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**A Mixed Methods Feasibility Study of Group-Based Acceptance and
Commitment Therapy with Older People with Mental Health Difficulties
and Clinical Research Portfolio**

Elizabeth Dewey

MA (Honours) English Literature and Classics

MSc Psychological Studies

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

Institute of Health and Wellbeing
College of Medical, Veterinary and Life Sciences
University of Glasgow

September 2018



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CHAPTER ONE: SYSTEMATIC REVIEW

The Effect of Executive Functioning on Cognitive Behavioural Therapy Outcomes for Depression and Anxiety Disorders: A Systematic Review

Elizabeth Dewey

Mental Health and Wellbeing
University of Glasgow
Gartnavel Royal Hospital
1055 Great Western Road
Glasgow
G12 0XY

e-mail: elizabethdewey@nhs.net

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Abstract

Background: There is variation in response to CBT for anxiety and depression that is not fully understood. Some mental health disorders are associated with executive functioning (EF) deficits. These EF deficits potentially have an important role in clients engaging with CBT, applying the principles and responding to it as an intervention. This systematic review explores whether EF is a predictor for CBT response.

Method: CINAHL, Cochrane Library, Embase, PsychINFO and Psychology and Behavioural Sciences Collection were systematically searched for studies published up to June 2018 that measured whether EF scores were related to post-CBT intervention symptom measures for adults. Risk of bias was measured by the Effective Public Health Practice Project (EPHPP) quality rating tool.

Results: Eleven studies met the inclusion criteria. Quality ratings ranged: five studies were found to be of moderate quality, four were 'weak' and two 'strong'. Two out of four papers that focused on OCD, and one GAD focused paper, found that a lower EF score at baseline predicted poorer CBT response. There was no support that EF predicted CBT outcome for depression.

Conclusion: Future research could: measure whether those with non-improved EF following CBT for anxiety predicts CBT response; examine whether there is a particular 'cut-off' of EF score that indicates a better CBT response, suggesting a threshold effect rather than linear; and creating composite EF scores for the aspects of EF rather than one composite score or a number of separate scores.

Keywords: Executive Functioning, CBT, Predictors of treatment response

1. Introduction

Cognitive Behavioural Therapy (CBT) is the first line psychological treatment for anxiety and depression disorders, according to NICE guidelines and the Matrix (NES, 2015). A number of systematic reviews contribute to this evidence by comparing the efficacy of CBT to treatment as usual, medication and other therapeutic modalities for depression and anxiety (Hofmann & Smits, 2008; Hofmann, Asnaani, Vonk, Sawyer & Fang, 2012). Due to variation between studies about CBT's effectiveness, the predictors and moderators of CBT outcomes have been examined to determine for whom CBT is most effective.

Previous studies indicate that patients with depression (Hammar & Årdal, 2009) and anxiety disorders (Bar-Haim et al., 2007), particularly OCD (Shin, Lee, Kim & Kwon, 2014), have impaired EF. EF incorporates a diverse range of cognitive abilities that control other cognitive processes including, “planning, working memory, attention, inhibition, self-monitoring, self-regulation, and initiation” (Goldstein & Naglieri, 2014, p3). Lezak and colleagues describe EF as being responsible for how and whether people do a task or goal directed activity and includes “the highest level of human functioning, such as intellect, thought, self-control, and social interaction” (2012, p42). Diamond (2013) argues there is general agreement for three core processes of EF: inhibition and interference control, working memory and cognitive flexibility. From these core processes arise “higher-order EFs”, for example reasoning, problem solving and planning. A challenge within the literature are the broad descriptions of EF processes and lack of unified definition due to its complexity.

In context of mental health, these impairments may present as rumination or apathy for depression (indicating difficulty in task switching or initiation), acting on obsessions and finding it difficult to stop in OCD (indicating a difficulty with inhibiting and task switching), and difficulties in ignoring irrelevant information and having a number of concurrent worries in GAD (indicating a difficulty in organising information and anxieties affecting working memory). It is currently unclear whether EF deficits are causal of mental health difficulties, or whether there is a correlation between the two (Moritz et al., 2002; Watkins & Brown, 2002). These EF deficits potentially have an important role in clients engaging with psychological therapy, applying the principles and responding to it as an intervention.

CBT involves a behavioural component requiring clients to set and work towards goals. It also involves problem solving skills and abstract thought to work with cognitions and create more psychological flexibility to allow clients to adapt to situations. The latter has been suggested to be prominent in understanding and improving psychological health (Kashdan & Rottenberg, 2010). This is important because if EF prevents CBT recipients from being able to engage and improve their psychological health, knowledge of this can help clinicians consider whether CBT is the most appropriate intervention and adapt to compensate for this deficit and optimise response.

Meta-analyses have reviewed the relationship between EF and pharmacological treatment for depression (Pimontel, Culang-Reinlieb, Morimoto & Sneed, 2012; McLennan & Mathias, 2010; Tunvirachaisakul et al., 2018). Findings were mixed but indicated that a higher score in some EF domains, such as planning, organisation and verbal fluency, had an association with a poorer anti-depressant response. To date there are no published systematic reviews specifically examining the role of EF on symptom reduction following CBT. This systematic review will consider this within anxiety and depression disorders to explore and clarify whether EF is a potential predictor for CBT response. Due to the inconsistencies of findings in other systematic reviews, the type of executive test, and what part of EF it measures, will be described.

2. Research Questions

- i. Does executive functioning affect CBT outcomes in adults with anxiety or mood disorders?
- ii. If EF affects CBT outcomes, what specific aspects/sub-elements are relevant to test?

3. Method

3.1 Search Strategy

This review followed PRISMA reporting standards. (Moher, Liberati, Tetzlaff, Altman & Prisma Group, 2009). Online bibliographic databases (CINAHL, Cochrane Library, Embase, PsychINFO and Psychology and Behavioural Sciences Collection- all years) were searched on 16th November 2017. Two key academic journals, *Journal of Clinical and Consulting Psychology* and *Behavioural Research and Therapy*, were manually searched in addition to references of the studies included in this review. The following terms were used to search the databases (see Appendix 1.2 for full search strategy): (executive

function* or dysexecutive function* or executive skills or neuropsych* predictors or executive deficits or predictors of treatment response) AND (cbt or cognitive behavio* or Third wave or 3rd wave or (acceptance n2 commitment therapy) or cognitive therapy or behavio?ral activation or cognitive behavio?ral analysis system of psychotherapy or dialectical behavio* therapy or meta cognitive therapy or metacognitive therapy or mindfulness based cognitive therapy or schema therapy or functional analytic psychotherapy or integrative behavio?r couple therapy or compassion focussed therapy or compassionate mind training or motivational interviewing).

3.2 Eligibility Criteria

Studies were included if they met the following criteria:

1. Clinical trial
2. Published in peer reviewed journal.
3. Participants aged 18 or over in inpatient and outpatient settings.
4. Participants had a DSM-IV or DSM-V anxiety or mood disorder.
5. CBT was one of the intervention conditions.
6. Specific EF tests were administered pre-intervention.
7. Reported statistical significant data on the influence of EF measures on primary diagnosis treatment response to CBT outcome.
8. Outcome measures used that aimed to measure symptoms of the participants' primary diagnosis.
9. In English language.

3.3 Data Extraction

A structured data extraction form (see Appendix 1.3) was used to collect data on a range of research and clinical characteristics.

To answer the research questions, the papers will be described and then analysed using narrative synthesis. As the statistical analysis, EF tests, and outcome measures varied between studies, a meta-analysis was not performed.

3.4 Quality Assessment

Risk of bias was evaluated using the Effective Public Health Practice Project Quality Assessment Tool (EPHPP) (Thomas, Ciliska, Dobbins & Micucci, 2004). The EPHPP is comprised of six components, scored as 'strong', 'moderate', or 'weak'. These feed into a

global rating of ‘strong’ (no components ‘weak’), ‘moderate’ (one component ‘weak’) or ‘weak’ (two or more components ‘weak’). It has good construct and content validity with a test-retest reliability Kappa statistic of 0.74 (Thomas et al., 2004) and excellent final grade inter-rater agreement in comparison to the Cochrane Collaboration Risk of Bias Tool (Armijo-Olivo, Stiles, Hagan, Biondo & Cummings, 2012). The author, and an independent rater, rated all papers independently before comparing scores. The EPHPP’s dictionary was used by both raters to maximise interrater reliability.

4. Results

4.1 Study Selection

The search strategy, conducted in November 2017, yielded 2232 papers following the exclusion of duplicates. The manual search of academic journals yielded no additional papers that were not found in the original search. The remaining 2232 were screened against the inclusion criteria via their title and abstract. This led to a further 2194 articles being excluded, leaving 38 articles for full review. Following full review, 28 articles were excluded. For thoroughness, these searches were re-run in June 2018 to include papers published between 2017-2018: one additional paper was identified and added so the final review set comprised 11 papers. Figure 1 illustrates the study selection process.

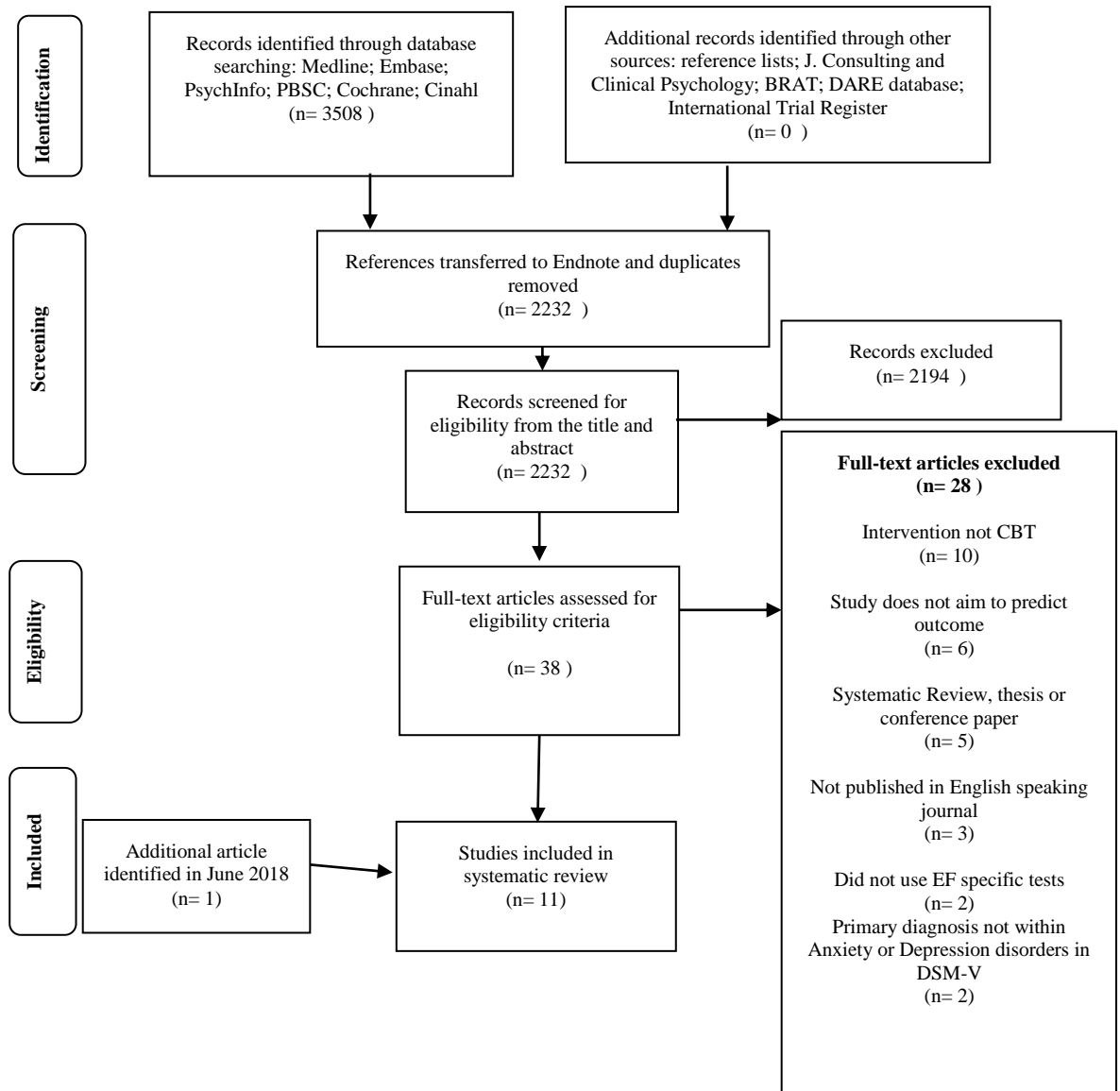


Figure 1. PRISMA Flow Diagram (Moher et al., 2009).

4.2. Descriptive Data

Table 1 reports key methodological descriptive features and summary of results from the studies.

4.2.1 Studies and Population

Six of the studies were conducted in the USA and in total 565 participants were included in the 11 studies' CBT intervention group pre-attrition. Mean ages ranged from 29.56-69.94. Years of publication ranged from 2003-2018. Seven of the studies (see Table 1) were secondary papers related to main clinical trial outcome papers. Consequently, the main papers' methodology sections were consulted when describing these papers, and when using the EPHPP. Quality ratings ranged: five studies were found to be of moderate quality; four were 'weak', and two 'strong'.

Table 1. Summary of Methodology, Results and Quality Ratings

Author/ Year [main trial paper]	Where	Inclusion/Exclusion Criteria (see Appendix 1.4 for full)	Age M (SD) CBT group	Attrition	Comparison Groups (n)	CBT Type	Design Study	Quality Rating	Comparison Outcome Measures	Summary of Key Results
Braga et al. (2016)	BRA	+ 18-65 Years + Primary diagnosis of OCD (SCID-I) - Lifetime diagnosis of neurological disorders - Psychosis, ASD, ID	43.4 (14.0)	31%	CBT (75) vs. WL (75)	12 Group Sessions	Non-controlled RCT	Weak	Y-BOCS	- YBOC-R (>35% reduction in YBOCS) performed better in Trails (B-A) $p = .011$ - Weak but partial association Trails (B-A)- responsible for 17.5% of Y-BOCS variation score $\beta = 0.211$ - No other significant differences
Carter et al. (2018)* [Carter et al., 2013]	NZ	+ 18 years and over + MDD (SCID) + Free of centrally acting drug other than hypnotic and contraception - Schizophrenia or bipolar diagnosis - Major medical condition - Failure to respond to trial of CBT/ST in the past year	38.2 (11.2)	50%	CBT (50) vs. ST (50)	Weekly individual sessions for 6 months, monthly boosters for 6 months	RCT	Moderate	MADRS	- Non-significant: $r = -0.24$ $p < 0.1$
D'Alcante et al. (2012)* [Belotto-Silva et al., 2012]	BRA	+ 18-65 Years + Primary Diagnosis of OCD (SCID-I) - Prior exposure to psychotropic medication or CBT - General medical condition - Severe mental illness other than OCD	32.7 (9.7)	24%	CBT (18) vs. DT (20)	12 Group Sessions, 3 follow up	Practical Clinical Trial	Moderate	Y-BOCS	- Shorter time to completion of part D of Stroop predictive of better response $p = 0.001$ - Longer time to complete Words in Stroop predictive of better response $p = 0.025$ - Fewer errors in Colour/Word in Stroop showed a better treatment response $p = 0.001$
Deckersbach et al. (2018)	USA	+ 18-65 Years + Diagnosis of Bipolar I (MINI) + Current MDD + Stable Pharmacology - Previous CBT treatment - Rapid cycling or current mixed episode Bipolar Disorder subtype - Serious medical conditions - Neurological disorder - Lifetime schizophrenia spectrum disorder	38.76 (13.8)	25%	CBT (17) vs. SP (15)	18 Sessions Individual, 3 Boosters	Pilot RCT	Moderate	HDRS	- No significant correlations with HDRS: - Trails switching: $r = -0.22$, $p = 0.31$; - Colour/word interference $r = -0.32$ $p = 0.13$ - Colour/word switching $r = -0.30$ $p = 0.15$ - Free sorting $r = -0.19$ $p = 0.40$

Dobkin et al. (2012)* [Dobkin et al., 2011]	USA	+ Diagnosis of Major Depression, Dysthymia or Depression NOS (SCID-I) + Diagnosis of Parkinson's Disease + Ages 35-85 + Stable Medication + Family Friend or Carer participate - Receiving CBT elsewhere - Dementia, Bipolar, Psychotic Spectrum, or Substance Abuse Disorders - Unstable medical condition	63.73 (9.89)	10%	CBT (41) vs. Clinical Monitoring (39)	10 Sessions Individual 4 caregiver sessions	RCT	Strong	HDRS BDI	- No significant moderator - EF related to CBT short term maintenance of treatment gains: Week 14 A Priori Model with BDI and Trails (B-A) $\beta=0.26$, $p=0.011$.
Goodkind et al. (2016)* [Thompson et al., 2005]	USA	+ 60+ years+ Primary diagnosis of major depression or dysthymia on MINI - Active suicidality, psychosis, substance/alcohol abuse - Manic episode in last year - <25 on MMSE	69.4 (7.1)	35% (156 recruited)	CBT (55)	12 Sessions Individual	Clinical Cohort Study	Weak	BDI-II	- Worse performance on WCST predicted better CBT response $\beta = -0.40$, $t=-2.64$ $p=0.01$ - Verbal Fluency ($\beta=0.07$ $t=0.48$ $p>0.05$) and Stroop ($\beta=0.04$, $t=-0.27$ $p>0.05$) not significant predictor
Julian & Mohr (2006)* [Mohr et al., 2001]	USA	+ Diagnosis of MS: relapsing-remitting or secondary progressive disease course + Diagnosis of current MDD (SCID-I) + No concurrent treatment - DSM-IV Axis I psychiatric disorder other than MDD or GAD - <5 th percentile on 3/6 cognitive domains - Current MS exacerbation - Head Injury or neurological disorder other than MS - Concurrent treatment for depression	44.08 (9.67) (all participants - CBT-group ages not reported)	15%	CBT (20) vs. Sertraline (15) vs. Supportive Expressive Group Therapy (24)	16 Sessions Individual	RCT	Strong	HDRS	- No significant predictors - Stroop condition $p = 0.72$, $f = 0.14$, $r^2 = 0.03$ (with alpha .01), $\beta = 0.09$ - Verbal Fluency $p = 0.26$, $f = 1.35$, $r^2 = 0.10$ (with alpha .07) $\beta = 0.27$
Mohlman & Gorman (2005)* [unreported]	USA	+ 60+ years + Diagnosis of GAD (SCID) + Read and write in English - Suicidality last 6 months - Concurrent treatment - Never experienced psychotic symptoms	68.75 (5.61)	19%	CBT Intact EF (10) vs. CBT Dysexecutive functioning (12) vs. Wait List Control Group (10)	13 Sessions Individual 6 Monthly Booster Sessions	Pilot RCT	Moderate	BDI BAI STAI-trait PSWQ SCL	- Split participants into 3 groups: intact EF; EDF; Improved EF, along with WL. - Improved EF group significantly greater decrease than EDF and WL on STAI-trait. - No statistics relating to this reported.
Mohlman (2013)	USA	+ 60+ years + Diagnosis of GAD (SCID) + +24 on MMSE + Average or better range in BNT - No anxiety medication	69.94 (6.68)	16%	GAD CBT (69) vs. Control Group (52)	8 Sessions Individual Outpatient	Clinical Cohort Study	Weak	PSWQ BDI GAD-Q	- Compare within and between group performance on Nonverbal Executive Skills Tests and Verbal Executive Skills Tests. - No significant result found.

Moritz et al. (2005)	DEU	+ OCD Diagnosis using neuropsychiatric interview + 18+ - Somatic or psychopathological syndromes	R: 32.59 (9.55) NR: 35.48 (10.79)	12%	CBT (156)	8 sessions Individual and Group, Inpatient and Outpatient	Clinical Cohort Study	Weak	Y-BOCS HDRS	- No significant results of EF scores between R (>35% reduction in YBOCS) and NR: Verbal Fluency $d = -.08$; WCST (perseveration $d = .28$; WCST Categories $d = .13$; DAT Errors $d = .61$; Digit Span Backwards $d = .06$, Trails B $d = .12$ - No neuropsychological tests correlate with differences in YBOCS score or HDRS $r < .30$
Vandborg et al. (2016)* [Vandborg et al., 2014]	DNK	+ OCD Diagnosis (DSM-IV) + 18-60 Years + Danish native language + 16+ Y-BOCS - HDRS > 17 - Pharmacological treatment other than SRIs - Onset of treatment with SRIs less than 3 months before onset of CBT	Recovered: 29.56 (8.85) Non-recovered: 30.74 (7.74)	7%	CBT (42)	Mean of 12.44 sessions Group (25) and Individual (14)	Clinical Cohort Study	Moderate	Y-BOCS HDRS	- None of baseline neuropsychological test variables predicted change in OCD symptoms after CBT - No statistics relating to this reported.

* denotes study that is a secondary paper to a larger trial

Abbreviations: ASD, Autism Spectrum Disorder; BAI, Beck Anxiety Inventory; BDI, Beck Depression Inventory; CBT, Cognitive Behavioural Therapy; DSM, Diagnostic and Statistical Manual of Mental Disorders; DT, Drug Treatment; EDF, Executive Dysfunction; LIFE-RIFT, Range of Impaired Functioning Tool; GAD, Generalised Anxiety Disorder; GAD-Q, Generalised Anxiety Disorder Questionnaire; HDRS, Hamilton Depression Rating Scale; ID, Intellectual Disability; MADRS, Montgomery-Asberg Depression Rating Scale; MDD, Major Depressive Disorder; MINI, Mini-International Neuropsychiatric Interview; MMSE, Mini-Mental State Examination; MS, Multiple Sclerosis; NOS, Not otherwise specified; OCD, Obsessive Compulsive Disorder; PSWQ, Penn State Worry Questionnaire; RCT, Randomised Control Trial; R, Responder; NR, Non-Responder; SCID, Structured Clinical Interview for DSM; SCL, Symptom Checklist; SP, Supportive Psychotherapy; SRI, Serotonin Reuptake Inhibitor; ST, Schema Therapy; STAI-Trait, State-Trait Anxiety Inventory; TBI, Traumatic Brain Injury; WCST, Wisconsin Card Sorting Test; WL, Waiting List; Y-BOCS, Yale-Brown Obsessive Compulsive Scale.

4.2.2. Quality Ratings

Using the EPHPP, it was found nine papers had complete global rating inter-rater agreement. Two papers did not meet agreement (Mohlman & Gorman, 2005; Vandborg, 2016). Disagreement in rating was agreed through discussion with both being rated as ‘moderate’ rather than ‘weak’. The two studies that were rated as ‘strong’ (Dobkin et al., 2012; Julian & Mohr, 2006) were clinical trials that provided the most detailed description (within their main trial paper) of their selection bias and blinding methods. The four studies that were rated as ‘weak’ had limited information these aspects (see Appendix 1.5 for full ratings).

4.2.3. Diagnosis and Outcome Measures

Target diagnosis for symptom reduction were either anxiety or depression disorders: four studies targeted OCD; five targeted depression, and two targeted GAD. Table 2 shows the five most used outcome measures and their mean severity of anxiety and/or depression according to the CBT group’s pre-outcome measures’ scores.

Table 2. Qualitative Descriptors of Mean score for CBT group’s pre-treatment symptom outcome measures

	Y-BOCS (Total)	HDRS	BDI	PSWQ	MADRS
What it measures	OCD	Depression	Depression	Pathological Worry	Depression
Description of measure	10-items Self-Report	17-items Clinician Rated	21-items Self- Report	16-items Self-Report	10-items Clinician Rated
Braga et al. (2016)	✓ Severe				
D’Alcante et al. (2012)	✓ Severe				
Moritz et al. (2005)	✓ Severe	✓ Mild			
Vandborg et al. (2016)	✓ Severe	✓ Mild			
Deckersbach et al. (2018)		✓ Severe			
Julian & Mohr (2006)		✓ Severe			
Dobkin et al. (2012)		✓ Severe	✓ Mild		
Goodkind et al. (2016)			✓ Moderate		
Mohlman (2013)			✓ Mild	✓ Moderate	
Mohlman & Gorman (2005)				✓ High Worry	
Carter et al. (2018)					✓ Moderate

In eight of the studies, participants fell within the highest severity of their primary outcome measure indicating comparable severity of symptoms. Due to the differences in primary

diagnosis, there was some variation in outcome measure. However, the HDRS and MADRS are positively correlated with the BDI, with respective correlation scores of $r=0.71$ (Beck, Steer & Brown, 1996) and $r=0.68-0.75$ (Wang & Gorenstein, 2013). This suggests the depression scales' descriptors are comparable.

4.2.4. Description of Executive Functioning Tests used

The number and type of EF tests used across the papers varied and are summarised in Table 3 alongside a key of what aspect of EF each test was described to have measured. Results reported in the studies are presented in Table 1. Authors were contacted when data was not reported due to non-significance. Unfortunately, due to inconsistency across the papers in how, or whether, the scores were reported, their baseline scores cannot be compared (see Appendix 1.6 for summary of available results).

In terms of EF tests, nine out of 11 of the papers used the Stroop test, which measures inhibition (colour/word trial) and switching (colour/word switching trial). The next two most common tests were card sorting test (six studies); measuring set switching and perseveration and Trails (five studies) measuring task switching.

Three papers created composite EF scores. Mohlman (2013) created a composite verbal EF score (COWAT; VPA Total; Stroop colour/word; Digit-Span Backwards) and non-verbal EF score (Trails B; Matrix Logic; Digit Symbol). Carter et al (2018) did this using four EF sub-tests (COWAT; Digit-Span; two CANTAB subtests). Mohlman and Gorman (2005) did this using WCST, Matrix Logic and Stroop Interference). These authors gave a composite score reported as a standardised z or t score, which was easier to interpret compared to raw scores.

Table 3. EF Measures Used and Aspect of EF they measure

<i>Test</i>	<i>Aspect of EF Tested*</i>	Braga et al (2016)	Carter et al., (2018)**	D'Alcante et al (2012)	Deckersbach et al (2018)	Dobkin et al (2012)	Goodkind et al (2016)	Julian & Mohr (2006)	Mohlman & Gorman (2005)	Mohlman (2013)**	Moritz et al (2005)	Vandborg et al (2016)	Total out of 11
<i>Stroop</i>	<i>Inh, MF, SA</i>	✓		✓	✓		✓	✓	✓	✓		✓	8
<i>Trails</i>	<i>MF</i>	✓			✓	✓				✓	✓	✓	6
<i>VF</i>	<i>VF</i>		✓				✓	✓		✓	✓	✓	6
<i>Card Sorting</i>	<i>CF, PS, AR, MF</i>			✓	✓		✓		✓		✓	✓	6
<i>Digit-Span</i>	<i>WM</i>	✓	✓	✓						✓	✓	✓	6
<i>Brixton</i>	<i>RA</i>			✓								✓	2
<i>Matrix Reasoning</i>	<i>AR, CF</i>								✓	✓			2
<i>OAT; Hayling; IGT</i>	<i>MF; Inh; DM</i>			✓									1
<i>DAT</i>	<i>WM</i>										✓		1
<i>ToL</i>	<i>Pl</i>											✓	1
<i>LNS</i>	<i>WM</i>	✓											1
<i>VPA; Digit Symbol</i>	<i>ns; MF</i>									✓			1
<i>CANTAB (Spatial)</i>	<i>WM</i>		✓										1

*According to descriptions in the papers **Created composite scores from tests

Abbreviations: AR, Abstract Thinking; CANTAB, Cambridge Neuropsychological Test Automated Battery; CF, Concept Formation; DAT, Delayed Alternation Task; DM, Decision Making; Inh, Inhibition; LNS, Letter Number Sequencing; IGT, Iowa Gambling Task; MF, Mental Flexibility; ns, not specified; OAT, Object Alternation Task; Pl, Planning; PS, Problem Solving; RA, Rule Attainment; SA, Selective Attention; ToL, Tower of London task; VF, Verbal Fluency; VPA, Verbal Paired Association; WM, Working Memory.

4.3. Synthesis of Results: Effect of EF on CBT Outcomes

Four of the 11 papers reported statistically significant results. Goodkind and colleagues (2016) reported that a worse performance on the WCST predicted a better CBT response. Braga and colleagues (2016) found those in the responders group performed better in Trails (B-A), which suggested it could predict whether individuals respond to CBT in terms of Y-BOCS score. D'Alcante (2012) found that participants with OCD who committed fewer errors on the colour/word subtest in the Stroop test were significantly more likely to respond better to CBT as measured by the Y-BOCS score.

These mixed results made it difficult to draw generalised conclusions. In terms of OCD, D'Alcante et al's (2012) significant results were not found by two of the other three OCD studies, with similar patient demographics (e.g. age and initial Y-BOCS scores), that used a Stroop test. One of those papers (Braga et al., 2016) was rated as poor quality, particularly due to dropout rate, whereas the other two were moderate. However, as D'Alcante's CBT participant number was low (n=17), it was difficult to give more weight to their result. Braga et al. (2016) did not find a significant result relating to Stroop but reported their 'responders' group performed better in Trails (B-A), which suggested task switching abilities predicted CBT response; however, none of the other five papers that used Trails found a significant result. In addition, this paper's low-quality rating— due to blindness, sample type and drop-out— indicated these results may not be generalised. Neither of the papers rated as 'strong' found that EF predicted CBT outcome in depression, which indicated that the evidence base is not strong enough to suggest a generalisable effect.

The quality of the studies, as measured by the EPHPP, was variable. Four studies were considered 'weak'. This lower rating was mostly due to selection bias (method of recruitment, or in particular not reporting the percentage of participation) and blinding, as it was not always stated whether it was single or double blinded. It is beneficial to report in more detail on both these components due to potential bias not been considered, such as whether the participants are representative or if they, or the researcher, are influenced by research knowledge.

Mohlman & Gorman (2005) split their sample into Intact EF (all three EF test t-scores 'average' to 'superior' range), Executive Dysfunction (EDF) (all three EF tests t-scores 'low-average' to 'impaired' range) and Improved EF (three EF test t-scores dysfunction at

pre-test and at intact level at post-test). This introduced an interesting perspective into considering the impact of EF on CBT outcomes as it suggested that outcome may be determined by how static the participant's EF abilities are. Namely, whether their EF is caused by the mental health difficulty or whether difficulties in EF is present independent of it. They found that their Improved EF group had a significantly greater decrease than EDF on STAI-trait (Mohlman & Gorman, 2005), suggesting those with a static EF are less likely to respond to CBT. They acknowledged that due to splitting their sample they were underpowered for subsequent results. Goodkind et al's (2016) surprising result may substantiate this; they found that those who performed worse on the WCST predicted a better CBT response for depression. They suggested that CBT provided a compensatory mechanism for those experiencing difficulties in cognitive flexibility. This supported the hypothesis that it may not be possible to predict CBT outcome from EF linearly as participant's EF may not be static.

4. Discussion

4.1 Does executive functioning affect CBT outcomes in adults with anxiety or mood disorders?

There is no evidence from the papers, including two papers of 'strong' quality, to support EF as having a role in CBT response for people with depression. There is mixed evidence that EF is associated with outcome of CBT for anxiety: one paper of 'moderate' quality found that deficits in inhibition (measured by Stroop) predicted a lower CBT response in OCD, whereas another paper of the same quality did not find comparable results. Two of four papers that focused on OCD, and one GAD focused paper, found that a lower EF score predicted CBT response.

How papers approach this question in terms of statistical tests provides a potential hypothesis of the role of EF. It appears that using regression or correlation to find a relationship between CBT outcomes and EF yields limited results, suggesting two possibilities.

First, there may be two types of participants: those with trait-related deficits (independent of diagnosis and therefore more static) and those with state-dependent deficits (dependent of diagnosis and therefore more flexible). Studies present varying evidence in relation to this. Mohlman & Gorman (2005) highlight that amongst their sample there was a difference in whether their participants had trait or state EF deficits. If a participant's EF

score did not improve following CBT, it negatively predicted CBT response. However, another OCD focused study found that their participants' EF deficits appear to be trait-related as they were unchanged even following a decrease in symptoms (Bannon, Gonsalvez, Croft & Boyce, 2006). It therefore may be that individuals with trait-related EF deficits are less likely to respond to CBT, as Mohlman & Gorman (2005) suggest. This is difficult to clarify prior to intervention, but it may be helpful to explore this potential relationship by measuring whether individuals with trait-related EF deficits have a poorer CBT response.

It should be noted that some of the papers that were excluded by this review's criteria, either due to not directly measuring the relationship between EF and CBT outcomes and/or having a therapy adjunct (such as cognitive remediation or problem solving therapy) in addition to CBT, may have provided additional knowledge in terms of this state/trait debate of EF and how psychological intervention could be adjusted to compensate for this. For example, one paper compared neuropsychological functioning pre/post CBT or Metacognitive Therapy (MCT). They found that mood and neuropsychological improvements were independent from each other and argued that cognitive remediation focused interventions (MCT in this case) were beneficial for mood; they suggested if EF traits are improved, such as decreased perseveration it leads to an improvement in mood, such as decreased rumination in depression or OCD. Consequently, this suggested that state-related EF benefited from additional EF related support.

This hypothesis was supported by an article that did not meet the review inclusion criteria (Beaudreau et al., 2015) that found older people with depression and deficits in inhibitory/attentional control, measured by Trails B, were more likely to respond to problem solving therapy (PST) and supportive psychotherapy (SP). They recommended that Trails B could be used as a screening cognitive tool to suggest whether a patient needs increased support and structure during psychological intervention to augment their response, which they argued that PST and SP provided. These findings suggest that CBT outcome may not be reliant on whether EF is state or trait, but instead how well the intervention incorporates support for EF.

These papers were not included in this review due to the already heterogeneous state of the literature. CBT may already provide some scaffolding that help overcome EF deficits, for

example through being structured or using visual material, which would support working memory and organisation difficulties. This may be why the papers included in this review have not suggested a unanimous finding. However, as the literature matures it may be possible to conduct a further review that includes additional psychological interventions. This would clarify whether EF should be assessed when deciding on the most appropriate psychological intervention. It remains to be determined whether patients with lower EF, both state and trait, need additional consideration and scaffolding around EF impairments to improve their response to psychological intervention; as well as what these adjustments would be.

The second possibility is that the relationship between EF and CBT outcome is not linear and is perhaps instead a threshold effect for EF (as Mohlman & Gorman, 2005, explored). Higher powered studies are needed to explore this hypothesis as it could give helpful information in relation to suitability of CBT for levels of EF.

4.2 If EF affects CBT outcomes, what specific aspects/sub-elements are relevant to test?

The studies use a number of different EF tests and three studies present composite scores from these tests. Mohlman (2013) argues that single EF test scores are an unreliable measure of ability and in their study, they combine the EF scores into verbal and nonverbal EF skills. Creating a composite score with multiple tests of EF is suggested as more reliable (Crane et al., 2008; Gibbons et al., 2012). This approach is also helpful when reviewing because the authors provide an interpretable standardised score rather than raw scores. As EF is a complex and multidimensional umbrella term, collapsing an EF score into one number may also not be reliable; particularly, when different mental health diagnoses indicate different EF difficulties (e.g. OCD and inhibition). As a result, composite scores may not capture the particular EF difficulty that the client group experience. In future research it may be helpful to create composite scores from multiple tasks that aim to measure the same aspect of EF – such as inhibition and interference control, working memory and cognitive flexibility - rather than completely collapsing them or presenting singular scores.

4.3 Strengths and Limitations

A strength of this review is that it is the first to synthesise studies that consider the role of EF on CBT outcomes. There were limitations relating to the state of the literature, which impacted on the conclusions that can be drawn. Firstly, seven of the studies are secondary findings of a larger trial and their study design was not tailored around examining EF as a predictor. Secondly, the majority of studies did not report a standardised EF score, which made it difficult to compare the participant's baseline EF. This study also did not consider other potential confounding factors on the efficacy of CBT, including fidelity to the model, competence of therapists and variance of dose. There were also potential confounding factors for papers that did not exclude a concurrent pharmacological treatment as medication could have an effect on EF scores. These factors could have been considered by expanding the quality-rating tool to include questions in relation to these confounding variables, so that quality of these papers are considered in relation to these factors. Finally, as discussed above, the inclusion criteria meant that papers focused on adjuncts to CBT and those that measured EF pre and post intervention were excluded. Although this was done to minimise an already heterogeneous set of papers, these excluded papers may have provided further information in relation to the state/trait EF debate and whether CBT, or other types of psychological therapy, improve EF. Given the heterogeneous nature of this literature, there is a need for studies that systematically examine the ways that EF may be modified with psychological therapies. This could include CBT based approaches as well as other interventions such as Cognitive Remediation Therapy.

4.4 Conclusion

Despite mixed results, these papers suggested some evidence for EF predicting CBT outcomes for anxiety, particularly OCD. As there is variation in response in CBT for anxiety there is value in understanding this potential interaction between EF and CBT outcomes, particularly in relation to whether there is a threshold effect for EF rather than the relationship being linear, and whether individuals with state-dependent EF deficits are more likely to respond to CBT. If there is further support for this interaction, it indicates that some patients may require more adaptation (James et al., 2008) around their EF deficits to help engagement.

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CHAPTER TWO: MAJOR RESEARCH PROJECT

A Feasibility Study of Group-Based Acceptance and Commitment Therapy with Older People with Mental Health Difficulties

Elizabeth Dewey

Mental Health and Wellbeing
University of Glasgow
Gartnavel Royal Hospital
1055 Great Western Road
Glasgow
G12 0XY

e-mail: elizabethdewey@nhs.net

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Plain English Summary

Title: A mixed-methods feasibility study of group-based Acceptance and Commitment Therapy with Older People with mental health difficulties

Background: Acceptance and Commitment Therapy (ACT) aims to change a person's relationship with their difficult thoughts rather than change or get rid of them (Harris, 2009). This has been suggested to be helpful for older people experiencing mental health difficulties as they often experience a number of difficulties, including ill-health, which they cannot change (Petkus & Wetherell, 2013). There is little research into whether over 65s find ACT beneficial for helping with their mental health difficulties.

Study Aims: This study aimed to evaluate the feasibility of running an ACT group for older people with mental health difficulties. The research aimed to answer the following questions:

1. Do people agree to take part in the study and attend the group?
2. Do participants like ACT and what parts are important for them?
3. Are the questionnaires suitable for the participants and do they show improvement?

Method: Participants included patients over 65 years old experiencing mental health difficulties. They were recruited from community mental health teams or an inpatient mental health ward. Patients were ineligible if they had a cognitive impairment or learning disability. Participants were referred to ACT groups as part of their routine care. At their pre-group assessment they were asked if they would like to take part in research. They were given time to consider this and if they agreed, an appointment was set up with the researcher to discuss the study further and gather consent to participate in the study. The ACT group consisted of 6 sessions, which were 2 hours long.

Design of Study: This study used data from questionnaires to find out if anything changed for participants (e.g. level of anxiety). Participants were asked to complete questionnaires at the researcher appointment before the group, after the final session and 12 weeks after the group ended. They also completed a short questionnaire after every session. Participants were invited to take part in a telephone interview to find out their views about the group.

Main Findings: 14 participants were recruited and 9 completed the group. Reasons reported for not attending included physical health difficulties (n=2), feeling they improved (n=1), not feeling that the group fit their difficulties (n=1), and no reason given (n=1). 7 group completers participated in an interview. Questionnaires indicated that after the group, participants' anxiety levels went down and that they did not feel as caught up with difficult thoughts. This was supported by the interviews and they noted that they particularly enjoyed feeling understood by what was being said by the group leaders, being given visual representations of their difficulties, and feeling more able to cope with their difficulties.

Conclusion: These results suggest that ACT is beneficial for older people. It would be helpful to repeat this study with more participants to find out whether the same findings arise.

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Abstract

Background: CBT has mixed findings for older people with mental health difficulties and has been described as no more efficacious than relaxation training for anxiety. Due to the types of difficulties associated with old age that cannot be changed, such as chronic health conditions and experiences of bereavement and retirement, a more acceptance-based approach, such as Acceptance and Commitment Therapy (ACT) could be more suitable; however, there are few clinical trials with ACT and older people.

Objectives: This feasibility study used mixed methods to explore the acceptability and feasibility of delivering ACT groups to inpatient and outpatient older people.

Method/Results: 14 participants were recruited, nine of these completed the group (defined as attending four of six sessions) and eight were interviewed. Results suggested that 12 weeks after the last session, completers' anxiety and cognitive fusion scores significantly decreased. Interviews suggested that ACT was acceptable to participants.

Conclusions: ACT is both a feasible and acceptable transdiagnostic intervention for older people in an outpatient setting. Preliminary quantitative analysis suggested the intervention reduced anxiety and cognitive fusion; however, this should be measured in future intervention studies with higher participant numbers. Qualitative analysis suggested older people engaged with ACT because of the focus on visual material and that it seemed to increase their perspective taking and self-efficacy. The latter needs to be explored quantitatively.

Keywords: Acceptance and Commitment Therapy, Older Adults, Feasibility Study

1. Introduction

It is estimated that by 2040, nearly one in four people in the UK will be over 65 (Age UK, 2018) and many people within this population experience mental health difficulties (Scottish Government, 2001). Consequently, mental health services in the NHS need to adapt to the needs of this growing demographic and provide evidence based and acceptable interventions for older people.

Research for older people's psychological treatment has focused on CBT, particularly for depression and anxiety, which has been found to be more effective than waiting list control conditions, but equivalent to other treatment conditions (Hofmann et al, 2012). However, Petkus and Wetherell (2013) have argued that CBT has mixed findings for non-primary care older people and for anxiety does not add anything beyond relaxation training (Thorp et al., 2009). Studies have explored the difficulties that this client group share and have suggested they may use unhelpful thought suppression coping strategies (Petkus, Gum & Wetherell, 2012); that is, attempting to stop thinking about a particular thought. This has been associated with poorer outcomes (Rosenthal et al., 2005) as thought-suppression can produce a 'rebound' effect when the frequency of thoughts increases the more they are suppressed. Given the mixed CBT evidence there is a need to explore other therapies (Roberts & Sedley, 2016).

Acceptance and Commitment Therapy (ACT) is a psychological approach that aims to foster willingness to experience unwanted thoughts and feelings without necessarily changing their form (Harris, 2009). In this regard, ACT differs from other branches of CBT, which explicitly aim to change the content of thoughts as means of reducing unwanted symptoms. ACT also includes a strong behavioural component; aiming to help clients identify their deeply held 'values' and commit to pursuing activity congruent with these principles (Harris, 2009). Consequently, ACT aims not to decrease symptoms of distress, but to relate differently to them.

It has been argued (Petkus & Wetherell, 2013) that ACT may be well suited for an older people population. Roberts and Sedley (2016) suggested a number of reasons why ACT may be particularly suitable for older people: the focus on reconnecting with values, which older people may have lost touch with as a result of significant life events; complexity of presenting difficulties and co-morbidities, requiring a transdiagnostic model; and

experience of significant life events, which cannot be changed and therefore require a modality that aims to accept these changes. However, the ACT evidence base for older people is currently at a very early stage of development. A recent meta-analysis of the efficacy of third-wave mindfulness-based therapies (Mindfulness Based Cognitive Therapy and ACT) for older people (Kishita, Takei & Stewart, 2017) reported a moderate effect for depression symptoms ($g=0.55$) and anxiety symptoms ($g=0.58$). Therefore, there is a need for studies that develop methods and measures to understand how ACT may be beneficial to older people that include ACT specific measures as the aim of ACT is not primarily symptom reduction.

As mentioned above, older age is associated with cognitive changes (Harada, Love & Triebel, 2013) and an aspect of cognition that may affect engagement with ACT is executive functioning (EF). There is no unified definition of EF, but it is generally agreed to be high-level cognitive function (Lezak, Howieson & Loring, 2012) comprising three core processes (Diamond, 2013): inhibition, working memory and cognitive flexibility; in addition to skills relating to these processes, such as reasoning, abstract thought, problem solving and planning. There are a limited number of studies with mixed outcomes specifically examining the relationship between EF and CBT symptom outcomes for older people (Mohlman & Gorman, 2005; Mohlman, 2013). As metaphors are at the core of ACT, requiring abstraction and metaphorical thinking, age related declines in EF may be a barrier to ACT implementation with older people. Consequently, this feasibility study will consider the role of EF in ACT, using a questionnaire measuring understanding of abstract concepts.

Research Aims

The principle objective of this study is to explore the feasibility and acceptability of ACT for older people. As this is a feasibility study, the focus is on descriptive and exploratory questions consistent with the MRC Complex Interventions Guidance (Craig et al., 2008), which describes the key elements of the feasibility/piloting process as: testing procedures and estimating recruitment/retention. In addition to exploring preliminary mechanism work to establish changes that are associated with treatment signals in an older person population. To establish this, it is recommended that using both qualitative and quantitative is needed to understand barriers; therefore, this study uses mixed methods. The research aims are:

1. Population: What are the characteristics of the people who might receive this treatment? What are the estimated rates of recruitment and retention of participants for future trials?
2. Intervention: Are ACT groups acceptable to this client group? Does ACT need to be adapted? Is taking part in a research trial acceptable to this client group?
3. Mechanisms for change: What are the possible/likely mechanisms for change during the intervention? Can we measure changes in these candidate mechanisms?
4. Outcome Measures: Can appropriate measures be identified to explore the impact of an ACT intervention for older people and are they acceptable and well tolerated by patients?

This information will be used to help the design of future research trials.

2. Method

2.1 Design

This study used a mixed methods feasibility design following the MRC Complex Intervention framework (Craig et al., 2008). Pre, post and 12-week follow up questionnaires were collected for quantitative data and post-group semi-structured interviews for qualitative data. As the primary aim was not to determine intervention efficacy and intervention groups were treatment as usual, it was not suitable to include a control group.

2.2 Participants

Participants were recruited from an NHS inpatient functional ward for older people, which serves all Lanarkshire localities, and two outpatient community mental health teams. ACT groups run routinely in these settings and are referred into by clinical treating staff. Prior to groups starting, patients were invited to an individual assessment session with one of the group facilitators (three qualified Clinical Psychologists). At this session, if they met the inclusion criteria described below, they were provided with the participant information sheet and asked whether the researcher could contact them after 24 hours to discuss the project with them at an appointment. During this appointment, if the client decided they wanted to participate, the researcher collected consent, and pre- outcome measures were collected at this time. The facilitators were not involved in the researcher appointment or post-group interview to minimise bias.

Inclusion criteria included: a) Capacity to consent to research; b) 65+ years old; c) Inpatients or Outpatients who have been invited to an ACT group; d) Subjective psychological distress. Exclusion criteria includes: a) Known learning disability; b) Any level of diagnosed cognitive impairment as defined by ICD-10; c) Psychiatric symptoms that would be likely to hinder appropriate engagement with the group.

2.3 Sample Size and Analysis

Based on the three groups planned to run during the recruitment period there were 24-30 potential group members to recruit. It has been recommended that a minimum of 12 participants per group should be recruited (Julious, 2005); consequently, although there is no control group, this trial will aim to recruit 12 participants. In relation to qualitative analysis, thematic analysis was used because of the specific research question and the interviews aimed to explore the participant's personal experience of the group and detecting patterns across the interviews. All participants who attended one or more group sessions were invited for interview and based on previous research (Braun, Clark & Terry, 2014), it was expected that saturation for this type of research question would be reached following 8-10 interviews.

2.4 Procedure

2.4.1 Ethical Approval

Ethical approval (17/WS/0191) was granted by West of Scotland Ethics Committee 1 in September 2017 and approved by NHS Lanarkshire Research and Development in October 2017. All participants gave written informed consent. Two minor amendments were sought: one to add a questionnaire that was not provided at the initial meeting (granted November 2017) and the other to open recruitment to community groups (granted January 2018).

2.4.2 Recruitment

Recruitment for the first inpatient group began in November 2017 and the group was delivered between November-December 2017. Recruitment for the second cycle of was between December 2017-January 2018. At this time, no patients were considered eligible for referral to the group. Consequently, after an amendment to include outpatient groups, recruitment for two groups that were commencing was between January-February 2018. These two groups were delivered between March-April 2018.

2.4.3 ACT Group Protocol

A protocol with adaptations for older people was developed by one of the group facilitators and another Clinical Psychologist in the department. The protocol comprised of six two-hour sessions occurring weekly (for the community group) and bi-weekly (for the inpatient group). The protocol (Appendix 2.2) was based on a core text (Harris, 2009) and the sessions roughly focused on an area of the ACT clinical model. Folders were provided to patients with written handouts given out every session. The ACT group was delivered by two of three qualified Clinical Psychologists (on rotation).

2.4.4 Measures

The Brief Experiential Avoidance Questionnaire (Gamez et al, 2014) is a 15-item measure of experiential avoidance with an internal consistency mean of $\alpha=0.86$. It has not been previously used in studies with older people.

The Valuing Questionnaire (VQ) (Smout et al., 2014) is a ten-item measure of values with a mean internal consistency mean $\alpha=0.95$ for successful valued living and $\alpha=0.93$ for disrupted valued living. It has not previously been used in an older adult population.

The Cognitive Fusion Questionnaire (CFQ) (Gillanders et al., 2014) is a seven-item measure of cognitive fusion. This measure has been used with an older adult population (Scott et al., 2016) with an internal consistency of $\alpha=0.74$.

The Hospital Anxiety and Depression Scale (HADS) (Zigmond & Snaith, 1983) is a 14-item measure of anxiety and depression with an internal consistency mean of $\alpha=0.83$ for anxiety and $\alpha=0.82$ for depression (Bjelland et al., 2002).

A session-by-session measure (Appendix 2.3) was created by the authors (The Acceptance and Commitment Therapy measure of change for Older Adults (ACT-OA)), with five items, was trialled to measure clarity of values, clarity of planned action, engagement in valued living and willingness to experience difficult thoughts and feelings.

The Therapeutic-Metaphors Interpretation Test (T-MIT) (Hains, 2013) is a six-item measure of abstract thinking associated with EF. This measure aims to explore an association between this and changes in other measures to consider whether the session content needs to be adapted further.

2.4.5 Data Collection

Pre-group measures were completed at consent appointment with the researcher. Participants were given the ACT-OA to complete at the end of every session. Time was given at the end of session six for participants to complete post-measures (all measures except for the T-MIT) or participants filled them in between the final session and post-group interview. Following the group, participants were offered the opportunity to opt-in to

attend a qualitative interview. Recordings of interviews were transcribed and anonymised, and then deleted to minimise identification. 12-weeks after session six, group completers were sent outcome measures to complete and return via post. Demographic and other relevant information was collected from participant's clinical notes.

3. Results

3.1 Feasibility

3.1.1 Sample Characteristics

Three groups were delivered: one inpatient group (group A) and two outpatient groups (B and C). In total 14 participants opted into the study: three into the inpatient group (A); four into group B; and seven into group C. Four were male (29%) and 10 were female (71%). They had a mean age of 70.79 (SD=5.06). Primary reasons for referral included depression (n=5), anxiety (n=2), adjustment disorder (n=3), psychosis (n=3), and panic disorder (n=1). Ten participants had comorbid diagnoses relating to mental health, including adjustment to chronic health conditions (n=5), anxiety (n=4) and depression (n=1). Two participants had previously received psychological input and four had current input from a psychiatrist and CPN. No participants had previously received ACT.

3.1.2 Recruitment

This research originally sought to only include inpatients. However, due to organisational factors, such as two functional wards being combined and NHS winter bed pressures, when recruitment came to its second cycle, the clinical treating staff indicated the clients were too psychologically or physically unwell to be considered for an ACT group. Consequently, a minor amendment was made to include older people ACT groups that were being run in the community in the same NHS board. This indicated feasibility issues relating to recruiting from an inpatient population; however, this issue was rectified following this amendment.

A total of 20 patients consented to take part in the group and 14 of these patients consented to participate in the study. Overall there was a 50% attrition rate from consent to 12-week follow-up. See Figure 1 for details of participant flow, including reasons for not consenting.

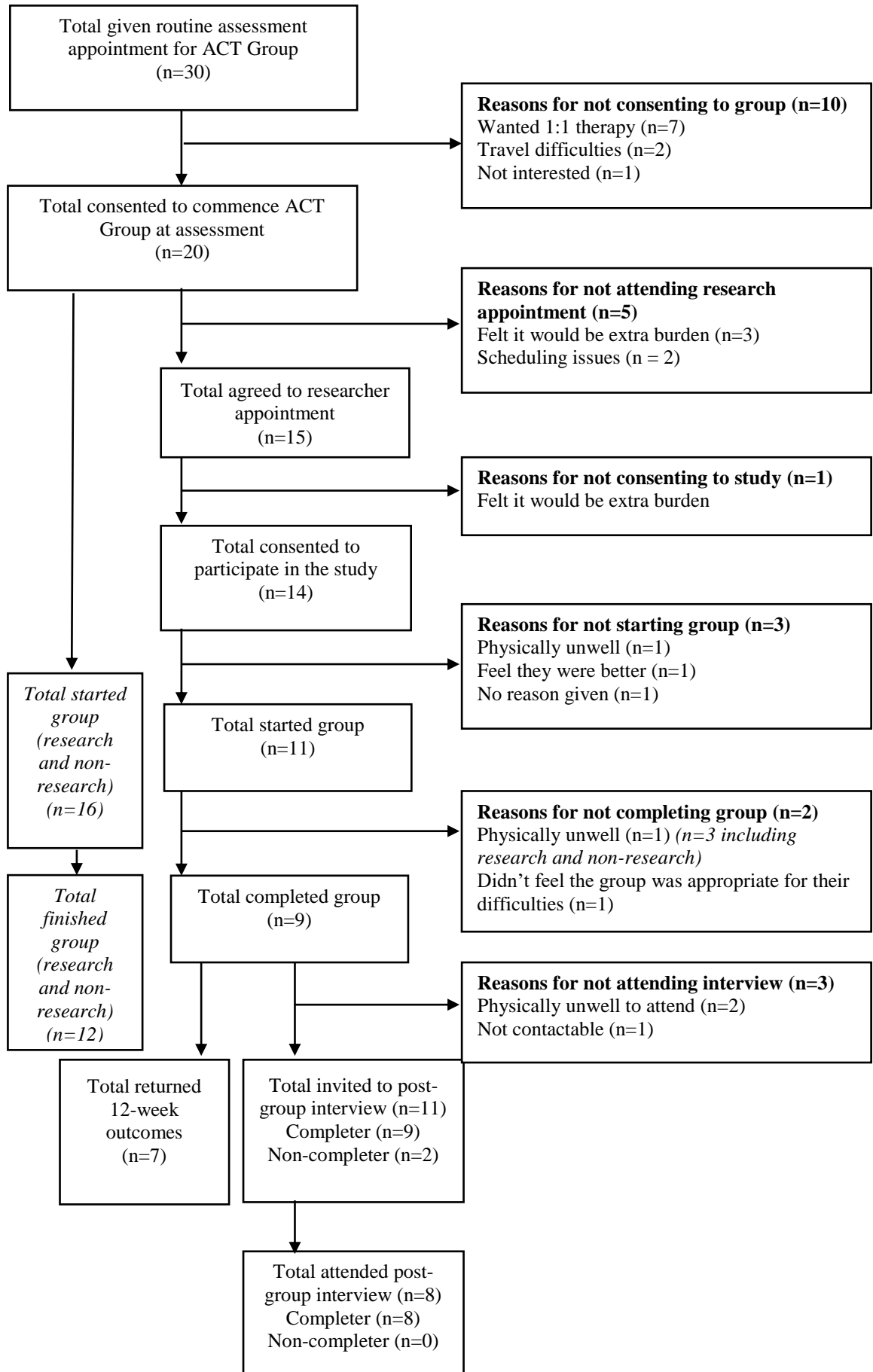


Figure 1. Recruitment Flowchart

3.1.3 Attendance

Of the 14 participants who started the group, three (21.4%) attended all six sessions, five (35.7%) attended five sessions, one (7.1%) attended four sessions, one (7.1%) attended two sessions, one (7.1%) attended one session. Three (21.4%) did not attend the first session following consent and pre-questionnaires. Reasons for non-attendance included physical health difficulties (n=1), planned holidays (n=1), funerals (n=1), and in the case of the inpatient group, discharge (n=2).

3.1.4 Group and Questionnaire Completion Rates

Completion was defined as having attended at least four sessions. Of 14 participants, 11 started the group and 9 completed (see Figure 1). In group A there were two completers (66.7%), in group B there were two completers (66.7%) and in group C there were five completers (71.43%). Combining all groups there was a 64.29% completion rate (of those who consented to take part in the study). Questionnaires had a 100% completion rate at all data points.

Of the 20 patients who initially agreed to attend the ACT group, 16 started and 12 completed. These numbers include both research consenters and non-consenters. This suggests ACT was acceptable for the majority of patients if they commenced the intervention. In addition, reasons for drop-out or non-completion were not solely due to finding the intervention unacceptable, with the most common reason being due to physical health.

3.2 Quantitative Results

Tests of normality of the outcome measures indicated that non-parametric analysis was most appropriate. Wilcoxon Signed-Rank Tests were performed to compare scores (Table 1).

Table 1. Median scores of completers across data collection points, associated Wilcoxon Signed-Rank Tests (WSRT) and effect sizes

Measure	Median (IQR)			WSRT: Pre-Post	Effect Size (<i>r</i>): Pre-Post	WSRT: Pre-12 Week	Effect Size (<i>r</i>): Pre-12 Week	WSRT: Post-12 Week	Effect Size (<i>r</i>): Post-12 Weeks
	Pre (n=14)	Post (n=9)	12-Week (n=7)						
HADS									
HADS-A	11 (6)	8 (5)	7.00 (4)	Z= -1.96, <i>p</i>=0.05*	0.41	Z= -1.58, <i>p</i> =0.16	0.35	Z= -0.46, <i>p</i> = 0.67	0.12
HADS-D	9 (3)	6 (6)	7.00 (7)	Z= -0.85, <i>p</i> =0.40	0.18	Z= -1.19, <i>p</i> =0.24	0.26	Z= -0.11, <i>p</i> =0.92	0.03
BEAQ	64 (9)	68 (26)	61.00 (34)	Z= -1.42, <i>p</i> =0.15	0.30	Z= -1.52, <i>p</i> =0.13	0.33	Z= -0.76, <i>p</i> =0.45	0.19
VQ									
VQ-Obstruction	18 (12)	20 (15)	18.00 (15)	Z= -1.42, <i>p</i> =0.15	0.30	Z= -0.93, <i>p</i> =0.35	0.21	Z= -0.21, <i>p</i> =0.83	0.05
VQ-Progress	21 (4)	24 (9)	25.00 (7)	Z= -1.02, <i>p</i> =0.31	0.21	Z= -0.85, <i>p</i> =0.40	0.19	Z=-1.24 , <i>p</i> =0.21	0.31
CFQ	37 (12)	39 (11)	29.00 (19)	Z= -1.20, <i>p</i> =0.23	0.25	Z= -2.39, <i>p</i>=0.02*	0.52	Z= -2.37, <i>p</i>=0.02*	0.59
ACT-OA	20 (7)	24 (9)	25.00 (2)	Z= -1.12, <i>p</i> =0.26	0.24	Z= -1.52, <i>p</i> =0.13	0.33	Z= -0.43, <i>p</i> =0.67	0.11
T-MIT	12 (4.5)								

*significant finding

Testing indicated a statistically significant improvement on the HADS-A from pre to post, which suggested anxiety decreased with a medium effect size ($r=0.41$). HADS-A clinical cut off scores indicated a clinically significant score from pre to 12-week as the decrease is from Moderate (pre) to Non-Clinical (12-week). A significant improvement on the CFQ from pre-group to 12-week and post-group to 12-week was also found, with a large effect size ($r=0.52-0.59$). This indicated participants had lowered cognitive fusion, and that this change took place between post and 12-week.

The relationship between EF (as measured by the T-MIT) and the change scores (pre/post group) of experiential avoidance (BEAQ), anxiety and depression (HADS), values (VQ), and cognitive fusion (CFQ) was investigated using Spearman's correlation coefficient (see Table 2).

Table 2. Spearman correlation coefficient and *p*-values of T-MIT with pre to 12-week change scores on validated questionnaires

	HADS-A Change Score	HADS-D Change Score	BEAQ Change Score	VQ Obstruction Change Score	VQ Progress Change Score	CFQ Change Score
<i>n=7</i>						
Correlation with T-MIT (<i>r</i>)	-0.36	-0.30	-0.26	0.07	0.39	-0.21
<i>p</i> value	0.43	0.52	0.57	0.88	0.39	0.41

No significant results were detected (p -values ranged from 0.39 to 0.88); although, there was a medium effect size between T-MIT and HADS-A, HADS-D and VQ-Progress. This indicated that a higher score in EF may be related to a decrease in anxiety, depression and increase in progress of valued living.

3.3 Qualitative Results: The Participant's Experiences

3.3.1 Sample Characteristics

Eight participants opted to attend a post group interview, six were female and two were male (mean age=71.63, SD=5.60). All were completers, with a modal dose of five and range of two.

3.3.2 Results

Thematic analysis was used using Braun and Clarke's (2006) six-phase process. Familiarisation with the data was established through transcription and noting down initial ideas. The transcripts were then coded and these codes were collated into potential themes.

Following this a thematic map of these themes was created, refined and given examples and descriptions within a table. See Table 3 for an outline of candidate and sub-themes.

Table 3. Candidate Themes and Sub-Themes

Candidate Theme	Sub-Theme	Number of participants who expressed this theme
Acceptability	Attitudes towards group	7
	Facilitators	8
	Resonance with content	6
Mechanisms of Change	Self-Perception	7
	Social Context	8
	Awareness of emotions	7
	Acceptance	5
Aids to Cognitive Understanding	Use of metaphor	8
	Visual	7
	Time to process	5
	Flexible Perspective	5

Theme 1: Acceptability

Attitudes towards group

Many participants expressed pre-group anxiety, particularly related to worries that they would be forced to talk about their difficulties, or that listening to other people's difficulties would be difficult; however, these difficulties were described as quickly alleviated during the first session.

“[I] was worried at the beginning that hearing other people's problems were just going to make me worse, but it didn't, it was the complete opposite” (Participant 10, p8L5-7)

A few participants also appeared to view the group as an opportunity to learn new skills, which seemed to be more acceptable to them as no participants described the experience as therapy.

“this is actually good groundwork / what I have got now is the skills” (Participant 11, p4L4-5 / p6L30)

Facilitators

All participants spoke positively about the group facilitators' qualities, which seemed to help participants engage with the group and its contents.

“[facilitator's name] had a lovely calm y'know presence I can't imagine they ever get wound up so when they y'know told you to close your eyes and relax it really worked” (Participant 14, p2L16-18)

A particularly appreciated quality was when facilitators noticed ambivalence around understanding on topics and used individual's examples to explain content in another way.

"they were very patient and understanding with us...they didn't go "what?" they were so oooh that's fine, that's fine and they would say things to make it clearer and that it's just the way you are" (Participant 6, p9L22-25)

"...and if there was any erm anything that hadn't been understood or whatever there was no hesitation...they would stop and would go round one-to-one and see how we're getting on and just getting stuck with the sentence you're trying to put and explained y'know what it is" (Participant 11, p4L17-23)

There was also a sense of appreciation about the help participants were receiving and putting value and trust into the facilitator's expertise.

"they're well qualified...and earned through and studied for it y'know...those people are taking their time to try and help you" (Participant 10, p10L1-3)

Resonance with Content

Many participants commented on how the content of the group and the way it was delivered made them feel understood or explained their situation.

"I mean I was sitting saying to myself that's exactly how I feel (.) that's exactly how I feel" (Participant 7, p2L15-16)

"just for the information in the handouts I thought well that's what's happening for me" (Participant 13, p3L5-6)

This resonance led some participants to feel that their situation was understood.

"there is light at the end of the tunnel even if it is speaking to someone and someone understanding how you feel" (Participant 7, p5L1-2)

Theme 2: Mechanisms of Change

The resonance with content discussed above appeared to be a precursor for the mechanisms of change that emerged from the transcripts.

Self-Efficacy

Self-efficacy appeared to be an important factor for participants in mediating understanding content and translating it to change. Many participants discussed learning that they had a role in their recovery when they were asked what they had gained from the group and what had changed.

"me, me is the main thing obviously not saying I'm perfect definitely not but I'm not what I would say I'm not perfect and erm there is never a way I would ask to be perfect but what I have got now is the skills and I've got the support and it's up to me" (Participant 11, p6L28-p7L1)

For all but one participant who discussed this sub-theme, this was viewed positively as they had more self-efficacious and hopeful attitudes towards themselves.

“I’ve happily learned (.) I’m stronger within myself yes and that wee group helped me to realise” (Participant 6, p2L10-11)

“I think it’s that instead of me taking these tablets these are short term I’m not wanting to be on them for life but I felt that the group and the mindfulness thing is something that’s always there you can always bring it back up which is what I’m aiming for” (Participant 7, p6L7-10)

Social Context

The self-efficacy discussed above was sometimes influenced by how individuals interacted with others in the group. Many participants described this experience as normalising.

“one of the things that was said was that everybody’s got a struggle, struggle in life and being part of the group made me realise y’know that how true that is” (Participant 13, p2L25-7)

“it was interesting hearing other people’s conversation as well problems their different problems but same end things y’know I mean experiences” (Participant 10, p7L23-5)

Most of the participants spoke about how they enjoyed being in a group and meeting others.

“it was really pleasant it was like friends meeting up y’know like talking about something that we (.) was really nice” (Participant 11, p4L29-31)

These interactions sometimes led to social comparison in emotional difficulties. A few participants discussed feeling comforted by comparing levels of difficulty and social support, which had helped in their changes.

“so what I get from the group is (...) comfort, comfort and not being on my own and knowing there’s a lot worse than me” (Participant 6, p9L13-4)

However, this comparison of social support was not described as helpful for all participants.

“I’ve come to realise that I don’t have any support... so it’s not all psychiatric it’s social” (Participant 13, p2L21-2)

Awareness of emotions

In addition to social context and self-perception as being mechanisms of change for individuals, many participants acknowledged an increased awareness in how they were feeling.

“I didn’t have a clue what was wrong with me I hadn’t a clue how I was feeling”
(Participant 7, p4L11-2)

For some, this change was described as being achieved through mindfulness.

“It brought me to a place where I could think of things and then stand back and just realise what was happening” (Participant 3, p2L22-4)

In addition, a few participants reported that completing the questionnaires had helped them become more aware of their feelings, both positively and negatively, which indicated increased contact with the present moment.

“but I think questionnaires are good in the respect that it helps me as well, knowing as well as yourself that it helps you to know er how you're going and what you're doing”
(Participant 3, p5L27-9)

“it made me realise when I was filling in the questionnaires how ill I am” (Participant 13, p5L21-2)

Acceptance

Acceptance seemed to be a mechanism of change that followed from awareness of emotions. For example, the following example illustrates how one participant became aware of their difficulties and how experiential avoidance through distraction had helped in the short-term but that following retirement it exacerbated their difficulties.

“I think what was wrong with me is I didn’t deal with what was wrong with me...or what happened to me years ago. I didn’t deal with my problem or how I felt and I had a busy job so that busy job kept me going and distracted so my problem wasn’t there all the time, and when I retired and I had nothing else but my problems went through my mind, and I really didn’t feel good at all in myself I really felt terrible in myself”
(Participant 7, p4L23-8)

The following quote illustrated the same participant’s more accepting stance towards their difficulties and feelings following the group.

“I’m realising that what’s happened is there y’know you can’t do anything about it and it’s got to be about what’s here and what’s coming, so I feel ok now about thinking about the past but I move on from it I feel more relaxed I certainly don’t have the anxiety I had... and I’ve just had to say to myself that I can’t change what’s happened and I just have to deal with it in a different way I’ve just got to get on with my life”” (Participant 7, p6L22-25, p6L30-p7L1)

Similar sentiments were echoed by many other participants, for example discussing how they now confront and “deal with” their difficulties rather than attempting to get rid of them.

“it helped me deal with some of the things I had in my mind it really did” (Participant 3, p1L4-5)

“I just got to get on with that just try and accept it’s there” (Participant 10, p6L20-1)

Others described acceptance of their ‘off days’ and emotions.

“whatever happens, whatever happens happens” (Participant 3, p2L18-9)

“There are days I feel [depressed] ...we all feel we do” (Participant 6, p3L18)

Although there was a number of examples of acceptance, participants also acknowledged that it was difficult and would result in frustration of trying to get rid of their difficulties.

“they [other group members] were quite frustrated y’know and they’ll do anything these people do anything to get rid of it y’know and sometimes they get frustrated because it’s not happening” (Participant 10, p7L26-8)

Another participant said acceptance had meant they were no longer ruminating about their difficulties.

“I keep hanging onto things and I couldn’t let them go and I saw that [metaphor] and I thought that is me... It tells me right you don’t need this you don’t need this, move on, right you can do this, you’ve done a lot more than this and I talk myself through it (.) and that it is it doesn’t sound maybe natural but it was letting go of the rope” (Participant 6, p2L19-20, 27-8)

Theme 3: Aids to Cognitive Understanding

Use of Metaphor

Many metaphors within the group were around acceptance of emotional struggle, and the previous quote highlighted a participant using metaphor to describe this struggle with acceptance. All participants cited a metaphor during their interview when asked about the group, highlighting it was an important aspect for them. Use of metaphors appeared to be an important part of helping participants to understand complex concepts; some participants explicitly acknowledged this.

“well the pictures I liked that they put things in a simple way... there was a monster and a boy (.) that put things simply” (Participant 14, p1L25, p2L1)

There seemed to be three levels of understanding in relation to the metaphors. Firstly, all participants were able to remember and concretely describe a metaphor.

“all it meant was you couldnae beat the monsters at the end of it” (Participant 2, p1L26-7)

Some participants were able to describe how the metaphor related to emotional difficulties.

“they did go through all of the things about the elephant in the room and the tug of war thing where you’re tugging with your emotions constantly erm and how you could deal with that and how you think you could deal with that” (Participant 7, p2L9-12)

A couple of participants were able to specifically describe their own situation using the metaphor and describe how to use this to facilitate acceptance, which was illustrated above (Participant 6, p2L19-20, 27-8). Consequently, it seems that metaphors were an important part of remembering and understanding concepts for all participants, but that there were different levels of abstract thinking around the metaphors.

Visual

Alongside finding that metaphors explained situations simply, participants commented on their visual nature, alongside other visual aspects of the group, such as handouts and writing on the whiteboard. For example, Participant 3 suggested that when information was presented visually it helped subsequent recollection.

“...the way it was done especially with the monster it gave you an idea sometimes things like that that look more simple that they're actually better for you because you can visualise that in your mind's eye and you think about that oh yeah the bus, the bus idea” (Participant 3, p3L12-5)

Other participants indicated that visual material helped concepts become more concrete and facilitate understanding.

“I think when you physically see something that definitely helps” (Participant 3 p4L27-8)

“putting it in black and white up on the board to see as well as having a handout to follow” (Participant 13, p4L16-7)

“taking notes or being able to see notes that was really important because the way that the people erm (.) like [facilitator's name] or [facilitator's name] they're giving the information erm and where we're going and what we're doing but I really need to get notes because there's no way I can carry that in my head” (Participant 11, p2L16-20)

A number of participants discussed the session-by-session visual handouts as being helpful and said they referred to them outside of sessions.

“I do think about what they said in the group I do fall back on it and say well I got my wee folder and I do fall back on it” (Participant 7, p5L9-10)

Time to Process

In relation to using the handouts between sessions, time was identified as a theme that participants said helped them to socialise to the model and cognitively process content. Some participants indicated they found the content difficult during the sessions but that

they used the time in between sessions to think about material, which helped their understanding.

“but I must say they didn’t always sink in there I’m more a thinker at night when I’m sitting and it would and I would get the things all out and I’d go right that was that, that was that, and it did eventually sink in” (Participant 6, p4L7-10)

“and the language y’know to pick up and that but I did catch on... I think it took me until the third week before I was starting to get a wee bit more about it” (Participant 11 p1L5-6, 8-9)

This suggested that number of sessions attended and time between them were important for participants to engage with content.

Flexible Perspective

Another subtheme that seemed to be an important cognitive aspect for some participants was acknowledging that the model presented another perspective.

“I just enjoyed going to it I felt as though they were erm giving me answers that I didn’t have before telling me how to deal with things telling me right you’re maybe feeling like this but you can also do that showing me that different ways to deal with my emotions” (Participant 7, p4L8-11)

In addition, some of these participants had taken the different perspective and assimilated it with their own.

“although I now don’t seem to go down that road anymore it’s as if my mind’s going a different way now” (Participant 3 p4L24-5)

This change in perspective, and defusion from their “mind’s” thoughts, may have helped to mediate the change described in Theme 2.

4. Discussion

This study provides one of the first explorations of the feasibility and acceptability of ACT for older people. Feasibility was assessed through gathering information on recruitment and retention of participants presenting with mixed anxiety and depression related problems. Acceptability was determined through quantitative questionnaires and qualitative interviews to consider potential mechanisms of change and participants’ views on the group.

4.1 Feasibility

Recruitment in the initial phase revealed a lack of patients who were appropriate for inpatient ACT groups. Consequently, it was found to be unfeasible to recruit from this setting and an amendment was made to include outpatients. Following this amendment, recruitment improved, which indicates it is more feasible to conduct research in outpatient ACT groups and that this population are more suitable for this intervention.

The observed attrition rate was high with three participants not attending the first session, two dropped out by session three and two did not return the 12-week questionnaires. This was comparable to a pilot study that offered ACT groups within a nursing home (Alonso et al., 2013) and reported a 49.06% (n=26) attrition rate. Reasons for drop out (physical health, feeling they no longer needed it and that it was not suited for their difficulties) were also comparable, indicating these issues are common within this population. Future trials may need to consider the impact of chronic health problems within the design of their studies. Outcome measure completion rate was good, meaning all data could be analysed, and that the session-by-session measure was not burdensome.

4.2 Acceptability

Attrition rates for the research arm of the trial between consent and group finishers was 35.7% and in the routine data arm was 25%. Although comparable to a pilot study with a similar client group (Alonso et al., 2013) it suggested that there may be high attrition in future studies with this client group. As the largest reason for drop-out or not starting the group was physical health difficulties, it may indicate that adjustments may need to be made for clients who have more severe physical health difficulties in future studies. This could be addressed within the exclusion criteria to include that clients who have a physical health difficulty that prevents them from being able to commit at least four sessions will be directed to individualised support to take these difficulties into account. This would be with the view that should the client's situation change in the future they could be included in future groups. In addition, physical health could be further considered within the assessment stage of the ACT group (prior to the appointment with the researcher). As ACT has been identified as an effective intervention for individuals with long term health conditions (Roberts & Sedley, 2016), it may be helpful to emphasise explicitly the transdiagnostic application of ACT for both mental health and physical health difficulties, as often for this population they are co-morbid. In addition, to support this the protocol could be further adapted to include discussion about application of the principals to both

physical and mental health. These adjustment considerations within future trials may help to improve attrition, which would in turn give a greater estimate of response to ACT.

The good completion rate on outcome measures indicated they were acceptable; when directly asked during interview about their experience of completing questionnaires, there was no negative feedback following this question and many participants commented on their helpfulness in measuring how they were feeling.

In the interviews, participants described ACT as relatable and consequently acceptable because of its use of examples and metaphors that resonated with their situations. This acceptability, together with the cognitive adjustments, through visual methods (using the whiteboard, handouts and some visual metaphors) for concreteness and memory aid and time between sessions to process, allowed participants to view their difficulties from another standpoint. These features of acceptability and cognitive understanding led to change if they had self-efficacy about their ability to change and social support to scaffold this. This may have enabled individuals to become more aware of their feelings and emotions through mindfulness and questionnaires, and some were able to take a more accepting approach to their difficulties with the use of metaphors and seeing themselves as able to make changes. This may be associated with self-as-context, which is a part of the ACT model that describes the concept that individuals can gain perspective through noticing. A change in self-as-context through ACT intervention has been suggested to be associated with improved functioning (Yu, Norton & McCracken, 2017), and these qualitative interviews may support this. Sub-themes may have acted as mediators for different candidate themes, and this is represented in the Venn diagram below (Figure 2). The function of a group rather than individual therapy also seemed to be an important factor as individual's emotional struggles were normalised and the group was viewed as supportive. These findings are consistent with another study that interviewed older people following an ACT group intervention (Jacobs, Luci & Hagemann, 2017).

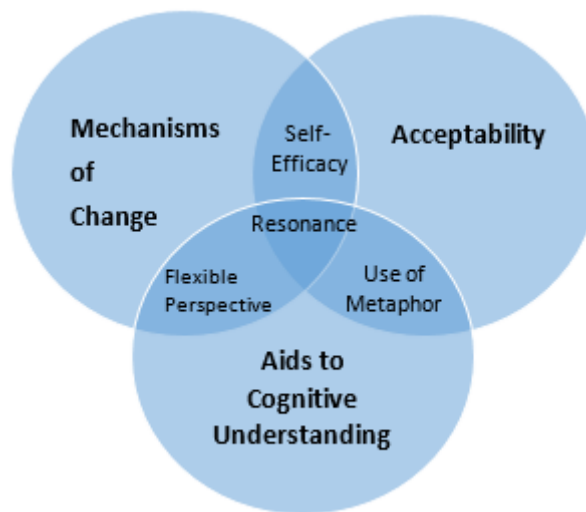


Figure 2. Venn diagram of Sub-Themes that mediated Candidate Themes

Exploratory analysis showed a clinically significant change between pre and 12-week from ‘Moderate’ anxiety to ‘Non-Clinical’ with a medium effect size. This effect of ACT having more of an effect on anxiety than depression has been found in other studies (Hofmann et al., 2010). It perhaps reflects ACT’s focus on acceptance (rather than experiential avoidance) meaning ‘difficult’ emotions (such as depression) are expected to remain but that clients are more willing to tolerate and accept these emotions, which may lead to decreased anxiety about the emotions (Harris, 2006). Qualitative interviews suggested some acute anxiety about starting the group itself, which may have elevated baseline scores. It therefore may be helpful to administer the HADS after session one to consider whether pre-group anxiety influences participants’ scores.

CFQ scores significantly decreased with a large effect size, between pre and 12-week with the change taking place between post and 12-week, signalling that cognitive defusion was a mechanism of change. This delay may be as a result of the importance of ‘time to process’ that participants discussed in interview. In addition, it may signal that a decrease in anxiety could be linked to subsequent cognitive defusion. As a feasibility study, the empirical outcomes were not being used to examine statistically significant changes in patient test scores. Rather, we set out to use change scores and measures of dispersion in the data to provide signals that could guide hypotheses and power calculations for future trials. Because of these considerations, a Bonferroni Correction was not applied as this would increase the possibility of a Type II error. In line with recommendations (Perneger, 1998), as this correction was not applied, statistical tests were described, and caution has been used when interpreting the results.

Petkus and Wetherell (2013) suggested that older people are more likely to engage with values rather than the concept of emotional struggle; however, interviews suggested that participants identified most with the metaphors around emotional struggle and tests indicated no significant change on the Valuing Questionnaire. Interestingly, correlations revealed a medium effect size between higher EF and increased progress with values, which may exist because the identification of values, and subsequent committed action, requires multiple aspects of EF such as mental flexibility, organisation and planning. As interviews highlighted that aids to cognitive understanding– such as time to process, offering alternative perspectives and visual concrete examples and handouts- were important, these findings may suggest that more adaptation is needed to aid patients with lower EF to engage with values.

4.3 Strengths and Limitations

A main limitation for this feasibility study was low participant numbers, as it has been found that the average sample size of feasibility studies is 30 (Billingham, Whitehead & Julious, 2013). This was a result of unforeseen systemic difficulties within the NHS that occurred during recruitment resulting in patients who were inappropriate for ACT. Although, this also provided helpful information about the difficulties around recruiting in these settings. An additional limitation was that intention-to-treat (ITT) analysis was not applied when conducting the exploratory analyses. Only data from treatment completers were used in order to address the study aim of exploring the potential mechanisms of exhibited by participants. If participants who had not received the treatment had been included the study may have been susceptible to a Type II error. As this understanding of this treatment approach increases, ITT analyses should be included in future clinical trials. This will include data from people who drop-out or do not comply with all study procedures and so will provide a clearer reflection of clinical practice. Hence, as this literature develops, it will be more appropriate to use designs that decrease the chance of a Type I error.

A strength of this study is that it amalgamated qualitative and quantitative analysis to examine whether ACT is acceptable for older people in line with recommendations (MRC, 2000). As a result, it has given a greater understanding of what has worked for participants, particularly in relation to cognitive adaptations. Although older age is related to a change in EF, which could be assumed to make aspects of ACT more difficult, such as using

metaphor and increasing flexibility around difficulties, the interviews indicated that for many participants the metaphors resonated with them and they recognised the facilitator's flexible perspective. The interviews were also able to detect a subtle change in understanding of metaphors between participants (concrete understanding, abstract understanding and understanding in relation to own situation) as described in the results section, which may be a difference that has a role in outcome.

4.4 Future Research

According to MRC (Craig et al., 2008) guidance in developing complex interventions, the next step following feasibility is to undertake a pilot study to examine the key uncertainties following a feasibility study. The key uncertainties from this study are: if significant results would occur with a control group and a larger sample; how values can be conveyed more concretely; and how the self can become more flexible, efficacious and compassionate, as this seemed to be an important mediator in this study in bridging understanding of the intervention to bringing about change. The importance of increases in self-efficacy is consistent with the suggestions of Arch and Craske (2008), that acceptance-based interventions may somewhat paradoxically increase individuals' perceived prediction and control of symptoms.

4.5 Conclusion

ACT is both a feasible and acceptable transdiagnostic intervention for older people in an outpatient setting. The protocol developed by the facilitators had appropriately adapted material to allow cognitive changes associated with older age as measured by the qualitative analysis. Although, sessions around values may need to be further adapted. Preliminary quantitative analysis suggested that the intervention reduced anxiety and cognitive fusion; however, this should be measured in future intervention studies with higher participant numbers. Qualitative analysis suggested older people resonated with the ACT material because of the focus on visual material and that it seemed to increase their perspective taking and self-efficacy. The latter needs to be explored quantitatively.

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Appendix 1.1 Author Submission Guidelines for *Journal of Anxiety Disorders*
<https://www.elsevier.com/journals/journal-of-anxiety-disorders/0887-6185/guide-for-authors>

Submission checklist

You can use this list to carry out a final check of your submission before you send it to the journal for review. Please check the relevant section in this Guide for Authors for more details.

Ensure that the following items are present:

One author has been designated as the corresponding author with contact details:

- E-mail address
- Full postal address

All necessary files have been uploaded:

Manuscript:

- Include keywords
- All figures (include relevant captions)
- All tables (including titles, description, footnotes)
- Ensure all figure and table citations in the text match the files provided
- Indicate clearly if color should be used for any figures in print

Graphical Abstracts / Highlights files (where applicable)

Supplemental files (where applicable)

Further considerations

- Manuscript has been 'spell checked' and 'grammar checked'
- All references mentioned in the Reference List are cited in the text, and vice versa
- Permission has been obtained for use of copyrighted material from other sources (including the Internet)
- Relevant declarations of interest have been made
- Journal policies detailed in this guide have been reviewed
- Referee suggestions and contact details provided, based on journal requirements

For further information, visit our [Support Center](#). Manuscripts based on original research are limited to 6000 words of main text (i.e., not including cover page, Abstract, and references) and reviews, meta-analyses, and theoretical treatises will be limited to 8000 words of main text. Tables and figures will be limited to 5 each, regardless of manuscript type. Longer manuscripts may be considered on occasion where there is a strong and compelling rationale supported by editorial pre-approval.

REVISED SUBMISSIONS

Article structure

Subdivision - numbered sections

Divide your article into clearly defined and numbered sections. Subsections should be numbered 1.1 (then 1.1.1, 1.1.2, ...), 1.2, etc. (the abstract is not included in section numbering). Use this numbering also for internal cross-referencing: do not just refer to 'the

text'. Any subsection may be given a brief heading. Each heading should appear on its own separate line.

Introduction

State the objectives of the work and provide an adequate background, avoiding a detailed literature survey or a summary of the results.

Material and methods

Provide sufficient details to allow the work to be reproduced by an independent researcher. Methods that are already published should be summarized, and indicated by a reference. If quoting directly from a previously published method, use quotation marks and also cite the source. Any modifications to existing methods should also be described.

Theory/calculation

A Theory section should extend, not repeat, the background to the article already dealt with in the Introduction and lay the foundation for further work. In contrast, a Calculation section represents a practical development from a theoretical basis.

Results

Results should be clear and concise.

Discussion

This should explore the significance of the results of the work, not repeat them. A combined Results and Discussion section is often appropriate. Avoid extensive citations and discussion of published literature.

Conclusions

The main conclusions of the study may be presented in a short Conclusions section, which may stand alone or form a subsection of a Discussion or Results and Discussion section.

Appendices

If there is more than one appendix, they should be identified as A, B, etc. Formulae and equations in appendices should be given separate numbering: Eq. (A.1), Eq. (A.2), etc.; in a subsequent appendix, Eq. (B.1) and so on. Similarly for tables and figures: Table A.1; Fig. A.1, etc.

Essential title page information

- The title page must be the first page of the manuscript file.
 - *Title*. Concise and informative. Titles are often used in information-retrieval systems. Avoid abbreviations and formulae where possible.
 - *Author names and affiliations*. Where the family name may be ambiguous (e.g., a double name), please indicate this clearly. Present the authors' affiliation addresses (where the actual work was done) below the names. Indicate all affiliations with a lower-case superscript letter immediately after the author's name and in front of the appropriate address. Provide the full postal address of each affiliation, including the country name, and, if available, the e-mail address of each author.
 - *Corresponding author*. Clearly indicate who will handle correspondence at all stages of refereeing and publication, also post-publication. **Ensure that telephone**

and fax numbers (with country and area code) are provided in addition to the e-mail address and the complete postal address.

- *Present/permanent address.* If an author has moved since the work described in the article was done, or was visiting at the time, a "Present address" (or "Permanent address") may be indicated as a footnote to that author's name. The address at which the author actually did the work must be retained as the main, affiliation address. Superscript Arabic numerals are used for such footnotes.

Abstract

A concise and factual abstract is required. The abstract should state briefly the purpose of the research, the principal results and major conclusions. An abstract is often presented separately from the article, so it must be able to stand alone. For this reason, References should be avoided, but if essential, then cite the author(s) and year(s). Also, non-standard or uncommon abbreviations should be avoided, but if essential they must be defined at their first mention in the abstract itself. The abstract should not exceed 200 words in length and should be submitted on a separate page following the title page.

Graphical abstract

Although a graphical abstract is optional, its use is encouraged as it draws more attention to the online article. The graphical abstract should summarize the contents of the article in a concise, pictorial form designed to capture the attention of a wide readership. Graphical abstracts should be submitted as a separate file in the online submission system. Image size: Please provide an image with a minimum of 531 × 1328 pixels (h × w) or proportionally more. The image should be readable at a size of 5 × 13 cm using a regular screen resolution of 96 dpi. Preferred file types: TIFF, EPS, PDF or MS Office files. You can view [Example Graphical Abstracts](#) on our information site. Authors can make use of Elsevier's [Illustration Services](#) to ensure the best presentation of their images and in accordance with all technical requirements.

Highlights

Highlights are mandatory for this journal. They consist of a short collection of bullet points that convey the core findings of the article and should be submitted in a separate editable file in the online submission system. Please use 'Highlights' in the file name and include 3 to 5 bullet points (maximum 85 characters, including spaces, per bullet point). You can view [example Highlights](#) on our information site.

Keywords

Include a list of four to six keywords following the Abstract. Keywords should be selected from the APA list of index descriptors unless otherwise approved by the Editor.

Abbreviations

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

Acknowledgements

Collate acknowledgements in a separate section at the end of the article before the references and do not, therefore, include them on the title page, as a footnote to the title or

otherwise. List here those individuals who provided help during the research (e.g., providing language help, writing assistance or proof reading the article, etc.).

Formatting of funding sources

List funding sources in this standard way to facilitate compliance to funder's requirements:

Funding: This work was supported by the National Institutes of Health [grant numbers xxxx, yyyy]; the Bill & Melinda Gates Foundation, Seattle, WA [grant number zzzz]; and the United States Institutes of Peace [grant number aaaa].

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

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

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

Math formulae

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

Footnotes

Footnotes should be used sparingly. Number them consecutively throughout the article. Many word processors build footnotes into the text, and this feature may be used. Should this not be the case, indicate the position of footnotes in the text and present the footnotes themselves separately at the end of the article.

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General points

- Make sure you use uniform lettering and sizing of your original artwork.
- Preferred fonts: Arial (or Helvetica), Times New Roman (or Times), Symbol, Courier.
- Number the illustrations according to their sequence in the text.
- Use a logical naming convention for your artwork files.
- Indicate per figure if it is a single, 1.5 or 2-column fitting image.
- For Word submissions only, you may still provide figures and their captions, and tables within a single file at the revision stage.
- Please note that individual figure files larger than 10 MB must be provided in separate source files.

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You are urged to visit this site; some excerpts from the detailed information are given here.

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Regardless of the application used, when your electronic artwork is finalized, please 'save as' or convert the images to one of the following formats (note the resolution requirements for line drawings, halftones, and line/halftone combinations given below):

EPS (or PDF): Vector drawings. Embed the font or save the text as 'graphics'.

TIFF (or JPG): Color or grayscale photographs (halftones): always use a minimum of 300 dpi.

TIFF (or JPG): Bitmapped line drawings: use a minimum of 1000 dpi.

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- Supply files that are too low in resolution.
- Submit graphics that are disproportionately large for the content.

Color artwork

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Ensure that each illustration has a caption. A caption should comprise a brief title (**not** on the figure itself) and a description of the illustration. Keep text in the illustrations themselves to a minimum but explain all symbols and abbreviations used.

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

Citation in text

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

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As a minimum, the full URL should be given and the date when the reference was last accessed. Any further information, if known (DOI, author names, dates, reference to a

source publication, etc.), should also be given. Web references can be listed separately (e.g., after the reference list) under a different heading if desired, or can be included in the reference list.

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

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Please ensure that the words 'this issue' are added to any references in the list (and any citations in the text) to other articles in the same Special Issue.

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Reference formatting

There are no strict requirements on reference formatting at submission. References can be in any style or format as long as the style is consistent. Where applicable, author(s) name(s), journal title/book title, chapter title/article title, year of publication, volume number/book chapter and the pagination must be present. Use of DOI is highly encouraged. The reference style used by the journal will be applied to the accepted article by Elsevier at the proof stage. Note that missing data will be highlighted at proof stage for the author to correct. If you do wish to format the references yourself they should be arranged according to the following examples: Oguro, M., Imahiro, S., Saito, S., Nakashizuka, T. (2015). Mortality data for Japanese oak wilt disease and surrounding forest compositions. Mendeley Data, v1. <http://dx.doi.org/10.17632/xwj98nb39r.1>

Supplementary material

Supplementary material such as applications, images and sound clips, can be published with your article to enhance it. Submitted supplementary items are published exactly as they are received (Excel or PowerPoint files will appear as such online). Please submit your material together with the article and supply a concise, descriptive caption for each supplementary file. If you wish to make changes to supplementary material during any stage of the process, please make sure to provide an updated file. Do not annotate any corrections on a previous version. Please switch off the 'Track Changes' option in Microsoft Office files as these will appear in the published version.

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This journal encourages and enables you to share data that supports your research publication where appropriate, and enables you to interlink the data with your published articles. Research data refers to the results of observations or experimentation that validate research findings. To facilitate reproducibility and data reuse, this journal also encourages you to share your software, code, models, algorithms, protocols, methods and other useful materials related to the project.

Below are a number of ways in which you can associate data with your article or make a statement about the availability of your data when submitting your manuscript. If you are sharing data in one of these ways, you are encouraged to cite the data in your manuscript and reference list. Please refer to the "References" section for more information about data citation. For more information on depositing, sharing and using research data and other relevant research materials, visit the [research data](#) page.

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Data statement

To foster transparency, we encourage you to state the availability of your data in your submission. This may be a requirement of your funding body or institution. If your data is unavailable to access or unsuitable to post, you will have the opportunity to indicate why during the submission process, for example by stating that the research data is confidential. The statement will appear with your published article on ScienceDirect. For more information, visit the [Data Statement page](#).

Appendix 1.2 Full Search Strategy

	String	
Search	S1	Executive Function*
Terms:	S2	Cognitive Behavior Therapy
Subject		
Headings		
Search Terms	S3	(executive function* or dysexecutive function* or executive skills or neuropsych* predictors or executive deficits or predictors of treatment response)
(Keywords, Title, Abstract)	S4	(cbt or cognitive behavio* therapy or Third wave or 3rd wave or (acceptance n2 commitment therapy) or cognitive therapy or behavio?ral activation or cognitive behavio?ral analysis system of psychotherapy or dialetical behavio* therapy or meta cognitive therapy or metacognitive therapy or mindfulness based cognitive therapy or schema therapy or functional analytic psychotherapy or integrative behavio?r couple therapy or compassion focussed therapy or compassionate mind training or motivational interviewing)
Combination	S5	S1 OR S3
of Search	S6	S2 OR S4
Terms	S7	S5 AND S6
	(Final)	

Appendix 1.3 Data Extraction Form

Article Code ____

Based on NICE data extraction form (BPS & Gaskell 2007)

Extraction Item	Details	
Citation		
Reviewer		
Type of Study <i>Type and part of bigger trial?</i>		
Study country		
Ethical standards		
Study Aims		
Sample		
Inclusion criteria		
Exclusion Criteria		
Participant Characteristics: Comorbidities; Previous/ concurrent treatments		
Sample Type and where recruited from		
Important differences between groups and was this controlled for?		
Was recruitment % reported		
Sample size and groups		
CBT type		
CBT Protocol Description		
Control Group Description (if applicable)		
Ethical considerations		
Allocation		
Randomisation and blinding (if applicable)		
Data Collection		
Executive Functioning Measures / What it measures		
Other Neuro Measures		
Symptom Measures		
Methods		
Data Analysis		
Analysis <i>Type of analysis</i>		
Attrition (%)		
Finding Summary		
Findings		
Implications		
Strengths		
Limitations		

Appendix 1.4 Full inclusion/exclusion criteria

Author/Year	Inclusion	Exclusion
Braga et al (2016)	+ 18-65 Years + Primary diagnosis of OCD (SCID-I) + 16+ on Y-BOCS	- Lifetime diagnosis of neurological disorders - Psychosis, ASD, ID - Current alcohol or drug abuse
Carter et al., (2018)	+ 18 years and over + MDD (SCID) + Free of centrally acting drug other than hypnotic and contraception	- Schizophrenia or bipolar diagnosis - Major medical condition - Failure to respond to trial of CBT/ST in the past year
D'Alcante et al (2012)	+ 18-65 Years + Primary Diagnosis of OCD (DSM-IV)	- Prior exposure to psychotropic medication or CBT - General medical condition - Severe mental illness other than OCD
Deckersbach et al (2018)	+ English Speakers + 18-65 Years + Diagnosis of Bipolar I (DSM-IV) + Current MDD + Stable Pharmacology	- Previous CBT treatment - Rapid cycling or current mixed episode Bipolar Disorder subtype - fMRI contraindications - Serious medical conditions - Neurological disorder (including TBI) - Lifetime schizophrenia spectrum disorder - Substance/alcohol use disorder within the last year - IQ < 80 (measured on WART)
Dobkin et al (2012)	+ Parkinson's disease by research criteria + Primary Major Depression, Dysthymia, or Depression NOS per the SCID DSM-IV + CGI-S ≥ 4 + Ages 35–85 + Stable medication regimen ≥ 6 weeks + Family member or friend willing to participate.	- Dementia [score below 5th percentile for age on memory and at least one other subscale on the Mattis Dementia Rating Scale) - Offtime $\geq 50\%$ of the day - Suicidal Ideation - Unstable medical conditions - Bipolar, Psychotic Spectrum, or Substance Abuse Disorders (DSM-IV); - Receiving CBT elsewhere.
Goodkind et al (2016)	+ 60+ years	- Active suicidality

	<ul style="list-style-type: none"> + Diagnostic criteria for minor/major depression + 15+ on CES-D + Primary diagnosis of major depression or dysthymia on MINI 	<ul style="list-style-type: none"> - Psychosis - Substance/alcohol abuse - Manic episode in last year - <25 on MMSE
Julian & Mohr (2006)	<ul style="list-style-type: none"> + Diagnosis of MS: relapsing-remitting or secondary progressive disease course + Diagnosis of current MDD (SCID) + 16+ on HAM-D and BDI + No other psychological or pharmacological treatment during study 	<ul style="list-style-type: none"> - DSM-IV Axis I psychiatric disorder other than MDD or GAD - <5th percentile on 3/6 cognitive domains - Severe suicidal ideation - Corticosteroid treatment within 30 days - Initiation of treatment with an interferon medication within previous 2 months - Current MS exacerbation - Head Injury or neurological disorder other than MS - Current or planned pregnancy - Impairment in visual acuity precluding assessment - Current psychological or pharmacological treatment for depression
Mohlman & Gorman (2005)	<ul style="list-style-type: none"> + 60+ years + Diagnosis of GAD (DSM-IV) + Read and write in English 	<ul style="list-style-type: none"> - Suicidality last 6 months - Concurrent treatment - Never experienced psychotic symptoms - No antidepressants or anxiolytics
Mohlman (2013)	<ul style="list-style-type: none"> + 60+ years + Diagnosis of GAD (SCID) + +24 on MMSE + Average or better range in BNT 	<ul style="list-style-type: none"> - No anxiety medication
Moritz et al (2005)	<ul style="list-style-type: none"> + OCD Diagnosis (DSM-V) using neuropsychiatric interview + 18+ 	<ul style="list-style-type: none"> - Somatic or psychopathological syndromes
Vandborg et al (2016)	<ul style="list-style-type: none"> + OCD Diagnosis (DSM-IV) + 18-60 Years + Danish native language + 16+ Y-BOCS 	<ul style="list-style-type: none"> - Neurological and psychiatric co-morbidity except anxiety disorders secondary to OCD and Cluster C personality disorders - HDRS > 17 - Pharmacological treatment other than SRIs - Onset of treatment with SRIs less than 3 months before onset of CBT

Appendix 1.5 Quality Ratings

Ratings: 1 = Strong 2= Moderate 3 = Weak	Global Rating	A. Selection Bias	B. Study Design	C. Confounders	D. Blinding	E. Data Collection Methods	F. Withdrawal and Drop-Outs	Number of EF Tests
Braga et al (2016)								2
Carter et al., (2018)								4
D'Alcante et al (2012)								6
Deckersbach et al (2017)								3
Dobkin et al (2012)								1
Goodkind et al (2016)								3
Julian & Mohr (2006)								2
Mohlman & Gorman (2005)								2
Mohlman (2013)								2
Moritz et al (2005)								3
Vandborg et al (2016)								6

Appendix 1.6 Table of Executive Functioning scores reported for each test pre-CBT

Appendix E											
Pooled		Stroop		Trails			Verbal Fluency	Card Sorting			Digit Span
What EF it tests		Inhibitory control, mental flexibility and selective attention		Mental Flexibility				Concept formation, problem solving, explaining groups abstractly			Working Memory
Subtest		CW Incongruent	Interference	Stroop Effect	B-A	Switching (DKEFS)	B	Perseverative error Percentage	Completed Categories	Free Sorting (DKEFS)	Backwards Total
Braga et al (2016) (Raw Score M (SE))		39.6 (1.60)	1.23 (1.00)		56.2 (6.89)						6.48 (0.31) 15.3 (0.58)
Carter et al., (2018) z scores M(SD)	0.15 (0.45)										
D'Alcante et al (2012) M (SE)				14.29 (1.35)			89.66 (9.55)	8.79 (2.47)	2.77 (0.31)		Not reported 16.22 (1.04)
Deckersbach et al (2017) Scaled Scores M (SD)		10.41 (2.00)	9.71 (2.62)			10.23 (2.08)				10.25 (3.00)	
Dobkin et al (2012) Seconds M (SD)					82.15 (71.20)						
Goodkind et al (2016)		Not reported					Not reported	Not reported			
Julian & Mohr (2006)		Not reported					Not reported				
Mohlman & Gorman (2005) M (SD)		Not reported						Not reported			
WL	138.38 (46.12)										
Intact EF	168.6 (10.45)										
Improved EF	117.00 (7.96)										
ED	116.26 (11.27)										
Mohlman (2013) t Scores M(SD)		50.42 (12.47)					50.98 (12.33) 52.18 (10.49)				50.39 (13.20)
Moritz et al (2005): Non-						81.16 (43.86) 76.47	13.21 (5.40) 13.64	22.65 (13.86) 19.01	3.75 (2.08) 4.02		7.36 (2.73) 7.21 (2.72)

respon;		(35.89)	(5.71)	(12.28)	(2.07)	
Resonders						
Vandborg et al	4.56 (9.32)	73.44	39.19		3.81	14.63
(2016) M(SD):	1.36 (4.70)	(39.53)	(14.04)		(2.26)	(3.93)
Recovered;		64.78	43.30		4.48	14.39
Non-recovered		(27.36)	(12.51)		(1.47)	(3.73)

Appendix 2.1 Author Submission Guidelines for *Cognitive and Behavioural Practice*
<https://www.elsevier.com/journals/cognitive-and-behavioral-practice/1077-7229/guide-for-authors>

Introduction

Cognitive and Behavioral Practice is a quarterly international journal with the primary mission of clinical dissemination: to bridge the gap between published clinical research and the actual clinical practice of cognitive and behavioral therapies. *Cognitive and Behavioral Practice* publishes clinically rich accounts of innovative assessment and therapeutic procedures that are clearly grounded in evidence-based practice. The primary focus is on application and implementation of procedures. Accordingly, topics are selected to address current challenges facing practitioners, both in terms of technique, process, and the content of treatment. To meet this goal, articles may include rich descriptions of clinical interventions, examples of client-therapist dialog, embedded video clips readers can view on line, and/or significant case descriptions. This journal is for the practicing mental health clinician, instructors, and researchers with an interest in the clinical dissemination of their findings. Continuing education examinations are included in each issue.

Types of contributions

1. **Teaching Clinical Strategies:** These papers focus on educating the readership about how to conduct assessments and/or treatments with particular populations within an empirically supported framework. They must include case illustrations and preferably will include transcript material or video demonstrations.
2. **Teaching about other aspects of Clinical Practice:** These papers might deal with supervision, legal and ethical issues, managed care issues, or giving legal testimony, for instance. There is no limit on the topics as long as they are relevant to clinical practice.
3. **Research Reports:** These are papers that present clinically relevant research results. They may present new data on assessment, treatment or psychopathology. If they are short articles, the authors need only to point out briefly the clinical utility of the findings. Longer papers must include detailed case illustrations and, hopefully, transcript material to make the research findings clinically realistic and immediate.
4. **Treatment Development Reports:** These papers might describe the theoretical foundation and iterative process used to develop a novel intervention or describe how an established treatment is adapted to a novel population or clinical setting. These papers might highlight issues of acceptability, feasibility, and initial outcomes, but competitive papers will highlight detailed description of the structure, strategies, and techniques the treatment employs. Case examples and/or video clips of interventions are encouraged that highlight how the treatment is implemented and how barriers/challenges are addressed.
5. **Special Series:** These are collections of papers focusing on a special clinical topic. There is a Series Editor who develops the theme and then invites other clinicians and scientists to write topical papers that fit into the theme.
6. **Case Conferences:** Like special series, case conferences are a collection of papers that focus upon a theme; in this instance, it is how to assess and treat a particular patient. The Case Conference Organizer writes up a detailed description of a case and selects four to eight Case Conference Respondents. The Case Conference Respondents write 6- to 20-page papers describing how they would assess and treat the patient. Also, the Respondents attend to special issues involved with treatment.

Typically, the Organizer writes up a summary of the similarities and differences among the approaches taken by the Respondents.

7. Expert Clinical Commentaries: These are brief articles (solicited and unsolicited) in which experts in the field comment on the most up-to-date clinical topics, controversies, or discoveries within their expertise, and/or comment on an agenda for clinical research. These are roughly 3,000 words in length and are structured as a launching point for clinical practice and/or future clinical research.
8. Clinical Reviews. These are regular length review articles that focus specifically on clinical strategy and existing evidence base for that strategy.

Contact details

Questions about the appropriateness of a manuscript for Cognitive and Behavioral Practice should be directed (prior to submission) to the Editorial Office, at bonnieb@bu.edu (Bonnie Brown, Editorial Assistant, Cognitive and Behavioral Practice, Center for Anxiety, Boston University, 648 Beacon Street, 6th Floor, Boston, MA 02215).

Submission checklist

You can use this list to carry out a final check of your submission before you send it to the journal for review. Please check the relevant section in this Guide for Authors for more details.

Ensure that the following items are present:

One author has been designated as the corresponding author with contact details:

- E-mail address
- Full postal address

All necessary files have been uploaded:

Manuscript:

- Include keywords
- All figures (include relevant captions)
- All tables (including titles, description, footnotes)
- Ensure all figure and table citations in the text match the files provided
- Indicate clearly if color should be used for any figures in print

Graphical Abstracts / Highlights files (where applicable)

Supplemental files (where applicable)

Further considerations

- Manuscript has been 'spell checked' and 'grammar checked'
- All references mentioned in the Reference List are cited in the text, and vice versa
- Permission has been obtained for use of copyrighted material from other sources (including the Internet)
- A competing interests statement is provided, even if the authors have no competing interests to declare
- Journal policies detailed in this guide have been reviewed
- Referee suggestions and contact details provided, based on journal requirements

For further information, visit our [Support Center](#).

Clinical trial results

Randomized Clinical Trials: Use of CONSORT Reporting Standards

Title of Manuscript

The title of a manuscript should be accurate, fully explanatory, and preferably no longer than 12 words. The title should reflect the content and population(s) studied. If the paper reports a randomized clinical trial (RCT), this should be indicated in the title, and the CONSORT (Consolidated Standards of Reporting Trials) criteria must be used for reporting purposes.

ABCT Journals require the registration of all clinical trials in a public trials registry. These registries set standards for the uniform reporting of the minimum registration data set as determined by the World Health Organization and the International Committee of Medical Journal Editors

(<http://www.clinicaltrials.gov>, <http://www.anzctr.org.au>, <http://www.umin.ac.jp/ctr>, <http://www.isrctn.com>, <http://www.trialregister.nl/trialreg/index.asp/>). Clinical trials are defined as any study that prospectively assigns human subjects to intervention or comparison groups to evaluate the cause-and-effect relationship between an intervention and an outcome.

Manuscripts that report randomized clinical trials are required to include a flow diagram of the progress through the phases of the trial and a checklist that identifies where in the manuscript the various criteria are addressed (see <http://www.consort-statement.org> for a full description of reporting procedures). The checklist should be placed in an Appendix of the manuscript for review purposes. When a study is not fully consistent with the CONSORT statement, the limitation should be acknowledged and discussed in the text of the manuscript. ABCT journals do not view single case studies as being included among randomized clinical trials and are, therefore, exempt for these standards.

For follow-up studies of previously published clinical trials, authors should submit a flow diagram of the progress through the phases of the trial and follow-up. The CONSORT checklist should be completed to the extent possible, especially for the Results and Discussion sections of the manuscript.

ABCT Journals require the use of the CONSORT reporting standards (e.g., a checklist and flow diagram) for randomized clinical trials, consistent with the policy established by the International Committee of Medical Journal Editors' Uniform Requirements for Medical Journals.

Article structure

Subdivision - unnumbered sections

Divide your article into clearly defined sections. Each subsection is given a brief heading. Each heading should appear on its own separate line. Subsections should be used as much as possible when cross-referencing text: refer to the subsection by heading as opposed to simply 'the text'.

If you are submitting original research, the structure of your paper should typically reflect the stages of the research process:

Introduction
Method
Results
Discussion

However, as contributions to this journal take various forms (including empirical research, review articles, methodological papers, and case studies), authors are urged to organize their manuscripts in ways that make sense to their particular article type.

A detailed description of all possible sections is shown below.

Introduction

State the objectives of the work and provide an adequate background, avoiding a detailed literature survey or a summary of the results.

Methods

Provide sufficient detail to allow the work to be reproduced. Methods already published should be indicated by a reference: only relevant modifications should be described.

Results

Results should be clear and concise.

Discussion

This should explore the significance of the results of the work, not repeat them. Avoid extensive citations and discussion of published literature.

Conclusions

The main conclusions of the study may be presented in a short Conclusions section, which may stand alone or form a subsection of a Discussion or Results and Discussion section.

Glossary

Please supply, as a separate list, the definitions of field-specific terms used in your article.

Appendices

If there is more than one appendix, they should be identified as A, B, etc. Formulae and equations in appendices should be given separate numbering: Eq. (A.1), Eq. (A.2), etc.; in a subsequent appendix, Eq. (B.1) and so on. Similarly for tables and figures: Table A.1; Fig. A.1, etc.

Essential title page information

- ***Title.*** Concise and informative. Titles are often used in information-retrieval systems. Avoid abbreviations and formulae where possible.
- ***Author names and affiliations.*** Please clearly indicate the given name(s) and family name(s) of each author and check that all names are accurately spelled. You can add your name between parentheses in your own script behind the English transliteration. Present the authors' affiliation addresses (where the actual work was done) below the names. Indicate all affiliations with a lower-case superscript letter immediately after the author's

name and in front of the appropriate address. Provide the full postal address of each affiliation, including the country name and, if available, the e-mail address of each author.

- ***Corresponding author.*** Clearly indicate who will handle correspondence at all stages of refereeing and publication, also post-publication. This responsibility includes answering any future queries about Methodology and Materials. **Ensure that the e-mail address is given and that contact details are kept up to date by the corresponding author.**

- ***Present/permanent address.*** If an author has moved since the work described in the article was done, or was visiting at the time, a 'Present address' (or 'Permanent address') may be indicated as a footnote to that author's name. The address at which the author actually did the work must be retained as the main, affiliation address. Superscript Arabic numerals are used for such footnotes.

The journal uses a masked reviewing system for all submissions. The first page of the manuscript should omit the authors' names and affiliations but should include the title of the manuscript and the date it is submitted. Footnotes containing information pertaining to the authors' identity or affiliations should not be included in the manuscript, but may be provided after a manuscript is accepted. Every effort should be made to see that the manuscript itself contains no clues to the authors' identity. Authors should be careful to keep a copy of the manuscript to guard against loss.

Cover Letter (including Authors' Names and Contact Information)

The cover letter accompanying the manuscript submission must include all authors' names and affiliations to avoid potential conflicts of interest in the review process. Addresses and phone numbers, as well as email addresses and fax numbers, should be provided for all authors for possible use by the editorial office and later by the production department.

Only original papers will be considered. Manuscripts are accepted for review with the understanding that the same work has not been and will not be published - nor is presently submitted - elsewhere, and that all persons listed as authors have given their approval for the submission of the paper; further, that any person cited as a source of personal communications has approved such citation. Written authorization may be required, at the Editors' discretion. Articles and any other material published in Cognitive and Behavioral Practice represent the opinions of the author(s) and should be construed as reflecting the opinions of the Editors, the Association, or the Publisher.

Abstract

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

Graphical abstract

Although a graphical abstract is optional, its use is encouraged as it draws more attention to the online article. The graphical abstract should summarize the contents of the article in a concise, pictorial form designed to capture the attention of a wide readership. Graphical abstracts should be submitted as a separate file in the online submission system. Image size: Please provide an image with a minimum of 531 × 1328 pixels (h × w) or proportionally more. The image should be readable at a size of 5 × 13 cm using a regular

screen resolution of 96 dpi. Preferred file types: TIFF, EPS, PDF or MS Office files. You can view [Example Graphical Abstracts](#) on our information site.

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Highlights are mandatory for this journal. They consist of a short collection of bullet points that convey the core findings of the article and should be submitted in a separate editable file in the online submission system. Please use 'Highlights' in the file name and include 3 to 5 bullet points (maximum 85 characters, including spaces, per bullet point). You can view [example Highlights](#) on our information site.

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Immediately after the abstract, provide 3-5 keywords, using American spelling and avoiding general and plural terms and multiple concepts (avoid, for example "and", "of"). Be sparing with abbreviations: only abbreviations firmly established in the field may be eligible. These keywords will be used for indexing purposes.

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

Acknowledgements

For reasons of assisting with double-blind review, collate acknowledgements in a separate section on the title page beneath the author information. List here those individuals who provided help during the research (e.g., providing language help, writing assistance or proof reading the article, etc.).

Formatting of funding sources

List funding sources in this standard way to facilitate compliance to funder's requirements:

Funding: This work was supported by the National Institutes of Health [grant numbers xxxx, yyyy]; the Bill & Melinda Gates Foundation, Seattle, WA [grant number zzzz]; and the United States Institutes of Peace [grant number aaaa].

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

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

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

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Follow internationally accepted rules and conventions: use the international system of units (SI). If other units are mentioned, please give their equivalent in SI.

Math formulae

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

Footnotes

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

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- Aim to use the following fonts in your illustrations: Arial, Courier, Times New Roman, Symbol, or use fonts that look similar.
- Number the illustrations according to their sequence in the text.
- Use a logical naming convention for your artwork files.
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- Size the illustrations close to the desired dimensions of the published version.
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Regardless of the application used other than Microsoft Office, when your electronic artwork is finalized, please 'Save as' or convert the images to one of the following formats (note the resolution requirements for line drawings, halftones, and line/halftone combinations given below):

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References

Citation in text

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As a minimum, the full URL should be given and the date when the reference was last accessed. Any further information, if known (DOI, author names, dates, reference to a source publication, etc.), should also be given. Web references can be listed separately (e.g., after the reference list) under a different heading if desired, or can be included in the reference list.

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This journal encourages you to cite underlying or relevant datasets in your manuscript by citing them in your text and including a data reference in your Reference List. Data

references should include the following elements: author name(s), dataset title, data repository, version (where available), year, and global persistent identifier. Add [dataset] immediately before the reference so we can properly identify it as a data reference. The [dataset] identifier will not appear in your published article.

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Please ensure that the words 'this issue' are added to any references in the list (and any citations in the text) to other articles in the same Special Issue.

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Users of Mendeley Desktop can easily install the reference style for this journal by clicking the following link:

<http://open.mendeley.com/use-citation-style/cognitive-and-behavioral-practice>

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Reference style

Text: Citations in the text should follow the referencing style used by the American Psychological Association. You are referred to the Publication Manual of the American Psychological Association, Sixth Edition, ISBN 978-1-4338-0561-5, copies of which may be [ordered online](#) or APA Order Dept., P.O.B. 2710, Hyattsville, MD 20784, USA or APA, 3 Henrietta Street, London, WC3E 8LU, UK.

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

Examples:

Reference to a journal publication:

Van der Geer, J., Hanraads, J. A. J., & Lupton, R. A. (2010). The art of writing a scientific article. *Journal of Scientific Communications*, 163, 51–59.

<https://doi.org/10.1016/j.Sc.2010.00372>.

Reference to a journal publication with an article number:

Van der Geer, J., Hanraads, J. A. J., & Lupton, R. A. (2018). The art of writing a scientific article. *Heliyon*, 19, e00205. doi:10.1016/j.heliyon.2018.e00205.

Reference to a book:

Strunk, W., Jr., & White, E. B. (2000). *The elements of style*. (4th ed.). New York: Longman, (Chapter 4).

Reference to a chapter in an edited book:

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

Reference to a website:

Cancer Research UK. Cancer statistics reports for the UK. (2003).

<http://www.cancerresearchuk.org/aboutcancer/statistics/cancerstatsreport/> Accessed 13 March 2003.

Reference to a dataset:

[dataset] Oguro, M., Imahiro, S., Saito, S., Nakashizuka, T. (2015). *Mortality data for Japanese oak wilt disease and surrounding forest compositions*. Mendeley Data, v1.

<https://doi.org/10.17632/xwj98nb39r.1>.

Reference to a conference paper or poster presentation:

Engle, E.K., Cash, T.F., & Jarry, J.L. (2009, November). The Body Image Behaviours Inventory-3: Development and validation of the Body Image Compulsive Actions and Body Image Avoidance Scales. Poster session presentation at the meeting of the Association for Behavioural and Cognitive Therapies, New York, NY.

Appendix 2.2 ACT Group Protocol Outline (developed by Dr Clive Ferenbach and Dr David Grinter)

Session	Theme	Summary of Content (Metaphors/Exercises)	Homework
1	Creative Hopelessness	(a) Monster and the rope; (b) Zebras don't get ulcers; (c) ACT in a nutshell	(a)'Just noticing' track on Mindfulness CD; (b) Adding to 'drop the rope' metaphor sheet
2	Values	(a) Passengers on a bus; (b) Verbal explanation of values; (c) Values and Goals as compass; (d) Miracle question; (e) Future birthday exercise (incorporating mindfulness)	(a) Daily practice of mindfulness; (b) Add to values worksheet; (c) Take values based steps
3	Noticing self, Present moment and Acceptance	(a) Noticing self exercise and discussion of thinking vs. Noticing self; (b) Mountain metaphor; (c) Mindful eating exercise; (d) Acceptance of emotion mindfulness exercise' (e) Discussion of metacognitive attitudes towards emotion	(a) Mindfulness exercises: 'Noticing self' and 'Everyday noticing; (b) Doing a task mindfully
4	Defusion, Acceptance and Conceptualise d Self	(a) Recap thinking vs. Noticing self; (b) Radio metaphor; (c) Nursery rhyme exercise; (d) Lemon, lemon, lemon exercise; (e) Writing thoughts on cards and using defusion; (f) Fly fishing metaphor; (g) Thoughts not controlling actions; (h) 'Yes' and 'no' exercise	(a) Mindfulness exercises: 'Leaves on a stream' and 'Calling out your struggle'; (b) Doing tasks mindfully and noticing thoughts/feelings
5	Committed action (Obstacles and future planning)	(a) General mindfulness exercise; (b) Recap passengers on a bus; (c) Flipchart exercise – obstacles and barriers to goals – solutions and compensatory strategies (SOC theory); (d) My action plan worksheet; (e) The travelling partners metaphor; (f) Acceptance of emotion mindfulness exercise; (g) My goals worksheet	(a) Continued mindfulness CD practice; (b) Piece of committed action; (c) Continue daily mindfulness of tasks; (d) Further work on 'My goals' worksheet
6	Summary	(a) Noticing self mindfulness exercise; (b) 'My goals' worksheet continuation; (c) School of fish exercise; (d) Leaves on a stream exercise; (e) Discuss endings	(a) Continuation of handouts

Appendix 2.3 ACT-OA Questionnaire (*Original text size 14*) (Developed by Dr Clive Ferenbach and Elizabeth Dewey)

**The Acceptance and Commitment Therapy measure of change
for Older Adults (ACT-OA)**

Please indicate the extent to which you agree or disagree with each of the following statements.

1	2	3	4	5	6
Strongly disagree	Moderately disagree	Slightly disagree	Slightly agree	Moderately agree	Strongly agree

Think of the last week or so when answering.

	Strongly disagree	Moderately disagree	Slightly disagree	Slightly agree	Moderately agree	Strongly agree
1. I was willing to experience unwanted or painful thoughts and feelings.	1	2	3	4	5	6
2. I felt clear about what's most important to me in life.	1	2	3	4	5	6
3. I felt able to take a step back from difficult thoughts, and avoid getting too caught up in them	1	2	3	4	5	6
4. I felt clear about how I could take steps to do more of what's important to me.	1	2	3	4	5	6
5. I didn't let my own fears and doubts get in the way of taking action toward my goals.	1	2	3	4	5	6

Sum items for total score out of 30.

Appendix 2.4 NHS Research and Development and REC Approval

WoSRES *West of Scotland Research Ethics Service*

Dr Hamish McLeod
Programme Director for Doctorate in Clinical
Psychology and Senior Lecturer
University of Glasgow
Mental Health and Wellbeing 1st Floor Admin
Building
Gartnavel Royal Hospital
Glasgow
G12 0XH



West of Scotland REC 1
Research Ethics
Clinical Research and Development
West Glasgow Ambulatory Care Hospital
Dalnair Street
Glasgow
G3 8SJ
(Formerly Yorkhill Childrens Hospital)

Date 22 September 2017
Direct line 0141 232 1807
E-mail WoSREC1@ggc.scot.nhs.uk

Dear Dr McLeod

Study title: **A Feasibility Study of the Process of Therapeutic Change Using Acceptance and Commitment Therapy (ACT) for Older People in an Inpatient Setting.**
REC reference: 17/WS/0191
IRAS project ID: 223222

Thank you for your letter of 14 September 2017, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information was considered in correspondence by a Sub-Committee of the REC. A list of the Sub-Committee members is attached.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to make a request to postpone publication, please contact hra.studyregistration@nhs.net outlining the reasons for your request.

Confirmation of ethical opinion

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

Conditions of the favourable opinion

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

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

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

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

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

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

Sponsors are not required to notify the Committee of management permissions from host organisations

Registration of Clinical Trials

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

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

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

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

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

Ethical review of research sites

NHS sites

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

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Covering letter on headed paper [Covering Letter]	v1	02 August 2017
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [GCU Insurance]		27 July 2017
GP/consultant information sheets or letters [Psychiatry Letter]	v1	19 June 2017
GP/consultant information sheets or letters [Elizabeth Dewey GP Letter of Participation]	v1	13 September 2017
Interview schedules or topic guides for participants [Interview Schedule]	v1	26 July 2017
Letter from sponsor [Letter of Sponsorship]		26 June 2017
Non-validated questionnaire [ACT-OA Questionnaire]	v1	24 July 2017
Non-validated questionnaire [Elizabeth Dewey T-MIT Questionnaire]	v1	01 July 2014
Other [Elizabeth Dewey Reminder Letter]	v1	13 September 2017
Participant consent form [Elizabeth Dewey Consent v1.2]	1.2	13 September 2017
Participant information sheet (PIS) [Elizabeth Dewey PIS v1.2]	1.2	13 September 2017
REC Application Form [REC_Form_07082017]		07 August 2017
Referee's report or other scientific critique report [Lisa Gadon Peer Review]		12 June 2017
Referee's report or other scientific critique report [Sue Turnbull Peer Review]		28 April 2017
Research protocol or project proposal [Elizabeth Dewey Proposal]	v5	15 May 2017
Response to Request for Further Information [Elizabeth Dewey Response Letter]	v1	14 September 2017
Summary CV for Chief Investigator (CI) [Hamish McLeod CV]		28 July 2017
Summary CV for student [Elizabeth Dewey CV]	v1	19 June 2017
Summary, synopsis or diagram (flowchart) of protocol in non technical language [Plain English Summary]	v1	15 May 2017
Validated questionnaire [BEAQ Questionnaire]		
Validated questionnaire [CFQ Questionnaire]		
Validated questionnaire [HADS Questionnaire]		

Statement of compliance

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

After ethical review

Reporting requirements

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

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

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

User Feedback

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

HRA Training

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

17/WS/0191

Please quote this number on all correspondence

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

Yours sincerely



On behalf of
Dr Malcolm Booth
Chair

Enclosures: List of names and professions of members who were present at the meeting and those who submitted written comments

"After ethical review – guidance for researchers"

Copy to: Mr Raymond Hamill, NHS Lanarkshire

West of Scotland REC 1

Attendance at Sub-Committee of the REC meeting on 18 September 2017

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Dr Peter Hutchison	GP (Vice Chair)	Yes	Chair of Meeting
Dr John D McClure	Statistician	Yes	

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Mrs Abibat Adewumi-Ogunjobi	Acting REC Manager



Dr Hamish McLeod
Senior Lecturer in Clinical Psychology
University of Glasgow
Mental Health and Wellbeing
1st Floor Admin Building
Gartnavel Royal Hospital
Post Code
G12 0XH

R&D Department
Corporate Services Building
Monklands Hospital
Monkscourt Avenue
AIRDRIE
ML6 0JS

Date 6 October 2017
Enquiries to Cynthia Dolier
R&D Facilitator
Direct Line 01236 712460
Email Cynthia.dolier@lanarkshire.scot.nhs.uk

Dear Dr McLeod

Project title: A Feasibility Study of Acceptance and Commitment Therapy, and the process of valued living, for older people in an Inpatient Setting

R&D ID: L17061

I am writing to you as Chief Investigator of the above study to advise that R&D Management approval has been granted for the conduct of your study within NHS Lanarkshire as detailed below:

NAME	TITLE	ROLE	NHSL SITE TO WHICH APPROVAL APPLIES
Elizabeth Dewey	Trainee Clinical Psychologist	Principal Investigator	NHS Lanarkshire

As you are aware, NHS Lanarkshire has agreed to be the Sponsor for your study. On its behalf, the R&D Department has a number of responsibilities; these include ensuring that you understand your own role as Chief Investigator of this study. To help with this we have outlined the responsibilities of the Chief Investigator in the attached document for you information.

All research projects within NHS Lanarkshire will be subject to annual audit via a questionnaire that we will ask you to complete. In addition, we are required to carry out formal monitoring of a proportion of projects, in particular those projects that are Sponsored by NHS Lanarkshire. In either case, you will find it helpful to maintain a well organised Site File. You may find it helpful to use the folder that we have included for that purpose.



For the study to be carried out you are subject to the following conditions:

Conditions

- You are required to comply with Good Clinical Practice, Ethics Guidelines, Health & Safety Act 1999 and the Data Protection Act 1998.
- The research is carried out in accordance with the Scottish Executive's Research Governance Framework for Health and Community Care (copy available via the Chief Scientist Office website: <http://www.show.scot.nhs.uk/cso/> or the Research & Development Intranet site: <http://firstport/sites/randd/default.aspx>).
- You must ensure that all confidential information is maintained in secure storage. You are further obligated under this agreement to report to the NHS Lanarkshire Data Protection Office and the Research & Development Office infringements, either by accident or otherwise, which constitutes a breach of confidentiality.
- Clinical trial agreements (if applicable), or any other agreements in relation to the study, have been signed off by all relevant signatories.
- You must contact the Lead Nation Coordinating Centre if/when the project is subject to any minor or substantial amendments so that these can be appropriately assessed, and approved, where necessary.
- You notify the R&D Department if any additional researchers become involved in the project within NHS Lanarkshire
- You notify the R&D Department when you have completed your research, or if you decide to terminate it prematurely.
- You must send brief annual reports followed by a final report and summary to the R&D office in hard copy and electronic formats as well as any publications.
- If the research involves any investigators who are not employed by NHS Lanarkshire, but who will be dealing with NHS Lanarkshire patients, there may be a requirement for an SCRO check and occupational health assessment. If this is the case then please contact the R&D Department to make arrangements for this to be undertaken and an honorary contract issued.

Please note that the Valuing Questionnaire (Smut), and the amendment to the ACT-OA Questionnaire, V1, dated 24 July 2017 cannot be used until REC approval/acknowledgement is obtained.

I trust these conditions are acceptable to you.

Yours sincerely

Raymond Hamill – Corporate R&D Manager

c.c.

NAME	TITLE	CONTACT ADDRESS	ROLE
Elizabeth Dewey	Trainee Clinical Psychologist	elizabeth.dewey@lanarkshire.scot.nhs.uk elizabethdewey@nhs.net	Principal Investigator
Clive Ferenbach	Senior Clinical Psychologist	cliveferenbach@nhs.net	Clinical Supervisor

Enc 1 x Site File 1 x Responsibilities as Sponsor Notes



Responsibilities as Sponsor

Site File

As an aid to the conduct of your study we have provided a Site File that you may wish to use. As Sponsor of the study we are required to carry out audit of all project, and to conduct detailed monitoring visits for a proportion (approximately 10%) - The study Site File should help you ensure that you have the relevant documentation to assist in this process. If your project is selected for monitoring, we will contact you well in advance to arrange a suitable time.

Our responsibilities as Sponsor are defined within the Research Governance Framework for Health and Community Care. A summary of these, along with those of the Chief Investigator, is provided in the following table for your information.

RESPONSIBILITIES OF CHIEF INVESTIGATOR	NHSL RESPONSIBILITIES AS SPONSOR
Obtain relevant / appropriate Research Ethics opinion.	Assess adequateness of the independent, expert review.
Obtain NHSL Research Management Approval.	Ensure that the Chief/Principle Investigator has the necessary expertise, experience and education to conduct the study.
Ensure that the members of the research team have the necessary expertise, experience and education to perform their roles.	Provide a formal written agreement of sponsorship conditions, and notification of confirmation of the sponsorship role.
Ensure the necessary resources are available for the study.	Provide NHS indemnity to the Chief Investigator and research team.
Act in accordance with regulations set out by your professional body(s) and the conditions of your employment contract.	Provide mechanisms and processes to exploit any potential Intellectual Property.
Identify archiving arrangements at the study outset.	Project monitoring commensurate with risk.
Record and review significant developments that may affect the study, particularly those which put the safety of the individuals at risk or affect the scientific direction and report to the sponsor as appropriate.	Make available local, national and international guidelines, regulations and legislation governing research in the UK.
Record, report and review all untoward medical occurrence (adverse events or reactions) including classification of causality, seriousness and expectedness.	Provide ongoing advice and guidance to promote quality study management and conduct.
Notify R&D and appropriate REC of significant news, changes, amendments and modifications to the study.	Determine the acceptability of the archive arrangements proposed by the Chief Investigator and, if the archive facility becomes unsuitable, provide alternative arrangements.
Maintain a record of all incidents, providing an annual report to the sponsor.	Determine length of archive/retention period for essential study documents and subsequent destruction date
Inform REC and R&D of the study end.	
Maintain a log of archived documents and their location.	
Inform R&D of any publications arising from the study or dissemination of findings.	
Inform R&D of any potential Intellectual Property.	

Appendix 2.5 Amendments to Research Confirmation

Amendment 1.

WoSRES
West of Scotland Research Ethics Service

Ms Elizabeth Dewey
University of Glasgow
Mental Health and Wellbeing
1st Floor Admin Building, Gartnavel Royal Hospital
G12 0XH



West of Scotland REC 1
Research Ethics
Clinical Research and Development
West Glasgow Ambulatory Care Hospital
Dalnair Street
Glasgow
G3 8SJ
(Formerly Yorkhill Childrens Hospital)

Date 15 November 2017
Direct line 0141 232 1807
E-mail WoSREC1@ggc.scot.nhs.uk

Dear Ms Dewey

Study title: A Feasibility Study of the Process of Therapeutic Change Using Acceptance and Commitment Therapy (ACT) for Older People in an Inpatient Setting.
REC reference: 17/WS/0191
Amendment number: REC Ref AM01
Amendment date: 07 November 2017
IRAS project ID: 223222

Thank you for your letter of 07 November 2017, notifying the Committee of the above amendment. The amendment relates to a change of wording in the ACT-OA questionnaire. The Validated valuing questionnaire has also been included due to initial omission.

The Committee does not consider this to be a "substantial amendment" as defined in the Standard Operating Procedures for Research Ethics Committees. The amendment does not therefore require an ethical opinion from the Committee and may be implemented immediately, provided that it does not affect the approval for the research given by the R&D office for the relevant NHS care organisation.

Documents received

The documents received were as follows:

Document	Version	Date
Non-validated questionnaire [ACT-OA Questionnaire]	1.2	04 October 2017
Notice of Non Substantial Amendment	REC Ref AM01	07 November 2017
Validated questionnaire [Valuing Questionnaire]		

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.

17/WS/0191:	Please quote this number on all correspondence
--------------------	---

Yours sincerely

Abibat Adewumi-Ogunjobi
REC Manager

Copy to: Mr Raymond Hamill, NHS Lanarkshire

Amendment 2.

Ms Elizabeth Dewey
University of Glasgow
Mental Health and Wellbeing
1st Floor Admin Building, Gartnavel Royal
Hospital
G12 0XH

West of Scotland REC 1
West of Scotland Research Ethics Service
Clinical Research and Development
West Glasgow Ambulatory Care Hospital
Dalnair Street
Glasgow G3 8SJ
www.nhsggc.org.uk
Date 23 January 2018
Direct line 0141-232-1806
e-mail WosRec1@ggc.scot.nhs.uk

Dear Ms Dewey

Study title: A Feasibility Study of the Process of Therapeutic Change Using Acceptance and Commitment Therapy (ACT) for Older People
REC reference: 17/WS/0191
Amendment number: REC Ref AM02
Amendment date: 19 January 2018
IRAS project ID: 223222

Thank you for your letter of 19 January 2018, notifying the Committee of the above amendment. The amendment is to open the inclusion criteria to include these patients who are already invited to these community ACT groups and not just inpatients

The Committee does not consider this to be a "substantial amendment" as defined in the Standard Operating Procedures for Research Ethics Committees. The amendment does not therefore require an ethical opinion from the Committee and may be implemented immediately, provided that it does not affect the approval for the research given by the R&D office for the relevant NHS care organisation.

Documents received

The documents received were as follows:

Document	Version	Date
Covering letter on headed paper	1	18 January 2018
GP/consultant information sheets or letters [Psychiatry Letter of Participation Outpatient]	1	16 January 2018
GP/consultant information sheets or letters [GP Letter of Participation outpatient]	1	16 January 2018
Non-validated questionnaire [The Acceptance and Commitment Therapy measure of change for Older Adults (ACT-OA)]	2	16 January 2018
Notice of Non Substantial Amendment	REC Ref AM02	19 January 2018
Other [Response Letter outpatient]	1	16 January 2018
Participant consent form [Outpatient]	1	16 January 2018
Participant information sheet (PIS) [Outpatient]	1	16 January 2018
Research protocol or project proposal	6	16 January 2018

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.

17/WS/0191:

Please quote this number on all correspondence

Yours sincerely



Kirsty Burt
Senior Co-ordinator

Copy to:

Mr Raymond Hamill, NHS Lanarkshire
Dr Hamish McLeod, University of Glasgow

Appendix 2.6 Participant Information Sheet



Mental Health & Wellbeing
Administration Building
Gartnavel Royal Hospital
1055 Great Western Road
Glasgow
G12 0XH

Participant Information Sheet

Study Title:

A Feasibility Study of Acceptance and Commitment Therapy with Older People.

Who is conducting the research?

This study is being carried out by:

- Elizabeth Dewey, Trainee Clinical Psychologist and Principal Investigator (NHS Lanarkshire and University of Glasgow)
- Dr Hamish McLeod, Chief Investigator (University of Glasgow)
- Dr Clive Ferenbach, Field Supervisor (Senior Clinical Psychologist, NHS Lanarkshire)

Invitation

You are being invited to take part in a research study. Before you decide if you would like to take part it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. One of the research team will go through this information sheet with you and answer any questions that you have. This should take about 15 minutes. It is important that you take time to decide whether or not you wish to take part.

What is the purpose of the study?

Acceptance and Commitment Therapy (ACT) is a psychological therapy that uses various strategies to help people to accept and respond more adaptively to troublesome thoughts and emotions. ACT also helps individuals to explore what is important in their life and helps people to behave in ways that are consistent with what they value. It can be an effective treatment for people with mental health difficulties. However, we need to learn about the suitability of and benefits of ACT for older people. This research will explore whether it is possible to deliver ACT groups to people over 65 and whether participants find it an acceptable approach. The research will mainly occur from October 2017 until July 2018, your connection to the study will last around 6 months.

The study will be submitted as part of Elizabeth Dewey's research portfolio as part of her requirements for completion of the Doctorate in Clinical Psychology at the University of Glasgow.

Why have I been invited?

We are looking for participants who are over 65 years old, experiencing symptoms of emotional distress, and are going to take part in group therapy. We asked clinicians working in older adult services in Lanarkshire to identify people who meet these criteria and may be interested in taking part in this research. By taking part in the study, your routine care and Mental Health Act status will not be affected.

Do I have to take part?

No, it is up to you to decide whether or not to take part in the research. Your access to the treatment group is not affected whether you agree to participate in the research. If you do decide to take part, you will be asked to sign a consent form. You are free to withdraw from the study at any time and without giving a reason. Regardless of whether you decided to participate or not, it will not affect any treatment you are currently receiving or any that you may need in the future. If you withdraw, the information we collected prior to this will be used in the study, but will be anonymised.

What will happen to me if I take part?

If you decide to take part and or would like more information, please tell the person who gave you this information sheet. They will pass your name to the researcher who will contact you to make an appointment. At this meeting, you can ask any questions that you have about the research. When you are sure that you would like to take part, the researcher will ask you to sign a consent form. You will attend the group treatment, which will take place once weekly and run for six weeks. Each group session will last for **2 hours** maximum with a break in the middle. Many of the questionnaires are already collected, so we will just ask for your consent to use these as part of the research data set. The additional tasks we will ask you to complete in addition to your participation in the group are:

- Questionnaires before starting the group. These will take around 15 minutes to complete
- One brief questionnaire after each group session, which will take around 5 minutes.
- Outcome questionnaires at the end of the 5 sessions. These will take around 10 minutes to complete.
- You will be posted these questionnaires 3 months after the group finishes. This will take around 15 minutes to complete.
- You will also be invited to attend an interview where you can share your experience of the group. If you do not complete all the sessions, we would still like to hear about your experience so we will contact you to invite you along to an interview and you can come along if you want too. This interview will last around 30 minutes and will be audio recorded. It will be anonymised so although we might use some of your quotes, your identity will be concealed and kept confidential.

What are the disadvantages and risk of taking part?

There is minimal risk of harm involved in taking part in this research project. There is a time burden associated with taking part in this research in that we ask you to complete some questionnaires that are additional to routine outcome monitoring. When filling out the questionnaires, difficult thoughts or feelings may arise when thinking of the answers. Similarly, you may experience some emotional distress when you are thinking about your life values and learning different ways to handle your difficult thoughts and feelings. These reactions are all within the scope of the kinds of experiences that people referred to psychology experience. If you do express feelings or thoughts of suicide or other

extreme forms of distress the researcher will inform a member of the clinical team so that you receive appropriate support and care.

What are the possible benefits of taking part?

There are no direct benefits. Some people find the experience of participating in the research interesting. Others have also reported that they enjoy contributing to the accumulation of new knowledge about ways to improve health care.

Will my Psychiatrist and GP be notified?

Yes, we will ask for your consent to inform your Psychiatrist (if applicable) and GP that you are taking part in the study. Your Psychiatrist will have no other involvement in the study. Clinical Psychologists will be running the groups.

What happens when the research study ends?

When the research study stops, you will no longer need to fill in questionnaires.

Will my taking part in this study be kept confidential?

All information that is collected about you during the course of the research will be kept strictly confidential. On all documents, an ID number will replace your name, and any personal information will be removed so that you cannot be identified from it. If you decide to take part in the post-treatment interview, this will be audio recorded. This recording will be transcribed, without your name being attached to it. The audio recording will be deleted to ensure privacy. Anonymous quotes from the interview may be used in the final report.

What will happen to the results of the study?

The results of the study will be written into a report and submitted to the University of Glasgow as part of Elizabeth Dewey's requirements for the Doctorate in Clinical Psychology. It is possible that this report will also be published in an academic journal. A summary of this report will be distributed to the old age teams within NHS Lanarkshire. It is expected that this report will be completed by July 2018.

Who is organizing and funding this research?

The research is organised via the University of Glasgow and is supported by the NHS. There is no commercial funding associated with this research.

Who has reviewed the study?

All research in the NHS is reviewed by an independent group of people called a Research Ethics Committee to protect your interests. The West of Scotland Ethics Committee has reviewed this study and favourable opinion has been given.

If you have any further questions

If you would like more information about the study and wish to speak with someone who is not closely linked to the study, please contact Dr Tom McMillan, University of Glasgow, email: thomas.mcmillan@glasgow.ac.uk, Tel no: 0141 2110354.

If you have a complaint about any aspect of the study

If you are unhappy about any aspect of the study and wish to make a complaint, please contact the researcher in the first instance. The normal NHS complaint procedure is also

available for you. The contact person for making a complaint in NHS Lanarkshire is: **Laura Jack**, NHS Lanarkshire Headquarters, Kirklands Hospital, Fallside Road, Bothwell, G71 8BB, Tel: 01698 858321, Email: laura.bryan@lanarkshire.scot.nhs.uk.

Contact details

If you would like further information, you can contact:

Main Researcher (Trainee Clinical Psychologist):

Elizabeth Dewey
University of Glasgow
Institute of Health and Wellbeing
1055 Great Western Road
Glasgow, G12 0XH
e.dewey.1@research.gla.ac.uk

Research Supervisors:

Dr Clive Ferenbach
Clinical Psychologist
Glendoe Building
Coathill Hospital
Coatbridge, ML5 4DN
Clive.ferenbach@nhs.net

Dr Hamish McLeod
University of Glasgow
Institute of Health and Wellbeing
1055 Great Western Road
Glasgow, G12 0XH
Hamish.McLeod@glasgow.ac.uk

A feasibility study of ACT with older people / PIS Outpatient v1 / 16.01.18

Appendix 2.7 Participant Consent Form



Mental Health & Wellbeing
Administration Building
Gartnavel Royal Hospital
1055 Great Western Road
Glasgow
G12 0XH

Participant Number:

Name of researchers: Elizabeth Dewey, Dr Clive Ferenbach, Dr Hamish McLeod

Title of Project: A Feasibility Study of the Process of Therapeutic Change Using Acceptance and Commitment Therapy (ACT) for Older People.

Consent Form

Please initial each box

I confirm that I have read and understand the information sheet dated _____ for the above study and have had the opportunity to ask questions.	<input type="checkbox"/>
I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.	<input type="checkbox"/>
I give consent to be contacted following the group to be invited to an interview, but understand that my participation in the interview is voluntary	<input type="checkbox"/>
I understand that relevant sections of my medical notes and data collected during the study, may be looked at by individuals from University of Glasgow, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.	<input type="checkbox"/>
I understand that if I decide to attend the interview, it will be audio recorded and quotations may be used in the final report. These quotations will be anonymous.	<input type="checkbox"/>

Appendix 2.8 Interview Schedule

Topic/Research Aim A: Acceptability to Older People

I'm interested in how you experienced the group. Can you tell me about what it was like for you?

- **What was the group like?** How did you find it? How was it for you?
- **What parts of the group did you like?** What made this enjoyable? What did you enjoy?
- **What about the things you didn't like?** What made this dislikeable? What did you not enjoy?
- **What parts of the group were you most interested in?** If people were to ask you about the group, what would you say?
- **Was there anything that surprised you?** What was this?
- **What would you change about the group?** Anything you would like more of? Anything you would like less of?
- **Was there anything the people who took the group said that you disagreed with?** What were these? What was it about what they said that you disagreed with?
- **Was there anything in the group you found hard to follow?** Anything you found a bit strange, or silly? Anything you didn't understand? Tell me more about that.

Topic/Research Aim B: Mechanisms of Change

Now that you've been to the group, I'd like to find out about your life now. Can you tell me about the impact the group has had?

- **Have things changed for you since participating in the group?** Have there been any changes in how you
- **What do you think is the reason for these changes?** Has there been anything about being in the group that would explain these?
- **What reasons have things stayed the same for you?** Has there been anything about being in the group that would explain these?
- **What were the most important things about the group for you?** Are they the reasons for things being better/worse?

Topic/Research Aim C: Being part of a trial

I'd now like to find out about how you found it being part of a research project. Can you tell me what it was like for you?

- **What were your initial thoughts about taking part in a research study?** How did you make your decision to take part in the study?
- **How did you find the questionnaires?** Were there any questions that stuck out for you or that you found difficult to answer? What were these?

End of Interview: Any other information

That's all I have to ask, have you anything else you'd like to say, or anything we haven't covered?

Appendix 2.9 Proposal

Abstract

Background: The majority of evidence for psychological interventions for depression, anxiety and psychosis, with older people (OP) has focused on Cognitive Behavioural Therapy (CBT), whereas it has been suggested that due to the chronicity and variety of mental health difficulties within this client group, Acceptance and Commitment Therapy (ACT) may be more suitable (Petkus & Wetherell, 2013). This is because ACT helps clients to relate differently to their difficulties and reconnect with values, rather than potentially unattainable symptom elimination.

Aims: The acceptability and feasibility of an ACT based group intervention for OP; particularly in relation to whether values are an important part of the intervention for participants' engagement with ACT.

Methods: This study will take a mixed methods approach within a feasibility design. Participants who are over 65 and current inpatients on a functional inpatient ward will take part in a five-session ACT group and complete pre-, session-by-session, and post-intervention measures. They will also be invited to take part in a qualitative interview following intervention.

Applications: The results will help inform whether participants find ACT an acceptable intervention, adding to its growing evidence base of ACT and OP. In addition, by measuring values clarity session-by-session it can consider whether this is an important part of the intervention for the client group.

1. Introduction

It's estimated that by 2040, nearly one in four people in the UK will be over 65 (Age UK); previous studies have indicated that within this population there are a number of mental health difficulties (MacDonald, Raab & Storkey, 2001). Consequently, mental health services in the NHS need to adapt to this growing demographic and offer acceptable and beneficial interventions for OP led by research.

Research for OP psychological treatment has focused on CBT, particularly for depression and anxiety, which has found to be more effective than waiting list control conditions, but as effective as other treatment conditions (Hofman et al, 2012 for a review of this literature). However, Petkus and Wetherell (2013) have argued that CBT has limited evidence for non-primary care OP clients and is suboptimal for anxiety. Many studies have

explored the difficulties that this client group share and have suggested that engaging in thought suppression, an attempt to stop thinking about a particular thought, is a large part of difficulties in this client group (Cukrowicz et al., 2011; Rosenthal et al., 2005).

ACT is a psychological approach that aims to foster willingness to experience unwanted thoughts and feelings without necessarily changing their form (Harris, 2009). In this regard, ACT differs from other branches of CBT, which explicitly aim to change the content of thoughts, and reduce unwanted symptoms. It also includes a strong behavioural component; aiming to help clients identify their deeply held 'values', and commit to pursuing activity congruent with these principles (Harris, 2009). Consequently, ACT aims not to decrease symptoms of distress but relate differently to them.

It has been argued (Petkus & Wetherell, 2013) that ACT may be well suited for an OP population. This is partly due to its transdiagnostic applicability, relatively strong evidence base in chronic health conditions, and the intuitive appeal of an 'acceptance' based approach to some of the challenges of aging; particularly when cognitive 'challenge' appears less appropriate. However, the evidence base for ACT in OP is currently at a very early stage of development. This study aims to contribute to explore methods and measures to understand how ACT may be beneficial to OP. It has been suggested that values work may be most beneficial to mention earlier in intervention and to a greater extent when working with OP (Petkus & Wetherell, 2013) because they may be more likely to relate to values than emotional struggle. Petkus and Wetherell (2013) argue this may be a result of the number of significant life events that occur in later life, such as retirement or chronic illness, which could result in the person losing touch with their values.

A range of measures have been used to measure the six processes of ACT (Acceptance; Contact with the Present Moment; Values; Committed Action; Self as Context; Cognitive Defusion) in addition to psychological flexibility, which these processes aim to target. Smout and colleagues (2014) have highlighted that there is not a measure that measures how clear an individual is about their values and whether their values are separate to what is expected from others. For example, someone may identify a value such as "being physically fit" because it is encouraged in their social system, but it may not be a personal value. As discussed before, it has been suggested that the identification and clarity of values may be more pertinent for this client group; however, there are no studies exploring

whether this is an important mechanism of change within this client group. Consequently, this study will measure this session-by-session with a new measure during the intervention; in addition to specifically asking participants about this process in interviews to consider whether values is an important mechanism of change, as Petkus and Wetherell (2013) suggest.

Work is currently underway in NHS Lanarkshire on functional inpatient wards and community settings to develop group based ACT interventions and this study would aim to utilise these groups to explore how feasible and acceptable they are to deliver. This proposal is being constructed with reference to the MRC Complex Interventions Guidance (Craig et al, 2008), which describes the key elements of the feasibility/piloting process as: testing procedures; estimating recruitment/retention; and determining sample size. To establish this, it is recommended that using both qualitative and quantitative is needed to understand barriers.

2. Aim

To find out more about the suitability and acceptability of ACT for OP.

Research Questions:

Population: Is taking part in a research trial acceptable to this client group? What are the estimated rates of recruitment and retention of participants for future trials? This will be determined by information from attendance, attrition rates, and qualitative interview.

Intervention: Are ACT groups acceptable to this client group? Does ACT need to be adapted? This will be determined by measuring attendance, attrition rates, and information from feedback forms, T-MIT and qualitative interview.

Mechanisms for change: What are the possible/likely mechanisms for change during the intervention? This will be determined by information from qualitative interview, and outcome measures.

Outcome Measures: Can appropriate measures be identified to explore the impact of an ACT intervention for OP and are they acceptable? This will be determined by completeness of questionnaires, satisfaction questionnaires, and qualitative interview.

3. Plan of Investigation

3.1 Participants

Participants will be recruited from older adult functional inpatient wards in NHS Lanarkshire, which are mixed bed mental health ward for patients over 65 who are experiencing varying presentations and severity of mental health difficulties and require support from a 24-hour service. Participants will also be recruited from patients who have been referred to psychology for a community ACT group.

3.2 Inclusion and Exclusion Criteria

Inclusion

- Capacity to consent to research
- Over 65 years old
- Patient on older adult functional inpatient ward or within community services

Exclusion

- Known learning disability
- Known cognitive impairment
- Psychiatric symptoms that would exclude meaningful participation in the group, as identified by the clinical treating staff, for example active psychotic symptoms that would prevent the participant's ability to attend/concentrate on the group

3.3 Recruitment Procedures

Participants will be recruited from older adult functional inpatient wards within NHS Lanarkshire; they will be patients who are already attending the ACT inpatient group. All patients who take part in the group have a pre-group assessment with the ward's Clinical Psychologist, who is not part of the research team. Participants will also be recruited from community older people's mental health teams. These participants will have been referred to psychology and been deemed suitable for a group intervention. During this pre-group assessment, an information sheet will be provided to the patient and they will be asked whether a researcher can contact them after 24 hours to discuss the project. Subsequently, if the patient agrees for the researcher to contact them, an appointment will be arranged to provide further information and ask whether the patient wishes to participate in the study.

3.4 Measures

The Brief Experiential Avoidance Questionnaire (Gamez et al, 2014) is a 15-item measure of experiential avoidance. The authors reported this measure to have a mean of $\alpha=0.86$. It has not been previously used in studies with OP.

The Valuing Questionnaire (VQ) (Smout et al., 2014) is a ten-item measure of values. The authors reported this measure to have a mean of $\alpha=0.95$ for successful valued living and

$\alpha=0.93$ for disrupted valued living. It has not previously been used in an older adult population.

The Cognitive Fusion Questionnaire (CFQ) (Gillanders et al., 2014) is a seven-item measure of cognitive fusion. The authors reported this measure to have a mean of $\alpha=0.90$. This measure has been used with an older adult population (Scott et al., 2016) with an internal consistency of $\alpha=0.74$.

The Hospital Anxiety and Depression Scale (HADS) (Zigmond & Snaith, 1983) is a 14-item measure of anxiety and depression. A study that reviewed 747 papers that used the HADS (Bjelland et al., 2002) found that the mean of the anxiety subscale was $\alpha=0.83$ and depression subscale was $\alpha=0.82$.

A session-by-session measure created by the authors (The Acceptance and Commitment Therapy measure of change for Older Adults (ACT-OA)), with five items, will be used to measure clarity of values, clarity of planned action, engagement in valued living and willingness to experience difficult thoughts and feelings. This is to clarify whether values are an important aspect of the ACT intervention for OP and whether each of these four areas influences another during intervention.

The Therapeutic-Metaphors Interpretation Test (T-MIT) (Hains, 2013) is a six-item measure of abstract thinking. Research suggests that some OP have executive deficits as a result of normal ageing (Mohlman & Gorman, 2005), which includes abstract thinking. Consequently, this measure aims to explore whether participants have an understanding of the therapeutic metaphors, which will help to explore whether the session content needs to be adapted.

3.5 Design

This is a feasibility study and will be a mixed methods design, using quantitative and qualitative methods, as recommended by the Medical Research Council guidance for complex interventions (Moore et al, 2015). In relation to the qualitative design, as the research question is experiential, Braun and Clarke (2013) recommend conducting interviews with a small (6-10)/moderate (10-20) sample size and using thematic analysis as this qualitative method aims to identify patterns across all participants, which fits with the research objectives.

3.6 Research Procedures

- Acceptance and Commitment Therapy Protocol

ACT has been more described as a general approach rather than being manualised (Petkus & Wetherell 2013). Therefore, the protocol has been developed by two NHS Lanarkshire Clinical Psychologists and is based on the outline of sessions in *ACT Made Simple* (Harris, 2009). This protocol has been rolled out twice and following this has created a protocol of 6 sessions with each session concentrating on a particular part of the hexaflex.

- Training

The group is delivered as part of standard care and is facilitated by Clinical Psychologists working with Psychological Therapies for OP in NHS Lanarkshire, who works four sessions on the ward. The Clinical Psychologists have attended ACT training and have a number of years experience delivering ACT individually and in groups.

- Data Collection

Questionnaires will be given to participants pre- and post- intervention and the session-by-session measure will be used every group session. Following the group, participants will be invited to attend a semi-structured interview, conducted by the Trainee Clinical Psychologist, to discuss particular aspects of the group. All participants will also be contacted by post 12 weeks after the end of the intervention with the measures.

Interviews will then be transcribed and following this the recording will be deleted. All confidential information will be removed and each transcription will be identifiable by number.

3.7 Data Analysis

Quantitative Analysis

Within subjects t-tests, or the non-parametric equivalent, will be used to explore group level change pre/post treatment, which, alongside interviews, will aid in looking at the possible mechanisms for change.

Descriptive analysis will be used to explore the T-MIT data, to explore potential adaptations needing to be considered in relation to abstract thinking and ACT.

Qualitative Analysis

Thematic analysis, using Braun and Clarke's (2014) guidelines, of qualitative interviews will be used to explore the research objectives of adaptations relating to ACT and whether the outcome measures are acceptable to participants.

3.8 Justification of Sample Size

As this is a feasibility study and therefore exploratory, a power calculation does not need to be completed and worked to. However, one of the outcomes from this study is to generate post-hoc power calculations from change scores on the outcome variables within the group to guide future studies. It has been estimated from previous groups that 6-8 participants will be in each group with two groups running (estimated total eligible pool = 16). As outlined above, for this study, Braun and Clarke (2013) recommend a small (8-10)/moderate (10-20) sample size. All participants will be invited for interview and saturation will be established during analysis; however, based on previous research, it would be expected that saturation would be reached by 12 interviews (Baker & Edwards, 2012).

3.9 Settings and Equipment

The groups will take place on a mental health ward for OP, as described above, or within a community setting.

Equipment	Source
<i>Group</i>	
Measures (BEAQ; CFQ; HADS; VQ; T-MIT; ACT-OA)	Available online (printing costs)
Information Packs and Consent Forms	Printing costs
<i>Interviews</i>	
Audio Recorder	Loan from University
Laptop and Foot Pedal	Loan from University

4. Health and Safety Issues

4.1 Researcher Safety Issues

The groups will be delivered on hospital grounds or community health centres within working hours, and therefore there will be a number of staff available. Procedures for panic alarms will be consulted prior to starting the groups, which is routine practice to know for each place of work, and the facilitators also have panic alarms.

4.2 Participant Safety Issues

As the setting is a functional ward, participants may become distressed during the group sessions. This has occasionally been the case with previous groups; however, as ward staff

will be aware of how patients respond, this information will be sought prior to commencing the group. This will be equally considered within the community groups. Any patients who become highly distressed during the group will be sensitively engaged by the facilitators and followed up after the session. This will be recorded in their notes and it will be discussed with the patient whether they feel able to continue in the session and/or with the research.

4.3 Ethical Issues

Ethics submission will be made to NHS REC. Management approval from NHS Lanarkshire R&D will be sought following ethical approval. All data will be stored in locked filing cabinets or password protected databases after anonymisation. Recording of the interviews will be destroyed following transcription. All transcripts will be anonymised using the Find and Replace function in word: e.g. Name replaced with {Person 1, 2, 3 etc.} to minimise direct and indirect threats to identification. Participants will also be informed that quotations will be used in the presentation of results. Within this patient group there may be difficulties around individual's capacity to consent as some patients on the ward may be detained under the Mental Health Act 1983; however, they may still be able to consent for research. The following conditions will be considered when assessing informed consent in potential participants (Van Staden & Kruger, 2002), their mental disorder should not prevent a patient from:

1. Understanding what they consent to
2. Choosing decisively for/against the intervention
3. Communicating their consent
4. Accepting the need for a medical intervention

5. Financial Issues

Costs would be based around paperwork for the study, including handouts and questionnaires. A recorder, laptop and pedal would be required for the researcher to transcribe the interviews, which may be available to borrow from the university.

6. Timetable

Date	Action
30th January 2017	MRP Proposal Submission
15th May 2017	Submit Final MRP Proposal and Paperwork to University
August 2017	Submit Ethics Application
October-December 2017	First and second cycle of ACT group delivery

	(delivery of 5 sessions and data collection, including post-intervention interviews)
January-April 2017	Data analysis and write up

7. Practical Applications

This study aims to explore the acceptability and feasibility of ACT based groups on older adult wards and in community settings. Consequently, it has practical applications because it can help inform the service whether the participants find ACT helpful as measured by the outcome measures and qualitative feedback. In addition, the results of this study can contribute to the small literature base of ACT and OP. Also, by developing a new measure looking at values and using it in this research project we are able to trial this outcome measure.

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