

# Group-Based Acceptance and Commitment Therapy and Long-Term Conditions: A Quantitative Exploration of Effectiveness

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Wales Programme in Clinical Psychology

## Summary of Thesis

Approximately a quarter of people with a long-term condition experience a comorbid mental illness. This can result in poor clinical outcomes, quality of life and prognosis. Cost-effective psychological interventions which can improve outcomes are required. Although empirical support for Acceptance and Commitment Therapy (ACT) has been growing in the last ten years, reviews in the context of group-based ACT are lacking.

Paper 1 presents a systematic review of randomised-controlled trials of group-based ACT for adults with long-term conditions. PsycINFO, MEDLINE and Web of Science databases were electronically searched and twelve studies met the inclusion criteria. Study quality was assessed and study outcomes are summarised across a range of domains including depression, anxiety, quality of life and disability. Overall, findings suggest that group-based ACT appears to be more effective than waiting list controls and as effective as other psychological interventions.

Paper 2 presents a randomised pilot study of group-based ACT for stroke survivors. To the authors' knowledge, this is the first randomised study of group-based ACT with stroke survivors. Fifty-three participants (60% male; mean age: 63 years) were randomly assigned to group-based ACT or to a treatment as usual (TAU) group. The ACT intervention consisted of four weekly 2-hour group sessions. Measures were completed at pre-treatment, post-treatment and two month follow-up. Results found that compared to participants in the TAU control, group-based ACT significantly reduced depression and increased self-rated health status and hopefulness in stroke survivors, with medium effect sizes. Significantly

more participants reached clinically significant change of depression in the ACT intervention in comparison to the control group.

Paper 3 is not intended for publication and consists of a critical appraisal of the research process. Strengths and limitations of the research are discussed, as well as implications for future research, theory and clinical practice. Personal-professional reflections are offered.

## Declarations

This work has not been submitted in substance for any other degree or award at this or any other university or place of learning, nor is being submitted concurrently in candidature for any degree or other award.

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This thesis is being submitted in partial fulfilment of the requirements for the degree of DClInPsy.

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This thesis is the result of my own independent work/investigation, except where otherwise stated, and the thesis has not been edited by a third party beyond what is permitted by Cardiff University's Policy on the Use of Third Party Editors by Research Degree Students. Other sources are acknowledged by explicit references. The views expressed are my own.

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Paper 1 has been prepared for submission to the British Journal of Health Psychology in accordance with the guidelines for authors (Appendix 1). Therefore, tables and figures are presented at the end of the paper.

**Paper 1: Group-based Acceptance and Commitment  
Therapy (ACT) for Long-Term Conditions:  
A Systematic Review of Randomised Controlled Trials**

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## Abstract

**Purpose:** Approximately a quarter of people with a long-term condition experience a comorbid mental illness which is likely to result in poorer clinical outcomes and prognosis. Psychological interventions which can improve outcomes are needed. Empirical support for Acceptance and Commitment Therapy (ACT) has been growing in the last ten years. Yet, reviews in the context of group-based ACT are lacking.

**Objectives:** To review randomised controlled trials of group-based ACT for adults with long-term conditions.

**Method:** PsycINFO, MEDLINE and Web of Science databases were electronically searched and reference lists examined for relevant peer-reviewed articles. All titles, abstracts and full-text papers were screened independently by two reviewers. Study quality was also rated independently by two reviewers and methodological rigour of reviewed studies discussed.

**Results:** Twelve studies were included from a range of health conditions with a total of 756 participants. Study outcomes are summarised across a range of domains including depression, anxiety, quality of life and disability. Group-based ACT appears more effective than waiting list controls and as effective as other psychological interventions.

**Conclusion:** Due to the increasing number of randomised controlled trials in this context, preliminary results are encouraging. Studies with enhanced methodological rigour are required, particularly when considering the utility of ACT in comparison to other active treatment approaches.

**Keywords:** Acceptance and commitment therapy, systematic review, long-term conditions, group-based, chronic illness.

## Statement of Contribution

What is already known on this subject?

People with long-term conditions are more likely to experience anxiety and depression which can result in poor prognosis and clinical outcomes. Empirical studies evaluating the effectiveness of ACT interventions across numerous clinical settings have reported mixed findings. There has been a recent surge of empirical studies examining the utility of group-based ACT in physical health settings.

What does this study add?

- The first review of RCTs of group-based ACT for adults with long-term conditions.
- Group-based ACT is more effective than TAU and as effective as other therapies.
- Study quality is reviewed and recommendations are provided for improved rigour.

## Introduction

### Long-Term Conditions

A long-term condition (LTC) or chronic illness is defined as a condition that cannot currently be cured but can be controlled with the use of medication and/or other therapies (Department of Health, 2010). Examples include arthritis, HIV, diabetes, chronic pain and cancer. An estimated 40% of the adult European population have a LTC, while two thirds of older adults have at least two (Legido-Quigley, Panteli, Car, McKee, & Busse, 2013; World Health Organization, 2011). Globally, low- and middle-income countries endure nearly 80% of the burden from LTC's and their associated disability (World Health Organization, 2011). Living with an LTC often means living with uncertainty as many people worry about their capabilities to maintain their desired lifestyle and to cope with pain and illness symptoms (Heijmans et al., 2004). Factors associated with psychological distress include disease severity, presence of pain and fatigue, disability, functional impairment, fear of activity and fear of death (Heijmans et al., 2004; Liddy, Blazkho, & Mill, 2014). Many cancer survivors live with the fear of cancer re-occurrence (Ferrell, Grant, Funk, Otis-Green, & Garcia, 1998; Mullens, McCaul, Erickson, & Sandgren, 2004) and the continued burden of testing and monitoring (Deimling, Bowman, Sterns, Wagner, & Kahana, 2006).

Approximately a quarter of people with an LTC experience comorbid mental illness which is two to three times more than the general population (Department of Health, 2009). People with comorbid LTCs and psychological distress are less likely to adhere to medication and/or self-management plans (Bruce, Hancock, Arnett, & Lynch, 2010; Egede, Ellis, & Grubaugh, 2009; Kalsekar et al., 2006; Tarrants, Oleen-Burkey, Castelli-Haley, & Lage, 2011), have increased contact with healthcare services (Levinson, Karger, & Haklai, 2008; McDonald,

2014), are at greater risk of health complications and/or disability (Lin et al., 2010; Tsai et al., 2012) and are more likely to experience reduced quality of life (QoL) (Gormsen, Rosenberg, Bach, & Jensen, 2010; Grandy, Chapman, & Fox, 2008; Rastenyte & Kranciukaite, 2007).

The UK's Departments of Health recognises chronic pain conditions as LTC's in their own right (Department of Health, 2012). This definition warrants chronic pain conditions to be included within this LTCs review to ensure inclusivity. Chronic pain conditions share common factors with other LTCs. The Global Burden of Disease study found that four of the top twelve most disabling conditions globally were chronic pain conditions (low-back and neck pain, migraine, arthritis, other musculoskeletal conditions) and low-back pain is ranked number one worldwide, of 291 LTCs, for years lost to disability (Hoy et al., 2014). Chronic pain conditions are associated with decreased health status and quality of life, and an increased risk of depression and loss of employment (Breivik, Eisenberg, & O'Brien, 2013; Breivik., Collett, Ventafridda, Cohen, & Gallacher, 2006).

### **Acceptance and Commitment Therapy (ACT)**

ACT suggests that psychological distress is a facet of the human condition and does not primarily aim to reduce distress. Instead ACT is based upon six principles to enhance 'psychological flexibility' which enables people to better handle painful thoughts, feelings and sensations whilst living a meaningful life despite these experiences (Harris, 2013). Explaining ACT in depth is beyond the remit of this review; however a brief overview is outlined in Table 1.

ACT interventions for depression and mixed anxiety disorders were evaluated as superior when compared to waiting list (WL) controls and equivalent to other active psychological interventions (e.g. cognitive behavioural therapy; CBT) (Ruiz, 2012; Soo, Tate, & Lane-Brown, 2011; Swain, Hancock, Hainsworth, & Bowman, 2013). ACT has been applied across numerous physical health settings and a recent review concluded that ACT elicited promising outcomes regarding improved lifestyle, QoL, disease self-management, and reduced psychological distress (Graham, Gouick, Krahé, & Gillanders, 2016). The use of ACT in chronic pain found significant effects for measures of pain intensity, pain-interference, disability, depression, anxiety and QoL. ACT also had significantly higher effects on depression and anxiety than mindfulness based interventions (Veehof., Trompetter, Bohlmeijer, & Schreurs, 2016). These findings support an earlier review (Veehof, Oskam, Schreurs, & Bohlmeijer, 2011). A review of 60 RCTs concluded ACT is 'probably efficacious' for a number of populations and better quality studies would increase the likelihood that ACT will be reviewed as efficacious (Ost., 2014).

### **Group-Based Interventions: Why Relevant?**

The rising prevalence of LTC's is the main challenge facing governments and health-care services worldwide (World Health Organization, 2011). Currently €700 billion are spent in the European Union annually on LTC's, accounting for 70-80% of health expenditure (Kuipers Cavaco & Quidbach, 2014). Therefore, psychological interventions which can reduce healthcare consumption and improve outcomes are vital to reduce the economic burden (Department of Health, 2012; National Collaborating Centre for Mental Health, 2010). Identification of efficient, innovative and cost-effective interventions and delivery formats, e.g. group-based interventions, are essential to manage LTC's, their consequences



and increase the accessibility of psychological therapies (Kuipers Cavaco & Quoidbach, 2014; National Collaborating Centre for Mental Health, 2010).

People with LTCs have reported that group-based intervention allowed them to meet people with similar experiences and undergoing similar medical procedures (Stafford et al., 2013; Wylde, Marques, Artz, Blom, & Goberman-Hill, 2014). This can stimulate a shared group identity, peer learning and acceptance of chronic illness (Chambers, Foley, Galt, Ferguson, & Clutton, 2012). Bringing people with LTCs together can decrease isolation, enhance emotional support, buffer against stress, and provide opportunities to gain knowledge (Nicholas, 2016). Therefore, group-based psychological interventions could be the prudent choice, not only for the aforementioned benefits for patients, but also for the healthcare provider due to being more cost- and time-effective compared to individual interventions (Nicholas, 2016).

## **Aims**

This review aimed to summarise RCTs of group-based ACT for adults with LTCs. Despite two recent reviews evaluating the use of ACT within health contexts (Graham et al., 2016; Veehof. et al., 2016); these papers amalgamated studies using both individual and group interventions. These reviews also separated chronic pain and other LTCs samples whereas this present review reports inclusively on all LTC samples that met the inclusion criteria. Graham and colleagues (2016) reviewed child, adult and indirect samples (e.g. parents) and did not limit studies to RCTs. Given the recent surge of group-based ACT RCTs in health contexts and the increasing pressure in healthcare settings to provide cost-effective and evidence-based treatments (Department of Health, 2012; Kuipers Cavaco & Quoidbach,

2014; World Health Organization, 2011), this is a timely review. To the author's knowledge, this is the first systematic review considering this specific use of group-based ACT.

## **Method**

### **Search Strategy**

PsycINFO, MEDLINE and Web of Science databases were searched for published articles until the 31<sup>st</sup> January 2017. No date restrictions or filters were placed on the search. Search terms were: 'acceptance and commitment therapy' (searched as a subject heading and as a keyword only) or 'acceptance and commitment' in combination with 'group\*' or 'workshop\*' or 'training' or 'course\*' or 'program\*'. As LTCs are categorised under a vast amount of diagnoses, a broad search strategy was completed.

### **Eligibility**

RCTs were included if they evaluated group-based ACT (delivered face-to-face) and used all principles of the ACT model with a sample of adults with an LTC. Articles were included if they were: quantitative, written in English and published in a peer-reviewed journal. Articles were excluded if the sample was indirect (e.g. staff groups, parents), or if they reported a secondary analysis on already published data.

### **Study Selection and Data Extraction**

All titles, abstracts and full-text papers were screened independently by two reviewers. Disagreements were resolved through discussion and a consensus was identified. A data extraction sheet was developed (Table 2) and one reviewer extracted the data from articles which met the inclusion criteria. The second author checked the extracted data to ensure

accuracy. Four authors were contacted for further information, however no responses were received.

### **Quality Assessment**

Study quality was assessed using the Psychotherapy Outcome Study Methodology Rating Form (POMRF, Appendix 2) which has good internal consistency (Cronbach's  $\alpha = .86$ ) and good interrater-reliability (intra-class correlation = .92) (Ost, 2008). The POMRF consists of 22 items and is designed to evaluate the methodological quality of psychotherapy-based studies. Each item is rated on a 3-point scale from 0 to 2, where 0 = poor, 1 = fair and 2 = good. Higher total scores suggest greater methodological quality. Items two and four, which are related to reliability and severity of psychiatric diagnoses, were removed in line with an article also reviewing physical health orientated studies (Graham et al., 2016). The maximum possible score was 40. Two reviewers independently assessed the articles which met the inclusion criteria against the POMRF and when inconsistencies occurred, the articles were reassessed by both reviewers and disagreements were discussed until a consensus was reached. Methodological quality rating totals are reported in Table 2 and individual item scores for each study can be seen in Appendix 3.

### **Results**

The initial search produced 711 papers, after duplications were removed. An additional paper was identified from full-text reference list searches. Of these 712 articles, all titles and abstracts were screened, 678 articles did not meet the inclusion criteria. Full texts were retrieved for the remaining thirty-four studies. Of these, twelve papers met the inclusion criteria. See Figure 1 for an overview of the study selection process.

## **Sample Characteristics**

Within the twelve studies, seven LTCs were represented: chronic pain (N=3), type-2 diabetes mellitus (T2DM; N=2), epilepsy (N=2), fibromyalgia (N=2), headache (N=1), breast cancer (N=1) and multiple sclerosis (MS; N=1). Studies totalled 756 participants with sample sizes ranging from 18 to 156 (mean=63). The majority of the participants were female (71.43%) and the average age was 46 years. Study origins were Sweden (N=3), Iran (N=3), USA (N=2), Spain (N=1), India (N=1), South Africa (N=1) and UK (N=1). Of the nine papers reporting the attrition rates of completing participants, the mean average was 17.81%.

## **ACT Intervention**

One study implemented a one-off seven hour workshop (Gregg, Callaghan, Hayes, & Glenn-Lawson, 2007) whereas the other ACT interventions consisted of several sessions lasting 1.5 - 4 hours per session. In these remaining eleven studies, the average number of sessions offered was eight, totalling an average of 15 hours. The number of people per group ranged from six to twenty-four. Four studies included LTC-specific psycho-education alongside the ACT material (Gregg et al., 2007; Lundgren, Dahl, Melin, & Kies, 2006; Lundgren, Dahl, Yardi, & Melin, 2008; Shayeghian, Hassanabadi, Aguilar-Vafaie, Amiri, & Besharat, 2016).

However, only four studies were deemed to have a 'good' explanation of the intervention (Lundgren et al., 2006; Lundgren et al., 2008; Mo'tamedi, Rezaemaram, & Tavallaie, 2012; Wicksell et al., 2013) therefore it is unknown if the other studies included additional information.

## **Control Conditions**

Eleven studies had one comparison group, except Luciano et al., (2014) who had two (recommended pharmacological treatment: RPT and WL). Of those with one comparison group, four studies applied a TAU/WL control. One study used supportive therapy as a control to provide equality of therapy hours (Lundgren et al., 2006). Six studies used active treatment comparisons (education, applied relaxation, relaxation training, yoga, or CBT). Six papers had treatment conditions which provided equality of therapy hours to both groups.

## **Study Quality**

Nine studies obtained more than half of the available points on offer by the POMRF. The mean score was 21.83 (SD: 6.07) and the range of scores were 9 – 33. The highest rated paper was Kemani et al., (2015) while the lowest was Mohabbat-Bahar, Maleki-Rizi, Akbari, & Moradi-Joo (2015). Eleven papers were rated as 'fair' for representativeness of the participant sample as they excluded participants with major disorders. Ten studies were deemed to use 'good' outcome measures with good psychometric properties. As well as pre and post measures, two studies conducted six and twelve month follow-up analysis (Lundgren et al., 2006; Lundgren et al., 2008), eight studies conducted a mixture of three and/or six month follow-up analysis, whereas two studies conducted only pre and post analysis (Mo'tamedi et al., 2012; Mohabbat-Bahar et al., 2015). Three studies (Gregg et al., 2007; Mohabbat-Bahar et al., 2015; Shayeghian et al., 2016) did not described the facilitators as practising therapists and/or clinically experienced. Two studies (Kemani et al., 2015; Wicksell et al., 2013) had three or more therapists delivering interventions and in the remaining ten studies, five had two therapists and five had only one. Despite all the studies being an RCT, only five papers were rated as having a 'good' assignment to treatment

strategy (Kemani et al., 2015; Luciano et al., 2014; Lundgren et al., 2008; Wetherell et al., 2011; Wicksell et al., 2013). In terms of treatment fidelity, the POMRF highlighted that treatment adherence (item 16) and therapist competence (item 17) were rated identically. Three papers scored 'good' across both items (Kemani et al., 2015; Mo'tamedi et al., 2012; Wicksell et al., 2013), four were rated as 'poor' (Gregg et al., 2007; Mohabbat-Bahar et al., 2015; Nordin & Rorsman, 2012; Shayeghian et al., 2016) and the remaining five papers were rated as 'fair'.

Some aspects of methodological quality were largely ignored, for example only four studies reported completing a power analysis prior to recruitment to inform sample size (Gregg et al., 2007; Kemani et al., 2015; Luciano et al., 2014; Shayeghian et al., 2016). None of the studies detailed 'good' assessor training (ten studies did not specify at all) and only one paper reported the use of blind assessors (Wetherell et al., 2011). No papers ensured that participants stopped all other treatments during the study although six studies asked participants to keep medication stable and/or discontinue other psychological therapies (Kemani et al., 2015; Lundgren et al., 2006; Lundgren et al., 2008; Mo'tamedi et al., 2012; Wetherell et al., 2011; Wicksell et al., 2013). Three studies did not state attrition rates (Lundgren et al., 2006; Lundgren et al., 2008; Mohabbat-Bahar et al., 2015) and in an additional study, despite stating the attrition rate, an intent-to-treat analysis was not reported (Shayeghian et al., 2016). Only four of the twelve papers reported Jacobson's criteria for clinical significance (Kemani et al., 2015; Luciano et al., 2014; Lance M. McCracken, Sato, & Taylor, 2013; Wetherell et al., 2011).

## Study Outcomes

### Depression.

All four studies with TAU/WL controls found ACT demonstrated significant improvements on depressive symptoms at post-intervention (Luciano et al., 2014; Lance M. McCracken et al., 2013; Mohabbat-Bahar et al., 2015; Wicksell et al., 2013). Effect sizes were reported as small ( $d = 0.44 - 0.46$ ) (Lance M. McCracken et al., 2013; Wicksell et al., 2013) and large ( $d = 1.01$ ) (Luciano et al., 2014). These significant group differences were maintained at three or six month follow-ups with medium to large effect sizes ( $d = 0.58 - 0.88$ ) (Luciano et al., 2014; Lance M. McCracken et al., 2013; Wicksell et al., 2013).

Four studies compared ACT to active treatment (Kemani et al., 2015; Luciano et al., 2014; Nordin & Rorsman, 2012; Wetherell et al., 2011) and findings were mixed. Two higher quality studies showed that when ACT was compared against CBT and applied relaxation, all three active treatment approaches demonstrated significant reductions for depression at post-intervention and six month follow-ups but no significant differences occurred between treatment approaches (Kemani et al., 2015; Wetherell et al., 2011). ACT was significantly more effective at reducing depression than RPT which was maintained at six month follow-up with small effect sizes ( $d = 0.43; 0.37$  respectively) (Luciano et al., 2014). Relaxation training demonstrated significant improvements for depression, in comparison to ACT, at post-intervention which was not sustained at three month follow-up (Nordin & Rorsman, 2012).

### **Anxiety.**

Four studies compared ACT to TAU/WL controls and found that ACT significantly reduced anxiety at post-intervention (Luciano et al., 2014; Mo'tamedi et al., 2012; Mohabbat-Bahar et al., 2015; Wicksell et al., 2013) with medium ( $d = 0.51 - 0.77$ ) (Luciano et al., 2014; Wicksell et al., 2013) and large ( $d = 2.54$ ) effect sizes (Mo'tamedi et al., 2012). Two of the four studies completed follow-up analysis and found these improvements were maintained at three months with medium ( $d = 0.55$  &  $0.74$ ) effect sizes (Wicksell et al., 2013) and at six months with a large ( $d = 0.85$ ) effect size (Luciano et al., 2014).

Four studies compared ACT to active treatment groups (Kemani et al., 2015; Luciano et al., 2014; Nordin & Rorsman, 2012; Wetherell et al., 2011). In a similar pattern for that of depression, when ACT was compared against active approaches of applied relaxation and CBT, all treatment approaches reported significantly reduced anxiety at post-intervention and follow-up but there were no significant differences between treatment groups (Kemani et al., 2015; Wetherell et al., 2011). ACT was significantly more effective at reducing anxiety than RPT at post-treatment with a small effect size ( $d = 0.36$ ) which was maintained at six month follow-up ( $d = 0.39$ ) (Luciano et al., 2014). However, in a lower quality study significant improvements from pre-treatment to three month follow-up were found in favour of relaxation training, when compared to ACT (Nordin & Rorsman, 2012).

### **Quality of life.**

Seven studies assessed for changes in QoL (Kemani et al., 2015; Luciano et al., 2014; Lundgren et al., 2006; Lundgren et al., 2008; Lance M. McCracken et al., 2013; Wetherell et al., 2011; Wicksell et al., 2013). A higher quality study found that both ACT and applied



relaxation improved QoL in a chronic pain sample ( $d = 0.79$ ) (Kemani et al., 2015). Other chronic pain studies found participant's QoL did not significantly change following ACT, CBT or TAU at post-intervention or follow-up analysis (Lance M. McCracken et al., 2013; Wetherell et al., 2011). ACT demonstrated significant improvements in mental health QoL when compared to WL controls with a large effect size at post-intervention ( $d = 0.84$ ) and three month follow-up ( $d = 1.06$ ) (Wicksell et al., 2013). However, no significant changes in either group were found for physical health QoL (Wicksell et al., 2013). ACT was significantly more effective at increasing QoL with fibromyalgia participants than RPT and WL controls at post-treatment and six month follow-up with medium to large effect sizes ( $d = 0.66 - 1.06$ ) (Luciano et al., 2014).

In a drug-refractory epilepsy sample, the Satisfaction With Life Scale (SWLS) outcome measure (Diener, Emmons, Larsen, & Griffin, 1985) changed significantly, in favour of ACT when compared with supportive therapy across all time points with large effect sizes, whereas the WHOQOL-BREF (Amir et al., 2003) showed significant group differences only at one year follow-up, again in favour of ACT ( $d = 1.78$ ) (Lundgren et al., 2006). Interestingly, in Lundgren et al., (2008) ACT showed significantly improved QoL when compared to yoga on the WHOQOL-BREF however yoga showed improved QoL when compared to the ACT on the SWLS.

### **Acceptance.**

Seven studies assessed changes in psychological and/or pain acceptance (Gregg et al., 2007; Kemani et al., 2015; Luciano et al., 2014; Lance M. McCracken et al., 2013; Nordin & Rorsman, 2012; Shayeghian et al., 2016; Wetherell et al., 2011). When ACT was compared

to CBT, relaxation training or applied relaxation, all groups showed significant and similar improvement in pain acceptance (Kemani et al., 2015; Nordin & Rorsman, 2012; Wetherell et al., 2011). However, in a higher quality study Kemani and colleagues (2015) found the ACT group had increased acceptance to a greater extent than the applied relaxation group ( $d = 0.90$ ). In comparison to RPT and WL groups, ACT was significantly more effective at improving pain acceptance at post-treatment and six month follow-up, with large effect sizes ( $d = 1.01 - 1.21$ ) (Luciano et al., 2014). In type-2 diabetes mellitus samples, significantly higher psychological acceptance was reported in the ACT group in comparison to education alone (Gregg et al., 2007; Shayeghian et al., 2016) with a large effect size (partial  $\eta^2 = .12$ ) (Gregg et al., 2007). In contrast, McCracken and colleagues (2013) reported there were no significant group differences between ACT and TAU in psychological or pain acceptance at post-treatment, however at three month follow-up pain acceptance did become significant in favour of ACT, with a medium effect size ( $d = 0.64$ ).

### **Disability.**

Six studies assessed disability (Kemani et al., 2015; Luciano et al., 2014; Lance M. McCracken et al., 2013; Mo'tamedi et al., 2012; Wetherell et al., 2011; Wicksell et al., 2013). ACT showed significant improvements in comparison to RPT and WL, at post-intervention and follow-up with small to large effect sizes ( $d = 0.41 - 2.35$ ) (Luciano et al., 2014; Wicksell et al., 2013). ACT also significantly reduced disability at post-intervention with medium to large effect sizes ( $d = 0.75 - 0.93$ ), in comparison to TAU and WL controls with chronic headache and fibromyalgia samples (Mo'tamedi et al., 2012; Wicksell et al., 2013), which was maintained at six month follow-up ( $d = 0.73$ ) (Wicksell et al., 2013). Both ACT and CBT

significantly improved pain interference from pre- to post-intervention, which was maintained at six month follow-up (Wetherell et al., 2011).

In two of the studies with chronic pain populations outcomes fluctuated across time points. McCracken and colleagues (2013) found no significant differences for disability at post-intervention yet at three month follow-up the ACT group showed significant improvements in comparison to the TAU group, with a medium effect size ( $d = 0.59$ ). Whereas, in Kemani et al., (2015) ACT significantly decreased pain disability in comparison to applied relaxation from pre- to post-analysis, however this was then mirrored by the applied relaxation group at follow-up.

#### **LTC-specific outcome.**

Significant findings with medium to large effect sizes ( $\eta^2 = .08 - .25$ ) were found at follow-up for diabetic control status ( $HbA_{1c} < 7.0\%$ ) and diabetic self-management ( $\eta^2 = .07 - .22$ ) in the ACT group when compared to education (Gregg et al., 2007; Shayeghian et al., 2016). Mediation analysis suggested that self-management and psychological acceptance mediated the impact of treatment on changes in  $HbA_{1c}$  (Gregg et al., 2007), whereas in the lower quality study effective coping style were shown to moderate the relationship between ACT and diabetic self-management (Shayeghian et al., 2016).

ACT, when compared to a supportive therapy, significantly reduced epileptic seizure frequency and index at post, six month and one year follow-up with large effect sizes ( $d = 0.89$  and  $d = 1.25$  respectively) (Lundgren et al., 2006). The participants in the ACT group had, on average, less than one seizure per month following the intervention yet the control

had no significant changes from pre-treatment. ACT and yoga both significantly reduced seizure index, however the ACT group's seizure index had reduced significantly more than the yoga group (Lundgren et al., 2008).

There were no significant differences in pain severity or intensity in groups of ACT, applied relaxation, CBT or WL controls at post or follow-up analysis in chronic pain and fibromyalgia samples (Kemani et al., 2015; Lance M. McCracken et al., 2013; Wetherell et al., 2011; Wicksell et al., 2013). However, ACT was significantly more effective at reducing subjective pain experience in fibromyalgia participants than RPT and WL groups at post-treatment and six month follow-up with small to large effect sizes ( $d = 0.47 - 0.93$ ) (Luciano et al., 2014). In a breast cancer sample, ACT produced a significant reduction in affective dimensions of pain (MPQ-SF) with large effect size ( $d=1.35$ ) when compared to TAU. However no significant findings were found on the sensory dimension of pain (Mohabbat-Bahar et al., 2015).

## **Discussion**

The aim of this review was to summarise RCTs of group-based ACT for adults with LTCs. Overall, twelve RCTs met the inclusion criteria for review and the findings from the higher quality papers suggest that group-based ACT significantly reduced anxiety and depression when compared to TAU/WL controls, and is equally as effective as other psychological treatments, such as CBT and applied relaxation. Group-based ACT was found to significantly improve (psychological or pain) acceptance in comparison to TAU, RPT, WL and education however ACT, CBT, applied relaxation and relaxation training showed no significant group differences. Similarly, ACT was superior at producing significant reductions in disability than WL, RPT and TAU conditions, whilst ACT, CBT and applied relaxation were generally equally

effective. ACT was effective at reducing epileptic seizure index and increasing diabetic control status and self-management. However, findings for pain severity and intensity were mixed. Mixed conclusions were also drawn regarding the impact of ACT on QoL with limited consensus across studies. Overall, group-based ACT interventions appear to be more effective than TAU/WL controls and as effective as other psychological therapies at reducing depression, anxiety and disability, and increasing acceptance and some LTC-specific outcomes in participants with LTCs. However, conclusions regarding the effectiveness of group-based ACT at reducing pain experiences and increasing QoL outcomes remain unclear.

A review which shares five papers with the current review also found limited evidence for the impact of ACT on pain intensity and the authors concluded that since pain control and reduction are not primary aims of ACT, it is unlikely that larger effects on participants' pain experiences would be achieved (Veehof. et al., 2016). Graham and colleagues (2016) (which shares four papers) made similar conclusions to this current review for outcomes of QoL but suggested that it was unclear whether ACT was superior to TAU and other psychological interventions for anxiety and depression, or whether the improvements observed were due to factors such as a regression to the mean, placebo or other therapeutic factors. The interventions in their review had a low number of sessions offered, with 58% of the ACT interventions consisting of five sessions or fewer (Graham et al., 2016). This is in contrast to the current review whereby only 25% of studies offered five sessions or fewer. This is an interesting difference as the dose-effect relationship suggests that those receiving more sessions have better outcomes (Kopta, 2003). In addition, group-based interventions may attract particular types of participants that are willing to engage in this format, as opposed

to individual therapy or medication, for example. This may lead to a self-selected sample, with a preference for this format and may skew research outcomes (Wylde et al., 2014). These non-specific therapeutic factors are important considerations when appraising the effectiveness of interventions, however Hayes and colleagues outlined the evidence-base for the individual components of the ACT model (as outlined in Table 1) highlighting the efficacy of ACT in impacting relevant behaviours and processes of change which go beyond non-specific factors (Hayes, Levin, Plumb-Villardaga, Villatte, & Pistorello, 2013).

Considering that the rising prevalence of LTC's is the main challenge facing governments and health-care services worldwide (World Health Organization, 2011), and comorbid LTCs and psychological distress result in poorer clinical outcomes and prognosis (Naylor et al., 2012), this review has found promising results for the utility of group-based ACT in this clinical sample. The vast mix of study origins included in this review is particularly interesting as five of the twelve reviewed studies derived from low- or middle-income countries where the World Health Organisation found that nearly 80% of the burden from LTC's occurs (World Health Organization, 2011). All five of these studies showed some significant findings in favour of ACT, in a similar pattern to the remaining seven studies, suggesting that ACT has some efficacy across cultures and languages. This warrants further investigation.

### **Strengths and Limitations**

To the authors' knowledge, this is the first systematic review of group-based ACT for adults with LTCs. Therefore, unlike previous ACT reviews, this paper has provided a focused framework to enhance the understanding of the effectiveness of ACT when specifically delivered in group formats. The literature search was conducted in line with the Preferred

Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines to ensure the search was systematic and transparent (Moher, Liberati, Tetzlaff, Altman, & The, 2009). Furthermore, this review has only included RCTs in an attempt to present the most efficacious research available.

Since this review covered seven different LTCs it is difficult to draw firm conclusions about the effectiveness of group-based ACT for specific conditions or more generally across chronic health. Although the studies measured largely similar components (i.e. depression, anxiety, etc.) many of the studies used different outcome measures meaning a meta-analysis was not possible. In addition, only one study (Kemani et al., 2015) assessed the cost-effectiveness of the ACT intervention. ACT is still seen as a relatively new therapy and nine of the reviewed twelve studies were published in the last five years. As interest in this therapy increases, particularly across different LTCs, a meta-analysis would be beneficial. In particular, focus is warranted on ACT in comparison to active interventions, as currently group-based ACT is generally only superior to TAU/WL controls and therefore it is difficult to determine any active agents of change.

The POMRF quality measure highlighted concerns regarding model adherence as low quality ratings were found for item 13 (manualised, replicable specific treatment programs), item 16 (checks for treatment adherence) and item 17 (checks for therapist competence).

Therefore, it was difficult to confirm if the ACT interventions were comparable and offered participant's similar information. However, the POMRF is an extensive tool, and to score highly, authors must include a high level of detail. Due to restrictive publication word counts, a study may have the appearance of poor methodological rigour however this does

not always mean high quality was not implemented (Swain, Hancock, Hainsworth, et al., 2013). Little is known about the association between POMRF scores and study outcomes.

### **Recommendations for Improving Study Quality**

Useful recommendations to improve methodological rigour were made by Graham and colleagues (2016). The current review highlighted further quality shortfalls and thus recommendations are:

- Describe the prevalence of comorbid disorders in the sample description.
- Compare ACT interventions to other active treatment and evaluate cost-effectiveness
- Complete a power analysis prior to recruitment and explicitly state that the sample size was decided accordingly.
- Describe proportions of attrition, preform a drop-out analysis and present the results using intent-to-treat analysis.

### **Conclusion**

This review highlighted promising findings for the use of group-based ACT across LTCs however high quality RCTs are required which compare group-based ACT against other active psychological therapies across a range of LTCs. It is hoped that this review will highlight the potential of group-based ACT for providing effective, timely and accessible psychological input for people living with LTCs and will encourage further research and clinical attention to this topic.



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## Contributors

SM designed the study, conducted literature searches and prepared the manuscript. RS acted as second reviewer. RM contributed to the manuscript preparation and supervised the project. All authors have approved the final manuscript.

## Conflict of Interest

The authors report no conflicts of interest.

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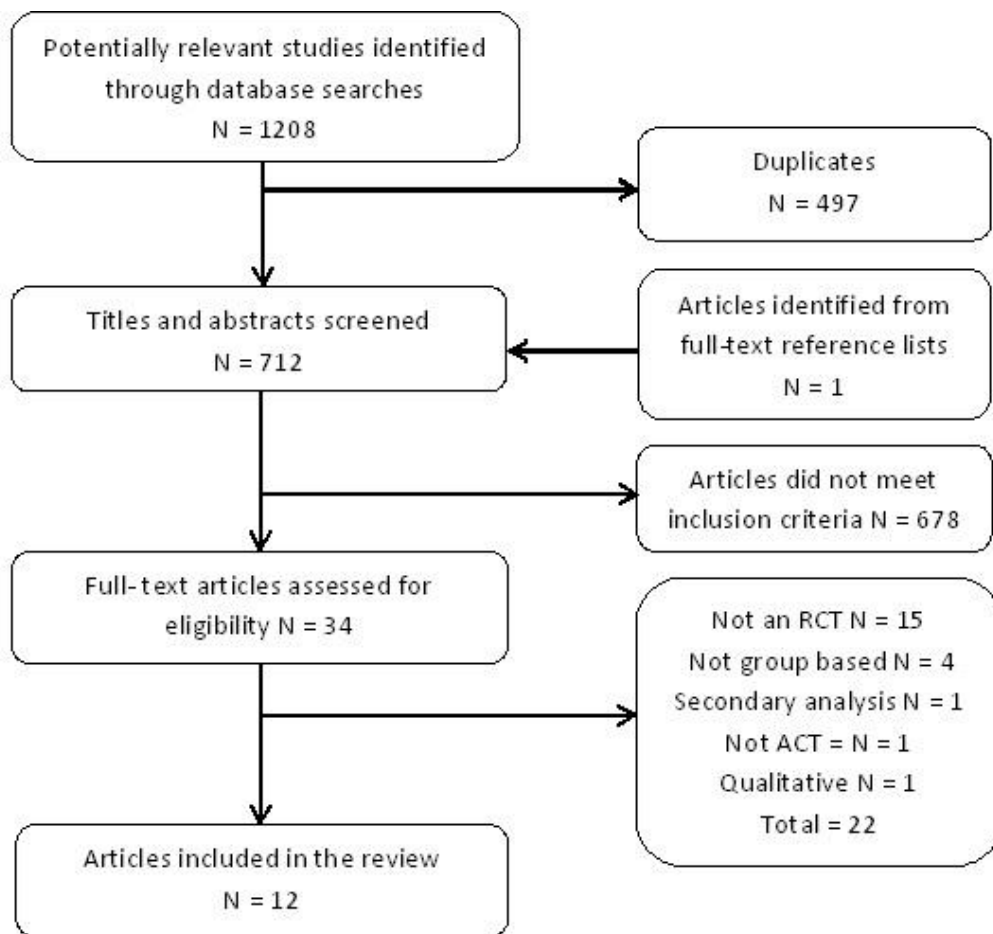
## Tables and Figures

**Table 1: An Overview of the Six Principles of ACT (Harris, 2013)**

<b>ACT Principle</b>	<b>Overview</b>
Experiential acceptance	An active embrace of unpleasant feelings and sensations (e.g. feelings of pain or anxiety) without attempts to change or suppress them.
Contact with the present moment	Instead of worrying about the past and future, contact with the present moment is being connected to what you are doing and experiencing in any given moment.
Cognitive defusion	Defusion is the distance between the person and their unpleasant and self-critical thoughts which become products of perception and consequently less believable, frightening and powerful.
Self-as-context	A viewpoint from which one can observe their thoughts and feelings, without judgement, in an act of pure awareness.
Values	Direction and connection with what is important to individuals, providing significance and meaning to life.
Committed action	Taking effective and committed steps towards goals in line with a person's values.



Figure 1: PRISMA Flow Diagram of Systematic Search.



**Table 2: Study Characteristics**

Study	POMRF quality score	Physical health condition	Country	Sample size (total)	Group sizes	Mean age (% female)	Control condition	ACT Sessions (total hrs)	Analysis time points	Attrition % (ITT reported?)	Outcome measures
<b>Gregg et al, (2007)</b>	22	Type-2 Diabetes Mellitus	USA	ACT: 43 E: 38 (81)	10-24	50.9 (46.9)	Education (E) 7hrs	one 7hr workshop (7hrs)	pre & 3 month follow-up	19 (Y)	Glucose level (HbA1C), understanding of diabetes (DCP), self-management (self-report adherence measure), psychological acceptance (AADQ)
<b>Kemani et al, (2015)</b>	33	Chronic pain	Sweden	ACT: 30 AR: 30 (60)	6	40.3 (73.3)	Applied relaxation 18hrs (AR)	12 sessions 1.5hrs (18hrs)	pre, mid, post, 3 & 6 month follow-up	38 (Y)	Pain disability (PDI), Pain (scale 0-6), QoL (SF-12), Anxiety & depression (HADS), Pain acceptance (CPAQ), Economic costs (TicP)
<b>Luciano et al, (2014)</b>	24	Fibromyalgia	Spain	ACT:51, RPT: 52, WL: 53 (156)	10-15	48.31 (96.2)	Medication (RPT) & waiting list (WL)	8 sessions, 2.5hrs (20)	pre, post, 3 & 6 month follow-up	13 (Y)	Fibromyalgia impact (FIQ), pain catastrophizing (PCS), anxiety & depression (HADS), pain acceptance (CPAQ), pain experience (PVAS), QoL (ED-5Q visual analog scale)
<b>Lundgren et al, (2006)</b>	22	Drug-refractory epilepsy	South Africa	ACT: 14, ST 13 (27)	13-14	40.68 (51.85)	Supportive therapy 12hrs (ST)	2 sessions, 3hrs + 4 1:1 sessions, 1.5hrs (12)	pre, post, 6 & 12 month follow-up	Unknown (N)	Seizure frequency, seizure index, QoL (WHOQOL-BREF), life satisfaction (SWLS)
<b>Lundgren et al, (2008)</b>	23	Drug-refractory epilepsy	India	ACT: 10, Yoga: 8 (18)	8-10	23.85 (33.33)	Yoga 12hrs	2 sessions, 3hrs + 4 1:1 sessions, 1.5hrs (12)	pre, post, 6 & 12 month follow-up	Unknown (N)	Seizure frequency, seizure index, QoL (WHOQOL-BREF), life satisfaction (SWLS)
<b>McCracken et al, (2013)</b>	21	Chronic Pain	UK	ACT: 37, TAU: 36 (73)	12-13	58 (68.5)	Treatment as usual (TAU)	4 sessions, 4hrs (16)	pre, post, 3 month follow-up	23.29 (Y)	Disability (RMDQ), depression (PHQ9), QoL (SF-36), pain intensity (scale 0-10), impression of change (PGIC), pain acceptance (CPAQ), psychological acceptance (AAQ-II)

<b>Mo'tamedi et al, (2012)</b>	22	Chronic Headache	Iran	ACT: 15, TAU: 15 (30)	15	36.03 (100)	Treatment as usual (TAU)	8 sessions, 1.5hrs (12)	pre & post	13.33 (Y)	Pain intensity (MPQ-SF), disability (MIDAS), anxiety (STAI-T)
<b>Mohabbat-Bahar et al, (2015)</b>	9	Breast Cancer	Iran	ACT: 15, TAU: 15 (30)	15	47.53 (100)	Treatment as usual (TAU)	8 sessions, 1.5hrs (12)	pre & post	Unknown (N)	Anxiety (BAI), depression (BDI-II)
<b>Nordin et al, (2012)</b>	19	Multiple Sclerosis	Sweden	ACT: 11, RT: 10 (21)	10-11	45.75 (76.19)	Relaxation Training (RT)	5 sessions (unknown)	pre, post & 3 month follow-up	4.76 (Y)	Anxiety & depression (HADS; BDI), psychological acceptance (AAQ-II)
<b>Shayeghian et al, (2016)</b>	16	Type 2 Diabetes Mellitus	Iran	ACT: 53 E: 53 (106)	/	55.44 (60)	Education (E) 2hrs	10 sessions (unknown)	pre & 3 month follow-up	6 (N)	Glucose level (HbA1C), self-care (SDSCA), psychological acceptance (AADQ), coping (COPE)
<b>Wetherell et al, (2011)</b>	30	Chronic Pain	USA	ACT: 57 CBT: 57 (114)	4-6	54.9 (50.9)	Cognitive Behaviour Therapy (CBT) 12hrs	8 sessions, 1.5hrs (12)	pre, post, & 6 month follow-up	25.44 (Y)	Pain interference (BPI), QoL (SF12), depression (BDI-II), disability (MPI), anxiety (PASS), pain acceptance (CPAQ-R), pain control (SOPA)
<b>Wicksell et al, (2013)</b>	21	Fibromyalgia	Sweden	ACT: 23 WL:17 (40)	6	45.1 (100)	Waiting List (WL)	12 sessions, 1.5hrs (18)	pre, post & 3 month follow-up	17.5 (Y)	Disability (PDI), fibromyalgia impact (FIQ), QoL (SF-36), depression (BDI), anxiety (STAI-T), pain scale 0-10, psychological inflexibility (PIPS)

RPT= recommended pharmacological treatment, ITT=intention-to-treat analysis, Y=yes, N=no, DCP=Diabetes Care Profile, AA[D]Q=Acceptance and Action [Diabetes] Questionnaire, PDI=Pain Disability Index, QoL=quality of life, SF-12/36=Short Form-12/36 Health Survey, HADS=Hospital Anxiety and Depression Scale, CPAQ=Chronic Pain Acceptance Questionnaire, Tic-P=Trimbos and Institute of Medical Technology Assessment Cost Questionnaire for Psychiatry, FIQ=Fibromyalgia Impact Questionnaire, PCS=Pain Catastrophizing, PVAS=Pain visual analog scale, EQ-5D=European quality of life scale- 5 dimensions, WHOQOL-BREF=World Health Organization Quality of Life instrument short version, SWLS=Satisfaction with Life Scale, RMDQ=Roland and Morris Disability Questionnaire, PHQ-9=Patient Health Questionnaire-9; PGIC=Patient global impression of change, MPQ-SF=McGill Pain Questionnaire-Short Form, MIDAS=Migraine Disability Assessment Scale, STAI-T=State-Trait Anxiety Inventory-Trait, BAI=Beck Anxiety Inventory, BDI-II=Beck Depression Inventory, BPI=Brief Pain Inventory Short Form Interference subscale, MPI=West Haven-Yale Multidimensional Pain Inventory, PASS=20-item Pain Anxiety Symptoms Scale-Short Form, SOPA=Survey of Pain Attitudes, PIPS=Psychological Inflexibility in Pain Scale, SDSCA=Summary of diabetes self-care activities, COPE=The brief COPE questionnaire

Paper 2 has been prepared for submission to the British Journal of Health Psychology in accordance with the guidelines for authors (Appendix 1). Therefore, tables and figures are presented at the end of the paper.

## **Paper 2: The Effectiveness of Group-Based Acceptance and Commitment Therapy (ACT) for Stroke Survivors: A Randomised Pilot Study**

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## Abstract

**Objectives:** To date, the effectiveness of Acceptance and Commitment Therapy (ACT) for stroke survivors has not been established. The aim of this pilot study was to evaluate the effectiveness of group-based ACT for stroke survivors in comparison to treatment as usual (TAU) controls.

**Design & Method:** Fifty-three participants were randomly assigned either to group-based ACT (ACTivate Your Life after Stroke) or to a TAU control group (60% male; mean age: 63 years). The ACT intervention consisted of four weekly 2-hour group sessions. Therapeutic effects were measured by examining changes in depression, anxiety, hope, health related quality of life, self-rated health status and mental wellbeing. Measures were completed at pre-treatment, post-treatment and two month follow-up. A mixed-design repeated measures multivariate ANOVA was conducted to analyse the findings.

**Results:** Analysis based on intention-to-treat found that compared to participants in the TAU control, group-based ACT significantly reduced depression and increased self-rated health status and hopefulness in stroke survivors, with medium effect sizes. Significantly more participants reached clinically significant change of depression in the ACT intervention in comparison to the control group.

**Discussion:** The results correspond with previous studies on group-based ACT with other long-term conditions. The findings from this current study suggest group-based ACT may have promising utility and could offer a suitable cost-effective low-intensity psychological intervention for stroke survivors. However further research is required.

**Keywords:** Acceptance and commitment therapy, group-based, stroke.

## Statement of Contribution

What is already known on this subject?

There are approximately 33 million stroke survivors living worldwide. Approximately a third experience post-stroke depression and a quarter are affected by anxiety. This can reduce stroke survivors' quality of life and increase mortality. National guidelines recommend that all stroke survivors are offered psychological support, yet evidence of cost-effective therapies are lacking.

What does this study add?

- This is the first randomised pilot study of group-based ACT with stroke survivors.
- ACT significantly reduced depression, increased health status and hope, with medium effect sizes.
- Clinically and statistically significant change in depression; 54% of ACT group vs. 7% of controls.

## Introduction

The World Health Organisation (WHO) defines stroke as “*rapidly developing clinical signs of focal (or global) disturbance of cerebral function, with symptoms lasting 24 hours or longer, or leading to death*” (WHO Monica Project Principal Investigators, 1988). Approximately 17 million strokes occur every year resulting in 5.9 million deaths, and 33 million stroke survivors living worldwide (Feigin et al., 2014). Stroke affects many physical functions and consequently, 40% of stroke survivors are discharged from hospital requiring support with activities of daily living (Royal College of Physicians, 2015). Stroke is considered to be one of the most common causes of complex disability, affecting over half of all stroke survivors (Adamson, Beswick, & Ebrahim, 2004). The worldwide burden of stroke-related disability, illness and premature death is set to double by 2030 (Feigin et al., 2014).

Psychological disabilities are common (Stroke Association, 2013). A third experience post-stroke depression which can persist long-term (Ayerbe, Ayis, Wolfe, & Rudd, 2013; Hackett, Yapa, Parag, & Anderson, 2005); Anxiety affects around 25%, with many stroke survivors reporting a fear of another stroke (Townend, Tinson, Kwan, & Sharpe, 2006). Moderate and severe fatigue affects 57% of stroke survivors (Lerdal et al., 2011). The Stroke Association (2016) found that 73% of stroke survivors lacked confidence, 56% felt people treated them differently and 55% felt unable to care for their families as before.

It is vital that evidence-based psychological interventions are available as stroke-related comorbidities and life-style changes are associated with reduced quality of life (Bays, 2001; Godwin, Ostwald, Cron, & Wasserman, 2013; Sturm et al., 2004) and increased mortality (Ayerbe et al., 2013). Psychological distress in stroke survivors is also associated with

increased healthcare utilisation (Appleby, Thompson, & Galea, 2012; Ghose, Williams, & Swindle, 2005; van Eeden et al., 2016) and reduced functional recovery (Gillen, Tennen, McKee, & Gernert-Dott, 2001).

### **Current Evidence for Psychological Interventions**

There is a lack of clarity regarding effective psychological interventions for stroke survivors (Royal College of Physicians, 2016). A randomised controlled trial (RCT) found limited evidence for the use of cognitive behavioural therapy (CBT) with stroke survivors and reported that cognitive strategies were challenging for participants to implement (Lincoln & Flannaghan, 2003). Several systematic reviews have concluded inconsistent and disappointing results regarding the effectiveness of psychosocial therapies including problem solving, goal setting, psycho-education and social support (Hackett, Anderson, House, & Halteh, 2008; Hackett, Anderson, House, & Xia, 2008; Sugavanam, Mead, Bulley, Donaghy, & van Wijck, 2013). The current guidance for brief psychological interventions in stroke services includes motivational interviewing (MI), problem-solving therapy, or behavioural therapy (Royal College of Physicians, 2016). An RCT reported that MI, delivered 1:1 over four sessions, showed significant effects on mood at three months after stroke in comparison to a TAU group, but no effects were found on function or expectation of recovery (Watkins et al., 2007). The MI group demonstrated improved mood and reduced mortality at twelve months post-stroke (Watkins et al., 2011). Behavioural therapy, when compared with TAU in an RCT found significant improvements in self-reported and observer-rated mood, and self-esteem, at three months in stroke survivors with aphasia and low mood (Thomas, Walker, Macniven, Haworth, & Lincoln, 2013). Behavioural therapy consisted of twenty hour-long sessions, delivered over three months at the participants'



home, yet cost analysis showed some savings in resource utilisation at six month follow-up, in comparison to a TAU group (Humphreys, Thomas, Phillips, & Lincoln, 2014). Group-based problem solving therapy, delivered over eight sessions, significantly improved task-oriented coping but not disease-specific quality of life in stroke survivors at six month follow-up in comparison to a TAU control (Visser et al., 2015). However these guidelines of psychological interventions for stroke survivors are based on only a few empirical studies and delivery formats were resource intensive (i.e. 1:1 or numerous group session). Therefore there are limited suitable options for stroke survivors and research is needed to investigate alternatives approaches.

### **Acceptance and Commitment Therapy (ACT)**

ACT suggests that psychological distress is a natural aspect of human experience and therefore its primary aim is not to rid a person of their distress. Instead ACT aims to increase 'psychological flexibility' which allows people to lead a valued life despite experiencing painful thoughts, feelings or sensations (Harris, 2013). ACT consists of six core principles (Harris, 2013):

- Experiential acceptance: opening up to unpleasant feelings without attempts to suppress or change them
- Contact with the present moment: being connected with the experience in any given moment rather than ruminating about the past or future
- Cognitive defusion: reducing the power and believability of thoughts by developing distance between the person and their unpleasant or self-critical thoughts
- Self-as-context: a viewpoint where a person observes their internal experiences without judgement

- Values: connecting with what is important to a person which provides meaning and significance to life
- Committed action: committing to goals which are in line with a person's values

There is a growing body of research in support of ACT across a wide range of clinical samples (Graham et al., 2016; Ost., 2014; Ruiz, 2012; Swain, Hancock, Dixon, Koo, & Bowman, 2013; Veehof. et al., 2016). Group-based ACT has been applied to several health conditions including cancer, multiple sclerosis, epilepsy, diabetes and chronic pain with promising findings in reducing depression, anxiety and disability and increasing acceptance and other condition-specific outcomes (Gregg et al., 2007; Kemani et al., 2015; Lundgren et al., 2006; Lundgren et al., 2008; Lance M. McCracken et al., 2013; Mohabbat-Bahar et al., 2015; Nordin & Rorsman, 2012; Wetherell et al., 2011). A single case report outlined benefits for the use of ACT with an adult experiencing post-stroke anxiety (Graham, Gillanders, Stuart, & Gouick, 2014). ACT does not require the ability to learn complex strategies nor rely on cognitive ability for high level reasoning therefore ACT is a promising intervention to consider for people with cognitive impairment (e.g. stroke survivors) and research suggests that ACT has utility in acquired brain injury (Kangas & McDonald, 2011; Soo et al., 2011).

### **Stroke and Psychological Provision**

The National Clinical Guidelines for Stroke suggest services should offer brief psychological interventions to all stroke survivors with, or at risk of, depression or anxiety (Royal College of Physicians, 2016). However, these stroke guidelines recognise many current commissioning arrangements do not include psychological provision (Royal College of Physicians, 2016). In one survey, almost three-quarters of stroke survivors experiencing

emotional distress felt their psychological needs were not being met (McKevitt et al., 2011). The guidelines urge commissioners to include clinical psychology in stroke rehabilitation multi-disciplinary teams, as well as to plan for the long-term management of psychological distress (Royal College of Physicians, 2016). The disability-adjusted life years (DALYs) lost post-stroke in low and middle-income countries, where resources are most stretched, was almost seven times higher than those lost in high-income countries (Feigin et al., 2014). Additionally, the UK's Department of Health (2012) acknowledged that people living with long-term conditions is currently the biggest challenge facing the National Health Service (NHS). Therefore, it is vital that research focuses on the effectiveness of innovative and cost-effective delivery formats, such as group-based interventions, to enhance the accessibility of psychological support (National Collaborating Centre for Mental Health, 2010).

### **Objectives of Current Study**

The aim was to assess the preliminary effectiveness of group-based ACT for stroke survivors ('ACTivate Your Life after Stroke') in comparison to a treatment as usual (TAU) control group. To the authors' knowledge, this is the first randomised pilot study of an ACT intervention with this clinical population.

Research suggests that non-acceptance of stroke-related disability is associated with depression after controlling for age, gender, original stroke severity and current disability at one month and nine months follow-ups (Townend, Tinson, Kwan, & Sharpe, 2010). The ACT intervention promotes acceptance of stroke-related disability therefore it was hypothesised that stroke survivors who attend the ACT intervention will have a reduction in depression

across pre-treatment, post-treatment and follow-up time points, in comparison to the control group, which would be evidenced by an ANOVA interaction between group and time. It was also hypothesised that significant interactions would occur in the ACT group for anxiety, health-related quality of life, self-reported health status, hopefulness and mental wellbeing, across the three time points in comparison to the TAU control group.

## **Methods**

### **Participants and Procedure**

Stroke survivors were invited into the study by clinical stroke teams across three NHS sites in south Wales and one in south west England if they: had at least one clinically diagnosed stroke, were discharged from hospital, were over 18 years old and did not have severe communication difficulties (e.g., aphasia) or cognitive impairments. Stroke survivors were not eligible if they had: another acquired brain injury (e.g. traumatic brain injury, encephalitis, tumours), a diagnosed degenerative condition (e.g. dementia), or a severe mental illness (e.g. psychosis). Potential participants were given an 'ACTivate Your Life after Stroke' course leaflet (Appendix 4), a participant information sheet (Appendix 5) and a consent form (Appendix 6).

Internet software ([www.randomizer.org](http://www.randomizer.org)) was used by the researcher to randomly generate a number sequence of 1's (intervention) and 2's (TAU control group who would then be invited to attend an ACT course when the study was completed) and a parallel group study design was utilised. Potential participants were referred by the clinical team to a designated person within each site (not the researcher), who was responsible for enrolling participants and group allocation. Once participants consented (in ignorance of the next assignment in

the sequence), their names were put into the spreadsheet in a consecutive manner and the associated number from the random number sequence indicated the group they were randomised to. No restrictions to randomisation were used. Letters were then sent to participants to let them know which group they had been allocated to and their course dates. For obvious reasons, this study could not be blinded. The study employed a longitudinal design using a questionnaire methodology. All outcome measures were collected by the researcher at pre-intervention (immediately prior to the first session), post-intervention (immediately following the final session) and at two month follow-up. The control group responded at the same time points and were returned by post or over the telephone.

## **Study Conditions**

### **ACT intervention.**

The ACT intervention, 'ACTivate Your Life after Stroke', consisted of two hour weekly group sessions, for four consecutive weeks. On sessions one and four an extra half an hour was allocated for study questionnaire completion. Due to the trans-diagnostic (applies to more than one condition) nature of ACT (Lang et al., 2012) carers were invited to the course but were not part of the study analysis. The material was psychoeducational and delivered by Microsoft PowerPoint with several non-interactive activities throughout, such as guided mindfulness practices. The intervention was developed from Professor Neil Frude's 'ACTivate your life' course (Cartwright & Hooper, in press), employed across NHS mental health services within south Wales, and was adapted for mild aphasia and included stroke specific examples. Adaptations to the presentation to account for mild aphasia consisted of reducing the number of words on the screen; minimising busy backgrounds; and avoiding

contrasting colours on the presentation i.e. to avoid red font against a blue background. Also, some stroke specific thought examples were added to the presentation e.g. “what if I have another stroke” or “you’re not improving as fast as you were before”. These modifications were consistent across all sites and were made in consultation with service users and professionals working in stroke rehabilitation settings. The session-by-session outline is illustrated in Table 1. A handout was provided for each session which included a session summary and suggested home activities.

All courses were run in community venues, e.g. local library, and each of the four sites (three NHS in south Wales and one third sector organisation in south west England) had at least two facilitators consisting of clinical psychologists, assistant psychologists or stroke care co-ordinators. All of the course facilitators received the same intensive two day training.

#### **TAU control group.**

Participants in the control group followed their usual treatments. After the two month follow-up data was collected, the control group were offered the intervention which consisted of the exact same material, course facilitators and time period as the first group.

#### **Measures**

##### **Socio-demographical information.**

The following information was collected: age, gender, date of first stroke and most recent stroke (if applicable), type and location of stroke (if known), employment status, living

arrangements and experience of mental health conditions since stroke and therapy received, if applicable (Appendix 7).

### **Primary Measure**

#### **Depression.**

Patient Health Questionnaire-9 (PHQ-9; Appendix 8) measure was used to screen for depression. The PHQ-9 is widely used and has good validity (sensitivity of 88% and specificity of 88%), internal reliability (Cronbach's  $\alpha$  of .89) and test-retest reliability (correlation = .84) in a primary care sample (Kroenke, Spitzer, & Williams, 2001) and performs well as a screening tool for post-stroke depression (Williams. et al., 2005).

### **Secondary Measures**

#### **Anxiety.**

The Generalized Anxiety Disorder-7 (GAD-7; (Appendix 9) measure was used to screen for anxiety (Spitzer, Kroenke, Williams, & Lowe, 2006). It has good validity (sensitivity of 89% and specificity of 82%), internal reliability (Cronbach's  $\alpha$  of .92) and test-retest reliability (intraclass correlation; ICC = .83) in a primary care sample. It is also moderately good at screening for a variety of other anxiety disorders (Kroenke, Spitzer, Williams, Monahan, & Lowe, 2007).

#### **Health related quality of life (HRQoL).**

The EQ-5D-5L (Herdman et al., 2011) (Appendix 10) has good internal reliability (ICC = .57) and test-retest reliability (ICC = .69) across health samples (Janssen, Birnie, Haagsma, & Bonsel, 2008) and has been validated in stroke samples (Dorman, Waddell, Slattery, Dennis,

& Sandercock, 1997; Golicki et al., 2015). Scores in this current study were converted to normed value sets (Devlin, Shah, Feng, Mulhern, & van Hout, 2016).

### **Self-reported health.**

Part two of the EQ-5D-5L (Herdman et al., 2011) (Appendix 10) was used to measure self-reported health. This consists of a 20cm visual analogue scale which asks users to indicate from 0 to 100 'how good is your health today?' Test-retest reliability was reported as ICC = 0.51 across health samples (Janssen et al., 2008) and has been validated in stroke samples (Dorman et al., 1997; Golicki et al., 2015).

### **Hope.**

The Adult Hope Scale (AHS; Appendix 11) (Snyder et al., 1991) was used to assess hope. Total scores from the eight active items range from zero to 48 and higher scores indicate greater hopefulness. The questionnaire is internally consistent (Cronbach's  $\alpha$  ranging from .74 to .84); shows good test-retest reliability (Cronbach's  $\alpha$  ranging from .73 to .85) and good validity across student and clinical populations (Snyder, 2002; Snyder et al., 1991).

### **Mental Wellbeing.**

Warwick and Edinburgh Mental Wellbeing Scale (WEMWBS; Appendix 12) has good validity, internal consistency (Cronbach's  $\alpha$  = .91) and test-retest reliability (ICC = .83) in general population and student samples (Tennant et al., 2007). It comprises of 14 items and a higher score indicates greater mental wellbeing. Mental wellbeing describes positive states of being, thinking, behaving and feeling.



## **Sample Size**

A similar randomised study (Lance M. McCracken et al., 2013) using the PHQ-9 to investigate the impact of group-based ACT in a health setting found the ACT group, in comparison to a TAU group, were significantly less depressed at post-treatment ( $d = .46$ ) and at three month follow-up ( $d = .58$ ). Based on these effect sizes, a power analysis was conducted using G\* Power (Faul, Erdfelder, Lang, & Buchner, 2007). In order for sufficient power (0.80) and using standard parameters of  $\alpha = 0.05$ , a total sample size of between 40 - 64 participants was required.

## **Statistical Methods**

An intention-to-treat (ITT) approach was used with imputation of missing data by last value carried forward (Streiner & Geddes, 2001). Effect sizes are reported as partial eta-squared (partial  $\eta^2$ ) and are categories against the suggested values of 01, .06, and .14 to indicate small, medium, or large effects (Richardson, 2011).

### **Primary outcome.**

A mixed-design repeated measure ANOVA was used to analyse the interaction between the two groups and depression outcome across the three time points. The experimental hypothesis stated there would be an interaction between group and time for depression therefore the group\*time interaction will be reported. There is no basis to report main effects because randomisation should insure that the scores of the two groups are equivalent at baseline which would mitigate any group differences across all three time points. To assess for group differences in clinically significant change, a Chi Square analysis was conducted. To identify when significant differences occurred between the groups two

mixed-design repeated measures ANOVAs were conducted (pre-intervention to post-intervention or pre-intervention to two month follow-up). This was conducted because although there were no significant differences between the groups at baseline, there were differences in the means, in that the ACT group had a higher mean (see Table 2); therefore differences would not necessarily be expected in means at post-treatment or at follow-up. However, it would be expected that a greater change would occur pre-treatment to post-treatment and pre-treatment to follow-up since the ACT group would change in a positive direction in comparison to the TAU group, hence interaction was tested for. As an index of change, interaction is a better measure than differences in means.

### **Secondary outcomes.**

A mixed-design repeated measures multivariate ANOVAs was used to analyse the interaction between the groups and the five aforementioned secondary outcome variables across the three time points. To assess where significant differences occurred between the groups two further mixed-design repeated measures multivariate ANOVAs were conducted (pre-intervention to post-intervention or pre-intervention to two month follow-up). The experimental hypothesis stated there would be an interaction between group and time for anxiety, quality of life, self-reported health, hope and mental wellbeing variables therefore the group\*time interaction will be reported. There is no basis to report main effects because randomisation should insure that the scores of the two groups are equivalent at baseline which would mitigate any group differences across all three time points.

### **Debrief**

At the end of the study, participants were given a debrief form (Appendix 13).

## **Ethical Approval**

This study was given a favourable opinion by the London - City & East Research Ethics Committee (Appendix 14 – 19).

## **Results**

### **Participant Flow**

Figure 1 illustrates the flow of participants through each arm of the study. Recruitment occurred between February and April 2016, the four courses of 'ACTivate Your Life after Stroke' intervention ran throughout April, one at each site, and two month follow-up data was collected in June 2016. Data on those initially invited to the study by the clinical teams could not be recorded as ethical approval allowed participant details to be collected only after consent. 53 participants were recruited in total and analysis was completed on all recruited participants in their original assigned groups, ACT N=26, control N=27. All 26 participants in the group-based ACT intervention attended at least three of the four sessions, of which 19 (73.1%) attended all four sessions. The attrition rate was low: 25 (96.2%) and 22 (84.7%) participants completed the post-treatment and the 2-month follow-up assessments in the intervention arm and 23 (85.2%) and 25 (92.6%) in the control arm. As a result of the low rate of dropouts, the predictors of dropout were not subjected to further analysis. Due to ethical reasons, the courses were open to stroke survivors and carers who did not wish to participate in the study. Total group sizes varied from six to twenty-two attendees across the four groups. Group sizes of stroke survivors who consented to participant in the research study varied from three to nine across the four groups which is detailed in Table 2.

## Sample Characteristics

The means and standard deviations of participant demographics and outcome measures at baseline are summarised in Table 3. Independent sample t-tests were conducted with Bonferroni correction, to compare the group at pre-intervention. Significant differences were found for gender whereby the ACT group had significantly more males. Although qualitative data were collected regarding stroke details (e.g. location and type), the data were too heterogeneous to analyse or comment on. There were no significant differences between the groups on the outcome measures at baseline, suggesting the groups were comparable on these measures as they entered into the study.

## Primary Outcome

A mixed-design repeated measures ANOVA revealed a significant overall time\*group interaction for depression, in favour of ACT over TAU,  $F(2, 102) = 3.875, p = .024$  with a medium effect size (partial  $\eta^2 = .071$ ). This interaction is shown in Figure 2 and means and standard deviations are illustrated in Table 4. This group differences remained significant at pre-treatment to post-treatment analyses  $F(1, 51) = 4.103, p = .048$  with a medium effect size (partial  $\eta^2 = .074$ ) and pre-treatment to two month follow-up analyses  $F(1, 51) = 5.901, p = .019$  with a medium effect size (partial  $\eta^2 = .104$ ).

### **Clinically significant change.**

The PHQ-9 defines clinically significant change as a score of  $\leq 9$  combined with improvement of 50% from the pre-treatment scores (Kroenke et al., 2001; McMillan, Gilbody, & Richards, 2010). At post-treatment a significant group difference occurred,  $\chi(1) = 5.352, p = .021$ , whereby 38.5% (N=10) of the ACT group had reached a clinically significant change, in

comparison to 11.1% (N=3) in the control group. This significant group difference continued at two month follow-up in favour of ACT,  $\chi(1) = 13.554$ ,  $p = .000$ . The total number of participants in the ACT group to reach a clinically significant change from pre-treatment was 53.8% (N=14) whereas in the control group it was 7.4% (N=2).

### **Secondary Outcomes**

A mixed-design repeated measures MANOVA across the three phases revealed a significant overall multivariate main effect for time\*group interaction, Wilks'  $\lambda = .56$ ,  $F(10, 42) = 3.26$ ,  $p = .003$ , partial  $\eta^2 = .437$ . Power to detect the effect was .97. Given the significance of the overall test, the univariate main effects were examined and significant findings were obtained in favour of ACT over TAU for self-reported health status  $F(1.75, 102) = 4.219$ ,  $p = .022$  and hopefulness  $F(1.65, 102) = 4.223$ ,  $p = .017$ , all with medium effect sizes (partial  $\eta^2 = .076$  for both variables). No significant effects were found for HRQoL, anxiety or mental wellbeing. These overall trends can be seen in Figure 2 and overall means and standard deviations are illustrated in Table 4.

To assess the outcome measures between the groups and across time points, two mixed-design repeated measures MANOVA's were conducted to evaluate the interaction from pre-treatment to post-treatment, and then from pre-treatment to follow-up. Pre-treatment to post-treatment analyses found a significant multivariate main effect for the time\*group interaction, Wilks'  $\lambda = .699$ ,  $F(5, 47) = 4.054$ ,  $p = .004$ , partial  $\eta^2 = .301$ . Power to detect the effect was .927. Univariate main effects revealed significant findings in favour of ACT in comparison to TAU for hopefulness  $F(1, 51) = 10.49$ ,  $p = .002$ , with a large effect size (partial  $\eta^2 = .171$ ). Although mental wellbeing did not reveal an overall effect across the three time

points in the initial repeated MANOVA, pre to post-intervention significance was reached in favour of ACT in comparison to TAU,  $F(1, 51) = 4.162$ ,  $p = .047$  with a medium effect size (partial  $\eta^2 = .075$ ). Self-reported health showed a strong trend in favour of ACT, but did not reach significance ( $p = .057$ ). Significant effects were not found for anxiety or HRQoL in this pre-post intervention analysis.

Pre-treatment to follow-up treatment analyses found a significant multivariate main effect for time\*group interaction, Wilks'  $\lambda = .779$ ,  $F(5, 47) = 2.666$ ,  $p = .033$ , partial  $\eta^2 = .221$ . Power to detect the effect was .763. There were no significant univariate effects.

## Discussion

The aim of this randomised study was to seek preliminary findings regarding the effectiveness of a group-based ACT intervention to assess if it appears to be a suitable psychological treatment for stroke survivors in comparison to a TAU control group. This study found that the ACT intervention significantly reduced depression and increased hopefulness and self-reported health status in stroke survivors in comparison to the TAU control group, with medium effect sizes.

The participants in the ACT group had a significant reduction of depressive symptoms from pre-treatment to post-treatment which was maintained during the two month follow-up period, with medium effect size, in comparison to the TAU control group. As a result, nearly 54% of participants in the ACT group had had a clinically and statistically significant change in depression scores at the two month follow-up in comparison to only 7% of the control group. As well as the overall interaction, hope scores revealed significant differences

between groups, in favour of ACT, from pre-treatment to post-treatment but this significant difference was not maintained at follow-up. As illustrated in Figure 2, the ACT group's improvement in hopefulness was maintained from post-intervention to follow-up but group differences were no longer found due to the control group's outcome scores becoming comparable at follow-up. In addition, self-reported health status followed a similar pattern to that of hope. Finally, the outcome variable for mental wellbeing did not produce an overall significant result across the three time points, however pre-intervention to post-intervention analysis found significant group differences, in favour of ACT. There were no significant group differences on measures of anxiety or HRQoL.

The reduction of depressive symptoms and the increase in self-reported health status and hopefulness in the participants who attended the ACT group are particularly interesting in the context of the aims of ACT, which does not primarily aim to reduce distress or improve health. Instead ACT aims to help people to live a valued life despite these unpleasant experiences (Harris, 2013). In line with this ethos, the improved hopefulness in the ACT group makes theoretical sense as participants were taught skills to take committed action to move towards a more meaningful life. Yet it is interesting that there were no significant differences in HRQoL. This may suggest that actual changes did not occur to participants' physical abilities in everyday tasks such as mobility, self-care and pain/discomfort, which would be an expected result of an ACT intervention. Yet despite such difficulties remaining relatively static throughout the study, the participants in the ACT group perceived their own health status as significantly better than the control group following the intervention. A cautious hypothesis of this outcome, in line with the ACT philosophy, is that the ACT intervention stimulated participants to experience a change of relationship with their health

difficulties as they learn to accept what they cannot change and focus on goals that are achievable and meaningful instead. However, these processes of change need much further investigation to be understood more clearly.

The significant reduction of depressive symptoms in the ACT group in comparison to the control group mirror findings of similar RCTs using group-based ACT with other physical health conditions, such as chronic pain, fibromyalgia and breast cancer patients (Luciano et al., 2014; Lance M. McCracken et al., 2013; Mohabbat-Bahar et al., 2015; Wicksell et al., 2013). When compared to TAU or waiting list controls, group-based ACT demonstrated significant improvements on depressive symptoms at post-intervention with small ( $d = 0.44 - 0.46$ ) (Lance M. McCracken et al., 2013; Wicksell et al., 2013) and large ( $d = 1.01$ ) effect sizes (Luciano et al., 2014). These significant improvements were maintained at three or six month follow-ups with medium to large effect sizes ( $d = 0.58 - 0.88$ ) (Luciano et al., 2014; Lance M. McCracken et al., 2013; Wicksell et al., 2013). However, it is important to note that when group-based ACT was compared to active treatments in chronic pain samples, such as CBT and applied relaxation, there were no significant differences between the interventions as all groups reported a reduction in depressive symptoms (Kemani et al., 2015; Wetherell et al., 2011). So the effectiveness of ACT in comparison to other treatments in stroke, as in other conditions, is an area requiring further research.

Outcome measures for hope do not appear to be commonly used in studies to assess the effectiveness of ACT-based interventions. One study was found which specifically assessed hope following a group-based ACT intervention in a health setting and it reported that the ACT intervention was effective in increasing hopefulness in patients with cancer (Ghasemi,



Dehghan, Farnia, Tatari, & Alikhani, 2016). Snyder and colleagues (1991) defined hope as a motivational state based on pathway thinking (a person's belief in their ability to produce and plan at least one effective path to their desired goals) and agency thinking (a person's belief in their ability to initiate and sustain the actions necessary to reach their goals). One aim of ACT is to support individuals to develop greater psychological flexibility through identifying their values, goal setting accordingly and choosing to take committed action to live a meaningful life (Harris, 2013). The significant increase in participants' hopefulness in the current study is relevant as higher levels of hope are associated with improved treatment adherence, ability to cope with illness and loss and enhanced psychological adjustment (Snyder, 2002; Van Servellen, Chang, Garcia, & Lombardi, 2002; Weis & Speridakos, 2011). However, the relationship between ACT and hopefulness requires further investigation.

### **Implications for Further Research and Service Delivery**

Although preliminary, these findings suggest that a full RCT of ACT for stroke would be viable and could provide confirmation of its efficacy. In countries such as the UK, many stroke units report no access to psychology services (Royal College of Physicians, 2012); yet 40% of stroke survivors felt abandoned after leaving hospital; 50% did not receive any information or support for anxiety or depression; and two-thirds said their emotional needs were not met as well as their physical needs following their stroke (Stroke Association, 2013). Healthcare cost for patients with long-term conditions and comorbid depression will typically be 45% greater than patients without comorbid depression (Naylor et al., 2012). Due to the non-interactive nature of group-based ACT it has potential to be a cost-effective

low intensity psychological intervention as, in principle, there is no limit to the number of people who can attend a course.

### **Strengths and Limitations**

Some strengths of this study are that the group-based 'ACTivate Your Life after Stoke' intervention was cost-effective, can be delivered by non-specialists with limited training, and was associated with favourable outcomes in depression, hopefulness and self-reported health status, with a sizeable proportion of participants reaching clinically and statistically significant change for depression. An additional strength was that this ACT intervention was specifically adapted by a team of service users and professionals from local stroke services to ensure the presentation accounted for mild aphasia and included stroke specific examples. The intervention offered stroke survivors access to a community-based psychological intervention, regardless of when their stroke occurred which is in line with guidance which recommends that all stroke survivors should be offered psychological support (Royal College of Physicians, 2016). To the authors' knowledge, this was the first study to explore the outcome of tailored group-based ACT for stroke survivors.

A limitation of this study is that the ACT intervention did not appear to make a differential impact on participants' anxiety levels beyond that of the TAU group. As anxiety affects around 25% of stroke survivors (Townend et al., 2006), this result is disappointing and will require further investigation. All outcome data were based on self-report measures, which is another limitation. As this study was a pilot study, not a clinical trial, the authors were unable to control for use of concomitant treatments and were also unable to gather data on the stroke survivors invited to the study by the clinical teams but declined to participate.

The type of participants that are willing to engage in group format psychological interventions, as opposed to individual therapy or medication only, may lead to a self-selected sample, which may in turn skew research outcomes (Wylde et al., 2014). It is recognised by the authors that a group setting may be sub-optimal for some patients and therefore referring professionals and course facilitators need to consider a range of interventions, tailored to patient need (Royal College of Physicians, 2016). Due to the resources available, this study was unable to: provide equality of therapy hours for the control group, compare against an active treatment or undertake checks for treatment adherence and therapist competence. All of which are outlined by the psychotherapy outcome study methodology rating form (POMRF) as an indication of good study quality (Ost, 2008).

### **Conclusions**

This pilot study was designed to consider the viability of studying a group-based ACT intervention for stroke survivors. Since there is limited research on cost-effective low intensity psychological interventions for stroke survivors and reports suggest stroke survivors' emotional wellbeing is being neglected, pilot studies such as this one are vital to progress our understanding of potentially effective and efficacious interventions. The results of this current study should be seen as preliminary as the sample size was small in comparison to trials intended to produce conclusive results. Recommendations for further research include a larger sample, with active comparison groups and to assess the cost-effectiveness of this intervention.

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## Conflict of Interest

The authors report no conflicts of interest.

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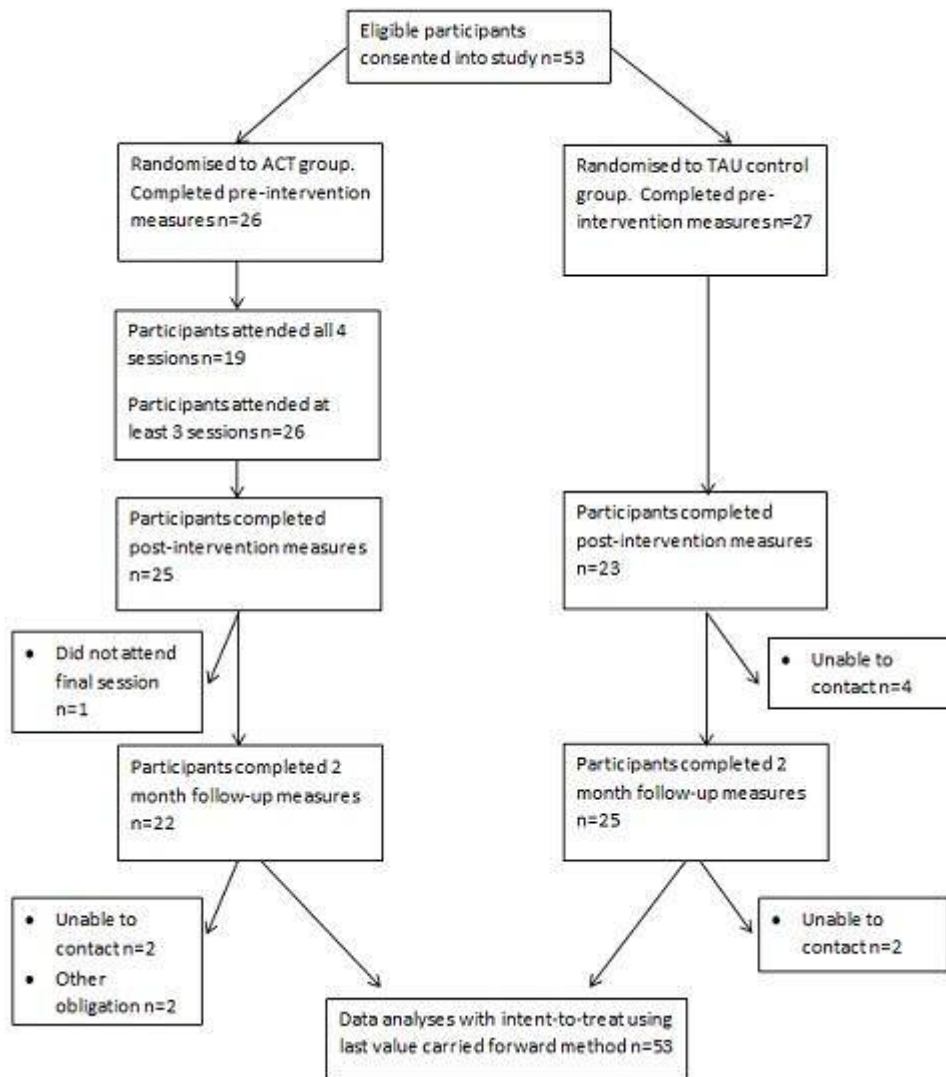
## Tables and Figures

**Table 1: Session-by-Session Outline of Activate Your Life after Stroke course**

Session	Content
<i>Week one:</i> <i>You are not your mind</i>	Creating the distinction between actions that are under our own (conscious, deliberate) control and actions that are controlled by our mind (e.g. on 'autopilot') including experiences of self-criticism and rumination. Introduced the idea of developing a viewpoint from which one can observe thoughts and feelings, non-judgementally.
<i>Week two:</i> <i>Facing up to life</i>	Focus on acceptance (not resignation) and willingness to experience unpleasant feelings and sensations (e.g. pain or anxiety) without attempts to fight, avoid or suppress them, which often causes suffering long-term.
<i>Week three:</i> <i>Being mindful</i>	Thoughts are thoughts, not facts. Several examples of thought defusion exercises presented. Explanation of mindfulness and non-interactive activities completed (e.g. body scan).
<i>Week four:</i> <i>Living wisely, living well</i>	Identification of individual values, distinction between values and goals and examples of committed action discussed.



**Figure 1: Flowchart of Participants in Randomised Groups**



**Table 2: Number of Group Members who took part in the research study**

	<b>Group 1 (n)</b>	<b>Group 2 (n)</b>	<b>Group 3 (n)</b>	<b>Group 4 (n)</b>	<b>Total</b>
ACT	7	7	3	9	26
CONTROL	4	6	7	10	27

**Table 3: Participant Characteristics at Baseline (Mean (SD) or n (%))**

Characteristics	ACT (n=26)	Control (n=27)	Overall (n=53)	P value
Mean age (years)	65.3 (11.9)	60.0 (15.6)	62.7 (13.9)	.184
Gender (% male)	21 (80.8)	11 (40.7)	32 (60.4)	.002*
Has had more than one stroke	6 (23.1)	8 (29.6)	14 (26.4)	.538
Months since most recent stroke	14.1 (14.5)	13.1 (13.3)	13.6 (13.7)	.824
Months since first stroke (if had multiple)	62.5 (73.7)	40 (37.1)	50 (50.8)	.380
Age left education	18.5 (3.6)	17.0 (2.1)	17.8 (3.0)	.090
Currently employed	4 (15.4)	10 (37)	14 (26.4)	.05
Currently retired	19 (73.1)	13 (48.1)	32 (60.4)	.124
Living circumstance:				.003
Living with carer	19 (73.1)	5 (18.5)	24 (45.3)	
Living with someone who is not carer	3 (11.5)	12 (44.4)	15 (28.3)	
Living alone	4 (15.4)	7 (25.9)	11 (20.8)	
Has previously received treatment for a mental health condition since stroke	11 (42.3)	9 (33.3)	20 (37.7)	.653
Treatment received:				.923
Medication	1 (3.8)	2 (7.4)	3 (5.7)	
Psychological therapies	4 (15.4)	2 (7.4)	6 (11.3)	
Both the above	3 (11.5)	1 (3.7)	4 (7.5)	
Not stated	3 (11.5)	4 (14.8)	7 (13.2)	
Study outcome measures at baseline				
PHQ-9	12.46 (6.3)	10.85 (7.5)	11.65 (6.9)	.402
GAD-7	9.77 (6.2)	7.85 (6.6)	8.79 (6.4)	.280
EQ-5D-5L	.65 (.26)	.61 (.28)	.63 (.27)	.554
Health (EuroQoL visual analogue)	59.62 (20.5)	55.67 (23.8)	57.6 (22.1)	.521
AHS	40.77 (14.3)	43.37 (13.3)	42.09 (13.7)	.496
WEMWBS	40.31 (10.5)	42.37 (12.7)	41.36 (11.6)	.522

ACT=acceptance and commitment therapy, TAU=treatment as usual, SD = standard deviation, PHQ-9 = patient health questionnaire-9, GAD-7 = generalized anxiety disorder-7, EQ-5D-5L = Euro-quality of life, AHS = adult hope scale, WEMWBS = Warwick and Edinburgh mental wellbeing scale

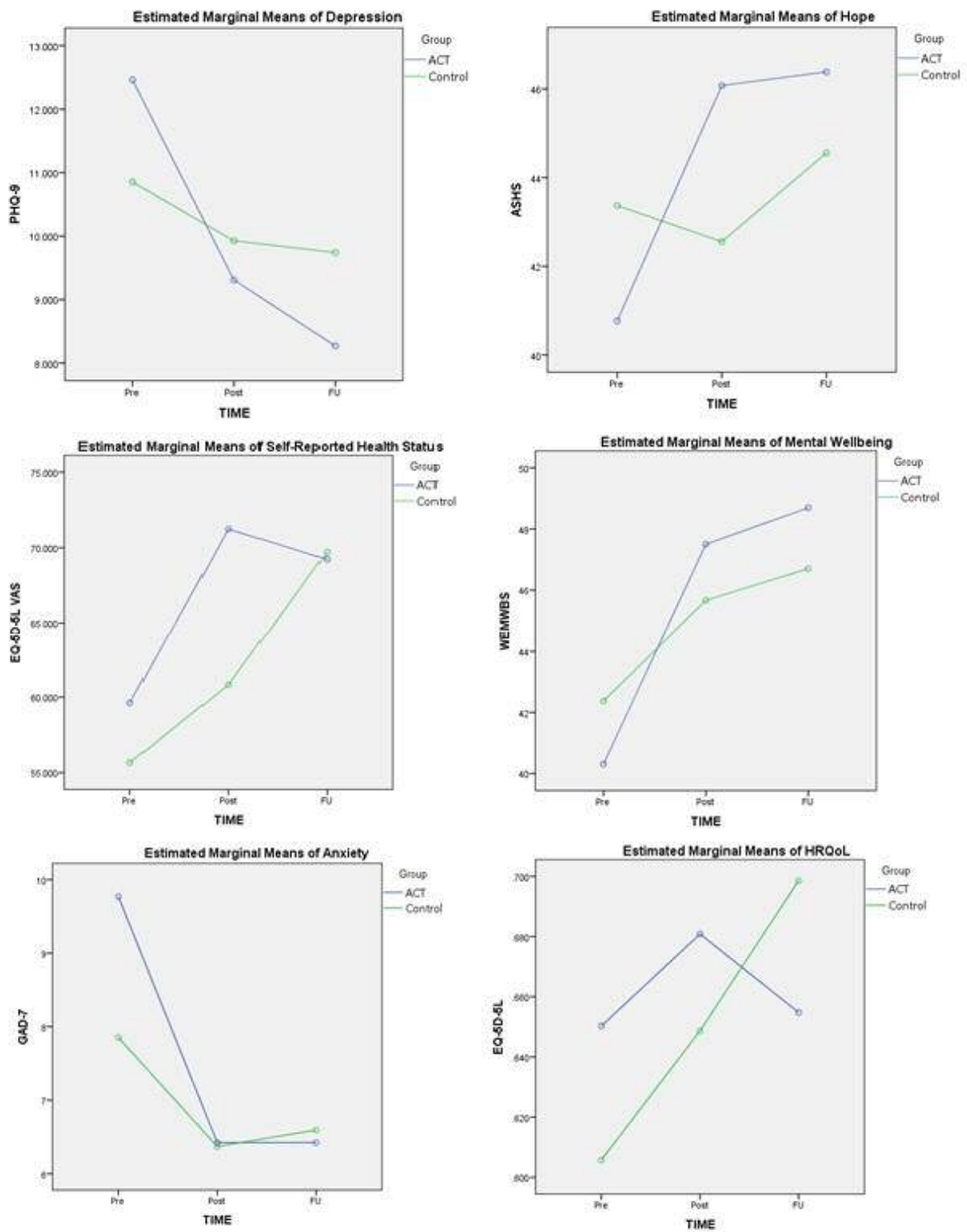
\* =significant P value after Bonferroni correction (.05/17 = .0029)

**Table 4: Means and Standard Deviation for all Outcome Variables**

		PHQ-9	GAD-7	EQ-5D-5L	Health (Euro-QOL visual analogue)	AHS	WEMWBS
T1	ACT	12.46 (6.3)	9.77 (6.2)	.65 (.26)	59.62 (20.5)	40.77 (14.3)	40.31 (10.5)
	TAU	10.85 (7.5)	7.85 (6.6)	.61 (.28)	55.67 (23.8)	43.37 (13.3)	42.37 (12.7)
T2	ACT	9.31 (6.7)	6.42 (5.5)	.68 (.22)	71.23 (17.2)	46.08 (10.3)	47.50 (12.0)
	TAU	9.93 (7.0)	6.37 (5.5)	.65 (.24)	60.81 (22.8)	42.56 (13.3)	45.67 (12.4)
T3	ACT	8.27 (6.5)	6.42 (4.9)	.65 (.26)	69.23 (16.8)	46.38 (12.2)	48.69 (12.9)
	TAU	9.74 (7.4)	6.59 (6.0)	.70 (.19)	70.0 (20.49)	44.56 (13.0)	46.70 (14.7)

T1= pre-intervention baseline, T2= post-intervention, T3=2 month follow-up, ACT=acceptance and commitment therapy, TAU=treatment as usual, PHQ-9 = patient health questionnaire-9, GAD-7 = generalized anxiety disorder-7, EQ-5D-5L = Euro-quality of life, AHS = adult state hope scale, WEMWBS = Warwick and Edinburgh mental wellbeing scale

**Figure 2: Line Graphs Illustrating Interactions for Each Outcome Measure between Groups across the Three Time Points**



Pre = pre-treatment baseline, Post = post-treatment, FU = 2 month follow-up

**Paper 3: A reflective paper providing a critical appraisal  
of the research process conducted for a  
Doctorate in Clinical Psychology Research Project**

**Sarah Majumdar**

**Word count (excluding references and tables): 8,085**

## **Introduction**

This paper presents a critical appraisal of the research conducted for this thesis and is not intended for publication. The appraisal will include a critical evaluation of both the systematic review and empirical study exploring the planning, implementation and interpretation of the research processes. Strengths and limitations are explored and personal-professional reflections will be offered.

### **Paper 1: Systematic Review**

#### **Strengths and Weaknesses of the Research Process**

##### **Rationale for Topic**

At the point of deciding on a review topic, I knew that my empirical study was an evaluation of a randomised controlled trial (RCT) of group-based Acceptance and Commitment Therapy (ACT) for stroke survivors. I was also aware that there had been previous reviews of ACT across a variety of clinical settings (Graham et al., 2016; Ost., 2014; Ruiz, 2012; Swain, Hancock, Hainsworth, et al., 2013; Veehof et al., 2011; Veehof. et al., 2016). However, many of the existing reviews mixed study populations and delivery formats i.e. children, adults, indirect (i.e. parents and staff groups), 1:1 and groups. I wanted to contribute to this knowledge about the effectiveness of ACT whilst facilitating additional understanding with a specific focus of ACT being delivered as a group format. To my knowledge, there are no other reviews reporting solely on the effectiveness of group-based ACT. I felt that this was a particularly relevant review due to recent austerity measures and the desire for cost-effective and accessible therapies, and innovative delivery formats, within healthcare settings (National Collaborating Centre for Mental Health, 2010).

### **Inclusion and Exclusion Criteria: Randomised Controlled Trials**

The decision was taken to include only RCTs in the systematic review because they are widely considered to be the “gold standard” for treatment efficacy studies (Shean, 2014) and therefore, systematic reviews of RCTs are considered to offer the highest level of evidence (Charrois, 2015). The Cochrane Collaboration is particularly encouraging of systematic reviews of RCTs and recommends inclusion of nonrandomised studies only when RCTs are lacking (Peinemann, Tushabe, & Kleijnen, 2013). Anecdotally, whilst reviewing full-text reviews I noticed that this seemed to make a difference to the fidelity of the ACT intervention that was evaluated in the individual empirical studies. For example, nonrandomised studies often included additional information and strategies alongside the ACT core principles (Goodwin, Forman, Herbert, Butryn, & Ledley, 2012; Lance M. McCracken et al., 2015; L. M. McCracken & Jones, 2012; Skinta, Lezama, Wells, & Dilley, 2015; Vowles & McCracken, 2008). Therefore, I feel that the exclusion of nonrandomised studies is a particular strength of this review.

### **Inclusion and Exclusion Criteria: Long-Term Conditions**

I came to the decision of focusing this systematic review on physical health related long-term conditions (LTCs) after several discussions with my academic supervisor. We discussed a variety to potential ways to focus this review, for example: whether to include only neurological conditions in line with my stroke-based empirical study, or to include conditions with known aetiology such as cancer and type-2 diabetes and we considered several definitions of LTCs. Due to the small numbers of RCTs published in the area we decided to be as inclusive as possible of all long-term physical health conditions, regardless of known aetiology, as research suggests that people experience chronic pain conditions as



just as disabling as conditions with known physiological aetiology. Worldwide low-back pain is ranked as number one for years lost to disability out of 291 LTCs and the Global Burden of Disease study found that four of the top twelve most disabling conditions globally were chronic pain conditions (Hoy et al., 2014). As outlined in paper one, just like other LTCs, chronic pain conditions are associated with decreased health status and quality of life, and an increased risk of depression and loss of employment (Breivik et al., 2013; Breivik. et al., 2006). Whilst I acknowledge that there are advantages and disadvantages to this approach, I believe that the inclusion of chronic pain conditions, including chronic headaches and fibromyalgia, is a strength of this review. This approach has also been taken by a recent article regarding LTCs which has been published in the same journal that my review has been prepared for (Bogosian et al., 2016).

#### **Inclusion and Exclusion Criteria: Peer-Reviewed Articles**

When abstracts from Dissertation Abstracts International arose in my initial screening, I took advice from the University Librarian for the standard protocol for including them or not. The advice was to exclude them to ensure use of the '*most rigorous possible evidence available*' (Appendix 20). A weakness of this decision is that this could have introduced a publication bias as studies with significant or clinically favourable findings are more likely to be published, which could lead to an overestimation of the treatment effects (Dwan et al., 2008). However, unpublished studies may be of lower methodological quality than published studies (Egger, Juni, Bartlett, Hoenstein, & Sterne, 2003) as the peer-reviewed process can act as a filter for poorly conceived or executed research (Ware & Monkman, 2008).

## Literature Search

The literature search was conducted in line with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines (Appendix 21) to ensure the search was systematic and transparent (Moher et al., 2009). In order to identify the widest scope of primary research, a thorough and complete search of the literature is required and the best way to accomplish this is to seek assistance from a librarian with expertise in the area of systematic reviews in defining the search terms, search strategies, and databases to be used (Charrois, 2015). Therefore, I contacted a Cardiff University librarian who assisted the development of the search terms and recommended databases to search. This was particularly helpful for considering MeSH subject headings and truncation commands. We discussed using specific or broad search terms for health conditions and decided that due to the vast number of possible LTC diagnoses and condition names, a broad search strategy would be paramount.

I used an online software programme ([www.covidence.org](http://www.covidence.org)), which is recommended by Cochrane, as a screening and data extraction tool to streamline the process of systematic reviews. I came across this software whilst assisting a PhD student as a second reviewer during my MSc and found it extremely useful for organising all of the potential studies, screening abstracts and full texts, and resolving disagreements. Therefore, I recommended this software to my doctorate cohort peers which received positive feedback. Since having two reviewers is recommended to enhance objectivity and reduce the possibility of rejecting relevant studies (Liberati et al., 2009), I paired up with a peer to act as second reviewers for one another's reviews. We decided to second review 100% of each other's abstracts, full-text articles, data extraction and study quality. This software helped us to

clearly separate the two reviews and eliminate confusion which I believe reduced errors in our screening processes. I created a data extraction form and a study quality spreadsheet for this review to provide standardisation, and eliminate discrepancies, between the two reviewers (Charrois, 2015). Several authors were contacted for missing information, however no responses were received and therefore, some data are missing as identified in table two in paper one and within the body of the data synthesis. Since many of the reviewed studies used various different outcome measure tools, a meta-analysis was not possible however, systematic reviews can still be highly relevant and useful without pooled data (Charrois, 2015).

### **Quality Assessment**

I found the process of choosing a quality assessment tool confusing as there does not appear to be a 'gold standard' or recommended tool. I considered both the Critical Appraisal Skills Programme (CASP) (2015) and the Specialist Unit for Review Evidence (SURE) (2013) tools. Whilst they both ask relevant questions regarding study quality, they have limited options to address the answers sensitively. The options to answer a question such as 'Was the assignment of patients to treatments randomised?' are 'yes', 'can't tell', 'no', therefore this creates limited distinction regarding processes that are completed vs. processes that are completed well and to high standard. They do provide you with 'hints' to consider each question in more detail, however this only provides qualitative information which makes it difficult to compare quality across studies. Therefore, the Psychotherapy Outcome Study Methodology Rating Form (POMRF) was chosen as it was designed to provide a rating of the methodological stringency and quality of the third wave psychotherapies, such as ACT (Ost, 2008). It was also found to have good internal

consistency (Cronbach's  $\alpha = .86$ ) and good interrater-reliability (intra-class correlation = .92) (Ost, 2008). I believe that using this quality tool was a strength of the systematic review as the tool encouraged clear distinction between levels of methodological rigour as each item is rated on a 3-point scale from 0 to 2, where 0 = poor, 1 = fair and 2 = good. This quantitative approach also allowed for a total score to be calculated for each study. Whilst these total scores are not attributed to overall qualitative meanings or categories of 'poor' or 'good' quality studies, they do allow for studies to be easily and directly compared to one another and against the mean of all the studies under review. It was valuable to have the second reviewer to rate all of the studies for quality against this tool as it was an arduous task and human error was likely. Discrepancies in scores were found for individual items and these were discussed until a consensus was reached. I considered whether I should set a minimal methodologic quality for review inclusion, however I decided setting a minimum overall total score was too subjective. I could not find any other reviews where this had been implement with this tool and I could not find any guidance on what total overall score deemed the study to be worthy of exclusion. Therefore, I decided it would be more appropriate to review all of the studies, whilst ensuring transparency of study quality throughout. Often, the main area of difficulty for researchers is how to incorporate this quality information into the data analysis (Charrois, 2015). I hope that by providing the total scores in table two, qualitative categories in the narrative synthesis i.e. 'a higher than average study found that...', and the individual item scores in the appendix, this has been achieved appropriately.

### **Specific Implications for Theory and Clinical Practice**

ACT is still a relatively new therapy and has had a recent surge of publications across multiple clinical populations. Nine of the twelve reviewed studies were published in the last five years. In comparison to Cognitive Behavioural Therapy (CBT), ACT still has some way to go in order to produce a similar level of evidence. However, I believe that this systematic review has highlighted that group-based ACT has utility as a low-intensity intervention in healthcare settings, particularly as it is the first review of its kind and has demonstrated promising findings. Group-delivered therapies based on alternative psychological theories are already used widely across community healthcare settings, such as CBT, mindfulness and Dialectical Behavioural Therapy (DBT). Therapies that can be delivered in a cost-effective, short term approach are of interest to Governments looking to commission such services in order to comply with national and international recommendations to increase the accessibility of evidence-based psychological therapies (Kuipers Cavaco & Quoidbach, 2014; National Collaborating Centre for Mental Health, 2010). I believe that ACT could be particularly successful due to the trans-diagnostic nature of the theory (Lang et al., 2012). It contrasts with group-based CBT, for example, patients are referred, based on a diagnosis, to different courses such as 'anxiety management' or 'low mood'. The CBT courses teach different strategies dependent on the diagnosis or presenting problem, which logistically will cost health services more as staff will require additional training to cover all techniques and multiple courses will need to be facilitated requiring increased staff time and venue hire costs. This is in contrast to ACT which provides the similar information and strategies for all presenting problems thus reducing facilitation costs as fewer courses, for the same number of patients, would be required. It is hoped that this systematic review will highlight the potential of group-based ACT in providing cost-effective, low-intensity and accessible

psychological input; will encourage further research; and will increase knowledge and interest in the theory of ACT and its clinical utility.

### **Suggestions for Further Research**

Recommendations for further research are outlined in the systematic review regarding:

- General topics to address where current evidence is lacking i.e. assessment of cost-effectiveness.
- Enhanced quantity of empirical studies i.e. more studies are required with LTCs samples to conduct a meta-analysis and draw firm conclusions about the effectiveness of group-based ACT for specific conditions and chronic health more generally.
- Enhanced study quality is needed, such as active treatment comparison groups.

As recommended by the university course tutors, once my systematic review was completed I submitted it to a journal. I had prepared the review in accordance to the author guidelines and, rather optimistically, submitted it to the Clinical Psychology Review which has an impact factor (2015) of 8.146. I chose this journal as a similar review had recently been published in it (Graham et al., 2016). I received the following feedback from the Editor:

*“Unfortunately, the literature is quite sparse and the wide range of procedures and conditions studied precludes meaningful conclusions. I suggest you consider submitting the manuscript to a behavioral health journal that would be receptive to an exploratory report.”*

I agree that the studies within the review do use a wide range of procedures and conditions which means it is difficult to draw firm conclusions regarding the effectiveness of group-based ACT. However, these early stage systematic reviews are important to identify these gaps in the knowledge base which can promote further research. Agencies who grant funding for empirical studies often require justification for these additional studies in the form of a systematic review (Moher et al., 2009). Therefore, I believe that this systematic review still plays a relevant and interesting role in shaping our knowledge about group-based ACT for LTCs and the requirements necessary for future research. My academic supervisor and I have agreed to submit the review to the British Journal of Health Psychology (impact factor: 2.895) and the review has been re-prepared to align with these journal guidelines which is the version submitted as paper one. This mostly involved reducing the word count in the main body of the text, excluding tables, figures and references, from over 6,500 words to less than 5,000 words. Now that this process has been completed, I feel that this was a worthwhile task as the review is now more succinct and concise.

## **Paper 2: Empirical Study**

### **Strengths and Weaknesses of the Research Process**

#### **Rationale for Topic**

I have always had an interest in clinical health psychology, initially developed pre-training whilst working in an IAPT service in England implementing a LTCs pathway for adults with diabetes, cardiac disease, chronic obstructive pulmonary disease, and weight management difficulties. I also co-facilitated group sessions for adults with chronic fatigue syndrome/ME. It was these clinical experiences that opened my mind to the psychological impact of LTCs. I

learnt from patients' stories about the circular nature of this issue: living with a LTC, and its consequences, caused many to feel low in mood and anxious whilst psychological distress impacted peoples' ability to accept and effectively manage their illness. I remember delivering CBT-based stress management sessions during cardiac and pulmonary rehabilitation programmes and feeling uncomfortable about facilitating thought challenging, as many of their LTC-relevant thoughts were accurate, e.g. *"I can no longer work and provide for my family"* or *"I cannot walk more than a few metres before being completely out of breath"*. I remember feeling like it was somewhat unhelpful to suggest that they should think differently when their thoughts reflected their reality. Although I value CBT ideas and use it regularly in clinical practice, I remember wondering if there was a more helpful way to approach psychological distress derived from physical health conditions.

Following on from this IAPT post I completed a health psychology MSc prior to starting this clinical doctorate. This MSc experience enabled me to consider the wider national and international public health context of LTCs and the importance of supporting people to take wise actions towards preventing, living with, and managing, their health condition to prevent premature mortality and to reduce morbidity. In addition, I learnt about the multifaceted burden on healthcare systems to support patients with LTCs. Since starting this clinical doctorate, we had introductory teaching on Acceptance and Commitment Therapy (ACT) which immediately interested me. Therefore, when the opportunity presented itself to evaluate the effectiveness of group-based ACT for stroke survivors I was feeling very motivated to engage with this research and to play an active role in the service development that was required to implement this group intervention across four sites. I was particularly keen to investigate alternative approaches, beyond CBT, for physical health



settings. Also, having come from England IAPT into Wales' services, I was very surprised at the lack of primary care mental health services. I was aware of the 'Activate your Life' courses, which alongside 'Stress Control' (White, 2005, 2010), appeared to me to be Wales' answer to IAPT and primary care. This is particularly relevant in the Welsh context, where over half of the study participants were recruited, as three of the seven NHS health boards were among the top 10% of primary care trusts across England and Wales for high rates of antidepressant prescribing (Roberts & Sedley, 2016). Furthermore, several systematic reviews have concluded inconsistent and disappointing results regarding the effectiveness of psychological therapies (problem solving, goal setting, psycho-education and social support) for stroke survivors (Hackett, Anderson, House, & Halteh, 2008; Hackett, Anderson, House, & Xia, 2008; Sugavanam et al., 2013). Therefore, I was excited by the idea of expanding knowledge of the effectiveness of low-intensity psychological interventions within NHS Welsh contexts.

### **Quantitative Approach**

Originally, in the early research development stage I was planning to facilitate focus groups alongside gathering the quantitative outcomes so that the empirical study could also report on qualitative data from attendees of the ACT intervention to gain their experiences of the course, and what they liked and disliked about attending the course. I was particularly interested to consider if the course materials and delivery format was acceptable to the stroke survivors as a psychological intervention and if they felt it had made a difference to how they related to their stroke and its consequences. Finally, I would have been interested to know if they would recommend the intervention to a friend and if they had any suggested changes. Qualitative methods can capture information which quantitative data

cannot about beliefs, values and feelings and can be used to learn from participants, to understand what is important to them, provide a context to apply meaning on quantitative results and to identify factors necessary to consider for future research (Berkwits & Inui, 1998). Although I feel this information would have provided an important layer to understand the findings in the empirical paper, after discussion with my academic supervisor and professional mentor it was decided that a single methodological approach was most practical than a mixed methods approach. The stakeholders involved in the research, (the stroke units' clinicians, course facilitators, the charity manager, Prof. Neil Frude who wrote the course and the service users) had engaged in the research on the initial understanding that the aim was to evaluate the course using a quantitative design which in turn could provide information useful for enhancing service delivery, for example, in future commissioning bids. Therefore, I decided to conduct a purely quantitative approach and a colleague from my cohort completed the qualitative research so that the evaluation of this ACT intervention could be completed in more depth across two LSRP's.

### **ACT Intervention**

The group-based ACT intervention for stroke survivors 'Activate Your Life After Stroke' was an adapted version of Professor Neil Frude's 'ACTivate Your Life' course (Cartwright & Hooper, in press) which has been facilitated since 2015 as a tier 0 primary care service across a number of health boards across south Wales alongside Jim White's 'Stress Control' (White, 2005, 2010) and Chris Williams' 'Living Life to the Full' (2007). There is no booking system for the original ACTivate Your Life course. The course is advertised in community venues such as GP practice surgeries and often recommendations are made by GPs or other health professionals. However there is no formal referral system and interested people can

just arrive to the first session. This course is delivered in several community venues across south Wales and is offered on a variety of days and times to increase access. A service evaluation was conducted of outcomes from 117 individuals who had attended at least one session. Significant positive differences were found from pre-treatment to post-treatment on measures of anxiety, depression, self-esteem, wellbeing, mindfulness-based self-efficacy and psychological flexibility (Cartwright & Hooper, in press). This course also has the support from the co-founder of ACT, Steven Hayes (Appendix 22).

### **Service User Involvement**

This research has been a vehicle for the shared engagement and activation of clinical staff and service users. During the adaptation process of the already existing 'ACTivate Your Life' course, service users played a key role. Their role was imperative to ensure the course material had relevant and appropriate stroke examples throughout as well as giving guidance on the presentation slides to reduce words and contrasting colours on the screen that would affect stroke survivors with aphasia. Being part of the truly collaborative process was extremely interesting as they gave feedback on things that I would never have considered, such as distracting swirling PowerPoint backgrounds that may have otherwise acted as a barrier to many stroke survivors attending to the course material.

### **Power Analysis and Sample Size Calculation**

A power analysis was conducted prior to recruitment using G\*Power (Faul et al., 2007) as an approach to calculate the required sample size. The statistical power of a study is influenced by multiple factors, such as the sample size, the study design, the number of conditions, the size of the effect being measured (Akobeng, 2005). Completing a power

analysis prior to recruitment can inform the researcher as to the required sample size in order to maximise the chance of answering the research question (Akobeng, 2005). When I completed the quality assessment tool for the systematic review, I noticed that many of the RCTs had not explicitly reported conducting a power analysis to inform their goal of recruitment figures. This is a failing, as when sample sizes are too small it reduces the chance of detecting any true differences between the groups. Therefore this would be a waste of resources, participants' time and may be unethical (Akobeng, 2005). Therefore, it is a strength of this empirical study that a power analysis was conducted in the planning stages so that enough participants could be recruited.

### **Selection of Outcome Measures**

The outcome measures that were chosen were largely influenced by what the clinicians; stroke services and my academic supervisor were familiar with and already using. Since my academic supervisor works clinically in stroke services and regularly conducts research with stroke survivors, he had a good grounding for which outcome measures were relevant and interesting. However, on reflection, if I had conducted my systematic review prior to making this decision I may have considered using different outcome measures which align with already published papers. In particular I may have used the Hospital Anxiety and Depression Scale (HADS) or the Beck Depression Inventory (BDI-II) instead of the Patient Health Questionnaire-9 (PHQ-9) to measure low mood as this was more widely used in previous studies and would help to facilitate any future meta-analyses. As a Trainee Clinical Psychologist, I have become accustomed to using outcome measures that services regularly use and are easily accessible. However, from a researcher's perspective, I should have given

consideration to the existing evidence base; therefore this has been a useful learning point for future research.

### **Advantages and Disadvantages of the Methodological Approach**

Double-blind RCT designs are widely considered to be the “gold standard” for treatment efficacy studies (Shean, 2014), therefore a disadvantage of the approach used for this empirical study is that it was not double-blind. This is a consequence of using a treatment as usual or waiting list control group as participants and researchers knew which was the active condition and therefore could not be blinded. However, an advantage of the methodological approach taken is that participants were randomised to treatment conditions which reduced allocation bias and minimises the risk of the known and unknown confounding factor (Akobeng, 2005). As such, RCTs are considered to provide the most reliable evidence on the effectiveness of interventions (Akobeng, 2005). The randomisation of participants resulted in the two groups being comparable at baseline on all outcome measures as illustrated in table two of paper two.

A common criticism of RCTs is that participants usually have one diagnosis based on a uncomplicated DSM-related symptom criteria and rarely have comorbidities, yet this is an unrealistic reflection of the individuals who actually seek psychological services in the general population (Shean, 2014). It is estimated that only 20% of people accessing psychological input have a single, uncomplicated diagnosis (Westen, Novotny, & Thompson-Brenner, 2004). Since ACT is trans-diagnosis (Lang et al., 2012), participants in this study were not included or excluded based on a diagnostic criteria thus this increases the external validity of the findings.

All of the measures used in this study were self-reported which can be problematic. Although all of the outcome measures used have good reliability and validity and are widely used, as outlined in paper two, self-reported measures rely on a certain level of self-reflection which suggests this could lead to a response bias. In addition, as the allocated treatment conditions could not be concealed from the participants, this may have increased the likelihood of social desirability influencing the outcomes whereby participants in the treatment group, may have presented their outcome responses in a favourable light, or ‘faked good’ to gain social approval (van de Mortel, 2008) as they would have known from the study’s participant information sheet (Appendix 5) that the aim was to assess if the ACT group was effective.

A disadvantage of the way this study was conducted is that the stroke survivors in either group were not asked to report information that may have acted as confounding variables and possibly created biases to the study findings. This includes information such as: their medication use and any changes to it, any contacts with healthcare professionals or services, other diagnoses, or adverse events that may have occurred over the study time period. However, collecting this vast amount of data would have been a complex challenge for a pilot study with one researcher.

## **Analysis**

The ACT model is trans-diagnostic (Lang et al., 2012), meaning the theories’ philosophy and strategies can be relevant for everybody and are not diagnostic-specific. It is well documented that the consequences of having a stroke affects the stroke survivor’s loved ones who often go on to become the stroke survivor’s official carer. A Stroke Association

survey (2013) found that 69% of carers experienced stress, 79% experienced anxiety, 84% experienced frustration and 60% experienced anger. Therefore, carers were invited to attend the group alongside stroke survivors and, if they wished, to be involved in the research. Twenty-four carers were recruited into the study (intervention group N = 15, control group N = 8) and were randomised in pairs alongside the stroke survivor for logistical reasons and to reduce contamination of the intervention materials to the control group. Their data was collected using the same methods as the stroke survivors across the three time points as outlined in paper two. The plan had been to analysis stroke survivor and carer data simultaneously. However, during initial data screening an independent samples t-test was conducted with Bonferroni correction, to compare the groups at baseline. Significant differences were found for the carers' data, demonstrating that the treatment and control groups were significantly heterogeneous at baseline, as illustrated in table one below. The carers' scores in the intervention group were very low for distress, creating a "floor effect". This skewed the overall data when stroke survivors' and carers data were analysed together making the overall treatment groups significantly heterogeneous at baseline. However, when the carers' data were removed, the stroke survivors' data became comparable at baseline between treatment groups, as demonstrated in table two of paper two. The decision to remove all of the carer data from the analysis was discussed with my academic supervisor and statisticians in the data clinics and we were all in agreement that since the course was originally designed for stroke survivors and they were the participants who had been primarily randomised into treatment groups it made sense to focus the analysis on these participants only.

Table one: Carer data at baseline (Mean (SD))

<b>Measure</b>	<b>Intervention N = 15</b>	<b>Control N = 8</b>	<b>P value</b>
Depression PHQ-9	3.53 (4.307)	11.00 (6.880)	.005*
Anxiety GAD-7	3.13 (3.461)	9.38 (6.844)	.008*

\* = Significant P value after Bonferroni correction (.05/2= .025)

The differences in carer data may have been caused because they were not officially randomised, unlike the stroke survivors. For example, several carers had decided to attend the course as they had to physically bring the stroke survivor anyway and decided that it would make sense to stay rather return shortly afterwards to collect them. Therefore, motivation to attend the course may have been linked to reasons other than wishing to access the psychological support for themselves. This may also explain why there were nearly double the numbers of carers in the intervention group than in the control group. I believe that making the decision to focus the analysis purely on stroke survivors was the right choice for this research because:

- The stroke survivors were the primary focus for the adapted ACT material.
- Stroke survivors had been the participants formally randomised into treatment groups, not the carers.
- The stroke survivors were experiencing psychological distress as per baseline measures in table two, paper two. However the carers in the intervention group were not, as illustrated in table one above.
- The stroke survivors' data was comparable at baselines between the two treatment groups as demonstrated in table two, paper two once the carer data had been removed.



- There were enough stroke survivors recruited to ensure the study had adequate power when the carers' data was removed from the analysis.

This decision was not addressed in paper two due to the finite word limit imposed by the journal as well as a desire to ensure a clear and concise narrative throughout the paper.

### **Intention to Treat Analysis**

An intention to treat (ITT) analysis was used as per CONSORT guidelines (Schulz, Altman, & Moher, 2010) and as a result of conducting the POMRF quality measure (Ost, 2008) during the systematic review. I developed an awareness that an ITT analysis can add to the quality of the paper as it accounts for noncompliance and missing outcome data through including every participant according to the randomised treatment assignment (Gupta, 2011). ITT analysis is often described as “once randomised, always analysed” (Kruse et al., 2002) and can reduce bias as participants who drop-out may do so as an adverse response to the treatment (Gupta, 2011). Furthermore, ITT analysis protects the sample size from dropouts which, in turn protects the statistical power of RCTs (Gupta, 2011). As ITT analysis is a cautious approach, it reduces the chance of a type I error. However critics have suggested that ITT analysis may be more susceptible to type II error (Fergusson, Aaron, Guyatt, & Hebert, 2002). Critics of ITT analysis suggest that analysing participants' data who have dropped out of treatment can dilute treatment effects, introduce heterogeneity within treatment groups, and participants who received very little of the treatment itself before dropping out provides insufficient information regarding the efficacy of any treatment (Heritier, Gebiski, & Keech, 2003). However these criticisms of ITT have limited application for this empirical study as all 26 participants in the group-based ACT

intervention attended at least three of the four sessions and 19 (73.1%) attended all four sessions. Whilst care was taken to reduce missing data and dropouts, this was very difficult to avoid completely due to the clinical nature of this research and that I was working alone collecting data for 53 participants (plus the 24 carers as mentioned above), over three time points. The last value carried forward approach was used for imputation of missing data across the six outcome variables. This approach replaces missing data with the last known value before the participant dropped out of the study. Criticism of the last value carried forward approach argue that it assumes that the outcome data at the point of dropout remains frozen or stable over the remaining study time points which is unrealistic and can introduce bias (Saha & Jones, 2009). However, this method for dealing with missing data is one of the most commonly used approaches and it is the common practice in the psychiatric literature (Saha & Jones, 2009). A review of the use of ITT analysis across 403 articles found that of the 249 (62%) articles which did report the use of ITT, the last observation carried forward imputation strategy was the most frequently used (Gravel, Opatrny, & Shapiro, 2007).

### **Use of a Multivariate ANOVA**

Mixed-design repeated measures multivariate ANOVAs were used to analyse the interaction between the groups. This was used to assess the PHQ-9 as the primary outcome and the other five outcome measures as secondary outcome variables, across the three time points. This approach was chosen over conducting individual ANOVAs for each outcome variable as the multivariate ANOVA takes into account the inter-correlations amongst the dependent variables and the combination of variables is therefore more meaningful. In addition,

repeating multiple ANOVAs can result in a Type I error due to multiple comparisons and therefore this approach is not recommended.

### **Write up**

This empirical study was written up in line with the CONSORT checklist guidelines (Schulz et al., 2010) which are outlined in Appendix 23.

### **Specific Implications for Theory**

As this is the first RCT of group-based ACT for stroke survivors, to the authors' knowledge, the implications for the ACT theory is that this empirical study demonstrates that ACT can have utility in this clinical sample, which until now was an unknown quantity. Although ACT theory suggests that its primary aim is not to reduce psychological distress, but instead to help people to live a valued life despite experiencing painful thoughts, feelings or sensations (Harris, 2013), this study has shown that this ACT intervention can make significant and clinical changes to patients levels of low mood as well as significantly improve their self-rated health status and hopefulness. This relationship between ACT and hopefulness requires further investigation to consider the implications for the theory more generally.

### **Suggestions for Further Research**

Although preliminary, these findings suggest that a full RCT of ACT for stroke survivors would be viable and could provide confirmation of its efficacy. One recommendation in the systematic review was that an active treatment comparison group would provide valuable information as the review found that, in general, ACT was more effective than treatment as usual and equally as effective as other active treatments such as cognitive behavioural

therapy and relaxation training for people with a range of LTCs. Suggested active treatment comparisons would be the current NICE recommended psychological therapies for stroke: motivational interviewing, problem solving and behavioural therapy (Royal College of Physicians, 2016). These active comparison groups should also provide equality of treatment hours in order to protect against non-specific therapeutic factors. Examples of this may be that attending the group, regardless of intervention model, allows participants to meet people who have had similar experiences. This can stimulate a shared group identity, peer learning and enhance acceptance of chronic illness (Chambers et al., 2012), which in turn can decrease isolation, enhance emotional support, buffer against stress, and provide opportunities to gain knowledge (Nicholas, 2016).

A future research suggestion is to use outcome measures that are more widely used in the LTCs literatures, as outlined in table two of paper one. The benefit of this is that it would increase the number of similar studies that could be compiled to conduct a meta-analysis to assess the effectiveness of group-based ACT for LTCs. It is also recommended that future research evaluates the cost-effectiveness of group-based ACT.

### **Specific Implications for Clinical Practice and Service Development**

The significant findings reported in this study are pertinent in relation to service delivery of psychological care within stroke units in the National Health Service across the UK.

Psychological provision appears to be inconsistent, with more than half of stroke units reporting no access to psychology services at all (Royal College of Physicians, 2012). Whilst acknowledging that we had a relatively small sample size, I feel that these findings are

relevant for health settings, particularly in a time of austerity where prudent healthcare is key.

This research was a vehicle for adding value directly into psychology services within the NHS and the participating charity. All four sites have continual access to the course materials so that they can now facilitate the group as and when required to address service demands and several of the sites have facilitated the group independently since the end of data collection. In particular for the charity involved, they have developed enhanced networks with the local NHS stroke team as a result of this study which involved the NHS stroke clinical team recruiting potential participants under a 'participant identification site'. In order to gain this NHS ethical approval for this site I met with the clinical stroke lead from the NHS team, alongside the charity's operational manager to discuss how connections could be increased between the two organisations to enhance services for local stroke survivors. Therefore, now that study has finished a lasting legacy has been left in all four sites to benefit clinical practice and service development.

The current system for stroke survivors in the NHS involves a six week discharge programme with limited capacity from the (frequently sole) clinical psychologist in the service to offer more. This is particularly important as the services cover vast geographical regions across south Wales. The National Clinical Guidelines for Stroke suggest services should offer brief psychological interventions to all stroke survivors with, or at risk of, depression or anxiety and to plan for the long-term management of psychological distress (Royal College of Physicians, 2016). Across the UK, 40% of stroke survivors felt abandoned after leaving hospital; 50% did not receive any information or support for anxiety or depression; and two-

thirds said their emotional needs were not met as well as their physical needs following their stroke (Stroke Association, 2013). Therefore, this group-based ACTivate your Life after Stroke course has been able to offer psychological input in the community beyond this usual six week discharge programme. Whilst it is acknowledged that group-based interventions are not for everybody and outcomes will not always be optimal, this empirical study highlighted that it is acceptable and can have significant effects for many people. This ACT course can be delivered by a range of presenters to a trans-diagnostic group of stroke survivors and it can produce significant outcomes. This suggests that it has a large potential as a cost-effective intervention.

### **Proposals for Dissemination**

I strongly believe in the importance of patients being protected from unnecessary research as well as benefiting from the subsequent improved outcomes and research informed care (Health Research Authority). Therefore, I have written both the systematic review and empirical study to the specifications of the British Journal of Health Psychology (impact factor: 2.895, ISI Journal Citation Reports<sup>®</sup> Ranking: 2015: 21/122 Psychology Clinical). Beyond publication in peer-reviewed journals, I plan to disseminate my empirical study findings at the following conferences:

- Division of Health Psychology Annual Conference 2017: Oral presentation (Accepted)
- Division of Clinical Psychology Annual Conference 2018: Oral presentation (Submitted abstract: awaiting decision)
- Welsh Stroke Conference 2017: poster presentation, see Appendix 24 (Submitted abstract: awaiting decision)

- OPSYRIS Conference 2017: oral presentation (awaiting call for abstracts)

In addition, once data analysis was completed I compiled a written summary to inform all of the stakeholders of the findings at the earliest opportunity as they were keen to know the outcomes so that they could continue to facilitate future groups.

### **Personal-Professional Development Reflections**

#### **Development of Research Ideas**

I feel that I have developed many research and clinical skills whilst conducting this research project. During initial meetings with all stake holders, I quickly learnt that site representatives (i.e. clinical psychologists, charity operations manager and stroke care co-ordinators) across the four sites (three NHS in south Wales and one charity in south west England) had their own expectations and priorities which had motivated them to engage in this research. It was my role to think about how I could keep all four sites engaging in all aspects of the research collaboratively and simultaneously to reduce bias that might occur between sites. In particular, three of the four sites had previously limited psychology input to cover vast geographical areas and were very eager to offer the course to as many stroke survivors as possible and as quickly as possible. I learnt to retain a firm stance on the importance of randomising participants to both conditions which did mean that half of participants would get a delayed intervention (if they had been randomised to the control group). I was aware of the charity being unable to randomise participants in previous research projects as they did not feel they could delay access to interventions which had led to heterogeneous treatment groups. Therefore, in order to minimise anxieties regarding

the intervention delay, I was keen to have the second group organised and fully planned (e.g. facilitators agreed, dates and rooms booked, etc.) which started immediately after the two-month follow-up period of the first group. This meant that as stroke survivors were randomised, clinical staff could give dates for either group which appeared to help with this process. I found it was also helpful to provide information regarding how randomised controlled trials could provide useful findings that could help in future commissioning bids, which in turn could provide interventions for many stroke survivors in the future, beyond this research. It was also beneficial to have full NHS ethical approval as the process of delaying treatment in the control group had been fully approved by the REC and R&D committees. On reflection, I felt torn between my clinical and research stance and I had to frequently remind myself that I was involved within a research capacity and that I had to ensure that NHS time and resources were used to their best potential to produce a relevant and sound empirical RCT study to the best of my ability given the circumstances.

Due to the constraints of conducting this research within the time scale of the doctorate course, I had applied for ethical approval for the empirical study and completed data collection before conducting my systematic review. I found this extremely frustrating as the findings from my systematic review, particularly my quality assessment, could have shaped my empirical study. I discussed this with my academic supervisor, which led to discussions regarding research run by clinical trials in comparison to what I could realistically achieve and that perhaps, actually, the empirical study would not have been very different, even if I had conducted the systematic review earlier. For example, I would not have been able to provide an active treatment group comparison with the resources available.



Completing research within the NHS has been a complicated experience. The process of completing NHS REC ethical approval and authorisation from four R&D sites was extremely taxing whilst juggling additional demands from the doctorate. On reflection I am very proud of this achievement. This process was hugely helped by my MSc dissertation experience which had also required NHS ethical approval. From this experience I had learnt small but useful tips such as dating all documents in the header with a version number so that myself and ethics committee had a clear trail of latest and updated documents. This more recent ethics approval process for this empirical study helped me to develop organisational skills as the four individual R&D sites, plus the REC site requested different changes to different documents meaning I was managing five sets of documents, changes, and correspondences.

Whilst collecting data from the control group who were not accessing any psychological input, I was curious regarding my clinical and ethical duty to action any information that was shared to me from participants, particularly regarding their safety. Whilst collecting data over the telephone, one participant disclosed to me that they were experiencing suicidal thoughts. I had explained my remit of confidentiality in the participant information forms (Appendix 5) and informed the participant I had a duty to pass on the information to the team's psychologist, which they understood and I acted on immediately. I felt torn between my clinical and research duties and had to remind myself of where my research duties ended and that I was not part of the participant's clinical team. This event highlighted the importance of having agreed pathways for how to act on this critical information and how to reach the psychologist involved to ensure participant safety.

During the data collection process, I was conscious of building a rapport with the participants, particularly the control group. I was mindful that they were spending time completing several questionnaires over three time points, whilst not receiving any immediate intervention as a consequence. I personally felt uncomfortable with this whilst also knowing in my academic mind that this is obviously the basis of an RCT with a control group and that they would be able to attend the course a few months later, if they wished. Every contact I felt a tension between being friendly and appreciative of their efforts but trying not to be drawn into their 'stories' some of them gave when answering the questionnaires. I was very aware that I did not want to provide any sort of 'intervention', even active listening therefore I worked hard to hold this in mind so to not introduce bias when collecting data and I also encouraged responses to be returned by post by providing self-addressed stamped envelopes which seemed to work well.

### **Professional Roles for Clinical Psychologists**

Working across the NHS and third sector organisations gave me a valuable insight into the process of implementing service developments. The three NHS clinical psychologists simply did not have the time or resources to logistically organise the planning of the course for example, room bookings. I took on the role of finding and booking free community venues such as local libraries and supermarkets whereas the charity had funds and resources to organise this themselves and pay for rooms. This made me reflect upon the role of a clinical psychologist with the NHS and that it is an expectation that we are at the fore-front of service development, particularly when it comes to increasing access to psychological therapies. However, given the high demands that are currently placed on public services, this can be difficult. This seems counter-intuitive as setting up psychological groups means

that many people can access services, yet the NHS pressures meant that staff members understandably were too busy engaging in existing clinical demands to implement this themselves.

### **Motivation for Future Research**

I have valued having the dedicated time to conduct this research and I am pleased that my findings have shown that this course has been of use to the participants. Whilst on my elective placement, also in a health service, I co-facilitate mindfulness sessions for medical staff during their lunch breaks. I am in the process of evaluating this and aim to write up the findings. This added level of evaluation to my clinical practice and plans for potential dissemination have come from my newly developed skills in research as a result of conducting this LSRP. I hope that once I qualify I will continue to hold formal evaluation and research in the fore-front of my mind, whilst I am also mindful of the time constraints and pressures that I am likely to face, that may act as a barrier. This tension is something I plan to discuss in future supervisions and appraisals, if appropriate, as I feel research really does need dedicate time and resources to be worthwhile and useful.

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## Appendices

### Appendix 1: Guide for Authors

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The aim of the British Journal of Health Psychology is to provide a forum for high quality research relating to health and illness. The scope of the journal includes all areas of health psychology as outlined in the Journal [Overview](#).

The types of paper invited are:

- papers reporting original empirical investigations, using either quantitative or qualitative methods, including reports of interventions in clinical and non-clinical populations;
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Authors who are interested in submitting papers that do not fit into these categories are advised to contact the editors who would be very happy to discuss the potential submission.

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## **Appendix 2: Psychotherapy Outcome Study Methodology Rating Form (POMRF; Ost, 2008)**

Note: If not enough information is given regarding a specific item a rating of 0 is given.

### **1. Clarity of sample description**

0 Poor. Vague description of sample (e.g. only mentioned whether patients were diagnosed with the disorder).

1 Fair. Fair description of sample (e.g. mentioned inclusion/exclusion criteria, demographics, etc.).

2 Good. Good description of sample (e.g. mentioned inclusion/exclusion criteria, demographics, and the prevalence of comorbid disorders).

### **2. Severity/chronicity of the disorder**

0 Poor. Severity/chronicity was not reported and/or subsyndromal patients were included in the sample.

1 Fair. All patients met the criteria for the disorder. Sample includes acute (≤1 yr) and/or low severity.

2 Good. Sample consisted entirely of chronic (>1 yr) patients of at least moderate severity.

### **3. Representativeness of the sample**

0 Poor. Sample is very different from patients seeking treatment for the disorder (e.g. there are strict exclusion criteria).

1 Fair. Sample is somewhat representative of patients seeking treatment for the disorder (e.g. patients were only excluded if they met criteria for other major disorders).

2 Good. Sample is very representative of patients seeking treatment for the disorder (e.g. authors made efforts to ensure representativeness of sample).

### **4. Reliability of the diagnosis in question**

0 Poor. The diagnostic process was not reported, or not assessed with structured interviews by a trained interviewer.

1 Fair. The diagnosis was assessed with structured interview by a trained interviewer.

2 Good. The diagnosis was assessed with structured interview by a trained interviewer and adequate inter-rater reliability was demonstrated (e.g. kappa coefficient).

### **5. Specificity of outcome measures**

0 Poor. Very broad outcome measures, not specific to the disorder (e.g. SCL-90R total score).

1 Fair. Moderately specific outcome measures.

2 Good. Specific outcome measures, such as a measure for each symptom cluster.

## **6. Reliability and validity of outcome measures**

0 Poor. Measures have unknown psychometric properties, or properties that fail to meet current standards of acceptability.

1 Fair. Some, but not all measures have known or adequate psychometric properties.

2 Good. All measures have good psychometric properties. The outcome measures are the best available for the authors' purpose.

## **7. Use of blind evaluators**

0 Poor. Blind assessor was not used (e.g. assessor was the therapist, assessor was not blind to treatment condition, or the authors do not specify).

1 Fair. Blind assessor was used, but no checks were used to assess the blind.

2 Good. Blind assessor was used in correct fashion. Checks were used to assess whether the assessor was aware of treatment condition.

## **8. Assessor training**

0 Poor. Assessor training and accuracy are not specified, or are unacceptable.

1 Fair. Minimum criterion for assessor training is specified (e.g. assessor has had specific training in the use of the outcome measure), but accuracy is not monitored or reported.

2 Good. Minimum criterion of assessor training is specified. Inter-rater reliability was checked, and/or assessment procedures were calibrated during the study to prevent evaluator drift.

## **9. Assignment to treatment**

0 Poor. Biased assignment, e.g. patients selected their own therapy or were assigned in another non-random fashion, or there is only one group.

1 Fair. Random or stratified assignment. There may be some systematic bias but not enough to pose a serious threat to internal validity. There may be therapist by treatment confounds. N may be too small to protect against bias.

2 Good. Random or stratified assignment, and patients are randomly assigned to therapists within condition. When theoretically different treatments are used, each treatment is provided by a large enough number of different therapists. N is large enough to protect against bias.

## **10. Design**

0 Poor. Active treatment vs. WLC, or briefly described TAU.

1 Fair. Active treatment vs. TAU with good description, or placebo condition.

2 Good. Active treatment vs. another previously empirically documented active treatment.

## **11. Power analysis**

0 Poor. No power analysis was made prior to the initiation of the study.



1 Fair. A power analysis based on an estimated effect size was used.

2 Good. A data-informed power analysis was made and the sample size was decided accordingly.

## **12. Assessment points**

0 Poor. Only pre- and post-treatment, or pre- and follow-up.

1 Fair. Pre-, post-, and follow-up o1 year.

2 Good. Pre-, post-, and follow-up X1 year.

## **13. Manualized, replicable, specific treatment programs**

0 Poor. Description of treatment procedure is unclear, and treatment is not based on a publicly available, detailed treatment manual. Patients may be receiving multiple forms of treatment at once in an uncontrolled manner.

1 Fair. Treatment is not designed for the disorder, or description of the treatment is generally clear and based on a publicly available, detailed treatment manual, but there are some ambiguities about the procedure. Patients may have received additional forms of treatment, but this is balanced between groups or otherwise controlled.

2 Good. Treatment is designed for the disorder. A detailed treatment manual is available, and/or treatment is explained in sufficient detail for replication. No ambiguities about the treatment procedure. Patients receive only the treatment in question.

## **14. Number of therapists**

0 Poor. Only one therapist, i.e. complete confounding between therapy and therapist.

1 Fair. At least two therapists, but the effect of therapist on outcome is not analyzed.

2 Good. Three, or more therapists, and the effect of therapist on outcome is analyzed.

## **15. Therapist training/experience**

0 Poor. Very limited clinical experience of the treatment and/or disorder (e.g. students).

1 Fair. Some clinical experience of the treatment and/or disorder.

2 Good. Long clinical experience of the treatment and the disorder (e.g. practicing therapists).

## **16. Checks for treatment adherence**

0 Poor. No checks were made to assure that the intervention was consistent with protocol.

1 Fair. Some checks were made (e.g. assessed a proportion of therapy tapes).

2 Good. Frequent checks were made (e.g. weekly supervision of each session using a detailed rating form).

### **17. Checks for therapist competence**

0 Poor. No checks were made to assure that the intervention was delivered competently.

1 Fair. Some checks were made (e.g. assessed a proportion of therapy tapes).

2 Good. Frequent checks were made (e.g. weekly supervision of each session using a detailed rating form).

### **18. Control of concomitant treatments (e.g. medications)**

0 Poor. No attempt to control for concomitant treatments, or no information about concomitant treatments provided. Patients may have been receiving other forms of treatment in addition to the study treatment.

1 Fair. Asked patients to keep medications stable and/or to discontinue other psychological therapies during the treatment.

2 Good. Ensured that patients did not receive any other treatments (medical or psychological) during the study.

### **19. Handling of attrition**

0 Poor. Proportions of attrition are not described, or described but no dropout analysis is performed.

1 Fair. Proportions of attrition are described, and dropout analysis or intent-to-treat analysis is performed.

2 Good. No attrition, or proportions of attrition are described, dropout analysis is performed, and results are presented as intent-to-treat analysis.

### **20. Statistical analyses and presentation of results**

0 Poor. Inadequate statistical methods are used and/or data are not fully presented.

1 Fair. Adequate statistical methods are used but data are not fully presented.

2 Good. Adequate statistical methods are used and data are presented with M and SD.

### **21. Clinical significance**

0 Poor. No presentation of clinical significance was done.

1 Fair. An arbitrary criterion for clinical significance was used and the conditions were compared regarding percent clinically improved.

2 Good. Jacobson's criteria for clinical significance were used and presented for a selection (or all) of the outcome measures, and conditions were compared regarding percent clinically improved.

### **22. Equality of therapy hours (for non-WLC designs only)**

0 Poor. Conditions differ markedly (>20% difference in therapy hours).

1 Fair. Conditions differ somewhat (10–19% difference in therapy hours).

2 Good. Conditions do not differ (<10% difference in therapy hours).

**Appendix 3: Table of Individual Papers Quality Ratings**

<b>POMRF</b>	<b><u>Gregg</u></b>	<b><u>Kemani</u></b>	<b><u>Luciano</u></b>	<b><u>Lundgren</u></b>	<b><u>Lundgren</u></b>	<b><u>McCracken</u></b>	<b><u>Mo'tamedi</u></b>	<b><u>Mohabbat-</u></b>	<b><u>Nordin</u></b>	<b><u>Shayeghian</u></b>	<b><u>Wetherell</u></b>	<b><u>Wicksell</u></b>
<b>Item</b>	<b>'07</b>	<b>'15</b>	<b>'14</b>	<b>'06</b>	<b>'08</b>	<b>'13</b>	<b>'12</b>	<b>Bahar '15</b>	<b>'12</b>	<b>'16</b>	<b>'11</b>	<b>'13</b>
<b>1</b>	1	2	1	1	1	2	1	1	1	1	2	1
<b>2</b>	/	/	/	/	/	/	/	/	/	/	/	/
<b>3</b>	2	1	1	1	1	1	1	1	1	1	1	1
<b>4</b>	/	/	/	/	/	/	/	/	/	/	/	/
<b>5</b>	2	2	2	1	1	2	2	1	1	2	2	2
<b>6</b>	2	2	2	2	1	1	2	2	2	2	2	2
<b>7</b>	1	0	1	0	0	1	0	0	1	0	2	0
<b>8</b>	1	1	0	0	0	0	0	0	0	0	0	0
<b>9</b>	1	2	2	1	2	1	1	1	1	1	2	2
<b>10</b>	2	2	2	1	2	0	1	0	2	0	2	0
<b>11</b>	2	2	2	0	0	0	0	0	0	2	0	0
<b>12</b>	1	1	1	2	2	1	0	0	1	1	1	1
<b>13</b>	1	1	0	2	2	1	2	1	1	1	0	2
<b>14</b>	0	2	0	1	1	1	0	0	1	0	1	2
<b>15</b>	0	2	2	2	2	2	2	0	2	0	2	2
<b>16</b>	0	2	1	1	1	1	2	0	0	0	2	1
<b>17</b>	0	2	1	1	1	1	2	0	0	0	2	1
<b>18</b>	0	1	0	1	1	0	1	0	0	0	1	1
<b>19</b>	2	2	2	0	0	2	2	0	1	0	2	0
<b>20</b>	2	2	2	2	2	2	2	1	1	2	2	2
<b>21</b>	1	2	2	1	1	2	1	1	1	1	2	1
<b>22</b>	1	2	0	2	2	0	0	0	2	2	2	0
<b>Total</b>	<b>22</b>	<b>33</b>	<b>24</b>	<b>22</b>	<b>23</b>	<b>21</b>	<b>22</b>	<b>9</b>	<b>19</b>	<b>16</b>	<b>30</b>	<b>21</b>

To find out more, or to  
book a place contact:

**Helping you  
re-build your life  
after stroke**



## **ACTivate Your Life After Stroke**

Acceptance and Commitment  
Therapy for people and carers  
living with stroke.



A short course to help you get  
on with your life after stroke.



---

## **What is ACTivate Your Life After Stroke?**

This course has been created especially for people who feel distressed or anxious after a stroke.

A stroke affects everyone differently but it can cause physical, emotional and social upheaval, not only for the person but for those closest to them.

The distress can often make people feel unable to get on with their lives.

Carers can have similar feelings and this course is also suitable for them.

## **How can the course help me?**

The ACTivate Your Life After Stroke course is based on a novel approach for helping called Acceptance and Commitment Therapy (ACT). ACT teaches that trying to get rid of our distress and pain only serves to increase it. It is often better to accept things we cannot control.

Such acceptance is not easy, but this course will teach you ways of accepting painful and distressing thoughts and feelings.

ACT also shows us how to make a commitment to act in ways that improve and enrich our lives despite having had a stroke or caring for someone who has had a stroke.

## **What is the course like?**

ACTivate Your Life After Stroke is a four-week course. Each session is two hours long.

It is an educational course that will teach you simple ways of dealing with your thoughts and feelings.

And think what you could gain: less suffering, greater control over your actions and increased inspiration to help you change your life for the better.

If you attend the course, you won't be asked anything about your personal circumstances or problems. Simply come along and see what you can take away.

## **The course consists of four sessions:**

**ACT 1:** How the Mind works

**ACT 2:** Facing up to Life

**ACT 3:** Being Mindful

**ACT 4:** Living Wisely, Living Well

## **I'm interested—how do I book a place?**

Details of the next course are given below.

**When:**

**Where:**

## Appendix 5: Participant Information Sheet

### Participant information sheet

We would like to invite you to take part in a research study to help us learn more about how to support people after stroke. There are two parts to this study, the details of which are explained below.

Before you decide to take part, it is important for you to understand *why* the study is being done and *what* you need to do. Please read this leaflet carefully.

Take time to decide whether or not you want to take part - talk it over with your family and friends, or ask us if you would like things explained or need more information.

Thank you for reading this!

---

#### Part 1 of the Study

What is the study?

We understand that a stroke can be life-changing for some survivors and their carers. Many stroke survivors find that they feel anxious or low in mood. We think that a model of therapy called Acceptance and Commitment Therapy (ACT) could be helpful in improving mood and well-being after stroke. This study aims to determine if ACT is effective to stroke survivors and carers.

ACT teaches people to accept what is out of our personal control. It is based on the idea that, generally, trying to rid ourselves of pain and distress only serves to increase it. The alternative then, is to accept it - but that doesn't mean being defeated or tolerating suffering. ACT is about learning skills and ways of managing to make room for painful feelings, thoughts, and sensations - allowing them to be there, without having to struggle against them. But it is more than just this, it is also about committing to action that improves and enriches our lives.

The aim of this project is therefore to look at how effective this therapy is in reducing levels of anxiety or depression, and improving well-being. In order to evaluate the effectiveness of this therapy properly, people who register their interest to participate in this study will be randomly allocated into one of two groups. Group one: will be invited to attend the ACT therapy course as soon as possible. Group two: will first go on a waiting list to receive ACT and then will be invited to attend the ACT course at a later date.

#### **Why are you doing this?**

When conducting research, there are lots of factors that may lead to change in how a person feels, for example, a person may simply feel better with time. One of the ways in which we try to 'control' for things like time, is to also include a 'control' or comparison group in the study. The people randomly allocated to the 'control' group serve as a comparison for the group that receive ACT. The

two groups are assessed in the same ways. Therefore, any difference between the two groups can be attributed to the intervention itself. The group assigned to the waiting list initially will then be invited to receive the intervention at a later date.

### **What will the course be like?**

The course is a four week therapeutic course called '*ACTivate Your Life After Stroke*'. It is very important that you can commit to attend all four sessions of this course since the sessions are closely linked. The sessions will last two hours per week (except the first and last session which will be two and a half hours). There will be a break included at the middle of each session. The layout of the sessions will be the same. There will be a presentation given and you do not have to contribute or speak at all if you do not wish to do so. We just ask that you listen to the session content with an open mind.

### **Can both the stroke survivor and his/her carer/spouse take part?**

Yes! Either one, or both are welcome to attend, but we do ask that ALL participants come to ALL four sessions.

### **What exactly is involved if I do agree to take part?**

If you decide to take part in the research there will be five questionnaires to complete. These should take no longer than 30 minutes in total. Both carers and stroke survivors will be asked to complete the same questionnaires at the start of the course and on completion of the course. We will ensure there is time to complete these questionnaires within the first and last session of the course. We would also like you to complete these questionnaires again two months after you finished attending so we can see how the benefits of ACT have been maintained. We may contact you via the telephone or post to complete these forms for the final time if you are willing for this.

If you are allocated into the waiting list group, we will ask you to complete the same questionnaires at the same three time points as the treatment group, as outlined above. This allows us to determine if ACT is better than no treatment. When you do attend the course, with your permission, we will ask you to complete the questionnaires three more times, at the start and end of the course and two months after the course has finished, as above. This will help us to evaluate the usefulness of the treatment.

### **How will my information be used?**

The results of the research will be written up as a thesis and an article and submitted as part of a Doctorate in Clinical Psychology. It is important that you know that no participants will be identified in any way as part of this process.

### **Do I have to take part?**

There is absolutely no requirement to participate in the research, and if you wish to join the course but not take part in the research you will still be welcomed as a valuable member. Whether you chose to participate in the study or not, this will have no impact on your treatment you receive from the stroke team.



**If I agree to participate in the study, can I change my mind later on?**

Yes, if you wish to withdraw from the study you can do this at any time. All your identifiable information and data collected from you, to date, will be destroyed and your name removed from all study files.

**Will my participation in the study be confidential?**

Your participation in the research will be kept strictly confidential. The questionnaires will be seen only by myself and my research supervisor (Reg Morris) and will be kept in a locked filing cabinet and identifiable information will be destroyed after 2 years.

I have a duty of care to protect people from harm, so there are some legal and ethical rules I must obey which could require me to over-ride confidentiality in the very unlikely event that there is a risk of harm.

**Will I be paid for this study?**

There is no payment for taking part in this study.

**Who has reviewed the study?**

This study has been reviewed by the London - City & East Research Ethics Committee. This means that the study processes involving the questionnaire data collection have been reviewed and given a favourable opinion by this NHS ethics committee (reference: XXXXX).

The second part of the study involves Stroke Survivors and will take place once the "ACTivate Your Life After Stroke" course has finished. We hope to learn more about the effectiveness of this psychological intervention by asking you some questions and exploring your personal views and experiences of the group.

We will invite some of you (25) to a short interview, approximately 45 minutes, in a location convenient to you. If you are keen to participate and would like to share your experiences of the group, or would like to know more information before consenting, please speak with your group facilitator. They will happily provide you with a participant information sheet detailing part 2 of the study in more depth, ensuring you are fully informed before making your decision.

**Further information**

If you have any further questions about taking part in the study or need further information please do not hesitate to contact the researcher (contact details below).

Thank you very much for taking the time to read this information sheet, your help is greatly appreciated. If you would like to participate in this study, please let your stroke clinician know.

If you would like more information about the project, please feel free to contact us:

**Researcher:**

Sarah Harris  
Trainee Clinical Psychologist, Postgraduate student.  
South Wales Doctoral Programme in Clinical Psychology  
11th Floor, School of Psychology, Tower Building,  
70 Park Place,  
Cardiff,  
CF10 3AT  
Email: sarah.harris7@wales.nhs.uk  
Tel: 029 2087 0582

**Academic supervisor:**

Prof. Reg Morris  
Consultant Clinical Psychologist  
South Wales Doctoral Programme in Clinical Psychology  
Cardiff & Vale UHB  
Email: Reg.Morris@wales.nhs.uk  
Tel: 029 2020 6464

## Appendix 6: Consent Form

### Consent form

Please read each statement below, and put your initials in the appropriate Yes or NO response e.g.

KP

I understand that my participation in this study is entirely voluntary and that I can stop attending the sessions, or filling out the questionnaires at any time, without giving a reason.

Yes  
 No

I understand that I am free to ask questions at any time. I am free to discuss my concerns with Professor Reg Morris, consultant Clinical Psychologist and Programme Director on the South Wales Doctoral Programme in Clinical Psychology.

Yes  
 No

I understand that the information provided by me will be held confidentially, such that only the researcher can trace this information back to me individually. The identifiable information will be retained for up to 2 years then it will be destroyed.

Yes  
 No

I understand that agreeing to participate in this research; I may be allocated onto the waiting list control group meaning I will have a wait before I can access the treatment group.

Yes  
 No

I understand that my participation in this study will involve completing five questionnaires, which should take no longer than thirty minutes and I may be asked to complete these questionnaires up to six separate occasions.

<input type="checkbox"/>	<b>Yes</b>
<input type="checkbox"/>	<b>No</b>

I give permission for the information to be used in reports with the understanding that it will be anonymous (i.e. my identity will not be revealed).

<input type="checkbox"/>	<b>Yes</b>
<input type="checkbox"/>	<b>No</b>

I understand that the researcher may post the questionnaires to me and may telephone me to collect my questionnaire answers.

<input type="checkbox"/>	<b>Yes</b>
<input type="checkbox"/>	<b>No</b>

I, \_\_\_\_\_ (please enter your NAME) consent to participate in the study conducted by Sarah Harris, who is working under the supervision of Professor Reg Morris.

Signed (participant): \_\_\_\_\_

Date: \_\_\_\_\_

Please delete as appropriate: I am a stroke survivor /carer

If verbal consent gained by participant, clinician to put initials in the box:

<input type="text"/>
----------------------

Signed (clinician): \_\_\_\_\_

Name (clinician): \_\_\_\_\_

Date: \_\_\_\_\_

## Appendix 7: Demographic Questionnaire

### Demographic Questionnaire for stroke survivor

The following information will be used anonymously in the study. Please answer as many questions as possible. However, you do not have to answer anything you don't want to. Thank you.

Today's Date: \_\_\_\_\_

Participant #: [office use] \_\_\_\_\_

Age: \_\_\_\_\_

Gender (please tick):

Have you had more than 1 stroke?

<input type="checkbox"/>	Yes
<input type="checkbox"/>	No

<input type="checkbox"/>	Male
<input type="checkbox"/>	Female

Date of first stroke: \_\_\_ / \_\_\_ / \_\_\_

Date of most recent stroke (if applicable): \_\_\_ / \_\_\_ / \_\_\_

Type of Stroke (if known): \_\_\_\_\_

Location of the Stroke (if known): \_\_\_\_\_

Age of leaving education: \_\_\_\_\_

Highest qualifications obtained: \_\_\_\_\_

Are you in employment?

<input type="checkbox"/>	Yes
<input type="checkbox"/>	No

Are you retired?

<input type="checkbox"/>	Yes
<input type="checkbox"/>	No

Current / previous work:

---

---

Living circumstances:

<input type="checkbox"/>	Living with a carer
<input type="checkbox"/>	Living with someone who is not a carer
<input type="checkbox"/>	Living alone

Have you been treated for any psychological condition (e.g. anxiety or depression) since your stroke?

<input type="checkbox"/>	Yes
<input type="checkbox"/>	No

If yes, what was the condition and what treatment did you receive?

---

---

Thank you

Appendix 8: PHQ-9

**PHQ-9**

Over the last 2 weeks, how often have you been bothered by any of the following problems?

(Use “✓” to indicate your answer”

	Not at all	Several days	More than half the days	Nearly every day
1. Little interest or pleasure in doing things.....	0	1	2	3
2. Feeling down, depressed, or hopeless.....	0	1	2	3
3. Trouble falling or staying asleep, or sleeping too much.....	0	1	2	3
4. Feeling tired or having little energy.....	0	1	2	3
5. Poor appetite or overeating.....	0	1	2	3
6. Feeling bad about yourself — or that you are a failure or have let yourself or your family down.....	0	1	2	3
7. Trouble concentrating on things, such as reading the newspaper or watching television.....	0	1	2	3
8. Moving or speaking so slowly that other people could have noticed? Or the opposite — being so fidgety or restless that you have been moving around a lot more than usual.....	0	1	2	3
9. Thoughts that you would be better off dead or of hurting yourself in some way.....	0	1	2	3

**Column totals**    \_\_\_ + \_\_\_ + \_\_\_ + \_\_\_

= **Total Score** \_\_\_\_\_

Appendix 9: GAD-7

**GAD-7**

Over the <u>last 2 weeks</u> , how often have you been bothered by the following problems? <i>(Use "✓" to indicate your answer"</i>	Not at all	Several days	More than half the days	Nearly every day
1. Feeling nervous, anxious or on edge	0	1	2	3
2. Not being able to stop or control worrying	0	1	2	3
3. Worrying too much about different things	0	1	2	3
4. Trouble relaxing	0	1	2	3
5. Being so restless that it is hard to sit still	0	1	2	3
6. Becoming easily annoyed or irritable	0	1	2	3
7. Feeling afraid as if something awful might happen	0	1	2	3

= **Total Score** \_\_\_\_\_

Appendix 10: EQ-5D-5L

<p><b>Under each heading, please tick the ONE box that best describes your health TODAY.</b></p> <p><b>MOBILITY</b></p> <p>I have no problems in walking about <input type="checkbox"/></p> <p>I have slight problems in walking about <input type="checkbox"/></p> <p>I have moderate problems in walking about <input type="checkbox"/></p> <p>I have severe problems in walking about <input type="checkbox"/></p> <p>I am unable to walk about <input type="checkbox"/></p> <p><b>SELF-CARE</b></p> <p>I have no problems washing or dressing myself <input type="checkbox"/></p> <p>I have slight problems washing or dressing myself <input type="checkbox"/></p> <p>I have moderate problems washing or dressing myself <input type="checkbox"/></p> <p>I have severe problems washing or dressing myself <input type="checkbox"/></p> <p>I am unable to wash or dress myself <input type="checkbox"/></p> <p><b>USUAL ACTIVITIES (e.g., work, study, housework, family or leisure activities)</b></p> <p>I have no problems doing my usual activities <input type="checkbox"/></p> <p>I have slight problems doing my usual activities <input type="checkbox"/></p> <p>I have moderate problems doing my usual activities <input type="checkbox"/></p> <p>I have severe problems doing my usual activities <input type="checkbox"/></p> <p>I am unable to do my usual activities <input type="checkbox"/></p> <p><b>PAIN/DISCOMFORT</b></p> <p>I have no pain or discomfort <input type="checkbox"/></p> <p>I have slight pain or discomfort <input type="checkbox"/></p> <p>I have moderate pain or discomfort <input type="checkbox"/></p> <p>I have severe pain or discomfort <input type="checkbox"/></p> <p>I have extreme pain or discomfort <input type="checkbox"/></p> <p><b>ANXIETY/DEPRESSION</b></p> <p>I am not anxious or depressed <input type="checkbox"/></p> <p>I am slightly anxious or depressed <input type="checkbox"/></p> <p>I am moderately anxious or depressed <input type="checkbox"/></p> <p>I am very anxious or depressed <input type="checkbox"/></p> <p>I am extremely anxious or depressed <input type="checkbox"/></p>	<p style="text-align: right;"><b>The best health you can imagine</b></p> <p>1. We like to know how is your health today.</p> <p>2. This scale is marked from 0 to 100.</p> <p>3. 100 means the best health you can imagine. 0 means the worst health you can imagine.</p> <p>4. Mark an X on the scale to indicate how is your health today.</p> <p>5. Now, please note the number you marked on the scale in the box below.</p> <div style="text-align: center;"> <p>Your Health Today = <input style="width: 30px; height: 20px; border: 1px solid black;" type="text"/></p> </div> <p style="text-align: right;"><b>The worst health you can imagine</b></p>
---	---

Figure 1 – EuroQOL-5 Dimensions score. To the left, the descriptive system that defines the health-related quality of life in five dimensions (HRQoL) and to the right, the visual scale in which the patients indicate the perception of their health status (Visual Analog Scale – VAS).



## Appendix 11: Adult Hope Scale

Read each item carefully. Using the scale shown below, please select the number that best describes you and put that number in the blank provided.

1=Definitely False  
2=Mostly False  
3=Somewhat False  
4=Slightly False

5=Slightly True  
6=Somewhat True  
7=Mostly True  
8=Definitely True

---

- 1. I can think of many ways to get out of a jam.
  - 2. I energetically pursue my goals.
  - 3. I fell tired most of the time.
  - 4. There are lots of ways around any problem.
  - 5. I am easily downed in an argument.
  - 6. I can think of many ways to get the things in life that are most important to me.
  - 7. I worry about my health.
  - 8. Even when others get discouraged, I know I can find a way to solve the problem.
  - 9. My past experiences have prepared me well for my future.
  - 10. I've been pretty successful in life.
  - 11. I usually find myself worrying about something.
  - 12. I meet the goals that I set for myself.
- 

Agency: \_\_\_\_\_

Add Scores on items: 2, 9, 10 and 12. Scores range from a 4 to a 32. Higher scores reflect higher agency.

Pathways: \_\_\_\_\_

Add scores on items: 1, 4, 6 and 8. . Scores range from a 4 to a 32. Higher scores reflect higher pathways thinking.

Total Hope Score: \_\_\_\_\_ (Add Score for Pathways to the Score for Agency)

Add the agency and pathway scores. Scores of 40 – 48 are hopeful, 48 – 56 moderately hopeful, and 56 or higher as high hope.

Snyder, C.R., Harris, C., Anderson, J.R., Holleran, S.A., Irving, L.M., Sigmon, S.T., &... Harney, P. (1991). The will and the ways: Development and validation of an Individual-differences measure of hope. *Journal of Personality and Social Psychology*, 60, 570-585.

## Appendix 12: Warwick and Edinburgh Mental Wellbeing Scale

### Box 1.1 Warwick-Edinburgh Mental Well-being Scale (WEMWBS)

Below are some statements about feelings and thoughts.  
Please tick the box that best describes your experience of each over the last 2 weeks.

STATEMENTS	None of the time	Rarely	Some of the time	Often	All of the time
I've been feeling optimistic about the future	1	2	3	4	5
I've been feeling useful	1	2	3	4	5
I've been feeling relaxed	1	2	3	4	5
I've been feeling interested in other people	1	2	3	4	5
I've had energy to spare	1	2	3	4	5
I've been dealing with problems well	1	2	3	4	5
I've been thinking clearly	1	2	3	4	5
I've been feeling good about myself	1	2	3	4	5
I've been feeling close to other people	1	2	3	4	5
I've been feeling confident	1	2	3	4	5
I've been able to make up my own mind about things	1	2	3	4	5
I've been feeling loved	1	2	3	4	5
I've been interested in new things	1	2	3	4	5
I've been feeling cheerful	1	2	3	4	5

Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS).  
© NHS Health Scotland, University of Warwick and University of Edinburgh,  
2006, all rights reserved.

## Appendix 13 Debrief Form

### Debrief form

I would like to thank you for taking part in this study! Your time and input is very much appreciated.

The aim of this study was to evaluate the effectiveness of Acceptance and Commitment Therapy at reducing distress and improving well-being in stroke survivors and carers. We have used the questionnaire data that you have kindly completed, to achieve this. The information you provided will help to plan care for stroke survivors and carers in the future.

If you wish to have information about the results of the study please contact Sarah Harris (contact details overleaf) and she will send you a summary of the results as soon as they are available.

Additionally, if you would like to make any comments please feel free to contact either myself or Professor Morris (contact details overleaf).

Many thanks,

Supervised by,

Sarah Harris  
Trainee Clinical Psychologist

Dr Reg Morris  
Consultant Neuropsychologist

If you would like more information about the project, please feel free to contact us:

#### **Researcher:**

Sarah Harris  
Trainee Clinical Psychologist, Postgraduate student.  
South Wales Doctoral Programme in Clinical Psychology  
11th Floor, School of Psychology, Tower Building,  
70 Park Place,  
Cardiff,  
CF10 3AT  
Email: sarah.harris7@wales.nhs.uk  
Tel: 029 20870582

**Academic supervisor:**

Prof. Reg Morris  
Consultant Clinical Psychologist  
South Wales Doctoral Programme in Clinical Psychology  
Cardiff & Vale UHB  
Email: Reg.Morris@wales.nhs.uk  
Tel: 02920 206464

If you have any concerns or complaints about the research you can contact the **School of Psychology Research Ethics Committee** in writing at:

Secretary to the Research Ethics Committee  
School of Psychology, Tower Building  
70 Park Place, Cardiff, CF10 3AT  
Email: psychethics@cardiff.ac.uk

## Appendix 14: NHS REC Ethical Approval Letter

  
**Health Research Authority**  
London - City & East Research Ethics Committee  
Bristol Research Ethics Committee Centre  
Whitefriars  
Level 3, Block B  
Leaving Mead  
Bristol  
BS1 2NT  
Telephone: 01173421386

19 February 2016

Miss Rebecca Large/Miss Sarah Harris  
South Wales Doctoral Programme In Clinical Psychology 11th Floor, School of Psychology,  
Tower Building, 70 Park Place,  
CF10 3AT

Dear Miss Large/Miss Harris

**Study title:** A mixed-methods evaluation of an adapted Acceptance and Commitment Therapy (ACT) group for stroke survivors and their carers: ACTivate Your Life After Stroke. N.B. Please note change of name from 'ACTION after Stroke' to 'ACTivate your life after stroke'. The former name appears on the sponsors letter, however the documents provided for review are the same. The name was changed to remain consistent across all research sites.

**REC reference:**  
**Protocol number:**  
**IRAS project ID:**

XXXXXXXXXX

Thank you for your letter of 15 February 2016, responding to the Proportionate Review Sub-Committee's request for changes to the documentation for the above study.

The revised documentation has been reviewed and approved by the sub-committee.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact the REC Manager Mr Rajat Khullar, nrescommittee.london-cityandeast@nhs.net. Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

### Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised.

### Conditions of the favourable opinion

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

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

*Management permission should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).*

*Guidance on applying for HRA Approval (England)/ NHS permission for research is available in the Integrated Research Application System, [www.hra.nhs.uk](http://www.hra.nhs.uk) 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 management permissions from host organisations.*

### Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database. This should be before the first participant is recruited but no later than 6 weeks after recruitment of the first participant.

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 request a deferral for study registration within the required timeframe, they should contact [hra.studyregistration@nhs.net](mailto:hra.studyregistration@nhs.net). The expectation is that all clinical trials will be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from the HRA. Guidance on where to register is provided on the HRA website.

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

### **Ethical review of research sites**

The favourable opinion applies to all NHS sites 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" above).

#### Approved documents

The documents reviewed and approved by the Committee are:

Document	Version	Date
Evidence of Sponsor Insurance or indemnity (non NHS Sponsors only) [sponsorship insurance certificate]		
Interview schedules or topic guides for participants [part 2: interview schedule]	2	14 December 2015
Letter from sponsor [Sponsorship letter]		22 December 2015
Other [Rebecca Large (CI) CV]		
Other [Part 2: Participant Information sheet and consent form]	2	13 January 2016
Other [Email from Louise Hesp re: consent process]		
Other [part 2: debrief form v1]	1	11 December 2015
Other [Part 1: debrief form v2]	2	29 November 2015
Other [demographic form for carers v3]	3	29 November 2015
Other [demographic form for stroke survivors v3]	3	29 November 2015
Other [ASH sample]		
Other [EUROQOL 5D sample]		
Other [Warwick and Edinburgh mental wellbeing scale sample]		
Other [PHQ-9 & GAD-7 sample]		
Other [Reply to REC panel]	1	10 February 2016
Participant consent form [part 1: consent form v2]	2	29 November 2015
Participant information sheet (PIS) [Part 1: Participant information sheet]	3	08 January 2016
REC Application Form [REC_Form_14012016]		14 January 2016
REC Application Form [REC_Form_12022016]		12 February 2016
Referee's report or other scientific critique report [supervisors letter of scientific review]		
Research protocol or project proposal [protocol ]	2	10 February 2016
Response to Request for Further Information [Cover Letter ]		15 February 2016
Summary CV for Chief Investigator (CI) [Sarah Harris CV]		
Summary CV for supervisor (student research) [Reg Morris CV]		

#### Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

#### After ethical review

#### Reporting requirements

## Appendix 15: Sponsor Letter

Research and Innovation Services  
Director Geraint W Jones  
Gwasanaethau Ymchwil ac Arloesi  
Gŵyneddler Geraint W Jones

22 December 2015  
Professor Reg Morris  
School of Psychology  
Cardiff University  
South Wales Clinical Psychology Doctoral Programme  
11<sup>th</sup> floor,  
Tower Building  
70 Park Place  
Cardiff, CF10 2AT



Cardiff University  
7th Floor  
30 - 33 Rowland Road  
Cardiff, CF24 0GE  
Wales, UK  
Tel: 0117 231 2000  
Fax: 0117 231 2001  
Email: [info@cardiff.ac.uk](mailto:info@cardiff.ac.uk)  
30 - 33 Rowland Road  
Cardiff, CF24 0GE  
Cymru: Y Ddraig Goch

Dear Professor Morris,

**Title: A mixed-methods evaluation of an adapted Acceptance and Commitment Therapy (ACT) group for stroke survivors and their carers: ACTION after Stroke**

**Short title: An evaluation of an adapted ACT group for stroke survivors**

I understand that you are acting as Chief Investigator for the above ClinPsy PhD project to be conducted by Rebecca Large and Sarah Harris.

I confirm that Cardiff University agrees in principle to act as Sponsor for the above project, as required by the Research Governance Framework for Health and Social Care.

#### Scientific (Peer) Review

I can also confirm that Scientific (Peer) Review has been obtained from Professor Reg Morris – South Wales Clinical Psychology Training Programme, Cardiff University.

#### Insurance

The necessary insurance provisions will be in place prior to the project commencement. Cardiff University is insured with UMAL. Copies of the insurance certificate are attached to this letter.

#### Approvals

On completion of your IRAS form (for NHS REC and NHS R&D approvals), you will be required to obtain signature from the Sponsor ("Declaration by the Sponsor Representative").

Please then submit the project to the following organisations for approvals:

- An NHS Research Ethics Committee;
- Health & Care Research Wales Permissions Coordinating Unit (formerly known as NISCHR PCU) -to arrange host organisation R&D approval for Welsh NHS sites);
- English NHS Site R&D Approvals:
  - 
  -

Once Research and Innovation Services has received evidence of the above approvals, the University is considered to have accepted Sponsorship and your project may commence.

#### Roles and Responsibilities

As Chief Investigator you have signed a Declaration with the Sponsor to confirm that you will adhere to the standard responsibilities as set out by the Research Governance Framework for Health and Social Care. In accordance with the University's Research Governance Framework, the Chief Investigator is also responsible for ensuring that each research team member is qualified and experienced to fulfill his delegated roles including ensuring adequate supervision, support and training.



Registered Charity, 1156655 (Guernsey)



Appendix 16: R&D Approval Letters Site 1

TRUST LOGO

Trust Address

18 April 2016

Service Address

Study Title: A mixed-methods evaluation of an adapted Acceptance and Commitment Therapy (ACT) group for stroke survivors and their carers: ACTivate Your Life After Stroke.

R&D Reference: [REDACTED]

IRAS Project ID: [REDACTED]

The above project was forwarded to [REDACTED] Health Board R&D Office by the Health and Care Research Wales Permissions Coordinating Unit. A Governance Review has now been completed on the project.

Documents approved for use in this study are:

Document	Version	Date
Participant Information Sheet and ICF: Part 2	2	13/12/2015
Debrief Form: Part 1	2	29/11/2015
Debrief Form: Part 2	1	11/12/2015
Interview Schedule	2	14/12/2015

We warrant that the information provided in this document is true and correct to the best of our knowledge and belief at the time of writing. This document is for internal use only and is not to be distributed outside the organization.



Document	Version	Date
Validated Questionnaire: ASH hope scale sample		01/01/1996
Validated Questionnaire: EQ-5D-Y		01/01/2008
Validated Questionnaire: GAD-7 and PHQ-9		01/01/1999
Validated Questionnaire: Warwick and Edinburgh mental wellbeing scale sample		01/01/2006
Demographic Questionnaire: Carer	3	29/11/2015
Demographic Questionnaire: Stroke Survivor	3	29/11/2015
Participant Consent Form: Part 1 Quantitative	2	29/11/2015

I am pleased to inform you that the UHB has no objection to your proposal and that this study has been classed as pathway-to-portfolio.

You have informed us that Cardiff University is willing to act as Sponsor under the Research Governance Framework for Health and Social Care. Please accept this letter as confirmation of permission for the project to begin within this UHB.

In order to comply with Health and Care Research Wales reporting requirements, you must inform the R&D Office of the date which this site opens to recruitment and the date that the first patient is recruited at this site. Please email this information to:

xxxx

May I take this opportunity to wish you success with the project and remind you that as Chief / Principal Investigator you are required to:

- Inform the R&D Office if this project has not opened within 12 months of the date of this letter. Failure to do so may invalidate R&D approval.
- Inform the Health and Care Research Wales Permissions Coordinating Unit and the UHB R&D Office if any external or additional funding is awarded for this project in the future
- Ensure that all study amendments are submitted to the Health and Care Research Wales Permissions Coordinating Unit by the Chief Investigator
- Ensure the Health and Care Research Wales Permissions Coordinating Unit is notified of the study's closure
- Ensure that the study is conducted in accordance with all relevant policies, procedures and legislation
- Provide information on the project to the UHB R&D Office as requested from time to time, to include participant recruitment figures

Yours sincerely,

XXXX

Prof  
R&D

CC

## Appendix 17: R&D Approval Letters Site 2

Trust LOGO and address

Miss Sarah Harris  
South Wales Doctoral Programme in Clinical Psychology  
11th Floor,  
School of Psychology,  
Tower Building,  
70 Park Place,  
Cardiff  
CF10 3AT

Dear Miss Harris,

Re: [redacted] **An evaluation of an adapted ACT group for stroke survivors**

Thank you for clarifying the points raised at the Risk Review Group (RRRG) held on 18<sup>th</sup> February 2016. I have pleasure in confirming that this project now has full approval to commence in the [redacted] with Board. However commencement of the project should be upon the receipt of ethical approval if required. If the project is a multi-site study it is advised that you also obtain approval from all other Health Boards before commencing the project at individual sites.

The Group reserve the right to information on the progress of the project at any time and should receive a progress report six monthly and a written report on completion.

Random audits will be carried out to ensure that projects comply with the clinical guidelines of research. Any serious adverse incidents relating to the project should be reported to the R&D office and a Clinical Incident Form filled in.

If your project includes participants or resources from other Health Boards it is your responsibility to contact the relevant R&D Office(s) in order to gain R&D approval to commence. Without individual R&D approval from all Health Boards involved in the study Welsh Risk Pool indemnity will not be afforded to the researcher.

On completion of the project it is important that you inform the Health Board Research & Development office.

It is a requirement of approval that a synopsis of your project and its findings (if not commercially too sensitive) be submitted to the R&D department upon completion. This synopsis can then be placed on the R&D departments' web page to provide a useful R&D resource for other research active professionals across the Health Board.



It is also a requirement that an abstract is submitted for review and possible inclusion in the Health Boards annual R&D conference. This facilitates the distribution of all researchers' findings and any resultant changes in clinical practice.

If your study is adopted onto the Health & Care Research Wales Clinical Research Portfolio (CRP), it will be a condition of this NHS research permission, that you will be required to regularly upload recruitment data onto the portfolio database.

To apply for adoption onto the Health & Care Research Wales CRP, please go to: <https://www.ukctg.nihr.ac.uk/> Once adopted, Health & Care Research Wales CRP studies may be eligible for additional support through the Health & Care Research Wales Workforce. Further information can be found from your NHS R&D office colleagues.

Uploading recruitment data will enable Health & Care Research Wales to monitor research activity within NHS organizations, leading to NHS R&D allocations which are activity driven. Uploading of recruitment data will be monitored by your colleagues in the R&D office. If you need any support in uploading this data, please contact, Research & Development department.

I would like to take this opportunity to wish you well with your research and look forward to the presentation of your findings.

If you require any further assistance please contact the Research & Development Department,

Yours sincerely

*MJC*



## Appendix 18: R&D Approval Letters Site 3



TRUST LOGO

TRUST ADDRESS

Miss Sarah Harris  
South Wales Doctoral Programme in Clinical Psychology  
11th Floor,  
School of Psychology,  
Tower Building, 70 Park Place,  
Cardiff  
CF10 3AT

18<sup>th</sup> March 2016

Dear Miss Harris,

Title: An Evaluation of an adapted ACT group for stroke survivors  
Chief Investigator: Miss Sarah Harris & Miss Rebecca Large

The [redacted] Health Board Research Risk Review Committee assessed the above study at their meeting on the 16<sup>th</sup> March 2016. Following clarification of the points raised at this meeting the Chairperson decided that overall the project does not appear to pose any risk to the Health Board and has therefore been approved.

The Chairman also noted that the project already has received favourable MREC/Local REC opinion.

If you or any member of your team require a Research Honorary Contract or Letter of Access please contact the R&D Department at the above email address.

May I take this opportunity to wish you success with your study and remind you that the study team are required to do the following:

- a) Inform the University Health Board R&D Office if any external funding is awarded for this study in the future.
- b) Inform the R&D Office of any substantial amendments/changes to your protocol.
- c) Maintain a record of the number of research participants recruited into the study.
- d) Complete any questionnaires sent to you by the University Health Board's R&D Office regarding this project.
- e) Comply fully with the Research Governance Framework , and co-operate with any audit inspection of the project files.
- f) Undertake the project in accordance with ICH-GCP and the University Health Board's Guidelines on Good Research Practice.
- g) Adhere to the protocol as approved by the Local Research Ethics Committee.
- h) Ensure that your research complies with the Data Protection Act 1998.
- i) Report any Serious Adverse Events to the R&D Office.
- j) Please note that approval lapses if the project does not commence within 12 months of approval.

If your study is adopted onto the Health and Care Research Wales Clinical Research Portfolio (CRP), it will be a condition of this NHS research permission, that you will be required to regularly upload recruitment data onto the portfolio database.

To apply for adoption onto the Health and Care Research Wales CRP, please go to <http://www.wales.nhs.uk/sites3/page.cfm?orgid=580&pid=31970>

Once adopted, Health and Care Research Wales CRP studies may be eligible for additional support through the Health and Care Research Wales Clinical Research Centre. Further information can be found at <http://www.wales.nhs.uk/sites3/page.cfm?orgid=580&pid=28571> and/or from your NHS R&D office colleagues. To upload recruitment data, please follow this link: [http://www.cmcc.nhr.ac.uk/about\\_us/processes/portfolio/p\\_recruitment](http://www.cmcc.nhr.ac.uk/about_us/processes/portfolio/p_recruitment)

Uploading recruitment data will enable Health and Care Research Wales to monitor research activity within NHS organizations, leading to NHS R&D allocations which are activity driven. The uploading of recruitment data will be monitored by your colleagues in the R&D office. If you need any support in uploading this data, please contact the

Yours sincerely

**Appendix 19: R&D Approval Letters Site 4**

From: [redacted]  
Sent: 22 March 2016 17:41  
To: [redacted]  
Cc: [redacted]  
- P  
fal  
He  
Do  
St

**Project Title: An evaluation of an adapted ACT group for stroke survivors**

**IRAS number:** [redacted]  
**R&D Reference:** [redacted]  
**Start Date:** 22/03/2016  
**End Date:** 29/09/2017

I am pleased to tell you that [redacted] Trust has agreed to act as a Participant Identification Centre (PIC) for the above study sponsored by Cardiff University.

We wish you every success with your study and are keen to support good research at [redacted] NHS Trust.

Agreement to act as a PIC is given on the understanding that this project be carried out according to ICH Good Clinical Practice guidelines and UK Statutory Instrument, and within the guidelines of the NHS Research Governance Framework for Health and Social Care.

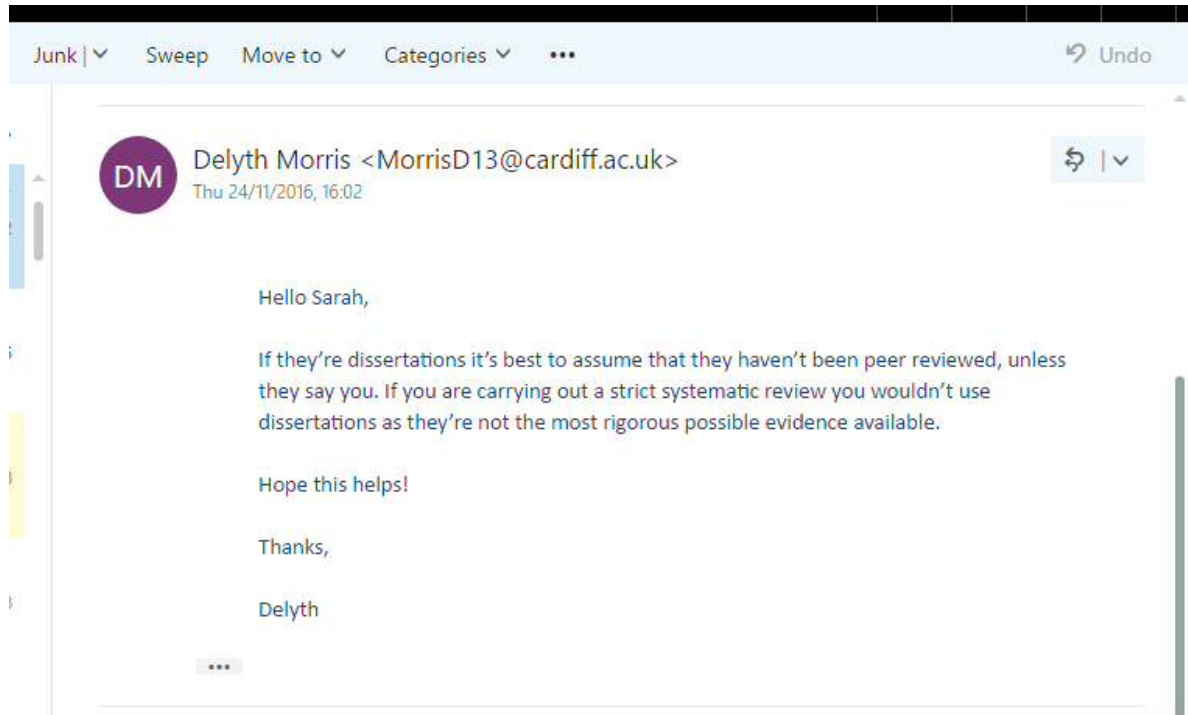
Many thanks

[redacted]

Trust address



## Appendix 20: Email from Librarian



## Appendix 21: PRISMA Checklist

Section/topic	#	Checklist item	Reported on page #
<b>TITLE</b>			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	10
<b>ABSTRACT</b>			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	11
<b>INTRODUCTION</b>			
Rationale	3	Describe the rationale for the review in the context of what is already known.	13-16
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	16
<b>METHODS</b>			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	-
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	17
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	17
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	17
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	17
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	17

Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	-
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	18
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	-
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., $I^2$ ) for each meta-analysis.	-

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	18
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	-
<b>RESULTS</b>			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	19 & 39
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	19
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	40 – 41
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	22 – 26
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	-
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	20
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	-
<b>DISCUSSION</b>			

Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	27-29
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	29
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	31
<b>FUNDING</b>			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	31

## Appendix 22: Email from Steven Hayes

From: Steven Hayes [<mailto:stevenhayes@gmail.com>]

Sent: 21 December 2014 13:09

To: Neil Frude

Subject: Re: FW: ACTivate Your Life

Sorry ... the flow of the events near the holiday is just overwhelms my ability to focus.

I finally went through the slides in presentation mode and they are really nice. I like them a LOT. (With your permission can I borrow some for workshops? I will credit you of course)

The language of your blurb looks right on to my eyes ... in actually expresses my feelings toward this project and your work very well:

I welcome the fact that Neil Frude's "ACTivate Your Life" course will bring many of the key ideas of ACT, and many effective strategies for helping people to live with their emotional and physical pain, to a wide audience in Wales and beyond. I am very pleased that there is such enthusiasm for this approach, that the course will be delivered widely and that the effects will be carefully evaluated

You can list my affiliation as below or edit it down. Sometimes for things like this people also add "Co-developer of Acceptance and Commitment Therapy" or more specific things (e.g., author of *Get Out of Your Mind and Into Your Life*)

Feel free to do what works best in these areas

Please do send me the rest of the course as it is worked out!

Best of luck with the project

- S

Steven C. Hayes  
Foundation Professor and Director of Clinical Training  
Department of Psychology  
University of Nevada

## Appendix 23: CONSORT Checklist

Section/Topic	Item No	Checklist item	Reported on page No
<b>Title and abstract</b>	1a	Identification as a randomised trial in the title	42
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	43
<b>Introduction</b> Background and objectives	2a	Scientific background and explanation of rationale	45-49
	2b	Specific objectives or hypotheses	49
<b>Methods</b> Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	49
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	n/a
Participants	4a	Eligibility criteria for participants	49
	4b	Settings and locations where the data were collected	49
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	50-51 & 76
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	52-53
	6b	Any changes to trial outcomes after the trial commenced, with reasons	n/a
Sample size	7a	How sample size was determined	54

	7b	When applicable, explanation of any interim analyses and stopping guidelines	n/a
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	50
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	50
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	50
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	50
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	50
	11b	If relevant, description of the similarity of interventions	-
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	54-55
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	n/a
<b>Results</b>			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	55-56 & 77
	13b	For each group, losses and exclusions after randomisation, together with reasons	56 & 77
Recruitment	14a	Dates defining the periods of recruitment and follow-up	55
	14b	Why the trial ended or was stopped	n/a

Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	56 & 78
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	56
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	56-57&79-80
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	n/a
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	n/a
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	n/a
<b>Discussion</b>			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	62
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	62
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	58-62
<b>Other information</b>			
Registration	23	Registration number and name of trial registry	-
Protocol	24	Where the full trial protocol can be accessed, if available	-
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	64



## Appendix 24: Paper 2 Poster Presentation

### Introduction

Stroke is considered to be one of the most common causes of complex disability, affecting over half of all stroke survivors. Approximately 33% of stroke survivors experience depression, 25% are affected by anxiety and 57% are affected by fatigue and cognitive problems. Psychological problems reduce stroke survivors' quality of life and functional recovery and increase healthcare utilisation and mortality. Group-based ACT can be beneficial for people with other health conditions. Benefits include: reduced depression, anxiety and disability; increased acceptance; and condition-specific positive outcomes.

### Methodology

All participants were randomised into the group-based ACT condition or a treatment as usual (TAU) condition. The stroke-adapted ACT intervention consisted of four weekly 2-hour group sessions and was facilitated in community settings across four sites in south Wales and south west England. Participants in the control group followed their usual treatments.

All participants completed these measures at baseline, post-intervention and at 2 month follow-up: depression (PHQ9), anxiety (GAD-7), quality of life & self-reported health status (EQ-5D-5L), mental wellbeing (WEMWBS), hopefulness (Adult Hope Scale).

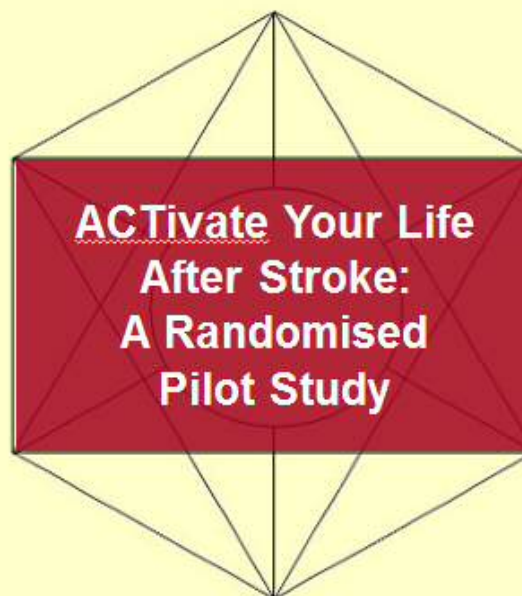


### Conclusions

This study suggests group-based ACT is promising. It could offer a suitable cost-effective low-intensity psychological intervention for stroke survivors.

Recommendations for further research include a larger sample, with active comparison groups.

Authors: Sarah Majumdar and Professor Reg Morris.  
Harriss34@cardiff.ac.uk



### Results

53 participants were recruited and randomised (60% male; mean age: 63 years). ACT N=26, control N=27.

**Analysis based on intention-to-treat found group-based ACT reduced depression and increased self-rated health status and hopefulness in stroke survivors. Effect sizes were medium in comparison to the TAU control group.**

**Significantly more participants reached clinically significant change for depression in the ACT intervention (53.8%) in comparison to the TAU control group (7.4%).**

No significant treatment effects were found for anxiety, quality of life or mental wellbeing.

