UNIVERSITY OF LINCOLN

PROTOCOL

Acceptance and Commitment Therapy for older adults experiencing psychological distress: A hermeneutic single case efficacy design (HSCED) series

ACT for older adults: a HSCED series

ACT OA: HSCED

Protocol Final Version 1.5
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SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement(s).

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor

I also confirm that I will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

Chief Investigator:

Signature: ..... Date: ...../...../.....

Name: Dr Nima Golijani-Moghaddam

STUDY/TRIAL CONTACTS

Chief Investigator	
Sponsor Contact details:	
Collaborators/Co-Investigators/Protocol Contributors	
Student researcher/therapist	

FUNDER DETAILS

FUNDER(S)	**FINANCIAL AND NON FINANCIALSUPPORT GIVEN**
Trent DClinPsy	• £500 research budget. • Research supervisors/supervision. • Relevant teaching/training.
Nottingham Healthcare NHS Foundation Trust (contact details above).	• Access to participants. • Use of clinical premises. • Clinical supervision.

STUDY SUMMARY

Study Title	Acceptance and Commitment Therapy for older adults: A hermeneutic single case efficacy design (HSCED) series
Study Design	Hermeneutic Single Case Efficacy Design (HSCED)
Intervention	Acceptance and Commitment Therapy
Study Participants	Older Adults (65 years+)
Eligibility Criteria	HADS Anxiety or Depression score ≥8; MoCA score ≥22-24 (criterion dependant on age & education history); active referral to Rushcliffe Mental Health Service for Older People; have capacity to consent to 1:1 therapy; be able to travel to service (alone or with support).
Planned Sample Size	Up to four
Study Duration	Up to 20 months
Objectives	Primary: Efficacy of ACT with older adults experiencing psychological distress. Secondary: Identify change processes of ACT with older adults, with emphasis on the impact of delivering ACT by telephone/videocall (following SARS-CoV-2 social distancing measures).
Outcome Measures	Primary: Quality of life (OPQOL-brief). Secondary: Cognitive functioning (MoCA); levels of anxiety/depression (HADS); Client's goals (PQ); quality of life/general outcomes (ORS); therapeutic alliance (SRS); client's views on the therapy session (HAT); psychological flexibility (CompACT-8); client's view on change (Change Interview); fidelity of treatment (ACT-FM). Exploratory: beneficial adaptations to ACT for older adults. Impact of telephone/videocall therapy on outcomes.
Data Analysis	Reliable Change Index; adjudication panel; Framework Analysis; correlations; visual analysis.

KEY WORDS

Older Adults

Acceptance and Commitment Therapy

Quality of Life

Hermeneutic Single Case Efficacy Design

Change processes

Non-specific factors

Table of Contents

LIST OF ABBREVIATIONS

AE	Adverse Event
ACT	Acceptance and Commitment Therapy
CF	Consent Form
CI	Chief Investigator
CRF	Case Report Form
FS	Field Research Supervisor
GCP	Good Clinical Practice
HRA	Health Research Authority
ISF	Investigator Site File (This forms part of the TMF)
ISRCTN	International Standard Randomised Controlled Trials Number
LIH	Lincoln Institute for Health
MHSOP	Mental Health Service for Older People
NHS R&D	National Health Service Research & Development
OA	Older Adult
PI	Principal Investigator
PIS	Participant Information Sheet
PRS	Primary Research Supervisor
QP1	Questionnaire Pack 1
RCT	Randomised Control Trial
REC	Research Ethics Committee
SAE	Serious Adverse Event
SOP	Standard Operating Procedure
SRS	Secondary Research Supervisor
TMF	Trial Master File
TMG	Trial Management Group
UoL	University of Lincoln

STUDY MANAGEMENT

ROLE OF STUDY SPONSOR AND FUNDER

The sponsor of the study is the University of Lincoln (UoL).

The Chief Investigator (CI) has overall responsibility for the study and shall oversee all study management. The CI is Dr Golijani-Moghaddam, who is also Secondary Research Supervisor to Jonathan O'Keeffe (Trainee Clinical Psychologist) the student researcher/therapist for this study. As the main researcher, the student researcher/therapist will complete the majority of work required for the study design, conduct, data analysis and interpretation, manuscript writing, and dissemination of results.

The student researcher/therapist will be supported by the research team of Primary Research Supervisor (Dr De Boos), Secondary Research Supervisor (Dr Golijani-Moghaddam) and Field Research Supervisor (Dr Burrell). Their involvement will vary depending on their role and expertise.

STUDY BACKGROUND and RATIONALE

In older adults (OAs), anxiety and depression are associated with increased levels of disability (Brenes et al., 2008). There are also high co-morbidity rates for physical illness in the population with around 30% of 60-64-year olds having more than one diagnosed condition, rising to around 75% by age 85 (Age UK, 2017). Interestingly, poor mental health in older age has a stronger association with lower life satisfaction than poor physical health (Puvill, Lindenberg, De Craen, Slaets & Westendorp, 2016). With the percentage of the population aged over 65 anticipated to double by 2050 (World Health Organisation, 2017), it is increasingly important that mental health treatment for OA are achieving maximum outcomes. First line treatments for OA mental health are usually pharmacological in nature (Andreescu & Reynolds, 2011), with adults aged 75+ ten times more likely to receive medication than psychological therapy (McManus, Bebbington, Jenkins & Brugha, 2016). This is contrary to current clinical guidelines for adults, where a stepped-care model recommends psychological interventions as primary treatment for mild to moderate anxiety/depression (National Institute for Health and Care Excellence [NICE], 2018, 2019). This high rate of pharmacological interventions is also problematic due to increased side effects, as well as OAs being underrepresentation in clinical trials (Fialová et al., 2019; Konrat et al., 2012). As age increases, rates for common mental health problems are lower and less severe (McManus et al., 2016), suggesting that standard treatment is out of sync with both clinical recommendations and client preferences.

There is evidence that OAs prefer psychological interventions over medication (Gum et al., 2006), however, older generations are less likely to talk about their feelings and vocalise a need for emotional support (Knight & Poon, 2008). Further barriers include that care for OAs focuses more on the practical and physical health aspects, rather than the emotional and psychological (McCabe, Davison, Mellor & George, 2009). If the OA population are framed through a medical model, perhaps there is a propensity to treat based in a medical manner (i.e. psychiatric and pharmacological). Hindering change in clinical practice is a relatively small evidence base of psychological treatments for OAs; due in part to the mismatch between strict randomised controlled trial (RCT) criteria and high co-morbidity rates in OAs (Gatz, 2006).

Following the outbreak of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in the UK in February 2020, social distancing measures have advised for all non-essential

contact between individuals to be ceased (Public Health England, 2020). Subsequently, the study will move to delivering the intervention by telephone or by video calling. Although there are some initial studies into the use of telephone-delivered ACT for smoking cessation (Bricker et al., 2010; Bricker et al., 2014), as well as a review of the impact of telephone support on self-directed ACT (French, Golijani-Moghaddam, & Schröder, 2017) this study will be the first to investigate the effectiveness of a phone/videocall therapist-delivered ACT intervention for older adults.

For younger/working age adults, cognitive-behaviour therapy (CBT) is the most evidence-based psychological treatment for mental health conditions (Hofmann, Asnaani, Vonk, Sawyer, & Fang, 2012). A recent meta-analysis demonstrated large effect sizes for CBT with working age adults, however, for OAs the effect size reduced to a moderate level (Kishita & Laidlaw, 2017). CBT works be emphasising the link between thoughts and feelings, and uses cognitive restructuring to facilitate improvement in psychological symptoms. When CBT was compared to Acceptance and Commitment Therapy (ACT; Hayes, Strosahl & Wilson, 1999) with individuals experiencing chronic pain, age was shown to moderate response to treatment, with older adults responding better to ACT (Wetherell et al., 2016).

ACT theorises that better quality of life can be achieved by developing psychological flexibility, an adaptive situational response to the competing demands of life (Kashdan & Rottenberg, 2011). Rather than altering the content of thoughts, the therapist guides a client through several interconnected processes (e.g. Acceptance, Values, or Committed Action). The goal is to develop a different relationship with thoughts and distress, rather than to eliminate these. Butler & Ciarrochi (2007) have demonstrated that older adults with higher psychological acceptance exhibited higher quality of life in areas of health, safety, community participation and emotional well-being.

Meta-analyses have demonstrated the efficacy of ACT compared to placebo, however, the way in which ACT is effective is less understood (Öst, 2014). Therefore, it is not only crucial to provide further evidence of whether ACT is an effective intervention for older adults, is important to understand the processes that make it effective. Randomised controlled trails (RCTs) are often used as the 'gold standard' in establishing the efficacy of a psychotherapeutic model (Hariton & Locascio, 2018). However, in order to demonstrate causality, RCTs require the application of strict criteria to the study variables (e.g. participant diagnoses, age range) or the removal of extraneous factors (e.g. preventing participants changing medications during the study). This has led to criticisms as to whether RCTs are wholly appropriate when investigating the complexities of how and why a psychotherapy is or is not effective (Elliott, 2002).

An ideal methodology to investigate such issues is the Hermeneutic Single Case Efficacy Design (HSCED; Elliott, 2002), which is a critical and interpretive approach to assess the intervention effects for single therapy cases in a naturalistic clinical setting. There are longstanding arguments whether psychotherapy operate through modality specific factors (ACT in this study), or through non-specific factors common to all psychotherapies (e.g. the therapeutic alliance or a client's expectations of treatment; Mulder, Murray & Rucklidge, 2017). It is also important to recognise the impact that events outside of the therapy session, extra-therapeutic factors, have on change within the client (e.g. a significant loss, change in medications). The HSCED acknowledges that there are numerous factors which contribute towards change (modality-specific, non-specific and extra-therapeutic), and it actively seeks to measure and analyse these. The utilisation of a case series (rather than individual case

study) allows for a cross-synthesis of what does and does not contribute towards change between-participants.

This study provides an original contribution towards the field as it applies a therapeutic intervention (ACT) that is under researched within the older adult population. Furthermore, it utilises a methodology that is not only ideal in addressing the complex processes of efficacy, but which has also never been used to investigate ACT with older adults experiencing psychological distress.

STUDY OBJECTIVES AND PURPOSE

PURPOSE

The purpose of the study is to examine whether ACT can be an effective intervention in increasing quality of life in older adults (aged 65+), presenting to older adult mental health service with psychological difficulties, as well as why ACT is effective.

PRIMARY OBJECTIVE

In this study we aim to investigate the efficacy of ACT for supporting older adult clients experiencing psychological distress.

SECONDARY OBJECTIVE(S)

In addressing the primary objective, we will be guided by three fundamental questions: (1) Do (meaningful) changes occur for client-participants over the course of ACT intervention? (2) Are observed changes broadly attributable to the ACT intervention? (3) What specific factors (ACT-specific, non-specific, extra-therapeutic) contribute to observed changes?

The study will also identify adaptations that may be facilitative of change when using ACT with older adult clients, with consideration of the impact that moving the study to a telephone/videocall delivered intervention.

OUTCOME MEASURES

PRIMARY OUTCOME MEASURE

1. Change in quality of life assessed using the Older People's Quality of Life questionnaire (OPQOL-brief; Bowling, Hankins, Windle, Bilotta, & Grant, 2013). Completed by participant.

SECONDARY OUTCOMES

Symptom measures

1. Client's level of cognitive functioning assessed using the Montreal Cognitive Assessment (MoCA; Nasreddine et al., 2005). Completed by MHSOP team with the participant.
2. Changes in symptoms of anxiety and depression assessed with the Hospital Anxiety and Depression Scale (HADS; Zigmond & Snaith, 1983). Completed by the participant.

Change measures

1. Change in/progress on client's goals assessed using the Simplified Personal Questionnaire (PQ; Elliot, Mack, & Shapiro, 1999). Completed by participant with guidance from therapist.
2. Client's attribution of change and view on therapy assessed with the Change Interview (Elliott, Slatick, & Urman, 2001). Conducted by secondary researcher with participant.

Process measures

1. Change in psychological flexibility assessed using the CompACT-8 (Morris, Dawson, & Golijani-Moghaddam, 2019). Completed by participant.

Session measures

1. Change in client's weekly level of quality of life assessed using the Outcome Rating Scale (ORS; Miller, Duncan, Brown, Sparks & Claud, 2003). Completed by participant.
2. Change in therapeutic alliance assessed with the Session Rating Scale (SRS; Duncan et al., 2003). Completed by participant.
3. Client's (qualitative) views on individual therapy sessions assessed with the Helpful Aspects of Therapy form (HAT; Llewlyn, Elliott, Shapiro, Firth, & Hardy, 1988). Completed by therapist in discussion with participant.

Fidelity measure

1. Adherence to ACT related processes assessed with the ACT Fidelity Measure (ACT-FM; O'Neill, Latchford, McCracken & Graham, 2019). Completed by therapist and secondary researcher.

EXPLORATORY OUTCOMES

Adaptations made to treatment will be recorded so that commentary can be made on what adaptations to ACT may be beneficial for older adult clients. Consideration of the impact that delivering the intervention in a remote manner will also be made and any adaptations that were made to facilitate this.

TABLE OF OUTCOMES

Objectives	**Outcome Measures**	**Timepoint(s) of evaluation of this outcome measure (if applicable)**
Primary Objectives	1. Quality of life (OPQOL-brief).	1. Baselines, pre-, mid- and post-intervention, and at six-week follow up.
Secondary Objectives	**Symptom measures** 1. Cognitive functioning (MoCA). 2. Changes in levels of anxiety and depression (HADS).	1. At initial contact, by service as standard practice. 2. At initial contact, by service as standard practice. Baselines, pre-, mid- and post-intervention,

		and at six-week follow up.
	Change measures 1. Client's goals (PQ). 2. Client's view on change (Change Interview).	1. Prior to each weekly treatment session. 2. One week after finishing treatment.
	Process measure 1. Psychological flexibility (CompACT-8).	1. Baselines, pre-, mid- and post-intervention, and at six-week follow up.
	Session measures 1. Quality of life/general outcomes (ORS). 2. Therapeutic alliance (SRS). 3. Client's views on the therapy session (HAT).	1-3. At the end of each weekly treatment session.
	Fidelity measures 1. Fidelity of treatment (ACT-FM).	1. At the end of each session (by therapist) and random sampling of all sessions (by Secondary Research Supervisor).
Exploratory/Tertiary Objectives	1. Beneficial adaptations for ACT. 2. Impact of telephone/videocall and adaptations to this.	1. Noted throughout the study by researcher and commented on in final write up. 2. Noted throughout the study by researcher, factored into impact of results, and commented on in final write up.

STUDY DESIGN

To address the aims and sub-objectives listed previously, the study will employ an adjudicated Hermeneutic Single Case Efficacy Design (HSCED) series. Following Elliott's

(2002; Elliott et al., 2009) approach, the first step for a HSCED is the formation of rich case records. Developed for each client, these consist of data from various time points in the study, and include demographic, quantitative (outcome measures, treatment fidelity measures etc.) and qualitative sources (Change Interview, therapy feedback, therapy process notes and recordings). The rich case records are then cross-referenced and synthesised into an affirmative and sceptic brief. These briefs are then presented to an expert panel to be adjudicated on the process of change (see Figure 1).

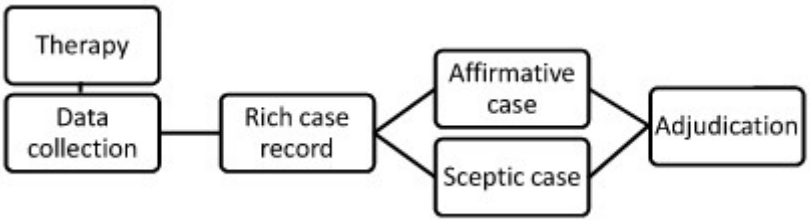


Figure 1: the HSCED process (Stephen et al., 2011).

Affirmative brief

The purpose of the affirmative brief is to demonstrate direct links between the therapeutic intervention and outcomes, and is divided into three parts: 1) a brief of the main lines of argument for these links; 2) a rebuttal against the arguments made in the sceptic brief; and 3) a concluding summary narrative (Stephen et al., 2011). The affirmative brief draws evidence from five areas (see Table 1), with evidence in at least two areas required to warrant adjudication (Elliott, 2002).

Sceptic brief

The opposing sceptic brief demonstrates possible nontherapy processes which could account for change (Table 2), and uses the same structure of a brief, a rebuttal, and a narrative summary. Elliott (2002) talks about the sceptic brief being developed in a manner of good-faith to determine what non-therapy effects may have led to change.

DATA ANALYSIS

To facilitate the cross-referencing of rich case records, several methods of analysis will be employed, dependent on the evidence area required for the affirmative or sceptic brief. These are outlined in Tables 1 and 2, respectively. All analyses will be completed using SPSS (Version 25.0; IBM Corp, 2017) or Microsoft Excel (Version 15.0.5179.1000; Microsoft Corporation, 2013). Analyses will be performed by the student researcher/therapist either at the MHSOP or the Universities of Lincoln or Nottingham. No data containing confidential information will be analysed outside of the MHSOP, in line with relevant NHS Trust policies.

Table 1

Direct evidence for links between therapy process and outcome, from Elliott (2002).

Direct evidence area	**Description**	**Method of evaluation (*specific analysis method*)**
1. Retrospective attribution	Change attributed by client to the therapy	Content of Change Interview (*Framework Analysis*)
2. Process-outcome mapping	Content of post-therapy changes correspond to specific processes within therapy	Correlations between within therapy measures (HAT), and quantitative outcome measures (*Pearson correlation, or Spearman correlation if assumptions of normal distribution not met*).
3. Within-therapy process-outcome correlation	In-therapy process variables covary with week-to-week changes in client problems	Correlations between ACT adherence and ORS, and the change questionnaire (i.e. the SPQ; *Pearson/Spearman correlation*)
4. Early change in stable problems	Therapy coincides with changes in long-standing client problems	Change in outcome measures from baseline to initial sessions (*Pearson/Spearman correlation, visual analysis*)
5. Event-shift sequences	Important events precede stable shifts in client problems, especially if therapy process and client change are logically related	Correspondence between within therapy measure (HAT) and variation in patient's problem (SPQ; *Pearson/Spearman correlation, visual analysis*)

Note: HAT – Helpful Aspects of Therapy form. SPQ – Simplified Personal Questionnaire.

Table 2

Evidence for links between nontherapy processes and outcome, from Elliott (2002)

Nonchange/ nontherapy area	**Changes are…**	**Method of evaluation (*analysis method*)**
1. Non-improvement	Either trivial or negative.	Assess reliable and clinical significance on measures (*RCI* calculations); ask ppt the importance and direction of any change (*Change Interview*).
2. Statistical artefacts	Reflect measurement error, outlier to the mean, or experimentwise error.	Assess for reliable change (*RCI calculations*); stability of client problems through multiple baselines (*Pearson/Spearman correlation, visual analysis*); replication of change over multiple measures (*RCI calculations*).
3. Relational artefacts	Superficial artefacts related attempts to please therapist/researcher.	Evaluate client social desirability and determine covariance with measures (*ANCOVA*); ask ppt their negative and positive descriptions of therapy (*Change Interview*).
4. Client expectations	Related to expectations or wishful thinking.	Assess client expectations at start; ask ppt whether changes were expected or surprising (*Change Interview*).
5. Self-correction	Reflect self-help or self-initiated remedy of temporary problems.	Determine direction and stability of measures from baseline to initial sessions (*Pearson/Spearman correlation*); ask ppt duration of problems using SPQ; look for self-help efforts begun before therapy via demographics form and assessment.
6. Extra-therapy life events	Attributed to life events, e.g., changes in clients' situation.	Monitor for such events; assess likelihood of change without therapy (*Change Interview*); consider mutual influence these factors have on each other.
7. Psychobiological factors	Attributed to medication, medical illness recovery etc.	Collect information on medication and physical health prior to, and during therapy.
8. Reactive effects	Due to being in research, sense of altruism in client, relationship with researcher.	Ask client directly about effects of research (positive and negative); use of external ratings; minimise research impact.

Note: ANCOVA – Analysis of Covariance; RCI – Reliable Change Index (Jacobson & Truax, 1991); SPQ – Simplified Personal Questionnaire (Elliot, Mack, & Shapiro, 1999); ppt – participant.

STUDY SETTING

The study will be a single centre study, run from a Mental Health Service for Older People (MHSOP) at Lings Bar Hospital, Nottinghamshire.

As standard practice for psychology referrals at the MHSOP, the initial assessment will be completed primarily by Dr Burrell, the Field Research Supervisor for the study. Dr Burrell will then screen psychology referrals for appropriate participants and inform them about the study. Following social distancing restrictions in place due to the SARS-CoV-2 outbreak, the MHSOP is currently only offering face-to-face appointments when necessary, offering telephone or videocall therapy appointment as a standard replacement. As such, the therapy in the current study will be offered by either telephone or videocall. At first contact, participants will be asked their preference and what technology provisions they have to facilitate videocalling (i.e. a smartphone or a laptop/PC with microphone and camera). The sessions will then be conducted using QHealth (MyMed Ltd, 2020), which is an NHS Digital and NHS England approved, centrally funded eConsultation supplier for the COVID-19 response. The therapeutic intervention will be conducted by the student researcher/therapist, Jonathan O'Keeffe. Clinical supervision will take place between student researcher/therapist and Dr Burrell at the MHSOP. Weekly ACT supervision will be conducted between student researcher/therapist and Secondary Research Supervisor via telephone or face-to-face.

SELECTION OF PARTICIPANTS

ELIGIBILITY CRITERIA

To be eligible for the study, participants must have first been referred to the MHSOP for psychological support. The study will recruit both male and female participants, aged 65 years or older (there is no upper age limit).

Inclusion Criteria

1. Be at least 65 years of age.
2. Score at least 8 on the Hospital Anxiety and Depression Scale (HADS; Zigmond & Snaith, 1983) on either the anxiety or depression sub-scale. The HADS is an outcome measure already used by the MHSOP.
3. Be referred to the MHSOP for psychological support.
4. Have capacity to give informed consent.
5. Be willing to engage in one-to-one psychotherapy over telephone or videocall.

Exclusion Criteria

1. A score lower than 22-24 on the MoCA. This is to screen for a level of cognitive deficit, which cannot be accommodated for in the current study, due to the adaptations which will be required (e.g. review sessions, carer enrolment to support memory consolidation). Cut-off limit is dependent on the individual's age and education history. The MoCA is administered by the MHSOP as standard practice.
2. Not rated higher than Cluster 8 (Mental Health Clustering Booklet 2013/14, Department of Health), a categorisation based on the Health of the Nation Outcome Scale (HoNOS; Wing et al., 1998). Clusters higher than 8 are associated with clients presenting with symptoms of psychosis and it is felt that this level of mental health problem would cause serious heterogeneity between client cases. As standard practice, the MHSOP at Ling Bar Hospital will have rated the client prior to consideration for the study.

3. Inability to understand English to a level required to participate fully in the intervention. This is due to a lack of ability to benefit from the intervention without an interpreter, and the impact an interpreter would have on the non-therapeutic processes (e.g. alliance) being measured in this study.
4. Not currently undertaking any other psychological therapy, talking therapy or counselling. This is due to the potential impact the other therapy could have on change and the inability to fully account for this.

Sampling and size of sample

The study will recruit up to four participants. Most Hermeneutic Single Case Efficacy Designs (HSCED) focus on one client (Stephen, Elliott, & Macleod, 2011). However, there have been recent calls to increase cross case synthesis to further validate the intervention being used (MacLeod, Elliott, & Rodgers, 2012). Three cases would fit with established guidelines for a single-case research series (Smith, 2012) and has shown to be feasible in previous HSCED research (e.g. Wall, Kwee, Hu, & McDonald, 2017). Drop-out or withdrawal would be a major concern with the current study, due to the extended participant contact time and the constraints on recruiting and treating further participants within schedule for Doctoral Thesis submission. With dropout rates around 25% (Grover, Dua, Chakrabarti, & Avasthi, 2018) recruiting up to four participants appears a sensible approach. A fourth participant will only be recruited up until July 2020, to allow for the completion of the intervention and requirements of submission for the Doctoral Thesis.

Sampling technique

The sample will be referrals from the MHSOP recruited in a convenience sampling method. As this study aims to reflect usual clinical practice, this is an adequate sampling method to recruit participants.

RECRUITMENT

Participants will be recruited from Rushcliffe Mental Health Service for Older People (MHSOP), Lings Bar Hospital, Nottinghamshire. The initial approach will be from a member of the patient's usual care team. Potential participants will be informed about all aspects pertaining to participation in the study.

It will be explained to the potential participant that entry into the trial is entirely voluntary and that their treatment and care will not be affected by their decision. It will also be explained that they can withdraw at any time, but attempts will be made to avoid this occurrence. In the event of their withdrawal it will be explained that their data collected so far may not be erased in accordance with the University's Research Privacy Notice and information given in the Participant Information Sheet and we will seek consent to use the data in the final analyses where appropriate.

Participant Payment

Clients will be reimbursed for the aspects of the study which are additional to usual practice. This is the extra number of questionnaires they need to complete, plus attending the Change Interview after treatment sessions have ended. Participants will be provided a voucher of their choosing for £40. Participants will also be reimbursed travel to the Change Interview (if social distancing is relaxed by the end of the study).

CONSENT

Following standard practice during social distancing, verbal informed consent will be accepted from all participants before they enter the study. During a phone/videocall

psychology referral assessment with potential participants whom have been referred for psychology support, a member of the MHSOP will explain the details of the study and enquire whether they would be interested in taking part. Hard copies of the Consent Form (CF) and Participant Information Sheet (PIS) will be posted out to participants so they able to read through, before a follow-up call is made (around a week later, usually by the same member of the MHSOP) to reiterate a summary of the study and allow an opportunity for any questions relating to the study. Potential participants will then be asked whether they would consent to taking part in the study. Should the potential participant need more time to consider, they will be called back a week later. If potential participants verbally consent, at the time, or after a week, they will be asked whether they consent to each point on the CF in turn. A note of this will be made on the participants clinical notes.

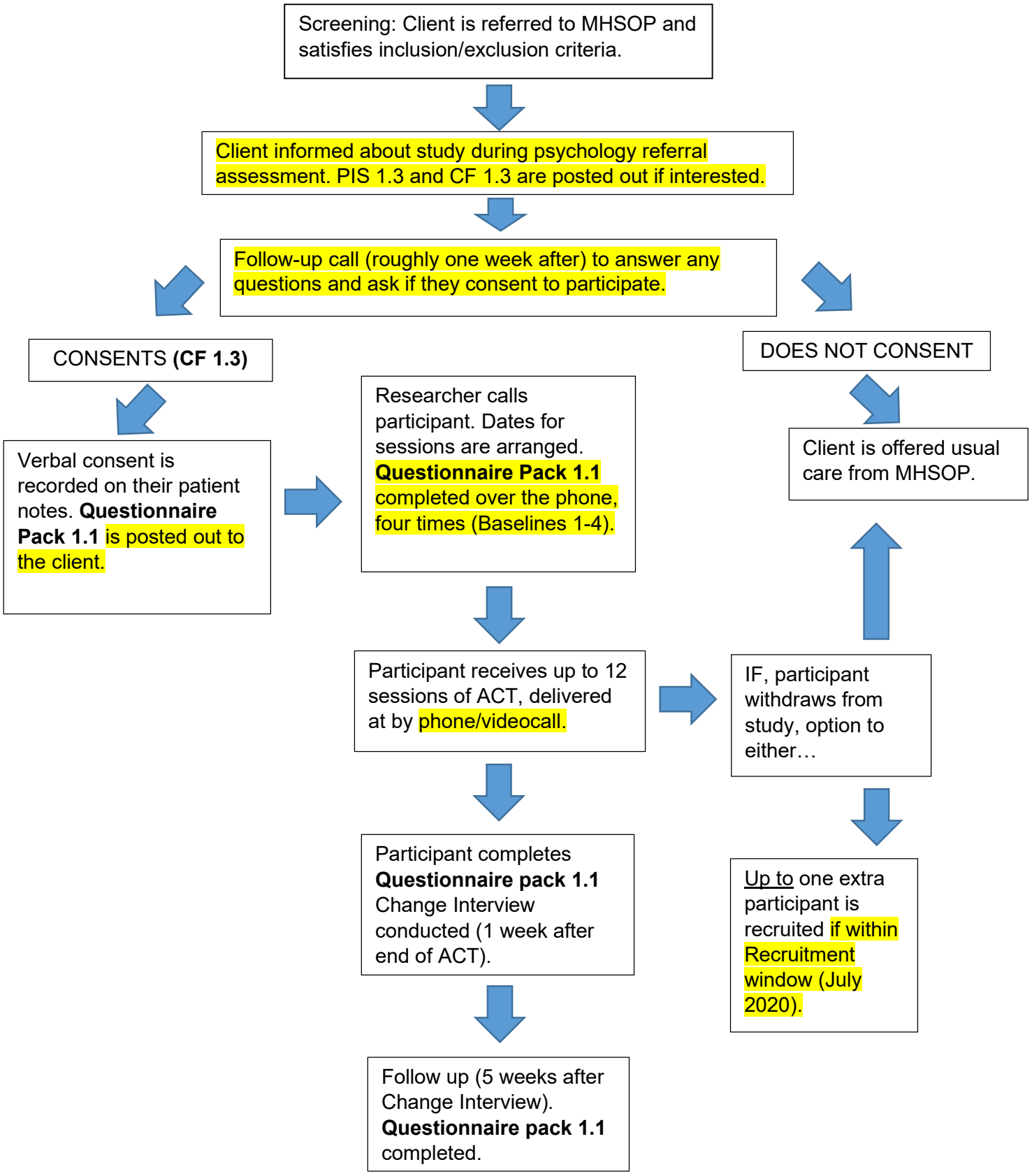
Should potential participants not consent to take part in the study, they will be offered usual care from the MHSOP (see STUDY FLOWCHART, below).

The process for obtaining participant informed consent will be in accordance with the REC guidance, and Good Clinical Practice (GCP) and any other regulatory requirements that might be introduced.

Should there be any subsequent amendment to the final protocol, which might affect a participant's participation in the trial, continuing consent will be obtained using an amended CF which will be signed by the participant.

STUDY PROCEDURES/REGIMEN

STUDY FLOWCHART



RANDOMISATION AND BLINDING

Participants in this study will not be randomised or blinded to any aspects of the study. The HSCED methodology allows for a naturalistic and transparent procedural approach to investigating psychotherapy efficacy.

STUDY REGIMEN

Screening and baseline

At the time of recruitment, all potential participants will be active referrals at the Rushcliffe Mental Health Service for Older People (MHSOP), Lings Bar Hospital, Nottinghamshire. They will also have been referred for further psychology support (i.e. any referral that is felt would benefit from individual clinical psychology sessions). Eligible clients (see inclusion/exclusion criteria) will be informed (through discussion and Participant Information Sheet) about the study during a psychology referral assessment with a Clinical Psychologist from the MHSOP (Dr Ruth Burrell, Field Research Supervisor for the study), delivered by phone/videocall due to social distancing requirements. Adaptations such as larger font to sheets will be determined as well as whether they would be able to facilitate videocall therapy. Potential participants that are interested in taking part will have the CF and PIS posted out to them, with a follow-up call around a week later to obtain consent. Clients that do not consent to take part will be offered usual care from the service.

The Assistant Psychologist from the team will call those participants that consent to determine the dates of the intervention. The Assistant Psychologist will also go through a pack of questionnaires (Questionnaire Pack 1.1 [QP1.1]), which will have been posted out to them. This date will act as Baseline 1. The Assistant Psychologist will then call back a following three times, acting as Baselines 2, 3, and 4, all a week apart. Baseline 4 will ideally be the same day as the start of the Acceptance and Commitment Therapy (ACT) intervention. The ACT intervention will be conducted by the student researcher/therapist via telephone or videocall, depending on the participants wishes. Sessions will be audio recorded using an NHS encrypted electronic device, with participant knowledge, to conduct fidelity checks of the treatment at a later date. Participants will be supported to complete questionnaires after the session which will have been posted out to them.

Therapeutic sessions

Up to 12 therapeutic sessions will be offered, delivered by the student researcher/therapist. At session 1 (week 4), confidentiality will be reiterated, including under what circumstances confidentiality would be broken (risk to them or others). They will also be explained the procedure of clinical supervision from Dr Burrell as well as ACT-supervision from Dr Golijani-Moghaddam (the latter supervision not using confidential information). Participants will then be supported to complete the Simplified Personal Questionnaire (SPQ), noting their expectations for therapy, the main problems they are bothered with and duration of these. Participants will then be introduced to the underlying concepts of ACT, before starting with the proposed ACT-protocol (adapted from Petkus & Wetherell, 2013):

ACT area	Sessions and content
Values	Sessions 1-3 1. Regaining contact with values: What matters? 2. The role of religion 3. Making the most of the remaining time
Acceptance/Willingness	Sessions 4-5

	1. What's worked? What hasn't? What are the costs? 2. Control is the problem 3. Experiencing vs. avoiding 4. How does this fit with values?
Defusion	Sessions 6-7 1. Awareness of internal experiences 2. A thought is just a thought 3. Having a thought vs. content of a thought 4. Defusion from damaged conceptualized self
Mindfulness and Self as Context	Sessions 8-9 (Mindfulness exercise conducted at the beginning of every session) 1. Being in the present moment 2. Not judging thoughts or feelings 3. Thoughts and selves
Committed Action	Begins during the Values sessions and continues throughout the intervention, but is emphasized during Sessions 10-12 1. What goals are consistent with values? 2. What actions work toward these goals? 3. Breaking it down into steps 4. Problem-solving potential barriers 5. Enlisting support
Therapeutic blueprint	Session 12 1. Summary of the content 2. Review of SPQ and any change experienced 3. Next steps and further support options

Therapy will use the above protocol as a guide for treatment; however, duration and content will be adapted based on the individual. Primarily this will be using extra sessions to focus on any content that participants may need further work with, but could also include a break in the middle of sessions. Sessions will predominantly be weekly and one hour in length, dependent on any required adaptations. Sessions will be delivered either over telephone or via QHealth. As ACT is a processes-based therapy, rather than a single manualised procedural treatment, adherence to a strict protocol is not theoretically mandated (Hayes & Hoffmann, 2017).

The basic structure of each session will be:

1. Participant completes weekly Personal Questionnaire before session.
2. Session begins with a mindfulness exercise.
3. Homework and concepts from previous session are reviewed.
4. New material for the session is covered.
5. Homework is assigned.
6. Therapist completed HAT with participant.
7. Participant is supported to complete ORS and SRS.

Following each session, the student researcher will receive clinical supervision with Dr Burrell by (secure) videocall or telephone to discuss any relevant case information, such as

risk and progress. A clinical note will be made on the participant's electronic case record, as in standard practice. The student researcher will also receive regular ACT supervision from Dr Golijani-Moghaddam, Secondary Research Supervisor/Chief Investigator to address any modality specific questions or dilemmas. Relevant discussions from this will be added to the participant's electronic case record as required.

At mid-point in therapy (usually session six), QP1.1 will be repeated at the start of the therapy session. QP1.1 will also be repeated at the final therapy session to act as the post-therapy time point.

During the final session, the PQ will be re-administered to determine whether there has been any change in their problem areas. Participants will also be given the opportunity to 're-author' their problem areas. This is to capture any theoretical change they may have occurred in identifying where problems at situation, as would be posited by the ACT theoretical framework (living with problems, rather than eliminating them). Participants will complete any required session questionnaires prior to filing in the PQ.

The final session will also cover a summary of the sessions, as well as providing the participant with a therapy blueprint of what they specifically found useful. This will include any next steps for the participant (e.g. whether they will continue to be seen by the MHSOP) and what the process is for them to follow if there is a deterioration in mental health. The participant will be reminded of the data processing details and asked again if they would like a summary of the findings from the study.

One week after the final session, participants will complete a Change Interview, facilitated by Kiran Badesh, Trainee Clinical Psychologist, either face-to-face of by telephone/videocall, depending on the social distancing restrictions at the time. The Change Interview is a semi-structured interview to determine whether the client experienced change during the treatment, what they attributed this towards (e.g. therapeutic factors, external factors). The Change Interview is completed by a member of the research team the participant has not had previous contact with (to encourage more honest responses), and will be recorded on a NHS encrypted device so that the answers can be transcribed at a later date. The participants will then receive reimbursement towards their travel (if applicable) and for the factors of research which were additional to normal clinical treatment (extra questionnaires, attending Change Interview).

One month following the Change Interview, participants will be called up again by the Assistant Psychologist to complete QP 1.1. This will act as six-week post-therapy follow-up.

Following final therapy sessions, a secondary member of the research team (likely to be the Chief Investigator) will complete fidelity checks to ensure that the modality (ACT) is sufficiently adhered to. This will be conducted using a random sampling method and the researcher will have access to anonymised audio files, stored on an encrypted NHS Trust device.

Data from throughout the study will be cross-referenced to develop the affirmative and sceptic briefs required for the HSCED. Pseudonyms will be used for the participants and there will be no patient identifiable information within the briefs. Once completed, the briefs will be sent to the expert panel of three Clinical Psychologist, with relevant interest and experience of psychotherapeutic change methods. The panel adjudicate over the case material using a semi-structured questionnaire to decide whether the client made a substantial change and where they attribute this towards (ACT-specific, non-specific, or extra-therapeutic factors). This process allows for a reduction in researcher bias.

SCHEDULE OF PROCEDURES

Procedures	**Visits**									
	Psychology Screening Assessment & Baseline 1 (wk1)	**Baseline 2 (wk2)**	**Baseline 3 (wk3)**	**Baseline 4 & Session 1 - pre (wk4)**	**Sessions 2-5 (wks 5-8)**	**Session 6 - mid (wk 9)**	**Sessions 7-11 (wks 10-14)**	**Session 12 - post (wk 15)**	**Change Interview (wk 16)**	**Six wk follow-up (wk 20)**
Informed consent	x									
Symptom, & process measures	x	x	x	x		x		x		x
Demographics	x									
Medical history	x						x			
ACT intervention				x	x	x	x	x		
Session, change, & fidelity measures				x	x	x	x	x		
Change Interview									x	

Note: wk = week; see Timetable of Measures for outline of when individual measures are administered.

WITHDRAWAL

Participants may be withdrawn from the trial either at their own request or at the discretion of the Investigator. The participants will be made aware that this will not affect their future care. Participants will be made aware (via the information sheet and consent form) that should they withdraw the data collected to date may not be erased in accordance with the University's Research Privacy Notice and information given in the Participant Information Sheet and may still be used in the final analysis.

Stopping rules and discontinuation:

-If a participant withdraws consent to continue.

-If a participant expresses that the intervention is causing their anxiety and depression to get worse.

-If a participant's physical health significantly deteriorates to a point where continuation would be impractical or create sufficient negative burden on them.

-If a participant fails to comply with the intervention.

-If new findings become published regarding likely risks or negative effects of ACT.

Should any of these criteria be met, the decision of whether the participant receives further support from the MHSOP will be decided by Dr Burrell and the wider MDT at the MHSOP. A replacement participant will be recruited, dependent of timeframe and ability to deliver therapy. Should criteria apply to all participants (such as evidence of the negative effects of ACT), the study as a whole will be temporarily stopped on ethical grounds. Interim analysis would be performed at this point to determine any negative effects of the intervention on the participants. Continuation of the study would be dependent on further guidance from the REC, NHS R&D and any other relevant parties.

ETHICAL AND REGULATORY CONSIDERATIONS

ASSESSMENT AND MANAGEMENT OF RISK

This study aims to reflect usual clinical practice where possible; therefore, the burden to participants will be of a similar level to treatment as usual. That is, they will be expected to attend one-to-one psychotherapy (either face-to-face or at distance) and to discuss their mental health difficulties; what contributed towards the development of their difficulties; and what is maintaining their difficulties. As with any psychological therapy, there is a potential risk that talking about distressing experiences will cause an increase in frequency or intensity of pre-existing mental health conditions.

These risks will be monitored through the study by the Trainee Clinical Psychologist (who is both researcher and therapist) through discussion with the participant, use of outcome measures and importantly by utilising weekly clinical supervision with Dr Burrell (Clinical Psychologist for the MHSOP). This allows a space for any concerns to be raised and for Dr Burrell to have clinical oversight of the participants. As part of standard clinical practice, and local NHS Trust policies, each participant will have a clinical risk assessment with the MHSOP. This will be reviewed by the researcher/therapist with Dr Burrell before starting therapy. Any relevant information will also be added to this, should anything relevant come up in therapy sessions.

The aspects of the study which are additional to usual practice are as follows: participants will be required to complete more questionnaires; participants will be required to come in for an interview after the block of therapy has ended. Every effort has been made to reduce the burden the questionnaires place upon participants. For instance, shorter questionnaires have been used where possible. Participants will also be asked about any adaptations required to complete questionnaires (e.g. larger font, someone completing questionnaires with them). Clients will be reimbursed for the aspects of the study which are additional to usual practice.

The interviews in this study may include sensitive topics; however, there are no anticipated adverse events for participants. Should there be an increase in intensity of mental health difficulties then any immediate risk will be discussed in sessions. The study will follow the Safeguarding policies and procedures of Nottingham Healthcare NHS Foundation Trust (the hosting Trust). In line with these procedures, should participants disclose anything to indicate that they or someone they know are at risk of harm, the researcher has a duty to report this. Participants will be informed of this where relevant and possible.

Once participants have finished with the research aspects of the study, participants will either be discharged from the MHSOP or continue to receive support. This will be dependent on the client's progress, any emergence of risk etc. Final clinical decision will be made by Dr Burrell, Clinical Psychologist/Field Research Supervisor, at the MHSOP.

There are minimal risks to the researcher associated with this study, although therapy sessions may involve hearing distressing and emotive topics. The researcher will utilise both clinical supervision (through the MHSOP) as well as ACT focused supervision (though the University of Lincoln) to manage and monitor this.

Individual participant medical information obtained as a result of this study are considered confidential and disclosure to third parties is prohibited with the exceptions noted. Medical information may be given to the participant's medical team and all appropriate medical personnel responsible for the participant's welfare.

If information is disclosed during the study that could pose a risk of harm to the participant or others, the CI will discuss this with the Field Research Supervisor in the first instance and where appropriate report accordingly.

ADVERSE EVENTS

An adverse event (AE) is any untoward medical occurrence in a study participant. An adverse event (AE) may therefore be any unfavourable and unintended sign (including an abnormal laboratory finding), symptom, or disease that develops or worsens during the study period.

An AE may include:

- Exacerbation of a chronic or intermittent pre-existing condition including either an increase in frequency or intensity of the condition.
- Significant or unexpected worsening or exacerbation of the condition/indication under study.
- A new condition detected or diagnosed after study therapy administration even though it may have been present prior to the start of the study.

- Pre- or post-treatment events that occur as a result of protocol-mandated procedures (e.g., invasive protocol-defined procedures, modification of a patient's previous treatment regimen).

An AE does **not** include:

- Medical or surgical procedures (e.g., colonoscopy, biopsy). The medical condition that leads to the procedure is an AE.
- Social or convenience hospital admissions where an untoward medical occurrence did not occur.
- Day to day fluctuations of pre-existing disease or conditions present or detected at the start of the study that do not worsen.
- The disease/disorder being studied, or expected progression, signs, or symptoms of the disease/disorder being studied unless more severe than expected for the patient's condition.

Adverse events of participation in this study may be: there are no anticipated adverse events for participants associated with this study.

A serious adverse event (SAE) means any adverse event, adverse reaction or unexpected adverse reaction, respectively, that:

a. results in death,
b. is life-threatening,
c. requires hospitalisation or prolongation of existing hospitalisation,
d. results in persistent or significant disability or incapacity, or
e. consists of a congenital anomaly or birth defect

Other 'important medical events' may also be considered serious if they jeopardise the participant or require an intervention to prevent one of the above consequences.

NOTE: The term "life-threatening" in the definition of "serious" refers to an event in which the participant was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe.

There are no serious adverse events anticipated with participating in this study.

Participant reporting of adverse events

The Investigator will review all documentation (e.g., hospital progress notes, laboratory, or diagnostic reports) relative to the event being reported. The Investigator or clinician will then record all relevant information regarding an AE/SAE. All adverse events will be recorded and closely monitored until resolution, stabilisation, or until it has been shown that the study treatment / intervention is not the cause.

Participant removal from the study due to adverse events

Any participant who experiences an adverse event may be withdrawn from the study at the discretion of the Investigator.

ETHICS REVIEW AND COMPLIANCE

The study shall not commence until the study protocol, information sheets and consent forms have been reviewed and approved from a Research Ethics Committee and relevant NHS/Social Care permission is obtained

The sponsor will be responsible for deciding whether amendments are substantial and non-substantial in collaboration with the Chief Investigator.

Where an amendment is required to study documentation that required REC approval, changes will not be implemented until REC approval and HRA categorisation is received. Where an amendment requires local approval, this shall be sought prior to the amendment be implemented at each site in accordance with the categorisation given on the HRA approval letter.

Should an amendment be required to eliminate an apparent immediate hazard to participants this may be implemented immediately and the REC/HRA and R&D will be notified as soon as possible.

Minor amendments for logistical or administrative purposes may be implemented immediately

Amendments will be logged on the Sponsor's Study Amendment Log and stored in the Trial Master/Site File(s).

Annual Progress Reports shall be submitted to the REC within 30 days of the anniversary date on which the favourable opinion was given – until the end of the study.

A final report shall (where possible) be submitted to the REC within one year after the end of the study.

If the study is terminated prematurely the CI will notify the REC, including the reasons for premature termination.

PEER REVIEW

As part of the requirements for the DClinPsy course, this research has been through a number of stages in order to check it meets scientific quality. Two academic research staff, one from the University of Nottingham and one from the University of Lincoln, have formally reviewed the project protocol. The outcome was that it is of pass standard, feasible and of clinical importance. Progress since submission of the protocol to the course (May 2019) was assessed at the Research Annual Review (October 2019), where it was agreed that the research was progressing to the sufficient level. Prior to submission for IRAS approval for the study has also been sought from the Sponsor of the research (University of Lincoln) and Trust R&D where the research will take place (Nottinghamshire Healthcare NHS Foundation Trust). IRAS will also involve review by a REC panel. Once the study has finished, the same academic research staff will mark the Thesis before submission of journal article to a peer-reviewed journal. This study will also be supported by the research team to ensure academic quality.

PUBLIC & PATIENT INVOLVEMENT

Participants will be provided a summary of the main findings from the study, should they request this when asked at the end of the study. A summary of the findings will also be presented to the Mental Health Service for Older People (MHSOP), where the study will be carried out. As the project is part of a Doctoral Thesis, a manuscript of the thesis will be stored on the University of Lincoln Repository, along with any journal articles that result from the study.

PROTOCOL COMPLIANCE

Accidental protocol deviations may occur at any time. Accidental protocol deviations will be adequately documented on the relevant forms and reported to the Chief Investigator and Sponsor immediately.

Therapy will use the ACT treatment protocol suggested by Petkus and Wetherell (2013), detailed above. However, this is only a guideline and may be adapted based on participant factors. As ACT is a processes-based therapy, rather than a single manualised procedural treatment, adherence to a strict protocol is not theoretically mandated (Hayes & Hoffmann, 2017). Hayes & Hoffmann, 2017). Content of all sessions will be noted so that later process-change analyses can be performed.

Deviations from the overall study protocol which are found to frequently recur are not acceptable, these will require immediate action and could potentially be classified as a serious breach.

DATA PROTECTION AND PATIENT CONFIDENTIALITY

All study staff and investigators will comply with the principles of the Data Protection Act (2018) in protecting the rights of study participants with regards to the collection, storage, processing and disclosure of personal information and will uphold the Act's/Regulations core principles.

Each participant will be assigned a study identity number, for use on CRFs other trial documents and the electronic database.

Personal data, research data and the linking code will be stored in separate locations. When stored electronically, this will include using encrypted digital files within password protected folders and storage media. Personal information shall be stored separately to research data and will be kept secure, and maintained.

Personal data will be stored for six months following the end of the study, so that the Chief Investigator may provide participants with a summary of the research (should they wish to receive a copy).

Data generated as a result of this study will be available for inspection on request by the participating physicians, the University of Lincoln representatives, the REC, local R&D Departments and the regulatory authorities.

INDEMNITY

Insurance and indemnity for trial participants and trial staff is covered within the NHS Indemnity Arrangements for clinical negligence claims in the NHS, issued under cover of HSG (96)48. There are no special compensation arrangements, but trial participants may have recourse through the NHS complaints procedures.

The University of Lincoln as research Sponsor indemnifies its staff, research participants and research protocols with both public liability insurance and clinical trials insurance.

ACCESS TO THE FINAL DATASET

In compliance with the ICH/GCP guidelines, regulations and in accordance with the University of Lincoln Code of Practice for Research, the Chief or local Principal Investigator will maintain all records and documents regarding the conduct of the study. These will be

retained for at least five years or for longer if required. If the responsible investigator is no longer able to maintain the study records, a second person will be nominated to takeover this responsibility.

Copies of the Trial Master File and trial shall be archived at secure archive facilities at the University of Lincoln. This archive shall include all trial databases, including transcripts of audio files and associated meta-data encryption codes.

Personal data (such as contact details) will be destroyed after it is no longer necessary to contact a participant. Research data (including the consent form) will be retained for a period of five years following first publication. Recordings should be anonymised and archived with the research data as source data.

DISSEMINATION POLICY

The data custodian will be the Chief Investigator on behalf of the University of Lincoln.

This study will be completed as part of a Doctoral Thesis in Clinical Psychology. A manuscript of the Thesis will be available from the University of Lincoln Repository. The Thesis manuscript will include a journal article which will be submitted for peer review, as well as extended information on relevant aspects of the study (e.g. methodology, design). The journal article will be submitted to the Journal of Contextual Behavior Science (JCBS), with anticipated date of July 2021.

A summary of the main findings will be disseminated to participants involved in the study, should they indicate interest when asked. A summary will also be provided to the Mental Health Service for Older People that are hosting the research.

Findings from the study will also be presented at any relevant conferences (e.g. related to Older Adults or Acceptance and Commitment Therapy), should there be an opportunity to do so. This would usually be in the form of a poster.

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