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**The Use of Acceptance and Commitment Therapy to Address Psychological Distress
Experienced by Caregivers: A Randomised Controlled Feasibility Trial
Clinical Research Portfolio**

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BA (Hons), MSc

Submitted in partial fulfilment of the requirements for the degree of
Doctorate in Clinical Psychology

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CHAPTER 1: SYSTEMATIC REVIEW

The Utility of Home-Practice in Mindfulness-Based Group Interventions: A Systematic Review

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Abstract

Background: A growing body of research supports the efficacy of mindfulness-based interventions (MBI) for a range of difficulties. These interventions consider home-practice as essential to increasing the therapeutic effects of the treatment. To date however, there has not been an adequate synthesis of the research relating to home-practice in MBI and the impact it has on outcomes.

Objective: This review aimed to conduct a narrative synthesis of published controlled studies, evaluating mindfulness-based group interventions, which have specifically measured home-practice. It endeavoured to address a number of pertinent questions linked to home-practice.

Method: Research literature published up until June 2016 was searched using five databases. The search strategy focused on mindfulness-based stress reduction, mindfulness-based cognitive therapy, and home-practice. To be eligible for inclusion studies needed to be controlled trials, recruit participants 18 years and above, evaluations of MBI, to have used standardised quantitative outcome measures, and measured home-practice using a self-reported measure. Fourteen studies met the criteria and were included in the review.

Results: Across all studies there was heterogeneity in the guidance and resources provided to participants and the approaches used for recording home-practice. In addition, the amounts of home-practice reported in all of the studies failed to meet the expectations set out by Mindfulness Based Stress Reduction (MBSR) and Mindfulness Based Cognitive Therapy practice (MBCT) guidelines. Finally, only seven studies examined the relationship between home-practice and clinical outcomes, of which four found that home-practice predicted improvements on clinical outcome measures.

Conclusions: Future research should adopt a standardised approach for monitoring home-practice across MBI. In addition, future studies should assess whether the amount of home-practice recommended to participants is in line with MBSR/MBCT guidelines. Finally, further research should utilise experimental methodologies to explicitly explore the relationship between home-practice and clinical outcomes.

Introduction

Mindfulness

Over the last twenty years there has been growing interest in the possible effectiveness of mindfulness-based interventions (MBI) in clinical settings. There is no clear consensus regarding the definition of 'mindfulness' (Analayo, 2016) however, a widely cited definition suggests that mindfulness involves "paying attention in a particular way: on purpose, in the present moment, and non-judgmentally" (Kabat-Zinn, 1994, p.4). A growing body of research supports the efficacy of various forms of mindfulness interventions, including mindfulness-based stress reduction (MBSR) (Kabat-Zinn, 1990) and mindfulness-based cognitive therapy (MBCT) (Segal, Williams and Teasdale, 2002), for a wide range of psychological, medical and psychosomatic conditions (Keng, Smoski & Robins, 2011; Grossman, Nieman, Schmidt & Walach, 2004). MBSR, was originally developed by John Kabat-Zinn and is a highly structured skill-based therapy that combines mindfulness meditation with Hatha yoga exercises (Kabat-Zinn et al., 1992). The intervention is generally an 8-week, group-based programme, 2.5 hour sessions, with an additional all-day silent retreat (Li, Yuan & Zhang et al., 2015). MBCT was developed by Segal, et al., (2002) and is a manualised 8-week group intervention of similar structure that draws on Kabat-Zinn's MBSR programme, but also incorporates cognitive therapy exercises.

Session Practice and Mindfulness

As the amount of research evidence investigating the efficacy of these interventions increases, interest in identifying the mechanisms by which MBI lead to symptom improvement has also grown (Hawley et al., 2014; Carmody & Baer, 2008; Del Re, Flückiger, Goldberg & Hoyt, 2013; Nyklíček & Kuijpers, 2008). One aspect of MBI hypothesised to be important for positive outcomes is home-practice. Home-practice in this context is a set of mindfulness exercises that are assigned to participants by MBI facilitators to be completed outside of treatment and after the intervention has ended. Both treatments emphasise the importance of daily mindfulness practice throughout treatment - recommending between 45-60 minutes of daily practice, 6 days a week, over the course of the 8 week group (Kabat-Zinn, & Santorelli, 2014; Segal, Williams & Teasdale, 2013). In both treatments, participants engage in mindfulness exercises that are either formally or informally structured. Formal practices involve providing participants with guidance on the nature and content of the

practice for a specific length of time. These practices include exercises such as mindful breathing, body scan and sitting meditation. During informal practices, participants bring mindful awareness to routine everyday experiences; these practices are less structured and therefore sometimes are not given a set length of time (Hawley et al., 2014).

MBI consider the combination of between-session and post-programme practice (henceforth referred to as 'home-practice') as one of the most essential components to increasing the therapeutic effects of the treatment (Vettese, Toneatoo, Stea, Nguyen & Wang, 2009). This is mirrored in other therapeutic interventions with home-practice assignments being highlighted as a critical and key component of efficacious psychotherapy (Kazantzis, Deane & Ronan, 2004). Regular home-practice has been posited to affect a number of purported cognitive behavioural mediators of psychopathology, including rumination, stress reactivity, self-criticism and experiential avoidance, factors identified as underlying a number of disorders such as depression, anxiety and addiction (Vettese et al., 2009, Hawley et al., 2014).

Rational for Current Review

Although home-practice is assumed to be an important contributor to the clinical changes found in MBI, this relationship remains somewhat unclear and there has been little by way of a systematic review of evidence relating to this in the literature published to date. Baer (2003) conducted an empirical review of 21 mindfulness intervention studies, of which only three studies reported total home-practice during the intervention and four studies reported home-practice at follow-up. Two studies investigated the relationship between practice and clinical change as assessed by outcome measures. The findings of these studies were mixed with Kristeller & Hallett, (1999) reporting a significant positive correlation between time spent practicing and improvements in depressive and binge eating symptoms. However, Astin (1997) found no significant relationship between practice and clinical change on the SCL-90-R. Vettese et al., (2009) conducted the only review to date of home-practice in MBCT and MBSR and its relationship to mindfulness programme outcomes. This review identified 24 controlled and non-controlled studies that evaluated the associations between home-practice and measures of clinical functioning. Eight of the studies provided support for the positive relationship between amount of home-practice and improvement in

clinical outcome measures. An additional five studies reported mixed findings, identifying support for this relationship on some measures, as well as an absence on at least one outcome measure. The remaining 11 studies did not find the expected relationship between home-practice and clinical outcomes. This review did not examine the guidance given to participants on home-practice or whether studies met the recommendations outlined by the MBI. In addition, it only included studies that included analyses linking home-practice to clinical outcomes.

The findings across these reviews demonstrated that there is uncertainty regarding whether home-practice influences outcome measures used to evaluate mindfulness interventions (Hawley et al., 2014). Hence there is disparity between what is recommended clinically on one hand, and what is known empirically, regarding the effects of home-practice. Given the emphasis placed on home-practice and the considerable time commitment required of participants to complete practice exercises, it is imperative that understanding is improved about the potential associations between home-practice and clinical benefits. It also raises key questions regarding: the way in which mindfulness home-practice is measured across studies; what guidance is given to participants regarding the completion of home-practice, and whether the reported home-practice in studies meet the recommendations set out by MBSR and MBCT. Answering these questions will be important for developing our understanding of the role of home-practice in MBI.

Aims and Objectives

The aim of this systematic review was to conduct a narrative synthesis of controlled trials that have evaluated mindfulness-based (mindfulness-based stress reduction and mindfulness-based cognitive therapy) group interventions and have measured home-practice. In addition to addressing pertinent questions relating to home-practice that are outlined below, the review also investigated the methodological quality of eligible studies.

The review aimed to investigate the following questions:

1. How did the included studies monitor home-practice?
2. What guidance and resources were participants in the included studies given to complete home-practice?

3. Did the study protocols of the included studies meet the requirements of MBSR and MBCT guidelines on home-practice? Guidelines in this study are: MBSR- 45 minutes per day of formal mindfulness practice and 5-15 minutes of informal practice, 6 days per week during the intervention (Kabat-Zinn et al., 2014) and MBCT- 45 minutes of formal mindfulness practice six days per week and informal mindfulness practice three times per day for the duration of the intervention (Segal et al., 2013).
4. Were higher levels of home-practice associated with better participant clinical outcomes in the included studies?

Methods

Protocol

The review was conducted and reported in line with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocol (PRISMA-P) guidelines (Moher et al., 2015).

Search Strategy

Firstly, a search of the Cochrane Database of Systematic Reviews was completed to identify existing systematic reviews, meta-analyses, and literature reviews. Thereafter, five databases (Web of Science Core Collection, EBSCO Psychinfo, Ovid Medline, EBSCO CINAHL and Cochrane Library) were searched from inception to 2nd June 2016 for original articles. A number of search terms were initially developed to decipher what combination would incorporate the widest span of research. The final search criteria utilised was: ***mindfulness-based stress reduction*** or ***MBSR*** or ***mindfulness-based cognitive therapy*** or ***MBCT*** or ***mindfulness*** combined with ***home-practice*** or ***homework*** or ***between session practice*** (see Appendix 1.2 for full search strategy). Reference lists of all potentially relevant articles and other reviews were assessed to identify any studies that may have been missed. Finally, the “Mindfulnet” website (www.mindfulnet.org) and the journal “Mindfulness” reviewed for relevant studies. All titles and abstracts were reviewed and if studies met the eligibility criteria they were read in full independently by the author. On four occasions there was ambiguity whether a study met the inclusion criteria, therefore the author discussed these individual studies with the supervisor of this project to resolve any uncertainty.

Eligibility Criteria

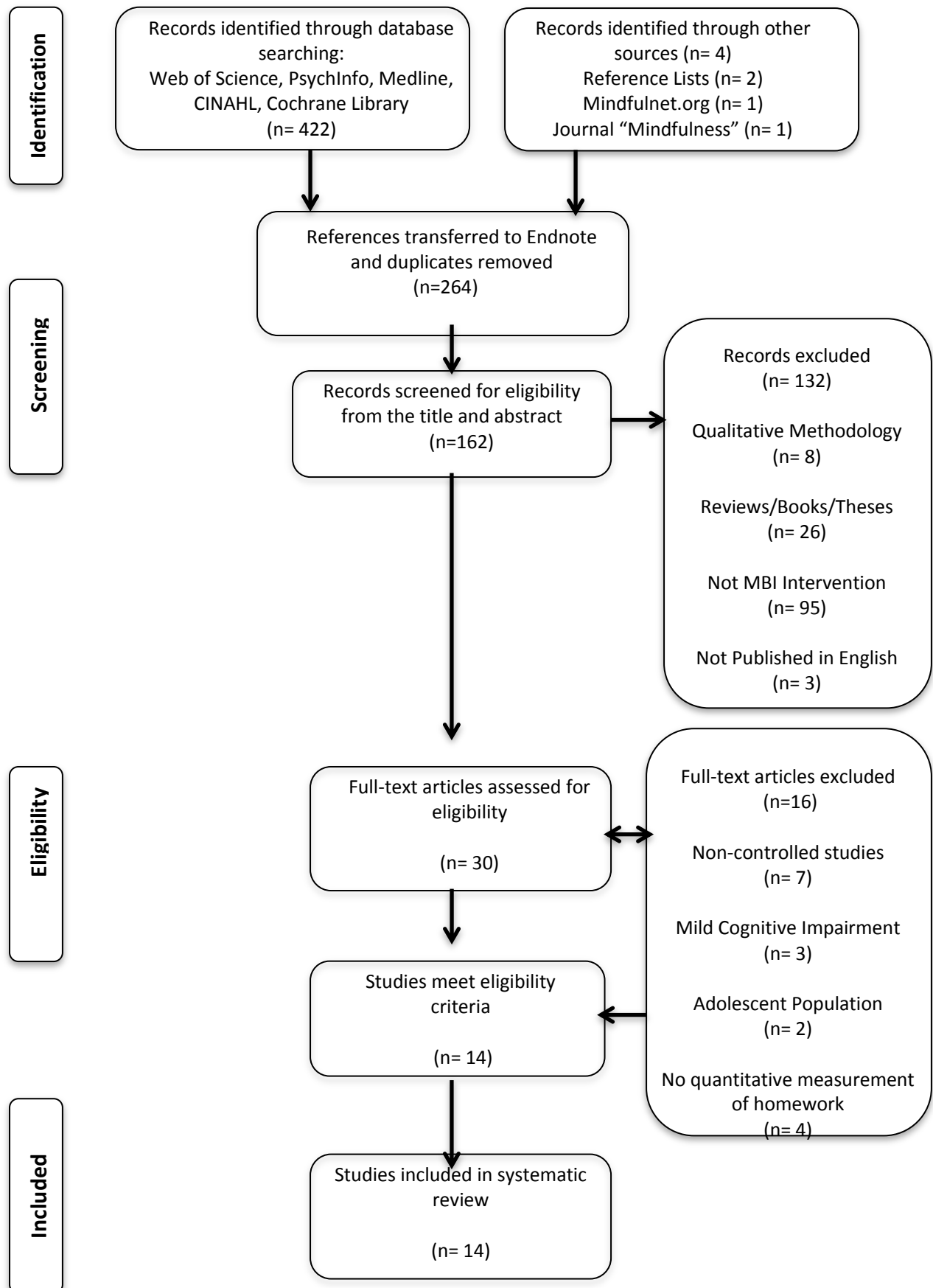
Studies included in the review met the following criteria:

1. Controlled research trials, papers written in English (or translated versions), and published in peer-reviewed journals.
2. Recruited participants 18 years and above. Studies that included interventions for individuals with cognitive impairment or a learning disability were excluded.
3. Implemented a mindfulness-based stress reduction or mindfulness-based cognitive therapy group intervention.
4. Collected primary data using standardised quantitative outcome and/or process measures.
5. Measured home-practice daily or weekly throughout the duration of the group intervention and/or at follow-up. Home-practice was operationalised as: participants practicing a set of tasks assigned to them by their group facilitator to be completed outside of the group intervention. 'Measurement' of home-practice was defined as including either or both of the following: participants were asked to log the frequency of their home-practice using a self-report measure such as a log/dairy/questionnaire/calendar or home-practice was tracked objectively through electronic means (e.g. a mobile phone app).

Search Outcome

A study selection flow diagram is outlined in Figure 1. The search strategy yielded a total of 426 articles. Search results from all five databases were exported to Endnote referencing software. 162 studies remained after duplicates were removed. The titles and abstracts of these articles were screened for eligibility, which resulted in the exclusion of a further 132 studies. The full texts of the remaining 30 were reviewed; following which 14 met all study eligibility criteria and were included in the final review.

Figure 1. Flow Diagram of Selection of Papers for Inclusion in the Systematic Review



Quality Appraisal

The methodological rigour of each study was assessed using the Clinical Trials Assessment Measure (CTAM) (Tarrier & Wykes, 2004) (see Appendix 1.3). This 15-item measure was developed from the relevant features of the CONSORT (CONsolidated Standards of Reporting Trials) guidelines (Moher et al., 2001). The CTAM provides an overall representation of methodological rigour through ratings on six areas of trial design: sample size and recruitment method; allocation to treatment; assessment of outcome; control groups; description of treatments; and analysis (Tarrier & Wykes, 2004; Lobban et al., 2013). Points are awarded for meeting quality standards on each of the subscales with a maximum score of 100. Wykes, Steel, Everitt and Tarrier (2008) proposed a CTAM score of 65 or above to indicate adequate methodology. Lobban et al., (2013) advised that studies should be compared based on subscales scores as a more appropriate appraisal as each category contributes a different weight to the overall score. The CTAM has shown adequate internal consistency and excellent concurrent validity (Wykes et al, 2008). To assess inter-rater reliability an independent reviewer rated all fourteen papers. Overall agreement was high and any discrepancies between reviewers were resolved through discussion.

Results

Description of Included Studies

A detailed description of the characteristics of included studies is shown in Table 1. This includes information on the study design, participant information, recruitment criteria, MBI and control conditions, outcome and process measures utilised and the key findings. Overall, the studies examined a total of 725 participants. The median number of participants was 61.50 (Interquartile Range = 55). All studies were conducted in the developed world. Three studies (Bondolfi et al., 2010; Crane et al., 2014; Perich et al., 2013) were conducted in Europe, and Australia and the remaining eleven studies were carried out in North America. The design of the studies included one secondary analysis of an RCT (Day et al., 2016); one non-randomised controlled trial (King et al., 2013) and the remaining twelve studies were RCT's. Six studies utilised MBCT (Bondolfi et al., 2010; Crane et al., 2014; Day et al., 2016; Dimidjian et al., 2016; King et al., 2013; Perich et al., 2013) and eight studies utilised a MBSR intervention (Cash et al., 2015; Gross et al., 2011; Johns et al., 2014; MacCoon et al., 2013; Specia et al., 2000; Wells et al., 2014; Whitebird et al., 2012; Davidson

et al., 2003). The durations of MBCT and MBSR were 8 weeks with two studies utilising a 7-week intervention (Johns et al., 2014; Specia et al., 2000), and class time was between 90 to 180 minutes per session. A wide range of outcome and process measures were used in studies including measures of psychological and physical functioning and measures of mindfulness.

Methodological Quality

Table 2. provides CTAM subscale and total scores for each of the fourteen studies reviewed. CTAM total scores ranged from 30 to 84 (Median = 53.50, Interquartile Range = 16). Only four studies (Perich et al., 2013; Bondolfi et al., 2010; Dimidjian et al., 2016, Crane et al., 2014) achieved a CTAM total score equal to or greater than the arbitrary cut off of 65 as suggested by Wykes et al., (2008), indicating adequate methodological quality. There was variability in methodology, with many limitations across studies resulting in low scores being allocated. Six studies (Perich et al., 2013; Crane et al., 2014; Bondolfi et al., 2010; Gross et al., 2011; Cash et al., 2015; Whitebird et al., 2012) scored full marks on the sample subscale utilising a geographic cohort and sufficient sample size. All studies except one (King et al., 2013) had random allocation, however the process of randomisation was not always described, and eight studies (Day et al., 2016; Dimidjian et al., 2016; Whitebird et al., 2012; Wells et al., 2014; King et al., 2013; Specia et al., 2000; Johns et al., 2014; Davidson et al., 2003) did not carry out randomisation independently from the trial research team. Generally poor scores were designated for the 'assessment' subscale, with ten studies (Day et al., 2016; Crane et al., 2014; Gross et al., 2011; Whitebird et al., 2012; Cash et al., 2015; Wells et al., 2014; King et al., 2013; Specia et al., 2000; Johns et al., 2014; Davidson et al., 2003) scoring only 6 out of a potential score of 32. This was mainly due to a lack of blinding and poor descriptions of blinding procedures.

Table 1. Characteristics and Findings of Included Studies

Study and Method	Participants	Recruitment	Intervention/ Conditions	Measures Utilised*	Key Findings
1. Bondolfi et al., (2010) RCT Country: Switzerland	60 randomised, 43 females; 17 males MBCT + TAU median age= 46 years TAU median age= 49 years	History of major depressive disorder ≥ 3 episodes In remission & not taking medication	MBCT + TAU: 8 weekly x 2hr sessions, French translation MBCT manual utilised 4 MBCT booster sessions provided over 3 months follow-up TAU: Seek treatment as normal	Outcome: SCID	Time to relapse was significantly longer for MBCT + TAU compared to TAU alone
2. Cash et al., (2015) RCT Country: USA	91 randomised, all female 18 years +	Diagnosis of fibromyalgia Females Available to attend weekly groups	MBSR: 8 weekly x 2.5 hr sessions Wait-list control: Offered the MBSR programme following study	Outcome: BDI CTQ-SF PSS SSQ FSI FIQ	MBSR significantly reduced perceived stress, sleep disturbance and symptom severity, gains maintained at follow-up MBSR did not significantly alter pain, physical functioning or cortisol

Study and Method	Participants	Recruitment	Intervention/ Conditions	Measures Utilised*	Key Findings
3. Crane et al., (2014) RCT Country: UK	274 randomised, 198 females; 76 males Mean age of sample= 43 years, range 18-68 years	History of major depressive disorder ≥ 3 episodes Remission for the previous 8 weeks Informed consent from primary care physicians	MBCT: 8 weekly x 2hr session & 2 follow-up sessions at 6 weeks and 6 months post-treatment Cognitive Psychological Education (CPE): 8 weekly x 2hr session & 2 follow-up sessions provided at 6 weeks and 6 months post-treatment TAU: Seek treatment as normal	Outcome: SCID CTQ HAMD Process: MBI-TAC	See home-practice findings
4. Day et al., (2016) Secondary analysis of a RCT Country: USA	36 randomised, 32 females, 4 males Mean age of total sample= 41.7 years	19 + years old ≥ 3 pain days per month due to a primary headache pain If using medication, must have begun ≥ 4 weeks before baseline assessment	MBCT: 8 weekly x 2hr session & 2 follow-up sessions at 6 weeks and 6 months post-treatment, continued medical treatment as usual Delayed Treatment (DT): Medical treatment as usual, then completed MBCT	Outcome: CSQ-8 WAI-SF BPI CPEG Process: MBCT-AAQS	Therapists' adherence and quality were both significant predictors of post-treatment client satisfaction Baseline pain intensity was positively associated with pre-treatment expectations, motivations and working alliance

Study and Method	Participants	Recruitment	Intervention/ Conditions	Measures Utilised*	Key Findings
5. Davidson et al., (2003) RCT Country: USA	41 randomised, 29 females, 12 males Average age of sample= 36 years, range= 23-56 years	Employees of Biotechnological corporation in Madison, Wisconsin Right-handed	MBSR: 8 weekly x 2.5-3 hr sessions, 7hr silent retreat Wait-List Control: Offered the MBSR programme following the study	Outcome: PANAS STAI	Meditation can produce increases in relative left-sided anterior activation that are associated with reductions in anxiety and negative affect and increases in positive affect
6. Dimidjian et al., (2016) Pilot RCT Country: USA	86 randomised MBCT-PD mean age= 31 years TAU mean age= 29 years	Pregnant adult women up to 32 weeks gestation History of major depressive disorder Available to attend weekly groups	MBCT-PD: Adapted MBCT for peri-natal depression, 8 weekly x 2hr sessions, 1 monthly follow-up class TAU: Free to continue or initiate mental health care	Outcome: SCID-I/P SCID-II CSQ LIFE EPDS	Significantly lower rates of relapse and depressive symptoms through 6 months post-partum in MBCT-PD compared to TAU MBCT-PD for at-risk pregnant women was acceptable based on rates of attendance and at-home-practice assignments
7. Gross et al., (2011) Pilot RCT Country: USA	30 randomised, 22 females, 8 males MBSR median age= 47 years PCT median age= 53.50 years	Diagnosis of primary insomnia Not taking sleep medication Adults English speaking	MBSR: 8 weekly x 2.5 hr sessions and a day-long retreat (6hrs) Pharmacotherapy (PCT): 3mg of eszopiclone nightly for 8 weeks & as needed for 3 months follow-up Plus 10 min presentation on sleep hygiene	Outcome: ISI PSQI DBAS-16 SSES STAI CES-D SF-12 Other: Sleep diary	MBSR achieved reductions in insomnia symptoms & improvements in sleep quality comparable to PCT Higher treatment satisfaction in MBSR compared to PCT

Study and Method	Participants	Recruitment	Intervention/ Conditions	Measures Utilised*	Key Findings
8. Johns et al., (2014) Pilot RCT Country: USA	35 randomised, 33 females, 2 males MBSR-CRF mean age= 58.80 years Wait-list control mean age= 55.70 years	Diagnosis of cancer and clinically significant cancer-related fatigue (CRF) for 8 weeks 18+ years old	MBSR-CRF: Adapted MBSR for cancer-related fatigue, 7 weekly x 2 hr sessions and brief psycho-education on CRF Wait-List Control: Offered the MBSR programme following the study	Outcome: FSI SF-36 SDS PHQ-8 ISI PHQGADS	MBSR demonstrated significantly greater improvements in fatigue interference than controls and significant improvements in depression and sleep disturbance, improvements in symptoms maintained at 6 month follow-up MBSR proved acceptable to fatigued cancer survivors
9. King et al., (2013) Pilot Non-randomised Controlled Trial Country: USA	37 participants MBCT mean age= 60.10 years TAU mean age= 58.30 years	Long-term >10 years PTSD or PTSD in partial remission All experienced combat-related traumas from military services	MBCT: Adapted for combat-related PTSD, 8 weekly x 2 hr sessions TAU: 8 x 1hr sessions of Psychoed: PTSD psycho-education and skills and IRT: 6 x1.5 hr sessions, of imagery rehearsal therapy	Outcome: PDS PTCI	MBCT proved an acceptable intervention for PTSD symptoms evidenced by engagement in programme and resulted in significant improvement in PTSD symptoms pre vs post MBCT compared to TAU and clinically meaningful improvement in PTSD symptom severity & cognitions

Study and Method	Participants	Recruitment	Intervention/ Conditions	Measures Utilised*	Key Findings
10. MacCoon et al., (2013) RCT Country: USA	63 randomised, 47 females, 16 males MBSR mean age= 44.50 years HEP mean age= 47.50 years	18-65 years Right handed No previous experience of meditation English speaking In good general health	MBSR: 8 weekly x 2.5 hr sessions, 7 hr day retreat Health Enhancement Programme (HEP): 8 weekly x 2.5 hr sessions, 7 hr day retreat, programme to match MBSR, activities valid active therapeutic ingredients but no mindfulness	Outcome: SCL-90-R MSC GSI	Significant improvements for general distress, anxiety, hostility & medical symptoms, but no differences between interventions, MBSR pain rating decrease compared to HEP HEP is an active control condition for MBCT
11. Perich et al., (2013) RCT Country: Australia	95 participants randomised, 62 females, 33 males No information on age provided	Diagnosis of bipolar I or II disorder, experienced 1+ episode over the past 18 months and lifetime of 3+ episodes Symptoms controlled on a mood stabiliser 18+ years of age, English speaking	MBCT: 8 weekly sessions, duration of each session not given. Followed Segal et al. (2002) protocol TAU: Treatment as usual Both conditions received weekly psycho-educational material on bipolar disorder	Outcome: DASS STAI YMRS MADRS CIDI SCID-I Process: MAAS TMS	See home-practice findings
12. Speca et al., (2000) RCT Country: Canada	90 randomised, 73 females, 17 males Mean age of sample= 51 years, age range= 27-75 years	Diagnosis of cancer at any time point were eligible to participate	MBSR: 7 weekly x 1.5 hr sessions, adapted version of Kabat-Zinn MBSR programme Wait-List Control: Offered the MBSR programme following the study	Outcome: POMS SOSI	MBSR effectively reduced mood disturbance, fatigue and a broad spectrum of stress-related symptoms

Study and Method	Participants	Recruitment	Intervention/ Conditions	Measures Utilised*	Key Findings
13. Wells et al., (2014) Pilot RCT Country: USA	19 randomised, 17 females, 2 males MBSR mean age= 45.90 years TAU mean age= 45.20 years	Diagnosis of migraine, ≥ 1 year history of migraines Available to attend weekly sessions 18+ years old English speaking	MBSR: 8 weekly x 2 hr sessions plus one-day (6 hrs) retreat. Utilised Kabat-Zinn protocol TAU: Continue with care as usual and asked not to start a yoga or meditation during study. Offered MBSR following the study	Outcome: HIT-6 MIDAS MSQ PHQ-9 STAI PSS-10 HMSSES Process: FFMQ	MBSR is safe and feasible for adults with migraines Secondary outcomes demonstrated that MBSR had a beneficial effect on headache duration, disability, self-efficacy and mindfulness
14. Whitebird et al., (2012) RCT Country: USA	78 randomised, 69 females, 9 males MBSR mean age= 56.40 years CCES mean age= 57.20 years	Self-identified as primary caregiver of family member with dementia 21+ years old English speaking	MBSR: 8 weekly x 2.5 hr sessions, 5-hr day retreat Community Caregiver Education Support (CCES): 8 weekly x 2.5 hr sessions, 5-hr retreat day. Education on issues affecting family caregivers and group social and emotional support	Outcome: PSS CES-D STAI SF-12 MBCBS MOSSSS	MBSR is a feasible and acceptable intervention for dementia caregivers, MBSR improved overall mental health, reduced stress and decreased depression at post-intervention compared to CCES Both interventions improved caregiver mental health, anxiety, social support and burden

*Glossary Attached see Appendix 1.4

Table 2. CTAM Subscale Scores

Study	Sample (10)	Allocation (16)	Assessment (32)	Control Groups (16)	Analysis (15)	Active Treatment (11)	Total (100)
Perich et al., (2013)	10	16	26	6	15	11	84
Bondolfi et al., (2010)	10	16	26	6	15	8	81
Crane et al., (2014)	10	16	6	16	9	11	68
Dimidjian et al., (2016)	7	10	16	6	15	11	65
MacCoon et al., (2012)	5	16	16	10	15	0	62
Gross et al., (2011)	10	16	6	10	9	3	54
Whitebird et al., (2012)	10	13	6	10	15	0	54
Day et al., (2016)	5	13	6	6	15	8	53
Cash et al., (2015)	10	16	6	0	15	3	50
King et al., (2013)	2	0	6	16	15	8	47
Specia et al., (2000)	7	13	6	0	15	6	47
Wells et al., (2014)	2	10	6	6	15	6	45
Johns et al., (2014)	2	13	6	0	9	3	33
Davidson et al., (2003)	2	10	6	0	9	3	30

With regards to control groups, eight studies (Day et al., 2016; Perich et al., 2013; Bondolfi et al., 2010; Dimidjian et al., 2016; Cash et al., 2015; Wells et al., 2014; Speca et al., 2000; Johns et al., 2014; Davidson et al., 2003) utilised either TAU or wait-list control groups and therefore non-specific treatment effects could not be controlled for, contributing to a poor rating on this subscale. All studies employed statistical methods deemed appropriate for the outcome measure, and ten studies (Day et al., 2016; Perich et al., 2013; Bondolfi et al., 2010; Dimidjian et al., 2016; MacCoon et al., 2012; Cash et al., 2015; Wells et al., 2014; Speca et al., 2000; King et al., 2013; Whitebird et al., 2012) conducted intent-to-treat analysis. Finally, with regards MBI interventions the delivery of treatment was guided by a treatment protocol for all studies except two (MacCoon et al., 2013; Whitebird et al., 2012), but for eight of the fourteen studies (MacCoon et al., 2012; Gross et al., 2011; Cash et al., 2015; Wells et al., 2014; Speca et al., 2000; Whitebird et al., 2012; Johns et al., 2014, Davidson et al., 2003) adherence to the treatment protocol or treatment quality was not assessed.

Home-Practice Characteristics

Table 3. outlines the monitoring, guidance, reporting and findings relating to home-practice across studies. This table includes some of the more detailed results of this review and complements the main findings. Therefore it should be referred to in addition to the following synthesis.

Table 3. Home-Practice Characteristics

Study	Guidance	Resources	Measurement	Total Reported Practice	Proportion of Recommended Practice Achieved	Home-Practice Findings
1. Bondolfi et al., (2010)	Frequency of practice not specified	2 CDs with recordings of body scan, sitting meditation, mindful movement & 3-min breathing space	Retrospective ad hoc self report questionnaire	% Practice once per week: Body scan: 65.4% Sitting Meditation: 88% 3-min breathing: 91.7% Informal practice: 76%	Could not be calculated	Amount of home-practice did not significantly differ between those who relapsed and those who did not Following treatment the frequency of informal home-practice remained unchanged over 14 months but longer formal meditation practice decreased over time
2. Cash et al., (2015)	45 minutes x 6 days a week, practice of body scan, sitting meditation, yoga positions	Workbook and audiotapes of mindfulness exercises	Self-report weekly log of home-practice & qualitative assessment of how much practice completing at follow-up	Reported practice 4.8 times per week at 2 month follow-up	Could not be calculated	Greater home-practice at follow-up was associated with reduced symptom severity of fibromyalgia

Study	Guidance	Resources	Measurement	Total Reported Practice	Proportion of Recommended Practice Achieved	Home-Practice Findings
3. Crane et al., (2014)	40 minutes x 6 days a week, both formal and informal practices required	CD of formal mindfulness exercises	Self-report weekly diary of home-practice	Reported formal practices on average 3.36 days per week, average duration was 21.31 minutes. Mean no. of units of informal practice was 80.44 over treatment	26.51%	A significant association between mean daily duration of formal home-practice and outcome in MBCT was found. Those who practiced on an average of three or more days per week were approximately half as likely to relapse to depression over 12 months follow-up as those who practiced less frequently. No association between amount of informal home-practice and outcome was found
4. Day et al., (2016)	45 minutes x 6 days a week, practice	No information noted	Self-report daily meditation practice diary (online administration)	Reported a mean total of 21.69 hours of practice throughout MBCT programme	60.25%	In session engagement significantly predicted client attendance and time spent in at-home meditation practice throughout treatment

Study	Guidance	Resources	Measurement	Total Reported Practice	Proportion of Recommended Practice Achieved	Home-Practice Findings
5. Davidson et al., (2003)	Assigned formal and informal practices 1 hr x 6 days a week	Guided audiotapes to guide mindfulness practices	Self-report daily log of the frequency, number of minutes and techniques of formal meditation practice	Reported mean practice on 2.48 days out of 6 and mean practice 16.19 minutes per time after intervention, after 4 month follow-up reported mean practice on 1.70 days out of 6 and mean practice 14.21 minutes per time	14.87%	There were no significant associations between the measures of practice and brain activity or biological or self-report measures
6. Dimidjian et al., (2016)	Specific practices assigned for 6 days each week but amount of time not specifically reported	Audio-files to guide mindfulness practices and a DVD to guide yoga practice	Self-report weekly log of no. of times and type of home-practice	67% provided practice data, on average practicing 30 out of the 42 assigned days, with a higher total frequency of informal practice than formal practice	Could not be calculated	None reported
7. Gross et al., (2011)	45 minutes of meditation x 6 days a week for 8 weeks & 20 minutes daily for 3 months follow-up	Audio-files of recorded meditations & handouts of assignments	Tracked electronically using a pocket-size logger which participants turned on every time they began a meditation	17 patients reported practice data mean 23.7 minutes per day during intervention & 16 participants reported 21.8 minutes per day during follow-up	61.44%	Reductions in DBAS-16 and activity limitation due to insomnia scores were significantly predicted by home-practice during intervention period

Study	Guidance	Resources	Measurement	Total Reported Practice	Proportion of Recommended Practice Achieved	Home-Practice Findings
8. Johns et al., (2014)	20 minutes practice of body scan, sitting meditation and yoga, no specific guidance reported on number of days per week to practice	Audio-recordings of guided meditations. Participants received \$5 for each weekly log submitted	Self-report weekly log of home-practice minutes per day and type of practice	16/18 submitted practice logs every week, average 35 minutes practice per day during programme, 6 month follow-up 20 minutes formal practice on 2 days & informal practice on 3.8 days per week	45.37%	None reported
9. King et al., (2013)	15-20 minutes of formal and informal practice 5 days a week, guidance on informal practice given	Received audio-files of formal mindfulness exercises	Self-report weekly log of home-practice minutes per day and what recordings they had listened to	Reported on average 102.3 minutes of formal practice per week and 12.2 additional minutes of informal practice on days practice was reported	37.88%	None reported
10. MacCoon et al., (2013)	45 minutes practice 6 days a week, no guidance on what exercises to practice reported	None reported	Self-report weekly log of minutes and sessions of informal home-practice during the MBSR programme and for the 4 month follow-up period	Average 1849 minutes of practice reported (44 minutes over 6 days), average 4394 minutes of practice reported during 4 month follow-up period (25 minutes 6 days a week)	85.6%	Home-practice was not related to change in outcome measures for pain or psychological distress

Study	Guidance	Resources	Measurement	Total Reported Practice	Proportion of Recommended Practice Achieved	Home-Practice Findings
11. Perich et al., (2013)	Formal practice for 5 weeks of programme was 40 min body scan or sitting meditation with CD and 2 weeks without aid of CD for 30-40 minutes	Received audio-files of formal mindfulness exercises	Self-report weekly log of daily practice. Recorded whether they had engaged in practicing particular exercises, did not measure time spent practicing	67% provided practice data, mean number of days engaged in at least 1 meditation practice per day was 26.4 days (range 5-44 days) during MBCT programme. 13 noted to continue practice at 12-month follow-up	Could not be calculated	A greater no. of days practicing during the MBCT programme was related to lower depression scores at 12-month follow-up. Evidence to suggest that practice was associated with improvements in depression and anxiety symptoms if a minimum of 3 days a week practice was completed during MBCT programme
12. Speca et al., (2000)	Specific weekly guidance on what exercises to practice reported but no information on the duration of practice or how many days a week to practice was stated	Received workbook and audiotape of guided meditation	Self-report record form of duration of participant's daily meditation practice	Average total daily practice MBSR group during programme was 32 minutes	82.96%	Home-practice significantly predicted change in mood disturbance resulting in those who practiced more outside of sessions having better outcomes at the end of the programme
13. Wells et al., (2014)	45 minutes per day, 5 days a week	Given guided audio recordings to follow during practice	Self-report daily logs of home-practice	Daily meditation average 34 ± 11 minutes, range 16-50 minutes per day	88.14%	None reported

Study	Guidance	Resources	Measurement	Total Reported Practice	Proportion of Recommended Practice Achieved	Home-Practice Findings
14. Whitebird et al., (2012)	No specific guidance reported	Given CDs and written material of home-practice	Self-report measure of minutes per day practice in health behaviour calendars	Reported an average of 6.8 sessions of practice per week and averaged 29.4 minutes per session during the MBSR programme	74.04%	None reported

Home-practice Monitoring

All 14 studies utilised self-report measures to monitor home-practice for both formal and informal practices. One study (Gross et al., 2012) used an electronic device (logger) to track the length of their home-practice. The logger was a pocket-size, battery-operated recording device, which stores a date/time stamp whenever it was switched on or off. A second study tracked home-practice using a health behaviour calendar (Whitebird et al., 2012). Similarly Bondolfi et al., (2010) used a self-report questionnaire rating practices on a 4-point likert scale. The remaining eleven studies utilised self-report logs or diaries to monitor practice. Cash et al., (2015) used both a log and a retrospective qualitative report of the number of times practiced per week at the end of each assessment period. Day et al., (2016) was the only study to administer their log of home-practice via an online portal. Johns et al., (2014) gave a financial incentive (\$5 for each weekly log) to participants to monitor their home-practice.

With respect to monitoring of home-practice frequency and duration, six studies (Whitebird et al., 2012; Gross et al., 2012; Day et al., 2016; Wells et al., 2014; Johns et al., 2014; Specia et al., 2000) monitored practice specifying the amount of minutes practiced per day. Another four studies (Bondolfi et al., 2010; Cash et al., 2015; Dimidjian et al., 2016; Perich et al., 2013) specified the frequency of times practiced per week. Finally, four studies (Crane et al., 2014; MacCoon et al., 2012; King et al., 2013; Davidson et al., 2003) evaluated both the minutes per day and the frequency of times practiced per week. No study reported on the psychometric properties of the monitoring methods nor included the log/diary in the appendices of the study. Overall, these findings illustrate the wide variation in how studies measure home-practice compliance and suggest that at present there is no evidenced-based manner in which to do so across mindfulness studies.

Guidance and Resources for Home-practice

Studies were reviewed for the guidance and resources given to participants for their home-practice across the MBI interventions. The formal practices noted across studies included sitting meditation, body-scan meditation, 3-minute breathing space, mindful movement and mindful yoga practices such as Hatha yoga and stretching exercises. Informal practices were not outlined in the majority of studies but suggestions such as mindfulness of routine

activities and bringing mindful awareness to moments in daily life were reported. Eight studies (Davidson et al., 2003; King et al., 2013; Wells et al., 2014; MacCoon et al., 2012; Day et al., 2016; Cash et al., 2015; Crane et al., 2014; Gross et al., 2012) reported both the length and frequency of mindfulness practice for participants: ranging from 1 hour practice x 6 days a week (Davidson et al., 2003) to 15-20 minutes formal practice x 5 days a week (King et al., 2013). In addition six studies, (Whitebird et al., 2012; Speca et al., 2000; Bondolfi et al., 2010; Dimidjian et al., 2016; Johns et al., 2014; Perich et al., 2013) outlined guidance on specific mindfulness practices for participants to complete, but did not report either the length or frequency that participants should spend engaging in this practice.

With respect to home-practice resources, two studies (Day et al., 2016; MacCoon et al., 2012) did not report any additional resources for participants. Across the other 12 studies, participants were given audio recordings; CD's or audiotapes of formal mindfulness exercises to utilise for home-practice. In addition, four studies (Wells et al., 2014; Cash et al., 2015; Gross et al., 2012; Speca et al., 2000) also gave participants' workbooks or written material to aid home-practice. Finally, one study (Dimidjian et al., 2016) gave participants a DVD to complete their yoga exercises. These studies illustrate that the home-practice guidance and resources given to participants varies widely across studies and is not universal across MBI interventions. Home-practice was adapted across studies based on the protocol utilised and the population completing the intervention.

Amounts of Home-Practice Across Studies

As outlined in Table 3, all studies reported the amounts of home-practice that participants engaged in throughout treatment except Cash et al., (2015) who although measured home-practice during treatment reported practice at follow-up only. There was inconsistency in how the quantity of the home-practice was reported. The length and frequency of practice was reported in seven studies (Speca et al., 2000; Wells et al., 2014; Whitebird et al., 2012; Davidson et al., Johns et al., 2014; Gross et al., 2011; MacCoon et al., 2013) ranging from 16.9 minutes on 2.48 days out of six (Gross et al., 2011) to 44 minutes six days a week (MacCoon et al., 2013). A number of studies divided amounts of practice into formal and informal mindfulness practice. This ranged from formal meditation practice on 3.36 days a week for 21.31 minutes and a mean of 80.44 times of informal practice throughout

treatment (Crane et al., 2014) to 102.3 minutes per week of formal meditation and an additional 12.2 minutes of informal meditation per day (King et al., 2013).

Maintaining Home-Practice Post-Intervention

Post-intervention home-practice was reported in six studies (Bondolfi et al., 2010; Davidson et al., 2003; Gross et al., 2011; Johns et al., 2014; MacCoon et al., 2013; Perich et al., 2013). Documented practice in these studies ranged from 14.21 minutes per session on 1.70 days out of six (Davidson et al., 2003) to 25 minutes six days a week (MacCoon et al., 2013) over follow-up periods of 4 months and 5 months (Gross et al., 2011). Four of these studies (Cash et al., 2015; Johns et al., 2014; Bondolfi et al., 2010; Perich et al., 2013) reported the maintenance of practice as frequencies per week over follow-up periods of 2 months, 6 months, 7-12 months and 12-months.

These findings indicate that the included studies varied extensively in how they reported home-practice during treatment and post-intervention. None of the included studies reported amounts of home-practice in control conditions.

Amount of Home-practice and MBSR/MBCT Guidelines

Studies were reviewed for reported amounts of practice and whether this met the requirements of home-practice set out by MBI guidelines. Kabat-Zinn and Santorelli (2014) outline the MBSR home-practice as including a minimum of 45 minutes per day of formal mindfulness practice and 5-15 minutes of informal practice, 6 days per week for the duration of the course. Segal, Williams and Teasdale's (2013) MBCT protocol outlines home-practice as 45 minutes of formal mindfulness practice six days per week and informal mindfulness practice three times per day for the duration of the intervention. Of the eight MBSR studies included in this review only four studies (Cash et al., 2015; Davidson et al., 2003; MacCoon et al., 2013; Gross et al., 2011) outlined formal home-practices exactly in accordance to the MBSR recommendations of 45 minutes x 6 days a week. However, only Davidson et al., (2003) included both the formal and the recommended 5-15 minutes informal practice in their guidance. One study (Johns et al., 2014) adapted their home-practice tasks for a cancer context and therefore reduced the amount of practice to 20 minutes sessions. Of the six MBCT studies only half (Crane et al., 2014; Day et al., 2016;

Perich et al., 2013) outlined home-practice in accordance to the MBCT recommendations of 45 minutes x 6 days a week. However, none of these studies included the three times a day informal practice in their guidance.

It was possible to calculate what percentage of the formal home-practice expectation set out in the MBI recommendations was achieved in ten studies. This was calculated by determining the total amount of practice reported over 6 days per week in each study and expressing this as a percentage of the recommended 45 minutes x 6 days a week outlined in the MBSR/MBCT recommendations. Table 3 outlines the percentages across all studies these ranged from 14.87% (Davidson et al., 2003) to 88.14% (Wells et al., 2014). For the remaining four studies (Dimidjian et al., 2016; Cash et al., 2015; Bondolfi et al., 2010; Perich et al., 2013) it was not possible to calculate the percentage of formal home-practice expectations met as these studies did not report home-practice in minutes. It was not feasible to determine the percentage of the informal practice expectations that were achieved in studies, as the majority of studies did not report the amount of informal practice that participants engaged in.

Associations of Home-practice and Clinical Outcomes

As outlined in Table 3 seven studies (Davidson et al., 2003; MacCoon et al., 2013; Specia et al., 2000; Perich et al., 2013; Gross et al., 2011; Crane et al., 2014; Cash et al., 2015) examined the relationship between amount of home-practice and measures of clinical outcome. In the majority of these studies, with the exception of two (Crane et al., 2014; Perich et al., 2013), these results were secondary as opposed to primary analyses of outcomes. Of these, four studies (Cash et al., 2015; Specia et al., 2000; Gross et al., 2011; Crane et al., 2014) demonstrated amounts of home-practice predicted improvements on clinical outcome measures (including SCID, POMS, VAS, FIQ, DBS, ALI). In addition, Crane et al., (2014) reported that participants who practiced on three or more days a week were almost half as likely to relapse as those who practiced less frequently (as measured by SCID). However, they found no effect of informal mindfulness practice and time to relapse. Perich et al., (2013) found no association between number of days practice and outcome measures (YMRS, MADRS, DASS, STAI) following treatment or at 12-month follow-up. They found those who practiced a minimum of once a day for 3 days a week compared to 2 days a week

or less resulted in significant differences in anxiety scores (STAI) and lower scores on depression outcomes (DASS). Furthermore, at 12-month follow up those who practiced more frequently during treatment had significantly lower depression scores (DASS). MacCoon et al., (2013) did not find a significant effect of practice on measures (SCL-90-R, MSC) or thermal pain. Davidson et al., (2003) did not find a significant correlation between amount of practice and brain, immune functioning or psychological functioning (PANAS, STAI).

Four studies (Perich et al., 2013; Day et al., 2016; Bondolfi et al., 2010; Crane et al., 2014) examined home-practice with measures other than clinical outcomes. Day et al., (2016) reported that participants with higher in-session engagement (therapist-rated) spent a greater amount of time practicing. However, they reported that fidelity to treatment ratings (measured by MBCT-AAQS) were not associated with amounts of home-practice. Bondolfi et al., (2010) found that amounts of home-practice did not differ between those who relapsed to depression ($n = 9$) and those who did not relapse ($n = 17$) (measured by SCID). Crane et al., (2014) found no relationship between treatment plausibility (idiosyncratic measure) and home-practice. Finally, Perich et al., (2013) was the only study to measure the relationship between home-practice and levels of mindfulness but found no significant differences in mindfulness (as measured by MASS) between those who continued home-practice at 12-month follow-up and those who did not. The remaining five studies (Wells et al., 2014; Whitebird et al., 2012; Johns et al., 2014; King et al., 2013; Dimidjian et al., 2016) did not evaluate the relationship between home-practice and clinical outcomes or other measures. These studies reported amounts of practice as an aspect of adherence, feasibility, acceptability and satisfaction or compliance and retention to treatment.

Discussion

One aspect of MBI posited to be important in increasing the therapeutic effects of the intervention is participants' engagement in regular home-practice. Despite this, the research findings evaluating home-practice and clinical outcomes are mixed (Vettese et al., 2009). There has been little by way of a systematic review of this literature and no review of controlled MBI studies and home-practice. Therefore this review examined available controlled group MBI literature that measured home-practice utilising a self-report

measure. Fourteen studies, that investigated associations between home-practice and a range of outcome measures, were included in this review.

A key aim of the review was to explore how home-practice was measured across different evaluations of MBI. There was wide variety in the methods utilised to monitor practice from an electric logger (Gross et al., 2012) to home-practice logs/diaries (Cash et al., 2015). There was limited information provided regarding the content of the measurements or how they were developed. The inconsistency in the monitoring of home-practice compliance is reflected in the data that these tools produced, which restricted meaningful interpretation of compliance rates across studies. All studies focussed on the monitoring of the *quantity* of home-practice rather than exploring ways of assessing and/or maximising the *quality* of this home-practice. The total duration of mindfulness practice has been hypothesised to be important for positive outcomes. However, adherence involves not only attempting the practice, but also adhering to the specific way in which mindfulness practices should be conducted (e.g. present moment attention). Therefore, quality of practice could be an important factor for predicting outcomes. One such tool that has been developed is the Practice Quality-Mindfulness (PQ-M) (Del Re et al., 2013) which could be implemented in studies. These findings indicate that there is a need for the development of greater sophistication and consistency in methods being employed to monitor home-practice across MBI. These measures need to monitor home-practice that corresponds to the guidelines of MBSR and MBCT, measuring both the minutes and frequency of practice.

Another important consideration for this review was the home-practice resources and guidance given to participants. The resources were varied but the majority of studies gave participants audio-files to enable practice of formal exercises. Research is needed to determine what specific resources increase engagement in home-practice. This review demonstrated that the majority of studies gave participants practice guidance that is approximately in line with MBI recommendations. Six studies did not give the specific details regarding duration of practice or adapted the recommended practice guidelines for the population completing the intervention. However, none of the included studies' reported mean quantities of practice that met the criteria set out in these guidelines; there was a range of between 14.87% to 88.14% regarding the proportion fulfilment of these

recommendations. This discrepancy between what is recommended and what is reported on home-practice in studies further contextualises the mixed findings on home-practice and its relationship to clinical outcomes. It may be that the relationship between practice and clinical outcomes could be strengthened by facilitating participants to engage better in home-practice.

Although the findings across the studies suggest that participants struggle to complete the stipulated amount of home-practice guidance, none of the studies explored the barriers that participants experienced in completing their home-practice. This is an important aspect that has been relatively overlooked in mindfulness research. In terms of cognitive behavioural therapy (CBT), Dunn, Morrison and Bentall (2002) found that factors such as motivation, recall of the assignment, difficulty, putting off, understanding of the rationale, perceived benefits, insight, effort and relevance effected home-practice compliance. MBSR and MBCT stipulate home-practice that requires significant time commitments from participants, which may impact on their engagement and motivation. It is important that the barriers to completing home-practice are explored in the context of MBI to help maximise the efficacy of the interventions.

Despite home-practice being hypothesized as an important factor for outcomes in MBI, only a small sample of the body of studies have investigated the relationship between home-practice and clinical outcomes. Of the included studies only half examined this relationship, of which four studies demonstrated a significant effect. These studies focused on a range of outcomes, both psychological and physical health, and analysed this relationship using a variety of statistical methods. In addition, only one included study examined the relationship between practice amounts and levels of mindfulness (as assessed by the MASS) in participants. These findings raise a number of criticisms of evaluations of MBI that are similar to the following ones by Vettese et al., (2009). Of the studies that investigated the relationship between practice and clinical outcomes most studies regarded the mindfulness practice component as a secondary rather than a primary focus of the research and the number of studies investigating the association between practice and levels of mindfulness is limited. It is key that future research routinely investigates whether duration of home-

practice increases levels of mindfulness, as this is posited to subsequently improve the therapeutic effects of the intervention (Kabat-Zinn, 1990).

Although MBI recommends both formal and informal practice, the included studies focused on the relationship between formal mindfulness practice and clinical outcomes and relatively overlooked informal practice. A number of studies have failed to find a direct relationship between informal mindfulness practice and associated changes on clinical measures (Carmody & Baer, 2008; Hawley et al., 2014). This may be as a result of the nature of informal practice, which is more difficult to isolate and therefore it is hard to measure the frequency and duration of this practice. Improved methods of monitoring this type of practice may be valuable in future research, as well as detailed investigation of the importance of living mindfully on psychological and health outcomes.

Limitations of Current Review

There are a number of limitations that should be taken into account when considering the conclusions of this review. Firstly, limitations of the use of the CTAM as an assessment of methodological quality must be acknowledged. The CTAM has been used to assess the methodological quality in a number of reviews (Tarrier et al., 2004; Wykes et al., 2011) and has shown good blind inter-rater agreement, adequate internal consistency, and excellent concurrent validity with other established rating scales designed to assess the generic quality of clinical trials (Lobban et al., 2013). That said, other tools such as The Cochrane Collaborations Risk of Bias Tool (2011) are supported by PRISMA-P guidelines which emphasize additional domains that may need to be considered when evaluating RCT's, such as the issue of selective reporting, which is not address by the CTAM (Lobban et al., 2013). Secondly, the heterogeneity of the included studies such as; study sample selection; outcome measures utilised; home-practice measurement and guidance and the range of presenting problems across studies; made direct comparisons, to comprehensively report on the effectiveness of home-practice in MBI, challenging. Additionally there was a lack of inter-rater reliability in the process of screening the abstracts for inclusion, as not all abstracts were second-screened by an independent evaluator. This may mean a small number of studies, which met inclusion criteria, were missed. Thirdly, there are limitations regarding the scope of this review, which included a small number of studies. Studies that

have measured home-practice in other ways (e.g. qualitative methods of enquiring about home-practice during and post- treatment) and non-controlled studies, of which there are a number of recent studies examining home-practice in MBI, were excluded. Finally, it is important to highlight the difficulties associated with the measurement of home-practice and the impact of this on the outcomes of MBI. The majority of studies utilise self-report measures to monitor home-practice. Given the subjective nature of this type of measurement there is no reliable way to ensure that this practice has occurred. Therefore, it is difficult to reliably draw conclusions regarding the relationship between the amount of home-practice completed and whether this improves MBI outcomes or not.

Recommendations and Conclusions

As a result of this review, a number of recommendations can be made that will serve to enhance future research on the efficacy of home-practice in group-MBI. It is evident from the appraisal of this research that the majority of studies have been conducted in North America. It is important that future MBI research is conducted in other areas of the world, to develop findings that can be generalised to various populations. The findings illustrate the need for mindfulness research to utilise experimental methodologies more consistently to allow for firm conclusions about the effects of home-practice on clinical outcomes. Inclusion of control “no practice” conditions, would allow for the direct comparison of the benefits of mindfulness practice. Another important consideration is the measurement and quality of home-practice. This review illustrates the need for the development of more standardised measures for monitoring practice. This would allow for reliable and valid measurements of home-practice and comparison of practice across studies. The findings of this review have led to the development of the *Mindfulness Home-Practice Monitoring Form (MHMF)*, a measurement tool that could be utilised to monitor formal and informal home-practice in future MBI studies (see Appendix 1.5). In addition, qualitative research involving exploration of the barriers participants’ experience in completing home-practice could help inform ways to facilitate better compliance.

In summary, mindfulness research is at an early stage of exploring the role of home-practice and its relationship to outcomes of mindfulness based interventions. Given the extensive time commitment required of participants to complete home-practice it is critical to

evaluate both experimentally and qualitatively the relationship of this practice and whether it improves clinical outcomes. In addition, the findings of this review illustrate the homogeneity in the measurement of home-practice across studies. It is vital that the mindfulness literature develop standardized and reliable measures to determine quantity and quality of home-practice that can be compared across studies. These developments would allow the mindfulness literature to determine more definitively the role of home-practice in mindfulness programs.

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CHAPTER 2: MAJOR RESEARCH PROJECT

The Use of Acceptance and Commitment Therapy to Address Psychological Distress Experienced by Caregivers: A Randomised Controlled Feasibility Trial

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Plain English Summary

Background: Research has extensively documented the negative impact caring for an individual with an acquired brain injury (ABI) can have, including financial difficulties, social isolation, relationship difficulties, role adjustment and psychological distress. Despite these findings, there is currently a limited range of interventions, specifically to improve psychological outcomes of ABI caregivers. Acceptance and commitment therapy (ACT) focuses on changing the relationship that individuals have with their difficult thoughts and emotions so individuals can better engage with their values. Preliminary findings have suggested that ACT may be a useful intervention for caregivers, however further research is needed to explore the use of this therapy with this population.

Aims of the Study: To investigate the feasibility of using an ACT intervention with ABI caregivers and assess whether ACT lowers levels of psychological distress and improves participant's relationship with their thoughts and emotions. This study also looked at the experience of ABI caregivers, including the challenges of such and what types of supports would be helpful in this role.

What the Study Involved: This study was conducted in two stages. In stage one, eighteen caregivers were recruited through a local brain injury unit and allocated to either the ACT group or a comparison support group. The ACT group was three sessions and the support group was two sessions. Assessments measuring psychological distress, value-based behaviour and flexibility of thinking were completed at the beginning of the groups and at the final session. The data from these were assessed to identify any changes in answers between time-points. A number of participants also completed interviews about their experiences of being a caregiver and the challenges of this.

Results: Participants were successfully recruited for both ACT and a comparison group. Individuals who completed the ACT group gave positive feedback and suggested the intervention was acceptable. However, half of ACT participants missed group sessions, due to work and personal commitments. Results did not show a difference between participants who received ACT and those who did not. Findings from the interviews illustrated the

impact of caring for an individual with an ABI, the challenges of such and the barriers to accessing support.

Conclusions: Results of this study highlight helpful ways to proceed with future research in this area. This could be an important intervention for ABI caregivers but barriers to accessing this support need to be addressed further and research conducted with a larger sample of carers. A key area for future research is ensuring participants attend a high proportion of sessions, as this could improve their outcomes during the intervention.

Abstract

Background: An extensive research literature has documented the impact of caring for an individual with acquired brain injury (ABI) on caregivers and family members, including role adjustment, psychological distress, social isolation, family tension and coping with the cognitive and behavioural difficulties of the injured person. Given these findings it is important this population have access to services and supports. Acceptance and Commitment Therapy (ACT) is an intervention that helps individuals to accept difficult experiences and commit to behaviour that is consistent with their values. Research into the effectiveness of ACT to support caregivers is at a preliminary stage.

Aim: To investigate the feasibility of using ACT to reduce psychological distress and increase psychological flexibility in ABI caregivers. A secondary aim was to gain an understanding of the experience of caregivers in this context and how this can inform the development and delivery of interventions for this population.

Method: Phase one was a randomised controlled feasibility trial of an ACT intervention for use with ABI caregivers. The parameters of this study were formulated around the PICO (population, intervention, control, and outcome) framework. Eighteen carers were recruited and randomised to ACT or an enhanced treatment as usual (ETAU) group. ACT was implemented over 3 sessions; and ETAU was implemented over 2 sessions. The General Health Questionnaire, Valuing Questionnaire, Acceptance and Action Questionnaire, Experiential Avoidance of Caregiving Questionnaire and the Flexibility of Responses to Self-Critical Thoughts Scale were administered to both groups at baseline and following the final session. Phase two used a retrospective qualitative design that involved conducting semi-structured interviews with four participants from phase one.

Results: ACT and control participants were successfully recruited. Positive feedback was obtained from ACT participants suggesting that the intervention was acceptable. There were no significant differences between the ACT and ETAU groups on outcome measures. However, there were challenges retaining participants and the overall attrition rate was high (44.44%). Therefore a number of participants did not complete the full complement of sessions, which may have impacted on this result. Qualitative results illustrated the

challenges this population face including significant adjustments in their life, the emotional impact of having a loved one with a brain injury and trying to adapt to the changes in the injured person. In addition, findings elucidated the types of support that this population would find helpful and the barriers to accessing same.

Conclusions: Findings from this study highlight factors that will help the development of this intervention further for a caring population. Recommendations for future implementation include completing some preparatory work with carers before beginning the intervention, consideration of a larger sample and wider recruitment strategy from local services, barriers to attending interventions and the possibility of holding groups in local venues.

Introduction

Caregivers and Well-Being

Acquired brain injury (ABI) causes enduring impairments in functioning in a variety of domains including cognition and memory, behavioural control, emotional regulation in addition to physical and sensory difficulties (Lezak et al., 2004; Williams, Vaughan, Huws & Hastings, 2014). In contrast to stroke or dementia, ABI has been noted to be predominately a problem of younger age groups (Jackson, Turner-Stokes, Murray, Leese & McPherson, 2009). This presents particular challenges for both patient rehabilitation and family adaptation. Family members of those with an ABI can assume the role of caregivers and frequently become the long-term source of support to the injured individual (Ponsford & Schönberger, 2010). An extensive research literature has documented the adverse impact of caring for an individual with an ABI with outcomes such as financial difficulties, family tension, social isolation, reduced involvement in pleasurable activities, relationship difficulties, and role adjustment all described (Boschen, Gargaro, Gan, Gerber & Brandys, 2007; Aitken et al., 2009). In addition, ABI caregivers have the further struggle of contending with so-called 'hidden' difficulties' (Jackson et al., 2009). These can include personality changes, cognitive deficits and unpredictable behaviours, which have been associated with further distress (Sinnakaruppan & Williams, 2001). Similarly, the sudden and precipitous onset of ABI may leave carers facing an abrupt change to their lives. Jackson et al., (2009) found that when outcomes for ABI caregivers were compared to dementia caregivers, both groups experienced high burden, poor mental health, and poor quality-of-life, however ABI caregivers' generally had more pronounced levels of these indices of burden.

Despite these findings limited knowledge exists regarding the qualitative experience and impact of this burden. Jordan and Linden (2013) conducted a qualitative investigation with a sample of mothers who care for their child with an ABI on the processes of caring and the impact of such on their mental health. Five key themes emerged: perpetually anxious, the guilty carer, the labour of caring, a self-conscious apologist and perpetually grieving. These findings describe the experience of carers living in a world of emotions including anxiety, guilt and loss that are an inherent aspect of caregiving. In addition they describe the 'daily grind' and profound weariness as a result of years of caring (Jordan et al., 2013).

Despite services and professionals best efforts, family members (especially those in a caregiving role) often report feeling poorly equipped and emotionally overwhelmed in trying to provide for the long-term needs of the injured individual (Kreutzer, Marwitz, Sima, & Godwin, 2015). A number of studies have looked at defining ABI family members needs. Frequently ranked highest are needs for emotional and psychological support, information and educational support and professional support. Many of these needs are also rated as unmet, indicating that support systems for families and caregivers are inadequate (Sinnakaruppan & Williams, 2001). Research has documented that a family's ability to cope with stress affects the quality of support provided to the injured person and subsequently the extent of neurobehavioural recovery (Testa, Malec, Moessner & Brown, 2006).

Interventions for ABI Caregivers

Given these extensive findings, it is important that this population has access to a range of services and supports. Recent research has begun to focus on the efficacy of psychological interventions for ABI carers. Kreutzer, Kolakowsky-Hayner, Demm, and Meade (2002) created an intervention entitled Brain Injury Family Intervention (BIFI). This approach utilised stress management skills and aimed to help caregivers manage difficult feelings about their situation. Kreutzer et al., (2009) conducted a prospective cohort study and found that caregivers reported fewer unmet needs and perceived fewer obstacles to receiving services following this treatment. Wade, Michaud, and Brown (2006) conducted a randomised controlled trial to assess the efficacy of a family problem solving intervention for families of children with brain injuries compared to usual care. Their findings showed improvements in child behaviour but no significant changes in parental distress in comparison to treatment as usual. Boschen et al., (2007) completed a critical review of the quality of research conducted on interventions with family caregivers of individuals with ABI. The findings illustrated that there is no strong research evidence supporting any specific intervention method for family caregivers of individuals with ABI at present. These findings point to the need for developing new pilot studies and rigorous evaluations of caregiver intervention effectiveness for patients of this population.

Acceptance and Commitment Therapy

In the context of caregiving, it is not unusual to find caregivers who try to free themselves of emotions and thoughts that occur due to the difficult circumstances associated with caring. For example, emotions such as sadness and grief or challenging thoughts relating to caring for the individual are inherent to the caregiving situation. Spira et al. (2007) found a significant association between caregivers' level of *experiential avoidance* and their degree of psychological distress. *Experiential avoidance* is the tendency to control and/or avoid the occurrence of difficult emotions, thoughts and sensations (Hayes, Wilson, Gifford, Follette, & Strosahl, 1996). The evidence base suggests that providing interventions that support caregivers in minimising avoidant coping, through the provision of alternative strategies, could be beneficial.

Traditional Cognitive Behavioural Therapy (CBT) interventions generally aim to change thoughts and behaviours associated with particular clinical presentations. In comparison, Acceptance and Commitment Therapy (ACT) concentrates on helping individuals to utilise mindfulness and acceptance approaches to relate to difficult thoughts and emotions, and consider whether avoidant patterns of coping are preventing them from engaging with valued life domains. ACT is one of the 'third wave' behavioural therapies aiming to increase 'psychological flexibility' (Flaxman & Bond, 2006). ACT theory proposes that psychological inflexibility is a cause of a variety of psychological problems, and that learning how to act in more flexible ways can be an effective intervention (Hayes et al., 2011). This perspective may be more suitable for use with carers, as caregiving is a life context, which strongly impacts caregiving values, life purpose and self-realisation, characteristics that represent a less symptom based view of well-being.

There have been a number of meta-analyses on ACT published during the last decade (Powers, Zum Vörde Sive Vörding & Emmelkamp, 2009, Jiménez, 2012; Öst, 2014). These meta-analyses have shown small-moderate effect sizes in favour of ACT when compared to control conditions. Öst (2014) conducted the latest systematic review and meta-analysis on the efficacy of ACT. This analysis of 60 RCT's suggested that ACT may be efficacious for a range of difficulties including psychiatric disorders, chronic pain and stress at work (Öst, 2014).

To date there is limited research exploring the use of ACT with caregivers. Márquez-González, Romero-Moreno and Losada (2010) conducted a pilot study exploring the use of an ACT intervention with 16 female dementia family caregivers and found a significant decrease in caregivers experiential avoidance in the ACT group intervention compared to a control condition (Losada & Marguez-Gonzalez, 2011). Previous research using an ACT-based stress management intervention with staff caring for individuals with learning disabilities, reported a reduction in general psychological distress (measured by the GHQ-12) from pre-test to 6-week follow-up (Noone & Hastings, 2009, 2010). Bethay, Wilson, Schnetzer, Nassar, and Bordieri, (2013) found similar results using a mindfulness and acceptance-based work stress reduction intervention for staff caring for individuals with learning disabilities.

Current Study

Given the emerging evidence relating to the efficacy of ACT as a psychological intervention and the evidence regarding caregiving avoidant coping strategies, it is hypothesised that ACT may be a beneficial intervention for improving psychological health in ABI caregivers. The primary outcome measure was psychological distress as measured by the GHQ-12. This study set out to investigate the feasibility of utilising an ACT based intervention with a group of ABI caregivers and conducted qualitative investigations into participants caring experiences and the supports that they require. When developing a complex intervention, significant development and piloting work is of great importance (Medical Research Council – MRC, 2008). According to the MRC (2008) guidelines on developing complex interventions, the feasibility and piloting stages include: testing procedures for their acceptability, estimating the expected rates of recruitment and retention of participants, and the calculation of appropriate sample sizes (MRC, 2008). These guidelines have informed the parameters and design of the current study.

Aims

Quantitative Phase 1- a feasibility study of an ACT intervention

The primary aim of this study was to investigate the feasibility of using an ACT intervention to reduce the psychological distress and psychological inflexibility of carers. The parameters

of this feasibility study were formulated around the PICO framework (Richardson, et al., 1995), which was used to guide this investigation:

1. **Population:** Can an appropriate group of carers be recruited? This will be determined by ascertaining whether participants can be identified and consented to participate in the study, and determining their baseline scores in psychological distress and inflexibility.
2. **Intervention:** Will an ACT intervention be acceptable to this population? This will be determined by measuring workshop attendance, attrition rates and analysing feedback forms.
3. **Control:** Can a group of carers be recruited as a control and followed up in parallel to the intervention group? This will be determined by investigating whether enhanced treatment as usual (ETAU) control group can be recruited to assess in parallel to the intervention group.
4. **Outcomes:** Can measures be identified to explore the impact of an ACT intervention on changes in psychological distress and psychological flexibility? What are the rates of discontinuation from intervention? Are there any identifiable characteristics of those who drop-out?

Qualitative Phase 2- a qualitative analysis of interviews

A secondary aim of this study was to gain an understanding of the challenges that carers face, the forms of support that they believe would be helpful, and the context in which this work will be delivered. This was explored using qualitative methods conducting interviews with a sub-section of the participants from phase one. The interviews focused on the challenges of being a caregiver of a brain injured individual, the barriers to accessing services for families and caregivers and the utility and acceptability of the intervention used in this study. Understanding the context of the intervention is critical for interpreting the quantitative findings of this study and informing the development of more refined feasibility studies and advancing services for this population.

Phase One: Quantitative Investigation

Method

Design

Phase one was a randomised controlled feasibility trial of an ACT intervention for use with ABI caregivers.

Eligibility Criteria

Inclusion Criteria: Participants were included on the basis that they were either the full-time or part-time family caregiver of an adult with an ABI. All participants were aged 18 years old or above.

Exclusion Criteria: Individuals were excluded if they had a learning disability or were not proficient in English.

Recruitment

Participants were recruited through the Brain Injury Rehabilitation Trust (BIRT) in Glasgow from January – May 2016. Caregivers of the patients who reside in Graham Anderson House (BIRT) in Glasgow were invited by Dr. Brian O'Neill by letter to participate in the study (see Appendix 2.1). In addition, carers of patients who have transitioned back to living in the community but who are still in contact with BIRT and may need support were also invited to participate. Carers who expressed an interest in participating in the research were then contacted by the main researcher and were provided with information sheets with the outline of the project and what participation involved (see Appendix. 2.2)

Participants

Twenty-seven caregivers expressed an interest in participating, of which 18 (66.67%) provided informed consent to participate in the study. Participants were randomly assigned to either the ACT intervention or Enhanced Treatment As Usual (ETAU) and were assessed in parallel to one another. Randomisation was completed with the Research Randomizer programme provided by the Social Psychology Network (<http://www.randomizer.org>). Permuted block randomization was used to ensure that an equal number of subjects were assigned to each group. A block size of 10 and an allocation ratio of 1:1 were utilised.

Demographic information about the participants can be viewed in Table 1 (see results section). The mean age of participants was 48.94 years (SD = 14.44, range = 21 – 74 years), 16 females (88.89%) and 2 males (11.11%). 18 participants completed baseline measures. Eight (44.44%) participants dropped-out during the delivery of the interventions, resulting in 10 (55.56%) participants completing measures at post-intervention.

Ethics

Research approval was gained from the West of Scotland Research Ethics Service Committee No. 3 (ref: 15/WS/0208) and Specific Site Approval (ref: 15/WS/0271) (see Appendix 2.3) granted from NHS Greater Glasgow and Clyde. In addition, ethical approval was also gained from the Disabilities Trust Research Ethics Committee (DTREC) granted from BIRT and Disabilities Trust (see Appendix 2.4). Participants' anonymity and confidentiality was paramount. Individuals were reminded that they could withdraw from the study at any point.

Arms of the Study

Acceptance and Commitment Training (ACT)

The ACT intervention utilised was an adapted manualised protocol following Paul Flaxman's 2+1 intervention (Flaxman, Bond & Livheim, 2013). The researcher facilitated the training and the first round of groups was co-facilitated by Dr. Ross White. In addition, the researcher received regular supervision from Dr. White to monitor the implementation of the intervention. All sessions were recorded to maximise fidelity. The ACT intervention consisted of three sessions, two on consecutive weeks and the final session two weeks later. Each session was 2 hours in duration, which included time for a mid-session break and completion of psychometric measures (Flaxman et al., 2013). (See Appendix 2.5 for session outlines).

Enhanced Treatment as Usual (ETAU)

In line with the ethical considerations as recommended by Reynolds et al. (2001), an enhanced treatment as usual (ETAU) condition was utilised to ensure that all participants received an intervention for their participation. ETAU consisted of two sessions and took the same format as the ACT intervention (i.e. lasting 2 hours in duration with a mid-session

break). The group was facilitated by the main researcher and took place over the same time period as the ACT group (i.e. the duration between the sessions was a 3-week period). The intervention sessions provided time for participants to speak together about their experiences and challenges as ABI caregivers, and the utilisation of relaxation techniques, including progressive muscle relaxation (PMR). This was accompanied by between session practice of PMR.

Procedure

Once participants verbally consented to participate, they were randomly allocated to ACT or ETAU and were given the dates of the groups. Two rounds of groups were completed over a three-month period. The final session of one of the ETAU groups was completed a week later than anticipated. This was due to the ETAU participants in this group being unable to attend the group on the scheduled date; therefore the group was ran the following week. All participants were allocated a participant number at recruitment to ensure anonymity. Written consent was obtained at the beginning of the first session of both the ACT and ETAU interventions (see Appendix 2.6). Assessment measures were completed with participants in both the ACT and ETAU groups over the same time points. Baseline measures were completed at the beginning of the first session and post-measures at the end of the final session. Participants were contacted via telephone or email if they missed a session to remind them of the date of next session. Data on reasons for missed sessions were collected during these contacts or some participants contacted the researcher independently to state why they could not attend.

Measures

General Health Questionnaire (GHQ – 12; Goldberg and Williams, 1988) is a widely used 12 item self-report scale measuring general psychological distress. Respondents are asked to indicate whether they have recently experienced a range of common symptoms of distress (e.g., “Have you recently... felt constantly under strain?”), on a four-point scale with higher scores indicating more psychological distress. The GHQ-12 can be dichotomised using cut-off scores to indicate levels of distress. The scale has demonstrated high levels of validity with overall sensitivity 76.30 and specificity 83.40 (Goldberg et al., 1997). The 12-item version has been shown to be as effective as the 28- item version (Goldberg et al., 1997).

Acceptance and Action Questionnaire - II (AAQ-II; Bond, et al., 2011) is a ten-item questionnaire, which measures psychological inflexibility. The AAQ-II was developed to specifically assess ACT outcomes. Respondents are asked to rate how true each statement is for them (e.g. “emotions cause problems in my life”) on a seven-point likert scale. Higher scores on the AAQ-II indicate greater psychological inflexibility, while low scores reflect greater acceptance and action. The scale has acceptable levels of internal consistency (α 0.84), and the 3 and 12-month test-retest reliability is 0.81 and 0.79 (Bond et al., 2011).

Valuing Questionnaire (VQ; Smout, Davies, Burns and Christie, 2014) is a 10-item scale measuring value-consistent behaviour. It has 2 factors: “Progress”; how much people feel they lived by their values in the past week, and “Obstructed”; how much cognitive and emotional barriers restricted the enactment of values in the past week. Respondents are asked to rate how true each statement is for them (e.g. “I felt like I had a purpose in life”) on a seven-point likert scale. Smout et al., (2014) found good internal consistency for both the progress scale (α = 0.81) and the obstruction scale (α = 0.79) of the VQ.

Experiential Avoidance in Caregiving Questionnaire (EACQ; Losada, et. al., 2014) is a 15-item self-rated scale, measuring experiential avoidance. Respondents are asked to rate the truth of each statement (e.g. “I cannot bear it when I get angry with my relative”) on a five-point scale. Higher scores indicate higher levels of experiential avoidance of difficult thoughts and emotions associated with being in caregiving role. An acceptable reliability index was found for the total scale (α = 0.70).

Flexibility of Responses to Self-Critical Thoughts Scale (FoReST-12; Larkin and White, in preparation) is a new twelve-item questionnaire, used to assess changes in a person's psychological flexibility in response to their self-critical thoughts. Respondents are asked to rate the truth of each statement (e.g. “I do things I later regret”) on a seven-point scale from (never true) to (always true). Higher scores indicate higher levels of psychological inflexibility in response to self-critical thinking. Research is currently being conducted on the reliability and validity of this scale (see Appendix 2.7)

Demographic Questionnaire recorded the demographic details of caregivers attending the groups including: age, gender, length of time being in a caring role, full-time or part-time carers, any other employment, number of individuals they care for, and their relationship to the individual they care for (e.g. mother, father, sister, other guardian) (see appendix 2.8).

Intervention Evaluation Form was a brief questionnaire used to gain feedback about the ACT intervention. This questionnaire evaluated areas such as the facilities, the content of the intervention and participant's subjective evaluation of the areas of ACT that facilitated change (see appendix 2.9).

Sample Size Justification

As investigations into ACT for carers are at a very preliminary stage, it meant that it was not possible to perform a sample size calculation for this feasibility study. According to the MRC (2008) guidelines on developing complex interventions, the remit of feasibility studies includes the estimation of expected rates of recruitment and retention of participants, and the calculation of appropriate sample sizes (MRC, 2008). This study was intended to help generate effect sizes, which can then be utilised by future researchers to inform calculations of the required sample sizes for further trials.

Data Analysis

All data were assessed for normality using Shapiro-Wilk tests and by examining the plots of each variable, including histograms, q-q plots and box-plots. Where normality assumptions were not met, non-parametric tests were utilised. Demographic information was collated using descriptive statistics. Independent sample t-tests were administered to compare between-group differences between ACT and control groups at baseline for normally distributed variables. The non-parametric equivalent of an independent t-test (Mann Whitney U) was used to determine differences between the ACT and control group on baseline measures not normally distributed. Fisher's Exact Test for independence was used for differences between groups on categorical variables at baseline. Wilcoxon Signed Rank test was conducted to perform within group analyses of change between baseline and post-treatment, as none of this data met normality assumptions. The group evaluation form was collated using descriptive statistics. Spearman's rho correlation co-efficient (two-tailed) was

used to test associations between measures at baseline and change scores for these variables between baseline and post-treatment for all participants. In order to reduce the risk of Type 1 errors the Bonferroni correction was applied to the correlation analyses. The adjusted p-value was 0.003. Change scores for each measure were calculated by subtracting baseline score from the post-intervention scores. Independent sample t-tests were administered to compare between group change scores for ACT and control groups for normally distributed variables. The non-parametric equivalent of an independent t-test (Mann Whitney U) was used to determine differences in change scores between groups not normally distributed. There were three data points (0.14%) missing across questionnaires. Data for these points were pro-rated based on the participants' answers on the remaining questions on the measure (e.g. inputting the mean score from the total questions answered).

Results

Recruitment and Attrition

Figure 1. outlines the number of individuals invited to participate, the number who volunteered, consented and the number who completed the intervention and outcome measures. In terms of attrition, four (40%) of the 10 ACT participants completed the full complement of three ACT intervention sessions: 2 (20%) missed one session and 4 (40%) missed two sessions. Five (62.5%) of the 8 control participants attended both ETAU sessions. Reasons for missing sessions included caregiving duties, work, holidays, the individual with ABI being taken to hospital, and participants indicating that they no longer felt that they needed an intervention. Across groups, 5 (50%) ACT participants and 3 (37.5%) control participants failed to attend the last session, and therefore did not complete follow up measures. There was no significant difference between groups in attrition rates ($p = 0.664$, Fisher's Exact Test).

Figure 1. Flow diagram of participants throughout the study

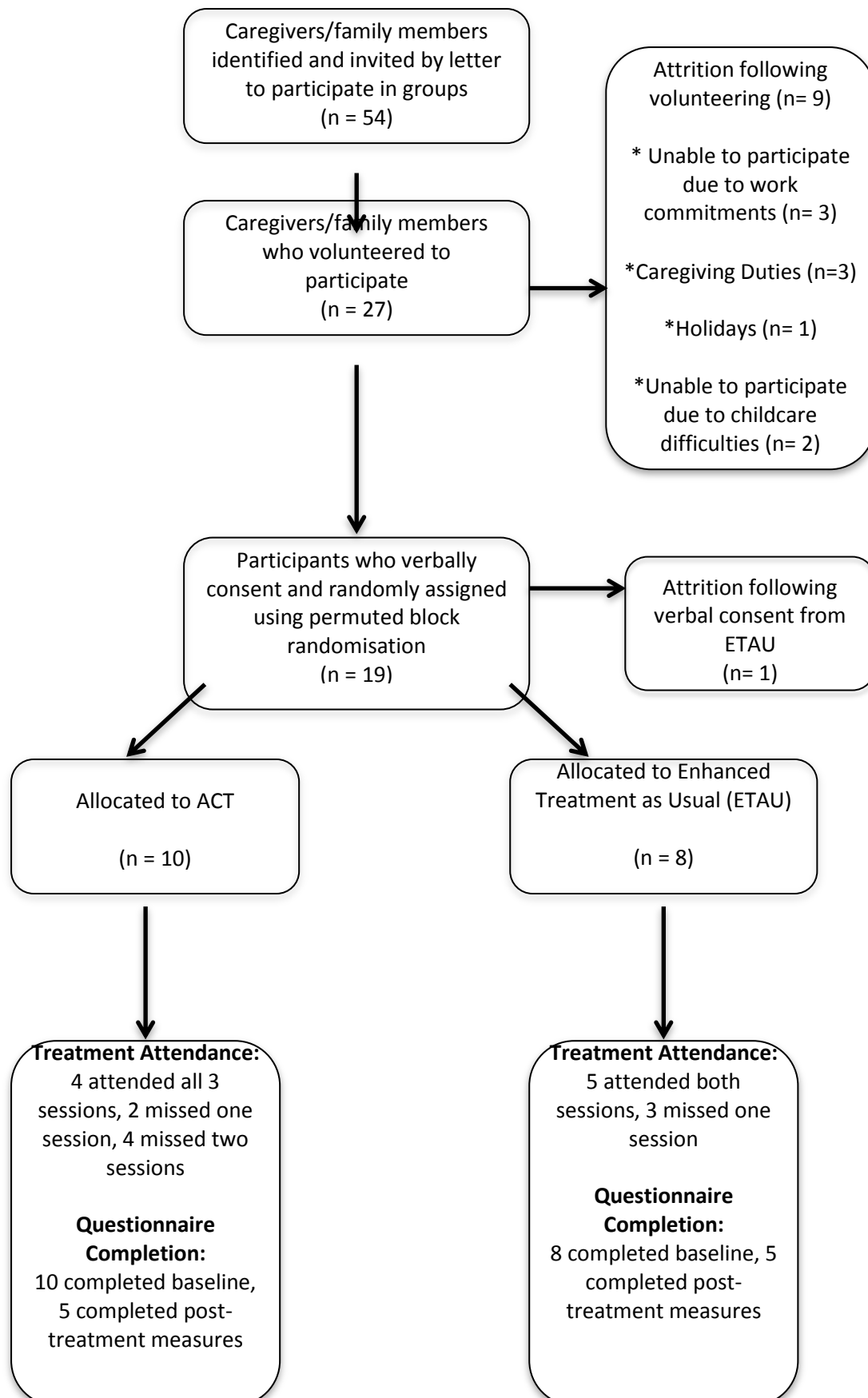


Table 1. outlines the demographics of the groups. No significant differences were found between the ACT and control group in relation to age, gender, length of time as a caregiver, hours per week in a caring role, the number of individuals that they care for or the age of their loved one with an ABI. Chi-squared analyses to determine whether there were differences between group's relationship to individual with ABI and causes of ABI were not possible as this data did not meet assumptions.

Table 2. provides a comparison between those who completed their allocated group and those who dropped out at baseline. There was one significant difference noted between the groups. Participants who dropped out before follow-up exhibited higher levels of psychological distress as measured by the GHQ-12, than participants who completed treatment, $t(16) = -2.25$, $p = 0.039 < 0.05$. The effect size for this difference was moderate ($d = 0.46$).

Caregivers' Measures at Baseline

Table 3. provides a comparison between groups on baseline measures. There were no significant differences noted between groups.

Although the difference in psychological distress between groups at baseline, as measured by the GHQ-12, was not significant, it is worth noting that it is just outside the limit of statistical significance, $t(16) = 1.79$, $p = 0.093$. The effect size for this difference is large ($d = 0.86$). When GHQ-12 cut-off scores for distress were applied across groups, 4 ACT (40%) and 1 control (12.5%) participant had a score above the cut-off evidencing 'distress' (score of >15) and 3 ACT (30%) and 2 control (25%) participants had a score above the cut-off for 'severe problems and psychological distress' (score of >20). There was no significant difference between groups for number of participants meeting GHQ-12 distress cut-off scores ($p = 1.00$, Fisher's Exact Test).

Within Group Changes in ACT and ETAU

Table 4. provides a within groups comparison across time-points. There were no significant differences noted within either groups.

Table 1. Demographic Information

Ψ Non-parametric tests used

Demographic Variable		ACT (n=10)	Control (ETAU) (n=8)	P-Value
Mean Age (Years) Ψ		46.20 (14.64)	52.40 (14.36)	0.824
Gender	Female	9(90%)	7(87.5%)	1
	Male	1(10%)	1(12.5%)	
Mean Length of Time as a Carer (Years) Ψ		6.60 (8.84)	5.20 (6.16)	1
Mean Time Spent in Caregiving Role (Hours per week) Ψ		87.20 (85.23)	33 (27.47)	0.549
Mean Number of Individuals Care for Ψ		1.20 (0.42)	1.10 (0.35)	0.680
Mean Age of Individual with ABI (Years) Ψ		36.10 (14.58)	52 (20.72)	0.129
Relationship to Individual with ABI	Mother	4(40%)	3(37.5%)	Analysis could not be conducted as data did not meet assumptions
	Sibling	3(30%)	1(12.5%)	
	Child	0	2(25%)	
	Wife	2(20%)	1(12.5%)	
	Other Relative	1(10%)	1(12.5%)	
Mean Age of Individual with ABI when Sustained Injury (Years) Ψ		29 (16.90)	46.88 (22.57)	0.075
Causes of ABI	Aneurysm	1(10%)	2(25%)	Analysis could not be conducted as data did not meet assumptions
	Encephalitis	1(10%)	0	
	Meningitis	2(20%)	0	
	Hypoxia	2(20%)	1(12.5%)	
	Trauma (Road traffic accident, assault, fall from a height)	4(40%)	5(62.5%)	

Table 2. Mean (SD) and Median (IQR) Baseline Scores for Treatment Completers and Non-Completers

Measures		Completers (n=10)	Non-Completers (n=8)	P-Value
GHQ-12		13.50 (5.50)	20.63 (7.93)	0.039*
AAQ-II Ψ		18 (16)	23 (18)	0.141
VQ	Progress	20.30 (5.68)	20.13 (6.98)	0.954
	Obstruction Ψ	16.50 (17)	18 (11)	0.591
EACQ Ψ		34 (20)	33.50 (12)	0.859
FoReST-12		30.90 (12.01)	29.38 (18.92)	0.838

Ψ Non-parametric tests used, therefore medians noted *Denotes $p < 0.05$

Table 3. Mean (SD) and Median (IQR) Group Baseline Scores

Measures		ACT (n=10)	Control (ETAU) (n=8)	P-Value
GHQ-12		19.30 (7.53)	13.38 (6.23)	0.093
AAQ-II Ψ		19 (13)	18 (18)	0.503
VQ	Progress	21.10 (5.24)	19.13 (7.24)	0.511
	Obstruction Ψ	18.50 (15)	16.50 (22)	0.447
EACQ Ψ		35.50 (15)	32.50 (31)	1
FoReST-12		31.50 (15.89)	28.63 (14.67)	0.699

Ψ Non-parametric tests used, therefore medians noted

Glossary: GHQ-12 = General Health Questionnaire; AAQ-II = Acceptance and Action Questionnaire; VQ = Valuing Questionnaire; EACQ = Experiential Avoidance in caregiving Questionnaire; FoReST-12 = Flexibility of Responses to Self-Critical Thoughts Scale

Table 4. Median (IQR) Within Group Scores from Baseline to Post-Treatment

Measures		ACT			Control (ETAU)		
		Baseline (n=10)	Post-Treatment (n=5)	P-Value	Baseline (n=8)	Post-Treatment (n=5)	P-Value
GHQ-12 Ψ		18 (6)	12 (11.50)	0.109	13 (11)	10 (7.50)	0.285
AAQ-II Ψ		19 (13)	18 (9.50)	0.223	18 (18)	8 (15.50)	0.109
VQ	Progress Ψ	20 (6)	21 (7.50)	0.078	17 (11.50)	23 (2)	0.892
	Obstruction Ψ	18.50 (14.50)	10 (14.50)	0.686	16.50 (21.50)	3 (11.50)	0.104
EACQ Ψ		35.50 (14.50)	36 (10.50)	0.686	32.50 (31)	41 (11.50)	0.357
FoReST-12 Ψ		30 (7)	37 (14.50)	0.078	27 (32.50)	27 (26)	1

Ψ Non-parametric tests used, therefore medians noted

Glossary: GHQ-12 = General Health Questionnaire; AAQ-II = Acceptance and Action Questionnaire; VQ = Valuing Questionnaire; EACQ = Experiential Avoidance in caregiving Questionnaire; FoReST-12 = Flexibility of Responses to Self-Critical Thoughts Scale

Relationships between Outcome and Therapy Specific Measures at Baseline

Table 5. outlines the associations between outcome and therapy-specific measures at baseline. The GHQ-12 had a significant positive correlation with the AAQ-II ($r = 0.660$, $p = 0.003$) and the EACQ ($r = 0.531$, $p = 0.023$). Furthermore, the AAQ-II had significant positive correlations with the FoReST ($r = 0.651$, $p = 0.003$), the EACQ ($r = 0.518$, $p = 0.028$) and the VQ obstruction scale ($r = 0.625$, $p = 0.006$). The FoReST had significant positive correlations with the VQ obstruction scale ($r = 0.561$, $p = 0.015$) and the EACQ ($r = 0.651$, $p = 0.003$).

Table 5. Spearman's rho (ρ) Correlations Between Outcome and Therapy-Specific Measures at Baseline

Measures	GHQ-12	AAQ-II	VQ Progress	VQ Obstruction	EACQ
AAQ-II	0.660***				
VQ Progress	0.105	0.306			
VQ Obstruction	0.352	0.625**	0.162		
EACQ	0.531*	0.518*	0.243	0.371	
FoReST-12	0.273	0.651***	0.103	0.561*	0.651***

* Correlation significant at 0.05 level (2 tailed) ** Correlation significant at 0.01 level (2-tailed) *** Correlation significant at 0.003 (Bonferroni correction)

Glossary: GHQ-12 = General Health Questionnaire; AAQ-II = Acceptance and Action Questionnaire; VQ = Valuing Questionnaire; EACQ = Experiential Avoidance in caregiving Questionnaire; FoReST-12 = Flexibility of Responses to Self-Critical Thoughts Scale

Relationships between Outcome and Therapy Specific Measure Change Scores

Table 6. outlines the associations between outcome and therapy-specific measures change scores. Analyses revealed changes in AAQ-II scores were significantly positively correlated to changes in FoReST scores ($r = 0.684$, $p = 0.03$). There were no other significant correlations noted between change scores.

Calculating numerous correlations increases the risk of a type I error, i.e. to incorrectly conclude the presence of a significant correlation. To avoid this, threshold levels of significance for correlation co-efficients were adjusted for multiple comparisons utilising Bonferroni's correction (i.e. $p = \text{value} < 0.003$). Overall, 8 of the 30 correlation co-efficients were significant, 3 at $p = \text{value} < 0.003$, 4 at $p = \text{value} < 0.01$ and 8 at $p = \text{value} < 0.05$.

Intervention Effects

Table 7. provides a comparison between the ACT and ETAU groups change scores across the time of the intervention. There were no significant differences between the groups. Although the difference in psychological flexibility between groups, as measured by the

AAQ-II, was not significant, it is worth noting that it is just outside the limit of statistical significance, $t(8) = 2.23$, $p = 0.055$. The effect size for this difference is large ($d = 1.42$).

Table 6. Spearman's rho (ρ) Correlations Between Change Scores on Outcome and Therapy-Specific Measures

Measures	GHQ-12	AAQ-II	VQ Progress	VQ Obstruction	EACQ
AAQ-II	-0.190				
VQ Progress	0.090	-0.082			
VQ Obstruction	0.308	0.384	-0.240		
EACQ	0.416	-0.113	0.274	-0.318	
FoReST-12	0.247	0.684*	-0.041	0.568	-0.322

* Correlation significant at 0.05 level (2 tailed)

Table 7. Mean (SD) and Median (IQR) Group Change Scores (post-intervention - baseline)

Measures		ACT (n=5)	Control (ETAU) (n=5)	t or U value	P-Value	Effect Size
GHQ-12 Ψ		-1 (8)	0 (6)	U = 9.50	0.517	$r = -0.25$
AAQ-II		2.80 (3.89)	-3.20 (4.55)	$t = 2.23$ df = 8	0.055	$d = 1.42$
VQ	Progress Ψ	5 (7)	-1 (12)	U = 7.50	0.287	$r = -0.34$
	Obstruction	-0.80 (12.46)	-6.80 (9.80)	$t = 0.846$ df = 8	0.422	$d = 0.54$
EACQ Ψ		3 (23)	5 (28)	U = 12	0.917	$r = -0.03$
FoReST-12		5.80 (5.02)	-5.40 (12.28)	$t = 1.88$ df = 8	0.096	$d = 1.19$

Ψ Non-parametric tests used, therefore medians noted

Glossary: GHQ-12 = General Health Questionnaire; AAQ-II = Acceptance and Action Questionnaire; VQ = Valuing Questionnaire; EACQ = Experiential Avoidance in caregiving Questionnaire; FoReST-12 = Flexibility of Responses to Self-Critical Thoughts Scale

Feedback about the Intervention

Five of the 10 (50%) ACT participants completed feedback. All participants reported that the intervention met the objectives identified. Figure 2 illustrates the feedback from participants about the ACT intervention. Overall, this feedback was positive with participants either strongly agreeing or agreeing that the intervention will help with their caring role, taught useful techniques, provided helpful material, was easy to follow, and the learning outcomes were followed throughout.

Figure 2. Participant Feedback on ACT Intervention

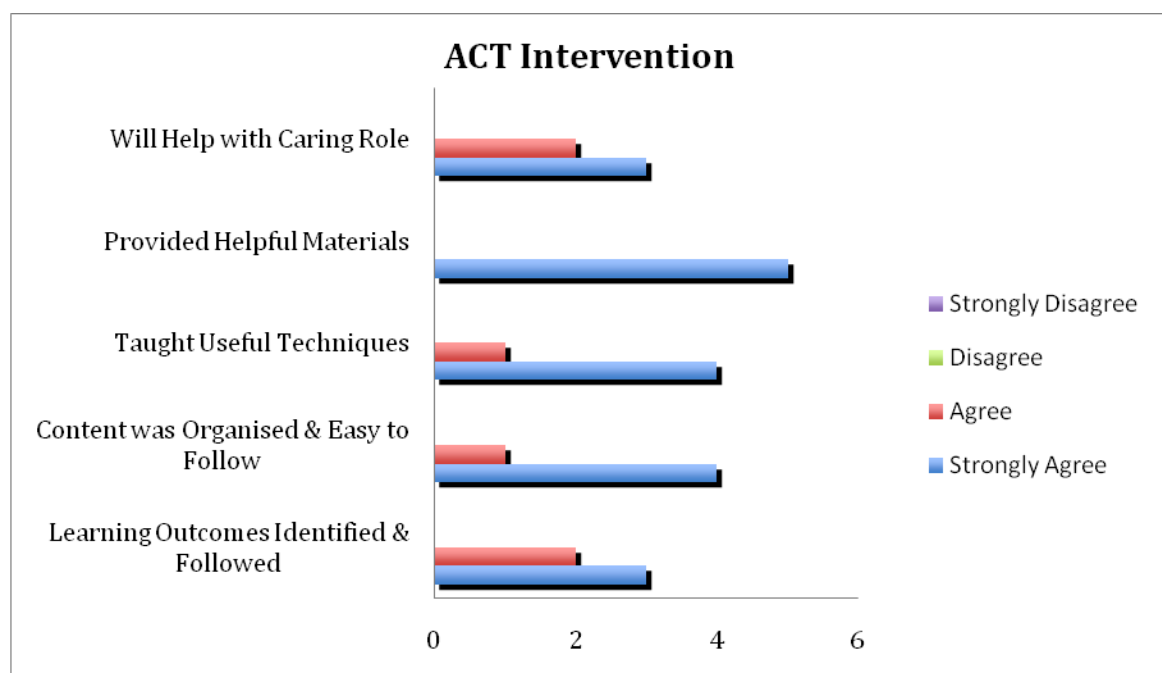
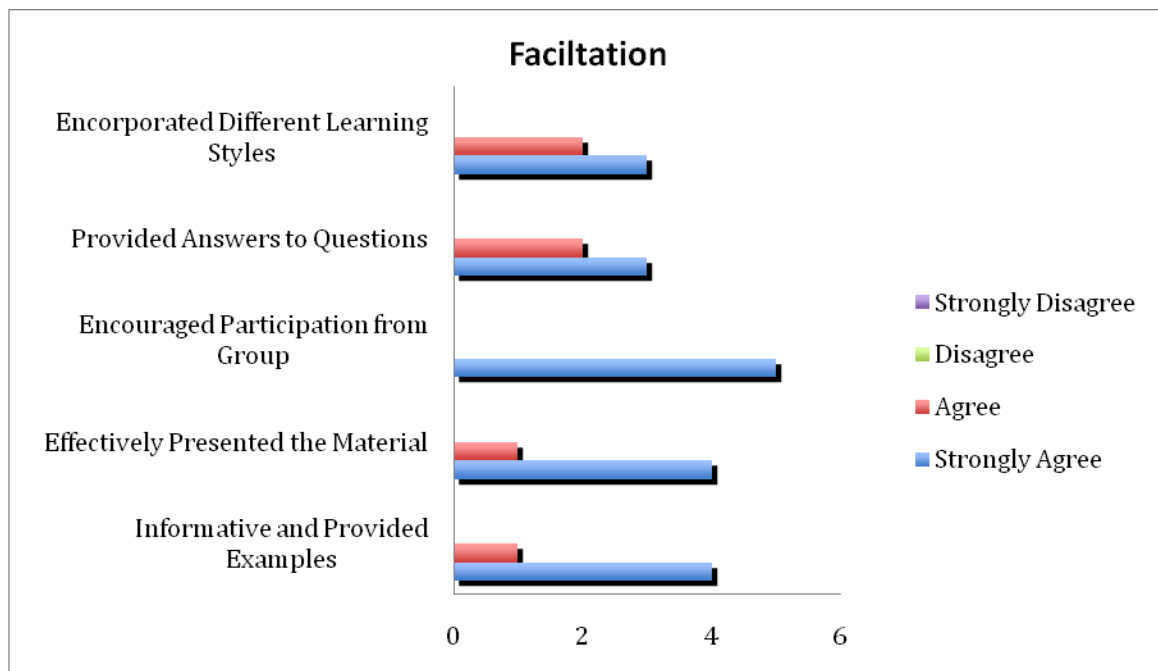


Figure 3. illustrates participant feedback about the facilitation of groups. Similarly, this feedback was positive with participants either strongly agreeing or agreeing that the facilitation incorporated different learning styles, provided answers to questions, encouraged participation from the group, effectively presented material and provided examples throughout.

Figure 3. Participant Feedback on the Facilitation of ACT Intervention



In addition, all five participants answered that what they learnt during ACT would be useful in their life and role as a carer. Participants highlighted that training *“ignited some thoughts of self-care”*, was *“invaluable experience and very useful as a carer”*, *“will apply to many different areas of life both at work and leisure”* and finally that *“value-based actions help keep me on track and feel good about your life”*. When asked whether they tried out the exercises and if they found them helpful four (4/5) participants indicated “yes”, reporting *“defining values and creating value-based actions”*, *“cognitive defusion”*, *“use of metaphors”* and *“mindfulness exercises”* most helpful. Other positive feedback noted was *“sessions were enjoyable and informative”*, they liked the *“casual venue and informality of group”* and *“the group was held in the same facility as loved one”*. One participant identified that *“more time to spend on exercises and discussion”* would be beneficial in the group and to *“explore more techniques to find one that suits each individual”*.

Phase One Discussion

Research has indicated the impact of caring for an individual with an ABI, with a range of difficulties noted (Sinnakaruppan & Williams, 2001). Despite these findings, there is no clear and consistent research evidence supporting any specific intervention method for ABI family caregivers (Boschen et al., 2007). Therefore, it is key that research on interventions to

support this population are developed and piloted. The exploration of ACT with a caregiving population is at a preliminary stage. This study set out to investigate the feasibility of utilising an ACT based intervention with a group of ABI caregivers.

One of the primary concerns for this feasibility study was the recruitment of an appropriate group of caregivers. Identifying a group of ABI carers did not prove difficult as BIRT management were agreeable to the implementation of ACT in their service. Twenty-seven caregivers expressed an interest in participating, of which 18 (66.67%) provided informed consent to participate in the study. This sample size is similar to preliminary work conducted by Márquez-González et al., (2010) who utilised a sample size of 16 to assess the efficacy of ACT with dementia family caregivers. It will be important for future research to assess the feasibility of recruiting individuals across multiple sites. The baseline scores of individuals who completed post-interventions assessment were compared with participants who did not. Participants who did not complete their allocated group had higher levels of psychological distress at baseline than those who completed their allocated group. This suggests that participants with higher levels of psychological distress are harder to engage in treatment. It is vital that caregivers who are in most need of treatment can access this and are encouraged to engage with services. This is particularly important given that a family's ability to cope with distress affects the quality of support provided to the injured person (Testa, et al., 2006). Our results point to the need for the development of pre-intervention consultation and support to help maximise caregivers' potential engagement with interventions.

A key aim of this feasibility study was to ascertain the acceptability of the intervention. Seven of the ten participants randomised to ACT attended the second session and five participants attended the final session and completed post-intervention measures. Although this sample was deemed to be very supportive of the development of services for this population, a key challenge was the retention of participants, with a high attrition rate across both arms of the study. ABI is predominantly a problem experienced amongst younger age groups, which results in family caregivers assuming a caring role at an early stage in life, when they still have other commitments (e.g. work and family and other caring duties related to children) (Sinnakaruppan et al., 2001). It was found that participants in this

study had a multitude of demands on their time and therefore it was hard for them to commit to attending the full complement of sessions. Future research investigating support for carers could evaluate the efficacy of self-help ACT resources or guided self-help with weekly online contact with a facilitator, that caregivers could access in their own time, which may be more suitable for this population. Phase 2 of this study also considered barriers to participation, which will be important to take into account in future research to improve retention rates.

Participant's feedback about the ACT intervention illustrated that participants evaluated the facilitation, content and quality of the sessions favourably. Furthermore, all five participants who completed the post-intervention evaluation indicated that ACT training would be useful in their life and role as a carer. Four out of five participants indicated that they had implemented the ACT techniques into their daily lives and found them beneficial. Our findings suggest that baseline psychological distress levels may be a factor in attrition from this study. Future research could explore whether additional between session support is required to sustain attendance at sessions. It appears that the ACT intervention was acceptable to family caregivers who completed the final session.

A group of control participants were recruited and assessed in parallel. There were no significant differences between the ACT and ETAU groups. In terms of attrition, similar to the ACT group five of the eight participants randomised to ETAU attended the final session and completed post-intervention measures. One of the final sessions of one control group was facilitated a week later than anticipated due to no participants attending the original date of the final session. One potential confounding factor that may have influenced this was the time between the two sessions. There were three weeks between the two ETAU groups compared to only two weeks between the last two ACT sessions, which may need to be addressed in future research. In summary, despite this difference, the control group acted as a reasonable comparison to the ACT group.

The identification of measures to assess the impact of ACT will be an important step for future research aiming to evaluate the utility and efficacy of ACT interventions for use with caregivers. This study chose psychological distress as the primary outcome measure.

Therapy-specific measures assessing psychological inflexibility, experiential avoidance and values-based living were also included. Analyses indicated that there were no significant differences in change scores between groups following treatment. This finding is not in line with recent research by Noone et al., (2009; 2010) who found that psychological distress (as measured by the GHQ-12) reduced following a short acceptance-based intervention over 1.5 days. However, this study was conducted with a follow-up period of 6 weeks and a half-day booster session, with reduction of psychological distress found over time. The lack of differences between treatment groups in the current study may also be due to insufficient power stemming from the small sample size, or due to participants with the highest levels of psychological distress dropping out of the study, and therefore participants who remained had lower levels of distress and possibly less room for improvement across both treatments. Future pilot work in this area should employ a longer follow-up assessment period such as that utilised by Noone et al., (2009), to allow for the exploration of delayed therapeutic effects.

A lack of significant differences in change scores between groups for psychological inflexibility, is similar to findings of McConachie, McKenzie, Morris and Walley (2014) who explored whether ACT increased psychological flexibility in staff caring for individuals with intellectual disabilities. It could be that the lack of change in psychological inflexibility may be because the current study included some participants who were not distressed at baseline, which is consistent with observations made by Flaxman and Bond, (2010). Future pilot work could benefit from screening people to determine levels of psychological distress before people are recruited to the trial.

The relationship between changes in outcome and therapy-specific measures was also examined. As expected, psychological inflexibility (AAQ-II) had a significant positive correlation with higher psychological distress (GHQ-12). This is consistent with findings from Spira et al., (2007) who investigated psychological inflexibility in dementia family caregivers. Psychological inflexibility was also associated with higher levels of experiential avoidance of difficult thoughts/ emotions associated with caregiving (EACQ), psychological inflexibility in response to critical thoughts (FoReST) and not living in accordance with your values (VQ). Similarly, higher psychological distress was significantly positively correlated with

experiential avoidance of difficult thoughts and emotions associated with caregiving. Psychological inflexibility in response to critical thoughts was significantly positively correlated with not living in accordance to your values and higher levels of experiential avoidance of difficult thoughts and emotions associated with caregiving. Taken together, these findings indicate the potentially important role that psychological inflexibility may play in the development or exacerbation of caregiver distress. An examination of change scores indicated that increases in psychological flexibility (as assessed by the AAQ-II) were associated to increases psychological flexibility in response to carers self-critical thoughts specifically (as assessed by the FoReST). This provides support for the validity of the FoReST, which is a newly developed measure that can be employed in evaluations of third-wave therapies such as ACT and Compassion Focused Therapy.

Phase Two: Qualitative Investigation

Method

Design

Phase two used a qualitative design that involved conducting semi-structured interviews with a sub-section of participants from Phase One.

Participants

Attempts were made by the author to contact all participants, from the ACT intervention in Phase One, via telephone to enquire about their interest in and availability to participant in this stage of the study. Contact was made with ten participants; seven expressed an interest in participating and four provided informed consent. Of those who expressed an interest but did not consent reasons included; anxiety, unable to attend due to caring duties and one individual did not attend for interview or could not be contacted following this.

Ethics

Ethical approval was granted from the West of Scotland Research Ethics Service Committee No. 3 (ref: 15/WS/0208) (see Appendix 2.3) to complete a qualitative Phase Two if recruitment during Phase One highlighted issues regarding potential retention of participants. A substantial amendment was submitted to, and approved by, the West of

Scotland Research Ethics Service Committee No. 3 (ref: 15/WS/0208) (see Appendix 2.10) to change the qualitative phase from a focus group format to individual interviews due to difficulties in recruiting sufficient numbers for a focus group.

Procedure

A framework based on issues that arose during the Phase One of this study was utilised to create a semi-structured interview. The data obtained was used to gain an understanding of the experience of being an ABI caregiver, the forms of support that they thought would be helpful, and the context in which this work should be delivered. See Appendix 2.11 for the interview schedule. Interviews lasted approximately 20-25 minutes, and were all transcribed by the author (transcriptions available on request). Participants received an information sheet about this phase of the study and provided written informed consent prior to participating in the interview (see Appendix 2.12 and 2.13).

Analysis

Framework analysis [developed by Ritchie & Spencer (1994)] was chosen as the method of qualitative analysis. Framework analysis may be shaped by existing ideas and is less focused on developing new theories. It was developed to address specific questions (Ward, Furber, Tierney & Swallow, 2013). As the author and academic supervisor identified specific questions to address from Phase One, this method of analysis was deemed most appropriate. The analysis of the data adhered to the five-step process outlined by Ritchie & Spencer (1994): 1) familiarisation; 2) identifying a thematic framework; 3) indexing; 4) charting and 5) mapping and interpretation. All transcripts were analysed by the author. A subsection of transcripts were also analysed by a trainee clinical psychologist to assess for inter-rater reliability and discuss wording of themes identified. From the four transcripts, quotes were required from at least half in order for a theme to be determined.

Results

See Table 8. for a summary of key themes linked to the particular category of the pre-conceived framework that emerged from the interviews. Fourteen themes emerged from the data, which are outlined below with supporting quotes. Information in brackets corresponds to the line and page number of individual transcripts.

Table 8. Summary of Key Themes from Qualitative Interviews

Category	Sub-Category	Themes
1. Experience of caregivers	1.1 Impact on life	Sudden Onset Adjustment to Change Strain on Relationships Emotional Highs and Lows
	1.2 Challenges of Caregiving	Changed Loved One Continual Role
	1.3 What supports are helpful	Talking Therapies
2. Interventions for Caregivers	2.1 Challenges in attending groups	Stages of Recovery
	2.2 Benefits of attending groups	Shared Experiences
	2.3 Facilitating attendance at groups	Ease of Access Consideration of Self-Care
3. Experience of Intervention	3.1 Helpful aspects of intervention	Learning Techniques
	3.2 Application of techniques	Struggling to Maintain
	3.3 Suitability of ACT for ABI caregivers	Value of Intervention

Categories

1. Experiences of Caregivers

This category highlighted the changes that families needed to make to adjust to their injured loved one. It also illustrated the difficulties adapting to the cognitive and behavioural changes associated with the brain injury, the weight of being in a caring role, the impact this had on various aspects of their life, and how psychological supports may be beneficial.

Under the sub-category *impact on life* four themes emerged:

- 'Sudden Onset'

Participant 2: *"What you feel is your core reality is no longer valid and will never be again"* (line 11, p.1)

Participant 4: *"The way I describe it is like a bomb going off and slowly trying to build back the pieces bit by bit"* (line 2, p.1)

- 'Adjustment to Change'

Participant 2: *"You are thrown in at the deep end and you don't know what to expect"* (line 23, p.1)

Participant 4: *"It's something you learn to live around..."* (line 5, p.1)

- 'Strain on Relationships'

Participant 1: *"We don't get on or talk at all anymore"* (line 18, p.1)

Participant 4: *"As a friend, I'm not the friend I would like to be any more as I can't do everything that I would like to be doing"* (line 23, p.1)

- 'Emotional Highs and Lows'

Participant 4: *"It's very frightening and raw for these people"* (line 111, p.4)

Participant 1: *"I let my anger go a long time ago but some people are angry for a long time or might always be"* (line 97, p.4)

Participant 4: *"Love takes you through that's the main thing"* (line 193, p.7)

Under the sub-category *challenges of caregiving* two themes emerged:

- 'Changed Loved One'

Participant 1: *"Now we can't even have a conversation because he can't speak"*
(line 4, p.1)

Participant 4: *"The child you once had is not the same, they are very different"*
(line 6, p.1)

- 'Continual Role'

Participant 1: *"I have devoted so much time to X"* (line 8, p.1)

"I didn't relax for thirteen years" (line 116, p.4)

Participant 4: *"The caring role never ends"* (line 28, p.1)

Under the sub-category *what supports are helpful* one theme emerged:

- 'Talking Therapies'

Participant 1: *"Talking the whole thing through and doing the exercises really helped"* (line 60, p.2)

Participant 2: *"For me the acceptance therapy really hit home with me"* (line 58, p.2)

Participant 3: *"The types of things that you were doing in the groups were helpful"*
(line 11, p.1)

2. Interventions for Caregivers

This category demonstrated that the stage of recovery of both the family and injured individual is a key barrier in attending interventions and the importance of sharing their stories with families who have shared the same experiences.

Under the sub-category *challenges in attending groups* one theme emerged:

- 'Stages of Recovery'

Participant 1: *"Some people are only weeks and months into it and they just look like they are shell-shocked and they can't think or they can't talk"* (line 135, p.4)

Participant 3: *"Someone might be at one end of the spectrum and another person just starting out"* (line 23, p.1)

Under the sub-category *benefits of attending groups* one theme emerged:

- 'Shared Experiences'

Participant 1: *"Sometimes I feel on my own so meeting in a group is really helpful as then I know there are other people going through the same thing"* (line 118, p.4)

Participant 4: *"It's a safe place to let out the tears, let out how it really is, how it really feels like looking after someone with an acquired brain injury"* (line 95, p.4)

Under the sub-category *facilitating attendance at groups* two themes emerged:

- 'Ease of Access'

Participant 2: *"Perhaps if it was in local venues"* (line 144, p.5)

Participant 3: *"Access to groups is very important, travel and timing of groups"* (line 42, p.2)

Participant 4: *"If it was local that might be better and a bit more lee-way around the timing of the group"* (line 84, p.3)

- 'Consideration of Self-Care'

Participant 1: *"They do other things in the group like pamper sessions with beauty therapists, which is really helpful"* (line 112, p.4)

Participant 3: *"Some sort of aromatherapy and massages could really be beneficial"* (line 18, p.1)

Participant 4: *"Some lightweight meetings, such as meeting in a café for some lunch or tea might be beneficial as well"* (line 162, p.6)

3. Experience of Intervention

This category highlighted the value of ACT to this population and some of the struggles maintaining the skills following the group.

Under the sub-category *helpful aspects of intervention* one theme emerged:

- 'Learning Techniques'

Participant 2: *"The tips about saying this is just a thought really helped"* (line 151, p.5)

Participant 3: *"Trying to imagine different thoughts and putting some distance between them was very helpful"* (line 58, p.2)

Participant 4: *"I think the mindfulness was really good"* (line 133, p.5)

Under the sub-category *application of techniques* one theme emerged:

- 'Struggling to maintain'

Participant 3: *"I wouldn't say I've done the specific exercises recently but I've certainly been aware of them in my life"* (line 63, p.3)

Participant 4: *"Initially very much so, but as times goes on I am losing my ability to use it"* (line 156, p.5)

Under the sub-category *suitability of ACT for ABI caregivers* one theme emerged:

- 'Value of Intervention'

Participant 1: *"Definitely, because there isn't many around"* (line 136, p.5)

Participant 3: *"Yes because the outcomes were good from the group"* (line 82, p.3)

Participant 4: *"Definitely yes, just being able to explore how you're feeling at the moment in time and make sense of it in that safe environment"* (line 161, p.6)

Phase Two Discussion

Phase Two aimed to gain insights into the experience of being an ABI caregiver, the forms of support that they believe would be helpful, and the context in which this work should be delivered. These insights can in turn help inform the development of future pilot studies. These findings provide valuable details regarding the multi-faceted nature of caring. Carers noted the significant impact the sudden onset of the brain injury had on their lives, the challenge of adjusting to this change and the behavioural and cognitive changes in their loved one, in addition to adjusting to being in a long-term caring role. They also reported the considerable emotional strain caring for a loved one with a brain injury has and noted the fear and anger associated with this but also how the unconditional love acts as a protective factor against this strain, *"Love takes you through that's the main thing"*. Jordan et al., (2013) found similar results reporting the enduring burden of tending to the physical and cognitive needs of their child, managing the on-going adaption to these changes and dealing with the contradictory emotions of frustration, love and guilt. It is evident from the

current study's findings that ABI has a considerable impact on the day-to-day lives of carers. The state of flux that ABI can bring to the lives of carers is reflected in the reasons cited for attrition to the ACT intervention in Phase One of this study.

Findings from Phase Two also address other barriers to engagement and possible ways to overcome these. Findings indicated that the stage of recovery of the family and the injured individual was a significant barrier to engaging in interventions. This may be due to the differences between families who are at the beginning of the caring journey and those who may be a number of years down the line. Participants felt this mismatch in stages could be off-putting for carers at either end of the spectrum, as those starting out are very hopeful and also in a state of high emotion, whereas those who are a number of years down the line are more realistic and have more acceptance for their stage of recovery. They stated the shared experience is a key benefit of accessing support. It may be that future research considers the stage of recovery when allocating carers to intervention groups i.e. stratifying participants on the basis of their carer-experience.

Participants also indicated that having interventions in more local venues and integrating elements of self-care or social support would be beneficial and may increase the likelihood of carers accessing interventions. This is similar to findings of Williams et al., (2014), in their qualitative investigation into spousal caregiver's experience of an ACT group, who recommended the provision of both group-based facilitated support in addition to informal support networks and how these can improve carers outcomes. These findings complement results from Phase One and point to the need for the development of pre-intervention support to help maximise caregivers' prospective engagement with interventions, this could potentially be in the form of a social support before offering an ACT-based programme.

Finally, these results illustrate the potential benefit of ACT interventions to this population, juxtaposed with the struggles participants encountered maintaining their skills, *"Initially very much so, but as times goes on I am losing my ability to use it"*. These findings, in addition to Phase One results, indicate that ACT is an acceptable intervention to this population that may benefit from further refinement. Future research may wish to utilise longer interventions or implement follow-up sessions to help carers maintain their progress.

Limitations of Phase One and Phase Two

There are a number of limitations that need to be considered. Firstly, the numbers recruited for both phases of this study were small. This had implications of the statistical analyses that could be undertaken and the associated conclusions that could be made. Feasibility studies tend to have smaller sample sizes than full scale RCT's, future sufficiently powered trials will be required to fully investigate potential treatment signals. Secondly, attrition rates within the study were high which impacted on the interpretation of findings and the conclusions about the efficacy of the ACT intervention. This study did not have a follow-up assessment period, which would have allowed for the exploration of delayed therapeutic effects. Finally, due to the small numbers in the qualitative phase these findings may not be generalisable to all ABI caregivers. Despite this, the results are a helpful starting point as they are indicative of themes and patterns that could be investigated further in a larger sample.

Recommendations and Conclusions

The MRC (2008) guidelines suggest that the feasibility stage of research is an iterative process and highlights that a number of pilots may be required to progressively refine the design, prior to developing a full-scale evaluation. The inclusion of a qualitative aspect to the research is in keeping with the recommendation that 'process evaluations' be embedded into the design of future pilots on the basis of MRC (2013) guidelines (Moore et al., 2013). Qualitative process evaluations are important for exploring fidelity and quality of implementation, clarifying causal mechanisms and identifying contextual factors associated with variation in outcomes, which are key in determining the effectiveness and utility of interventions. The results of this feasibility study have provided important insights into how investigations into the efficacy of ACT interventions to alleviate psychological distress experienced by ABI caregivers can be further refined. Future studies in this area should develop pre-intervention support, which could take the form of social support, to help maximise caregivers' potential engagement and retention within studies. The findings of Phase Two identified shared experiences as important benefits to attending groups. Future interventions should include a pre-intervention session, which would allow caregivers a space to discuss and explore their similar stories. This could also help engage participants in the intervention following this session. Furthermore, it is important that for future interventions both the ACT group and the control group are the same number of sessions in

duration, to ensure that this difference does not impact on outcomes. Finally, in addition to the ACT principals and exercises incorporated into the intervention it is recommended that future interventions consider tailoring some of the examples and exercises to a caring population, such as those utilised by Losada and Marguez-Gonzalez, (2011).

Additionally, it is recommended that testimonies from people who have completed the intervention are gathered and incorporated into future information sheets to help orientate potential recipients to the benefits that the intervention can offer. This could also help with engaging those who are experiencing particularly high levels of psychological distress at baseline. Recruiting carers from a wider range of catchment areas and holding multiple intervention groups specific to local areas could increase the sample size in future studies. Finally, further feasibility work would benefit from employing a follow-up assessment period to explore the long-term effects of ACT within this population.

To conclude, larger sample sizes in both a quantitative feasibility and a qualitative process evaluation study are required in future studies in order to obtain more conclusive outcomes on the appropriateness and effectiveness of ACT as an intervention for ABI caregivers. It is envisaged that by addressing barriers and limitations identified in the current research, and by making amendments accordingly, the recruitment and retention of participants in future pilot trials will be improved.

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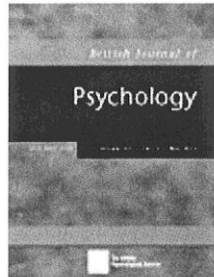
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Appendices

Appendix 1.1: Submission Requirements for the British Journal of Psychology

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Appendix 1.2: Search Strategy for Systematic Review

Database	Search Terms Utilised	Results- Number of Studies
Web of Science- Core Collection	“Mindfulness” OR “Mindfulness-Based Cognitive Therapy” OR “MBCT” OR “Mindfulness-Based Stress Reduction” OR “MBSR” AND “Homework” OR “Between Session Practice” OR “Home practice”	190
EBSCO- PsychInfo	DE “Mindfulness” OR “Mindfulness-Based Cognitive Therapy” OR “MBCT” OR “Mindfulness-Based Stress Reduction” OR “MBSR” AND DE “Homework” OR “Between Session Practice” OR “Home practice”	66
OVID- Medline (R) 1946 to Present	“Mindfulness” OR “Mindfulness-Based Cognitive Therapy” OR “MBCT” OR “Mindfulness-Based Stress Reduction” OR “MBSR” AND “Homework” OR “Between Session Practice” OR “Home practice”	111
EBSCO- CINAHL	MH “Mindfulness” OR “Mindfulness-Based Cognitive Therapy” OR “MBCT” OR “Mindfulness-Based Stress Reduction” OR “MBSR” AND “Homework” OR “Between Session Practice” OR “Home practice”	17
WILEY- Cochrane Library	MeSH “Mindfulness” OR “Mindfulness-Based Cognitive Therapy” OR “MBCT” OR “Mindfulness-Based Stress Reduction” OR “MBSR” AND “Homework” OR “Between Session Practice” OR “Home practice”	104 including systematic reviews (only 38 trials exported to endnote)

Appendix 1.3: The Clinical Trials Assessment Measure

The Clinical Trials Assessment Measure (CTAM)

Clinical Trials Assessment Measure (CTAM)

Sample—two questions: maximum score = 10

Q1: is the sample a convenience sample (score 2) or a geographic cohort (score 5), highly selective sample, e.g., volunteers (score 0)

Convenience sample—e.g., clinic attenders, referred patients or *Geographic cohort*—all patients eligible in a particular area

Q2: is the sample size greater than 27 participants in each treatment group (score 5) or based on described and adequate power calculations (score 5)

Allocation—three questions: maximum score = 16

Q3: is there true random allocation or minimisation allocation to treatment groups (if yes score 10)

Q4: is the process of randomisation described (score 3)

Q5: is the process of randomisation carried out independently from the trial research team (score 3)

Assessment (for the main outcome)—five questions: maximum score = 32

Q6: are the assessments carried out by independent assessors and not therapists (score 10)

Q7: are standardised assessments used to measure symptoms in a standard way (score 6), idiosyncratic assessments of symptoms (score 3)

Q8: are assessments carried out blind (masked) to treatment group allocation (score 10)

Q9: are the methods of rater blinding adequately described (score 3)

Q10: is rater blinding verified (score 3)

Control groups—one question: maximum score = 16

Q11: TAU is a control group (score 6) and/or a control group that controls for non-specific effects or other established or credible treatment (score 10)

Analysis—two questions: maximum score = 15

Q12: the analysis is appropriate to the design and the type of outcome measure (score 5)

Q13: the analysis includes all those participants as randomised (sometimes referred to as an intention to treat analysis) (score 6) and an adequate investigation and handling of drop outs from assessment if the attrition rate exceeds 15% (score 4)

Active treatment—three questions: maximum score = 11

Q14: was the treatment adequately described (score 3) and was a treatment protocol or manual used (score 3)

Q15: was adherence to the treatment protocol or treatment quality assessed (score 5)

where the criterion is not reached for any question score = 0

Total score: maximum score = 100

Appendix 1.4: Glossary of Outcome and Process Measures

Outcome Measures

Abbreviation	Full Questionnaire Name and (Author)
BDI	Beck Depression Inventory (Beck et al., 1961)
BPI	Wisconsin Brief Pain Inventory (Teske et al., 1983)
CES-D	Centre for Epidemiological Studies Depression Scale (Redloff & Teri, 1986)
CIDI	Composite International Diagnostic Interview (WHO, 1997)
CPEG	Checklist of Patient Engagement in Group Form (Mignogna et al., 2007)
CSQ	Client Satisfaction Questionnaire (Attkisson & Zwick, 1982)
CTQ	Childhood Trauma Questionnaire (Bernstein & Fink, 1997)
CTQ-SF	Childhood Trauma Questionnaire- Short Form (Bernstein & Fink, 1998)
DASS	Depression Anxiety Stress Scale (Lovibond & Lovibond, 1995)
DBAS-16	Dysfunctional Beliefs and Attitudes about Sleep (Morin, 2003)
EPDS	Edinburgh Postpartum Depression Scale (Cox et al., 1987)
FIQ	Fibromyalgia Impact Questionnaire (Burckhardt et al., 1991)
FSI	The Fatigue Symptom Inventory (Hann et al., 1998)
GSI	Global Severity Index (Thompson, 1989)
HAMD	Hamilton Rating Scale for Depression (Hamilton, 1960)
HIT-6	Headache Impact Test-6 (Kosinski et al., 2003)
HMSES	Headache Management Self-Efficacy Scale (French et al., 2000)
ISI	Insomnia Severity Index (Bastien et al., 2001)
LIFE	Longitudinal Interval Follow-up Evaluation (Keller et al., 1987)
MADRS	Montgomery-Asberg Depression Rating Scale (Montgomery & Asberg, 1979)
MBCBS	Montgomery Borgatta Caregiver Burden Scale (Montgomery et al., 2000)
MIDAS	Migraine Disability Assessment (Stewart et al., 2001)
MOSSSS	Medical Outcomes Study Social Support Survey (McDowell & Newell, 2006)

MSC	Medical Symptoms Checklist (Travis, 1977)
MSQ	Migraine Specific Quality of Life Questionnaire (Martin et al., 2000)
PANAS	Positive and Negative Affect Schedule (Watson et al., 1988)
PDS	PTSD Diagnostic Scale (Foa et al., 1997)
PHQ-9	Patient Health Questionnaire (Kroenke et al., 2001)
PHQGADS	Patient Health Questionnaire Generalized Anxiety Disorder (Spitzer et al., 2006)
POMS	Profile of Mood States (McNair et al., 1992)
PSQI	Pittsburgh Sleep Quality Index (Buysse et al., 1995)
PSS-10	Perceived Stress Scale (Cohen et al., 1983)
PSS	Perceived Stress Scale (Cohen & Williamson, 1988)
PTCI	Posttraumatic Cognitions Inventory (Foa et al., 1999)
SCID	Structured Clinical Interview for DSM-IV (First et al., 1996)
SCID-II	Structured Clinical Interview for DSM-IV Axis II Personality Disorders (First et al., 1997)
SCL-90-R	Symptom Checklist-90-Revised (Derogatis, 1983)
SDS	Sheehan Disability Scale (Sheehan et al., 1996)
SF-12	Short-Form 12 Item Health Survey (Ware, 1996)
SF-36	Medical Outcomes Study 36-item Health Survey (Ware et al., 1996)
SOSI	Symptoms of Stress Inventory (Leckie & Thompson, 1979)
SSES	Sleep Self-Efficacy Scale (Lacks, 1987)
SSQ	Stanford Sleep Questionnaire (Douglass et al., 1994)
STAI	State-Trait Anxiety Inventory (Spielberger et al., 1970)
WAI-SF	Working Alliance Inventory- Short Form (Horvath et al., 1989)
YMRS	Young Mania Rating Scale (Young et al., 1978)

Process Measures

Abbreviation	Full Questionnaire Name and (Author)
FFMQ	Five Facets Mindfulness Questionnaire (Baer et al., 2006)
MAAS	Mindfulness Attention Awareness Scale (Brown & Ryan, 2003)
MBCT-AAQS	MBCT Adherence, Appropriateness and Quality Scale (Day et al., 2014)
MBI-TAC	Mindfulness-Based Interventions-Teaching Assessment Criteria Scale (Crane et al., 2012)
TMS	Toronto Mindfulness Scale (Lau et al., 2006)

Appendix 1.5:

Mindfulness Home-Practice Monitoring Form (MHMF)

Formal Practice

	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
✓ Day Practiced	✓ Yes						
Practices Completed (Minutes Practiced)	Ex. Sitting Meditation (20)						
	Body Scan (5)						
Resources Used	Mindfulness CD						

Informal Practice

	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
✓ Day Practiced							
Minutes Practicing							
How did you incorporate mindfulness into your daily routine this week?							
What barriers prevented you from							

practicing this week?	
-----------------------	--

Appendix 2.1: Letter of Invitation to Study



University of Glasgow | College of Medical,
Veterinary & Life Sciences



Graham Anderson House
Springburn Road
Glasgow
G21 1UU
Telephone: 0141 404 6060
Date: 21/12/15

Title of Project: Acceptance and Commitment Therapy and Carers

Dear Sir/Madam,

I am writing to you to give you the opportunity to participate in a study of an intervention for family carers that is being conducted at Graham Anderson House over the coming months. It is important that carers and family members of individual with brain injuries have access to adequate support to ensure the maintenance of their own well-being. Therefore, we are exploring the use of Acceptance and Commitment Therapy (ACT) to help promote the mental health of carers and family members of those with an acquired brain injury. Previous ACT research has shown that the intervention can:

- * Reduce stress
- * Improve mental health
- * Optimise learning and performance
- * Facilitate trust and openness

We hope that this intervention might be of benefit to you and your family. If you are interested in finding out more about the study or taking part please contact a member of the BIRT staff team at Graham Anderson House on 0141 404 6060. Thank you for taking the time to read this letter, and we hope that we might see you in the near future.

Yours Sincerely,

Dr. Brian O'Neill,
Consultant in Neuropsychology and Rehabilitation

Appendix 2.2: Quantitative Participant Information Sheet



PARTICIPANT INFORMATION SHEET (QUANITATIVE PHASE)

Title of Project: The Use of Acceptance and Commitment Therapy to Address Psychological Distress in Carers: A Randomised Controlled Feasibility Trial

My name is Annette Lloyd. I work in NHS Greater Glasgow and Clyde as a Trainee Clinical Psychologist. I am studying at the University of Glasgow for my Clinical Psychology Doctorate. I am conducting this research to fulfil the requirements of the course. I also have particular interests in Acceptance and Commitment Therapy (ACT) and the well-being of carers of individuals with an acquired brain injury.

I would like to invite you to take part in this research study. Please take the time to read the following information carefully. Feel free to ask me if there is anything that is not clear or if you would like more information. Take time to decide whether you wish to take part.

Please note that you do not have to participate in this study. If you wish to take part, you need to understand why the research is being done and what it would involve for you.

What is the purpose of the Study?

We are exploring the piloting the use of a technique called Acceptance and Commitment Training to help promote the mental health and well-being of carers.

Firstly... it may be useful to explain what Acceptance and Commitment Therapy is.

ACT aims to teach us to accept what is out with our personal control and commit to take action that enriches our life. ACT has been shown to have beneficial effects on mental health

How does ACT work?

ACT teaches us skills to handle painful thoughts and feelings effectively, in such a way that they have less impact and influence – these are known as mindfulness skills. It also helps us to clarify what is truly important and meaningful to us – that is, clarify our values – and use that knowledge to guide, inspire, and motivate us to set goals and take action that enriches our life.

Why have you been invited to participate in the study?

It is important that carers and family members of individual with complex needs (such as adults with an acquired brain injury) have access to adequate support to ensure the maintenance of their own well-being and mental health. We are

therefore asking the carers of individuals with an ABI, who are currently residing in the BIRT unit in Glasgow or who have previously resided here to participate.

Do I have to take part?

NO. It is up to you to decide. I will describe the study by going through this information sheet. You will also receive your own copy. If you agree to take part, I will ask you to sign a consent form to show you have agreed to take part. Your participation would be greatly appreciated. However, please understand you do not have to take part. You are free to withdraw at any time. You do not have to give a reason.

What will happen to me if I take part?

Once we have determined who would like to part in the study, you will be asked to sign a consent form. Individuals will be randomly assigned to take part in an Acceptance and Commitment Therapy intervention or to participate in a control group, which will take the form of a support group.

The ACT therapy group will be delivered, in a group format (approximately 8 carers), by a Trainee Clinical Psychologist and a Clinical Psychologist. In total there will be three sessions to attend, each taking two hours. The first two groups are held a week apart, and then the 3rd group will take place two weeks later. The groups will be held in Graham Anderson House in Glasgow.

The control group support will also be delivered, in a group format (approximately 8 carers), by a Trainee Clinical Psychologist. In total there will be two sessions to attend, each taking two hours. The two sessions will be held a month apart and will be held in Graham Anderson House in Glasgow.

All participants will be asked to complete 6 questionnaires at different stages. At first you will be asked to complete pre treatment questionnaires at the first session and follow up questionnaires will be completed at the end of the final session. Filling out of these questionnaires should take approximately 20 mins of your time. All sessions will be audio-recorded. This is so a clinical psychologist and ACT expert can verify that the sessions are conducted correctly. You can ask for the audio-recording to be stopped at any point. Following this verification, all copies of the audio will be destroyed.

Are there benefits associated with taking part?

I cannot be certain that participating in the study will benefit you directly. **However**, taking part in this pilot study does offer the possibility of accessing training and support systems. Previous ACT research has shown that the intervention can:

- * Reduce stress
- * Improve mental health
- * Optimise learning and performance
- * Facilitate trust and openness

Are there risks associated with taking part?

It is possible that some of the material that is discussed may be upsetting to you, however care will be taken to support you if this happens. Some people may not like to work in a group setting. However, nobody has to divulge any personal information and any information shared will be kept confidential, and not discussed outwith the group setting. Individual attendance at the group will not be confidential. However, attendance will be at clinical settings that participants routinely attend to visit family members with an ABI.

What will happen if I do not want to carry on with the study?

You can stop at any time. This training is completely voluntary. Individuals have the *right to withdraw at any point* in the process.

Complaints

If you have concerns about any aspect of this study, please contact me or the chief investigator of this research on the contact details outlined at the end of this information sheet.

Will taking part in this study be kept confidential?

Your confidentiality will be safeguarded during and after the study. All the information you provide in questionnaires during the course of the research will be kept strictly confidential. My supervisor looks at this information to make sure the study is being carried out correctly. We all have a duty of confidentiality to you as a research participant and we will do our best to meet this duty. Your G.P will be informed of your participation in the group, with your permission.

The information you complete in the questionnaires will have your personal details removed, so that you cannot be recognised. The group sessions will be recorded on a Dictaphone. However, I will only share this information with the chief investigator who is bound by the same rules and regulations as I am. I will also record, process and store confidential information in a way to avoid disclosure (in line with Data Protection, 1998).

Breach of Confidentiality

All research staff involved in this project are bound by the University of Glasgow rules on Confidentiality. Should something be disclosed during the study, which gives cause for concern, the investigator has a duty of care to report such a disclosure to the appropriate agencies.

What will happen to the results of the research study?

The results of the research will be written up in a report. If you wish, you can receive a copy of this report. Some of the information you give, including direct quotes, will be used in the report but no one will know it comes from you, as it will be anonymous. The results also be published in journal publications and presented at research conferences by the researcher. This is a pilot study and it may be that further studies are conducted in this area after this one. The results from this study

may therefore be used in future studies. However, no one will know it comes from you, as it will be anonymous.

Who has reviewed the study?

The research has been reviewed and approved by NHS Ethics Committee. The methodology has also been approved by Academic staff in Mental Health and Well-being at the University of Glasgow.

Further information and Contact Details

If you wish to know any more information about the study, contact details are:

Annette Lloyd,
of Research)
Trainee Clinical Psychologist,
University of Glasgow
1st Floor, Administration Building
Gartnavel Royal Hospital,
1055 Great Western Road,
Glasgow, G12 OXH.

Telephone: 077 15977497

Dr Ross White (Chief Investigator
Senior Lecturer
University of Glasgow
1st Floor, Administration Building
Gartnavel Royal Hospital,
1055 Great Western Road,
Glasgow, G12 OXH.

Telephone: 0141 211 3905

Thank you for taking the time to read this information sheet about our research project, if you have any further questions please do not hesitate to ask.

Appendix 2.3: NHS Ethics and Specific Site Approval Letters

WoSRES
West of Scotland Research Ethics Service



West of Scotland REC 3

Ground Floor – The Tennent Institute
Western Infirmary
38 Church Street
Glasgow G11 6NT

www.nhsggc.org.uk

Dr Ross White
Senior Lecturer
University of Glasgow
1st Floor Administration Building
Gartnavel Royal Hospital
1055 Great Western Road
Glasgow
G12 0XH

Date 16th October 2015
Your Ref
Our Ref
Direct line 0141 211 2123
Fax 0141 211 1847
E-mail WOSREC3@ggc.scot.nhs.uk

Dear Dr White

Study title: The Use of Acceptance and Commitment Therapy to Promote Well-Being and Psychological Flexibility in Carers: A Randomized Controlled Feasibility Trial
REC reference: 15/WS/0208
IRAS project ID: 184441

Thank you for your email of 16th October 2015. I can confirm the REC has received the documents listed below and that these comply with the approval conditions detailed in our letter dated 02 October 2015

Documents received

The documents received were as follows:

Document	Version	Date
GP/consultant information sheets or letters [GP Letter]	Version 1	06 October 2015
Letters of invitation to participant [Letter of Invitation to Participant]	Version 1	05 October 2015
Non-validated questionnaire [Demographic Questionnaire]	Version 3	05 October 2015
Participant consent form [Participant Consent Form (Qualitative)]	Version 2	05 October 2015
Participant consent form [Participant Consent Form (Quantitative)]	Version 3	05 October 2015
Participant information sheet (PIS) [Participant Information Sheet (Qualitative)]	Version 2	05 October 2015
Participant information sheet (PIS) [Participant Information Sheet (Quantitative)]	Version 3	05 October 2015

Approved documents

The final list of approved documentation for the study is therefore as follows:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Insurance Policy]		12 August 2015
GP/consultant information sheets or letters [GP Letter]	Version 1	06 October 2015
Letters of invitation to participant [Letter of Invitation to Participant]	Version 1	05 October 2015
Non-validated questionnaire [Intervention Evaluation Form]	2	13 August 2015
Non-validated questionnaire [Demographic Questionnaire]	Version 3	05 October 2015
Participant consent form [Participant Consent Form (Qualitative)]	Version 2	05 October 2015
Participant consent form [Participant Consent Form (Quantitative)]	Version 3	05 October 2015
Participant information sheet (PIS) [Participant Information Sheet (Qualitative)]	Version 2	05 October 2015
Participant information sheet (PIS) [Participant Information Sheet (Quantitative)]	Version 3	05 October 2015
REC Application Form [REC_Form_11092015]		11 September 2015
Research protocol or project proposal [Project Proposal]	7	26 August 2015
Summary CV for Chief Investigator (CI) [Summary CV for CI]		
Summary CV for student [Student CV]		
Summary CV for supervisor (student research) [Summary CV for supervisor]		25 February 2015
Validated questionnaire [AAQ-II]	2	13 August 2015
Validated questionnaire [EACQ]	2	13 August 2015
Validated questionnaire [FoReST Questionnaire]	1	26 August 2015
Validated questionnaire [GHQ-12]	2	13 August 2015
Validated questionnaire [Valuing Questionnaire]	2	13 August 2015

You should ensure that the sponsor has a copy of the final documentation for the study. It is the sponsor's responsibility to ensure that the documentation is made available to R&D offices at all participating sites.

15/WS/0208	Please quote this number on all correspondence
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Yours sincerely



Liz Jamieson
REC Manager

Copy to: Ms Annette Lloyd
Ms Emma-Jane Gault

West of Scotland REC 3
Ground Floor – The Tennent Institute
Western Infirmary
38 Church Street
Glasgow G11 6NT
www.nhsggc.org.uk

Dr Ross White
Senior Lecturer
University of Glasgow
1st Floor, Administration Building
Gartnavel Royal Hospital
Glasgow

Date 6th November 2015
Your Ref
Our Ref
Direct line 0141 211 2123
Fax 0141 211 1847
E-mail WOSREC3@ggc.scot.nhs.uk

Dear Dr White

Study title:	The Use of Acceptance and Commitment Therapy to Promote Well-Being and Psychological Flexibility in Carers: A Randomized Controlled Feasibility Trial
REC reference number:	15/WS/0208
SSA reference number:	15/WS/0271
IRAS project ID:	184441

The REC gave a favourable ethical opinion to this study on 02 October 2015.

Following site-specific assessment by the Committee, I am pleased to confirm the extension of the favourable opinion to the new site and investigator listed below:

Site	Principal Investigator
Graham Anderson House	Dr Ross White

The favourable opinion is subject to management permission or approval being obtained from the host organisation prior to the start of the study at the site concerned.

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.

15/WS/0208

Please quote this number on all correspondence

Yours sincerely



Liz Jamieson
REC Manager

Copy to:

Ms Emma-Jane Gault

Appendix 2.4: BIRT Ethics Letter

32 Market Place
Burgess Hill
West Sussex
RH15 9NP
Tel: 01444 239123
Fax: 01444 244978
Email: info@thetdgroup.org

Ms Annette Lloyd
~~32 Burgess Hill~~
Glasgow
G12 8PT

23 November 2015

Dear Ms Lloyd,

THE DISABILITIES TRUST RESEARCH ETHICS COMMITTEE (DTREC) APPROVAL

Study Title: The Use of Acceptance and Commitment Therapy to Promote Well-Being and Psychological Flexibility in Carers: A Randomized Controlled Feasibility Trial.

We are pleased to inform you that the DTREC has APPROVED the abovementioned project.

The documents reviewed are:

Document	Date
DTREC Brief Application Form	19/10/2015
NHS Ethics Approval Letter (15/WS/0208)	16/11/2015
Applicant CV	10/01/2015
Clinical supervisor CV	16/11/2015
NHS REC application form	13/08/2015
Participant Information Sheet (version 3)	05/10/2015

The approval period is from **23 November 2015** to **22 November 2016**.

The following are to be observed upon DTREC approval:

- 1) The study will be conducted in accordance with Trust's relevant policies.
- 2) The Researcher should promptly report the DTREC of:
 - i. Deviations from, or changes to the protocol.
 - ii. New information that may affect adversely the risk to the participants or the conduct of the study.
 - iii. Completion of the study.
- 3) A Study Status Report should be submitted for the following:
 - i. Study completion or termination: the Final Report is to be submitted within three months of study completion or termination.

- 4) Any dissemination of the findings should acknowledge the support of the Brain Injury Rehabilitation Trust and The Disabilities Trust in the study.

On behalf of the DTREC, I would like to wish you the best with your study.

Yours sincerely,



Professor Ian Power
Chair of the DTREC
32 Market Place
Burgess Hill
RH15 9NP

Cc: Dr Brian O'Neill, Consultant Clinical Psychologist, Graham Anderson House

Appendix 2.5: ACT Training Outline

ACT Session 1

Introduction to Mindfulness and Values-Based Actions

Aims of Session:

- Develop rapport with and between group members, and create a climate of safety and warmth.
- Describe the basic format, content, and aim of training.
- Instill hope that the training has the potential to be useful, interesting and effective.
- Introduce two core skills: mindfulness and action-based values.

1) Introduction

- Fill out questionnaires
- Introduce self, and thank participants for attending
- Explain confidentiality and freedom to withdraw from the group at any time. Explain research and purpose of study
- Housekeeping: fire exits, toilets, coffee break...
- Reiterate why you're here/indicate awareness of issues faced by this caring population
- Ground rules: Have own rules already prepared on flip chart.
- Participant's hope/expectations (write expectations on flip chart to be referred back to during final group session)

2) Carer Burden/Experiences

- What are the challenges that you face caring for an individual with an ABI and how have you tried to deal with these?
- Participants are told that these sessions are not designed to change the individual or the caring related sources of stress; rather, they will focus on changing how individuals react to these challenges.
- **Utilising the Tap analogy:** "Consider for a moment that you are a bathroom sink. The sources of stress/burden that we have just discussed are like taps that can pour water (or stress) into a sink and the more taps that flow, the more water that is poured into the sink. Now, under most circumstances a sink will not overflow with water, if it is unplugged, but if it is plugged the sink will become over whelmed with water and overflow, causing damage. The goal of this training is not to stop the water from flowing but rather to help you to unplug your sinks so that the challenges that you encounter will not overwhelm you".

3) Describe the Basic Format and Content of Training

- It is important to attend every session.
- Each session will include a mixture of presentation from the facilitators; group and pair based discussions and skill practice.
- Practicing skills between the sessions is an essential part of the training and is supported by a series of exercise hand-outs. Example learning to drive, will get better with practice.
- Introduce ACT and two main skills; mindfulness and value-based action: Introduce ACT using metaphor at the door and missing out on life.

4) Introduction to Mindfulness

- “Aim for the rest of the session is to gain a good introduction to the two core skills: mindfulness and value-based action. We are going to begin with some basic mindfulness skills. Ask the group: has anyone heard of mindfulness?” Discuss with group. Link between POWER and mindfulness.
- “There are various ways of developing basic mindfulness skills, the first of which we are going to explore is present-moment awareness”.
- Fred the bus driver
- “I’m wondering if we could take a moment to think of how ‘being present’ can apply to something that is probably quite familiar to most of us. If we think about a bus driver, let’s call him Fred. What does he need to do to drive the bus well? ... (Pause)... Concentrate on the road in front of him and use the mirrors to check behind, pay attention to other vehicles on the road, pedestrians, and signs on the road, actually drive the bus which involves changing gears, using the accelerator, clutch and brake, as well as pay attention to his passengers. This is the full breadth of his experience of driving the bus.” Allow time for answers.
- “If Fred wasn’t ‘being present’, if he was only focussing on a dirty mark on his windscreen and nothing else that was going on around him, how effective would his driving be? Or if he was planning his dinner for that night, thinking about the house work he should have done the day before, what might he miss?”
- “It’s important to note that being present doesn’t just refer to noticing only the pleasant things in life, but also accepting the presence of not so pleasant, difficult, or even distressing experiences. Mindfulness can be seen as an alternative to the on-going struggle to avoid difficult thoughts and emotions. It is important to not see it as giving in, but instead seeing it as a willingness to have all experiences and to live one’s life around these experiences.”

5) Mindful Eating Exercise and Discussion

- “I would like you to join me in a mindful eating exercise. I’ll guide you through the exercise, which only takes a few minutes and we can discuss it afterwards”.

- Hand out sweets (M&M's, jelly beans) and ask them to put it in the palm of their hands.
- "During this exercise, I'm simply going to ask you to use all of your senses to explore this object, first paying attention to the feel and look of this item and then being very aware of its tastes and texture".
- **Use script from manual**
- Discuss experience in pairs and then feedback to group. Encourage participants to share their direct sensory experiences of the exercise.
- Ending "This ability to step out of automatic pilot and become more present in life is like a psychological muscle, it naturally develops with repeated practice". Example driving a car. Ask participants to pick one routine activity that they would be willing to perform with more awareness over the next week.

Tea/Coffee Break

6) Body and Breathing Awareness Exercise

- Emphasize that mindful eating and mindfulness of the body are two ways of developing the same basic mindfulness skills.
- **Body and breath exercise script**
- Following exercise again invite participants to share their experiences in pairs for a few minutes.
- Feedback: "What did you notice during this exercise?"

7) Introduction to Values-Based Action

- Introduce values highlighting the distinction between behavioural values (desired life directions, personal strengths, or qualities of action) and goals (specific outcomes).
- Card sorting task: Card-sorting task (could have a sheet with all qualities from the Survey of Life Principles (SLP) written on it and get participants to pick top 5 from this). Then give out hand-out based on their role as a carer and get participants to write out the personal strengths or behavioural qualities they would like to express in their role as a carer.
- Get participants to brainstorm a range of specific value-based actions that they could perform over the next week to bring their values to life, and select 3 for homework.
- Anticipating barriers to value-based actions. Use flipchart and divide page into external and internal barriers and get examples from the group.

8) Ending of Session, Summary and Homework

- Summarise session. Homework: explain what we would like participants to practice between now and session 2 (handout). Pick one activity and carry it out mindfully daily & 3 values-based actions. If you are finding it difficult to complete the homework we ask you just to notice that you're not engaging in the tasks and the possible reasons why not.

ACT Session 2

Untangling from Internal Barriers to Values-Based Action

Aims of Session:

- Develop rapport with and between group members, and create a climate of safety and warmth.
- Describe the basic format, content, and aim of training.
- Instill hope that the training has the potential to be useful, interesting and effective.
- Focus on reduction of excessive entanglement with unhelpful thought content, undermine experiential avoidance and cultivate acceptance skills.

1) Introduction

- Thank participants for attending.
- Explain confidentiality and freedom to withdraw from the group at any time.
- Recap of session 1 and thoughts about last session.

2) Mindfulness of Breath Practice and Review Home Assignments

Mindfulness Exercise

- “We’re going to do a short mindfulness exercise to help us to settle into today’s session. I invite you to find a comfortable position in your chair, sit upright with your feet flat on the floor, your arms and legs uncrossed and your hands resting on your lap. Either close your eyes or fix your eyes on a spot in-front of you, whichever you prefer.”
- **Mindfulness of breath script**

Review of Homework

- “Last week we focussed on contacting the present moment, how to let go of the on-going struggle we may be experiencing and instead show a willingness to allow all experiences, including difficult and distressing thoughts and feelings.
- “There are various ways of developing basic mindfulness skills, and one we looked at last week was present-moment awareness”.

Fred the Bus Driver

- “I’m wondering if we could take a moment to think of how ‘being present’ can apply to something that is probably quite familiar to most of us. If we think about a bus driver, let’s call him Fred. What does he need to do to drive the bus well? ... (Pause)... Concentrate on the road in front of him and use the mirrors to check behind, pay attention to other vehicles on the road, pedestrians, and signs on the road, actually drive the bus which involves changing gears, using the accelerator,

clutch and brake, as well as pay attention to his passengers. This is the full breadth of his experience of driving the bus.” Allow time for answers.

- “If Fred wasn’t ‘being present’, if he was only focussing on a dirty mark on his windscreen and nothing else that was going on around him, how effective would his driving be? Or if he was planning his dinner for that night, thinking about the house work he should have done the day before, what might he miss?”
- “It’s important to note that being present doesn’t just refer to noticing only the pleasant things in life, but also accepting the presence of not so pleasant, difficult, or even distressing experiences. Mindfulness can be seen as an alternative to the on-going struggle to avoid difficult thoughts and emotions. It is important to not see it as giving in, but instead seeing it as a willingness to have all experiences and to live one’s life around these experiences.”
- Review of mindfulness home practice: how did participants find the assignment, any challenges?
- Reiterate that mindfulness is like a psychological muscle and it develops through repeated practice. Example of driving.
- Review of values-based action homework. Reflect on the ease or difficulty of performing their 3 value-based actions; any internal/external barriers; their general impressions of this practice of deliberately using a value as a guide to action.
- “Today we are going to spend some time exploring why difficult or distressing thoughts can very easily fill our minds and affect what we do in our daily lives. We will then talk about and practice some techniques that we can use to gain some distance from these difficult thoughts and reduce the effect they have on us.”

3) Cognitive Fusion/Defusion

- “As we have discussed, some of the most powerful barriers to greater well-being and life effectiveness are internal, our own thoughts, moods and emotions. We deal with not only the external world but also this internal world that’s influencing our behaviour, often in rather subtle ways”.
- Emphasis on thoughts and how to become more mindful of our thoughts.
- Nature of our minds: “Our minds very often have an automatic thinking style”, for example, if I say “Jack & Jill went up the...” (pause) “It’s raining cats and ...” (pause) “Humpty Dumpty sat on the ...” (pause) what do you notice your mind doing? Were you able to automatically complete the titles without really thinking about it?”
- “Humans evaluate themselves all the time – more so than any other animal. The mind constantly makes evaluations and judgements, for example, “Am I good enough? Am I in danger? Is this person trustworthy?” and it makes comparisons, for example, “Am I as good as you? Am I stronger than you?” These comparisons can be quite painful. We might be tempted to try to turn them off. Sometimes we don’t want these painful thoughts going through our heads...”

- “When you feel/are upset, what automatically comes into your mind?
- “Take a moment to think about a recent time that you were upset. How would you complete this sentence, “I am...”? How about this sentence, “Other people think I am...”?
- “There’s actually a very good reason for why there is no shortage of negative thoughts in our minds.... Explain nature and evolution of human thinking.

Hands as Thoughts Exercise

- Imagine for a moment that your hands are your thoughts. I’d like you to hold your hands together, palms open, as if they’re the pages of an open book. Then I’d like you to slowly and steadily raise your hands up toward your face. Keep going until they are covering your eyes. Then take a few seconds to look at the world around you through the gaps in between your fingers and notice how this affects your view of the world.
- So what would it be like going around all day with your hands covering your eyes in this manner? How much would it limit you? How much would you miss out on? How would it reduce your ability to respond to the world around you? This is what we call fusion: we become so caught up in our thoughts that we lose contact with many aspects of our here and now experience and our thoughts have such a huge influence over our behaviour that our ability to act effectively is significantly reduced.
- I would like you to lower your hands from your face very, very slowly. As the distance between your hands and your face increases, notice how much easier it is to connect with the world around you. What you just did is what we call defusion. How much easier is it to take effective action without your hands covering your eyes? How much more information can you take in? How much more connected are you with the world around you?

Tea/Coffee Break

Passengers on the Bus

- Before the break we used our hands to signify difficult thoughts or feelings, and holding them right up close to our faces was an example of how getting caught up in or hooked by our thoughts can affect how we engage with the world around us. By gaining some distance from them, we are not allowing them to define us; instead we are showing a willingness to have them with us as we go about our day.”
- “Remember Fred the bus driver? Last week we discussed how important it is for him to be in contact with the present moment so that he can effectively and safely drive

the bus, and we explored what could happen if he gets caught up in thoughts about the past or the future. What if the passengers that Fred has on his bus are his thoughts, for example one may be, "I'm not a good enough driver", what are the consequences of Fred getting caught up in that thought? If he keeps going over and over it, again and again, or he keeps trying to struggle with it, to throw it off the bus even though the more he tries the stronger the thought gets, what is he missing by being hooked by this thought?"

- "Imagine that you are the bus driver and the passengers on your bus are your difficult thoughts, distressing memories, hurtful feelings. If you can remember the thought that came into your mind earlier on today, the one starting "I am..." or "others think I am..." I invite you to write it down, or another one that you feel you regularly struggle with. This passenger is very good at hooking you, causing you to miss out on the here and now, stopping you from doing things that are important to you... Something interesting to note is that the simple process of writing down the difficult thought or feeling is a way of unhooking or distancing yourself from it"
- "Let's try doing something more to the thought once it is written down. You each have a piece of card there; I invite you to write down your thought on the card (pause). Now start a new line, and write "I'm having the thought that..." (pause), and then start a third line with, "I notice I'm having the thought that...". Now take a moment to read the third line back to yourself and see if there are any differences to how line one and line three make you feel (pause). I wonder if anyone would like to share anything they noticed?"

4) Mindfulness of Mood and Emotion

Bubble Wand Exercise

- "I invite you to find a comfortable position in a chair, sit upright with your feet flat on the floor, your arms and legs uncrossed and your hands resting on your lap. Either close your eyes or fix your eyes on a spot in-front of you, whichever you prefer." **Bubble wand exercise script**
- Feedback experiences to group

5) Defining Values

- Define values in another role (self-care).
- Select three value based actions that can be performed mindfully over the next two weeks.

6) Ending of Session, Summary and Homework

- Summarise session. Homework: explain what we would like participants to practice between now and session 3 (hand-out). If you are finding it difficult to complete the homework we ask you just to notice that you're not engaging in the tasks and the possible reasons why not.

ACT Session 3

Consolidating Mindfulness and Values-Based Action skills

Aims of Session:

- Develop rapport with and between group members, and create a climate of safety and warmth.
- Describe the basic format, content, and aim of training.
- Instill hope that the training has the potential to be useful, interesting and effective.
- Consolidate previous learning, build on progress and

1) Introduction

- Thank participants for attending.
- Explain confidentiality and freedom to withdraw from the group at any time.
- Housekeeping: fire exits, toilets, coffee break...
- Recap of session 2

2) Mindfulness of Breath Practice and Review Home Assignments

- Open with mindfulness of **breath exercise- follow script**. "Last week we focussed on contacting the present moment, and how to notice our negative thoughts and feelings and how to create some distance from them".
- Review of mindfulness home practice: how did participants find the assignment, any challenges? Notice thoughts?
- Reiterate that mindfulness is like a psychological muscle and it develops through repeated practice. Example of driving.
- Review of values-based action homework: "I'm curious about how your experiences using personal values as a more prominent guide to goals and actions?"

3) Mindfulness of Mood and Emotion

- **Physicalizing Exercise- follow script**

4) Defusion Techniques

- Milk, milk, milk word repetition exercise.
- Participants are asked to say the word milk once or twice and notice what comes to mind- what thoughts, images, smells, tastes or memories?
- Then asked to repeat the word milk over and over out loud for 30 seconds until the meaning of the word disappears. See the word for what it truly is: an odd sound, a vibration, a movement of mouth and tongue.
- Ask participants to write one or two words on sticky notes and put in a bowl, use selfish. Then repeat using the words picked by the group. Just a meaningless sound after repeating over and over. But when that very same word pops into our head and we fuse with it, it has a lot of impact on us.

Tea/Coffee Break

5) Mindfulness of Thoughts

- "I invite you to find a comfortable position in a chair, sit upright with your feet flat on the floor, your arms and legs uncrossed and your hands resting on your lap. Either close your eyes or fix your eyes on a spot in-front of you, whichever you prefer."
- **Bubble wand exercise follow script**

6) Defining Values- Eightieth Birthday Exercise

- 80th Birthday-use script from ACT made simple
- Write down the things that came to mind
- Communicate that the aim is now for participants to continue building upon these values across different areas of their life.
- Continue defining your values, keep your values close, dedicate a particular time to values, take valued actions in the presence of unhelpful thoughts and feelings and know that you can reconnect with your values at any time.

6) Ending of Session, Summary and Homework

- Summarise session and overall training.
- Personal reflections from group. Any impact the training has had on their lives role as carer, what they will take away with them and useful for their caring role?
- Environmental cues: get stickers and give one out to each participant to stick on their phones etc... to remind them to practice skills during the week.
- Thank participants for their involvement and explain what will happen from now.
- Fill out questionnaires.

Appendix 2.6: Quantitative Participant Consent Form



CONSENT FORM QUANTITATIVE PHASE

Title of Project: The Use of Acceptance and Commitment Therapy to Address Psychological Distress in Carers: A Randomised Controlled Feasibility Trial

Name of researcher: Annette Lloyd

Participant Identification number for this Trial:

Please
Initial Box

1. I confirm that I have read and understand the information sheet (version 3 05/10/15) for the above study. ☐
2. I consent to the group sessions being audio-recorded. ☐
3. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐
4. I understand that my participation is voluntary and that I am free to withdraw at any time without given any reason. ☐
5. I understand that information from the questionnaires I complete will be kept strictly confidential, and any information about me will have my personal details removed so that I cannot be recognised. Any quotes used from the audio-recordings will be anonymised. ☐
6. I consent to the results from this study being used in future studies. ☐
7. I consent to my G.P being informed of my participation in this group. ☐

8. I understand that relevant sections of my care record and data collected during the study may be looked at by responsible individuals from the sponsor or host organisation or from regulatory authorities where it is relevant to taking part in this research.

☐

9. I agree to take part in this study.

☐

Name of Participant Date:
Signature:

Name of Person Date:
Taking Consent Signature:

Appendix 2.7: FoReST Questionnaire



University of Glasgow | College of Medical,
Veterinary & Life Sciences



Title of Project: The Use of Acceptance and Commitment Therapy to Address Psychological Distress in Carers: A Randomised Controlled Feasibility Trial

Name of researcher: Annette Lloyd

Participant Identification number for this Trial:

Date: _____

The Flexibility of Responses to Self-critical Thoughts Scale

Below you will find a list of statements. Please rate how true each statement is for you by circling a number next to it. Use the scale below to make your choice.

1	2	3	4	5	6	7
Never true	Very seldom true	Seldom true	Sometimes true	Frequently true	Almost always true	Always true

When I have a critical thought about myself....

- | | | | | | | | |
|---|---|---|---|---|---|---|---|
| 1) It makes me lose control of my behaviour | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 2) I do things I later regret | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 3) I feel so disgusted at myself that I don't act the way I should. | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 4) I feel so ashamed that I don't act the way I should | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 5) I don't treat others the way I would like | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 6) I act in a way that makes life more difficult for me | 1 | 2 | 3 | 4 | 5 | 6 | 7 |

- 7) I don't treat myself the way I would like 1 2 3 4 5 6 7
- 8) It gets me so down that I don't act the way I should 1 2 3 4 5 6 7
- 9) I try to ignore it 1 2 3 4 5 6 7
- 10) I try not to think about it 1 2 3 4 5 6 7
- 11) I try to block out any feelings it creates 1 2 3 4 5 6 7
- 12) I pretend it's not there 1 2 3 4 5 6 7

Appendix 2.8: Demographic Questionnaire



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Veterinary & Life Sciences



DEMOGRAPHIC QUESTIONNAIRE

Title of Project: The Use of Acceptance and Commitment Therapy to Address Psychological Distress in Carers: A Randomised Controlled Feasibility Trial

Name of researcher: Annette Lloyd

Participant Identification number for this Trial:

1) Age:

2) Gender:

3) Length of time as a carer (years):

4) How many hours (approximately) per week do you care for an individual with an acquired brain injury?

5) Do you have any other form of employment?

6) How many individuals do you care for?

7) What is the relationship between yourself and the individual/s that you care for (e.g. mother, father, sister)?

8) What age is the individual/s that you care for?

9) Does the individual/s that you care for reside with you? If no, what type of facility does the individual/s that you care for reside in?

10) How did the individual that you care for sustain their acquired brain injury?

11) What age was the individual that you care for when they sustained their acquired brain injury?

Appendix 2.9: Intervention Evaluation Form



EVALUATION FORM

Title of Project: The Use of Acceptance and Commitment Therapy to Address Psychological Distress in Carers: A Randomised Controlled Feasibility Trial

Name of facilitator(s): Annette Lloyd and Dr. Ross White

Participant Identification number for this Trial:

Did the intervention meet the learning objectives specified? Yes No

Learning objectives:
Introduction to ACT
Introduction to Mindfulness skills
Beginning to explore our values

About the intervention:

	Strongly agree	Agree	Disagree	Disagree Strongly	No Opinion
The learning outcomes were identified and followed	1	2	3	4	0
The content was organised and easy to follow	1	2	3	4	0
Taught me useful techniques and skills	1	2	3	4	0
Provided useful aids and materials	1	2	3	4	0
Will help me with my caring role	1	2	3	4	0

About the facilitator(s):

	Strongly agree	Agree	Disagree	Disagree Strongly	No Opinion
Was informative and provided examples	1	2	3	4	0
Effectively presented the material	1	2	3	4	0
Encouraged participation from all the group	1	2	3	4	0
Provided answers to my questions	1	2	3	4	0
Incorporated different learning styles	1	2	3	4	0

Do you think what you have learned in this course will be useful to you, in your life in general and in your role as a carer?

If you have tried out any of the exercise or ideas presented during the course, did you find them helpful? If yes in what ways were they helpful?

Any other comments – how could it be improved, what you liked about it, venue?

Appendix 2.10: Ethics Amendment Letter

WoSRES
West of Scotland Research Ethics Service



West of Scotland REC 3
West of Scotland Research Ethics Service
West Glasgow Ambulatory Care Hospital
(former Royal Hospital for Sick Children Yorkhill)
Dalnair Street
Glasgow G3 8SW
www.nhsggc.org.uk

Dr Ross White
Senior Lecturer
University of Glasgow
1st Floor, Administration Building
Gartnavel Royal Hospital
1055 Great Western Road
Glasgow
G12 0XH

Date 10th June 2016
Your Ref
Our Ref
Direct line 0141 232 1805
E-mail WOSREC3@ggc.scot.nhs.uk

Dear Dr White

Study title:	The Use of Acceptance and Commitment Therapy to Promote Well-Being and Psychological Flexibility in Carers: A Randomized Controlled Feasibility Trial
REC reference:	15/WS/0208
Amendment number:	AM02
Amendment date:	07 June 2016
IRAS project ID:	184441

The above amendment was reviewed by the Sub-Committee in correspondence.

Summary of Amendment

Change to optional Phase 2

The change proposed in this section is that the interview will not be conducted in a group format but rather completed individually with each participant. The numbers of potential participants being recruited have also been lowered from 6-8 to 5-7. These changes are being made as it has proved very difficult to organise the participants who have expressed an interest to complete the interview to attend all on the same day. Running the qualitative section in a group format is hindering the number of participants that are available to complete this phase therefore it would be advantageous to change this to individual interviews to give participants the flexibility in when they can attend for an interview.

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

The Sub-Committee agreed that there were no real ethical issues as a result of this amendment.

Approved documents

The documents reviewed and approved at the meeting were:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Notice of Substantial Amendment (non-CTIMP)	AM02	07 June 2016
Participant consent form [Qualitative Phase]	3	02 June 2016
Participant information sheet (PIS) [Qualitative Phase]	3	02 June 2016
Research protocol or project proposal	9	02 June 2016

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.


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.

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

15/WS/0208:	Please quote this number on all correspondence
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Yours sincerely



Liz Jamieson
REC Manager
On behalf of Dr Adam Burnel, Chair

Enclosures: List of names and professions of members who took part in the review

Copy to: Ms Emma-Jane Gault, NHS Greater Glasgow and Clyde – R&D

Appendix 2.11: Qualitative Interview Schedule

Semi-Structured Interview

1. Experience as a caregiver/family member of an individual with an ABI

- How has caring for your loved one with an ABI impacted on your life?
- Are there aspects of caregiving that you find particularly challenging? If so, please say more about what these are.
- Are there any types of support you find/would find particularly beneficial in terms of helping you cope? What do you think would be particularly helpful about these types of support?

2. Interventions for Caregivers

- What challenges do you think caregivers/family members face in attending support groups or interventions offered by services?
- What are the benefits of attending a group meeting?
- What are the drawbacks of attending a group meeting?
- How do you think attending a group could be made easier?

3. Experience of the Group

- Were there any aspects of the group sessions that you attended that you found particularly helpful? If so, can you say more about these?
- Have you applied anything that you learned in the group in your life in general or in your role as a carer? If so, please say more about this?
- Do you think this type of group is a worthwhile service for a caring population of those with an ABI? If so why?
- Is there anything else you would like to say about your experience as an ABI caregiver/family member?

Appendix 2.12: Qualitative Participant Information Sheet



PARTICIPANT INFORMATION SHEET (QUALITATIVE PHASE)

Title of Project: The Use of Acceptance and Commitment Therapy to Address Psychological Distress in Carers: A Randomised Controlled Feasibility Trial

My name is Annette Lloyd. I work in NHS Greater Glasgow and Clyde as a Trainee Clinical Psychologist. I am studying at the University of Glasgow for my Clinical Psychology Doctorate. I am conducting this research to fulfil the requirements of the course. I also have particular interests in Acceptance and Commitment Therapy (ACT) and the well-being of carers of individuals with an acquired brain injury.

I would like to invite you to take part in this research study. Please take the time to read the following information carefully. Feel free to ask me if there is anything that is not clear or if you would like more information. Take time to decide whether you wish to take part.

Please note that you do not have to participate in this study. If you wish to take part, you need to understand why the research is being done and what it would involve for you.

What is the purpose of the Study?

We are exploring the possible ways to help promote the mental health and well-being of carers and we would like to hear your experiences as a carer, the challenges this brings and what types of support would be helpful for you.

Why have you been invited to participate in the study?

It is important that carers and family members of individual with complex needs (such as adults with an acquired brain injury) have access to adequate support to ensure the maintenance of their own well-being and mental health. We are therefore asking the carers of individuals with an ABI, who are currently residing in the BIRT unit in Glasgow or who have previously resided here to participate.

Do I have to take part?

NO. It is up to you to decide. I will describe the study by going through this information sheet. You will also receive your own copy. If you agree to take part, I will ask you to sign a consent form to show you have agreed to take part. Your participation would be greatly appreciated. However, please understand you do not have to take part. You are free to withdraw at any time. You do not have to give a reason.

What will happen to me if I take part?

Once we have determined who would like to part in the study, you will be asked to sign a consent form. You will be given a copy of your signed consent form to keep. Individuals will be asked to participate in a once-off interview which will last approximately 20-30

mins and focus on your experiences as a carer, the challenges this brings and what types of support would be helpful for you.

This interview will be audio-recorded. This is so I can listen and analyse the interview to pick out particular themes that might emerge, for the results of my research. All information from the interview will be anonymised and therefore will not be identifiable to you. My supervisor Dr. Ross White and I will be the only people to have access to the recordings of the interview.

Are there benefits associated with taking part?

I cannot be certain that participating in the study will benefit you directly. **However**, taking part in this pilot study does offer the possibility that supports and interventions may be developed that will help carers of individuals with an ABI. It will also inform others of the experiences and challenges of caring for someone with complex needs.

Are there risks associated with taking part?

It is possible that some of the material that is discussed may be upsetting to you, however care will be taken to support you if this happens. However, nobody has to divulge any personal information and any information shared will be kept confidential, and not discussed outwith interview setting. Individual attendance at the interview will not be confidential. However, attendance will be at clinical settings that participants routinely attend to visit family members with an ABI.

What will happen if I do not want to carry on with the study?

You can stop at any time

Participation is completely voluntary. Individuals have the **right to withdraw at any point** in the process.

Complaints

If you have concerns about any aspect of this study, please contact me or the chief investigator of this research on the contact details outlined at the end of this information sheet.

Will taking part in this study be kept confidential?

Your confidentiality will be safeguarded during and after the study. All the information you provide during the course of the research will be kept strictly confidential. My supervisor looks at this information to make sure the study is being carried out correctly. We all have a duty of confidentiality to you as a research participant and we will do our best to meet this duty. Your G.P will be informed of your participation in the interview, with your permission.

The interview will be recorded on a Dictaphone. However, I will only share this information with the chief investigator who is bound by the same rules and regulations as I am. I will also record, process and store confidential information in a way to avoid disclosure (in line with Data Protection, 1998).

Breach of Confidentiality

All research staff involved in this project are bound by the University of Glasgow rules on confidentiality. Should something be disclosed during the course of the study, which

gives cause for concern, the investigator has a duty of care to report such a disclosure to the appropriate agencies.

What will happen to the results of the research study?

The results of the research will be written up in a report. If you wish, you can receive a copy of this report. Some of the information you give, including direct quotes, will be used in the report but no one will know it comes from you, as it will be anonymous. The results also be published in journal publications and presented at research conferences by the researcher. This is a pilot study and it may be that further studies are conducted in this area after this one. The results from this study may therefore be used in future studies. However, no one will know it comes from you, as it will be anonymous.

Who has reviewed the study?

The research has been reviewed and approved by NHS Ethics Committee. The methodology has also been approved by Academic staff in Mental Health and Well-being at the University of Glasgow.

Further information and Contact Details

If you wish to know any more information about the study, contact details are:

Annette Lloyd,
Research)
Trainee Clinical Psychologist,
University of Glasgow
1st Floor, Administration Building
Gartnavel Royal Hospital,
1055 Great Western Road,
Glasgow,
G12 OXH.
Telephone: 077 15977497

Dr Ross White (Chief Investigator of
Senior Lecturer
University of Glasgow
1st Floor, Administration Building
Gartnavel Royal Hospital,
1055 Great Western Road,
Glasgow,
G12 OXH.
Telephone: 0141 211 3905

Thank you for taking the time to read this information sheet about our research project, if you have any further questions please do not hesitate to ask.

Appendix 2.13: Qualitative Participant Consent Form



CONSENT FORM QUALITATIVE PHASE

Title of Project: The Use of Acceptance and Commitment Therapy to Address Psychological Distress in Carers: A Randomised Controlled Feasibility Trial

Name of researcher: Annette Lloyd

Participant Identification number for this Trial:

Please
Initial Box

1. I confirm that I have read and understand the information sheet (version 3 02/06/16) for the above study. ☐
2. I consent to the group session being audio-recorded. ☐
3. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐
4. I understand that my participation is voluntary and that I am free to withdraw at any time without given any reason. ☐
5. I understand that information from the interview will be kept strictly confidential, and any information about me will have my personal details removed so that I cannot be recognised. Any quotes used from the audio-recordings will be anonymised. ☐
6. I consent to the results from this study being used in future studies. ☐
7. I consent to my G.P being informed of my participation in this group. ☐

8. I understand that relevant sections of my care record and data collected during the study may be looked at by responsible individuals from the sponsor or host organisation or from regulatory authorities where it is relevant to taking part in this research.

☐

9. I agree to take part in this study.

☐

Name of Participant Date:
 Signature:

Name of Person Date:
Taking Consent Signature:

Appendix 2.14: Major Research Project Proposal



University
of Glasgow

DOCTORATE IN CLINICAL PSYCHOLOGY

SUBMISSION COVER SHEET

Trainee Name	Annette Lloyd
Matriculation Number	2109096
Name of Assessment	MRP Proposal
Submission Date	02/06/16
Version number	9
Proposal Title	The Use of Acceptance and Commitment Therapy to Address Psychological Distress in Carers: A Randomised Controlled Feasibility Trial
Word count	4,090
Academic Supervisor (s)	Dr. Ross White
Clinical Supervisor (s)	Dr. Brian O'Neill, BIRT
Additional information	

Abstract

Background: Research has extensively documented the adverse impact that caring for an individual with an acquired brain injury can have including financial difficulties, social isolation, family tension and conflict, relationship difficulties, role adjustment and psychological distress (Foster et al., 2012). Research has indicated that Acceptance and Commitment Therapy (ACT) shows promise for increasing well-being and psychological flexibility in caregivers and could be a useful intervention for use with this population.

Aims: The primary aim of this study is to investigate the feasibility of using an ACT intervention to enhance the well-being and the psychological flexibility of carers using the Population, Intervention, Control, and Outcomes (PICO) framework.

Methods: The current study is a randomised control design, exploring the feasibility of comparing the efficacy of an ACT intervention to Enhanced Treatment As Usual (ETAU), to improve the well-being of the carers of adults with an acquired brain injury (ABI). Participants will be recruited from the Brain Injury Rehabilitation Trust (BIRT) in Glasgow and randomly assigned to either an ACT intervention group or TAU control group. Both will be assessed in parallel to one another completing a range of baseline and post-baseline measures.

Applications: This feasibility study will provide information for further research on the utilisation of an ACT intervention to improve the well-being of carers and whether this is an acceptable intervention for this population.

Introduction

Carers and Well-Being

An extensive research literature has emphasized the burden carers face in providing care, compounded by a lack of formal and informal support (Jordan & Linden, 2013; Armstrong & Kerns, 2002). Given this burden, the adverse impact of caring for an individual has been widely documented, with outcomes such as financial difficulties, family tension and conflict, social isolation, reduced involvement in pleasurable activities, relationship difficulties, and role adjustment all described (Ergh, Rapport, Coleman, & Hanks, 2002). Psychological distress in caregivers has also been extensively documented. Cummins (2001) found that primary carers were at a considerably higher risk of increased stress, clinical depression and a lowered subjective quality of life. It has been shown that family caregivers of individuals with acquired brain injury (ABI) and other chronic disabilities experience long-term adjustment problems within the entire family system (Boschen, Gargaro, Gan, Gerber & Brandys, 2007).

Current Interventions for Carers

Given the extensive findings on the burden caring for an individual can have on the carer, it is important that this population have access to a range of services to supports their needs. The Carers Strategy for Scotland 2010-2015 identifies the significant psychological and emotional impact on caregivers caring for an individual with complex needs (The Scottish Government, 2010). Despite theses findings, this strategy does not identify any specific intervention for carers to support this population with their own well-being and mental health. Boschen et al., (2007) completed a critical review of the quality of research conducted on interventions with family caregivers of individuals with ABI. The findings illustrated that there is no strong research evidence supporting any specific intervention method for family caregivers of individuals with ABI at present. These findings point to the need for developing new pilot studies and rigorous evaluations of caregiver intervention effectiveness for patients of this population.

Acceptance and Commitment Therapy (ACT)

In the context of caregiving, it is not unusual to find caregivers who try to free themselves of emotions, and thoughts that occur due to the difficult circumstances associated with caring for an individual. For example, emotions such as sadness and grief for the loved one or challenging thoughts relating to caring for the individual are inherent to the caregiving situation. Spira et al. (2007) found a significant association between caregiver's level of *experiential avoidance* and their degree of psychological distress. *Experiential avoidance* is the tendency to control and/or avoid the occurrence of difficult emotions, thoughts and sensations (Hayes, Wilson, Gifford, Follette, & Strosahl, 1996). Traditional cognitive behavioural therapy (CBT) interventions generally aim to reduce or eradicate clinical symptoms, such as depression, stress, and anxiety. In comparison, ACT interventions concentrate on helping individuals establish whether avoidant patterns of coping are preventing them from engaging with valued life domains. This perspective may be more suitable for use with carers, as caregiving is a life context, which strongly impacts caregiving values, life purpose and self-realisation, characteristics that represent a less symptom based view of well-being.

Acceptance and Commitment Therapy (ACT) is one of the 'third wave' behavioural therapies aiming to increase 'psychological flexibility' which is a process of change that addresses experiential avoidance. ACT includes six core treatment processes of acceptance, defusion, contact with the present moment, self as context, values, and committed action (Flaxman & Bond, 2006). The key objective of ACT is not to decrease the individual's distress but to help people live the lives they want to live, aiming to act according to their values (Losada, Marguez-Gonzalez, Romero-Moreno and Lopez, 2014). Therefore ACT embraces a eudemonic perspective of well-being, one that could be potentially fundamental in understanding and intervening on caregivers well-being.

There have been a number of meta-analyses on ACT published during the last decade (Hayes, Luoma, Bond, Masuda, & Lillis, 2006; Powers, Zum Vörde Sive Vörding & Emmelkamp, 2009; Öst, 2014). These meta-analyses have shown small-

moderate effect sizes in favour of ACT when compared to control conditions. Öst (2014) conducted the latest systematic review and meta-analysis on the efficacy of ACT. This analysis of 60 RCT's suggested that ACT may be efficacious for a number of range of difficulties including psychiatric disorders, chronic pain and stress at work (Öst, 2014).

To date there is limited research exploring the use of ACT with caregivers. Márquez-González et al., (2010) conducted a pilot study exploring the use of an ACT intervention with 16 female dementia family caregivers and found a significant decrease in caregivers experiential avoidance in the ACT group intervention compared to a control condition (Losada & Marguez-Gonzalez, 2011). Previous research using an ACT-based stress management intervention with staff caring for individuals with learning disabilities reported a reduction in general psychological distress from pre-test to 6-week follow-up (Noone & Hastings, 2009, 2010). Bethay et al. (2013) used a mindfulness and acceptance-based work stress reduction intervention for staff caring for individuals with learning disabilities and found similar results.

These results suggest that ACT could be an acceptable intervention for use with other populations involved in a caring role. This study will set out to investigate the feasibility of utilising an ACT based intervention with a group of carers formulated around the PICO framework (Richardson, et al., 1995). When developing a complex intervention, significant development and piloting work is of great importance (Medical Research Council – MRC, 2008). According to the MRC (2008) guidelines on developing complex interventions, the feasibility and piloting stages include: testing procedures for their acceptability, estimating the expected rates of recruitment and retention of participants, and the calculation of appropriate sample sizes (MRC, 2008). These guidelines have informed the parameters and design of the current study.

Aims

The primary aim of this study is to investigate the feasibility of using an ACT intervention to address psychological distress of carers. The parameters of this feasibility study which were formulated around the PICO framework (Richardson, et al., 1995) will be used to guide this investigation:

1. **Population:** Can an appropriate group of carers be recruited? This will be determined by ascertaining whether participants can be identified and consented to participate in the study.

2. **Intervention:** Will an ACT intervention be acceptable to this population? This will be determined by measuring workshop attendance, attrition rates and analysing feedback forms.

3. **Control:** Can a group of carers be recruited as a control and followed up in parallel to the intervention group? This will be determined by investigating whether ETAU control group can be recruited to assess in parallel to the intervention group.

4. **Outcomes:** Can measures be identified to explore the impact of an ACT intervention on changes in well-being and psychological flexibility? Efforts will be made to identify treatment signals in the outcome and therapy-specific measures.

Plan of Investigation

Participants

Participants will be recruited through BIRT and will be the carer of an individual with an ABI.

Inclusion Criteria

Inclusion Criteria

Participants must be either the full-time or part-time carers for an adult with an acquired brain injury. Participants must also be aged 18 years or above.

This participant sample can also include family members who are involved in caring for their relatives with an ABI.

Exclusion Criteria

Individuals with a learning disability or those who are not proficient in English will be excluded from the study.

Recruitment

Participants will be recruited through the above service from September 2015 – May 2016. Carers of the patients with ABI who currently reside in Graham Anderson House (BIRT) in Glasgow will be invited by Dr. Brian O'Neill to participate in the study. In addition, carers of patients who have transitioned back to living in the community but are still accessing services from BIRT and carers who attend the support group in BIRT will also be invited to participate. They will be provided with information sheets with the outline of the project and what participation would involve. Carers can express an interest in participating in the research by consenting for their contact details (name and telephone number) to be given to the main researcher. She will then make contact with these identified carers to gain informed consent to participate in the research. They will be recruited on a first come basis and recruitment will continue until the required number of participants has been met.

Measures

Demographics: The demographic details of carers attending the groups will be recorded including: age, gender, length of time being in a caring role, full-time or part-time carers, any other employment, number of individuals they care for, and their relationship to the individual they care for (e.g. mother, father, sister, other guardian) (see Appendix 1).

General Health Questionnaire: (GHQ – 12; Goldberg and Williams, 1988) is a 12 item self-report scale measuring psychological well-being. Respondents are asked to indicate whether they have recently experienced a range of common symptoms or distress. Cronbach alphas are 0.90 and 0.93 (Flaxman and Bond, 2010).

Acceptance and Action Questionnaire: (AAQ-II; Bond, et al., 2011). The AAQ-II is a ten-item questionnaire, which measures psychological flexibility on a seven point likert scale. The mean alpha coefficient is 0.84 (0.78 - 0.88), and the 3- and 12-month test-retest reliability is 0.81 and 0.79 (Bond et al, 2011).

Valuing Questionnaire: (VQ; Smout, Davies, Burns and Christie, 2014). This 10-item scale measures the extent to which people think they have lived their values in the last week. Smout et al., (2014) found good internal consistency for both the Progress scale ($\alpha = 0.81$) and the Obstruction scale ($\alpha = 0.79$) of the VQ.

Experiential Avoidance in Caregiving Questionnaire: (EACQ; Losada, et. al., 2014). The EACQ is a 15-item self-rated scale, which measures experiential avoidance in carers on a five point likert scale. Acceptable reliability indexes (Cronbach's alpha) were found for each factor and the total scale ($\alpha = 0.81$).

Flexibility of Responses to Self-Critical Thoughts Scale: (FoReST-12; Larkin and White, in preparation). The FoReST is a new twelve-item questionnaire, used to assess changes in a person's psychological flexibility in response to their self-critical thoughts, on a seven point likert scale.

Workshop Evaluation Form: A brief form will be used to gain feedback about the workshops. This will evaluate areas such as the training facilities, the content of training and participant's subjective evaluation of the areas of training that facilitated change.

Design

The design of this study will be a randomised control design. Participants will be randomly assigned to either an ACT intervention group or an enhanced treatment as usual (ETAU) control group and will be assessed in parallel to one another.

Procedure

The ACT intervention utilised in this study will be a manualized protocol following Paul Flaxman 2+1 intervention (Flaxman, Bond & Livheim, 2013). The main researcher will deliver this intervention and the first round of groups will be co-facilitated by Dr. Ross White to ensure treatment fidelity. In addition, the main researcher will receive regular supervision from Dr. White to monitor the implementation of the intervention. All ACT sessions will be audio-recorded so Dr. White can verify adherence and competence of the facilitator and their application of the ACT protocol. Recordings will not be transcribed, participants will have given their consent to the session being recorded prior to participation. Following the verification, all copies of the audio will be destroyed.

The ACT intervention will be carried out over three sessions. Two of these groups will be on consecutive weeks and the third group will take place two weeks later. Each session will be 2 hours in duration, which includes time for a mid-session break and completion of psychometric measures (Flaxman et al., 2013). The ETAU control group will consist of two sessions and take the same format as an ACT-group session (i.e. lasting 2 hours in duration with a mid-session break). This control group will be a space for carers and family members to speak about their experiences and stresses caring for an individual with an ABI. The main researcher will facilitate these groups and they will take place over the same time period as the ACT group (on the first and final week of the ACT groups).

Participants will be randomly assigned to either the ACT intervention or ETAU. Randomisation will be accomplished through the Research Randomizer programme provided by the Social Psychology Network (<http://www.randomizer.org>). Permuted block randomization will be used to ensure that an equal number of subjects are assigned to each group. A block size and allocation ratio will be specified, and participants will be randomly allocated within each block. For this study, a block size of 8 and an allocation ratio of 1:1 will be utilised. Participants in both the ACT and ETAU groups will complete their baseline measures at the first session and complete their post-measures at the end of the third session. The researcher will collect these

psychometric measures at the groups in person. If there is attrition at the final stages of either the ACT group or ETAU group and post-measures have been unable to be completed, the researcher will contact the participants who were unable to attend and seek consent to post or email the post-psychometric measures to them. The posted measures will contain stamped addressed envelopes back to the researcher.

Optional Phase 2

Should the research recruitment to the feasibility RCT not be suitably successful, an optional qualitative phase will be implemented. Approximately 5-7 participants for this phase will be recruited. Individual interviews will be conducted with participants, which will last approximately 20-30 mins in total. The interview will focus on the experience and challenges of carers and family members caring for an individual with an ABI. The interviews will be audio-recorded. The audio-recordings will be transcribed and Framework Analysis will be used to identify relevant themes from the interviews. Participants will be recruited and informed consent obtained by the same means used in phase one, using a separate consent and information sheet for this phase only. They will be recruited on a first come basis and recruitment will continue until the required number of participants has been met

Data Analysis

Kolmogorov-Smirnov analyses will be conducted to determine if variables are normally distributed. Independent group t-tests will be used to compare between group differences between ACT and ETAU arms of the study at baseline for normally distributed variables. For variables that are not normally distributed the non-parametric equivalent of an independent t-test (Mann-Whitney U) will be used to assess differences between the ACT and ETAU arms of the study at baseline. Independent group t-tests will be used to compare between change scores (calculated by subtracting the post-baseline scores from the baseline scores) for the ACT and ETAU arms of the study at baseline for normally distributed variables. For variables that are not normally distributed a Mann-Whitney U tests will be used to compare between change scores for the ACT and ETAU arms of the study.

Spearman's *rho* correlations (two-tailed) will be used to test associations between change scores for the general outcome measures and the therapy-specific measures for the individuals in the ACT arm of the study.

Should the qualitative phase of this study be completed this data will be analysed using Framework Analysis to identify the recurring and significant themes in the data (Smith & Firth, 2011).

Justification of Sample Size

The fact that investigations into ACT for carers are at a very preliminary stage means that it is not possible to perform a sample size calculation. In fact this is one of the key aims of the current research. According to the MRC (2008) guidelines on developing complex interventions, the remit of feasibility studies includes the estimation of expected rates of recruitment and retention of participants, and the calculation of appropriate sample sizes (MRC, 2008). This study will generate effect sizes, which can then be utilised by future researchers to inform calculations of the required sample sizes for further trials. This study aims to run two rounds of groups in total, with 6-8 participants in each group. Should the research recruitment not be suitably successful, as outlined above, an optional qualitative phase will be implemented. This will aim to recruit approximately 6-8 participants for a semi-structured interviews.

Settings and Equipment

The ACT and ETAU groups will be delivered in Graham Anderson House in Glasgow in conjunction with BIRT. The researcher requires computer and printer access along with access to a photocopier, which are available in the Mental Health and Well-Being Administration Building at Gartnavel Royal Hospital.

Dissemination of Findings

Findings from this study will be written up as part of the researcher's Clinical Psychology Doctorate Major Research Project (anticipated completion/ deadline July 2016.) Once fully completed, a copy of the dissertation will be held in Glasgow

University Library. The researcher will seek publication of these results with peer-reviewed scientific journals. The research may also be presented at pertinent conferences. A lay summary of the results can be given to any participant who requests this, as outlined in the participant information sheets.

Health and Safety Issues

Researcher Safety Issues

There is the potential that during the delivery of the intervention and follow-up interviews, the researcher may identify risk associated with participants or particularly distressing accounts may be disclosed, which may impact on well-being of the researcher. Should this occur the researcher would seek supervision from her supervisor and access further support if necessary. The ACT groups will take place in Graham Anderson House in Glasgow. This building is staffed 24 hours a day and should the researcher need assistance she can gain support from BIRT staff. She will also have access to a panic alarm, which can be utilised in case of emergency.

Participant Safety Issues

The safety of the room will be ensured, so that all participants are aware of and have access to fire exits. There is the potential that participants may recount some distressing experiences and should they need further support they will be directed to their GP or additional services if necessary. Participants will be provided with support numbers and information sheets signposting carers to additional support should they require it.

Ethical Issues

Information about the aims of the research and the procedure for participation will be provided to carers and informed consent will be sought prior to participation. Data collected will be anonymised using a coding system to ensure confidentiality of participant information. Electronic data will be stored in line with University of Glasgow data governance policy, on an encrypted laptop. In addition a copy of the data will also be stored on Dr. Ross White's University of Glasgow account which will be backed up to the University IT network. Data will be saved for ten years following the

end of this study. Paper copies of the data will be stored in a locked filing cabinet in the Mental Health and Well-Being Administration Building at Gartnavel Royal Hospital.

Financial Issues

No funding will be needed for the psychometric measures used, as these are available for use for free. Participants will not receive financial remuneration for participation. Funding is required for paper, printing, pens, A4 envelopes and miscellaneous items such as tea/coffee and biscuits for group comfort breaks.

Practical Applications

This feasibility study will provide information for further research on the utilisation of an ACT intervention to improve the well-being of carers and whether this is an acceptable intervention for this population.

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