18	13.77±14.93
		13.25±6.98	18.53±10.94
		d=.79	d=.36
Fonagy et al.,	51 (76%)	Full Remission:	Partial Remission:
2015		9.4%	46.7%
	46 (74%)	6.5%	28.2%
		Non-Sig	Non-Sig
		Partial Remission:	
		32.1%	
		23.9%	
		Non-Sig	
Watkins et al	21 (100%)	5.48±5.15	12.71±11.37
2011		9.05±5.25	20.71±10.84
	19 (90.4%)	d=.94	d=1.11
Harley et al.,	10 (77%)	11.3 ±5.3	15.1 ±12.1
2008	9 (82%)	17.1 ±6.2	25.9 ±16.3
		d= 1.45	d=1.31
Wiles et al.,	14 (100%)	N/A	Scores not reported:
2008			ITT analysis:
	9 (81.8%)		Regression coefficient=-8.4, 95%CI: -21.9,
			5.1
Thase et al.,	59 (91%)	Remission:	8.2±5.1
2007	95 (81%)	23.1%	8.2±4.8
(Augmentation)		33.3%	Non-Sig
		Non-Sig	
Thase et al.,	30 (83%)	Remission:	9.1±5.4
2007	63 (73%)	25.0%	9.1±5.0
(Substitute)		27.9%	Non-Sig
		Non-Sig	
Blackburn &	6 (35%)	8.6 ± 5.6	14.2 ± 9.9
Moore, 1997	5 (25%)	9.3 ± 7.2	18.1 ± 13.1
		Non-Sig	Non-Sig

Mindfulness Based Cognitive Therapy (MBCT)

Results indicated that mindfulness based cognitive therapy generally resulted in improvements in a reduction of depressive symptoms.

In Eisendrath et al. (2016) which was rated as good in quality, they compared MBCT to Health Enhancement Program (HEP). Patients improved in both conditions post treatment, however there were no significant differences between groups for percent remitted on HAM-D (MBCT = 22.4%, HEP = 13.8%; p > 0.05).

In Chiesa et al. (2015) a significantly larger improvement in HAM-D scores were observed in the MBCT group compared to the psychoeducation group both in short and long-term periods (short term: F=6.82, d.f.=2,80, p=0.002, between groups d=0.54; long-term: F=4.28, d.f.=4,160, p=0.002, between groups d=0.79).

Cognitive Therapy (CT)

Studies examining cognitive therapy interventions had mixed results. These mixed findings may however reflect methodological shortcomings.

The augmentation arm of STAR*D found patients improved in both conditions post treatment, however there were no significant differences between groups for percent remitted on HAM-D (cognitive therapy = 23.1%, antidepressants = 33.3%; p > 0.05). Similarly in the substitution arm of STAR*D, whereby patients discontinued citalopram and either switched to 16 sessions of CT or treatment with bupropion, sertraline, or venlafaxine, patients improved in both conditions for percent remitted on HAM-D (CT = 25.0%, antidepressants = 27.9%).

No significant differences were found in Blackburn and Moore (1997) study between cognitive therapy and TAU groups for mean scores on HAM-D (CT equals 8.6; antidepressant equals 9.3; p >0.05). It is important to note however this study had significant limitations including poor retention rates (less than 35%) and lack of statistical power.

In intention to treat analysis (Wiles et al., 2008) cognitive therapy showed an eight-point reduction in BDI scores, however results were not statistically significant (Regression coefficient=-8.4, 95% CI: -21.9, 5.1). Results from this study should be interpreted with caution given the significant study limitations such as small sample size, a lack of clinically administered depression measure and an absence of baseline data outlining participants history of depression.

Rumination Focused Cognitive Behavioural Therapy (RFCBT)

RFCBT was found to lead to significant improvements with fewer residual depressive symptoms post intervention compared with TAU group (F= 7.68, d.f.=1,39, p=0.009).

Dialectical Behavioural Therapy (DBT)

Greater clinical improvements were found using HAM-D within DBT treatment condition than waiting list control group (F = 4.63, P < 0.05) (Harley et al., 2008). However these outcomes are confounded by the small sample size.

Interpersonal Psychotherapy (IPT)

The addition of IPT to TAU did not produce more benefits in terms of depressive symptom reduction compared with TAU alone (Souza et al., 2016). The authors conclude that if one of these two treatments are superior the difference is small.

Intensive Short-Term Dynamic Psychotherapy (ISTDP)

The study investigating ISTDP (Town et al., 2017) found HAM-D full remission of 36.0% for those in ISTDP compared to 3.7% in TAU group. Furthermore statistical modelling showed a significantly greater increase in remission over time for patients treated with ISTDP as opposed to TAU.

Long Term Psychoanalytic Psychotherapy (LTPP)

Complete remission (HAM-D <8) was infrequent in both LTPP and TAU groups at the end of treatment (9.4% vs. 6.5%) similarly partial remission (HAM-D <12) was not significantly more likely in LTPP than in the control group at the end of treatment (32.1% vs. 23.9%) Improvements in depression were found to be modest but comparable between LTPP and control group until termination of treatment, while differences emerged from 24 months post randomisation with LTPP group maintaining the gains achieved while control group appeared to be at greater risk of relapse. At a two-year follow-up period approximately one third of participants treated with LTPP remained in partial remission compared with only 4% in the control group. Similarly 44% of LTPP group no longer met diagnostic criteria for major depressive disorder, compared to 10% from TAU group.

In summary both ISTDP and LTPP were found to produce beneficial symptom reduction over a longer period of time when compared to TAU. Similarly MBCT, RFCBT and DBT also appeared to produce a reduction in symptoms. IPT was found to be no more effective than TAU. CT yielded mixed results although no significant difference was found between intervention and control group.

Discussion

The current evidence examining the effects of psychotherapy as augmentation or substitute to pharmacological interventions for TRD is sparse and the results are mixed. While all the included

studies indicated a reduction in depressive symptoms as measured by HAM-D, the majority of studies found no significant difference between psychotherapy interventions and control groups.

Psychotherapy may offer benefits over pharmacological interventions for TRD which have not been captured fully by the included studies. This systematic review examined symptom reduction as measured by HAM-D as its primary outcome. It is possible that psychotherapy offers benefits such as improved quality of life, cost effectiveness of treatment (Russell et al., 2004), greater patient satisfaction with treatment and therefore subsequent greater adherence to the treatment intervention. As TRD can have a complex pattern of relapse and spontaneous remission, large high quality long-term RCTs are needed to evaluate the longer term impact of treatment in addition to measuring effectiveness beyond mere symptom reduction (Bower et al., 2006).

How might psychotherapy work in TRD?

Both ISTDP and LTPP overlap in the use of common techniques (Town et al., 2017). They view patients with TRD as having problems with psychosocial functioning leading to impaired help-seeking and illness-combating behaviours (Taylor, 2015). Therapy enables patients to internalise a psychological capacity to relate to pathological personal experiences in a more active and effective manner (Milton, 2001).

DBT considers patients with depression as feeling worthless resulting in an overwhelming sense of sadness which invalidates their everyday life experiences (Lynch et al., 2003). DBT offers coping mechanisms that allow patients to address the negative aspects of their lives by emphasising validation and tolerance. In addition to this it is believed patients make gains from psychosocial support from the therapy being delivered within the context of a group (McDermut et al., 2001).

RFCBT suggests there are distinct constructive and unconstructive forms of rumination (Watkins, 2008). Patients with depression become stuck on unconstructive cognitions. As such the aim of therapy is to coach individuals to move from unconstructive rumination to constructive rumination by the use of experiential/imagery exercises and behavioural experiments (Watkins et al., 2011). MBCT operates in a similar way, viewing depression as the result of dysfunctional and automatic cognitive styles. MBCT teaches patients to become more aware of their incoming thoughts, feelings and bodily sensations and to relate to them with an accepting and non-judgemental attitude (Burchett, 2010).

Limitations

There are several limitations with the current systematic review. All trials included in this review consisted of published journal articles. Research indicates that published and unpublished studies often differ in both effect size and the statistical significance of the study results. This is referred to as publication bias (Onishi & Furukawa, 2014).

Within the published literature there are very few RCTs that sufficiently address the role psychotherapy may play in TRD. Of the studies that were found a large proportion of them included relatively small samples of patients thus rendering the study underpowered to detect moderate to large treatment effects. Furthermore there was significant heterogeneity in study designs and patient populations. Some studies recruited solely from CMHTs while others recruited from a range of primary care settings, self-referral from the community and psychiatric inpatient settings. It is likely that the differences in referral settings may produce differences in the responsivity of participants. Hoult et al. (1983) highlights that community treatment is considered to be more helpful by both patients and their relatives and also resulted in clinically superior outcomes when compared to inpatient treatment.

There was also significant heterogeneity in the definition of TRD and the measures utilised to diagnose MDD. The range of measures used in studies included clinician administered scales such as HAM-D, self-report scales such as BDI-II and diagnostic manuals such as DSM-III-R or DSM-IV. Given the lack of a homogenous definition of TRD and universally accepted measure of symptoms, it remains impossible to sufficiently compare treatment outcomes between studies as one cannot say with certainty that outcomes speak to the same phenomena.

There were also considerable differences between the treatments in the studies that made up this review. Some studies did not control for the treatment as usual conditions and allowed treatment providers to decide what interventions they were going to offer as way of treatment. This meant for some patients they could have experienced a range of antidepressant medication in addition to psychological interventions that were not the experimental psychological intervention under investigation. As a result of this it is not possible to state that the experimental psychological intervention is more or less effective than an alternative treatment because the treatment as usual condition varied so significantly between patients. McPherson et al (2005) highlight the importance of using appropriate control conditions in studies examining TRD given the conditions' symptomatic fluctuations. Without appropriate controls it becomes difficult to ascertain if post-treatment change has occurred as a result of treatment or by other unknown factors.

There were vast differences between the types of psychological interventions being investigated between studies. The most prominent psychological intervention in this review was cognitive therapy and its variants (i.e. MBCT, RFCBT). The manualised version of MBCT is eight weeks in duration. In comparison to this standard the treatment phase for interpersonal psychotherapy lasts between 16 and 19 weeks (Souza et al., 2016) while the long-term psychoanalytic psychotherapy treatment in the study by Fonagy et al. (2015) lasts for 60 sessions spread over 18 months. Due to the discrepancies between the duration of treatment it becomes difficult to establish whether differences in outcomes between studies are as a result of the intervention per se or the dose administered. The noted differences between duration of treatment also raises questions around the acceptability of treatment in various settings. For example services are favouring brief therapies that can be delivered by non-specialist mental health professionals as a first step treatment for depression in primary care settings. This approach has been demonstrated to be both an effective form of treatment as well as being acceptable to patients (Wolf & Hopko, 2008). Therefore while studies included in this review may provide some insight into how effective certain psychological treatments are for TRD, they fail to address the question of acceptability and efficacy within different settings.

This review failed to establish which components of a therapy are likely to be efficacious. Additionally studies were unable to indicate the minimum intervention needed to produce change. Studies that utilise a randomised dismantling trial methodology may prove useful in addressing these aspects (Stirman et al., 2003). Given the lack of dismantling studies in the literature, the evidence base has yet to reach a stage whereby the effective components of a psychotherapy can be established.

Only a handful of studies included in this review made attempts to monitor treatment fidelity to psychotherapy protocols by video recording the delivery of psychotherapy sessions and scoring them against treatment fidelity psychometrics specifically designed for the therapeutic intervention. Some studies highlighted the level of training and qualification of the therapists delivering the intervention, as a means of demonstrating the quality of the intervention delivered. The majority of studies included failed to make reference to treatment fidelity and as such it is possible that results from the studies reflect the therapists' style and adherence or lack of, to the therapeutic model rather than the therapy per se.

Conclusion

There is a need to conduct further RCTs to examine the role that psychotherapy may play as a second step treatment for patients with TRD who have not responded to an initial adequate dose of

antidepressant medication. However it is imperative that the field develops a standardised operational definition of TRD. Despite this need having been highlighted in earlier systematic reviews (Stimpson et al., 2002) the research literature has made little progress in addressing the need for a universally accepted definition of TRD. The lack of a standardised definition for TRD has made it difficult to draw comparisons between studies.

In addition to conducting studies to examine the effectiveness of psychotherapy in terms of symptom reduction for TRD, there is a need for more studies to be conducted to examine the acceptability of treatment options for TRD. While evidence suggests that patients generally find psychotherapy a more acceptable treatment option than medication (Gaudiano et al., 2013), little is known about the acceptability between psychotherapies. If acceptable and effective treatments are found, then attrition rates will be significantly reduced resulting in better clinical outcomes.

Finally, none of the studies included in this review addressed issues around cost effectiveness of different treatment options. It is important that effective treatments are also able to demonstrate cost effectiveness in order for them to be embedded into routine clinical practice. Future studies should address cost effectiveness by incorporating longer follow-up periods and specific measures of direct costs, indirect costs and costs associated with comorbid conditions. By having longer follow-up periods it will allow for measuring the impact treatment has on societal costs in the long term.

The current review has been unable to establish specific treatment guidelines for TRD due to the heterogeneity of studies. Results indicate an absence of strong support for the use of psychotherapy for TRD. Of the included studies in this review results suggested either small effects or non-significant findings. When considering factors such as publication bias, whereby primarily favourable results from studies tend to be published over studies which find no effect or a detrimental effect, it is probable that psychotherapy is generally less effective for TRD than studies included in this review might suggest.

There are several possible reasons why psychotherapy might not be effective for TRD. Treatment efficacy in this review is being assessed by the therapies' ability to produce reductions in symptomatology on psychometrics such as the BDI or HADS. Many of the included therapies' primary treatment targets are not directly based on symptom reduction, but rather on other dimensions such as improving quality of life with any reduction in symptoms being a secondary benefit. In addition to a lack of clarity around what constitutes TRD, little is known about the individual factors of people who are diagnosed with TRD. It is possible that TRD actually represents a dimension of

another psychiatric condition and as such psychotherapies may not be targeting the correct underlying processes of the condition. Similarly little is known about the demographics of people with TRD. It is possible that social determinants such as poverty, unemployment and low social status may reinforce symptoms of depression, thus undermining treatment interventions.

There is a need for a consensus for a definition for TRD to enable it to be accurately researched. Upon achieving this definition, the research literature should attempt to profile the characteristics of people with TRD to elucidate targeted interventions.

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Paper Two: Empirical Study

Investigating the Utility of Family Liaison Meetings in an Adult Mental Health Rehabilitation and Recovery Unit

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Paper two has been prepared for submission to Community Mental Health Journal (see appendix 4 for submission guidelines). For ease of reading, figures have been included in the text rather than in appendices as per journal guidelines.

Word Count = 6539 (excluding tables, figures and references).

Abstract

This study explores family liaison meetings in an adult mental health rehabilitation and recovery unit.

It aimed to describe the experiences and views of staff involved in the implementation of family

liaison within the service. A convenience sample took part in this qualitative study. Interviews were

semi-structured and transcribed verbatim. Thematic analysis was carried out by the first author and

reviewed and discussed with the second author. Two overarching themes were developed:

"Repositioning of Families within Mental Health Services and Enhancing Understanding". Results

indicated that staff perceived family liaison meetings to be valuable in addressing the challenges of

working with families and carers.

Keywords: family liaison, community mental health, rehabilitation, recovery.

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Introduction

The current provisions for community mental health care comprise of a diverse range of services, such as assertive outreach, early intervention teams, community recovery and rehabilitation services (Sainsbury Centre for Mental Health, 2003). While recently there has been a shift in emphasis placed upon the use of community care, the notion of providing care outside of institutions is not a new phenomenon (Wright et al., 2008). Care provided outside of institutions in the form of family and neighbourhood support has always been the dominant form of care provision in numerical terms (Thomson, 1998). While community provisions for mental health care have existed for a considerable time, in the last two decades there has been a shift towards adopting a person centred recovery approach in community mental health (Adams and Grieder 2005; Borg et al., 2009; Davidson et al., 2008). This has led to the development of recovery orientated residential mental health rehabilitation services in the community. These services aim to target people with severe and enduring mental health difficulties (Killaspy et al., 2011). As a result of community services providing for people with severe psychiatric conditions there is a higher demand for increased quality of mental health provisions (Moran & Nemec, 2013).

The most common severe and enduring mental health conditions are psychotic disorders affecting approximately 1% of the population (NICE, 2014). Due to psychotic disorders potentially affecting all aspects of life, the traditional treatment model was long-term institutional care (McGorry, 2000). There has been an increasing trend towards dehospitalisation beginning in the late 1960s, with an emphasis placed on returning patients who were suffering from long-term and enduring mental health conditions back into society (Maeng et al., 2016). However due to the complexities of some enduring mental health conditions, such as the emotional and financial burdens placed upon families caring for an individual with a mental health condition, communities have lacked the basic resources to support patients (Rössler et al., 2005). This has led to the development of rehabilitation recovery orientated residential mental health services aimed at addressing the needs of people with severe persisting mental illness and supporting their transitions back into the community (Killaspy et al., 2011).

System theorists observed that many families of psychotic patients appeared to be 'unusual' and that contact with the family often precipitated a relapse or exacerbation in symptomatology (Burbach, 1996). Research in the late 1960s and 70s was undertaken to examine whether family atmospheres influenced the prognosis of illness in schizophrenia (Askey et al 2007). Findings indicated that service users living in a family environment which exposes them to high levels of criticism, hostility or over involvement are more likely to have a relapse in their mental health than service users whose family environment contained less heightened 'expressed emotions' (EE) (Brown et al 1972). Kavanagh

(1992) claimed that measures of EE have enabled research into family interventions which "may prove to be the most significant treatment breakthrough in schizophrenia since the discovery of neuroleptic medication". These findings led to what became termed as 'theories of family causation', whereby the social context was held to be responsible for the development of schizophrenia rather than biology (Bateson et al., 1956). Additional social family factors that may influence the development of and subsequent relapse or exacerbation of schizophrenic symptoms include: families which have perpetuated neglect, physical or sexual abuse (Teicher et al., 2016).

These family causation theories led to the development of new treatment approaches and gained publicity through the writings of R.D. Laing in the 1960s. Despite this most professionals in the field of mental health opposed these concepts due to a lack of sufficient evidence for the efficacy of interventions based on family causation (Burbach, 1996). As such by the 1970s systemic family therapy with schizophrenics was no longer a preferred treatment option. As a result of this decline in systemic family therapy, new approaches for working with families which moved away from theories of family causation were being developed (McFarlane & Beels, 1983). The advent of 'Family Management' established by Leff et al (1994), was based on the acceptance of the biological basis for schizophrenia and thus ameliorating family blaming. Additionally family management advocated that working with patients' families would reduce stress and improve prognosis for individuals with schizophrenia.

Including Families in Mental Health Services

The inclusion of family members in supporting the recovery and rehabilitation of people with severe and enduring mental health difficulties is recognised as an important process. The benefits associated with family focused interventions consist of fewer relapses in mental health, a reduction in mood disorder symptoms and an improvement in long-term prognosis (Glynn et al., 2006; Falloon, 2003; Li & Arthur, 2005). The evidence base indicates service users who receive support from family members will have a better prognosis and improved quality of life (Xia et al., 2011). The family's role in supporting the service user is multifaceted. Families tend to be the first to notice early warning signs of relapse indicators, as well as providing emotional and at times financial support to service users (Maeng, 2016). Consecutive NICE guidelines for the treatment of schizophrenia places an emphasis on the need to work with families in supporting patients (NICE, 2014; NICE, 2009). Family therapy has been demonstrated to be an effective intervention for serious and enduring mental health conditions and consequentially relationship difficulties that can accompany this (Stratton, 2011; Lobban et al., 2013; Yesufu-Udechuku et al., 2015).

Due to the historic nature of institutionalised care, traditionally individuals with severe mental health difficulties have found themselves socially isolated because of being detained in hospitals (Mizuno et al., 2012). However there continues to be a disconnect from both their families and community resources following admission to inpatient care. Research indicates service users in inpatient settings becoming isolated from community resources can result in delays to discharge and increased likelihood of readmission to services (Reed et al., 2013).

Whilst traditional mental health inpatient care has the potential to act as a barrier to service users utilising the support of the family system around them, a high proportion of service users still maintain significant relationships with their families. Sixty percent of people experiencing the first episode of severe mental health difficulties will be discharged back to live with their families (Barraclough, 2003).

It is acknowledged that coping with psychosis is not just challenging for the service user but also for everyone within the family system (Smith et al., 2014). There can be a burden resulting in significant levels of stress, depression and anxiety for families that provide support and care. The mental well-being of carers is inversely correlated with the amount of care they provide (Kuipers et al., 2010). Similarly, the well-being of caregivers is associated with the quality of care and support they can provide (Noh & Turner, 1987). In recognition of this, carer specific family interventions have been developed which aim to enhance the family's capacity for coping and thus ultimately improve their ability to provide support (Sin & Norman, 2013; Chakrabarti, 2016).

Welsh government have recognised the importance that families and carers play in the recovery and rehabilitation of a person with a severe mental health difficulty. Similarly, they have identified that families are more likely to be placed under increased pressures to provide care and support as a result of a move from hospitalisation care to community care. They have legislated under the Carers Strategy (Wales) Measure 2010 which requires the NHS in Wales to outline how information and guidance will be provided to carers to assist them in their role.

In recognition of this legislation Abertawe Bro Morgannwg Health Board have implemented a Carers' Partnership Information and Consultation Strategy (2013-2016) which aimed to outline how carers will be consulted with and involved in decisions affecting them and those they care for. Furthermore, it advocates that all staff undertaking the care coordinator role as defined by the mental health measure are to be provided with training to enhance their skills in engaging and consulting with carers.

The Challenges of Developing Family-Orientated Mental Health Services

While both empirical research and Welsh government policy places a strong emphasis on the importance of involving patients' families within their care, there are several identified challenges to implementing family orientated services within adult mental health.

Paradigms

The traditional paradigms of adult mental health services have operated at an individualistic, biological level which has made family work appear to be secondary or optional (Brent & Giuliano, 2007; Fadden, 2009). The role of professionals has been a "didactic problem solver" (Fadden, 2009) however there is a need for a culture change with staff required to adopt a collaborative approach viewing the family as equal partners (James et al., 2006; Haun et al., 2013).

Organisational

There are several practical challenges faced when implementing family work. Research literature indicates family work requires time, resources and funding and is potentially difficult to integrate with the demands of other clinical casework (Butler et al., 2014). Family work has been identified as having specific needs such as flexible hours (Del Vecchio et al., 2011; Balaji et al., 2012; Kazdin, 2017), the need for childcare facilities (Cohen et al., 2010) or home visits (Campbell, 2004). Additionally difficulties have been encountered from services with managers failing to make time allowances for family work by either not providing time in lieu for out of hours work (Magliano et al., 2005) or being obstructive by refusing the release of staff for training or supervision (Fadden, 2009).

Skills

Previously, mental health professionals have avoided communicating with family carers due to fear of breaching service users confidentiality (Leggatt, 2011). Despite this, research indicates when families, service users and professionals meet and work together, issues pertaining to privacy and confidentiality tend to dissipate (Falloon, 2003). Families come to understand and respect that some aspects of care will remain confidential between the treating clinicians and service users. While these findings are established within the literature, the majority of professionals remain unaware that family inclusion may combat concerns around confidentiality.

Even when professionals do perceive the benefits of working with families they often do not have the specialised skills and knowledge to conduct this type of work (Kim & Salyers, 2008; Kaas et al., 2003). This is likely in part due to the majority of professional training programs not including

specific skills for working with families (Stacey and Rayner, 2008). Professionals have highlighted that due to the complexities of working with both patients and families in mental health settings it requires a specific skill set in being able to manage both the service user's symptoms and family dynamics (Piippo & MacGabhann, 2016). Staff are often faced with the challenge of meeting the service user's needs whilst also managing relatives' own potential emotional and affective problems (Tompson et al., 2000). Staff have expressed frustrations at the lack of service provisions for family interventions (Absalom et al., 2012). Previous research indicates staff do not receive adequate support to work with individuals with complex problems in providing family interventions (Geelan & Nickford 1999, Absalom et al., 2010 Michie et al., 2007, Sin & Scully 2008, Cohen et al., 2008). Without effective training staff lack confidence to appreciate which aspects of this work falls under their professional remit (Reed et al., 2013).

Assessing the Need for Staff Training for Working with Families

The research literature of specific training programs designed to increase staff's involvement with family members in adult mental health rehabilitation and recovery settings is limited. Le Boutillier et al. (2015) argue that it is important to understand the perspectives of staff working within recovery orientated services because the nature of this work requires a paradigm shift in attitudes to care as opposed to a shift in the content and structure of programs delivered. As such, perceptions of professionals working in these services is invaluable to understanding and improving the way they operate (Parker et al., 2016).

There has been a substantial investment in upskilling mental health workers in providing family focused interventions (Ward et al., 2017). However there remains a disparity in the provision of family focused interventions between different professional groups as well as different healthcare settings within the same country. To add complications, the term 'family intervention' has yet to be qualified in policy documentation, and journal articles often use the terms 'family work', 'family intervention' and 'family therapy' interchangeably (Davies et al., 2014). Research indicates that psychiatric nurses are less likely than social workers and psychologists to engage in family interventions. This problem has been attributed to differences in philosophical paradigms within professions (Maybery et al., 2014). It is argued that adult mental health services have been less family focused in comparison to other community-based organisations due to a heavy reliance upon the medical model, "patient" orientation (Lauritzen et al., 2014).

Evidence suggests that the utilisation of a 'top-down' approach to training some staff members to carry out family work is insufficient for embedding family involvement within a service (Eassom et

al., 2014). To effectively embed family involvement in care, a 'whole team approach' should be adopted, whereby all members of the clinical team receive training and regular supervision around working with families (Fadden, 1997). The literature suggests 'ownership' has been an issue with different staff groups viewing family work as falling under the remit of other disciplines and not theirs (Goudreau et al., 2006; Cohen et al., 2010). Whole team training approaches have ameliorated this by encouraging multidisciplinary co-working and peer supervision which have been found to aid implementing family work into everyday practice (Fadden, 2009; Kelly & Galvin, 2010; Haun et al., 2013).

In addition, staff training programs have been demonstrated to improve attitudes of staff towards involving families (Stanbridge et al., 2013). Prior to training, professionals expressed concerns that family involvement could potentially burden the family and worsen the service user's symptoms (Peters et al., 2011).

The Somerset Service

Due to advances in research and theory in the area of family interaction and schizophrenia there is a propensity for models to integrate both family management and family therapy approaches (Burbach, 1996). One service developed to meet the challenges of family orientated mental health services is the Somerset service. This service is multifaceted in that it has blended the aforementioned theories and interventions of family management and family therapy with family liaison meetings (Burbach & Stanbridge, 2006). Additionally the service invested in the training of staff to be able to work with carers/family members (Burbach & Stanbridge, 2008). The Somerset intervention was one way of meeting the requirements of The Triangle of Care in England. The Triangle of Care was implemented in July 2010 as a joint piece of work between Carers Trust and the National Mental Health Development Unit, emphasizing the need for better local strategic involvement of carers and families in the care planning and treatment of people with mental illness and improving carers' engagement in acute inpatient settings (Worthington et al., 2013).

Family Liaison Meetings (FLM)

The Somerset Family Liaison Service has been successfully implemented across seven inpatient wards (adult acute, adult intensive acute and older person's wards). Due to the development of the service within inpatient settings, it has been evaluated as a suitable intervention for acute patients (Burbach, 1996) The aims and content of a typical FLM are outlined in Table 6.

Table 6: Aims and Content of Family Liaison Meetings

Aims of Family Liaison Meetings

- Create a rapport with the family
- Identify and value the role of the family and to encourage the maintenance of relationships
- Create a forum for future collaborative conversations between the unit, the patient and the family, including discussions around confidentiality
- Develop shared understandings/aims
- Develop an appreciation of the context of people's lives

Content of Family Liaison Meetings

- Obtain contact details, rationale for meeting, non-problem talk, who is in the household/family/friends?
- Explore family's account of the development of the patients' difficulties:
- Initial onset of difficulties
- How did the family respond?
- Experiences of services?
- Who else has been involved?
- How have things developed?
- What sense do the family make of what has happened?
- Explore the impact of the problem on the family
- Explore expectations regarding future, including outcome of mental health input and family goals.
- Inquire into family members' attitudes to working collaboratively:
- Discussion around confidentiality and information sharing
- Involvement in CTP and processes
- Provide information about support and practical help for carers including offering a carers' assessment.

The aims of the training programme were to raise awareness of the role families and carers play in supporting service users. In addition to this, training aims to develop the confidence and skills for staff to be able to effectively support and include families in care. The Somerset training model formed the basis for the training programme implemented in ABMU LHB rehabilitation and recovery mental health services. Modifications were made to the training to ensure it was an effective fit within the services context (See Table 7 for outline of training).

Table 7: Learning Outcomes of Family Liaison Training

Learning outcomes for whole staff team (day 1)

Attitude and awareness

- To have an awareness of family/carer views on mental health services.
- To have an awareness of research findings on the impact of caring for someone with severe mental health difficulties.
- To have an awareness of the benefits of involving families in patient care, including the theory and evidence base for family work.
- To have an awareness of thinking systemically and to be able to consider the person in the context of their relationships and social network.
- To have considered their therapeutic stance in relation to working with families.
- To have considered best practice in relation to confidentiality and information sharing.
- To have awareness of the unique needs of young carers.

Additional learning outcomes for staff identified to be offering FLMs (days 2&3).

Skills

To have practised the following skills in family interviewing:

- Engaging with families
- Conducting an initial family meeting
- Balancing the needs of individual family members
- Information sharing and developing a collaborative relationship
- Genograms and additional skills

The majority of the multidisciplinary team attended a one day training session. Staff who had been identified to facilitate FLMs within the unit attended days two and three of the training programme. The second day of the training programme immediately followed day one with the third day's follow-up training taking place once FLMs had been embedded within the rehabilitation and recovery unit. The training was facilitated by two clinical psychologists who are qualified systemic psychotherapists and who work within the health board but outside of the rehabilitation and recovery unit.

Aims

The present study aims to explore the experiences and perceptions of staff working in a residential rehabilitation and recovery service for adult mental health, based within South Wales, after implementing FLMs and staff training into the service.

Method

Research Site

The research site was based at an 18 bedded rehabilitation and recovery unit in South Wales. The project emerged as a result of the service and management asking the second author for training in working with families. The facility provides recovery focused rehabilitation for residents with severe enduring mental health difficulties. It aims to assist residents to gain skills and live a positive life under optimal conditions, despite experiencing mental health problems.

Subjective Positioning

The researcher's world view and background affects the way in which they construct the world, use and interpret language, ask questions and filter the information gathered and make meanings from it. Thus the researcher's world view ultimately shapes the findings and conclusions of the study (Kacen & Chaitin, 2006).

This research was undertaken by a Clinical Psychology Trainee under the supervision of the Clinical Psychologist/ Family Psychotherapist who delivered the current training to the service.

In an attempt to maintain reflexivity throughout the research the first author kept a research diary as a form of self-supervision and in addition to this discussed their positioning with the second author (clinical research supervisor). Although supervision offered a different lens through which to reflect upon my positioning, it could be argued that supervision was not truly external to the process. The supervisor was invested in the research, both in terms of supervising the project and wishing it to come to fruition but also as a result of her own professional training as both a clinical psychologist and a trained family therapist working within adult mental health in Abertawe Bro Morgannwg University Health Board. Therefore to some extent we shared a similar positioning in relation to the research in that we both have experience of working within adult mental health and will tend to view the world through the lens of a clinical psychologist.

Ethical Approval

This study has been approved by the Research Ethics Committee (Wales REC 6) and Cardiff University School of Psychology (See appendix 5).

Participants

All participants were provided with an information sheet (See appendix 6) about the project and gave voluntary informed consent prior to engaging in the research (See appendix 7). Convenience sampling was employed to select participants willing to engage in the research. The inclusion criteria consisted of health professionals from Cefn Yr Afon who have participated in family liaison training. The exclusion criteria consisted of temporary staff and students.

Participants were recruited from two cohorts. The first cohort consisted of five mental health professionals (a clinical psychologist, an occupational therapist, and three mental health nurses) who had attended the two-day training in FLM plus an additional one day's follow-up training and are currently involved in facilitating FLMs.

The second cohort consisted of five mental health support workers and two mental health nurses who had attended the one day team training in FLMs. The differences in the amount of training received between each cohort reflected the service demands and lack of resources to allow for all staff to be trained to be FLM facilitators at the same time. In total 12 participants were interviewed for this research. The sample consisted of 11 female members of staff and one male. This reflected the gender mix of the service. The sample for this study represented 100% of the staff who had received training to become FLM facilitators.

Procedure

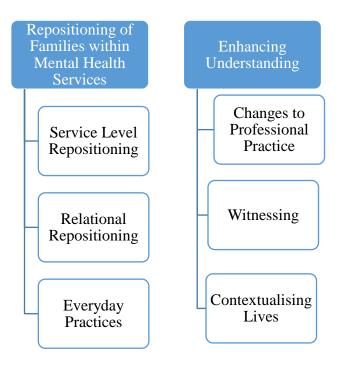
Interviews were facilitated via semi-structured interviews (See Appendix 8 for interview schedule) consisting of open-ended questions to explore their experiences of training in family liaison and their perceptions of including families within the service. The interviews utilised a conversational approach allowing for flexibility to ask spontaneous questions in response to the interviewees' narratives. Interviews lasted between 45 minutes to one hour and were audio recorded and transcribed verbatim before commencing the next interview. This approach allowed for naive reading of the transcripts so that emerging patterns could be identified along with developing preliminary codes. This in turn guided potential areas of inquest in the subsequent interviews. In addition to this a research journal was kept so that reflections could be made of the author's own assumptions and biases (Merriam, 1998).

Analysis

The whole data corpus was analysed using an inductive thematic analytic framework to allow for predominant themes and recurring patterns to emerge (Saldaña, 2009). Braun and Clarke (2012) six

stages of thematic analysis was followed to guide the coding process (See appendix 9 for a coded excerpt). A list of preliminary codes was produced during the data collection phase. Transcripts were frequently read and re-read and relevant sections of text were assigned to the existing codes. New codes were subsequently developed to capture data that did not fit into the existing codes. Each code was assigned an operational definition to highlight how the code was to be applied during the coding process. The complete coding of all transcripts produced 64 tentative codes, refined to 42 codes (See appendix 10). Codes were then grouped together based on conceptual similarities, creating 6 subthemes and 2 overarching themes (See Figure 2, See appendix 11 for full thematic maps).

Figure 2 Themes and Subthemes



Results

Each theme and subtheme are outlined in bold in the text below along with a selection of narrative excerpts that have been edited (e.g., speech errors removed) to improve clarity.

Theme One - Repositioning of the Family within Mental Health Services

The introduction of training in FLMs for staff in addition to implementing the model within the service led to a repositioning of families in relation to the service. This repositioning took place by three distinct processes: service level repositioning, relational repositioning and everyday practice.

Service level repositioning

Interviewees shared how the service had changed since the implementation of FLMs. There was a greater emphasis placed upon the service structuring itself in a way to best meet the needs of families:

"We've always usually been good with relatives but I don't think we set the time aside for them to air their views as much and get them involved in the patient's care as much."

(Participant 10)

Many of the interviewees reported that having the support of management from the unit was beneficial in acting as a facilitator for allowing staff to work more inclusively with families.

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"Our manager is very supportive of us pursuing them [FLMs]" (Participant 1)
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Despite this, however, it was still recognised that there was a requirement for a great deal of organising and planning in order to ensure FLMs took place.

"That's the biggest thing. That's the only difficult bit about the whole thing is getting them organised, getting them in the diary and making sure they happen."

(Participant 1)

While the consensus among interviewees was that the service was "moving in the right direction" (Participant 9), with the support of local level management in actively including families, it was felt that wider organisational issues such as staffing levels and time constraints acted as a barrier to the service's wish to reposition families within the care model.

"But it's just the time out to actually do it because a lot of the time we don't actually have the time."

(Participant 4)

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Staff highlighted that for the family liaison part of the service to function it at times required a particularly high level of staff dedication, including staff members to work overtime, come in on their days off or swap their days of working to be flexible enough to meet the needs of a family.

"staff will come in an hour and a half earlier... staff are very accommodating to run family liaison meetings"

(Participant 8)

While all interviewees expressed that they felt FLMs were beneficial to the service, some felt that they often placed additional demands upon their work role, requiring them to be flexible in their working hours. Interviewees highlighted that they felt it was important to provide a family with a sense that they have as much time as they need in a FLM to talk about the issues they wish to. However at the same time this also proved a point of conflict for professionals as there was a feeling that they were under resourced and therefore often felt a pull between providing high quality FLMs and the pressures of meeting the rest of their job role:

"Obviously we want to give the family as much time as they need so they don't feel any pressures and the meetings to be as beneficial as possible but at the same time you are thinking I've got all these other things I need to be getting on with back at the unit."

(Participant 3)

Although many interviewees did not feel that FLMs should be an additional task to their job role:

"We should be doing these things anyway it's part of being a nurse to get to know the family and interact with them."

(Participant 5)

This feedback would suggest a belief that mental health services should be positioning families as actively involved in care by the very nature of a professional's job role. However by the process of training and implementation of FLMs this approach has explicitly made the service reposition families as an integral part in the service user's recovery.

Some of the interviewees reported the service's use of specific interventions to ensure the repositioning of families. This process included changes in team communication, with the development of specific templates for sharing information related to the family.

"We developed prompt sheets after the training to help us think about what we wanted to know when we ran family liaison meetings. This has been particularly useful because it enabled us to tailor what we had learnt on training to our service in particular."

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(Participant 1)
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This process created an ethos within the service whereby team members valued both FLMs as a tool as well as the role family members play in their relative's recovery.

"They are such a valuable part of what we do which is what is actually ingrained in what we do"

(Participant 2)

"but to have the family's viewpoint is the best thing in the world because as I say it's them that know these people so well and may learn a lot from them rather than doctors' reports or psychologists' reports of social workers."

(Participant 9)

Relational Repositioning

Interviewees highlighted a repositioning in the relationship between both families and the mental health service, as well as between families and staff. This relational repositioning for families with mental health services was a novel experience for them.

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"They said they hadn't experienced this before from services" (Participant 5)
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"Some of them haven't experienced that before in 20 or 30 years of using services." (Participant 3)

"The parents I'm speaking about they didn't have this and they had never had it" (Participant 9)

The use of FLMs provided an opportunity for families to feel listened to. In addition families reported feeling that they were valued by professionals and could see that staff cared not just about their relative but also about the family unit.

"One family I was working with said how much they appreciated just being listened to but not only that but they really felt that we could see how important they were in helping their relative get better."

(Participant 2)

This approach led to a staff perception of improved communication between themselves and families.

"I think we are breaking down barriers and we are definitely being seen as more accessible by family members."

(Participant 11)

The relational repositioning of families with the service had been suggested as being a factor changing the way families maintained contact with the service. It was felt that families were more inclined to make contact with the service and sought out specific named members of staff. In addition to this due to the supportive relationships built between families and the service, staff noted that many family members continue to maintain some level of contact with the service even after their relative has been discharged.

"Some people have said they just want to phone the unit every now and again and just pass on how things are going from their view."

(Participant 1)

The repositioning to include families within the care approach was perceived by staff as placing families in more control leading them to feel empowered and able to serve a purpose in the recovery of their relative.

"So one of the functions really is to get the family more involved in taking over relatives cares and to empower families really to air any views that they've got...."

(Participant 10)

"the relatives have a good say what's happening and are empowered and influence our placements and the treatment."

(Participant 11)

Everyday Practices

The implementation of FLMs stimulated staff to think about the positioning of the family within the service and what changes the service can make to everyday practice to enable family inclusion as much as possible:

"The meetings have really made me think how can we include the family more in our service? I run a coffee morning where family members can attend just for an informal chat and feel more connected to our service. We've also had residents cooking meals for their family in the communal dining room. And that's been really good to help them maintain that contact and just normal family life."

(Participant 1)

One function staff identified everyday practice served was the provision of psychoeducation to families helping them to overcome the stigma of mental illness.

"I think before the stigma of mental illness was always there but using family liaison has certainly helped to break that down more."

(Participant 11)

In helping to overcome the stigma of mental illness there is a drive by the service to maintain a sense of "normal life" (Participant 12) for families.

"We've had residents cooking meals for their family in the communal dining room and that's been really good to help them maintain that contact and just normal family life."

(Participant 1)

The implementation of FLMs also place the family within a position to receive pragmatic care that ordinarily they would not have received. This care consisted of the family being helped with problem-solving tasks as well as them being able to access the full range of mental health professionals to provide them with a level of support in undertaking their role as carers.

Theme Two - Enhancing Understanding

The second theme in the data related to the role that FLMs play in enhancing staff's understanding of issues related to families. This understanding appeared to be enhanced by three distinct processes; changes to professional practices, directly witnessing the impact of FLMs and what it offers families and service users, in addition to enhancing understanding by contextualising lives, whereby staff are able to understand the individual beyond their diagnostic label.

Changes to Professional Practice

Interviewees reported that the implementation of FLMs had resulted in changes at an individual level to their professional practice. There was a sense that staff felt they were more confident in their abilities to work with families and family related issues as a result of implementing the model into the service:

"I think it's improved staff's confidence in working with families and that they're able to work more with families."

(Participant 10)

With this increased confidence staff felt they could ask questions and potentially elicit information which ordinarily would have been missed in their day to day practice:

"And it definitely feels a lot easier to approach families when they've been involved because we know then their views on things we find it easy to approach them and just ask them questions on things."

(Participant 10)

In addition to this staff identified that the process of thinking about family inclusion within the service led to a greater level of self-awareness of their professional practice. This in turn seemed to result in staff feeling they were less judgemental and more empathic in delivering care:

"It gives you a lot more empathy I think for the family and it makes you realise the struggles they've had as well."

(Participant 9)

Witnessing

The subtheme of staff witnessing the impact of FLMs was prevalent in the data. Interviewees observed that FLMs provided families and service users an opportunity to talk affording them different types of conversations, that staff believe would not ordinarily have taken place had they not participated in FLMs:

"I think they talk about things with their relative that they wouldn't in any other context" (Participant 5)

"it's a way of them offloading as well and it's got that mediator between them as well so they are happy to have that discussion maybe like with a safety net and I think they think liaison is like a safety net"

(Participant 12)

Many interviewees were surprised to see how emotive the meetings were for both family members and service users. This was largely framed as a positive experience for those participating in FLMs and was not viewed as having any detrimental effects for the family or service users:

"because I remember the mum was crying and the patient had to walk out and I wasn't really expecting the emotional impact of it"

(Participant 4)

"they do show all this raw emotion and passion and unconditional love for their children" (Participant 4)

Ultimately staff felt they were observing improvements in the communication between families and service users as a result of FLMs:

"Because of the meetings it got family members and the residents talking about things that had been unsaid for years"

(Participant 1)

Contextualising Lives

Interviewees also explained that as a result of families feeling more involved in the care of their relatives in the rehabilitation and recovery service they were also more forthcoming with clinically relevant information for the team should circumstances change for the client. This demonstrates how the gathering of clinically relevant information continues beyond the more formal FLMs:

"Since running family meeting I've had a resident's sister stop me and tell me that they are concerned their brother is not ready for discharge. That when he is on leave to the family home he's not actually doing the things he tells us he is doing. I don't think they would have told me this before the family meeting as they were desperate to have their brother home. But I think since having the meeting they can see we all want to work together in the best interest of their brother."

(Participant 4)

Interviewees highlighted that family members were able to play a pivotal role in helping the service to plan care and treatment beyond discharge from the rehabilitation and recovery service. Family members were able to feel comfortable discussing with staff concerns with their relatives regarding issues such as a risk or progress within the treatment pathway:

"Families are definitely a lot more open with us after the meetings. I've had one person's father tell me that he doesn't want his daughter discharged to the Swansea area because that's where she used to do drugs."

(Participant 3)

As a result of families being included in their relative's care and treatment both staff and family members are able to work cohesively together. This approach was highlighted as being particularly useful when considering aspects related to risk. As a result of the open relationship, issues pertaining to risk have been able to be freely discussed and risk care plans adjusted accordingly.

While the primary aim of FLMs is not to address clinical issues and introduced change in the way that traditional psychotherapy operates, many of the interviewees stated however that improvements took place between family members, clients and staff due to a change in dynamics and interactions. Interviewees reported that one of the most significant aspects to FLMs was the different types of conversations that would take place only within the confines of a formal FLM. Staff hypothesised that the name 'family liaison meeting' gave special permission to talk about issues which ordinarily would not have been addressed:

"I think the name family liaison meeting sets it apart from other meetings and lets families know this is for you. Because of that I think they talk about things with their relative that they wouldn't in any other context."

(Participant 5)

As a result of the special status given to FLMs, an emphasis was placed on service users and their families being able to address communication and relationship issues within the meeting. Many of the interviewees talked about how emotive FLMs can be for both the family members and service users. However none of the interviewees felt that this was detrimental to the health or well-being of either the family or the service user. One interviewee highlighted that they found FLMs beneficial in being

able to allow people to express emotion within the safe confines of a meeting facilitated by professionals. The interviewee believes that these types of conversation were a new thing for both family members and service users and resulted in bringing about a change in the system:

"One family was able to talk to their daughter... about their concern around her choice of partner. He was supplying her with drugs. She subsequently separated from him and I don't think that would have happened as the family would never have told her what they really thought."

(Participant 4)

Discussion

The purpose of the current research was to explore the impact and utility of FLMs within a rehabilitation and recovery setting by examining the perspective of staff who work in this model.

Implementing FLMs brought about many benefits in clinical practice. Staff highlighted that meetings resulted in improved communication both between family members and service users as well as between families and professionals. This is consistent with previous findings from Gore and Stanbridge (2012) who note FLMs provided an opportunity to improve family interactions and communication. With this improvement in communication between families and professionals it was noted that this also resulted in improvements to risk assessments as families were more forthcoming with information which otherwise would not have been shared. The sharing of risk information has also been noted to be one of the benefits of FLMs in previous studies (Stanbridge, 2012). Staff reported that since the implementation of FLMs into the service there has been an increased awareness of the needs of families and carers. After receiving training in the model staff felt more confident in their ability to engage with families and incorporate them in care planning. This is consistent with other studies (Clarke, 2004; Fadden, 2006; Schweitzer et al.,2007; Worthington and Rooney, 2010).

The results from the current study highlighted that FLMs acted as a service level intervention. As well as improving communication for families at an individual level, by implementing the model the service repositioned itself culturally to meet the needs of families and carers. As a result, FLM as a model acted as a way to change practice and culture within the service. Participants highlighted that FLMs in particular served as an impetus to generate interventions that help to ameliorate the impact of

stigma from mental health disorders. This is in keeping with the evidence base which suggests that interventions with social contact or first person narratives were more effective than others in reducing stigma (Yamaguchi et al., 2013; Corrigan et al., 2012; Mansouri et al., 2009).

Despite staff in the current study feeling that FLMs were beneficial they also highlighted several barriers to being able to implement the model effectively within the service. Staff reported that they did not feel enough members of staff in the unit were trained to be facilitators for running the meetings. They also raised concerns about time constraints and competing demands on their practice thus limiting at times the opportunity they had to run meetings. In addition to this many staff reported that they did not feel that the service would have been a success if it were not for them and their colleagues working outside of their contractual hours (e.g. working unpaid overtime, coming in to work on their days off). These organisational difficulties which require staff to be flexible in overcoming such obstacles, is well documented by Mansell and Fadden (2009). As a result of these finding the service has commissioned training for an additional 20 members of staff to overcome the burden of a limited facilitator pool.

Implications for Policy and Practice

The results from the current study are clinically important and of relevance to mental health systems at both policy and practice levels. National policies encourage mental health staff to include families and carers in their practices as part of a drive towards co-production and a recovery orientated ethos, yet they need to offset this against managing competing organisational pressures which at times compromised their ability to fully include families. The results indicate that staff value a family inclusive approach to the delivery of care however there are often organisational barriers to overcome. Staff valuing family inclusive practices and adopting a flexible working approach has been a significant factor in influencing the success of implementing FLMs within the service. However staff working in a flexible way is often heavily reliant upon goodwill, with staff working outside of their contracted hours of employment. This raises service level questions around the sustainability of FLMs. Ultimately there is a need for services to demonstrate the value they see in FLMs with adequate investment of resources.

Limitations

As with all qualitative research, the findings from the present study are context dependent, as such they may not be generalisable to other settings. There is currently a lack of similar studies in this area

to allow for comparison of results to other services. This however also represents one of the strengths of this study in that it is seminal.

While efforts were undertaken to create unthreatening environments for interviewing participants there was however power differentials due to the dual roles that researchers held. This situation may have inhibited participants making more negative disclosures (Karnieli-Miller et al., 2009). The act of participants being aware that they were having their responses analysed for a research project may have led to a 'Hawthorne Effect' whereby they change their behaviour as an act of being observed. Such an effect is endemic to all social research and is impossible to fully account for its presence and thus ameliorate it. The positive responses from participants may reflect a possible feeling of being "special", in that they were the first members of staff to be trained in the intervention. As such this may have potentially skewed their judgments of the intervention.

There was a noticeable absence in the data of staff talking about how emotive meetings affected them personally. This may be due to a need to maintain what they perceive as a professional stance during the research interviews. It is possible that delivering FLM as an intervention may have an emotive impact on staff, which has gone unreported. This personal impact could increase the risk of staff burnout, which in turn may jeopardise the sustainability of the service.

Conclusions

Despite national policy advocating for partnership working with families and carers, and trained staff identifying the benefits of using this approach in a rehabilitation and recovery service, FLMs are currently rarely used within these services. This study has identified that staff value FLMs as a means of addressing the challenges to working with families. FLM within the current service has been supported by managers, in addition to whole team training which has in part led to its successful implementation. Other services considering applying FLM need to be aware that it requires investment in terms of training and support from management in order for the service to be sustainable.

There is a need for services to recognise that while FLMs serve as a useful tool in fostering coproduction between families, carers, service users and professionals, there is also a need for significant investment in terms of time, staffing levels and service organisation. Services need to commission additional training in working with families in order to develop staff's confidence and meet the requirements of national policies and guidelines for adult mental health.

Further research in multiple sites that have implemented this model is needed. It would also be beneficial to conduct comparative research into similar services which do not currently operate FLMs to ascertain the differences FLMs make to a service. In addition to this the routine collection of data on all cases involved in the service should be undertaken to allow for the monitoring of the intervention and providing feedback which can influence the wider mental health system. Quantitative measures of referrals to the service, number of families who engaged with the service and those that have declined further contact have historically been used to evaluate the Somerset model and would prove useful to implement within the current service as a means of evaluating and improving service provision (Burbach & Stanbridge, 2006). Similarly in-depth qualitative family satisfaction research can be useful in evaluating the acceptability of the intervention to service users and carers. Such research leads to a collaborative needs led service (Stanbridge et al., 2003).

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Paper Three: Critical Reflections on the Thesis Process

Paper three is not intended for publication. Paper three will critically reflect on elements of my research as reported in paper one and two. The implications of the research for clinical practice and the relevance to the role of clinical psychology will be discussed.

Word Count: 9621

(excluding references)

Introduction

As part of the doctoral training course in clinical psychology, there is a requirement to submit three papers which constitute the doctoral thesis: an empirical paper, a literature review and a critical appraisal paper, the last of which is described here.

This paper will seek to both provide a critical appraisal of the process of conducting research as well as providing reflections on the personal experiences. The critical evaluation will focus on the strengths and weaknesses of the empirical research, paying particular attention to the methodological issues and considering alternative methodologies that could have been implemented. This paper will consider the implications for clinical practice as well as service development on the basis of the findings from the empirical paper two. The paper will conclude by highlighting for the reader the proposed plans for dissemination of the research.

Personal Context

Before starting the doctorate in clinical psychology, my research experience has been somewhat limited. My primary exposure to research had consisted of small scale service audits and completion of a Master's dissertation in applied forensic psychology utilising quantitative methodology. Having worked both within the NHS and private healthcare systems I had viewed myself primarily as a clinician, however still valuing the impact that research has for guiding clinical practice. As such a key competency that I wished to develop during my training is to enhance my research skills so that I am able to make meaningful contributions to the evidence base that guides clinical practice. I view this development as being essential to the role of clinical psychologists as scientist practitioners. Given my limited experience in the use of qualitative research methodologies I was particularly keen to undertake research that would utilise this approach and further develop my research skills. I hoped in doing so that on completion of training I will be suitably equipped to continue to conduct research as and when needed within my clinical practice by having competencies in a variety of methodological approaches.

My clinical experiences have consisted of almost 10 years of direct clinical work, primarily within the field of adult mental health ranging from forensic secure services, intensive psychiatric care, acute admissions, through to community mental health and long-term rehabilitation and recovery. As a result of working as a clinician in these settings, I felt it important that my research should complement this. It is most likely that my future long-term career will consist of continuing to work within the field of adult mental health and therefore it was hoped that by conducting research in this

area it would not only enhance my awareness as a practitioner but it would also further develop my skills and knowledge in conducting research within the settings of adult mental health. This will be pertinent to enable me to continue the role of scientist practitioner in these settings in the future.

Having worked extensively within secure services and inpatient mental health settings I became aware of how isolated service users were not just from society in general but also specifically from their family as a result of them being treated under section away from their family environment. Despite such isolation from the family being the norm for service users in adult inpatient mental health services, NICE guidelines recommend family involvement and support as treatment for psychiatric conditions such as schizophrenia. While these recommendations exist, in reality they are rarely put into practice. As a result of this when I became aware of the implementation of family liaison with in adult mental health in Abertawe Bro Morgannwg University Health Board and the opportunity arose to join in a pathway to portfolio research project in this area, I was keen to be involved in conducting this research.

Paper One: Systematic Review

Developing a Question for a Systematic Review

I was clear that I wanted to explore issues that affect patients within adult mental health rehabilitation and recovery services. My primary interest was around the treatment of schizophrenia with family interventions in comparison to either waiting-list controls or cognitive behavioural therapy. However, upon initial scoping review I discovered a few recent high quality reviews that were conducted addressing this (Claxton et al., 2017; Sin et al., 2017). I then considered conducting a review of family liaison meetings more generally, however because this is an emerging field of research the literature base is currently too sparse to produce a substantive review. In interviewing participants for my empirical research paper, many of them expressed how useful they felt family liaison meetings had been for their service users suffering from treatment resistant depression. In explaining this they highlighted that treatment resistant depression is one of the most prominent conditions that they work with in their service. This led me to become interested in how clinicians attempt to address a condition which by its very name suggests it may be futile in treating.

After scoping the literature base I discovered a previous systematic review of RCTs for pharmacological and psychological therapies for treatment resistant depression that found no strong evidence to guide the management of such people (Stimpson, 2002). Similarly McPherson et al. (2005) summarised the evidence for psychological therapies from both controlled and uncontrolled

studies however the literature was only reviewed up until October 2002. As such the evidence base had not been systematically reviewed in almost 15 years. The Cochrane library recommends that systematic reviews should be updated every 3 to 5 years or sooner if the subject matter is a rapidly developing field. When reviewing the Cochrane Library I discovered a protocol existed for a systematic review examining psychological therapies for treatment resistant depression (Wiles et al., 2013). While the protocol existed there was no evidence that the review had ever been undertaken. For me this raised ethical questions in that the authors had clearly identified a gap and therefore a need for a systematic review in this area however had failed to undertake this review. As such I felt it was important to conduct this review to update the current knowledge base around psychological treatments for treatment resistant depression.

Literature Search

The Cochrane Handbook (2012) states that systematic reviews for interventions need to utilise an objective, thorough and reproducible search of a range of sources to identify as many studies as possible. However such searches also need to be balanced against finite nature of resources available to the researcher such as researcher time, money and access to databases. I was particularly conscious of the need to strike this balance, in terms of being aware that this systematic review was being conducted for a thesis for clinical psychology training, which places additional pressures on my time as a researcher in terms of needing to meet clinical placement and academic obligations.

Databases

CENTRAL, Medline, PsycINFO and EMBASE were chosen as the most appropriate databases for this systematic review. These databases have been used in previous systematic reviews in this subject area, and I was also recommended to use the chosen databases when consulting with the university librarian who specialises in medical and psychological systematic reviews. I had originally intended to also use PubMed as I noted this database had featured in some systematic reviews. However I was advised against the use of PubMed by the librarian as its search abilities operate on algorithms similar to that of Google Scholar, and I was informed that this does not allow for an accurate and systematic search of the literature.

Search Terms

The search terms used in this systematic review are those outlined in Wiles et al. (2013) protocol. I considered adapting the search terms, but in consultation with psychologists working in the field of adult mental health it was decided that the previously outlined search terms were sufficient for returning relevant literature and any additions would not improve the search. In addition to these

search terms I combined it with search strategy designed specifically for returning literature related to random controlled trials (ISSG Search Filters Resource). This search strategy has been empirically tested and found to be of a suitable sensitivity for returning relevant literature (O'Rourke et al., 2016).

Randomised controlled trials were chosen as the methodological focus for this systematic review because it is one of the most widely used experimental methods in medical research and is considered to be the gold standard of evidence-based medicine (OCEBM levels of evidence working group, 2011). Furthermore Margaliot and Chung (2007) argue that systematic reviews based on RCTs will likely be more valid and accurate than a review based on observational studies or case reports.

Quality Assessment

There is no single agreed approach to assessing the quality of studies included in systematic reviews (Petticrew & Roberts, 2006). A study using a Delphi consensus method with experts in assessment of quality in RCTs, was unable to establish a definition of quality that was acceptable to all (Higgins & Green, 2008). Therefore the choice of assessment tool largely comes down to individual preference and its suitable fit with the chosen methodology of the review.

The current systematic review used Cochrane collaboration's risk of bias tool (Higgins et al., 2011). This was chosen as it fits with the methodology of the review. Studies were assessed for quality by a second independent rater. While historically it has been suggested that quality should be assessed under blind conditions to reduce selection bias (Chalmers et al., 1981), there is a lack of empirical evidence to support this practice (Irwig et al., 1994; Fisher et al., 1994). Due to this reason and in addition to blinding being a time-consuming process which is considered to be unlikely to alter the results of the review (Berlin, 1997) quality assessment in the current review was not conducted under blind conditions.

Data Extraction

Data was extracted into an electronic form (see appendix 3) based loosely on 'PICOS' (population, intervention, comparison, outcomes and study design). The use of a standardised data extraction form provided consistency, reduced bias and improved the validity and reliability of data included in the review (Higgins & Deeks, 2008).

Ideally I would have used a second researcher to independently extract data from the studies however I was unable to recruit anyone for this. Instead I extracted the data and had a second researcher independently check the data extraction forms for accuracy and completeness. This approach is

accepted as a minimum standard for data extraction (Tacconelli, 2010). This method potentially may result in significantly more errors than had I used two researchers to independently perform data extraction (Buscemi et al., 2006).

Data Synthesis

The current systematic review utilised a narrative synthesis. This was chosen as the most appropriate means of data synthesis for two reasons. Firstly, meta-analysis was not possible due to the diversity of methodologies and studies included in the systematic review. Secondly, I was informed by the research director that conducting meta-analysis for a systematic review would be beyond the scope of what would be required for a clinical doctorate thesis and therefore a narrative synthesis approach would be more suitable.

Due to narrative synthesis being more subjective than meta-analysis it was important that the synthesis was transparent and results were trustworthy. As such, guidance on conducting narrative synthesis was followed to ensure that the synthesis in the current review met this objective (Popay et al., 2006; Rodgers et al., 2009).

Limitations of Current Review

There are several limitations to the current systematic review. There is no standardised definition of what constitutes treatment resistant depression and as such this has made it difficult for previous researchers to accurately assess the efficacy of treatment. I chose to use the definition of treatment resistant depression in Wiles et al. (2013) protocol as it is similar to that used in other systematic reviews (McPherson et al., 2005; Stimpson et al., 2002). This allows for findings from the current systematic review to be easily compared to previous reviews. While it is important to maintain inclusion criteria I am also aware that this definition has precluded results from many well-designed studies which have used a different definition for treatment resistant depression.

As with all systematic reviews it is limited by the quality of the constituent studies. There is a need for further research as findings currently are not strong enough to support the development of clinical guidance. This impart has also been influenced by the lack of a consistent definition for treatment resistant depression. As such there is a need first for a consensus on a definition of treatment resistant depression to enable research to establish what treatments if any are beneficial so that clinical guidance can be developed. Furthermore the interventions were so diverse, it proved difficult to perform quantitative synthesis. Such limitations have also been documented in previous systematic reviews by Stimpson et al. 2002 and McPherson et al. 2005.

All the studies included in the current review were conducted by proponents of the experimental treatment which can increase the likelihood of an allegiance effect (Luborsky et al., 1999). Allegiance effects have been showing to lead to overestimation is of treatment effects in psychotherapy effectiveness studies (Baldwin & Imel, 2013).

The current systematic review may well suffer as a result of publication bias whereby only articles that show positive treatment effects and statistical significance become published. One way of attempting to ameliorate publication bias is to search for unpublished studies via conference proceedings and correspondence with experts. This was not undertaken for this systematic review as it was beyond the scope for a clinical psychology thesis.

It could be argued that the current review is limited by the number of databases used. No single database is likely to contain all published studies related to the subject. The Cochrane library recommends as a minimum a systematic review should search two or more databases. The current systematic review searched four databases and as such there is a possibility that relevant literature is not obtained as it was not in these databases. Many systematic reviews with large teams of researchers search for more databases, however this was beyond the scope for the current review.

The current systematic review only reviewed studies published in English. As such there was a language bias in this review. Studies conducted in non-English-speaking countries which produce statistically significant results are more likely to be published in English language journals than non-significant results (Egger et al., 1997). Therefore it is possible that the studies I reviewed, when combined produce an overestimated treatment effect. Moher et al. (2000) argues that even if language bias does not influence effect estimates it is likely to impact on precision because analysis will be based on fewer data. Despite concerns of language bias in the current systematic review a study investigating the inclusion of non-English language reports in RCTs in systematic reviews found that language restrictions do not appear to bias the estimates in reviews of conventional interventions, however may bias results of complementary or alternative medicines (Moher et al., 2003).

Implications for Practice

Treatment resistant depression is common in clinical practice however there is insufficient evidence to inform its management. Unfortunately the current review was unable to comprehensively establish a robust enough evidence base for the development of clinical guidelines. As such clinicians must rely upon their own clinical judgement in deciding the most suitable treatment options for patients with

treatment resistant depression. The current review highlights the need for further research with a particular focus on the use of RCTs studying the effectiveness of psychotherapy as this represents a popular and acceptable treatment option for many patients (Hanson et al., 2016).

Target Journal

The target journal for this systematic review was the Journal of Affective Disorders. This journal was chosen for two reasons; firstly the journal has a high impact factor (yearly impact factor = 3.432, five year impact factor = 3.845) meaning if this review was successfully published it is likely be utilised as part of the evidence base in this subject area, secondly many of the studies into treatment resistant depression were published in this journal, indicating that if this review were published in this journal it stands a greater chance of being accessed by the target audience with an interest specifically in treatment resistant depression.

Paper Two: Empirical Paper

Research Subject

In my time as a trainee with links via my professional mentor to the Caswell Clinic, a medium secure forensic unit in South Wales, I became aware that it was different from the majority of such services throughout the country in their provision of family therapy for patients detained by the Ministry of Justice/Mental Health Act. It was as a result of this that I became aware that ABMU health board were investing in providing training to mental health professionals around including family members within a patient's care. While policy documents advocate for the inclusion of family support systems in the care of people with mental health difficulties (Welsh government policy 2010, NICE guidelines for schizophrenia, 2014, 2009), the reality indicates that family inclusion is still a novelty and additional staff training in this area remains a rarity. More widely the research literature around inclusion of family is relatively sparse. As such the opportunity to research staff's perceptions around training and subsequent inclusion of family members via family liaison meetings in adult mental health seemed pertinent to investigate further.

The subject of the empirical paper was a qualitative exploration of staff's experiences of training in and implementing family liaison meetings within an adult mental health rehabilitation and recovery unit. This was complemented by a literature review which focused on reviewing the evidence base for psychological treatments for treatment resistant depression, which is one of the most prevalent psychiatric conditions within adult mental health rehabilitation and recovery settings.

My interest in this subject area dates back to my time working as an assistant psychologist within a range of adult mental health inpatient services. In particular it was noticeable during my time working within forensic inpatient settings how removed a service user was from not just society but also their social network in the form of their family. This exclusion of family involvement with people who are treated for severe or enduring mental health difficulties within inpatient settings was a recurrent theme throughout my time working in such services. It became apparent through my experiences that not only are the majority of mental health professionals inadequately trained in working with family members, but the concept of including family in inpatient care had not even entered the majority of professionals' consciousness. It is likely that this reflects a heavily dominant medical model within mental health services which has had a tendency to neglect the role of an individual's social context. Research has suggested that excluding an individual's social context from their care can not only delay their discharge from services but also increase their risk of future admissions (Reed et al., 2013). Therefore it seems important to examine how social and family inclusion can be incorporated into a patient's care to ameliorate such risks. Unfortunately there is a paucity of research into family inclusion in services, therefore the empirical paper two presented in this thesis represents a necessary but tentative exploratory piece of research.

Qualitative Methodological Approach

My choice for using a qualitative methodological approach was twofold. Firstly the purpose of the study was to explore and understand the impact of running family liaison meetings in an adult mental health rehabilitation and recovery unit and as such a qualitative approach is more appropriate for explorative work than quantitative approaches which would aim to seek to confirm a hypothesis about a phenomenon (Creswell, 2013). Secondly, as previously mentioned, I have little experience in the use of qualitative research and conducting a study using this methodology provided me with an opportunity to develop my professional research skills further.

Choosing Thematic Analysis

Holloway and Todres (2003) highlight that it is important to choose a method that is appropriate to the research question rather than falling victim to what they have termed as "methodolatry", whereby researchers are aligned to a methodological approach prior to establishing what it is they wish to investigate and as such implement an inappropriate methodological approach for answering the research question. As such I reviewed several methodological approaches to determine which is the most suitable for my study.

The use of Grounded Theory Analysis was rejected for this study due to it relying on theoretical sampling and the construction of a theoretical model upon completion of the data analysis (Glaser & Strauss, 1967). As the research study was exploratory in nature, due to a lack of sufficient research literature in this area, as yet there would be no theoretical models upon which to guide the use of Grounded Theory Analysis. While I was mainly interested in understanding staff subjective experiences, I did not want to negate potential social, cultural and political issues associated with the service context. These features may have been overlooked had I used Interpretative Phenomenological Analysis (Guest et al., 2012; Smith et al., 2009) as the focus in this approach is on the meanings that people ascribe to their lived experiences. Similarly discourse analysis was rejected as this places emphasis on the micro-processes of interactions which would neglect the content of participants' narratives and more importantly the understanding that can be generated by analysing the data as a whole (Smith & Sparkes, 2005).

Thematic analysis was chosen for this study as it is a theory-free, epistemologically neutral approach that can be used flexibly to analyse, explore, understand and report patterns in qualitative data (Braun & Clarke, 2006). As such thematic analysis provided an analytical framework from which I could interpret patterns in the data. Thematic analysis allowed for me to organise the data into key themes and analyse meanings of the participants' accounts (Guest et al., 2012).

Concerns About Quality in Qualitative Research

As previously mentioned my familiarity with the use of qualitative research methodology was somewhat limited prior to conducting this research project. As such I had concerns as to whether the qualitative research I was conducting was of a significant standard of quality. Initially I found this difficult to judge due to having limited experience with this approach by which to benchmark it against. As a result of this I attempted to find a criteria checklist by which to judge the quality of the research I had conducted to ensure that it was of a high standard. I discovered that there is a debate which exists within qualitative research between the demands for an explicit criterion by which to measure quality in order to serve systematic reviewing and evidence based practice and arguments to the contrary whereby some qualitative researchers claim that quality criteria are not only unnecessary but also undesirable (Hammersley, 2007). Smith (1984) argues that the use of a single set of criteria by which to measure the quality of qualitative research is impossible to implement given the heterogeneity of qualitative research.

The question of the value of qualitative research appears to have largely been stimulated by external criticisms that have stated that qualitative research does not serve evidence-based practice well

(Trinder & Reynolds, 2000; Pring & Thomas, 2004; Biesta, 2007). Furthermore, critics have argued that much of qualitative research is of a poor standard or that there is no clearly defined set of quality criteria by which to judge research and thus it is of uncertain quality at best. These criticisms, if founded, were particularly concerning for me given my belief that research within the domain of clinical psychology should be to produce evidence by which best practice can be refined as is in keeping with the role of scientist practitioners. If qualitative research is incapable of achieving this in anyway then in my opinion the value of such research is significantly compromised. However, it is important to note that qualitative research is judged in its quality by standards from within its own epistemological approach rather than generalisability of findings as is typical of quantitative research.

To some extent the criticisms levied at qualitative research have been beneficial in encouraging me to question my own research. I do not believe that I would have taken such a critical stance had I employed a quantitative research methodology as I would be more likely to be inclined, although falsely, to accept the methodology is a guarantee of quality.

Whilst having an awareness of the importance that my research should demonstrate scientific rigour and be of a high quality, being relatively inexperienced in conducting qualitative research resulted in me being uncertain that my research sufficiently demonstrated such quality. As a result of this I read extensively into the literature for demonstrating quality in qualitative research to try to ensure that my research would adhere to any identified guiding principles. The difficulty with this arose from the discrepancies around what researchers view as benchmarks of quality when utilising a qualitative methodological approach. Some have tried to apply traditional scientific concepts such as validity and reliability to qualitative work, however others have claimed that the very nature of qualitative research does not lend itself to such criteria. Instead they have stated qualitative research is of value and quality in terms of "giving voice" to the marginalised or bringing about practical improvements. However when taken to the extreme others have argued that there can be no criteria to effectively sort out the trustworthy from the untrustworthy results (Smith, 1984; Schwandt, 1996). These opposing views added to my curiosity around conducting qualitative research and its ability to demonstrate quality. In ensuring quality within my research I considered my reflexivity and positioning as a researcher, which is outlined below.

Reflexivity

One way of maintaining quality in qualitative research was by me considering the role of reflexivity in my study. The use of reflexivity in qualitative research has been recognised as a crucial strategy in the process of generating knowledge (Ahmed Dunya et al., 2011; Gerstl-Pepin & Patrizion, 2009;

Blaxter et al., 2006; D'Cruz et al., 2007). Berger (2015) argues reflexivity reflects a broader debate about ontological, epistemological and axiological components of the self, intersubjectivity and the colonisation of knowledge. As a result of this there is a need for researchers to focus and be aware of self-knowledge and sensitivity. It is important that researchers self monitor the impact of their prior knowledge, biases and beliefs as well as personal experiences upon the research they are conducting. Reflexivity is the process of continued internal dialogue and critical self-evaluation that this prior knowledge and experiences may affect the research process and outcome (Bradbury-Jones, 2007). The use of reflexivity enables the researcher lens to be turned on oneself to consider and take responsibility for one's own situatedness and the effect it potentially has on those engaged as participants, the questions being asked, how the data is collected and subsequently interpreted. Ultimately reflexivity challenges the view of knowledge production as being independent of the researcher producing it and of knowledge as objective. The use of reflexivity is rarely considered within quantitative research, despite such effects existing in all types of research (Drake, 2010). One of the strengths of qualitative research is making it explicit to readers, as a result of time and energy spent considering reflexivity, how the researcher's own position has influenced the research.

The position of the researcher may impact the research in three major ways. Firstly it can affect access to the 'field' as research participants may be more inclined to share their experiences and divulge significant information to a researcher whom they perceive as sympathetic to their situation (De Tone, 2006). Secondly, positioning can shape the nature of researcher-researched relationships that may affect the information that participants are willing to share. Finally the researcher's world view and background affects the way in which they construct the world, use and interpret language, ask questions and filter the information gathered and make meanings from it. Thus the researcher's world view ultimately shapes the findings and conclusions of the study (Kacen & Chaitin, 2006). Therefore using reflexivity to monitor these effects enhances the accuracy of the research and the credibility of the findings, leading to heightened rigour and ethics (Bradbury-Jones, 2007; Gemignani, 2011; Cutcliffe, 2003).

Reflexivity has traditionally been considered to be a process of personal self supervision (Russell & Kelly, 2002). However there is now a shift towards including teams where members attend to their own biases as well as having the benefit of examining one another's reactions (Horsburgh, 2003). There are several strategies identified for maintaining reflexivity during research. These include: repeated interviews with the same participants, prolonged engagement, forming a peer support network and keeping a research diary for the self supervision of the researcher's reasoning, judgement and emotional reactions (Valentine, 2007; Padgett, 2008; Vicary et al., 2016).

In my own attempts to maintain reflexivity throughout my research I kept a research diary as a form of self-supervision and in addition to this I discussed my positioning with my clinical research supervisor. Some areas of research literature recommends the use of repeated interviews with the same participants, this was not possible during my own research due to both the time constraints for me to recruit participants as well as the service demands and time pressures only allowing for participants to spare up to an hour to be interviewed for the research. Similarly prolonged engagement was also not an option due to the aforementioned reasons. Due to the small size of the empirical research study, there was no possibility of forming a peer support network to monitor my own biases. As such the use of supervision with my supervisor became the only available option for external exploration of my positioning. While this was beneficial in that it added to the rigour of the study, there were also some issues with this process that I needed to be aware of. One of the primary concerns was that although supervision offered a different lens through which to reflect upon my positioning, it could be argued that my supervisor was not truly external to the process. My supervisor was invested in the research, both in terms of supervising the project and wishing it to come to fruition but also as a result of her own professional training as both a clinical psychologist and a trained family therapist working within adult mental health in Abertawe Bro Morgannwg University Health Board. Therefore to some extent we shared a similar positioning in relation to the research in that we both have experience of working within adult mental health and will tend to view the world through the lens of a clinical psychologist.

Insider's Positioning

Through exploring my own positioning in relation to the research project I was able to identify that I had an insider's perspective to many of the issues discussed by participants, in that I too am a member of staff working within the NHS, but more specifically within adult mental health in ABMU. Thus, to some extent, I found myself being part of the group under study. This resulted in me "simultaneously being an onlooker in the stalls and a member of the cast" (Shaw, 2011). Being in the position of an insider and studying the familiar does however provide advantages (Padgett, 2008; Kacen & Chaitin, 2006). Firstly it provided me with a head start in knowing about the topic and subsequently by having an understanding of NHS working practices it enabled me to understand the reactions of the participants when discussing organisational issues. My knowledge of the organisation provided me with what Berger (2004) has termed as 'cultural intuition and insight'. This meant I was able to address certain topics more easily as many of the research participants knew that I understood what they were talking about without them needing to provide a lengthy explanation. This however often led to information not being explicitly expressed within the research interview as participants assumed

an understanding and often left sentences unfinished or punctuated with "you know...". Daly (1992) states when researchers and participants share experiences there is a tendency for participants to assume information to be obvious to the researcher as a result of their familiarity, similarly researchers can overlook certain aspects of the participants' experience. As well as having an understanding about what participants were trying to express, my prior knowledge also made me aware of what is not being said in the interviews and should be addressed. By having this shared experience position, I was able to understand implied content and have a familiarity of the technical language used within adult mental health recovery services which meant I was able to probe more efficiently around the unsaid content, something that a researcher unfamiliar with this subject area may have missed.

As well as there being benefits in researching an area of familiarity from an insider's position, it also poses risks of blurring boundaries. Drake (2010) highlights that a 'dual identity' of a researcher and member of the community being studied shapes the research process and can lead to researchers imposing own values, beliefs, perceptions and projecting biases. While I was aware of the risks of my dual identity status as both a researcher and an NHS employee, it felt impossible to maintain total neutrality to the research material. While I have my own beliefs and perceptions about what it is like to work in the NHS, there is a risk that I would disavow these in an attempt to maintain total neutrality to the research material. However a researcher naive to the research area might not be so inclined to suppress their own beliefs in relation to the research material. Instead it seemed more appropriate to recognise my position, the potential impact that has had on my research and owning it as such rather than attempting to create an artificial neutrality.

Shared experiences of the researcher and participants can impact the power relationship (Berger, 2015). It can create for participants a feeling of comparison and competition which would inevitably affect participants' responses (Ahmed Dunya et al., 2011). It is possible that these power dynamics played out during the interviews that I conducted. I reflected upon the hesitancy of some of the healthcare assistants when talking with me during interview. I questioned whether this could be related to a perceived power dynamic whereby they assumed that they needed to censor their responses in order to provide a 'correct' answer to someone they may have perceived as a more senior clinician. Similarly when interviewing a clinical psychologist I wondered if their responses would have been different if the researcher was not also from a psychology background and that maybe there was a pressure in the interview to demonstrate their competency within the role of clinical psychologist. Considering how the power relationship during the interviews may have impacted on participants' responses is important as the findings of research represents the interpretations that the

researcher has made of constructs developed and conveyed by participants (Horsburgh, 2003). As such when transcribing and subsequently analysing the data I found myself questioning the impact potential power dynamics may have played upon participants' responses and my subsequent interpretation.

Outsider's Positioning

While acknowledging that I occupied somewhat of an insider's position during this research due to working with in adult mental health in the NHS, I was also aware that at the same time I occupied an outsider's position due to me not working in the rehabilitation and recovery service in which the research took place, nor having any direct experience of the process of running family liaison meetings. Being unfamiliar to the nuances of the culture in which the research is conducted can both help and hinder the interpretation of the narrative data (Reich, 2003). One identified advantage that studying the unfamiliar offers is that the researcher is ignorant and it puts participants in an expert position which may be perceived as an empowering experience (Berger & Malkinson, 2000). Some of the research participants viewed me solely as a student with little, to no knowledge of mental health services. This had the advantage of me being able to ask probing questions by maintaining a position of naivete.

One challenge in studying the unfamiliar is being able to conceptualise research questions that are relevant to the participants' experiences (Berger, 2015). My lack of familiarity around family liaison meetings at times made this potentially difficult to know what the most pertinent questions were to ask around participants' experiences of running these meetings. This challenge was further compounded by what Fawcett and Hearn (2004) argue that a researcher cannot totally comprehend what it is like in certain situations if they have not personally experienced it. Similarly Pillow (2003) has stated that participants' experiences cannot truly be conveyed or understood by the researcher if they themselves have not experienced it, even with the use of reflexivity as a vehicle for making the research process visible. While there may be some truth to this argument, if it is followed to the extreme, one could argue that the very nature of research becomes redundant as consumers of research could only understand what is being conveyed if they themselves had that shared experience. Similarly Pillow's argument raises the question that having experienced one family liaison meeting results in a researcher being able to understand the experiences that participants have had in all family liaison meetings. As such research could never fulfil its function of communicating evidence to the wider audience. While I accepted that I may never fully understand what the individual experiences were like for each of the participants, I still felt that it was important to convey as best I could my understanding of their experiences. This often led me to clarify my interpretations of what participants

were trying to express within the interviews in order to ensure a reasonably accurate interpretation. One technique that could potentially have been employed in this research to ensure the data analysis was a trustworthy representation of the themes in the narratives rather than a reflection of my own biases could have been the use of triangulation. This would have involved myself and a co-researcher comparing the analysis of the same content. While this approach may have been of some benefit, it was not utilised as the technique is not advocated by Braun and Clarke (2006) for the research methodology on which this study was based. Berger (2015) has argued that a researcher's positioning can evolve over time and that these evolving experiences can colour the research. Berger advocates for the use of a comparison matrix in which pre and post analysis are compared for each section of the transcript to identify any changes that may reflect the researcher's evolving experience. This approach was not utilised in this study because data collection and analysis took place over a relatively condensed timeframe and as such my researcher position did not have an adequate amount of time in which to evolve to such an extent that it impacted on the trustworthiness of the analysis.

Data Collection

Participant Recruitment and Sample Size

From discussions with service managers I obtained a list of all staff working at the unit who had received training in family liaison meetings. From this list I emailed all staff who were suitable for inclusion in the study with information outlining the purpose of the study and asking if they would be willing to participate (see appendix 6). The uptake from these emails was minimal. Therefore I attended handover meetings at the unit to promote the research using what Luker (2008) has termed as 'the hook' to entice people to participate. This consisted of stating what the research is about, why I am interested in it, why they should be interested in it and why they are the key people needed to help me understand the experiences of family liaison meetings. This approach resulted in a greater response rate of participants willing to take part in the research.

Guidelines for sample size for professional doctorate research using interviews recommends between 6 to 15 participants (Braun and Clarke, 2013, cited in the Sage Handbook of Qualitative Research, 2017). While these recommendations are in place it is important to note that quantity of sample size does not necessarily equate to quality of data. What is key in the use of thematic analysis is that the sample is adequate to produce accounts of patterns across the dataset. My own sample size of 12 participants both adhered to Braun and Clarke's recommendations for sample size, but also it represented 100% of the phenomena under investigation, in that it captured all trained staff in the unit.

While participants were free to take part in the study I did wonder if they felt a pressure to take part due to a sense of duty to my research supervisor who had delivered their training and provides supervision to the service. While there may be no way to mitigate for this I did ensure to state clearly that their participation is optional, that their data is anonymised, and that they are able to withdraw from the research up to the point that their data has been analysed.

Ethical approval

This research project had already received ethical approval from the NHS (see appendix 5). Despite this the project still needed to be approved by Cardiff University. This should have been a relatively straightforward process given the benign nature of the research. However I encountered some difficulty in relation to completing risk assessments for the project. The risk committee stated I had not adequately risk assessed the "potential of being assaulted either verbally or physically by participants" in my research, nor had I adequately risk assessed "potential harm from the use of equipment in the research such as the recording device". These criticisms seemed disproportionate to the nature of the project and in my opinion reflected a lack of understanding on behalf of the ethics committee around the nature and context of this research project. Unfortunately this incurred a delay in me being able to collect data until I had received approval for the amended risk assessment. In hindsight I believe it would have been beneficial to have met with the ethics committee in person to advocate my stance as opposed to having to do so via written correspondence.

Semi Structured Interview

The current empirical study used a semi structured interview as the form of data collection as this was the most appropriate means of gathering data for qualitative description. The use of a structured interview was ruled out as it is dependent upon underlying theoretical framework and as my research was explorative it could not be aligned to a predetermined theoretical framework. Similarly an unstructured interview was deemed inappropriate as the methodology for the current study was not hermeneutic phenomenological in nature (Van Manen, 2014).

The intention of using an interview is to collect data that will address the overall purpose of the research study (Creswell, 2007). The use of a predetermined set of questions in combination with broad prompts allowed me to elicit more information to provide rich details.

As previously mentioned in this paper, under the section on reflexivity, multiple factors can affect the data collected in both terms of content and quality (Manderson et al., 2006). In addition to structural factors such as age, gender and class that influence the researcher-researched relationship, more

general factors such as the rapport a researcher builds with participants prior to beginning the interview has also been found to enhance the quality of information expressed in interview and subsequently improve the data analysis (Elmir et al, 2011). At times during the current study it felt difficult to be able to build the necessary rapport with the research participants prior to beginning the interview. This was often due to having booked time to meet with participants, only to turn up to the unit to find that they were busy and unable to meet. However another member of staff who was suitable for the research was available. This meant that participants' recruitment was often opportunistic, thus not necessarily affording me the time to build a significant amount of rapport prior to engaging with them. Another barrier to building rapport that I noticed throughout the process of interviewing participants was the influence that having the Dictaphone visible throughout the interview played. I noticed in some of the interviews participants were talking at ease and then would glance towards the Dictaphone and stop speaking. Due to this observation in the latter interviews I decided to obscure the view of the Dictaphone by placing a piece of paper over it while still informing participants at the start of the interview, for ethical reasons, that the interview would be recorded and subsequently transcribed. This adaptation appeared to result in a more informal conversational style to the interviews.

Connelly and Peltzer (2016) argue that qualitative interviews that do not pay attention to the use of indepth prompts and probes nor the consideration of the relationship between the researcher and research participant results in the production of superficial data that does not have the depth to provide substantive findings. One of the aspects I became aware of through the use of a research diary was that the overall quality of my interviews appeared to improve over the duration of the research as I became more familiar with the research topic, subsequently knowing what areas to prompt and probe on as well as becoming more aware of the relationship between myself and the research participants. The initial interviews I conducted were with staff that were actively part of the family liaison meeting facilitation team and therefore probably had the greatest awareness of the role of family liaison meetings. With hindsight I think it would have been beneficial to have interviewed these staff members towards the end of the research when my skills in conducting interviews in this subject area where more enhanced.

Data Analysis Process

Transcription

When working with verbal data such as the data collected from my interviews, it needs to be transcribed into written form in order to conduct thematic analysis (Braun and Clarke, 2006). While many researchers outsource the transcribing of their data as this can be a time-consuming, frustrating

and potentially tedious task, Riessman (1993) states that the act of transcription is an excellent way to familiarise yourself with the data. This is further supported by Bird (2005) who argues transcription is a key phase of data analysis within interpretative qualitative methodology and as such it represents an interpretive act where the meanings of the data are constructed as opposed to mechanically putting the spoken sounds on paper (Lapadat & Lindsay, 1999). Lindsay and O'Connell (1995) highlight that transcribers as language users frequently transcribe unreliably. As such it was important to me that I should conduct the transcription as the interpretation of the verbal data would reflect my own perceptions and biases which would be accounted for in the process of reflexivity as opposed to the biases, which I may never be aware of, from a third party transcriber. Due to these reasons I felt it was important that I transcribe the recorded interviews myself as opposed to outsourcing this.

When transcribing the interviews I adhered to standard orthography approach. In standard orthography transcripts are based on the norms of written language and as such makes the task of transcribing easier. However it also fails to take account of idiosyncrasies of speech such as omissions of individual sounds or coughs. I used standard orthography because other approaches to transcription such as phonetic transcription provide too much information thus making it difficult to use and read. Furthermore only the features of conversational behaviour that will actually be analysed should be transcribed (Nikander, 2008; O'Connell & Kowal, 1995). As the content of what participants said rather than how they said it was the basis of my analysis there was little point me transcribing the idiosyncrasies of speech. This chosen approach to transcription is further justified by the argument that transcription convention needs to be practically suited to the purpose of analysis (Edwards, 1993).

Manual Data Analysis

During the analysis process I had considered the use of computer supported methods such as NVivo. The use of computer supported software can result in potential methodological benefits. For example there can be a higher efficiency in the way data is organised resulting in economising on time and human resource. This in turn makes it possible to process large quantities of data and therefore work with larger samples (Kelle & Laurie, 1995) although it is important to be mindful that a large sample does not necessarily lead to a higher validity of results. An additional argument in favour of the use of computer-assisted analysis is that researchers are freed from laborious mechanical tasks and therefore are motivated to more carefully study the relationship between categories within the data, potentially resulting in more space for creative and investigative aspects of the data analysis (Fielding & Lee, 1998). However in contrast to these benefits, concerns have been raised that the methodological assumptions that underlie analytic software may unwittingly influence the analytical process. Coffey et al (1996) highlight that many software packages are orientated towards the use of grounded theory.

Furthermore there are warnings within the literature that the use of computer software may result in a preoccupation with coding categories leading to textual interpretation becoming overlooked (Seidel & Kelle, 1995). Due to these concerns in using computer software to analyse data, coupled with my lack of familiarity with qualitative analytic software and therefore the amount of time it would take for me to become competent with the software package, the negatives for the use of computer assisted analysis outweighed any potential gains. As a result of this I chose to analyse the data by hand.

Coding Data

The process of coding forms part of the analysis in thematic analysis (Miles & Huberman, 1994). Coding consists of organising the data into meaningful groups (Tuckett, 2005). Data coding can occur in two ways, depending on whether the themes derived are likely to be more data driven or theory driven. As my research was exploratory in nature the coding became data driven. Prior to formal coding I read and re-read the transcripts from a naive stance to familiarise myself with the data. During this phase I made some initial notes demarcating my ideas and areas of interest within the data before starting coding formally. As previously mentioned I coded the data manually, writing notes on the transcripts and using highlighters and coloured pens to indicate potential patterns. Following the advice of Braun and Clarke (2006) I coded for as many potential themes as time allowed. I also paid particular attention to ensuring that the coded extracts of data included some surrounding data to ensure context is maintained (Bryman, 2015). Some authors argue that it can be beneficial to have outside peer reviewers also code the data for consistency (Connelly & Peltzer, 2016), however Braun and Clarke do not advocate the use of a second reviewer for the coding of data. In fact as coding is a primary analytical process and ultimately reflects the interpretation of the researcher it is important that any derived codes should be generated by the researcher who is ultimately making the interpretation of the data rather than a secondary party. With this in mind I made the decision not to involve external people in reviewing the coding of the data in order to maintain quality.

Themes

When compiling themes the focus of the analysis was at a broader level, sorting the different codes into potential themes. This process involved me combining codes to form overarching themes. I did this process by the use of a combination of mind maps, coding tables and also hardcopy paper format organising codes into thematic piles. Once initial themes had been established I reviewed the themes following Patton's (1990) dual criteria for judging themes. This argues that data within themes should cohere together in a meaningful way while there should also be clear distinctions between themes. In achieving this I reviewed the data at the level of the coded data extracts by reading the collated extracts for each theme to determine if they present a coherent pattern. In doing this it led to what

Braun and Clarke term a candidate thematic map. Once this was established I reviewed the entire dataset to consider the validity of individual themes in relation to the dataset as a whole and if the candidate thematic map reflects the meaning from the dataset as a whole. One identified pitfall in developing themes occurs when researchers use existing concepts or terms which have a long conceptual history (Sandelowski & Barroso, 2003). I noticed I had a tendency to make sense of the data in the candidate thematic maps via the use of existing concepts. This led to the need to go back and refine the maps before developing the overarching themes.

The Role of Evidence-Based Practice Research within Mental Health Recovery

Since the early 1990s there has been a drive within mental health systems to promote the adoption of evidence-based practices whilst at the same time incorporating a recovery focused vision for the services they provide (Anthony, 2000; Jacobson & Curtis, 2000). Unfortunately a large proportion of published research on evidence-based practices was developed without an understanding or focus on mental health recovery (Anthony et al., 2003). One of the strengths of my research paper is that it has been conducted with clinicians working in the field of mental health recovery and as such the research findings are directly applicable to the planning and delivery of mental health recovery services.

Implications for Clinical Services and Practice

The current study has solidified the position of family liaison meetings within Cefn Yr Afon by demonstrating that the intervention operates at a service level resulting in cultural changes in care. The study also highlighted that family liaison meetings are valued by staff who in turn feel that families and service users benefit from this. Therefore it would indicate that family liaison is a service worth investing in, both in terms of finance and resource. The study emphasised the challenges and barriers to implementing both family liaison meetings and family inclusion within adult mental health services. In drawing attention to barriers such as lack of time, not enough trained staff and the need for ongoing supervision, has allowed for service managers to plan more effectively how they will address these barriers in order to successfully implement family liaison meetings as a model into services.

The current study highlighted a demand for additional training for staff working in rehabilitation and recovery settings. Consequently the service has commissioned another 20 members of staff to be trained to facilitate family liaison meetings in the autumn of this year.

Target Journal

The Community Mental Health Journal was selected as the target journal for paper two due to its focus on publishing research related to psychiatric rehabilitation. While the journal's impact factor is not that large (2016 impact factor = 1.154), the journal will primarily be read by the target audience that I wish to disseminate the research to.

Disseminating the Research

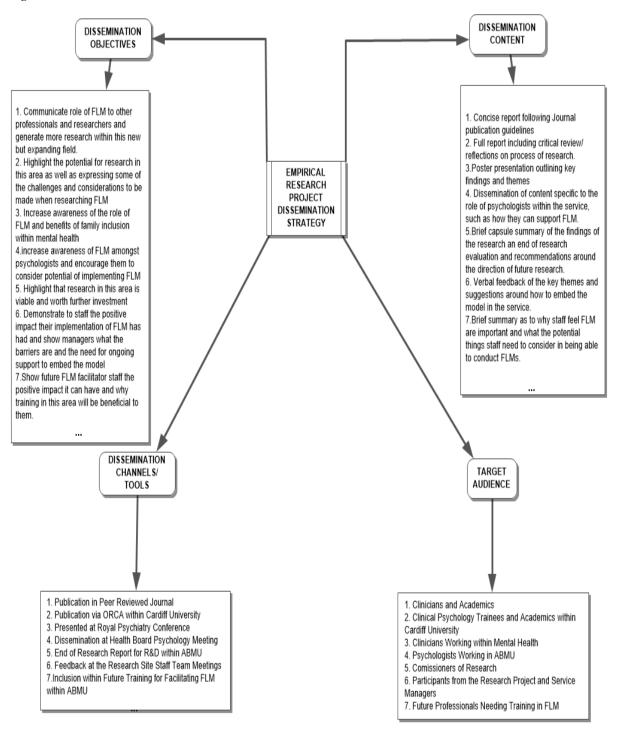
Research within healthcare aims to produce results which lead to revised methods of treatment and care for patients in line with what has been identified as best practice, which if implemented appropriately has the potential to improve the quality of life for patients (Cummings et al., 2011). However it is of note that a simple increase in the amount of research data available does not automatically translate into changes resulting in improved patient care and treatment (Brown & McCormack, 2005; Rangachari et al., 2013). The research literature highlights a substantial gap between the health care that patients receive and the type of care that is recommended as a result of research outcomes (Kristensen et al., 2016). This discrepancy between what patients receive in healthcare settings against what research recommends has been termed within the literature, researchpractice gap, evidence-practice gap or knowing-doing gap (Pfeffer & Sutton, 1999; Real & Poole, 2005; Lilienfeld et al., 2013). Significantly evidence indicates that it can take up to a decade to implement research results into clinical practice, furthermore there are difficulties in sustaining innovations from research outcomes over time (Dilling et al., 2013). This delay in disseminating and subsequently implementing research findings into practice is detrimental for two reasons. Firstly patients are unable to capitalise on outcome research to receive the best care and treatment possible (Donaldson et al., 2004). Secondly research comes with a financial burden and failure to effectively disseminate findings results in healthcare organisations potentially missing out on financial value gains and returns on their investments (Brown et al., 2014).

In the UK it is estimated that in the region of £7.2 million is spent annually on all clinical psychology LSRPs. In addition to this trainees on doctorate of clinical psychology are often reticent to publish their research in peer-reviewed journals leading to very low publication rates for trainees' research. This ultimately results in a financial burden to the National Health Service who fund trainees to conduct research and yet they rarely reap the benefits of their investment. With these concerns in mind it was important for me to establish a strategy to disseminate the findings from my research so that maximum impact could be achieved.

Dissemination Strategy

Increasing the number of ways that research findings reach key audiences increases the chance of uptake and action (Panisset et al., 2012). With this in mind it is important that I developed a dissemination strategy that utilises multiple tools to ensure that the different audiences are reached effectively. Figure 3. highlights the dissemination strategy, demonstrating what content and how the research plans are to be disseminated, to whom and the objectives for this.

Figure 3: Dissemination Plan



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Appendices

Appendix 1 Submission Guidance for Journal of Affective Disorders

Articles should be in English. The title page should appear as a separate sheet bearing title (without article type), author names and affiliations, and a footnote with the corresponding author's full contact information, including address, telephone and fax numbers, and e-mail address (failure to include an e-mail address can delay processing of the manuscript).

Papers should be divided into sections headed by a caption (e.g., Introduction, Methods, Results, Discussion). A structured abstract of no more than 250 words should appear on a separate page with the following headings and order: Background, Methods, Results, Limitations, Conclusions. A list of three to six key words should appear under the abstract. Authors should note that the 'limitations' section both in the discussion of the paper AND IN A STRUCTURED ABSTRACT are essential. Failure to include it may delay in processing the paper, decision making and final publication.

Figures and Photographs

Figures and Photographs of good quality should be submitted online as a separate file. Please use a lettering that remains clearly readable even after reduction to about 66%. For every figure or photograph, a legend should be provided. All authors wishing to use illustrations already published must first obtain the permission of the author and publisher and/or copyright holders and give precise reference to the original work. This permission must include the right to publish in electronic media.

Tables

Tables should be numbered consecutively with Arabic numerals and must be cited in the text in sequence. Each table, with an appropriate brief legend, comprehensible without reference to the text, should be typed on a separate page and uploaded online. Tables should be kept as simple as possible and wherever possible a graphical representation used instead. Table titles should be complete but brief. Information other than that defining the data should be presented as footnotes. Please refer to the generic Elsevier artwork instructions: http://authors.elsevier.com/artwork/jad.

Preparation of supplementary data

Elsevier accepts electronic supplementary material to support and enhance your scientific research. Supplementary files offer the author additional possibilities to publish supporting applications, movies, animation sequences, high-resolution images, background datasets, sound clips and more. Supplementary files supplied will be published online alongside the electronic version of your article in Elsevier web products, including ScienceDirect: http://www.sciencedirect.com. In order to ensure that your submitted material is directly usable, please ensure that data is provided in one of our recommended file formats. Authors should submit the material in electronic format together with the article and supply a concise and descriptive caption for each file. For more detailed instructions please visit our Author Gateway at: http://www.elsevier.com/authors

Use of word processing software

It is important that the file be saved in the native format of the word processor used. The text should be in single-column format. Keep the layout of the text as simple as possible. Most formatting codes will be removed and replaced on processing the article. In particular, do not use the word processor's options to justify text or to hyphenate words. However, do use bold face, italics, subscripts, superscripts etc. When preparing tables, if you are using a table grid, use only one grid for each individual table and not a grid for each row. If no grid is used, use tabs, not spaces, to align columns. The electronic text should be prepared in a way very similar to that of conventional manuscripts (see also the Guide to Publishing with Elsevier). Note that source files of figures, tables and text graphics will be required whether or not you embed your figures in the text. See also the section on Electronic

artwork.

To avoid unnecessary errors you are strongly advised to use the 'spell-check' and 'grammar-check' functions of your word processor.

Abstract

A concise and factual abstract is required. The abstract should state briefly the purpose of the research, the principal results and major conclusions. An abstract is often presented separately from the article, so it must be able to stand alone. For this reason, References should be avoided, but if essential, then cite the author(s) and year(s). Also, non-standard or uncommon abbreviations should be avoided, but if essential they must be defined at their first mention in the abstract itself.

Keywords

Immediately after the abstract, provide a maximum of 6 keywords, using American spelling and avoiding general and plural terms and multiple concepts (avoid, for example, 'and', 'of'). Be sparing with abbreviations: only abbreviations firmly established in the field may be eligible. These keywords will be used for indexing purposes.

Abbreviations

Define abbreviations that are not standard in this field in a footnote to be placed on the first page of the article. Such abbreviations that are unavoidable in the abstract must be defined at their first mention there, as well as in the footnote. Ensure consistency of abbreviations throughout the article.

Acknowledgements

Collate acknowledgements in a separate section at the end of the article before the references and do not, therefore, include them on the title page, as a footnote to the title or otherwise. List here those individuals who provided help during the research (e.g., providing language help, writing assistance or proof reading the article, etc.).

Formatting of funding sources

List funding sources in this standard way to facilitate compliance to funder's requirements: Funding: This work was supported by the National Institutes of Health [grant numbers xxxx, yyyy]; the Bill & Melinda Gates Foundation, Seattle, WA [grant number zzzz]; and the United States Institutes of Peace [grant number aaaa].

It is not necessary to include detailed descriptions on the program or type of grants and awards. When funding is from a block grant or other resources available to a university, college, or other research institution, submit the name of the institute or organization that provided the funding.

If no funding has been provided for the research, please include the following sentence:

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Nomenclature and units

Follow internationally accepted rules and conventions: use the international system of units (SI). If other quantities are mentioned, give their equivalent in SI. You are urged to consult IUPAC: Nomenclature of Organic Chemistry for further information.

Math formulae

Please submit math equations as editable text and not as images. Present simple formulae in line with normal text where possible and use the solidus (/) instead of a horizontal line for small fractional terms, e.g., X/Y. In principle, variables are to be presented in italics. Powers of e are often more conveniently denoted by exp. Number consecutively any equations that have to be displayed separately from the text (if referred to explicitly in the text).

Footnotes

Footnotes should be used sparingly. Number them consecutively throughout the article. Many word processors can build footnotes into the text, and this feature may be used. Otherwise, please indicate the position of footnotes in the text and list the footnotes themselves separately at the end of the article. Do not include footnotes in the Reference list.

Tables

Please submit tables as editable text and not as images. Tables can be placed either next to the

relevant text in the article, or on separate page(s) at the end. Number tables consecutively in accordance with their appearance in the text and place any table notes below the table body. Be sparing in the use of tables and ensure that the data presented in them do not duplicate results described elsewhere in the article. Please avoid using vertical rules and shading in table cells.

References

Citation in text

Please ensure that every reference cited in the text is also present in the reference list (and vice versa). Any references cited in the abstract must be given in full. Unpublished results and personal communications are not recommended in the reference list, but may be mentioned in the text. If these references are included in the reference list they should follow the standard reference style of the journal and should include a substitution of the publication date with either 'Unpublished results' or 'Personal communication'. Citation of a reference as 'in press' implies that the item has been accepted for publication.

Data references

This journal encourages you to cite underlying or relevant datasets in your manuscript by citing them in your text and including a data reference in your Reference List. Data references should include the following elements: author name(s), dataset title, data repository, version (where available), year, and global persistent identifier. Add [dataset] immediately before the reference so we can properly identify it as a data reference. The [dataset] identifier will not appear in your published article.

Reference management software

Most Elsevier journals have their reference template available in many of the most popular reference management software products. These include all products that support Citation Style Language styles, such as Mendeley and Zotero, as well as EndNote. Using the word processor plug-ins from these products, authors only need to select the appropriate journal template when preparing their article, after which citations and bibliographies will be automatically formatted in the journal's style. If no template is yet available for this journal, please follow the format of the sample references and citations as shown in this Guide.

Reference style

Text: All citations in the text should refer to:

- 1. *Single author*: the author's name (without initials, unless there is ambiguity) and the year of publication;
- 2. Two authors: both authors' names and the year of publication;
- 3. *Three or more authors:* first author's name followed by 'et al.' and the year of publication. Citations may be made directly (or parenthetically). Groups of references should be listed first alphabetically, then chronologically.

Examples: 'as demonstrated (Allan, 2000a, 2000b, 1999; Allan and Jones, 1999). Kramer et al. (2010) have recently shown'

List: References should be arranged first alphabetically and then further sorted chronologically if necessary. More than one reference from the same author(s) in the same year must be identified by the letters 'a', 'b', 'c', etc., placed after the year of publication.

Examples:

Reference to a journal publication:

Van der Geer, J., Hanraads, J.A.J., Lupton, R.A., 2010. The art of writing a scientific article. J. Sci. Commun. 163, 51–59.

Reference to a book:

Strunk Jr., W., White, E.B., 2000. The Elements of Style, fourth ed. Longman, New York. Reference to a chapter in an edited book:

Mettam, G.R., Adams, L.B., 2009. How to prepare an electronic version of your article, in: Jones, B.S., Smith, R.Z. (Eds.), Introduction to the Electronic Age. E-Publishing Inc., New York, pp. 281–304.

Reference to a website:

Cancer Research UK, 1975. Cancer statistics reports for the UK.

http://www.cancerresearchuk.org/aboutcancer/statistics/cancerstatsreport/ (accessed 13.03.03). Reference to a dataset:

[dataset] Oguro, M., Imahiro, S., Saito, S., Nakashizuka, T., 2015. Mortality data for Japanese oak wilt disease and surrounding forest compositions. Mendeley Data, v1. https://doi.org/10.17632/xwj98nb39r.1.

Appendix 2 Database Search Terms

- 1. (RECURRENT DEPRESSION or TREATMENT RESISTANT DEPRESSION).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
- 2. depressi*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
- 3. (refractory* or resistan* or recurren*).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
- 4. (augment* or potentiat*).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
- 5. (chronicity or "chronic* depress*" or "depressed chronic*" or "chronic major depressi*" or "chronic affective disorder*" or "Chronic mood disorder*" or (chronic* and (relaps* or recurr*))).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
- 6. (persistent* depress* or depression persistent* or persistent major depress* or persistense of depress* or persistense of major depress*).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
- 7. (nonrespon* or non-respon* or non respon* or "not respon*" or no respon* or partial respon* or partially respon* or in-complete respon* or incomplete* respon* or unrespon*).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
- 8. (failed to respond or failed to improve or failure to respon* or failure to improve or failed medication* or antidepressant fail* or treatment fail*).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
- 9. (inadequate* and respon*).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
- 10. treatment resistant depression.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
- 11. (recurrence or recurrent depression or recurent disease).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
- 12. drug resistance.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease

supplementary concept word, unique identifier, synonyms]

- 13. treatment failure.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
- 14. drug potentiation.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
- 15. augmentation.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
- 16. Randomized Controlled Trial.pt.
- 17. Pragmatic Clinical Trial.pt.
- 18. exp Randomized Controlled Trials as Topic/
- 19. "Randomized Controlled Trial (topic)"/
- 20. Randomized Controlled Trial/
- 21. Randomization/
- 22. Random Allocation/
- 23. Double-Blind Method/
- 24. Double Blind Procedure/
- 25. Double-Blind Studies/
- 26. Single-Blind Method/
- 27. Single Blind Procedure/
- 28. Single-Blind Studies/
- 29. Placebos/
- 30. Placebo/
- 31. (random* or sham or placebo*).ti,ab,hw,kf,kw.
- 32. ((singl* or doubl*) adj (blind* or dumm* or mask*)).ti,ab,hw,kf,kw.
- 33. ((tripl* or trebl*) adj (blind* or dumm* or mask*)).ti,ab,hw,kf,kw.
- 34. or/16-33

Appendix 3 Data Extraction Form

non significant reduction on HAM-D with HAM-D score > 16 following at least one course of antidepressant medication	Study	TRD Definition	Treatment	Study	Participant	Results	Quality Rating
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- Schizophrenia episodes: assessment?: Y				- Schizophrenia	episodes:		assessment?: Y
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- Bipolar disorder Number of Outcomes					Number of		Outcomes
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			psychotic features Substance or alcohol use or dependence within past 6 months	ants previously taken in lifetime (Median): ISTDP: 3 TAU: 2		Y Dropout rate < 30%?: Y Differential dropout rate < 10%?: Y Incomplete data addressed adequately?: Y Conflict of interest?: N Overall quality rating: Fair
2016	Persistent Depression: Despite treatment with antidepressant with 4 or more weeks of minimum dosage equivalent to at least 75 mg of amitriptyline. Study does not state measure of non- responsiveness	y: TAU+ITP (ITP consisted of 16 weekly sessions lasting 40 minutes each) Comparator: TAU (TAU consisted of monthly clinical management sessions and treatment with clinicians choice of drug combinations and doses).	Geographical location: Porto Alegre, Brazil Setting: Tertiary outpatients service Study design: Pragmatic RCT Number of participants enrolled: Total: 40 TAU+IPT:17 TAU:23 Duration of follow up: weeks 8, 12, 19 and 24 Inclusion criteria: One trial of antidepressant medication at adequate therapeutic does DSM-IV diagnosis of MMD Exclusion criteria: Intellectual disability Schizophrenia	Age: [mean (SD)] TAU +IPT: 49.3 (12.31) TAU: 49.18 (12.5) Sex: [Female, n (%)] TAU + IPT: 15 (88.2%) TAU: 19 (82.6%) Race/ethnici ty: Not reported Duration of current episode in Months (Mean): TAU +IPT: 33.5 TAU: 29.05	The mean depressive symptoms scores on HDRS significantly improved over time in both conditions from baseline until 24 weeks: TAU(mean dif. 4.57; CI95%: 0.59-8.55; d= 0.73; CI95%: 0.08-1.36) vs. TAU +IPT (mean dif. 5.86; CI95%: 1.50-10.22; d= 0.93; CI95%: 0.19-1.63) Intention to treat sample the differences in response rates and remission were not significant.	Comments: study had a small sample which limits ability to detect differences between treatment. Therapists were not fully qualified which may have reduced quality of psychotherapy. Due to pragmatic design medication was clinicians free choice which could favour a bias between groups. Although pragmatic design helps clinicians decide whether or not to add IPT to TAU. Quality assessment: Randomization adequate?: Y Allocation concealment adequate?: Y Baseline comparability?:

Eisendrath et	Persistent	Psychotherap	Caggraphical	Number of antidepress ants previously taken in lifetime: Not reported	МВСТ	Y Dropout rate < 30%?: Y Differential dropout rate < 10%?: Y Incomplete data addressed adequately?: Y Conflict of interest?: N Statistical power calculated at 72% Overall quality rating: Fair Comments:
al 2016	Depression: non significant reduction on HAM-D with HAM-D score >14 following at least two courses of antidepressant medication at adequate dose.	y: Mindfulness-based cognitive therapy (MBCT) consisting of 8 weekly group sessions lasting 2h and 15 min with additional 45min homework 6 days per week.	Geographical location: San Francisco, USA Setting: outpatients and general medical clinics Study design: RCT Number of participants enrolled: Total: 173 MBCT:87 HEP:86 Duration of follow up: Week 8, 24, 36, 52. Inclusion	Age: [mean (SD)] MBCT: 47.1 (13.46) HEP: 45.2 (11.19) Sex: [Female, %] MBCT: 75.9 HEP: 76.7 Race/ethnicit y: [Caucasian, %] MBCT: 80	produced	facilitator fidelity to each model and competency was monitored. Participants were not blind to intervention assignment which may introduce some bias. Changes in medication was not limited during treatment period. Patient preference for treatment was not measured before randomisation. Quality assessment: Randomization adequate?: Y

		health enhancement program (HEP) consisting of 8 weekly group sessions lasting 2h and 15 min with additional 45min homework 6 days per week.	criteria: - Score of 14+ on HAM-D - Needed to be taking medication with evidence of 2 or more adequate trials - DSM-IV diagnosis of MMD Exclusion criteria: - Intellectual disability - Schizophrenia - Bipolar disorder - MDD with psychotic features - Substance abuse - High suicide risk	Duration of current episode in Months (Mean): MBCT: 84.4 HEP: 78.5 Number of prior episodes(Mean): MBCT: 3.8 HEP: 3.5 Number of antidepressants previously taken in lifetime: Not reported.	p=0.03) based on HAM-D at end point. No statistically significant difference was found for rates of remission (22.4 vs. 13.9%; p=0.15) No differences based on gender were found. 52 week outcome using HAM-D indicated MBCT significantly greater for percent responding but	Allocation concealment adequate?: Y Baseline comparability?: Y Valid outcome assessment?: Y Subject/providers blind?: Y Outcomes assessed blind?: Y Dropout rate < 30%?: Y Differential dropout rate < 10%?: Y Incomplete data addressed adequately?: Y Conflict of interest?: N Overall quality rating: Good
Chiesa et al 2015	Persistent Depression: A diagnosis of MD, single or	MBCT MBCT consisted of eight group	Geographical location: Bologna, Italy Setting: From	Age: [mean (SD)] MBCT: 50.91 (11.48)	•	Comment: number of prior episodes of depression was not reported nor
	recurrent episode, as diagnosed by DSM-IV-TR, as measured by Mini International	sessions lasting two hours each. Comparator psychoeducat ion	general community and treated at institute of psychiatry Study design: RCT Number of participants	EDUC: 46.70 (10.89) Sex: [Female, %] MBCT: 70 EDUC: 75	symptoms, as measured with the HAM-D was observed in MBCT group compared to	was number of antidepressants previously taken in lifetime. Evidence suggests number of previous episodes is directly correlated with decreased remission from

		included one	years			-
	weeks and failure to	included one	- aged between 18 and 65	[mean)]:	groups'	adequate?: Y
	achieve	hour of	- DSM-IV-TR	MBCT: 93.86	d=0.54; long-	Allocation
	remission as	teaching	diagnosis of MD	EDUC:	term: F=4.28	concealment
	defined by	focused on a	- being on	129.37	d.f.=4, 160,	adequate?: Y
	HAM-D	specific topic	adequate dose of	Nbassac	p=0.002,	Baseline
		followed by	antidepressant	Number of	between	comparability?: Y
		one hour of	for at least eight weeks	prior	groups'	Valid outcome
		group	before starting	episodes(Me	d=0.79;)	assessment?: Y
		discussion.	study failure to	an): Not reported		Subject/providers
			achieve	Not reported		blind?: ?
			remission on	Number of		Outcomes
			HAM-D>8	antidepressa		assessed blind?: ?
				nts		Dropout rate <
			Exclusion	previously		30%?: Y
			criteria:	taken in		Differential
			- current or past	lifetime:		dropout rate
			psychosis, bipolar	Not reported.		< 10%?: Y
			disorder, or	Not reported.		Incomplete data
			substance abuse			addressed
						adequately?: Y
			- severe			4
			physical or			Conflict of
			physical or neurological conditions - no			Conflict of
			physical or neurological conditions			Conflict of
			physical or neurological conditions - no antidepressant treatment or inadequate			Conflict of interest?: N
			physical or neurological conditions - no antidepressant treatment or			Conflict of interest?: N Overall quality
			physical or neurological conditions - no antidepressant treatment or inadequate antidepressant treatment - high suicide			Conflict of interest?: N Overall quality
			physical or neurological conditions - no antidepressant treatment or inadequate antidepressant treatment			Conflict of interest?: N Overall quality
			physical or neurological conditions no antidepressant treatment or inadequate antidepressant treatment high suicide risk concurrent psychotherapy			Conflict of interest?: N Overall quality
			physical or neurological conditions - no antidepressant treatment or inadequate antidepressant treatment - high suicide risk - concurrent			Conflict of interest?: N Overall quality
			physical or neurological conditions no antidepressant treatment or inadequate antidepressant treatment high suicide risk concurrent psychotherapy or engagement in meditation or yoga			Conflict of interest?: N Overall quality
Fonagy et al	Persistent	Long-term	physical or neurological conditions no antidepressant treatment or inadequate antidepressant treatment high suicide risk concurrent psychotherapy or engagement in meditation or yoga practice	Age:	Assessments	Conflict of interest?: N Overall quality rating: poor
Fonagy et al 2015	Persistent Depression: DSM-IV	Long-term psychoanalyti	physical or neurological conditions no antidepressant treatment or inadequate antidepressant treatment high suicide risk concurrent psychotherapy or engagement in meditation or yoga	Age: [mean (SD)]	Assessments	Conflict of interest?: N Overall quality

diagnosis of	c		LTPP+TAU:	conducted at	blind.
Maj	psychotherap	Setting: Primary care	42.7 (10.4)	six, 12 and 18	Quality
depression as	y (LTPP)	-	TAU: 46.7	months over	assessment:
ascertained by	+TAU	Study design: RCT	(9.9)	the course of	Randomization
structured	consisted of			treatment and	adequate?: Y
clinical	60 (50	Number of participants	Sex:	at 24, 30 and	Allocation
interview;	minutes)	enrolled:	[Female, %]	42 months	concealment
minimum	sessions of	129	LTPP+TAU:	during follow-	adequate?: Y
duration of	once weekly	Duration of	66.7	up.	Baseline
two years;	individual	follow up: 2 years	TAU: 66.1		comparability?: Y
minimum	psychoanalytic	years		Complete	Valid outcome
score of 14 on	psychotherapy	Inclusion criteria:	Race/ethnicit	remission was	assessment?: Y
HDRS-17 and	over 18	- Age 18-65	y:	infrequent in	Subject/providers
of 21 on BDI-	months.	- Met criteria for DSM-IV	Not reported	both groups at	blind?: ?
II; and at least		MDD		the end of	Outcomes
two failed	Comparator	- 14> on HDRS- 17	Duration of	treatment.	assessed blind?:
treatment	TAU	- 21> on BDI-II	current	Partial	Y
attempts, one	TAU	- 2 failed treatment	episode in	remission was	Dropout rate <
of which must	consisted of	attempts one	years [mean	not	30%?: Y
have included	interventions	of which must be	(SD)]:	significantly	Differential
treatment with	as directed by	antidepresant	LTPP+TAU:	more likely in	dropout rate
an	referring	medication	3.7 (3.4)	the LTPP than	< 10%?: Y
antidepressant	practitioner.	Exclusion	TAU: 3.8	in the control	Incomplete data
medication		criteria:	(2.6)	group at the	addressed
and the other		 receiving psychodynami 		end of	adequately?: Y
either an		c	Previous	treatment. The	Conflict of
antidepressant		psychotherapy in the past two	failed	odds of partial	interest?: N
medication or		years	treatment	remission	
psychological		- currently, or in the past five	[Mean(SD)]:	increased for	Overall quality
intervention		years meeting	LTPP+TAU:3	both groups	rating: fair
		DSM-IV criteria for	.5 (1.4)	during the	
		psychotic	TAU: 3.9	review period,	
		disorder or bipolar	(1.8)	but was 40%	
		disorder		higher per six	
		- receiving psychiatric	Number of	month period	
		input for	antidepressa	for the LTPP	
		substance dependence in	nts	group.	
		the past two	previously		
		years - moderate or	taken in	Improvements	
		severe	lifetime:	in depression	
		learning disability or	Not reported.	were modest	
		evidence of		while	
		brain disorder		differences	
		ı			

Watkins et al 2011	Persistent Depression: DSM-IV criteria for major depression with residual symptoms reaching at least eight on HRSD and nine on BDI- II	Psychotherap y: rumination focused cognitive behavioural therapy (RFCBT). Consisting of 12 manualised individual sessions scheduled weekly or fortnightly.	Geographical location: United Kingdom Setting: multicenter CMHT in south-east London and Devon Study design: RCT Number of participants enrolled: 42 RFCBT: 21 TAU: 21 Duration of	Age: [mean (SD)] RFCBT: 43.05 (11.09) TAU: 45.24 (9.35) Sex: [Female, %] RFCBT: 67 TAU: 48 Race/ethnicit y: [Caucasian, %]	emerged from 24 months post randomisation with the LTPP group mostly maintaining the gains achieved while the control group appeared to be at greater risk of relapse. At two year follow-up almost one third of participants receiving LTPP were still in partial remission compared with only 4% of those in the control group. Rumination focused CBT group reported significantly fewer residual depressive symptoms post intervention compared with the TAU group, after co-varying initial level of baseline symptoms, for	Comments: some patients in TAU group were receiving psychological treatment follow-up. Does not report exact timeframe. Trial used a small sample limiting power to detect differences between groups and
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		Comparator:	follow up: post-	RFCBT: 95	both BDI-II	generalisability of
		TAU.	treatment	TAU: 95	and HRSD.	results. Very
			follow-up. Does	1A0. 93	and TIKSD.	,
			not report exact timeframe	Duration of	D	short-term
		ongoing		current	Participants in	follow-up of
		maintenance	Inclusion criteria:	episode in	the rumination	treatment results
		antidepressant	- Age 18+	years [mean	focused CBT	i.e. less than two
		medication	- Met criteria	_	group	years.
		and outpatient	for medication refractory	(SD)]:	improved	
		clinical	residual	Not reported	significantly	Quality
		management.	depression Residual		more than	assessment: Randomization
		Some patients	symptoms	Previous	those in the	adequate?: Y
		were receiving	reaching at	episodes of	TAU group.	Allocation
		psychological	least eight on the HDRS and	major		
		treatment	9 on BDI-II.	depression		concealment
		however none	- taking antidepressant	(mean (SD)):		adequate?: Y
		would receive	medication at	RFCBT:5.43		Baseline
		RFCBT	therapeutic dose and/or	(2.93)		comparability?: Y
		KICDI	equivalent	TAU: 4.84		Valid outcome
			225mg of	(3.02)		assessment?: Y
			amitriptyline for at least			Subject/providers
			eight weeks			blind?: Y
			continuously. Exclusion			Outcomes
			criteria:	Number of		assessed blind?: ?
			- history of	antidepressa		Dropout rate <
			bipolar	nts		30%?: Y
			disorder, psychosis,	previously		Differential
			current drug or	taken in		dropout rate
			alcohol dependence,	lifetime:		< 10%?: Y
			intellectual	Not reported.		Incomplete data
			disability, organic brain	F		addressed
			damage and			adequately?: Y
			concurrent psychotherapy			Conflict of
			at point of			interest?: N
			entry to study.			
						Overall quality
						rating: Poor
Harley et al.,	Persistent	Psychotherap	Geographical	Age:	Interviewer	Comments:
2008	Depression: Despite	y: Dialectical	location: Boston, MA	[mean] Total: 41.8	rated	Small sample
	stable,	Behavior	,		depression	sizes, limited
	adequate	Therapy	Setting: MHC; participants	Sex:	severity:	information
	medication	(DBT) Group	were referred by	[female %]		provided on
	treatment for	DBT based	outpatient providers.	Total: 75%	HAM-D at	samples' baseline
	MDD (as	depression		10mi. 15/0	baseline: [mean	characteristics,
	iiiDD (ds	acpression	Study design:			

determined by	skills group;	RCT	Race/ethnic	(SD)]	and confound of
consensus of	16 weekly	Number of	ity: [white (%)]	DBT: 16.15	individual
2 senior	sessions	participants	Total: 83%	(4.47)	therapy.
psychiatrists	lasting 90	enrolled: Total: 24		WL: 18.64	
with expertise	minutes each.	DBT: 13	Duration of	(4.72)	Quality
in MDD),		WL: 11	current		assessment: Randomization
patients still	Comparator: Wait List	Duration of	episode in	HAM-D at	adequate?: Y
met criteria	(WL)	follow up: 16	days: [mean	follow-up:	Allocation
for MDD on	Pts in this	weeks	(SD)]	[mean (SD)]	
the SCID-I.	group continued	Inclusion	DBT:	DBT: 11.30	concealment
	treatment as	criteria: - Age 18-65	201.00	(5.31)	adequate?: Y
	usual, which included	- Principal	(131.59)	WL: 17.11	Baseline
	taking	diagnosis of MDD on	WL: 292.40	(6.23)	comparability?:
	prescribed medications	SCID	(374.94)		Y
	and meeting	- Have an established		DBT group had	Valid outcome
	with psychiatrists	treatment	Number of	significantly	assessment?: Y
	and other	relationship with a	lifetime	lower HAM-D	Subject/provider
	providers as usual.	psychiatrist	antidepress	scores than WL	s blind?: N
		- Stabilized on adequate dose	ant trials:	(F=4.63;	Outcomes
		of	[mean (SD)]	p<.05;	assessed blind?:
		antidepressant medication	DBT: 3.31	D=1.45).	Y
		before	(1.70)		Dropout rate <
		entering study (no dosage	WL: 4.27	2) Self-	30%?: Y
		change for at	(2.45)	reported	Differential
		least 6 weeks before study		depression	dropout rate
		entry)	Number of	severity:	< 10%?: Y
			hospitalizati	severity.	Incomplete data
		Exclusion criteria:	ons: [mean	BDI at	addressed
		- Bipolar	(SD)]	baseline: [mean	adequately?:
		disorder - Psychotic	DBT: 0.85	(SD)]	Unknown
		spectrum	(0.99)	DBT: 27.31	Conflict of
		disorders - Active	WL: 0.27	(8.83)	interest?: N
		substance	(0.65)	WL: 27.44	
		abuse or dependence		(11.66)	Overall quality
		- Mental	Age at first	(11.00)	rating: Fair
		retardation - Pervasive	MDE:	BDI at follow-	
		developmental	[mean (SD)]	up: [mean	
		disorder - Active	DBT: 27.08	(SD)]	
		suicidality	(14.23)	DBT: 15.10	
		- Severe or unstable	WL: 25.18	(12.13)	
		medical	(15.20)	WL: 25.89	
		conditions		(16.30)	
		- Patients with previous or	Engaged in	(10.50)	
		current CBT	_ = =		

depression: Step 1: Medical Cognitive Therapy (CT) charts were screened for current adequate antidepressant use for at least 6 weeks. Step 2: BDI and Morisky Scale were mailed to this pool of potential pot	Wiles et al.,	Persistent	Psychotherap	experience Borderline Personality Disorder	concurrent non-CBT individual therapy: Total: 83%	DBT group had significantly lower BDI scores than WL (F=9.50; p<.01; D=1.31).	Comments:
adherence to antidepressant medications were invited for eligibility screening. Step 3: Patients were administered computerized version of the Revised Clinical Interview Schedule. If patients met ICD-10 criteria based on this, they were considered treatment resistant. Age 18-65 Met criteria for ICD-10 after screening indicated BDI ≥ 15 Duration of depressive episode in medication Duration of depressive episode in medication No significant dequate? Yallocation CT: 85.7% Duration of depressive episode in months: Duration of depressive episode in months: No significant dequate? Unknown CT: 85.7% Duration of depressive episode in months: Duration of de		depression: Step 1: Medical charts were screened for current adequate antidepressant use for at least 6 weeks. Step 2: BDI and Morisky Scale were mailed to this pool of potential participants. Patients who had BDI ≥15 and self- reported adherence to antidepressant medications were invited for eligibility screening. Step 3: Patients were administered computerized version of the Revised Clinical Interview Schedule. If patients met ICD-10 criteria based on this, they were considered treatment	y: Cognitive Therapy (CT) 12-20 sessions delivered over 4 months. Comparator: Usual care; although unrestricted, majority reported being on antidepressant medication at	location: United Kingdom Setting: Primary care Study design: RCT Number of participants enrolled: 25 Duration of follow up: 4 months Inclusion criteria: - Age 18-65 - Met criteria for ICD-10 after screening indicated BDI ≥ 15 - Adherent to medication Exclusion criteria: - Bipolar, psychosis, personality d/o, major substance abuse - Current or past cognitive therapy - Receiving secondary care for depression - Continual depression for more than 5 years - Inability to complete	(SD)] CT: 45.5 (12.8) Usual care: 45.1 (11.1) Sex: [female, n (%)] CT: 12 (85.7%) Usual care: 9 (81.8%) Race/ethnic ity: Not reported Duration of depressive episode in months: CT: 85.7% >1 year Usual Care: 81.8% >1 year Number of prior episodes of MDD:	rated depression severity Not administered 2) Self- reported depression severity: BDI: Regression coefficient=- 8.4, 95%CI: - 21.9, 5.1 No significant differences	Small sample sizes, limited information provided; lack of clinician administered measure limits conclusions. Usual care was unrestricted. Study was conducted as a pilot for a pragmatic RCT. Quality assessment: Randomization adequate? Y Allocation concealment adequate?: Unknown Baseline comparability?: Y Valid outcome assessment?: N Subject/provider s blind?: N Outcomes assessed blind?: Unknown Dropout rate <

<u> </u>			Г	Т	L 70.00
					Differential
					dropout rate
					< 10%?: N
					Incomplete data
					addressed
					adequately?: Y
					Conflict of
					interest?: N
					Overall quality
					rating: Poor
Thase et al., Persis depres		Geographical location:	Age: [mean (SD)]	1) Interviewer	Comments:
2007 Gepres		14 Regional	Switch to	rated	Due to
	ent with Therapy (CT)	centers across	CT: 43.4	depression	equipoise-
citalop mg/da	ram (20 16 sessions y to delivered	USA	(14.7) Augment	severity:	stratified
start, 4	0 twice weekly	Setting: 18-	CT= 40.6		randomization,
mg/day week 4		Primary Care, 23 MHC	(11.5) Switch	HRSD at start	<1/3 agreed to
maxim	weekly for 8		AD=41.5	of Level 2:	randomization.
potenti dosage		Study design: randomized	(13.3) Augment	[mean (SD)]	Low rates of
mg/day	y by	multistep	AD=39.7	Switch to CT:	psychotherapy
week 6	5) for 14 Switch to CT: Pts	clinical trial	(13.5)	16.4 (6.2) Augment CT:	acceptability are
patient		Number of	C	17.8 (5.7)	at odds with real
had H		participants	Sex:	Switch AD:	world experience
D≥14.	and began CT.	enrolled: Total: 304	[female, n	17.7 (6.6) Augment AD:	of the STAR*D
	Augment CT:	Switch to	(%)]	16.0 (6.7)	authors.
	Pts continued on citalogram	CT=36 Augment	Switch to CT: 22		audiois.
	and added CT.	CT=65	(61.1%)	Met remission	Baseline
		Switch AD=86	Augment	criteria on	
	Comparator: Antidepressan	Augment AD=117	CT: 41 (63.1%)	(HRSD≤7) at	differences in Augment CT
	t Medication	T	Switch AD:	end of Level 2:	
	(AD)	Duration of follow up: 14	53 (61.6%) Augment	Switch to CT:	more impaired &
	Switch AD:	weeks	AD: 78	25.0% Augment CT:	lower QOL than
	Pts discontinued	Inclusion	(66.7%)	23.1%	Augment AD
	citalopram	criteria:	Dec. 1.43	Switch AD:	and Switch to
	and began	- Age 18-75	Race/ethnic ity: [white,	27.9% Augment AD:	CT lower income
	bupropion, sertraline, or	- Non psychotic MDD	n (%)]	33.3%	than Switch AD.
	venlafaxine.	- HRSD17≥14	Switch to CT: 28		
	Augment AD:		(77.8%)	No significant	Numerous
	Pts continued	Exclusion criteria:	Augment CT: 52	differences	pharmaceutical
	on Pris continued	- Bipolar,	(80.0%)	between groups.	companies
	citalopram	schizophrenia, eating d/o,	Switch AD: 63 (73.3%)		supported the
	and added	OCD	Augment	2) Self-	project.
		- Hx of	AD: 99	reported	
	bupropion or	intolerability	(84.6%)	depression	Quality

		buspirone.	≥1 Anti-dep	Duration of	severity:	Randomization
		buspii one.	with adequate	depressive	severity.	adequate?: Y
			dosage	-	OTD 0 0 .	Allocation
			- ≥7 days Citalopram	episode in	QIDS-C at	concealment
			use prior to	months:	start of Level	adequate?: Y
			study enrollment	[mean (SD)]	2: [mean (SD)]	Baseline
			- non-	Switch to	Switch to CT:	comparability?:
			responsive ≥16	CT: 17.4 (31.2)	11.2 (4.3) Augment CT:	Y
			session of CT in current	Augment	11.9 (4.3)	Valid outcome
			MDD episode	CT: 29.6	Switch AD:	assessment?: Y
			- Medical	(49.4) Switch AD:	12.1 (4.6) Augment AD:	
			contraindicatio n	26.5 (54.0)	12.0 (4.6)	Subject/provider
			- Pregnant	Augment ADM: 20.0		s blind?: N
			females Requires	(47.5)	QIDS-C at end	Outcomes
			psychiatric		of Level 2:	assessed blind?:
			hospitalization,	Number of	[mean (SD)]	Y
			_	prior	Switch to CT:	Dropout rate <
			antipsychotics,	episodes of	9.1 (5.4) Augment CT:	30%?: Y
			or mood	MDD:	8.2 (5.1)	Differential
			stabilizers	[mean (SD)]	Switch AD: 9.1 (5.0)	dropout rate
				Switch to	Augment AD:	< 10%?: Y
				CT: 8.7 (18.8)	8.2 (4.8)	Incomplete data
				Augment	No significant	addressed
				CT: 7.3		adequately?: Y
				(14.1) Switch	differences	Conflict of
				ADM: 8.4	between groups.	interest?: Y
				(16.0) Augment		interest 1
				ADM: 4.6		Overall quality
				(5.4)		rating: Good
D11-h 6-	Danaistant	Danish o4h ouon	Geographical	A [1) Intonnion	_
Blackburn &	Persistent depression:	Psychotherap y:	location:	Age: [mean (SD)]	1) Interviewer	Comments:
Moore, 1997	Despite	Cognitive	Scotland	CT: 37.8	rated	Reviewers
	showing significant	Therapy (CT) 27 sessions	Setting: MHC;	(13.1)	depression	decided based on
	reduction in	delivered over	participants	AD: 40.1	severity:	data after 16
	depressive	2 years, with pts being seen	were recruited from outpatient	(12.7)		weeks of
	symptoms over 16 weeks	3 times in 1 st	referrals to		HRSD baseline	treatment that
	of treatment	month, twice	consultants in a	Sex:	after 16 weeks	samples met
	with antidepressant	in 2 nd month, and monthly	large teaching psychiatric	[female, n	acute med	criteria for
	medication of	thereafter.	hospital and	(%)]	treatment:	persistent
	the general practitioner's	Comparator:	from 2 general practices.	CT: 17/22	[mean (SD)]	depression.
	choice	Antidepressan	•	(77%)	CT: 11.8 (6.3)	
	(prescribed at or above	t Medication (AD)	Study design: RCT	AD: 17/26	AD: 10.6 (6.8)	ANCOVAs
	therapeutic	Maintenance		(65%)		compared 3
	doses),	l	Number of	(05/0)	HRSD	groups, not just
		AD was of	narticinante		IIKSD	groups, not just
	patients on average continued to	AD was of general	participants enrolled: Total: 37 (48	Race/ethnic	interpolated	the 2 groups of

	have	practitioner's	initially)	Not given	over 24 months	interest.
	depressive	choice	CT: 17 (22		follow-up:	11101030.
	symptoms in		initially)	Duration of	_	250/ rotanti
	the moderate range on the	(tricyclics,	AD: 20 (26 initially)	current	[mean (SD)]	35% retention
	BDI and	MAOIs,		episode in	CT: 8.6 (5.6)	for CT and 25%
	above the traditional cut	SSRIs), as	Duration of follow up: 24	months:	AD: 9.3 (7.2)	retention for AD.
	point of 11 on	long as	months	[mean (SD)]		
	the HAM-D.	prescribed at		CT: 7.0	ANCOVA	Quality
		or above	Inclusion criteria:	(1.4)	showed no	assessment: Randomization
		recognized	- Age 18-65	AD: 6.9	significant	adequate?: Y
		maintenance	- Diagnosis of primary major	(1.3)	difference	Allocation
		dose.	unipolar	(1.5)	between	concealment
			depression, non-psychotic	Number of	treatments	adequate?: Y
			- Score of at		(F=0.31; d.f.=2,	Baseline
			least 16 on	prior	55; NS).	
			HRSD - Current	episodes:		comparability?:
			episode had to	[mean (SD)]	2) Self-	Y
			be at least second MDE	CT: 4.1	reported	Valid outcome
			Second WiDE	(3.4)	depression	assessment?: Y
			Exclusion	AD: 3.2	_	Subject/provider
			criteria:	(2.2)	severity:	s blind?: N
			- Having another		DDII II	Outcomes
			primary Axis I	Number of	BDI baseline	assessed blind?:
			disorder - Organic brain	hospitalizat	after 16 weeks	Y
			damage	ions: [mean	acute med	Dropout rate <
			- History of bipolar illness	(SD)]	treatment:	30%?: N
			- Alcohol or	CT: 0.7	[mean (SD)]	Differential
			drug misuse	(0.9)	CT: 20.4 (11.1)	dropout rate
			- Could not be prescribed	AD: 0.8	AD: 19.7 (14.2)	< 10%?: N
			antidepressant	(2.3)		Incomplete data
			medication for medical	,	BDI	addressed
			reasons	Number of	interpolated	adequately?: Y
			Unwilling to be	suicide	over 24 months	Conflict of
			randomly	attempts:	follow-up:	interest?: N
			allocated to	[mean (SD)]	[mean (SD)]	mulcst:. 19
			treatment		CT: 14.2 (9.9)	O11 - 1''
				CT: 0.4	AD: 18.1 (13.1)	Overall quality
				(0.7)		rating: Poor
				AD: 0.9	ANCOVA	
				(1.9)	showed no	
				*Data based	significant	
				on initially	difference	
				enrolled	between	
				participants.	treatments	
					(F=0.72; d.f.=2,	
-		· · · · · · · · · · · · · · · · · · ·	107			

		53; NS).	

Appendix 4 Submission Guidance for Community Mental Health Journal

Manuscripts should be submitted in Word.

- Use 10-point Time New Roman font for text
- Use italics for emphasis
- Use the automatic page numbering function to number the pages
- Do not use field functions
- Use tab stops or other commands for indents, not the space bar
- Use the table function, not spreadsheets, to make tables
- Save your file in doc format. Do not submit docx files.

Adhere to Journal style and include the following sections: Abstract, Introduction, Methods, Results, Discussion, and References.

All studies must be approved by human subjects committees (also known as institutional review boards). At the end of the Methods section, authors must state which human subject committee (institutional review board) approved the study.

The title page should include:

- The names(s) of the author(s)
- A concise and informative title
- The affiliation(s) and address(es) of the author(s)
- The e-mail address, telephone, and fax numbers of the corresponding author

Please provide an abstract of 100 to 150 words. The abstract should not contain any undefined abbreviations or unspecified references.

Please provide 4 to 6 keywords which can be used for indexing purposes.

Limit Articles to 16 pages of text, exclusive of references, tables, and figures. Brief Reports should be no longer than 10 pages of text, and should not include any tables or figures.

Abbreviations should be defined at first mention and used consistently thereafter.

Tables:

- All tables are to be numbered using Arabic numerals
- Tables should always be cited in text in consecutive numerical order
- For each table, please supply a table heading. The table title should explain clearly and concisely the components of the table.
- Identify any previously published material by giving the original source in the form of a reference at the end of the table heading.
- Footnotes to tables should be indicated by superscript lower-case letters (or asterisks for significance values and other statistical data) and included beneath the table body.

For the best quality final product, it is highly recommended that you submit all of your artwork – photographs, line drawings, etc. – in an electronic format. Your art will then be produced to the highest standards with the greatest accuracy to detail. The published work will directly reflect the quality of the artwork provided.

References

List alphabetically, adhering strictly to APA style (Publication Manual of the American Psychological Association, 4th or 5th edition). Authors are responsible for providing accurate references.

Conflict of Interest

Authors must address possible conflicts of interest which can include (a) consulting fees or paid advisory boards for the past two years or known future; (b) equity ownership and-or stock options in publicly or privately traded firms; (c) lecture fees from speaking at the invitation of a commercial sponsor, for the past two years or known future; (d) employment by the commercial entity that sponsored the study; or (e) patents and/or royalties from, service as an expert witness to, or performance of other activities for an entity with a financial interest in this area. Authors should include a sentence toward the end of the Methods section listing possible conflicts of interest or stating that there are no known conflicts of interest.

Authors must certify their responsibility for the manuscript. In so doing, the authors certify (a) that they accept responsibility for the conduct of the study and for the analysis and interpretation of the data, (b) that they helped write the manuscript and agree with the decisions about it, (c) that they meet the definition of an author as stated by the International Committee of Medical Journal Editors, and (d) that they have seen and approved the final manuscript. In certifying responsibility for the manuscript, authors also certify that neither the article nor any essential part of it, including tables and figures, will be published or submitted elsewhere before appearing in the Journal. Authors should include a sentence at the end of the Methods section saying that all authors certify responsibility.

Permissions

Authors wishing to include figures, tables, or text passages that have already been published elsewhere are required to obtain permission from the copyright owner(s) and to include evidence that such permission has been granted when submitting their papers. Any material received without such evidence will be assumed to originate from the authors.

Supplements

The Journal is dedicated to rapid dissemination of research on therapeutic treatments or preventive interventions. Supplements to the Journal can be used to publicize findings newly presented at conferences or symposia.

Please contact the Managing Editor for information about supplemental issues of the Journal.

Appendix 5 Ethical Approval

From: psychethics

Sent: 15 December 2016 10:43 **To:** Brian Pert; Dougal Hare

Subject: Ethics Feedback - EC.16.11.08.4751

Dear Brian

The Ethics Committee has received the copy of your project proposal: Evaluation of the introduction of pilot Family Liaison Meetings (FLM) to two inpatient Rehabilitation and Recovery units.

The Committee has noted that the proposal has already received ethical approval from the NHS in November 2014 (IRAS: 164143) and an amendment was approved in November 2016.

The proposal has been registered on our database, and has been given the following reference number: EC.16.11.08.4751.

If any changes are made to the above project please notify the Ethics Committee quoting the above reference.

Best wishes, Mark Jones Part of the research infractructure for Wales funded by the National Institute for Social Care and Health Research, Welch Government.

Ye than a sell-waith yearly of Cymru a ariannir gan y Sefydliad Canadiaethol ar gyfer Ymchwil Gofal Cymdeithanol ac leddyd, Llywodraeth Cymru



Wales REC 8 Floor 8 38 Orohard Street Swansea SA1 6AG

Telephone : 01782 807418

Fax: 01792 607533 E-mail: penny.beresford@wales.nhs.uk

Website: www.nres.nhs.uk

21 November 2014

Dr Andrea Davies
Chief Investigator (Clinical Psychologist)
Abertawe Bro Morgannwg University Health Board
Colty Clinic
Princess of Wales Hospital
Bridgend
CF31 1RQ

Dear Dr Davies

Study title: Evaluation of the Introduction of the pilot Family Liaison

Meetings (FLM) to two inpatient Rehabilitation and Recovery units within Abertawe Bro Morgannwg

Universify Health Board.

 REC reference:
 14/WA/1228

 Protocol number:
 Project Teulu

 IRAS project ID:
 164143

The Research Ethics Committee reviewed the above application at the meeting held on 19 November 2014. Thank you for attending to discuss the application.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details, unless you expressly withhold permission to do so. Publication will be no earlier than three months from the date of this favourable opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to make a request to postpone publication, please contact the REC Manager Ms Penny Beresford, penny.beresford@wales.nhs.uk.

The members of the Committee present gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

- The Information sheet should refer to Wales REC 6 as having reviewed the study.
- The Information sheet should explain what is going to happen to the data and tapes once transcribed.



Cynhelir Cydweithrodiad (hwyddor Iochyd Academaidd y Sefydliad Cenedlaethol ar gyfer Ymchwil Oofid Cymdeithasol ac lochyd gan Pwrdd Addysgu Iechyd Powys

The National Institute for Social Care and Health Research Academic Health Science Collaboration is hosted by Powys Teaching Health Board



- The Information Sheet should include a sentence that the study is open to audit and inspection.
- The Consent Form should ask participants to just initial rather than only initial those to which they agree.

You should notify the REC in writing once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which can be made available to host organisations to facilitate their permission for the study. Failure to provide the final versions to the REC may cause delay in obtaining permissions.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the integrated Research Application System or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations.

Registration of Clinical Trials

All clinical trials (defined as the first four categories on question 2 of the IRAS filter page) must be registered on a publically accessible database within 6 weeks of recruitment of the first participant (for medical device studies, within the timeline determined by the current registration and publication trees).

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to contest the need for registration they should contact Catherine Biewett (catherinebiewett@nhs.net), the HRA does not, however, expect exceptions to be made. Guidance on where to register is provided within IRAS.

It is the responsibility of the sponsor to ensure that all the conditions are compiled with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites

NHS Sites

The favourable opinion applies to all NHS sites taking part in the study taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Summary of discussion at the meeting

Other general comments

It was noted that the study will be open to audit and inspection – the Committee agreed that this should be mentioned in the information Sheet.

The Committee asked what would happen to the data and whether you intended storing the transcripted material and tapes.

It was confirmed that you would be storing both. The Committee agreed that participants should be made aware of what happens to the data and tapes and this should be included in the information sheet.

The documents reviewed and approved at the meeting were:

Document	Version	Date
Covering letter on headed paper [Covering letter]	1.0	29 October 2014
Interview schedules or topic guides for participants [Teulu - Interview schedule family member/service user]	1.0	30 October 2014
Interview schedules or topic guides for participants [Teulu Interview Schedule Health Professionals]	1.0	30 October 2014
IRAS Checklist XML [Checklist_03112014]		03 November 2014
Letter from funder [Davies, Andrea Pathway to Portfolio Award]	1.0	23 July 2014
Participant consent form [Teulu Participant Consent Form]	1.0	30 October 2014
Participant Information sheet (PIS) [Teulu Participant Information Sheet]	1.0	30 October 2014
REC Application Form [REC_Form_03112014]		03 November 2014
Referee's report or other scientific critique report [TEULU JSRC approval letter]	1.0	06 June 2014
Research protocol or project proposal [Teulu Protocol]	1.3	20 October 2014
Summary CV for Chief Investigator (CI) [Andrea Davies CV]	1.0	14 May 2014
Summary, synopsis or diagram (flowchart) of protocol in non technical language [TEULU Study Summary]	1.0	27 October 2014

Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

After ethical review

Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

Notifying substantial amendments

Z/ETHICS/CORRESPONDENCE/2014 correspondence/14 WA 1228 Fav Opinion letter(A Davies/21-11-14) doc

- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Training

We are pleased to welcome researchers and R&D staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

14/WA/1228

Please quote this number on all correspondence

With the Committee's best wishes for the success of this project.

Yours sincerely

PΡ

Prof Roy L. Evans

Chairman

E-mail: penny.beresford@wales.nhs.uk

Enclosures: List of names and professions of members who were present at the

meeting and those who submitted written comments

"After ethical review - guidance for researchers"

Copy to: Anne-Claire Owen, ABMU Health Board

Appendix 6 Participant Information Sheet







Participant information Cover Letter

Evaluation of the introduction of pilot Family Liaison Meetings (FLM) to two inpatient Rehabilitation and Recovery units within Abertawe Bro Morgannwg University Health Board (Project Teulu)

My name is Brian Pert and I am a Trainee Clinical Psychologist on the South Wales. Doctorate in Clinical Psychology, Cardiff University.

I would like to invite you to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the additional participant information sheet.

I am supervised for this research project by a Clinical Supervisor, Dr Andrea Davies and an Academic Supervisor, Dr Dougal Hare.

Clinical Supervisor:

Dr Andrea Davies, Clinical Psychologist and Systemic Psychotherapist, Cotty, Clinic -Adult Mental Health Unit, Princess of Wales Hospital, Cotty, Road, Bridgend, CF31 1RQ, Email: Andrea Davies (Dwales Inhs. uk

Academic Supervisor:

Dr Dougal Hare, Consultant Clinical Psychologist and Research Director, School of Psychology, Floor 11, Tower Building, 70 Park Place, Cardiff. CF10 3AT. Email: Hared@cardiff.ac.uk

What will happen to the findings of the study?

This study will be written up as a Doctoral Project and submitted as part of the Doctorate in Clinical Psychology. It is hoped that the study will be written up for publication in a journal.

If you would like a summary of the Doctoral Project following completion of the study, please contact me via email: Perto@cardiff.ac.uk

Thank you for considering taking part in this study and for taking the time to read this information sheet

Participant Information Sheet (Version 1.2/19.09.2016)





Evaluation of the introduction of pilot Family Liaison Meetings (FLM) to two inpatient Rehabilitation and Recovery units within Abertawe Bro Morgannwg University Health Board (Project Teulu)

We invite you to take part in a research study.

- Before you decide whether to take part it is important for you to understand why the research is being done and what it will involve.
- Please take time to read the following information carefully. Discuss it with someone if you wish.
- You are free to decide whether or not to take part in this study. If you choose to take part you are free to withdraw at any point.
- Please feel free to ask the study lead, Andrea Davies (details below), if there is anything that is not clear or if you would like more information.

Important things that you need to know.

- We want to find the best way to deliver meetings between patients, their family members and the care team. These meetings are called Family Liaison Meetings or FLM.
- We will be carrying out interviews to explore views and experiences of people involved in these meetings.
- Taking part in this study will not affect any other aspects of your care or work.
- You can withdraw from the study at any time without explanation.
- This study is being carried out by Abertawe Bro Morgannwg University Health Board (ABMU)

Contents

- 2. Why are we doing this study?
- 2. What is involved in this study?
- 3. What would taking part involve?
- 3. What are the possible benefits of taking part?
- 3. What are the possible disadvantages or risks of taking part?
- 3. Is there any further information?
- 4. I would like to take part in the study, what do I need to do now?

How to contact us?

If you have any questions about this study, please contact:

Chief Investigator, Andrea
Davies on 01656752269
Andrea.Davies@wales.nhs.uk

Why are we doing this study?

Research and government policy have emphasised that involving family members in the everyday care of service users is very important. We are looking at the best way to do this and have chosen to use Family Liaison Meetings or FLM. These meetings involve service users, family members and the care team discussing how to best support each other in the everyday care of the service user. The benefits of these meetings have been shown in the care of inpatients in Somerset. We would like to see how useful the FLM meetings are in Rehabilitation and Recovery adult mental health services in Bridgend and Swansea. We are interested in the views of people who have taken part in the meetings. As part of the study we will be speaking to serviceusers, family members and staff.

What is involved in this study?

This study will be carrying out interviews with service-users, family members and staff who have been involved in FLM. We will be looking at:

- What makes the meetings difficult or easier?
- What is helpful or unhelpful about the meetings?
- Who will benefit most from taking part in FLM?
- Which types of staff are most suitable for delivering the FLM (e.g. support staff, psychologists or nurses amongst others)?

The Family Liaison Meetings will involve talking about:

- Gathering information about who is in the family and the household.
- Explore the family's explanation of the service users' difficulties.
- Explore the impact of the problem on the family.
- Explore what is expected in the future.

 Provide support and practical help.

As part of this study we will be interviewing service users, family members and staff members. A total of 26 people will be interviewed.

YOU CAN STILL
TAKE PART IN
THE FAMILY
LIAISON
MEETINGS IF YOU
DO NOT WANT
TO TAKE PART IN
THE STUDY

What would taking part involve?

Taking part would involve agreeing to participate in an interview and completing a consent form which you will need to sign ahead of being interviewed. If you agree your information will be passed to the research team who will contact you to arrange the interview.

This interview will involve being asked questions by a researcher and you responding to these question. The interview will last no longer than 1 hour. The interview will take place either face-to-face or over the telephone, at your convenience. If face-to-face, they will be conducted at the Rehabilitation and Recovery Unit in Bridgend. The interview will involve answering questions about your views and experiences of taking part in the FLM. It is entirely up to you which questions you answer and how much or how little you say.

With your permission, the interview will be audio recorded and a written version will be made for analysis purposes (transcribed). The written version will be anonymised. At the point of transcription all identifying information will be replaced with false information. You will be paid any 'out of pocket' expenses incurred.

What are the possible benefits of taking part?

We cannot guarantee that taking part in the study will be of personal benefit to you. However, you will be taking part in a study that is aimed at developing and improving the way that mental health services work with patents and their families.

What are the possible disadvantages or risks of taking part?

People sometimes find it uncomfortaphoto talk to someone they don't know, but our researchers are experienced at speaking to people and you will probably get use to talking to them quite quickly.

You will be required to give up some of your time, however the researcher will talk with you at a time that is best for you.

If you had a difficult time in your family liaison meeting, you might not be sure about talking to us about it. We are still interested in your view because it is important to us to be able to improve the way that we offer the family liaison meetings in adult mental health services.

Is there any further information?

What if I want to leave the study?

You can leave the study at any time. If you do want to leave the study you should contact the Chief Investigator, Andrea Davies on 01656 752269 or andrea.davies

How will my information be kept confidential?

The study will follow ethical and legal guidelines to make sure that all data stays confidential. That means that no-one will know that you have taken part in the study. Your conversation will be anonymised. That means that you name will not be on the written account of the conversation that you have with the researcher. Any information you give us will be kept safe. It will be locked away at the health board and at Swansea University. Information will be kept on a computer which will be protected by a password. Only people involved in the study will have access to this. All of your contact details will be kept separately to any information you provide during the interviews. All recording of interviews will be transferred to a secure computer and will be password protected. The original recording will be deleted from the recording device.

The type of research that we are doing means that when we write about the study findings, we might use quotes from what people have said to us. Your name will not be linked with any quotes that are taken from your conversation. Any names that are used, will be pseudonyms (false names).

It is possible that during the interview you may discuss something which suggests harm may come to yourself or someone else. If this happens the researcher will be obliged to report this to firstly the research team and possibly the care team. This is to ensure no undue harm come to anyone.

Who has approved this study?

The study has been reviewed and approved by the Wales REC 6, as well as the Joint Scientific Review Committee of the ABMU LHB Research and Development Department.

The study is open to audit and inspection.

How is this study funded?

This study has been funded by the ABMU Pathway to Portfolio fund.

What will happen to the results of the study?

A final report will be written, as well as a summary of the findings. You will be asked if you would like a copy of the summary sent to you. We also hope to write about the study for journal publication, so that we can share the research with other mental health professionals around the country.

No information, which can be directly traced back to you, will be included in any report or publication.

Can I speak to anyone who is not part of the study to discuss taking part or make a complaint?

Yes, you can contact Anne-Claire Owen who is part of the Research and Development department in ABMU, on 01792

Appendix 7 Participant Consent Form

Participant Consent Form (Version 1.1/19.09.2016)





Evaluation of the introduction of pilot Family Liaison Meetings (FLM) to two

Inpatient Rehabilitation and Recovery units within Abertawe Bro Morgannwg University Health Board (Project Teulu)				
Participant	t ID: Date:			
Please initia which you a	I the box if you agree to the following statements. Please only initial thos gree:	e to		
1.	I confirm that I have read and understand the Information Sheet (version 1.2 19.09.2016) for the above project and have had the opportunity to ask questions and have had these answered satisfactorily.			
2.	I confirm that I have had sufficient time to consider whether or not I want to participate in the project.			
3.	Lagree to participate in an interview to discuss my views and experiences of Family Liaison Meetings (FLM).			
4.	I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason and without my care or legal rights being affected.			
5.	I agree that the information provided can be used for educational and research purposes including publications and presentations.			
6.	I have been assured that confidentiality of my information will be protected as specified by the information sheet and my data will be stored carefully.			
7.	I agree to the interview being recorded and transcribed.			
8.	I understand that data will remain anonymous and agree to the use of anonymised quotations being used in any study outputs.			
9.	I agree to take part in the above project.			

Name of participant (printed)	Date	Signature
Name of person taking consent (printed)	Date	Signature
	-	

If you have any questions or concerns, contact

Andrea Davies, Chief Investigator (ABMU Health Board)
01656 752269, andrea.davies@wales.nhs.uk

Interview Schedule Health Professionals (Version 1.0/30.10.14)





Evaluation of the introduction of pilot Family Liaison Meetings (FLM) to two inpatient Rehabilitation and Recovery units within Abertawe Bro Morgannwg University Health Board (Project Teulu)

Participants will be contacted to arrange a convenient day/time. Explain to the participant that the purpose of the interview is to explore the participant's views and experiences of taking part in the Family Liaison Meetings (FLM)

Also include: "Your information will be very valuable/helpful and inform us of things we don't know and therefore I would like to speak to you uninterrupted for up to one hour".

Confirm the participant is happy to take part in the interview and that they are happy for the interview to be recorded. Ensure this is recorded on the recorder.

Ensure that consent form v 1.0 has been completed.

- Could you tell me about when you were first approached to take part in the Family Liaison Meetings?
 - a. Who spoke to you?
 - b. What were the circumstances?
 - c. How did you feel about this?
- 2. Could you tell me about the training you received for the FLM?
- 3. Was there anything that was particularly useful in the training?
- 4. Was there anything that wasn't particularly useful in the training?
- How many FLMs have you been involved with?
- 6. Could you tell me about your role in setting up the meetings?
- Could you tell me about any barriers to setting up the meetings?
 - Family travel.
 - family or service-user not wanting to participate.
 - c. time or resources
 - d, other service issues.

8.	Could you tell me about anything that helped with setting up the meetings? a. Support from others b. Family or service users wanting the meetings
9.	Could you tell me about the way the meetings were facilitated? a. Ask them to use an example of a meeting.

- 10. Is there anything you would want to change about the way the FLM is delivered?
- 11. What impact do you think the FLM has had on a) service-users b) family members c) staff involved. Why?
- 12. What are your views on using FLM in a rehabilitation and recovery setting?
- 13. Which health professionals do you think are best suited to facilitating FLM? Why?

Ask participant if there is anything else they would like to discuss.

Thank the participant and emphasise that if they wish to speak to anyone they can talk to either the researchers whose details are in the information sheet or a member of the care team.

End of interview schedule.

Why?

Appendix 9 Transcript Excerpt and Coding

Can you tell me your experiences of family

liaison meetings?

Family liaison meetings are important because it gives permission to ask more in-depth questions rather than superficial stuff. I think it's important most their time was about discussing family members and about their time discussing how this affects them. It allows them to tell their story.

What do you think are the benefits of that?

One: is the first time anyone's ever been interested in us and how this is affecting us as a family. Two: you gather loads of information that you never had. Three you've got more of an understanding of how things get to a certain point and gives you more empathy by understanding a little bit more of the background to lots of things.

At times the family members got a bit upset and they brought things out that they've maybe forgotten about even that turned into positives and it was something that they needed to talk about may have forgotten it was there.

Opportunity to ask questions

Different types of conversations

Family perspective

Families experience of services Listened to

Information gathering

Understanding client's problems
Family perspective
Increased empathy
Understanding client's problems

Emotive

Thinking about the training that you had for running the family liaison meetings what did that consist of?

The most we got out of the training was confidence building. I found most of the time when we are in training the facilitators would start us off on something and then sit back and all of a sudden you'd be thinking hang on they are sat over there now and we are talking, what's that all about? It was more thought-provoking getting us to think about things in our group. That allowed our service to have more ownership over it and once we'd been on training we decided that we would develop a prompts sheet for running the meetings so that we could put our own stamp on it

What impact do you think family liaison meetings have had on service users?

A massive impact. Because as I said in one it has got them talking to one another, so that is move the people on it might never have happened if it wasn't for family liaison meetings the fact that they felt comfortable to sit down in front of us and say these things to one another. Two: It's given us information in a quicker form which wouldn't have happened if we hadn't had

Lack of confidence/confidence

Concepts in mind

Ownership

Embedding FLM in service

Ownership

Improved communication between client and family

Trust

Forthcoming with clinical information

Different types of conversations

the family liaison meetings. Three: its allowed us to get to know the family relations with them a lot quicker and build rapport, than if we had been seeing them for 10minutes once a week or in an MDT situation because if you've ever been in someone's MDT is so formal and so scary for everybody that's involved that I don't think they ever feel that they are at a point where they are going to start sharing something really personal in front of all these professionals.

We sometimes have had to moderate between families to a degree but nothing out of hand. Sometimes we check out things and say just be careful... This must be difficult for you to hear.

What has helped set up the meetings?

The relatives have been a great support. When we've asked them I think has only been the one with me that has cancelled and not wanted to do it, the others have been fully on board and said yes we would like to be part of this and involved in their care. The relatives have been great we've done all we can to facilitate meeting. The relatives have been great and our line manager at the time said if there is a meeting going ahead

Building rapport with family

Formal meetings

Managing difficult interactions

Emotive

Families not wanting meetings

Active involvement in care and treatment

certain time I'll try my best to rotor you on and she did.

Because staffing issues have been a bit low recently we haven't had that days... Because before it used to be FLM on the rotor to say not in the numbers but now if I'm on and to say let's go and do it if the relatives are on board.

It has been more difficult to run the meetings with the staff shortages.

We have two members of staff to run the meetings. We are trying to book one in the next two weeks which means I'm gonna be out the numbers for a couple of hours and I know that I will ask the nurse if it's okay for me to be out the numbers.

Before we are running on higher levels of staffing service absolutely fine tried someone on for that day but now it's just when we can do and we try our best to the meet with the family.

What are the barriers to running the meetings?

There were no barriers really. I think the meetings have lasted roughly around 1 ½ two hours I think but I know I have had to come in for one of them when I wasn't rota on but didn't mind doing it just because timing can be an

Flexible working

Management

Flexible working

Staffing levels

Staffing levels

Organisation/planning

issue because they work 9 to 5 and we are on shiftwork. And if I don't then can't meet with them and I do like to be part of them if I can.

Staffing levels

Time constraints

Is there anything that you would like to change about the way family liaison meetings are delivered?

No I would like to do more but staffing can be an issue but that's the only thing. I would like to have time out to do it. Our band six will try her hardest. But is just the time out to actually do it because a lot of the time we don't actually have the time.

Time constraints

Flexible working
Time constraints

Flexible working. Staffing levels

They've got rid of overtime since September and we can't use agency now so some days one shift we might just work one nurse and if it's one nurse we can't do anything really. Yet the health board is having an impact on running these meetings.

Time constraints
Time constraints
Staffing levels
Staffing levels

Staffing levels

Could you give me some examples of the meetings that you facilitated what something stood out?

The one meeting I said about where the patient was giving all this information about boyfriend

Information Gathering
Forthcoming with clinical information

Risk

giving her the illicit substances and a split afterwards and in the same meeting she said she had taken an overdose in that same week with paracetamol and she said that she went to the Tesco's down the road and just bought them all. And that was significant because of I don't think she would have ever have told us that she did it four days before and she would have never told us that if it wasn't for the meeting so that was significant and that changed our assessments and how we look at the patient. Even though the meetings are the family's time to talk about what they want to I have felt able to ask questions that maybe I wouldn't have felt comfortable asking outside of these meetings. I think it's because the meetings show the family we are genuinely interested and care and we are asking these questions because of that...

What impact do you think family liaison meetings have had for family members?

I think they are more open with us. They trust us and give us more information. It leads to improved communication between them and us. After a few I did one in particular with the mum getting quite emotional I feel that she was more open with us and trust us a little bit more after

Risk

Forthcoming with clinical information

Trust

Risk

Opportunity to ask questions ordinarily wouldn't

Staff Care

Trust

Forthcoming with clinical information

Improved communication between families and staff

Emotive

Trust

Forthcoming with clinical information

giving us that little bit more information and there was a lot of stuff that she said that we didn't know about previous stuff. I didn't realise how difficult it had been for them both. And I could really empathise then. And there was one time we were querying whether this patient was suffering from a mental illness because he didn't give us any of the positive or negative symptoms but then when she was giving us all of this information I was just shocked really because I didn't know how unwell he had been. So just gave a completely different picture.

Information gathering

Empathy

Forthcoming with clinical information

Appendix 10 Code Transformation

64 tentative codes were established as per stage 2 of Thematic Analysis (Braun & Clarke, 2006). These became reduced to 42 codes upon further grouping and refinement as part of the analysis process (Stage 3 of Thematic Analysis). These 42 codes clustered around 6 sub theme, allowing for the defining and naming of 2 overarching themes (Stage 5 of Thematic Analysis).

Tentative Codes (64)	Code (42)	Sub Themes (6)	Themes (2)
Work as a team/collaborating	Staff Care	Relational	Repositioning of
		Positioning	Families within
			Mental Health
			Services
Usefulness of training	Families listened to	Service Level	Enhancing
		Repositioning	Understanding
Job role	Improved	Everyday Practices	
	communication		
	between families		
	and staff		
Lack of confidence/confidence	Family	Change to	
	empowerment	Professional	
		Practice	
Demand for family work	Families placed in	Witnessing	
	control		
Informal work	Including the family	Contextualising	
	perspective	Lives	
Increased awareness of family	A different		
issues	experience of mental		
	health services		
Role-play	Families maintaining		
	contact with services		
Ownership	Families valued by		
	professionals		
Reflective space	Job role		
Staffing levels	Flexible working		
Formal meetings	Change in ethos		

Supervision	Value families in	
	recovery	
Time constraints	Under resourced	
Concepts in mind	Time	
Organisation/planning	Team	
	communication	
Opportunity to talk	Overcoming stigma	
Listened to	Problem solving for	
	families	
Management	Maintaining normal	
	family life	
Valued by the team	Service supporting	
	families	
Information gathering	Families actively	
	involved in care	
Flexible working	Staff being less	
	judgmental	
Team communication	Team collaboration	
Communicating meetings to	Less directive	
families		
Less directive	Keeping family	
	work concepts in	
	mind	
Families in control	Increased confidence	
Active listening	Opportunity to ask	
	questions ordinarily	
	wouldn't	
Understanding client's problems	Holding multiple	
	perspectives	
Family perspective	Increased empathy	
Self awareness of professional	Self awareness and	
practice	reflectivity	
Increased empathy	Opportunity to talk	
Less judgemental	Different type of	

	family conversations	
Holding multiple perspectives	Emotive meeting	
Empowerment	Change in family	
	dynamics	
Respected by professionals	Improved	
	communication	
	between family and	
	clients	
Opportunity to ask questions	Information	
	gathering	
Improved communication	Having the family	
between client and family	perspective	
Improved communication	Understanding the	
between family and	clients problems	
professionals		
Families experience of services	Families opportunity	
	to talk	
Trust	Trust	
Families view professionals as	Risk	
caring		
Active involvement in care and	Family more	
treatment	forthcoming with	
	clinical information	
Maintaining contact with		
service		
Changes in service provision		
Maintaining normal life		
Forthcoming with clinical		
information		
Risk		
Different types of conversations		
Emotive		
Confidentiality		
Problem solving		

Environment		
Embedding FLM in service		
Timing of meetings		
Staff attitude/dedication		
Overcoming stigma		
Suitable staff to run FLM		
Service supporting family		
Family supporting service user		
Building rapport with family		
Managing difficult interactions		
Change in patient care		
Families not wanting meetings		
Service users not wanting		
meetings		
Appreciation		

Appendix 11 Thematic Maps

