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**Acceptance and Commitment Therapy with a Community Older Adult
Sample: a Feasibility Study Investigating Mechanisms of Change.**

And Clinical Research Portfolio

David McGraw

BA (Honours) Psychology

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

July 2019



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CHAPTER ONE: SYSTEMATIC REVIEW

CBT for Older People with Depression: a Systematic Review and Narrative Synthesis of Recommended and Reported Treatment Modifications.

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Prepared in accordance with the requirements for submission to

Journal of Mental Health (see Appendix 1.1)

Abstract:

Background: Policy and national guidance strongly recommend specific approaches different to those of working age counterparts, should be used to meet the mental health needs of older people. Depression is a substantial mental health problem, and common approaches such as Cognitive Behavioural Therapy (CBT) may be effective. Previous reviews have examined the ways in which therapy is modified for older people with anxiety difficulties, however, this has not been systematically analysed for older people with depression.

Aims: To review and synthesis recommended and reported modifications to CBT for older people with depression.

Method: Systematic review and narrative synthesis of review articles to extract recommended modifications to CBT, and examination of reported modifications from intervention studies. Quality of intervention studies was appraised using a modified intervention section of the CONSORT checklist for non-pharmacological treatments (Boutron et al., 2008).

Results:

A framework of commonly suggested modifications was developed from the review articles. Nine areas of difficulty or need were identified: four were in the cognitive domain (e.g. memory or attention difficulties), two were related to conceptual cohort factors (e.g. beliefs related to ageing), one was related to physical health status (e.g. poor health or sensory issues), one was systemic (involvement of family & MDT), and one was both cognitive and conceptual (inclusion of patient strengths- cognitive or life experience). When applied to intervention studies, there was a substantial lack of reporting of recommended modifications.

Conclusions: There was a significant lack of reporting of modifications in trials. This may result from changing reporting standards, participant profile, or shift from procedural to more conceptual modifications.

Key words: CBT, Older people, Modifications, Depression.

1. Introduction

1.1 Mental health of older people/aging population

The World Health Organisation (WHO) identified major depression as a leading global cause of disability (WHO, 2013), with prevalence rates for community dwelling older people of 5% (Taylor, 2014). Clinical services, already struggling to meet the health needs of this population, predict demand will only increase. Therefore, evidenced approaches suiting the characteristics of this growing population are required.

1.2 CBT for older people

Focussing on the interplay among thoughts, feelings and behaviour, CBT has been established as an effective treatment for depression in older people in comparison to waiting list control, but there is a lack of evidence comparing the intervention to active treatments (Gould, Coulson, & Howard, 2012; Pinquart, Duberstein, & Lyness, 2007). Raue, McGovern, Kiosses, and Sirey (2017) argued that modifying existing treatment protocols and tailoring CBT to older adults is essential to meet the complex needs of this group. These complexities can be conceptualised as an interaction between poor physical and cognitive health, but more recent work has also outlined the importance of going beyond practical modifications, to formulation based modifications that address age-related issues (James, 2008). Understanding how CBT should be modified, and gaining information on recent practice in trials, is required to enhance treatment for this population.

1.3 Specific challenges in treating older people

Several challenges exist in meeting the mental health needs of older people. Cohort beliefs around older people and psychotherapy have changed historically, impacting the

views of clinicians, referrers and patients. Hughes (1991) quoted Freud and his view of older people:

“elasticity of the mental processes on which the treatment depends is, as a rule, lacking”

Attitudes have progressed since this view was held and older people express a strong preference for psychological interventions (Luck-Sikorski et al., 2017). However, there are barriers to older people accessing psychotherapies, e.g. transportation and misinterpretation of symptoms as part of normal ageing (Pepin, Segal, & Coolidge, 2009; Wuthrich & Frei, 2015).

Sadavoy (2009) outlined five older adult specific challenges: *complexity, chronicity, comorbidity, continuity, and context*. Authors have highlighted how mental health problems may present differently in older people compared with younger adults, e.g. higher rate of comorbidity (Laks & Engelhardt, 2010). Increasing access to psychological therapies for older people was identified by Royal College of Psychiatrists (2018) in their report: “Suffering in Silence: age inequality in older people’s mental health care” which called for services and treatment to be designed to meet the specific needs of older people.

2. Aims of the present study

Although there is a strong case for modifying CBT to meet the specific needs of older people, it is unknown if this is being done in intervention trials. A recent meta-analysis comparing CBT for older people with CBT for working age adults with anxiety difficulties, highlighted the need for clear reporting of modifications, and older age specific training for practitioners (Kishita & Laidlaw, 2017). Laidlaw and Kishita

(2015) argued the importance of basing conceptual modifications on theories of gerontology, concluding that this has been relatively ignored.

Following the methodology demonstrated by Gallagher, McLeod, and McMillan (2019) in their narrative synthesis of CBT modifications in head injury, this review aims to examine the literature on CBT and older people with depression, addressing the following questions:

- What are the recommended modifications to be made to CBT for older people?
Data will be extracted from review studies.
- How many studies have reported making older adult modifications? (assessed using recommendations extracted from review articles).
- How are these reported? What is the relationship between recommended adaptations and reported adaptations?

Finally, this review will conduct a quality appraisal of the intervention studies using a modified version of the intervention section of the CONSORT non-pharmacological extension (Boutron et al., 2008).

3. Methods

Search Strategy

The search strategy followed the PRISMA guidelines (Moher, Liberati, Tetzlaff, & Altman, 2009). An initial search was conducted through the following online databases (CINAHL, PsycInfo, Medline & Embase) search terms for depression, older people and CBT (see appendix 1.2 for an example search strategy).

This produced an initial pool of papers from which review articles and intervention studies were extracted. Titles and abstracts were screened producing a smaller pool of articles which were full text reviewed using the below criteria:

Review articles were included if they:

- Were a meta-analytic review, systematic review, narrative review, or other reviews
- Made recommendations on modifying cognitive behavioural therapy for older people.
- The target problem or presentation was depression
- Published in an English peer reviewed journal.

Review articles were excluded if they:

- Review other areas of old age, ageing or gerontology, without offering recommendations for adapting CBT for this population.
- Made recommendation on modifying CBT for older people with dementia or mild cognitive impairment.
- Made recommendations on modifying CBT for older people in long term care or residential care setting.
- The target problem or presentation was specifically something other than depression, e.g. anxiety or psychosis

Intervention studies were eligible for inclusion if they met the following criteria:

- Participants were older people
 - Age range classified as adults aged 65 or over. Scoping of the literature suggests some studies may include working age adults and older adults.

Studies such as those, will be included if they provide a breakdown of age groups and specific data for older participants.

- Participants were recruited from a treatment setting (inpatient or outpatient).
- Published in an English peer reviewed journal.
- Psychological treatment was CBT, either solely or as part of a group of treatments, as long as a breakdown of results per treatment was provided.
- Quantitative research designs - RCTs and case studies.
- The target problem or presentation was depression

Intervention studies were excluded if:

- CBT was delivered in a format other than face-to-face with a clinician (e.g. computerised or telephone)
- Treatment comprised of other psychological therapies, e.g. Schema therapy or third wave CBTs, e.g. Acceptance and Commitment Therapy.
- The work was non peer reviewed, e.g. unpublished dissertations or conference abstracts
- The target problem or condition did not come under depression e.g. anxiety, personality disorder or complex trauma.
- The participants were noted to have a diagnosis of dementia or mild cognitive impairment.
- Participants were recruited from a long-term care or residential care setting.
- The intervention is adapted for a specific physical health condition, e.g. diabetes, kidney disease, breast cancer, epilepsy.

Citation searching yielded two additional papers. See figure 1 for PRISMA flowchart.

3.3 Data extraction and synthesis

Popay et al. (2006) outlined three stages of a narrative synthesis:

- 1) Developing a preliminary synthesis
- 2) Exploring relationships between articles,
- 3) Assessing the robustness of the synthesis.

Using the methodology of M. Gallagher, et al. (2019) the articles were examined.

Stage 1: Preliminary synthesis Creation of a data-extraction framework from review articles.

Preliminary synthesis of intervention studies

Creation of a framework for modification from reviews for extracting data from intervention studies. Recommended CBT modifications were extracted from review articles. Using thematic analysis (Braun & Clarke, 2006), recommendations were analysed and themes established. ***Examples of recommended modifications:*** Crowther, Scogin, and Johnson Norton (2010) recommend that age related cognitive changes (e.g. poorer memory) should be mitigated by adaptations such as slowing the pace of therapy and repetition of new information. Similarly, Chand and Grossberg (2013) suggested presenting new information in different ways, slowing down the pace of therapy, and using repetition to aid memory. Both addressed cognitive difficulties, particularly, problems with memory. Subsequently, both were grouped in *Memory difficulties: Processing and retention of new information in session and retention of content between sessions*. The modification extraction list was created which included the area

of difficulty or need and rationale for modification. The list provided an overview of recommended modifications of CBT with depression.

Preliminary synthesis of intervention studies was conducted through tabulation of data, including study design, detail of sample, number of sessions, treatment description, and evidence of recommended modifications.

Stage two. Exploring relationships between recommended modifications and reported modifications

The relationship between recommended modifications and those reported in intervention studies was explored. Following creation of the modification extraction list, this was applied to extracted intervention modifications exploring the relationship between the two. Lastly, any modifications for late life depression in intervention studies not captured in the modification extraction list, were collected and thematically analysed (Braun & Clarke, 2006).

The quality of reporting of the intervention studies was assessed using a modified version of the intervention section of the CONSORT non-pharmacological extension (Boutron et al., 2008) (outlined in table 2):

Table 1: Quality Appraisal scoring guidance

Item	Scoring
1. Evidence of efforts made to modify the experimental treatment for older people	0 or 1
2. Precise details of the experimental treatment were offered	score of 0, 1, or 2
3. Details of the control or comparator treatment were given	0, 1 or N/A
4. Details of how the intervention was, or	0 or 1

could be standardised were included	
5. Details of how adherence to the protocol was assessed or enhanced were included	0 or 1

A subset of intervention trials were rated by a second reviewer on the quality rating system and Modification-Extraction List (50%, n=7). Agreement was 94.3% for quality appraisal and 95.2% for the Modification-Extraction List. Disagreements were resolved through discussion.

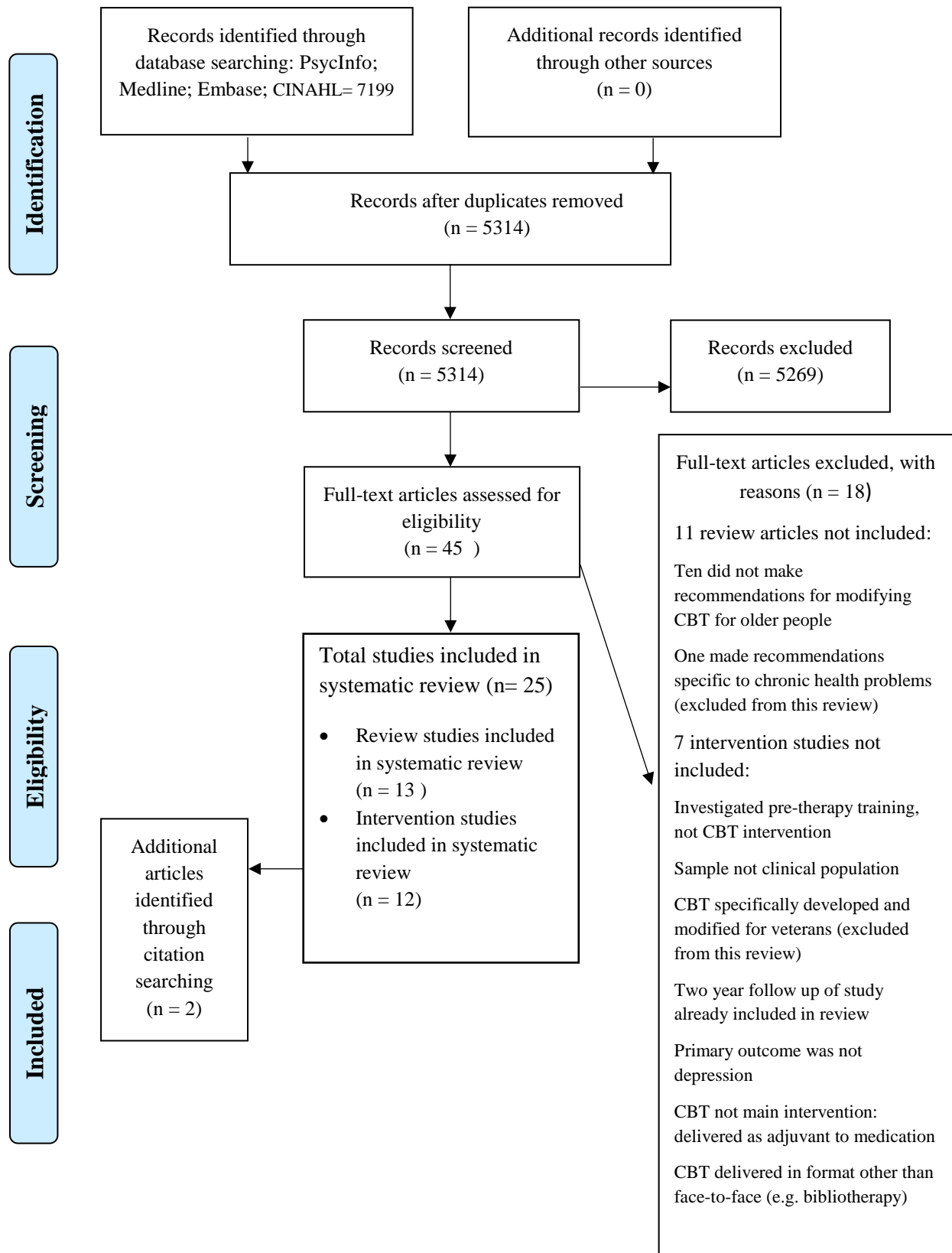
3.3.3 Stage three. Assessing the robustness of the synthesis

Popay, et al. (2006)'s methodology comprised the critical use of quality appraisal tools by two independent raters, with critical discussion employed to resolve disagreement as reported above. The methodology includes an opportunity to proffer subjective reflection on the strength and depth of the articles in relation to saturation of themes.

4. Results

The initial search of databases yielded 7199 papers. Of this number 1885 were removed as duplicates. A hand search of key academic journals retrieved no additional papers. The remaining 5314 were screened against the inclusion/exclusion criteria via their title and abstract. Following this step, 5269 were excluded leaving 45 papers for full article review. This was comprised of 13 reviews and 12 intervention studies for inclusion in the review. See figure 1 for more detail. Citation searching identified two further intervention studies.

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



4.1 Stage one: Creation of a data-extraction framework from review articles

The result of the first stage of the synthesis is the Modification-Extraction list created from thematic analysis of the review articles (see table 2). All areas of difficulty were recommended by at least three reviews, and the maximum number of recommendations was seven for *memory difficulties*. Themes were clustered conservatively, resulting in inclusive areas of difficulty. Further details on which specific review articles made recommendations on each area can be found in Appendix 1.3.

Table 2: Modification-Extraction List, with number of intervention studies which recorded each modification as being incorporated in intervention

Area of difficulty/need and rationale for modification	Detail on/examples of modification	Included in N /14 of intervention studies
1. Memory difficulties <i>Processing and retention of new information in session and content between sessions</i>	<ul style="list-style-type: none">• Use of repetition of new information• New skills explained, demonstrated and practiced• Records of session content is encouraged.<ul style="list-style-type: none">• Notes taken by patient, or written summaries provided by clinician.• Audio recordings• New information presented in different forms/ modalities, e.g. written, audio	4
2. Problem solving difficulties <ul style="list-style-type: none">• <i>Issues with processing challenging and complex stimuli</i>	<ul style="list-style-type: none">• Problems reduced into component and simplified• Frequent reworking of problems	0
3. Generalisation of skills and concepts outside of session, and completion of homework tasks	<ul style="list-style-type: none">• Phone prompts/alarms as reminder to action homework, e.g. breathing exercises.• With consent, relatives/carers attending sessions as co-therapist to become familiar with strategies performed• Carer involvement in assessment/treatment of patient,	2

Area of difficulty/need and rationale for modification	Detail on/examples of modification	Included in N /14 of intervention studies
	e.g. encouragement re. homework tasks	
4. Attention difficulties: <i>Staying focussed and on task</i>	<ul style="list-style-type: none"> • Clinician taking active/directive role • Active efforts to keep clients focused, e.g. redirecting attention to session topics • Use of agenda, clearly visible, e.g. on white board or on table between therapist and client. 	1
5. Inclusion of patient strengths <ul style="list-style-type: none"> • <i>Life skills & preserved cognitive abilities, e.g. recognition memory</i> 	<ul style="list-style-type: none"> • A perspective is adopted valuing life skills older people posses • Use of neurocognitive aids to maximise preserved abilities, e.g. bibliotherapy adjuncts, scaffolding, verbal memory recognition cues. 	2
6. Cohort beliefs <i>Addressing:</i> <ul style="list-style-type: none"> • <i>Age and possibility of change</i> • <i>Value of therapy</i> • <i>Over emphasis of physical health in conceptualisation</i> 	<ul style="list-style-type: none"> • Evidence of acknowledgment of this, inclusion in formulation • Specific attention to socialisation to model, to address negative cohort beliefs. 	2
7. Losses/transitions in role <ul style="list-style-type: none"> • <i>e.g. bereavement, loss of role/purpose, retirement</i> 	<ul style="list-style-type: none"> • Evidence of specific focus, e.g. in formulation or session materials • Assist patients in identifying alternative ways of thinking about situation; enabling adaption to losses/transitions. 	0
8. Family and wider system	<ul style="list-style-type: none"> • Inclusion of systemic factors in formulation, e.g. tensions between family members, and differences in generational expectations • Involvement of family members/carers and MDT • Clinician may take role of case coordinator, liaising with MDT 	1

Area of difficulty/need and rationale for modification	Detail on/examples of modification	Included in N /14 of intervention studies
9. Physical health problems/sensory difficulties	<ul style="list-style-type: none"> • Realistic goals; acknowledging physical health difficulties, e.g. mobility • Transport difficulties addressed • Addressing sensory difficulties e.g. lighting, larger print of text, sitting closer for hearing, use of different modalities for materials. 	2

The second part of the first stage of the review was a preliminary synthesis of the data in the form of a descriptive table of the intervention studies (table 3).

Table 3: Descriptive table of intervention studies

Reference	Design/Sample	Length of therapy	Treatment description	Main outcomes	Evidence of recommended modifications	Adaptions score	Quality rating
Steuer, Mintz, and Hammen (1984)	N-RCT. CBT vs psychodynamic group psychotherapy Total group: N=33, Median age=66, age range=55-78, 26 females and 9 males.	Twice weekly groups (10 weeks), once weekly (remaining 26 weeks), total:46 sessions, nine months. Session: 1.5 hours	CBT group and group psychodynamic therapy used manualised approaches, specific modification for older people not reported. CBT: Behavioural element: weekly activity schedules, mastery and pleasure log, and graded task assignments. Cognitive: recording of negative cognitions empirically testing out of thoughts, examining cognitive distortions (e.g., overgeneralizations), and generating new ways of thinking. Psychodynamic group: psychoanalytic concepts, focus on group cohesion, relieving	Both groups showed statistically and clinically significant reductions on HAMD, Z- SDS and the BDI. Statistically significant difference between groups on BDI in favour of CBT.	None	0/9	4/6

			symptoms, and addressing patterns of socially maladaptive behaviour.				
Leung and Orrell (1993)	Prospective cohort study. Efficacy of brief CBT, comparing patients with diagnosis of MDD (N=13) to other disorders (n=14) N= 27, 19 females, 8 males, mean age 70.4, range= 61-82 years	7 sessions of 1.5 hours	Brief group CBT intervention: Session 1: introduction to CBT model of depression Session 2: personal rules of living 3 rd , 4 th and 5 th sessions: cognitive traps, dilemmas and snags, vicious circles. Session 6: awareness of feelings and life values. Final session: goals and values.	MDD group improved on all 3 measures (GHQ-28, BDI and PGC), pre to post; other disorders did not improve on any.	None	0/9	2/6
Huang, Liu, Tsai, Chin, and Wong (2015)	RCT- PFE (N=19) vs. CBT (N=18) vs control group (N=20) Total N= 57, 27	12 weekly sessions, 60-80 minutes	PFE: regular exercise programme, 150 minutes per week, 3 x 50 minute sessions in groups of 2-4 participants. Sessions included warm up, cardiovascular exercises, muscle strength exercises and cool	Post intervention significant decreases in GDS-15 for both experimental conditions, no significant differences between CBT and PFE, but longer lasting	None	0/9	3/6

	males, 30 females, mean age= 76.53 years		<p>down.</p> <p>Three CBT phases: behavioural activation, cognitive restructuring, and core beliefs/dysfunctional coping. Groups of 3-5 participants.</p> <p>Control group received no extra care.</p>	effect (9 month follow up) for PFE.			
Chaowanee, Darawan, Ratchneewan, and Wanchai (2018)	<p>RCT: CBT vs TAU</p> <p>Total N=60, all female, CBT (N=30, mean age=70.67 years), TAU (N=30, mean age=70.40)</p>	<p>12 group-sessions of 45-60 minutes.</p> <p>Three times weekly over four weeks.</p>	<p>CBT manual developed by authors: psychoeducation, case formulation, identifying NATs, evaluating, responding, homework assignments, evaluation/feedback.</p> <p>TAU: Activities normally provided by nursing teams, e.g. advice to exercise 30-45 minute at least 2-3 times per week.</p>	Mean depression scores on PHQ-9 in the CBT condition at every point were significantly lower than at baseline and statistically lower than those of the usual care condition post treatment.	Integrating homework assignments with local culture, emphasizing importance of homework, and involvement of family. Multiple opportunities to go over techniques and concepts. Shorter sessions of 45-60 minutes to account for fatigue	5/9	5/6

					and short-term memory difficulties. Support for transport.		
García-Peña et al. (2015)	RCT CBT group vs TAU CBT (N=41, mean age=71.3) Control (N=40, mean age= 69.7), Total participants: 84% female	Weekly group sessions (90 minutes) for 12 weeks	CBT condition (manualised): Psychoeducation, identifying depressive thoughts, substitute them for more realistic and positive thoughts and regular measurement of mood states. Goal setting and developing pleasurable activities, improving social relationships. Control group referred to family physician for TAU.	Significant improvement for CBT group in PHQ-9, Control group displayed a marginal gain.	None	0/9	2/6
Cappeliez (2000)	Prospective cohort study. Efficacy of CBT N= 21, 19 females and 2 males, median	Weekly 90-min sessions were scheduled over 12 weeks	Manualised approach, Groups of 3-5 participants: psychoeducation on depression, activity scheduling, identifying the relationships between thoughts and feelings, monitoring dysfunctional	Factors associated with less favourable outcome included depressive symptomatology, negative health evaluation, and negative view of self.	None	0/9	3/6

	age= 69 years		cognitions.	Severely depressed participants demonstrated a significant decrease in depressive symptoms (BDI & GDS-15) but still presented residual depressive symptoms post treatment.			
Thompson, Coon, Gallagher-Thompson, Sommer, and Koin (2001)	RCT comparing CBT vs desipramine vs combined Desipramine (n=33, mean age=66.8) CBT (n=31, mean age= 66.5), Combined (n=36, mean age=67.2), Total N=100 total mean age= 66.85, total	16-20 sessions over 3/4 months. Twice weekly in first four weeks, once weekly for remainder. 50-60 minute sessions.	CBT: manualised approach modified for older people. Identifying, monitoring, and challenging negative cognitions. Developing more adaptive cognitions. Desipramine: followed drug condition protocol (NIMH-TDCRP), with minor modifications. Combined condition: patients saw both a psychiatrist a CBT therapist in separate contacts for each of the 16–20 sessions.	Significant reduction in HDRS in all conditions. Per session rate of change for combined was significantly greater than for separate interventions. No significant differences between interventions.	Strategies to facilitate learning, e.g. repeated presentation of information using different modalities, slower rates of presentation, use of practice, greater use of structure and modelling.	0/9	3/6

	gender: 33 male, 67 female						
Thompson, Gallagher, and Breckenridge (1987)	RCT: Group BT vs group CT vs psychodynamic group psychotherapy vs control (DTC). BT (n=25, mean age= 66.88), CT (N=27, mean age= 67.07), BPT (N=24, mean age= 66.71), control (N=19, mean age= 67.63), Total N=95, gender: 31 male, 64 female	16-20 sessions over 3/4 month period. Seen twice weekly in first four weeks, once weekly for remainder. 50- 60 minute sessions	Manualised CT and BT. Therapists in psychodynamic condition followed a prescribed outline with variation depending on progress. Control condition was a delayed treatment control.	Treatment conditions had significantly better scores than delayed treatment control on BDI, HDRS, BSI: depression and anxiety, BSI: global severity. No significant differences on any outcome among 3 treatments.	None	0/9	1/6
Serfaty et al.	RCT: CBT plus	All conditions:	CBT: Manualised treatment and	Statistically significant	CBT: increased	5/9	5/6

(2009)	<p>TAU vs. TAU plus TC vs. TAU plus CBT.</p> <p>Total (N=204), mean age= 74.1 years; 79.4% female; 20.6% male, CBT (n=70, mean age= 74.4) TC (n=67, mean age= 75.0), TAU (n=67, mean age= 72.8)</p>	twelve 50 minute sessions	<p>older adult bibliotherapy.</p> <p>TC: therapists asked to show interest/warmth, discussing neutral topics e.g. Hobbies. No advice or problem solving given, and little focus on emotional issues. TAU: routine treatment by GP, e.g. medication, support.</p>	improvements on BDI in CBT group vs.TC and TAU.	<p>structure to facilitate recall.</p> <p>Inclusion of patients' beliefs about negative effects of physical ill health and perceptions of their ageing. Transport support provided.</p> <p>Participants offered more sessions.</p>		
Laidlaw et al. (2008)	<p>RCT: CBT (N=20, mean age= 70.00) vs TAU (N=20, mean age= 74.05)</p> <p>Total (N=40, mean age=</p>	Average of 8 sessions of CBT (range= 2-17)	<p>CBT based on previous older people modified protocol.</p> <p>Cognitive: training in self-monitoring and recording of negative thoughts. Behavioural: activity scheduling.</p> <p>TAU: GP standard care, e.g. medication</p>	Significant reduction in both groups on BDI, GDS, and HDRS. No significant difference between groups	Specific modifications made, but no detail provided.	0/9	5/6

	74.03, 11 males and 29 females)						
Gallagher and Thompson (1982)	<p>RCT: BT vs CT vs BIP.</p> <p>CT (N=10, mean age= 68.3), BT (N=10, Mean age=66.0), BIP (N=10, mean age= 69.0) Total: N=30, mean age= 67.7, gender= 7 male, 23 female).</p>	<p>All conditions: 16 individual sessions (12 weeks). Seen twice weekly for four weeks; then once weekly for remaining 8 weeks.</p> <p>Sessions: 90 minutes</p>	<p>BT and CT based on previous older people modified protocol.</p> <p>BT: increasing pleasant events and decreasing unpleasant events. Skills: relaxation; social skills and problem solving.</p> <p>CT: influence of negative views about oneself, experiences, and the future on depression. Techniques: reattribution, examining the evidence, pros and cons of thoughts.</p> <p>BIP: eclectic/dynamic orientation. Treatment: agreeing on goals, using therapeutic alliance.</p>	<p>No significant differences between 3 groups after treatment. However, reduction in all 3 groups on HDRS, BDI, and Z-SDS.</p> <p>Better maintenance of improvement at 1 year follow up in CT and BT than BIP.</p>	Use of bibliotherapy in CT and BT.	1/9	5/6
Dolores E. Gallagher and Thompson (1983)	<p>RCT: BT vs CT vs IOP</p> <p>Total (N=30, 7 males and 23 females)</p> <p>10 in each treatment</p>	<p>16 sessions over 12 week period, 90 minute sessions</p>	<p>BT and CT based on previous older people modified protocol.</p> <p>CT: monitoring and modifying thoughts, addressing underlying themes/beliefs.</p> <p>BT: monitoring mood and daily activities, and formulating change</p>	<p>Participants with nonendogenous depression had significantly lower depression scores at end of treatment vs. participants with endogenous depression on HDRS and BDI but not Z- SDS. Significantly</p>	None	0/9	3/6

	condition, CT (mean age=68.3) BT (mean age=66.0), IOP (mean age= 69.0)		plans in relation to pleasurable activities. IOP: eclectic/dynamic orientation. Emphasis placed on therapeutic relationship.	higher percentage of participants with nonendogenous depression were responders at end of treatment (BDI10)			
Fry (1984)	N-RCT: CBT vs. DTC Total N= 35, mean age= 65.1, of larger group 16 received the treatment immediately and 12 assigned to DTC.	Individual 60 minute sessions, 3 times a week, duration of therapy is unclear.	CBT protocol designed by authors. Cognitive: training in self-monitoring of thoughts. Behavioural: training in self-control.	In the treatment condition, significant reduction in depression measured by the MMPI-D at three time points (post, 1 month & 2 months). Significant improvements in the DEQ variables (Dependency, Self-criticism & Self-efficacy) were found.	Participants paired and agreed to phone each other between sessions to reinforce session content.	1/9	4/6
Floyd, Scogin, McKendree-Smith, Floyd, & Rokke (2004)	RCT: Immediate-treatment bibliotherapy vs. immediate-CBT vs. DTC. Total: 35 females and 11 males. Average age= 68, age	12 to 20 sessions of cognitive therapy. Bibliotherapy lasted 4 weeks- as did DTC.	Bibliotherapy: given CT self-help book. Participants asked to read and complete homework exercises within one month. Weekly brief phone calls; monitoring adherence to treatment and answering questions. CBT: manualised protocol modified previously for older	Both treatments superior to DTC at all time points on all measures, CT superior to bibliotherapy at post treatment, but no difference at 3 month follow up (HAMD, GDS, GSI- BSI).	Provided: cues to maintain attention, advance notice of tasks to complete, and ways to assist with retention of the clinical concepts.	1/9	5/6

	range=60 to 80, CT (N=16), Bibliotherapy (N=16), DTC (N=14)		people. DTC: asked to return in 4 weeks for another pre-treatment assessment at which point they would be assigned to treatment.				
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Key to abbreviations: MDD= Major Depressive Episode; RCT=Randomised Control Trial; N-RCT= Non randomised control trial

Treatment abbreviations: CBT= Cognitive Behavioural Therapy; CT= Cognitive Therapy; PFE= Physical Fitness Exercise; TAU=treatment as usual; DTC= Delayed Treatment Control; BT= Behavioural Therapy; TC= talking control; BIP= Brief Insight Psychotherapy; IOP= Insight Orientated Psychotherapy

Assessment measures abbreviations: HAMD= Hamilton Depression Scale; Z-SDS= Zung Self-Rating Depression Scale; BDI= Beck Depression Inventory; GHQ-28= General Health Questionnaire; PGC= Philadelphia Geriatric Centre Morale Scale; GDS-15= Geriatric Depression Scale- 15; PHQ-9= Patient Health Questionnaire-9; MMPI-D= Minnesota Multiphasic Personality Inventory- Depression sub scale; GSI- BSI= Global Symptom Index of Brief Symptom Inventory.

4.2 Stage two. Exploring relationships between recommended modifications and reported modifications

Table 1 illustrates the frequency with which recommended modifications were reported in the intervention studies. Further detail on this is explored below in order of frequency.

The first item, *Memory difficulties*, was the most frequently reported modification (four of 14 studies), and relates to processing and retention of new information during and between sessions. For example: behavioural rehearsals of new skills and multiple repetitions of a technique (Chaowanee, et al., 2018).

Thompson, et al. (2001) reported the use of strategies such as repeated presentation of materials in different forms and modelling behaviour.

Four modifications were each reported in two of 14 studies.

1. For *Use of skills outside of session and completion of homework tasks*, Fry (1984) paired participants and asked them to phone each other between sessions; reinforcing the use of therapeutic techniques.
2. *Inclusion of patient strengths* included incorporating life skills & preserved cognitive abilities. Some used adjunctive bibliotherapy to maximise older people's relatively preserved recognition memory and ability to extract main points from prose material (Crowther, et al., 2010; Serfaty, et al., 2009).
3. Addressing *Cohort beliefs*, - Serfaty, et al. (2009) reported exploring patient's beliefs about the negative perceptions of ageing.
4. *Physical health problems/sensory difficulties* included addressing the impact of physical health problems. Chaowanee, et al. (2018) provided transport for participants and Serfaty, et al. (2009) offered home visits for those unable to travel.

Chaowanee, et al. (2018) were the only authors who reported on *Family and wider system*; encouraging participants to have family assist with homework tasks. Attention difficulties were only reported in one study (Serfaty, et al., 2009).

4.2.2 Further modification themes which emerged from the intervention studies

Only three of the 14 studies made such recommendations, and these were in relation to numbers of sessions and session duration. Serfaty, et al. (2009) suggested offering more sessions (12); arguing the recommended 6-8 would not be enough time for older people to learn techniques. Chaowanee, et al. (2018) recommended shorter sessions of 45-60 minutes to account for fatigue and short-term memory difficulties.

4.2.3 Quality appraisal of the intervention studies.

Study quality was analysed and considerable variation was found (n=14, median=3.5, range=1-5, maximum score of 6). All studies offered *details of the experimental treatment*, e.g. García-Peña, et al. (2015) gave a brief overview of the rationale and aims of CBT. These studies received a score of 1. This item afforded the opportunity to score a study higher (2) if the treatment could be replicated from the description. Three of the 14 studies were given the higher score of 2. For example, Huang, et al. (2015) gave more detailed explanations of the different phases involved in the intervention, and similarly detailed quantitative information on the treatment, e.g. number of, frequency and duration of the sessions. *Details of the control or comparator treatment were given* by nine of 14 studies (not applicable for 2).

Details of how the intervention was, or could be, standardised were specified by ten of 14 studies; referencing use of protocols, and detail on therapist training.

Eight of the 14 studies reported *efforts made to modify the experimental treatment for older people*. This item was highly sensitive to identifying a minimum standard of modification.

Half of the intervention studies provided *details of how adherence to the protocol was assessed or enhanced*. This was lowest scoring item. Examples included supervision of therapists and reviewing session audiotapes (Floyd, et al., 2004).

See appendix 1.4 for quality appraisal per trial.

4.3 Stage three: Assessing the robustness of the synthesis

Although, treatment manuals were not requested from authors, it was judged the reviewer had sufficient information to make decisions relating to eligibility of papers.

5. Discussion

A narrative synthesis of the modifications made to CBT for older people with depression was carried out, using established methodology (Popay, et al., 2006; Gallagher, et al., 2019); thematic analysis of extracted data from review studies was undertaken. A modification extraction list was developed which was systematically applied to intervention studies. Nine areas of difficulty and need for modification were identified (see table 4). There were mixed results and evidence of poor reporting of modifications.

5.1 Recommended modifications

Variation exists within the nature of identified modifications. Some could be considered practical or technical changes, e.g. *memory difficulties: use of repetition of new information*, whereas some are more conceptual in nature, e.g. *Losses/transitions in*

role. Laidlaw and Kishita (2015) argue for moving from procedural modifications to augmenting practice with concepts from gerontology theory. Laidlaw's comprehensive contextualisation framework emphasised the importance of enhancing CBT with contextual factors, e.g. *socio-cultural context*, relating to attitudes towards ageing, held particularly by older people and clinicians. Laidlaw has more recently posited the use of gerontology theory to enhance further this understanding and practice. For example, the use of Selection, Optimisation and Compensation (SOC) theory (Freund & Baltes, 1998) has been suggested, to strengthen and contextualise the problem solving element of CBT; supporting older people to adapt to loss of ability/resources, whilst maintaining valued goals. With this approach, the aim becomes less about making procedural changes to a therapeutic approach, and more about placing an established therapeutic practice it in an older people's context.

5.2 Reported treatment modifications

Six of 14 studies demonstrated no evidence of CBT modifications for older people. Moreover, when explored in more detail, fewer than one third of older people CBT treatment studies showed evidence of adaptations in line with recommendations. It is difficult to determine if the overall performance is due to modifications not being reported sufficiently, or if it is down to therapy not being modified. It could be argued many of the intervention studies focussed on efficacy and not adaptations, resulting in the latter not being a priority. It could be that the samples included did not require modifications to therapy. Other than more specialised areas (e.g. chronic health problems, or residential settings), it has been argued CBT for older people with depression samples comprise healthy older people, without significant physical or cognitive health problems (James, 2008). Laidlaw, Thompson, and Gallagher-Thompson (2004) argued the trial research has applied a working age adult model of

CBT to an older age adult population. There was insufficient detail to appraise this area of the methodologies. Future research should aim to record the physical and cognitive health of participants who take part in intervention trials.

Moving to conceptual changes based on theory may be a useful and necessary step, and Laidlaw's work (2001; 2004) was included in the creation of the modification framework. However, in comparison to practical changes (e.g. memory aids), it may be more difficult to operationalise this when appraising trial reporting. This may be reflected in the poorer results in the current review on conceptual items (e.g.

Losses/transitions in role). Of note, the review articles were more recent than intervention studies (publication dates: 1982-2018 & 1991-2015, respectively).

Intervention studies included six (of 14) studies published before 2000; only three of the review articles (n=13) were pre-2000. Therefore, some more recent recommendations will not have influenced earlier trials. Thus more recent recommendations will not have influenced earlier trials within an emerging research area.

Thematic analysis of the intervention studies produced a further modification in the number and length of sessions providing a useful practical addition to the framework and an area to consider for future trials. However, James (2008) argued that procedural modifications should be generalised with caution, emphasising the heterogeneity of the population.

5.3 Quality of reporting

The quality of reporting was analysed using an adapted version of the 'treatment' section of the CONSORT checklist for non-pharmacologic treatments (Boutron, et al., 2008). There was considerable variation in the quality of treatment description. For example, all studies offered *details of the experimental treatment*, but only half gave

details of how adherence to the protocol was assessed or enhanced. 57% of treatment studies reported efforts made to modify the experimental treatment for older people; this could be considered an indication of low quality given the aims of this review.

5.4 Implications of research

This review provides a useful analysis of the quality of reporting on modifications made to CBT for older people with depression. The significant lack of reporting of modifications hinders the optimisation of treatments for older people and better quality reporting is required. This review also provides a framework that may act as a useful clinical tool to be utilised in similar future research. Recognising the limitations of this review, the modification list should not be considered exhaustive; rather this review will contribute to an important debate on the context of modifying CBT for older people as it moves to a more conceptual and theoretical perspective.

5.5 Limitations

Screening and reviewing of papers in relation to the eligibility criteria, and the qualitative analysis of modification themes, was carried out by a sole researcher. Whilst it may be appropriate in the context of a doctoral project and conducted under supervision; it is acknowledged that a team approach would have reduced the impact of individual bias.

Copies of treatment manuals (which may have provided further detail contributing to thematic analyses) were not requested due to the time constraints. The resulting thematic analysis of modifications should therefore be generalized with caution.

James (2008) argued there may be learning points from working with older people which can be applied with younger adults, and a potential criticism of the current review

is that modifications would be appropriate to a greater or lesser extent to younger adults, therefore not specific to older people. However, the authors of reviews specifically proffered the modifications for the older adult population, in line with policy guidance and the rationale pertaining to the importance of modifying therapeutic approaches for older adults. A related issue, and criticism of the literature in this area, is that of the age of participants in the reviewed studies. As studies in this review comprised participants with an age range of 65-70 years, it could be argued these participants may now be considered part of the working age population.

5.6. Conclusions

This systematic review and narrative synthesis explored the modifications made to CBT for depression to address the therapeutic needs of older people. A range of modifications recommended in review articles were found. However, there was little evidence of reporting of these in intervention studies. This may be due to a poor standard of reporting. It may also be related to participant profile in studies which was largely a younger, older adult population. Both the nature of modifications and their application are challenged within the literature. Better reporting standards are required in order for future research and clinical practice to optimise treatment for this population. The modification framework could be useful for guiding future research into the value and utility of different changes to CBT to better meet the needs of this population.

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CHAPTER TWO: MAJOR RESEARCH PROJECT

Acceptance and Commitment Therapy with a Community Older Adult Sample: a Feasibility Study Investigating Mechanisms of Change.

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Plain English summary

Title: Acceptance and Commitment Therapy with a community older adult sample: a feasibility study investigating mechanisms of change.

Background

It is crucial to meet the mental health needs of older people. Acceptance and Commitment Therapy (ACT) encourages participants to pay attention to the present moment, and be more accepting of uncomfortable thoughts and feelings as opposed to considering other ways of thinking about a situation (Harris, 2009). It also encourages people to do more of what is important to them. ACT may be a good fit for older people who can have multiple health and social problems that can be difficult to change (Petkus and Wetherell, 2013). Only a small amount of research has been done on ACT with older people, and little is known about how easy or difficult it is for older people to change their behaviour.

Aims of the Study

- Do people attend the group and complete questionnaires?
- Is there improvement on the questionnaires over time?
- What might help or be a barrier to older people putting ACT into practice?

Methods

Community patients, aged 60 or over were recruited. Patients were not involved in the groups if they had a learning disability or cognitive impairment, or if part of their mental health difficulties meant they could not meaningfully participate in the group. Participants were asked if they wanted to take part in a six session ACT group, and in addition, if they wished to take part in research. Research involved filling out

questionnaires and being interviewed when the groups finished. Questionnaires were filled out, such as level of depression, before, after, and 12 weeks after, completion of the group.

Main findings

75% of participants attended at least four sessions and were judged to have completed the group. There were also positive rates of completion of measures pre, post and 12 weeks after the group. The results of questionnaires suggest measures of anxiety and depression went down, participants were more able to let go of difficult thoughts, and able to do more of what is important to them.

The interviews suggest difficult emotions can make it more difficult to change behaviour, but issues such as memory problems were not a major factor. People who thought ageing was negative influence appeared to think changing their behaviour was less likely to occur. Moreover, having social supports was reported as being important in relation to living more in line with values.

Conclusions:

The group treatment appears to be feasible with older people as there were positive rates of group completion and questionnaire completion. There was positive improvement on questionnaires and the interviews provided an insight into the factors encouraging or getting in the way of older changing behaviour to do the things that matter to them.

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Abstract

Background: Older people have specific health needs, different to those of working age adults. Acceptance and Commitment Therapy (ACT) may be useful for older adults who often face unchangeable difficulties, and can show a higher motivation to live in line with values. The evidence base is in the early stages, and more information on feasibility and how easy or difficult it is to change behaviour and put the therapy into practice. The COM-B model of behaviour change posits capability, opportunity and motivation as necessary prerequisites for behaviour change.

Aims: To investigate the feasibility of an ACT group intervention; exploring acceptability and suitability. Moreover, using the COM-B model of behaviour change this study aimed to investigate the facilitators and barriers to living in line with values.

Methods/Results: Participants were recruited from a community older adult psychology service, and seeking treatment for mental health disorders such as anxiety and/or depression. Of the 16 participants recruited, 12 attended four or more sessions. Of 20 participants invited to a post intervention qualitative group, 16 attended. Using a mixed methods design, the study also included quantitative measures (e.g. Hospital Anxiety and Depression Scale) at different time points (pre, post & 12 week follow up), and post group interviews with a topic guide derived from the COM-B model. Qualitative data were analysed using Framework Analysis.

Findings suggest that 12 weeks after the intervention finished there was a reduction in anxiety, depression and cognitive fusion scores, and a positive increase in behaving in line with values. From interviews, barriers to behaviour change include: difficult emotions and negative views of ageing. Memory problems were not reported as a

significant factor, but social supports was reported as being an influential factor in relation to living in line with values.

Conclusions:

The group treatment appears to be feasible with older people as there were positive rates of group completion and questionnaire completion. Additional preliminary data from measures of mood and ACT processes suggests these measures are responsive to change following the intervention. Qualitative data provided an insight into the factors which may facilitate or discourage behaviour change for older people in relation to living in line with one's values.

Key words: Acceptance and Commitment Therapy, Older Adults, Feasibility Study, Behaviour Change, COM-B.

1. Introduction

1.1 Context of older adult psychopathology

Health services struggle to meet the mental health needs of older people and forecasts suggest this will increase (Royal College of Psychiatrists, 2018). Cognitive Behavioural Therapy (CBT) is the main therapy recommended for a range of mental health disorders with older adults according to the Psychological Therapies Matrix (NES, 2015).

However, CBT has a limited evidence base for non-primary care older adults, may be suboptimal for anxiety and there is a lack of evidence comparing the intervention to other treatments (Petkus & Wetherell, 2013; Gould, Coulson, & Howard, 2012).

Acceptance and Commitment Therapy (ACT) may provide an effective alternative for addressing the mental health needs of older people.

1.2 Acceptance and Commitment Therapy (ACT)

ACT is a “third wave” cognitive behavioural therapy that aims to increase “psychological flexibility” using acceptance and mindfulness practices to encourage a willingness to experience difficult internal experiences, whilst maintaining a behavioural focus on living in line with one’s values (Hayes, Pistorello, & Levin, 2012).

In practice ACT takes a non-judgemental and present moment approach to thoughts and feelings, with the aim of achieving distance from difficult thoughts, augmenting this with a behavioural focus on identifying and behaving in line with one’s values (Kishita, Takei & Stewart, et al. 2017). In relation to adults of all ages, a meta-analysis by A-Tjak and colleagues (2015) concluded that ACT is more effective than treatment as usual or placebo, and may be as effective as CBT, with several psychiatric diagnoses, including anxiety and depression.

1.3 ACT with older people

The evidence base for ACT with older people is promising in relation to old age anxiety difficulties, depression and chronic pain (Wetherell et al., 2011; Davison, Eppingstall, Runci, & O'Connor, 2017; Scott, Daly, Yu, & McCracken, 2017).

There is a strong rationale for ACT with older people, a population more aware of the fact that life is limited, and more motivated to live in ways consistent with their values (Roberts & Sedley, 2016). The transdiagnostic nature of ACT is apposite for a heterogeneous population who often present with a wide spectrum of difficulties.

Finally, an acceptance focus may be useful for older people who can face challenges that are often difficult to escape or change, e.g. death of spouse, significant chronic health problems.

1.4 Mechanisms of change in ACT

In line with The Medical Research Council (MRC) guidance for progressing intervention research, feasibility studies provide useful information (e.g. response rates & attendance) as to whether or not an intervention should be further researched at pilot stage (Craig et al., 2008; Arain, Campbell, Cooper, & Lancaster, 2010). The framework also emphasises the importance of process evaluation: considering mechanisms of change and understanding the context in which interventions take place (Eldridge S, 2005; Moore, et al., 2015). The evidence from component and mediational analyses suggests ACT works through the specific theoretical processes it posits (Zettle, Rains, & Hayes, 2011; Levin, Hildebrandt, Lillis, & Hayes, 2012).

Committed action is concerned with one's behaviour being consciously linked to one's values, and is under-researched within ACT. Although investigated in the area of

chronic pain, there is a dearth of information on the contextual factors that may play a role in an older person having the opportunity to put values into practice and change their behaviour. The field of behaviour change is improving the understanding of how this can be supported. Models such as COM-B (Capability, Motivation, Opportunity-Behaviour) (Michie, et al., 2011) provide an overarching framework (with no psychotherapeutic affiliation) to explore participants' experience of the intervention and the extent to which ACT meets its ultimate goal of promoting adaptive behaviour change (Hayes, et al., 2012). The framework postulates that people require the Capabilities, the Opportunities and the Motivation to perform Behaviour. It explores the opportunities and barriers for older people living in the community who are attempting to behave in ways consistent with their values.

In summary, there is a strong rationale for using ACT with older adults, but the evidence base is limited and little is known about the change processes involved with this population. Using quantitative and qualitative methods, the current study aims to explore the acceptability and feasibility of an older adult ACT group protocol that is running in NHS Lanarkshire with a community sample. Crucially, it aims to add to the literature by exploring the internal and contextual factors at play that facilitate or discourage opportunity for behaviour change in older people.

2. Research questions

Primary feasibility question:

Is the ACT group intervention acceptable and suitable for a community older adult sample?

Secondary questions:

Are measures (mood & ACT processes) responsive to change at pre, post and 12 weeks after intervention?

What might be facilitators/obstacles to behaviour change in ACT?

3. Method

3.1 Design

Primary data collection took the form of feasibility data. In addition, using a mixed methods design, questionnaire data were collected pre-group, post-group and at 12-week follow-up. A control group was not included in this study as the primary focus was on feasibility. Qualitative data collection took the form of semi-structured interviews, the design of which was guided by the COM-B model of behaviour change (Michie, et al., 2011).

3.2 Participants

Participants were eligible for inclusion if they were over 60 years old, had capacity to consent to research, and were an accepted referral to the Psychological Therapies for Older People community team. Exclusion criteria included:

- significant cognitive impairment
- a level of distress which would make it difficult to function in group
- personality factors that would make it difficult to participate appropriately

In line with the transdiagnostic nature of ACT, participants had a variety of mental health difficulties and presentations, but primarily mixed symptoms of anxiety and depression, along with adjustment to chronic health conditions and major life transitions (e.g. bereavement or retirement).

3.3 Sample size

Three groups were run in the timeframe for data collection. The first group was only eligible for the qualitative part of the study and the second and third groups were eligible for all aspects of the project. The present study had a quantitative sample of 16. An aim of this study was to ascertain the feasibility of recruitment within this population.

Employing Framework Analysis (FA) (Ritchie, 1994), qualitative sample size was influenced by factors like saturation (Merriam, Tisdell, Askews, & Holts Library, 2016). Hennink, Kaiser, and Marconi (2017) concluded that conventional saturation was reached at nine interviews, but 16-24 provided a more comprehensive saturation. The current study had a qualitative sample size of 16, and with the consistency observed in interviews, saturation was reached at this point.

3.4 Procedure

3.4.1 Ethical approval

Ethical approval (18/EM/0393) was granted by East Midlands - Leicester South Research Ethics Committee on 5 December 2018, and subsequently by NHS

Lanarkshire Research and Development on 10 December 2018 (see Appendix 2.1)

Written informed consent was given by all participants

3.4.2 Recruitment

Potential participants were offered an assessment appointment with a group facilitator; guided by the inclusion/exclusion criteria. Participation in the group intervention, and additional involvement in the present research were discussed. Patients were given an information sheet and time to consider if they would like to participate. If patients did not opt in to research, they were still able to receive the group intervention. Data were collected by the main researcher (Trainee) and clinicians who facilitated the groups.

3.4.3 ACT group protocol

The group consisted of six weekly, two-hour sessions and was facilitated by qualified clinical psychologists. An ACT group intervention protocol for older people has been developed locally by one of the group facilitators. Handouts were provided and between session homework exercises were included.

Session topics:

1. Exploring beliefs about mental health and ageing, creative hopelessness
E.g. Use of Monster and the rope metaphor to illustrate the impact of cognitive control strategies on wellbeing and ability to enjoy life.
2. Values
E.g. Verbal explanation of values, such as concept of moving towards values, as opposed to achieving goals.
3. Noticing self, Present moment and Acceptance
E.g. Mindfulness practice in session and discussion of being mindful whilst doing everyday activities.

4. Defusion, Acceptance and Conceptualised Self

E.g. Building on mindfulness with concept of cognitive defusion: guided imagery exercise about lemons to illustrate the impact of thoughts on physical experience.

5. Committed action (Obstacles and future planning)

E.g. Discussing plans for putting values into action, in the form of goals.

6. Summary and relapse prevention

E.g. Troubleshooting problems that may arise in putting therapy into practice after group intervention is complete.

See appendix 2.2 for a more detailed outline of the protocol.

3.4.4 Measures

- 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 found that the mean of the anxiety subscale was $\alpha=0.83$ and depression subscale was $\alpha=0.82$ (Bjelland, Dahl, Haug, & Neckelmann, 2002).

ACT measures:

- The Brief Experiential Avoidance Questionnaire (BEAQ) (Gámez et al., 2014) is a 15-item measure of experiential avoidance. The authors reported this measure to have a mean of $\alpha=0.86$. To date, it has not been used in research with older people.
- The Valuing Questionnaire (VQ) (Smout, Davies, Burns, & Christie, 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. To date, it has not been used in research with older people.
- 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

$\alpha=0.90$. Scott and colleagues (2016) used this questionnaire with an older population and reported internal consistency of $\alpha=0.74$.

- The Acceptance and Commitment Therapy measure of change for Older Adults (ACT-OA) is a session-by-session measure created by Psychological Therapies for Older People service (NHS Lanarkshire) designed to measure clarity of values, clarity of planned action, engagement in valued living and willingness to experience difficult thoughts and feelings (see appendix 2.3).
- The Self-Experiences Questionnaire (SEQ) (Yu et al., 2016) is a 15-item measure of self as context. This measure has not employed in a specifically older adult setting.

3.4.5 Data Analysis Plan

Quantitative: To explore feasibility, the study focussed on determining rates of recruitment and feasible sample parameters for future studies. To explore treatment signals, effect size calculations were conducted based on the pre and post change scores in the above outcomes measures at three time points (pre, post and 12 week follow up). The quantitative data analysis plan included comparison of average scores at the different time points with consideration given to normality of the data (such as type of variable, e.g. ordinal data & statistical tests of normality) to select the appropriate statistical method.

Qualitative: Participants were invited to attend a post group interview and the main researcher transcribed and anonymised interviews. Framework analysis (FA) (Ritchie, 1994) was selected as it can be inductive and guided by existing theories, and allows for specific questions to be addressed (Ward, Furber, Tierney, & Swallow, 2013). Questions for qualitative interview were developed to explore the extent to which different aspects of COM-B were adequately addressed by the intervention; what

remained as obstacles to behaviour change, and what further supports would be necessary for an older adult population (see appendix 2.4 for schedule). Analysis followed the five-step process outlined by Ritchie (1994): 1) familiarisation; 2) identifying a thematic framework; 3) indexing; 4) charting 5) mapping and interpretation. Supervision was used in this process and there was more focussed input from the academic supervisor in the form of co-interpretation and revision of the thematic framework.

4. Results

4.1 Main outcome: Feasibility findings

4.1.1 Sample characteristics

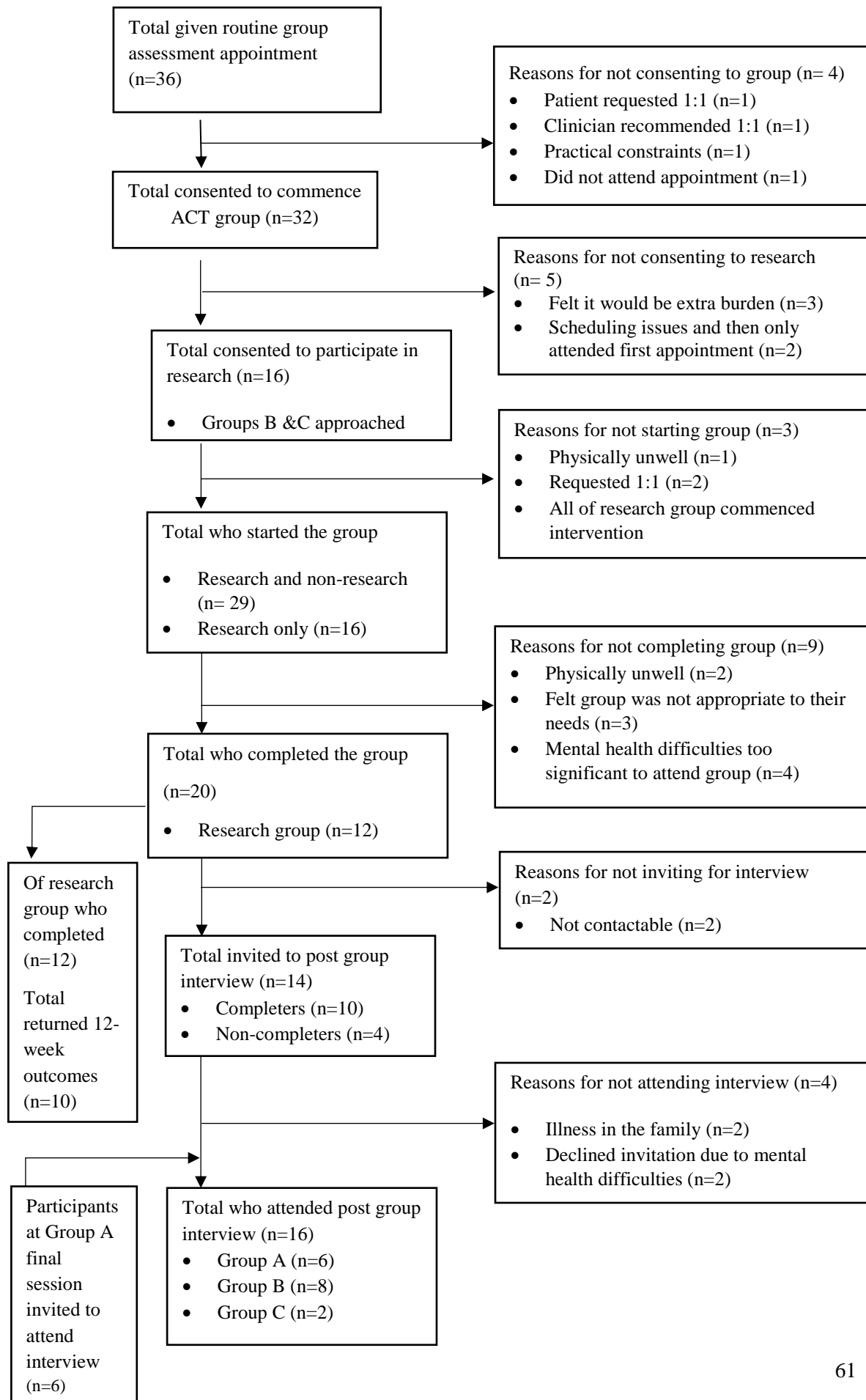
Three groups were delivered. Participants from the first group (A) were ineligible for the quantitative element of the study as the group had commenced before the study received ethical approval. Groups B and C were approached for the quantitative element of the study. All three groups were approached to take part in the post group interview. Group A commenced with nine participants, group B with 13 and group C with seven.

Of the total who commenced the intervention in all groups (n=29), 21 were female (72.4%) and eight were male (27.6%). They had a mean age of 72.4 (SD=6.67). The commonest primary reason for referral was mixed anxiety and depression (n=21). Other primary reasons for referral were depression (n=6) and anxiety (n=2). Assessed through clinical interview by the group facilitators, a variety of comorbid problems were reported: psychosis (n=1) and chronic health difficulties (n=5).

4.1.2 Recruitment

See Figure 1 for details of participant flow, from the three groups.

Figure 1: Recruitment flow chart



4.1.3 Group attendance

The median number of sessions attended was five, with a range of one to six. Of the 16 participants who started the group, five (31.25%) attended all six sessions, five (31.25%) attended five sessions, two (12.5%) attended four sessions, one (6.25%) attended three sessions, two (12.5%) attended two sessions, and one (6.25%) attended one session.

Reasons for non-attendance included hospital appointments, physical health difficulties, planned holidays, other family commitments or forgetting about the session.

Completion of the group was defined as attendance at least four of the six sessions. Of the 16 participants 12 (75%) completed the group. In group B the completion rate was 81.82% and in group C the completion rate was 60%. See figure 1 for more detail, including non-research participants.

4.1.4 Completion of outcome measures

Completion rates varied from 80-100% and were calculated based on the number of participants who returned any measures at the time points (see appendix 2.5).

4.2 Quantitative Results: trends and treatment signals

As assumptions of normality were violated on all quantitative measures, non-parametric analysis was indicated as the most appropriate statistical approach. Wilcoxon Signed-Rank Tests were performed to compare scores in relation to three time points. Table 1 outlines the available outcome data for all participants.

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

Measure	Median			WSRT Pre-Post	Effect Size (r): Pre-Post	WSRT: Pre-12 Week	Effect Size (r): Pre-12 Week	WSRT: Post-12 Week	Effect Size (r): Post-12 Weeks
	Pre	Post	12-Week						
HADS-A	15.5	15	10.5	$p = 0.03^*$ n= 7	0.57	$p = 0.02^*$ n= 7	0.64	$p = 0.04^*$ n= 8	0.51
HADS-D	13	10	7.5	$p = 0.04^*$ n= 7	0.55	$p = 0.02^*$ n= 7	0.64	$p = 0.02^*$ n= 8	0.58
BEAQ	67	59.5	54.5	$p = 1.00$ n= 9	0.00	$p = 0.123$ n= 9	0.36	$p = 0.152$ n= 9	0.32
VQ-Obstruction	22.5	17	15	$p = 0.80$ n= 8	0.06	$p = 0.324$ n= 8	0.25	$p = 0.203$ n= 8	0.32
VQ-Progress	15.5	15	20	$p = 0.06$ n=8	0.47	$p = 0.34$ n= 8	0.24	$p = 0.05^*$ n= 8	0.50
CFQ	39	33	30	$p = 0.62$ n= 8	0.12	$p = 0.10$ n= 9	0.39	$p = 0.02^*$ n= 9	0.55
ACT-OA	16	21	20.5	$p = 0.91$ n= 8	0.40	$p = 0.05^*$ n= 9	0.46	$p = 0.93$ n= 9	0.02
SEQ	50	47	47	$p = 0.86$ n=9	0.04	$p = 0.58$ n=8	0.14	$p = 0.78$ n=8	0.07

*significant finding if $p = <.05$

There was improvement on the HADS-A and D in all time pairings (medium effect sizes, $r=0.51-0.64$). Effect sizes were interpreted using the Cohen (1988) convention for effect size interpretation (Lakens, 2013). HADS clinical cut off scores indicated a clinically meaningful change. HADS A moved from the *Severe* category (pre) to the *Mild* category (12 week follow up). HADS D moved from the *Moderate* category (pre) to the *mild* category (post) and to the *Non clinical* category (12 week follow up).

There was an improvement on Valuing Questionnaire-Progress sub scale and the CFQ, from post group to 12-week follow up, with a medium effect sizes ($r=0.50$ & 0.55). Finally, there was significant improvement on the ACT-OA measure from pre group to 12-week follow up, with a small effect size ($r=0.46$).

Regarding future research, using the data above and the G Power software, it is estimated that 40 participants would be required in each of the control and experimental groups (α level $P=0.05$, power 80%) in order to detect a statistically significant difference in mean scores on pre to 12 week follow up HADS between the two groups.

.4.3 Qualitative Results: The Participant's Experiences

4.3.1 Sample Characteristics

Sixteen participants consented to and attended an interview post-intervention, eleven were female and five were male with a mean age of 71.81 (SD= 6.73). All were completers, range of 4-6 sessions.

4.3.2 Results

Framework analysis (FA) (Ritchie & Spencer, 1994) was selected as it allows for a specific theory to be applied to the data. The COM-B model of behaviour change was utilised to answer specific questions, i.e. pertaining to the facilitators and barriers to

changing behaviour and living in line with values. Table 2 demonstrates an overview of the COM-B components and the themes which emerged from interviews.

Table 2: Qualitative COM-B components and themes

<u>COM-B component</u>	COM-B sub-component	<i>Theme</i>
<u>Capability</u>	Psychological	<i>Useful techniques</i>
		<i>Difficult emotions</i>
		<i>Cognitive factors</i>
	Physical	<i>Physical health</i>
<u>Opportunity</u>	Social	<i>Social supports</i>
	Physical	<i>Financial</i>
<u>Motivation</u>	Reflective	<i>Ageing</i>
		<i>What motivates?</i>
	Automatic	<i>Persisting when faced with challenges</i>

Each section below begins with a brief definition of the relevant component of the model. These definitions were not derived from the interviews, but instead provide an example of the COM-B theory from recent papers which used COM-B (Barker, Atkins, & de Lusignan, 2016; Bentley, Mitchell, Sutton, & Backhouse, 2019). Each section then provides detail on the experiences of participants in relation to the theory.

Capability

The capability component of the COM-B model relates to the individual's psychological and physical capacity to engage in a behaviour.

Psychological capability- “It made you think, yeah I want to do that, how will I do it? So you make time for yourself, to do it” (P1p2L54-55)

The behaviour change literature details *Psychological Capability* as the knowledge, emotional or cognitive factors involved in enacting a behaviour. Within this sub-category, *Useful techniques* was an important factor that emerged in many accounts. Taking small steps, and using a graded approach to new behaviours was identified as a useful approach. One participant reflected on how this was personally a new approach.

“I’ve got to take small steps towards it, not jump in to it because sometimes in the past I’ve gone into something in great gusto, and then you find I’ve dropped really quickly. So now I’m drawing back a little bit, thinking about it, before I move forward.” (P7 p1 L35-38)

Moreover, participants spoke of the importance of taking the first step in doing something that mattered to them.

“If you want to do something, you have to take the first step. You don’t have to start small but it doesn’t matter how little or big it is; you still have to take that first step” (P14 p1 L26-27)

As part of *Useful techniques*, *approaches* specific to the ACT group intervention were also referenced as useful. This included mindfulness which many participants reported as beneficial.

“It was quite calming and I could put myself in that mode. To get rid of any obstructions, to try and unload it from yourself. Send it down the stream on a leaf” (P3 p1 L27-29)

Participants also reported moving beyond formal mindfulness practice, e.g. listening to a mindfulness recording, to changing their behaviour to incorporate mindfulness practice in to everyday life.

“Just standing doing my dishes in the morning and looking out the window, I’ve got a beautiful big garden and I’ve started sort of really noticing things, (...), I’m trying to take time to notice things around me, which I got from the group”
(P10 p3 L80-82)

However, some participants did not report finding mindfulness a useful technique. There was a feeling of frustration when this was a case, and perhaps a sense of missing out on an important part of the intervention.

“The only thing I couldn’t get was the meditation. Just didn’t work for me, tried it in the house, in the car, tried it when I was doing a job, just didn’t work” (P12 p1 L6-9)

Another central tenet of the ACT model, acceptance, was reported by many as a useful approach and technique for relating differently to problems and starting to change behaviour. Some expressed that it was a new and in some cases unusual concept for them.

“Well I thought the group was different from the norm by accepting the problem not just trying to put it away, and that was a different way of looking at it” (P8 p1 L11-12)

Acceptance seemed to be a key facilitator for helping participants to focus on behaviour change. For some there was a sense that acceptance was a key underpinning element of

becoming psychologically capable of making changes to increasingly live in line with values.

Difficult emotions

The impact of emotions was salient within Psychological capabilities. Mental health difficulties, and in particular difficult emotions, were referenced on several occasions, and seemed to be a significant barrier to committed action. For one participant this seemed to be an obstacle to engaging meaningfully with family.

“The anxiety was stopping me from doing certain things, it was stopping me from actually going any distance in the car. Like you know, to visit, I have a son up North, not that far away, but the thought of the journey was worrying and I couldn’t do it” (P3 p1 L15-17)

However, acceptance appeared to have a positive impact on this.

“It was definitely a different way for me of looking at it you know, cause I’ve always felt I need to get better before I’ll feel better and get rid of all these fears and panics, but it sort of said, you don’t need to get rid of it you just to learn to live with it” (P13 p1 L30-32)

Cognitive factors

In relation to cognitive factors, such as memory and attention difficulties, a few participants reported some difficulty with engaging with the group concepts and retaining session content between group sessions. One participant related this to the frequency of sessions.

“I found the week quite long in between, so you had to really refresh your memory, although if you were doing the exercises, which I was doing most of them, but I think sometimes a week can be too long” (P11 p1 L14-16)

In this regard, the role of the facilitators was valued, and they appeared to be able to mitigate any difficulties and facilitate better engagement with the intervention.

“[Facilitator] was very good at explaining things, if you didn’t understand, at the beginning, never having done anything like that before, I thought; what does that mean? But [Facilitator] and [Other facilitator] were very good at discussing things with you and making you think” (P1 p2 L48-50)

A strength of the group protocol appeared to be the use of metaphors. Many participants referenced specific metaphors and appeared to be able to operationalise them in their lives.

“The other thing that sticks out in my mind, [Facilitator] said it’s like a hill with the sheep going round and round and round for years and it makes a path, and he says, every year they go that same path, and it is getting off that path, he says cause you’ll just keep going round and round on the same path. Get off by taking a first step, he says you weren’t going to go but you went, so you’ve jumped off the path” (P12 p4 L133-137)

Overall, cognitive capability was not raised as a significant factor or barrier to committed action, and many reported engaging comfortably with ACT concepts.

Considering psychological capability as a sub component of behaviour change, some participants did raise concerns about being capable of putting concepts in to practice.

There was a sense that this component is important, but interaction with other factors may be required to increase the likelihood of a behaviour being enacted.

“I understood what they were talking about, but I wanted to know how to put it into practice, right I know that, I could tell the person sitting next to me this is what you need to do, but I’m not, I don’t know how to put that into practice myself” (P9 p1 L31-34)

Physical Capability

Michie, et al. (2011) posited that this element of COM-B is concerned with factors related to physical health or procedural skills.

For the older adult sample interviewed in this study, *physical health* was a salient issue. When asked if participants felt able to make changes in their lives, different physical health factors were raised as potential barriers to committed action. For this participant there seemed to be the view that taking steps to live in with their values was contingent on physical health problems being resolved.

“Too much going on medically at the moment, that I need to get sorted first, and I need to find out what’s causing a lot of these medical, go and get testing or different things done, so that’s all going on in my head at the moment, I need to get these things sorted” (P13 p1 L36-39)

In addition to the presence of such difficulties, participants spoke of the impact of poor physical health on the type of behaviour they felt able to engage in.

“Hmm, two sores knees, two knee implants, two artificial knees. My spine is crumbling at the bottom, the discs. So physical things are quite hard, when

you're saying trying and go a hike or try and go a walk, things like that are hard"

(P11 p4 L141-143)

This participant also effectively illustrated the finding that many of the group reported a multitude of physical difficulties. This impact of this also appeared to interact with other salient themes such as low mood and activity levels.

"As I say it does get me down a bit, I'm trying to curtail it, I know the cellulitis, I've had that before, that hopefully will go, but this neuropathy, it's a burning in the both feet. I've probably got stuck with that, and it does have an impact on my mobility" (P4 p4 L135-138)

In a similar vein, poor physical health appeared to interact negatively with opportunities. One participant described feeling significantly frustrated and disappointed at one missed opportunity.

"We had to cancel a big holiday later 2017, and I know she (wife) likes holidays but not managed to get a way because of my health problems which aggravated, I felt like she's desperate to get away" (P4 p4 L160-162)

Opportunity

The opportunity element of the COM-B model is concerned with the social and physical factors, outside of the individual, that act to prompt or impede the behaviour.

Social Opportunities

Social supports

There was a sense that social support was a significant factor in changing behaviour and living in line with values. Many participants emphasised the importance and value of

having a supportive network of family and friends who can facilitate opportunity. One participant described her joy when a family member enabled a long held dream.

“I would like to do Shetland and I was so thrilled when my son said to me: I’ll do it with you mum, (...) That sort of thing lifts me so much. I phoned up and the brochure has come through (P5 p5 L170-173)

Another particularly valued quality was the empathy and understanding family can provide.

“I tell them things that I didn’t before, and I guess they make allowances now that they maybe didn’t before, you know. They told me they knew something wasn’t quite right.” (P16 p2 L54-55)

In more detail, this participant spoke of how relatives’ flexibility and understanding in what they expected of participants, allowed them to make smaller progress free of comparison to what might have previously been expected. Although most referenced family support, some also reported receiving social support from sources outside of family, such as church.

“It’s a good group of folk and I look forward to it. It’s kind of social life and, they were very good, very supportive in phoning up when I was at my lowest.” (P4 p6 L241-244)

However, some participants spoke of difficulty utilising support from family. There was a view that by asking for their support, participants may be burdening their younger relatives, and impacting negatively on the lives of their loved ones.

“But I don’t like to use people I feel they’ve got their own lives. I’ve had mine” (P5 p2 L58)

When there was a lack of social support, this was raised as a significant barrier to doing things of value to the individual. Social connectedness was of value to the participants, therefore the absence of this presented significant difficulties. In relation to moving to a new area in later life, and trying to meet people and taking up new activities, one participant said:

“Well it’s having the friendships, having that. People I feel I can trust, that’s a big thing for me, being on my own, I suppose that’s maybe a bit more anxious”
(P7 p3 L84-85)

An interesting development which emerged from two accounts was that providing a caring or supportive role to family this could dominate time and have a negative influence on the likelihood of committed action. One participant described their frustration at being asked to this by a relative, and later spoke of the impact on her time, and opportunity to do other things that mattered to them.

“I just, want to strangle him at times. I think this just all built up in me. He’s always on the phone, mum I need a favour, mum I need a favour. And I can’t say no” (P1 p1 L36-38)

The same participant spoke of the social implications of making changes to one’s behaviour and in this case this took the form of a camper van trip that the participant had long been hoping to do.

“So we’re going away for a month. I know the boys will need picked up from school but he’ll have to make arrangements you know. It’s just a case of. I’m just, and I don’t feel guilty about it, (P1 p4 L150-152)

When asked about opportunity to do what is of value to oneself, one participant said:

“I’m at the age now when people are unwell, people are dying and people are bereaved and all that, and I feel I’ve got to go out and see to them and meet them and all that, and that’s probably something that I do and it takes a lot out of me”
(P8 p2 L61-65)

For some older people, social relationships could feel like obligations and in later life this could involve bereavements and illness. Retirement was also salient and specific to the older adult experience. It was perceived by some to have a negative impact on committed action and general wellbeing. For one participant there was a sense that retirement was a thing to be feared.

“When I retired I met my old, I was his apprentice like, ‘you retired wee man?’ I said: ‘Aye’. He gave me a word of advice, don’t pack it in, see sitting in the house all day, it will do your box in.” (P12 p4 L162-164)

The day-to-day implications of retirement included a loss of routine and for some, a change or loss in purpose.

“So at least when I was going to work, I was getting up in the morning, getting washed and dressed and going out. When that stopped I really felt you know in limbo” (P15 p8 L235-237)

Physical Opportunities

Two participants referenced their *financial situation* in facilitating opportunity to do what they value., but in general this sub-component of the COM-B model was not a salient feature of the interviews.

Motivation

This component of the COM-B behaviour change model relates to the brain processes that energise and direct behaviour. In general, participants appeared to think changing behaviour was worthwhile, and fundamental to life.

“Oh uh huh, if you don’t do what matters to you, there’s no point. You’ve got to have something to grasp in life, something to like or look forward to or that really matters to you. You’ve really got to” (p11 p6 L211-212)

However, a strong behavioural link was apparent between mood and low motivation. This is in keeping with low mood and associated motivational difficulties, and also outlines the significance of motivation as a potentially predictive component in behaviour change.

“I was at the stage where I didn’t want to do anything, I’d rather just stay in than go out. I went out like for shopping and I picked my grandsons up from school, but other than that, I wasn’t interested in going anywhere else (P1 p1 L16-18)

Moreover, maintaining motivation was a difficulty reported by some, and one participant described making efforts to sustain a hobby with their partner.

“So we did that for a time and we, both of us felt great, and then it slid away, and I don’t know, I don’t know what actually stopped us. But then again when I slid into, as I say, my depressive state. Obviously that was gone, the main motivation to do anything was gone” (P15 p8 L223-226)

The COM-B literature further defines Motivation as reflective, involving conscious processes, or automatic motivational processes. In the present study the latter was not

such a salient area, but reflective processes did present as a substantial part of behaviour change for older people.

Ageing as a factor

Within reflective motivation, participants' perception of age and its implications for changing behaviour was a salient factor in the interviews. Participants were asked about the impact of age on motivation to change behaviour, and a mix of views was evident.

“No I wouldn't say it makes. I think it's equal, you know, it doesn't matter what age you are. I think that's the right answer” (P15 p4 L105-106)

The above participant appeared uncertain on the issue, but on the contrary, many participants seemed more certain that age was a negative factor.

“Being older, everybody would rather be younger, and that might be a part of it, you're getting to the other side of your life and that plays on you a wee bit.

Thinking about all the things you've not done yet” (P14 p2 L64-66)

In relation to changing behaviour, there was a sense that ageing had a negative influence on living in line with your values. It may present as a barrier to motivation and discourage the view that change is possible and worthwhile.

“Em, it's made me think more about trying to do more, to the future and not thinking well that's me 73 and that's the end of it all. It's not, this is how my life is going to be now, I'll just be stuck in most of the time. And the thought of that's not good” (P3 p5 L159-161)

This aspect of reflective motivation can interfere with previous meaningful activity. A negative view of ageing can have an impact on previously established hobbies and interests.

“That’s right. During all my life I sang professionally with Scottish opera quite involved in that for many years, but now I’m getting to the end of this bit of my life that I enjoyed, I think I don’t sing with Scottish opera now, I do the odd concert here and there, something I miss.” (P8 p3 L86-88)

As mentioned, it was not the case that all participants viewed ageing negatively. Different views were expressed and some thought it was an insignificant factor.

“Not so much, it’s all in the head, age really” (P16 p3 L91)

Moreover, some took a more adaptive view of ageing, acknowledging that expectations may have to be more realistic, in some cases, a task or activity does not have to be done today.

“What does it matter really? When you sit and think about it. Like that it’s just something you’ve always done and it’s only time and common sense really, isn’t it? You’ll say, well why do I need to do that, don’t need to do it today.
(P6p6L190-192)

What motivates?

A variety of motivating factors were referenced in relation to what drives their behaviour. This appears to be an individual issue. Some participants spoke of getting healthier, getting better, or having a motivation to change their emotional state.

“Motivates me to do something to make myself feel better, to try and get rid of this feeling of anxiety, and make life easier, and for my family too” (P8 p5 L166-167)

In turn, some spoke of the impact changing behaviour may have on being able to do the things that are important to them. For one participant this meant being able to spend time with, and support family.

“Just want to keep healthy, I want to be well I want to be out there, be able to look after my grandchildren, help my family” (P7 p3 L101-102)

5. Discussion

Using a mixed methods approach this study explored the feasibility and acceptability of an ACT group intervention for older people. Information gathered on recruitment and retention speaks to the primary outcome of feasibility data. Acceptability and possible mechanisms of change were explored through variance in quantitative measures at three time points. Incorporating the views and experiences of patients, with the use of a behaviour change model, allowed the exploration of barriers to, and facilitators of, behaviour change for this population.

5.1 Feasibility

The most common primary reason for referral was mixed anxiety and depression. This fits with the transdiagnostic nature of ACT, suggesting the intervention is appropriate for the types of difficulties with which the population presents. Considering the local delivery of the intervention, three groups were run in a time frame of roughly six months.

Completion rates of the intervention are promising for future research and clinical applications, and are favourable in comparison to a similar study by Alonso and colleagues (2013) who had a lower completion rate. Some reasons for non-attendance at the group did not appear to be specific to older people, e.g. holidays, but some were issues pertinent to older people, such as hospital appointments and poor physical health. These reasons for attrition were similar to Alonso and colleagues (2013) and group facilitators may decide to offer additional support to those who miss appointments. Reasons for not starting the group included being physically unwell (n=1) and requesting 1:1 input (n=2). Regarding the feasibility of conducting research on ACT with this group, the main reason for this was viewing the research component as too burdensome. Completion rates of measures were positive and suggest a delayed follow up is viable and acceptable for this population. Regarding the post group interview, 80% of those invited to attend did so, suggesting qualitative research is also feasible with this population.

5.2 Quantitative analysis: trends and treatment signals

As the present research was a feasibility study, and in acknowledgement of the lack of control group and the feasibility aim of this study, a cautionary approach should be taken to the results and extent to which the changes on measures can be explained by the intervention alone. However, the results show promising improvement on mood measures and key ACT processes; indicating this intervention is acceptable and may be beneficial for older people.

A Wilcoxon Signed-Rank test revealed a statistically significant decrease in anxiety and depression, as measured by the HADS. In addition, the change was judged to be clinically meaningful. Promising findings were evident on the VQ-Progress sub-scale,

CFQ and the ACT-OA measure (all medium effect sizes). Future research should aim to explore this in larger trials to examine if ACT effects change through the mechanisms it posits. Three of six ACT measures were not significant across time points, suggesting these ACT processes, e.g. Experiential Avoidance were not sensitive to change.

Presence of change was found at different time points, e.g. a significant decrease on the HADS-D from pre group to post, pre to 12-week follow up and post to 12-week follow-up. This suggests there may be change or continue to be change after the intervention sessions have finished.

The results suggest the intervention is feasible and acceptable for this population.

Building on these promising results, a power calculation revealed the likely parameters required in an efficacy trial.

5.3 Qualitative analysis of participants' experience of behaviour change

The COM-B framework was applied to participants' experiences of the group. Within Psychological capability, knowledge of *useful techniques* for behaviour change was apparent and included: "taking small steps". *Techniques and concepts related to the ACT intervention* were also reported as helpful in addressing difficult emotions, and may have an indirect influence on behaviour change through impact on mood. Many participants found mindfulness to be acceptable and described moving beyond formal mindfulness practices to apply techniques in everyday life. Acceptance was described as an alternative, and useful perspective on difficult experiences. These findings are in keeping with the positive quantitative results on ACT process measures, and suggest there is potential for change in ACT mechanisms. *Difficult emotions* were reported as a common barrier to behaviour change. This fits with the mental health difficulties the group aims to address, and perhaps illustrates the clinical challenge for facilitators. The

facilitators appeared to play a positive role in mitigating any *cognitive difficulties*, but in general this was infrequently reported as a barrier to changing behaviour and engaging in committed action. In contrast, physical capability, and in particular *physical health problems*, were reported by many as a barrier to being able to engage in meaningful activities. Future interventions and research may decide to provide additional assistance in this area. For example, recent work with older adults with chronic pain augmented ACT with a theory of adaptive ageing based on Selection, Optimisation and Compensation theory (Freund & Baltes, 1998) increasing day-to-day autonomy (Alonso-Fernández, López-López, Losada, González, & Wetherell, 2016).

Within social opportunity, *social supports* were illustrated as a complex factor that could manifest in different ways, having a substantial impact on behaviour change for older people. Participants highlighted the value of social supports (family, friends, church); whereas the lack of social opportunities was identified as a barrier to behaviour change. Within this theme, retirement was highlighted as a negative factor. Group facilitators may decide to explore this in assessment; considering what might be creative approaches to addressing these issues as barriers to behaviour change. This relates to pertinent older adult issues, and recent efforts at government level to address loneliness and social isolation (Scottish Government, 2018). Physical opportunities were discussed but there was less reported on this, relative to other components of COM-B.

Lastly, within the COM-B component of Motivation, the most salient theme reported was *perception of age* which seemed to have an impact on whether change was desirable and viewed as possible. This is in line with gerontology theory such as Socioemotional Selectivity Theory which suggests perception of age and time play a significant role in motivation and emotional regulation (Carstensen, Isaacowitz, & Charles, 1999). Moreover, in CBT, Laidlaw's (2004) comprehensive contextualisation

framework (CCF) for working with older people, the authors emphasise enhancing CBT with contextual factors such as *socio-cultural context* which relates to attitudes towards ageing. This highlights the importance of the first session on “myth busting” in the current protocol.

Little has been written on the contextual factors that play a role in whether or not an individual has the opportunity to put values into practice to change behaviour. The COM-B model provided a useful framework and vehicle for exploring these aims, and appears to be a good fit with the ACT model. It allowed for the external and internal processes involved in behaviour change to be explored with a focus on the *committed action* element of ACT.

5.4 Strengths and limitations

A strength of this project was its use of a mixed methods approach to examine the acceptability of an ACT intervention for an older population, and in particular, investigating the importance of a participant’s circumstances in relation to how they interact with an intervention (Moore, et al., 2015). This process plays an important role in the development of complex interventions and acknowledges that the same type of service sufficient for working age adults cannot be assumed sufficient for older adults. (The Royal College of Psychiatrists, 2018).

Another strength of the study was the relative independence of the main researcher from the clinical activity involved in facilitating the intervention. This reduced the likelihood of bias in data gathered at interview, and increases the potential for critical feedback from participants. Potentially influencing participants’ responses, a limiting factor was the involvement of the clinicians who facilitated the groups in the collection of questionnaire data. Although this project involved substantial supervision, with specific

input on, and revision in relation to identifying a thematic framework, the main researcher conducted most of the qualitative research. This was appropriate in the context of a doctoral project, but a team approach allows for a mix of skills and experiences, reducing bias and fostering reflexivity (Parkinson, Eatough, Holmes, Stapley, & Midgley, 2016). A further strength of this project was the use of a 12 week follow up; increasing the chance of capturing the continued effect of the intervention over time.

Due to the small sample size, the quantitative results should be treated with caution. However, this is not considered to be a substantive limitation in the context of a feasibility study and doctoral project.

Future research could enhance the validity of the qualitative interviews by using videotaping to improve richness of data and capture nonverbal communication. There was occasional ambiguity in relation to the target behaviour or outcome; instead of committed action, the participant may have been referencing a more general improvement in mental health.

5.5 Future research

In line with MRC guidance, feasibility projects should progress to pilot studies and larger trials. On a smaller scale, pilot studies would allow researchers to test out how the different components of a larger trial might work in practice. Conducting research on a larger scale, and using more robust recruitment measures, would allow statistical exploration of quantitative outcome measures (Arañ, et al., 2010).

5.6 Conclusions

This research adds to the developing evidence base for ACT, and contributes to a better understanding of the feasibility of the intervention with this population. The findings suggest ACT is feasible and acceptable for older people, and the use of COM-B offers a unique methodological approach in exploring behaviour change; providing insights into how interventions could be improved. The qualitative findings suggest physical health problems and/or a lack of social opportunities may be barriers to behaviour change. In addition, older people's perception of ageing may be an important factor in motivation to change behaviour. The preliminary quantitative findings presented in this study suggest promising presence of change on measures of anxiety and depression, and ACT processes, following participation in the group intervention.

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Headings: Please indicate the level of the section headings in your article:

1. First-level headings (e.g. Introduction, Conclusion) should be in bold, with an initial capital letter for any proper nouns.
2. Second-level headings should be in bold italics, with an initial capital letter for any proper nouns.
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4. Fourth-level headings should be in bold italics, at the beginning of a paragraph. The text follows immediately after a full stop (full point) or other punctuation mark.
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Tables and figures: Indicate in the text where the tables and figures should appear, for example by inserting [Table 1 near here]. You should supply the actual tables either at the end of the text or in a separate file and the actual figures as separate files. You can find details of the journal Editor's preference in the Instructions for Authors or in the guidance on the submission system. Ensure you have permission to use any tables or figures you are reproducing from another source.

Please take notice of the advice on this site about [obtaining permission for third party material](#), [preparation of artwork](#), and [tables](#).

Running heads and received dates are not required when submitting a manuscript for review; they will be added during the production process.

Spelling and punctuation: Each journal will have a preference for spelling and punctuation, which is detailed in the Instructions for Authors. Please ensure whichever spelling and punctuation style you use, you apply consistently.

Appendix 1.2 Full search strategy (PsycInfo, EBSCOhost, 29/05/2019)

		Search
Depression		
S1	Search terms	TI ("Major depression" OR "major depressive disorder" or MDD OR depression OR "depressive symptom*") OR AB ("Major depression" OR "major depressive disorder" or MDD OR depression OR "depressive symptom*")
S2	Subject headings	DE "Major Depression" OR DE "Anaclitic Depression" OR DE "Dysthymic Disorder" OR DE "Endogenous Depression" OR DE "Late Life Depression" OR DE "Postpartum Depression" OR DE "Reactive Depression" OR DE "Recurrent Depression" OR DE "Treatment Resistant Depression" OR DE "Depression (Emotion)"
S3	Combination:	S1 OR S2
Older People		
S4	Search terms	TI (((older W2 adult*) OR (older W2 people) OR geriatric* OR senior*) OR AB (((older W2 adult*) OR (older W2 people) OR geriatric* OR senior*)
S5	Subject headings	DE "Geriatric Patients"
S6	Combination:	S4 OR S5
CBT		
S7	Search terms	TI (CBT OR "cognitive therap*" OR "cognitive behaviour* therap*" OR "cognitive behavior* therap*") OR AB (CBT OR "cognitive therap*" OR "cognitive behaviour* therap*" OR "cognitive behavior* therap*")
S8	Subject heading	DE "Cognitive Therapy" OR DE "Cognitive Behavior Therapy" OR DE "Cognitive Techniques" OR DE "Cognitive Restructuring" OR DE "Cognitive Therapy" OR DE "Self-Instructional Training" OR DE "Psychotherapy" OR DE "Individual Psychotherapy" OR DE "Geriatric Psychotherapy" OR DE "Group Psychotherapy"
S9	Combination:	S7 OR S8
S10	Final combination	S3 AND S6 AND S9

Appendix 1.3 Modification Extraction List with review studies

Area of difficulty/need and rationale for modification	Detail on/examples of modification	Review articles which identified modification area
1. Memory difficulties <i>Processing and retention of new information in session and content between sessions</i>	<ul style="list-style-type: none"> • Use of repetition of new information • New skills explained, demonstrated and practiced • Records of session content is encouraged. <ul style="list-style-type: none"> • Notes taken by patient, or written summaries provided by clinician. • Audio recordings • New information presented in different forms/ modalities, e.g. written, audio 	(Areán, 2004) (Crowther, Scogin, & Johnson Norton, 2010) (Grant & Casey, 1995) (James, 2008) (Satre, Knight, & David, 2006) (Chand & Grossberg, 2013) (Hughes, 1991)
2. Problem solving difficulties <ul style="list-style-type: none"> • <i>Issues with processing challenging and complex stimuli</i> 	<ul style="list-style-type: none"> • Problems reduced into component and simplified • Frequent reworking of problems 	(James, 2008) (Koder, Brodaty, & Anstey, 1996) (Agronin, 2009)
3. Generalisation of skills and concepts outside of session, and completion of homework tasks	<ul style="list-style-type: none"> • Phone prompts/alarms as reminder to action homework, e.g. breathing exercises. • With consent, relatives/carers attending sessions as co-therapist to become familiar with strategies performed • Carer involvement in assessment/treatment of patient, e.g. encouragement re. homework tasks 	(Chand & Grossberg, 2013; Grant & Casey, 1995) (Satre et al., 2006) (Koder et al., 1996)

4. Attention difficulties: <i>Staying focussed and on task</i> <ul style="list-style-type: none"> 	<ul style="list-style-type: none"> Clinician taking active/directive role Active efforts to keep clients focused, e.g. redirecting attention to session topics Use of agenda, clearly visible, e.g. on white board or on table between therapist and client. 	(Crowther et al., 2010) (Wilkinson, 2013) (Agronin, 2009)
5. Inclusion of patient strengths <i>Life skills & preserved cognitive abilities, e.g. recognition memory</i>	<ul style="list-style-type: none"> A perspective is adopted valuing life skills older people possess <p>Use of neurocognitive aids to maximise preserved abilities, e.g. bibliotherapy adjuncts, scaffolding, verbal memory recognition cues.</p>	(Crowther et al., 2010; Laidlaw & Kishita, 2015) (Satre et al., 2006) (James, 2008)
6. Cohort beliefs <i>Addressing:</i> <ul style="list-style-type: none"> Age and possibility of change Value of therapy Over emphasis of physical health in conceptualisation 	<ul style="list-style-type: none"> Evidence of acknowledgment of this, inclusion in formulation Specific attention to socialisation to model, to address negative cohort beliefs. 	(James, 2008) (Satre et al., 2006) (Laidlaw & Kishita, 2015) Laidlaw 2004 (Koder et al., 1996) (Areán, 2004) (Grant & Casey, 1995) (Hughes, 1991)
7. Losses/transitions in role <ul style="list-style-type: none"> e.g. bereavement, loss of role/purpose, retirement 	<ul style="list-style-type: none"> Evidence of specific focus, e.g. in formulation or session materials Assist patients in identifying alternative ways of thinking about situation; enabling adaption to losses/ transitions. 	(Chand & Grossberg, 2013) (Koder et al., 1996) (Grant & Casey, 1995;

		Laidlaw, Thompson, & Gallagher-Thompson, 2004)
8. Family and wider system <ul style="list-style-type: none"> • 	<ul style="list-style-type: none"> • Inclusion of systemic factors in formulation, e.g. tensions between family members, and differences in generational expectations • Involvement of family members/carers and MDT • Clinician may take role of case coordinator, liaising with MDT 	Laidlaw 2004 (Koder et al., 1996) (Grant & Casey, 1995) (Crowther et al., 2010) (Areán, 2004), (Agronin, 2009; Grant & Casey, 1995)
9. Physical health problems/sensory difficulties	<ul style="list-style-type: none"> • Realistic goals; acknowledging physical health difficulties, e.g. mobility • Transport difficulties addressed <p>Addressing sensory difficulties e.g. lighting, larger print of text, sitting closer for hearing, use of different modalities for materials.</p>	Kodder et al 1996 (Grant & Casey, 1995) (Hughes, 1991) (Areán, 2004) (Crowther et al., 2010) (Agronin, 2009)

Appendix 1.4 Quality rating scores

Study	1. Evidence of efforts made to modify the experimental treatment for older people (0 or 1)	2. Precise details of the experimental treatment were offered (0,1, or 2)	3. Details of the control or comparator treatment were given (0, 1 or N/A)	4. Details of how the intervention was, or could be, standardised were specified (0 or 1)	5. Details of how adherence to the protocol was assessed or enhanced were included (0 or 1)
Steuer et al. (1984)	0	1	1	1	1
Leung et al (1993)	0	1	N/A	1	0
Huang et al (2015)	0	2	1	0	0
Longchoopol et al (2018)	1	2	1	1	0
Garcia-Pena et al (2015)	0	1	0	1	0
Cappeliez (2000)	1	1	N/A	0	1
Thompson et al (2001)	1	1	1	0	0
Thompson et al (1987)	0	0	0	1	0
Serfaty et al (2009)	1	1	1	1	1
Laidlaw et al (2008)	1	1	1	1	1
Gallagher & Thomson (1982)	1	1	1	1	1
Gallagher & Thomson (1983)	1	1	1	0	0
Fry (1984)	0	2	N/A	1	1
Floyd et al (2004)	1	1	1	1	1

Appendix 2.1 NHS Research and Development and REC Approval



Health Research Authority

East Midlands - Leicester South Research Ethics Committee

The Old Chapel
Royal Standard Place
Nottingham
NG1 6FS

05 December 2018

Professor Hamish McLeod
University of Glasgow
Mental Health and Wellbeing
1st Floor Admin Building, Gartnavel Royal Hospital, 1055 Great Western Road, Glasgow
G12 0XH

Dear Professor McLeod

Study title:	Acceptance and Commitment Therapy with a community older adult sample: a feasibility study investigating mechanisms of change.
REC reference:	18/EM/0393
Protocol number:	L18073
IRAS project ID:	246614

Thank you for your letter of 30 November 2018, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

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 HRA and HCRW Approval (England and Wales)/ NHS permission for research is available in the Integrated Research Application System, at 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 publicly 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:

Document	Version	Date
GP/consultant information sheets or letters [GP Letter]	2	07 November 2018
GP/consultant information sheets or letters [Psychiatry letter v 2]	2	07 November 2018
Interview schedules or topic guides for participants [COM-B interview schedule v2]	2	30 November 2018
IRAS Application Form [IRAS_Form_05112018]		05 November 2018
Non-validated questionnaire [The Acceptance and Commitment Therapy measure of change for Older Adults (ACT-OA)]	1.2	04 October 2017
Non-validated questionnaire [Therapeutic Metaphor Interpretation Test (T-MIT)]	1	01 July 2014
Other [Participant reminder letter]	2	07 November 2018
Other [Cover letter to reply to provisional opinion]		30 November 2018
Participant consent form [Consent form A- measures and qualitative interview v2]	2	30 November 2018
Participant consent form [Consent form B- qualitative interview only v2]	2	30 November 2018
Participant information sheet (PIS) [Participant Information Sheet A- measures and qualitative interview v2]	2	30 November 2018
Participant information sheet (PIS) [Participant Information Sheet B- qualitative interview only v2]	2	30 November 2018
Referee's report or other scientific critique report [Peer review]		19 October 2018
Research protocol or project proposal [Major Research Project – Protocol-Proposal]	7	04 November 2018
Summary CV for Chief Investigator (CI) [Chief Investigator CV]		09 August 2018
Summary CV for student [Student CV]		07 November 2018
Summary CV for supervisor (student research) [Field supervisor academic CV]		
Summary CV for supervisor (student research) [Academic supervisor CV]		09 August 2018
Validated questionnaire [Self Experiences Questionnaire 15 item (SEQ)]		
Validated questionnaire [The Cognitive Fusion Questionnaire (CFQ)]		
Validated questionnaire [Hospital Anxiety and Depression Score (HADS)]		
Validated questionnaire [Valuing Questionnaire]	1.2	04 October 2017
Validated questionnaire [The Brief Experiential Avoidance Questionnaire (BEAQ)]		

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/>

18/EM/0393

Please quote this number on all correspondence

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

Yours sincerely



Mr John Aldridge
Chair

Email: NRESCcommittee.EastMidlands-LeicesterSouth@nhs.net

Enclosures: "After ethical review – guidance for researchers"

Copy to: Mr Raymond Hamill
Mrs Cynthia Dolier, Lead R&D Facilitator, R&D Department



Dr Hamish McLeod
University of Glasgow
Institute of Mental Health and Wellbeing
Gartnavel Royal Hospital
GLASGOW
G12 0XH

R&D Department
Corporate Services Building
Monklands Hospital



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 relevant UK and EU Data Protection legislation.
- 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/randc/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.

I trust these conditions are acceptable to you.

Yours sincerely,

Raymond Hamill
Senior R&D Manager

c.c.

NAME	TITLE	CONTACT ADDRESS	ROLE
David McGraw	Trainee Clinical Psychologist	David.McGraw@lanarkshire.scot.nhs.uk	Principal Investigator
Raymond Hamill	Senior R&D Manager	Raymond.Hamill@lanarkshire.scot.nhs.uk	Sponsor Contact
Clive Ferenbach	Clinical Psychologist	Clive.Ferenbach@lanarkshire.scot.nhs.uk	Named Contact

Dear Dr McLeod

Project title: Acceptance
investigation

R&D ID: L18073

I am writing to you as Chief Investigator
for the conduct of your study

NAME	TITLE
Mr David McGraw	Trainee

As you are aware, NHS Lanarkshire has a number of responsibilities in relation to your study. To help with this we have provided the following information.

All research projects within NHS Lanarkshire are complete. In addition, we have a number of projects that are Sponsored by NHS Lanarkshire. You may find it helpful to

L18073_ACT_NHS_Lanarkshire

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	NHS RESPONSIBILITIES AS SPONSOR
Obtain relevant / appropriate Research Ethics opinion.	Assess adequateness of the independent, expert review.
Obtain NHS 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 2.2 Outline of ACT Group Protocol (developed by Dr Clive Ferenbach, NHS Lanarkshire)

Session topic	Summary of session content	Homework exercises
1. Exploring beliefs about mental health and ageing, creative hopelessness, & introduction to the aims of ACT	(a) Exploring beliefs about mental health and ageing; (b) Psychoeducation about anxiety – fight/flight (c) Monster and the rope; (d) brief mindfulness exercise; (e) ACT in a nutshell exercise - introduction to the aims of ACT	(a) 'Just noticing' track on Mindfulness CD; (b) 'calling out your struggle' track on CD; (c) Adding notes to 'drop the rope' metaphor sheet
2. Values	(a) Passengers on a bus; (b) Verbal explanation of values, examples of personal values and goals; (c) Values and Goals as compass; (d) Miracle Question as eyes closed exercise - discuss behavioural goals as group, extracting values from them; (e) write own notes on values/goals worksheet (f) Future birthday eyes closed exercise; (g) Yes/No acceptance exercise	(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 (on flip chart)	(a) Mindfulness exercises: 'Noticing self' and 'Everyday noticing'; (b) Doing a task mindfully; (c) name your mind
4. Defusion, Acceptance and Conceptualised Self	(a) Recap thinking vs. Noticing self; (b) Radio metaphor; (c) Nursery rhyme exercise; (d) Lemon, lemon, lemon exercise; (e) Writing thoughts	(a) Mindfulness exercises: 'Leaves on a stream' and 'Calling out your struggle'; (b) Doing tasks mindfully and noticing thoughts/feelings

Session topic	Summary of session content	Homework exercises
	on cards and using defusion; (f) Fly fishing metaphor; (g) sentence completion exercise to illustrate conceptualised self (h) Thoughts not controlling actions; (i) Leaves on a stream	
5. Committed Action: Considering Obstacles and future planning	(a) General mindfulness exercise; (b) Recap passengers on a bus, read over own values/goals worksheet from session 2; (c) Flipchart exercise: obstacles and barriers to goals- recognising what internal factors need defused from, and what external factors need worked around(e) The travelling partners metaphor; (f) brief acceptance of emotion mindfulness exercise; (g) Introduce 'My Goals' worksheet, behavioural planning: brainstorming solutions to obstacles, and use of compensatory strategies (based on Selective Optimisation and Compensation theory);	(a) Continued mindfulness CD practice; (b) Piece of committed action as noted on homework sheet; (c) Continue daily mindfulness of tasks; (d) Further work on 'My goals' worksheet
6. Summary	(a) Mindfulness exercise; (b) Discussion of, and troubleshooting around, committed action (c) further planning with 'My goals; (d) Acceptance of emotion exercise, debrief with School of fish worksheet; (e) Leaves on a stream exercise (or other experiential as seems appropriate; (e) Discuss endings, and summary of group messages	(a) Encourage continued use of handouts, principles conveyed in group, as they move forward

Appendix 2.3 ACT-OA Questionnaire (Original text size 14) (Developed by Dr Clive Ferenbach and Dr 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 Interview Schedule-COM-B Topic Guide

I'm interested in your experience of the group. I'm also interested in your experience of making changes to your behaviour and doing what is important to you.

TOPIC 1- CAPABILITIES (psychological and physical)

Main questions:

- *Do you feel able to make changes to your everyday behaviour?*
- *In what ways, if any, did the group help you identify steps you can take to improve your situation, or to do more of what's important to you?*
- *Did the group help clarify what you'd like to change in your life?*
- *Do cognitive factors, e.g. memory, affect your ability to do what is important to you?*
- *Did emotional factors, e.g. worry, affect your ability to do what's important to you?*
- *How much have your physical abilities (i.e. mobility etc.) affected doing what's important to you?*

Optional follow up questions:

- *Did the group help you see emotion differently? Was there any change in your view of emotions as an obstacle to doing what's important to you?*
- *Did the group help you see thoughts differently? Was there any change in your view of thoughts as an obstacle to doing what's important to you?*

TOPIC 2- OPPORTUNITY (physical, social, cultural)

Main questions:

- *How much opportunity is there in your life to do what's important to you?*
- *What are the factors that affect your opportunity to do what's important to you?*
- *In what ways if any, did the group affect your view of the opportunities to do what's important to you?*

Optional follow up questions:

- *Do you think there are currently opportunities in your life, whereby you could improve your interpersonal relationships?*
- *Do you think there are currently opportunities in your life, whereby you could expand your leisure activities?*
- *Do you think there are currently opportunities in your life, whereby you could work on personal growth, spirituality and health?*
- *Do you think there are currently opportunities in your life, whereby you could forward your work or education?*
- *Do you feel circumstances in your life are making it difficult for you to do more of what's important to you?*

TOPIC 3- MOTIVATION (Reflective and automatic mechanisms that activate or inhibit behaviour)

Main questions:

- *What motivates you to make sustained changes in your life?*
- *What if anything did the group teach you about avoidance?*
- *What if anything did the group teach you about persisting with behaviours when you face challenges?*
- *What if anything did the group teach you about why changing your behaviour is worthwhile?*

Optional follow up questions:

- *Do you see the potential benefit (or point) in changing your everyday behaviour?*
- *Have you got the motivation, or 'get up and go', to make changes?*
If not, what do you think would have to change for you to be more motivated?

TOPIC 4- OTHER FACTORS (An opportunity to mention other relevant behaviour change factors not contained within the main three topics)

Main questions:

- *Is there anything else that you think is important for making sustained changes in your life?*
- *When it comes to doing what is important to you, what other factors are involved in being able to change your behaviour?*
- *What issues get in the way of you making sustained changes to your behaviour?*

Appendix 2.5: Completion rates for outcome measures

Measure	Pre group (n=16)	Post Group (n=10)	12 week follow up (n=10)
	Completion %	Completion %	Completion %
HADS-A	87.5%	80%	80%
HADS-D	87.5%	80%	80%
CFQ	93.75%	100%	100%
VQ	87.5%	90%	90%
BEAQ	87.5%	90%	90%
SEQ	93.75%	90%	90%
ACT-OA	93.75%	100%	100%
Average for time point	90.18%	90%	90%

WRST= Wilcoxon Signed-Rank Test; HADS-A or D = Hospital Anxiety and Depression Scale- Anxiety or Depression; BEAQ= The Brief Experiential Avoidance Questionnaire, VQ= Valuing Questionnaire; CFQ= Cognitive Fusion Questionnaire; ACT-OA= The Acceptance and Commitment Therapy measure of change for Older Adults; SEQ= Self-Experiences Questionnaire

Appendix 2.6 Participant Information Sheet



University
of Glasgow



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

Participant Information Sheet

Study Title:

Acceptance and Commitment Therapy with a community older adult sample: a feasibility study investigating mechanisms of change

Who is conducting the research?

This study is being carried out by:

- David McGraw, Trainee Clinical Psychologist and Principal Investigator (NHS Lanarkshire and University of Glasgow)
- Professor Hamish McLeod, Chief Investigator and Academic Supervisor (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. It is important that you take time to decide whether or not you wish to take part.

What is the purpose of the study?

We are trying to improve psychological treatment options for Older Adults and have been examining Acceptance and Commitment Therapy (ACT). ACT is a psychological therapy that uses various strategies to help people to respond more effectively to troublesome thoughts and emotions. ACT also helps individuals to focus on what is important in their life and 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 aged over 60 and whether they find it an acceptable approach. The research will mainly occur from late 2018 until July 2019, your connection to the study will last around 6 months.

The study will be submitted as part of David McGraw's research portfolio as part of his 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 60 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 so that we could see if they are interested in taking part in this research. It is important to note that taking part in the group sessions will be part of your standard care and this is separate to taking part in this research study which is outlined below. Therefore, your access to the group will not be affected if you choose not to take part in the research.

Do I have to take part in the research?

No, it is up to you to decide whether or not to take part in the research. As stated above, 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 to indicate that you understand what is involved and agree to participate. You are free to withdraw from the study at any time and without giving a reason. If you withdraw, information collected up to that point 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. The research involves completing questionnaire measures at different points and being part of an interview after the group sessions have finished. 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 routinely collected, so we will just ask for your consent to use these as part of the research data set. The additional tasks (which are part of the research) 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 between 1 and 3 months after the group finishes. This will take around 15 minutes to complete.
- You will also be contacted about attending an interview with the researcher where you can share your experience of the group. If you do not complete all the group treatment sessions, we would still like to hear about your experience

so we will contact all people who start the group to an interview. This interview will last around one hour and will be audio recorded. Your identity will be concealed and kept confidential. No one will be identifiable from any quotes published as part of the write up of this research.

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. But, 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? How will my information and data be handled?

What will happen?

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. The spreadsheet linking a participant with their number will be a password encrypted document, which will be stored on an NHS computer drive, to which only the main researcher has access. We will obtain your mailing addresses in order to send out questionnaires three months after the group has ended. 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 after it has been transcribed and anonymised. Anonymous quotes from the interview may be used in the final report.

Whilst confidentiality will be respected, this will be broken in the event of a reportable disclosure such as the potential to harm self or others.

NHS Lanarkshire is the sponsor for this study based in the United Kingdom. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. NHS Lanarkshire will keep identifiable information about you [for 6-12 months after the study has finished]. The University of Glasgow will also store and use your anonymised research data in order to conduct this study.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, and as outlined above, we will use the minimum personally-identifiable information possible.

NHS Lanarkshire will keep your name, NHS number and contact details confidential and will not pass this information to other organisations. NHS Lanarkshire will use this information as needed, to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Certain individuals from NHS Lanarkshire and regulatory organisations may look at your medical and research records to check the accuracy of the research study. NHS Lanarkshire will only receive information without any identifying information. The people who analyse the information will not be able to identify you and will not be able to find out your name, NHS number or contact details.

You can find out more about how we use your information by contacting the main researcher, David McGraw or one of the research team as detailed within this leaflet. Please note that NHS Lanarkshire's Data Protection Notice can be viewed on NHS Lanarkshire's public website: <http://www.nhslanarkshire.scot.nhs.uk/data-protection-notice>, or you can also ask a member of staff for a copy.

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 David McGraw'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 2019.

Who is organizing and funding this research?

The research is organised via the University of Glasgow and is indirectly funded by NHS Education for Scotland (who fund Clinical Psychology training in Scotland). 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 East Midlands - Leicester South Research 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:

Professor 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.

For independent information, advice and support in relation to dealings with the NHS you can contact:

The Patient Advice and Support Service:
Tel: 0800 917 2127, Email: pass@cas.org.uk
Website: www.patientadvicescotland.org.uk/
Speak in person at any Scottish citizens advice bureau.

Contact details

If you would like further information, you can contact:

Main Researcher (Trainee Clinical Psychologist):

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University of Glasgow
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Glasgow, G12 0XH
Hamish.McLeod@glasgow.ac.uk

Appendix 2.7 Consent form



Mental Health & Wellbeing

Administration Building
Gartnavel Royal Hospital
1055 Great Western Road
Glasgow
G12 0XH

Name of researchers: David McGraw, Dr Clive Ferenbach, Professor Hamish McLeod

Title of the Project: Acceptance and Commitment Therapy with a community older adult sample: a feasibility study investigating mechanisms of change.

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.

☐

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.

☐

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

☐

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 Health Board, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.

☐

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 and the recording will be destroyed once the transcription process is completed.

☐

I agree to my Psychiatrist (if applicable) and GP being informed of my participation in the study.

☐

I understand that participation in the study may involve disclosure of my views and experiences, and with that, difficult thoughts or feelings may arise.

☐

I understand that if the researcher is concerned about my ongoing levels of psychological distress they might refer me for further support from clinical services

☐

I agree to take part in the above study.

☐

Name of Participant

Date

Signature

Name of Person taking consent

Date

Signature

1 copy to the participant, 1 copy to the researcher, 1 original for the participant's case-notes

Appendix 2.8 Thesis Proposal (04/11/2018)

Abstract

Background: As the population ages, and with a focus on acceptance and reconnecting with values, rather than symptom elimination, Acceptance and Commitment Therapy (ACT) may be useful and suitable therapeutic intervention for an older population who often face unchangeable difficulties, and may show a higher motivation to live in line with values (Petkus & Wetherell, 2013).

Aims: To investigate the acceptability and suitability of an ACT group intervention/study for a community older adult setting. To commence preliminary exploration of possible change mechanisms in ACT, e.g. self-as context and opportunity to behave in line with values (using COM-B model of behaviour change).

Methods: ACT group: community dwelling older adult participants, accepted as referrals to older adult psychology service. Mixed methods design, consistent with the MRC complex intervention framework early stage trials. Completion of measures before, during and after intervention. Participants invited to be part of post intervention interview.

Applications: To add to the growing evidence base of ACT with older people and research on mechanisms of change, inform future evaluative studies, and first use of COM-B in this setting.

1. Introduction

1.1 Context of older adult psychopathology

The UK population is ageing, and in 2014, the average UK age exceeded 40 for the first time (Government Office for Science, 2016). Clinical services are already struggling to meet the health needs of this population and these statistics suggest the demand will only increase. This highlights the importance of drawing on evidenced psychotherapeutic approaches that suit the characteristics of this growing population.

Cognitive Behavioural Therapy (CBT) is the main therapy recommended for a range of mental health disorders with older adults (NES, 2015). However, it has been argued that CBT has limited evidence base for non-primary care older adults and is suboptimal for anxiety (Petkus & Wetherell, 2013). Acceptance and Commitment Therapy (ACT) may provide an effective alternative to addressing the mental health needs of older people.

1.2 Acceptance and Commitment Therapy (ACT)

ACT is a “third wave” cognitive behavioural therapy that aims to increase “psychological flexibility” using acceptance and mindfulness practices to encourage a willingness to experience difficult internal experiences, whilst maintaining a behavioural focus on living in line with, one’s values (Hayes et al, 2012). A large meta-analysis by Tjak and colleagues concluded that ACT is more effective than treatment as usual or placebo, and may be as effective as CBT, with several psychiatric diagnoses.

1.3 ACT with older people

The evidence base for ACT with older people is emerging and suggests the therapy is acceptable for older adults and may be an effective treatment for GAD, depression and chronic pain (Wetherell, 2011, Davison et al 2017 & Scott et al 2017).

Roberts and Sedley (2016) presented a rationale for ACT with older people, and argued that this population are more aware of the fact that life is limited, and consequently they

have a higher motivation to focus on values. The transdiagnostic nature of ACT may be useful, as older people often present with heterogeneous difficulties. Finally, an acceptance focus may be appropriate for older people who often face stressors and losses that are unchangeable and difficult to escape, e.g. death of spouse, significant health problems.

1.5 Researching complex interventions

The Medical Research Council (MRC) outlined four stages in progressing intervention research: development, feasibility/piloting, evaluation and implementation (Craig et al, 2008). Feasibility studies provide useful information (e.g. response rates & attendance) as to whether or not an intervention should be further researched at pilot stage (Araín et al, 2010).

1.6 Mechanisms of change in ACT

The MRC framework advocates the importance of process evaluation: considering mechanisms of change, and also an understanding the context in which interventions take place (Moore et al, 2015). Feasibility studies therefore provide information on implementation challenges, and the cost-effectiveness of interventions (Eldridge et al, 2005). The ACT literature has focused on, and developed measures for, the six processes within the model that aim to increase psychological flexibility: acceptance, cognitive defusion, being present, self as context, values and committed action. There is growing evidence from component and mediational analyses that ACT works through the specific theoretical processes it posits (Zettle et al 2011 & Levin et al 2012). Self as context (SAC) has been relatively under researched. ACT conceptualises three types of self: self as content (thoughts, feelings, beliefs about the self), self as process (noticing thoughts about the self), and self as context (stable sense of self that transcends the

changing context of internal & external experiences) (Moran et al, 2018). Yu and colleagues (2016, 2017) developed the Self Experiences Questionnaire (SEQ), and positive change in SAC appears to be associated with positive change in psychological flexibility. The SEQ measure is yet to be used with older adults.

Another under-researched change process is committed action, which is concerned with one's behaviour being consciously linked to one's values. The Committed Action Questionnaire (McCracken et al 2015) has been developed in the area of chronic pain, but little has been written on the contextual factors that may play a role in whether or not an individual has the opportunity to put values into practice and change his or her behaviour. The MRC highlights the importance of a participant's circumstances in relation to how they interact with an intervention (Moore et al, 2015). The COM-B model provides an overarching framework (with no affiliation to a therapeutic approach) to describe the necessary factors for successful behaviour change, including contextual factors. COM-B posits that people require the Capabilities, the Opportunities and the Motivation to perform Behaviour (Michie et al 2011). COM-B offers a useful model to explore the extent to which given ACT interventions meet their ultimate goal of promoting adaptive behaviour change (Hayes et al, 2012). To date, the framework has not been used in relation to psychological therapies for mental health difficulties.

In summary, there is a strong rationale for using ACT with older adults, but the evidence base is limited, little is known about the change processes involved with this population, and established protocols were not developed with older adults in mind. An ACT group protocol for older people has been developed in NHS Lanarkshire. At present, this is running in both inpatient and community settings. Using quantitative and qualitative methods, the current study aims to explore the acceptability and feasibility of this therapy protocol in a community sample.

2. Proposed research

2.1 Aim

To investigate the feasibility of ACT groups with a community older people sample, and to explore possible mechanisms of change.

2.2 Research questions

1. Is research on this intervention, with this client group, feasible?

Also, are the outcomes measures of ACT sub-processes acceptable for this client group?

Assessed using: attendance/attrition rates, completeness of measures and qualitative feedback after the groups.

2. Is the ACT group intervention acceptable and suitable for a community older adult sample?

Assessed using: attendance/attrition, change on ACT measures, and qualitative data from interviews after the intervention is complete.

3. What might be the processes of change with ACT in this client group, and what might be impasses/obstacles to progress with behaviour change?

Qualitative interviews guided by COM-B model and ACT processes

Change/variability across time points in specific ACT sub-process
outcome measures

3. Plan of Investigation

3.1 Participants

Community dwelling older adults recruited from the Psychological Therapies for Older People service in NHS Lanarkshire. In line with the transdiagnostic nature of ACT, participants will have a variety of mental health difficulties and presentations, primarily mixed symptoms of anxiety and depression.

3.1.1 Inclusion/ Exclusion Criteria

Inclusion criteria

- Accepted referrals to the Psychological Therapies for Older People service.
- Capacity to consent to research (evaluated by Clinical Psychologist)
- Community dwelling patients
- Over 60 years old: lowered from 65 to acknowledge equality legislation and drive for “ageless services”. It is hoped this will still encapsulate developmental issues specific to older adults.

Exclusion criteria

- Unable to meaningfully participate in the group, or other psychological intervention more appropriate as a first line of treatment e.g.:
 - Identified learning disability or cognitive impairment
 - Florid psychotic symptoms
 - First presentation panic disorder
 - Significant personality problems or difficulties
- Formally assessed (determined from health record) and found to not have capacity to consent
- Status may change over time: patients can be asked to leave the group if clinician believes it is no longer of benefit

- Level of risk (of suicide, self harm, or harm to others) that would be difficult to manage safely within group context

3.2 Recruitment Procedures

A specific recruitment procedure will include: clients who have been referred (from Primary Care & Secondary Care Mental Health Services) for input from the Psychological Therapies for Older People service being offered an assessment appointment (guided by the inclusion/exclusion criteria), whereby potential participation in a group intervention will be discussed. This pre-group assessment appointment will be carried out by a clinician other than the lead researcher. This will involve discussion of what the group involves, e.g. boundaries, confidentiality, and the involvement in a research study. Patients will be given an information sheet and time to consider if they would like to participate. Patients will be able to participate in the group but opt out of the additional research elements.

Some participants will be recruited at the end of an ACT group which has recently commenced. At the final session of this group, the facilitators will discuss involvement in the research study. Patients will be given an information sheet and time to consider if they would like to participate. The information sheet for this group will differ from that of the main group of participants. As the group has started, this pool of participants will be consented to take part in the semi-structured interview, and not the outcome measures.

3.3 Measures

ACT 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 older people.
- 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 $\alpha=0.74$.
- A session-by-session measure created by Psychology Therapies for Older People (NHS Lanarkshire) (The Acceptance and Commitment Therapy measure of change for Older Adults (ACT-OA), with five items, designed to measure clarity of values, clarity of planned action, engagement in valued living and willingness to experience difficult thoughts and feelings.
- The Self experiences questionnaire (SEQ) (Yu et al., 2016) is a 15 item measure of self as context. This measure has not been used with older adults.

Other measures:

- 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 $\alpha=0.82$.

- 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.

The measures selected will allow the study to explore the mechanisms of change, and in turn this will allow investigation of the feasibility of different measures.

3.4 Design

This project would use a mixed methods design, incorporating quantitative and qualitative methods. This would be consistent with guidance on the development of complex interventions (Craig et al 2008 & Moore et al, 2015).

3.5 Data Collection

Plan for data collection outlined in the table below:

Time point	Action
Pre intervention	ACT process measures, HADS and demographic details.
Session by session	ACT-OA and attendance rates.

Post intervention	ACT process measures and HADS
Weeks following intervention	Semi-structured interview will be conducted by the researcher in an NHS Lanarkshire premises.
1-3 months post intervention	ACT process measures and HADS

3.6 Data Analysis

Quantitative

Data analysis would explore pre and post treatment differences using within subjects t-tests (or non-parametric equivalent). This will provide a small amount of data on presence of change. Comparison of change on different measures will look for signals of possible change mechanisms and test out which theoretically relevant change processes show signs of changing across the trial. Attendance, completion of outcome measures and attrition rates will be analysed using descriptive statistics to inform regarding the feasibility of the groups and future research into ACT and this population.

Qualitative

Both Interpretative Phenomenological Analysis and Grounded Theory were ruled out due to their inductive approach. Thematic Analysis was judged to be insufficiently focussed on relating data to theory. Framework analysis (FA) (Ritchie & Spencer, 1994) was selected as it can be inductive and guided by existing theories, and allows for

specific questions to be addressed (Ward et al 2013). As the proposed study intends on utilising a specific framework (COM-B) for analysis, and plans to answer specific questions (i.e. pertaining to feasibility and acceptability), FA was identified as the most appropriate qualitative approach. Questions for qualitative interview will be developed to explore the extent to which different aspects of COM-B were adequately addressed by the intervention; what aspects of the COM-B remained as obstacles to behaviour change; what further supports would be necessary for an older adult population. The analysis of the data will adhere to the five-step process outlined by Ritchie & Spencer (1994): 1) familiarisation; 2) identifying a thematic framework; 3) indexing; 4) charting and 5) mapping and interpretation.

3.7 Sample size

Given previous group timescales within the service, it is likely that a maximum of 3 groups will run in the timeframe for data collection. Previous groups have aimed for 8-10 participants, but have commonly had 6-8. As this is a feasibility study, we are interested in determining rates of recruitment and feasible sample parameters for future studies. Effect size calculations will be conducted based on the pre and post change scores in outcomes measures. The completion of these measures and variability across time points will provide information as to the feasibility of ACT process measures and potential mechanisms of change in with older people.

There is less guidance on qualitative sample size and it is influenced by factors like saturation (Merriam & Tissdale, 2015). Recently the concept of “information power” has been proposed which argues “The larger information power the sample holds, the lower N is needed” (Malterud et al 2016). Hennink and colleagues (2017) concluded

that conventional saturation was reached at 9 interviews, but 16-24 provided a more comprehensive saturation.

3.8 Settings and Equipment

The main equipment required for the ACT group would be therapeutic handouts and measures. The groups would take place in NHS Lanarkshire premises.

4. Health and Safety Issues

This approach is currently a standard treatment option for clinicians in this service. Therefore, it is estimated that there will be no safety issues beyond those included in routine treatment which adheres to NHS Lanarkshire Health and Safety policies and procedures.

5. Ethical Issues

NHS ethical and management approval will be sought through the Integrated Research Application System (IRAS). Confidentiality will be discussed with participants. As this is an older population, capacity to consent will be carefully considered. Data will be securely stored and handled in line with Data Protection Act (1998).

6. Financial Issues

The estimated costs associated with this project will be minimal. These will include stationary (paper for handouts) and the use of a university computer for data collection and transcription.

7. Timetable

Date	Action
22 nd September 2017	Outline submitted.
28 th November 2017	Met with Professor Hamish McLeod (Academic supervisor) and Dr Clive Ferenbach (Field Supervisor) to discuss outline and progress of project.
4 th December 2017	Draft proposal submitted.
January 2018	Met with supervisors to discuss draft proposal/progress of project
29 th January 2018	Proposal submitted for blind marking
May 2018	Final proposal submitted
June-July 2018	Ethics applications through IRAS
November – March 2019	Data collection to be carried out
March – July 2019	Data analysis and write up.

11. Practical Applications

This research will contribute to the growing evidence based for ACT and older people, and contribute to a better understanding of the mediators of success in this therapeutic approach. The use of COM-B offers a unique methodological approach in evaluating behaviour change, and offers insights into how interventions could be improved for this population.

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