UNIVERSITY OF LINCOLN

PROTOCOL

Acceptance and Commitment Therapy guided self-help for adults with a diagnosis of Autistic Spectrum Disorder experiencing psychological distress.

Guided ACT and for adults with ASD

Protocol Version ***03***
Date 16.04.2020

IRAS Project ID	245597
Registration ID	Insert ISRCTN and/or clinicaltrials.gov reference
Sponsor	University of Lincoln
Sponsor ID	190731
Funder	Trent Course Doctorate in Clinical Psychology.

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 publically 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: 16/04/20

Name: Dr David Dawson

STUDY/TRIAL CONTACTS

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Statistician	N/A
Trials Pharmacist	N/A

FUNDER DETAILS

FUNDER(S)	FINANCIAL AND NON FINANCIALSUPPORT GIVEN
Trent Course Doctorate in Clinical Psychology.	

STUDY SUMMARY

Study Title	Acceptance and Commitment Therapy guided self-help for adults with a diagnosis of Autistic Spectrum Disorder experiencing psychological distress.
Study Design	Single Case Experimental Design (SCED)
Study Participants	Aged 18+ adults who have received a diagnosis of Autistic Spectrum Disorder (ASD), and who are expiring moderate anxiety, depression or stress as measured by the Depression, Anxiety and Stress Scale (DASS).
Eligibility Criteria	1. 18+ years old with a formal diagnosis of Autistic Spectrum Disorder, without a diagnosis if an Intellectual Disability. 2. To be over the age of 18 years. 3. Experiencing elevated anxiety, and / or stress, and /or depression and meet the clinical threshold or moderate on the Depression, Anxiety and Stress Scale. 4. Access to the internet via an electronic device (to complete electronic measures). 5. Agreement and knowledge of the time commitment for the completion of the intervention, competition of measure and change questionnaire at the end of the study.
Planned Sample Size	6-8 participants
Study Duration	Participant duration: 5 months Total study duration: 7 months
Objectives	Primary: To examine whether an ACT bibliotherapy intervention for adults with a diagnosis of Asperger Syndrome who experience psychological distress increases psychological flexibility. Secondary: To examine whether psychological flexibility mediates changes in; personally-identified therapeutic goals, increasing psychological wellbeing and decreasing anxiety, stress and depression.
Outcome Measures	Primary: CompACT (Francis, Dawson & Golijani-Moghaddam, 2016). Secondary: Depression, anxiety and stress scale- DASS (Lovibond, & Lovibond, 1995). World Health Organization Quality of Life -WHOQOL-BREF (Skevington, Lotfy, & O'Connell, 2004). Simplified Personal Questionnaire –PQ (Elliott, Shapiro & Mack, 1999)

Data Analysis	SCED data will be predominantly analysed using visual analysis. Data will be plotted onto graphs to analyse the direction of the data (trend), the "magnitude" (level) (Gast, 2005) and the variability of the data (stability) (Lane & Gast, 2014). To find out if change from pre and post scores is reliable, a Reliable Change Index (RCI) will be conducted. To determine if any change is clinically significant, a Clinically Significant Criterion (CSC) will be conducted (Jacobson, Follette & Revenstorf, 1984).

KEY WORDS

Autistic Spectrum Disorder (ASD)

Acceptance and Commitment Therapy (ACT)

Psychological Distress

Stress

Anxiety

Depression

Psychological Flexibility

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LIST OF ABBREVIATIONS

AE	Adverse Event
ACT	Acceptance and Commitment Therapy
ASD	Autistic Spectrum Disorder
CF	Consent Form
CI	Chief Investigator
CRF	Case Report Form
GCP	Good Clinical Practice
HRA	Health Research Authority
ICF	Informed Consent Form
ISF	Investigator Site File (This forms part of the TMF)
ISRCTN	International Standard Randomised Controlled Trials Number
LIH	Lincoln Institute for Health
NHS R&D	National Health Service Research & Development
NCAS	Nottingham City Autism Service
PI	Principal Investigator
PIS	Participant Information Sheet
REC	Research Ethics Committee
SAE	Serious Adverse Event
SOP	Standard Operating Procedure
TMF	Trial Master File
UoL	University of Lincoln

STUDY MANAGEMENT

ROLE OF STUDY SPONSOR AND FUNDER

The sponsor of the study is the University of Lincoln.

The Chief Investigator has overall responsibility for the study and shall oversee all study management.

Megan Mellor will be the primary researcher and is funded to complete the research as part of her Doctorate in Clinical Psychology.

STUDY BACKGROUND and RATIONALE

Autistic Spectrum Disorder

Autistic Spectrum Disorder (ASD) is a neurodevelopmental condition, characterized by persistent deficits in social communication and interaction across multiple contexts; alongside restricted, repetitive patterns of behavior, interests, or activities (American Psychiatric Association [APA], 2013). ASD is also associated with executive functioning difficulties. These include difficulties with higher order cognitive functioning such as planning, strategy use, cognitive flexibility, working memory and inhibition (Happe, Booth, Charlton, & Hughes, 2006). Recent estimates indicate that around 2% of the population have a diagnosis of ASD (Kim Szatmari, Bryson, Streiner & Wilson, 2000) and the rate of diagnoses being made for this condition is increasing.

There are high levels of psychiatric co-morbidity between ASD and other conditions, including stress (Hirvikoski & Blomgvist, 2015), anxiety, depression (Bruggink *et al*., 2016) and OCD (Ghaziuddin, 2005). Experiencing high levels of anxiety is prevalent in adults with ASD; Davis, *et al*. (2011) found that self-reported experiences of anxiety increase from young adulthood to older adults; which has a profound impact on their lives (Robertson *et al.*, 2018). Hirvikoski and Blomqvist's (2015) study indicated that autistic traits are associated with self-perceived distress and a reduced ability to cope with external stressors. This is supported by Gillott and Stanton (2007) who identified coping with change, anticipation, sensory stimuli and unpleasant events all positively correlate with high levels of anxiety and stress. Adults with ASD experience more stressful life events and perceived stress, which is associated with social difficulties related to ASD (Bishop-Fitzpatrick, Minshew, Mazefsky & Eack, 2017).

Kelly, Garnett, Attwood and Peterson (2008), reported that depression is a secondary consequence of social difficulties experienced in children with ASD. A systematic review including 19 articles indicated there is a higher prevalence of depression in people with an ASD diagnosis without an intellectual disability (1%-47%) compared to general population prevalence rates (2.5%-10.7%), (Wigham, Barton, Parr &hg Rodgers, 2017). For adults with ASD 34% of families report unmet mental health needs (Nicolaidis *et al*., 2013). Interventions for mental health have been highlighted as important areas of research (van Steensel, Bogels & Dirksom, 2012).

ASD and Cognitive Behavioral Therapy

The National Institute for Care and Excellence (NICE) recommends the use of Cognitive Behavioral Therapy (CBT) in the treatment of anxiety disorders and depression (NICE, 2011); in combination with medication (specifically, selective serotonin reuptake inhibitors; SSRIs) for anxiety. However, evidence for the efficacy of SSRIs in the treatment of anxiety in adults with ASD is limited (Williams, Wheeler, Silove, & Hazell, 2011). The majority of evidence for adapted CBT in ASD populations derives from child and adolescence, little research has considered CBT over the lifespan for this population. A systematic review and meta-analysis

identifying CBT research undertaken in adult ASD populations indicates that; CBT has small-medium effect sizes for affective disorders using self-reported measures (g=0.48) (Weston, Hodgekins & Langdon, 2016). Therefore, the effectiveness of CBT specifically for adults with ASD remains unclear and further research studying the effectiveness of CBT and 'third wave' CBT psychotherapies in an adult ASD population is required.

What is Acceptance and Commitment Therapy?

Acceptance and Commitment Therapy (ACT) is a psychotherapeutic approach and is referred to as a "third wave" CBT. It is based upon Relational Frame Theory which is a theory of human language, and argues that language specifies the strength and type of relationship to stimuli and along which dimension, which is an example of higher cognition (RFT; Hayes, Barnes-Holmes, & Roche, 2001). RFT focus on how humans learn language through interactions with the environment which is underpinned by a functional contextualist epistemology (Hayes, Hayes, Reese & Sarbin, 1993) which seeks to predict and influence events using empirically based rules and concepts. ACT aims to teach strategies that enable people to live their life in accordance with their values (value consistent behavior). Through strategies of "acceptance" and "cognitive defusion" ACT aims to facilitate willingness in to experience thoughts and feelings as they are, without attempting to change, challenge, or avoid them (experiential avoidance). ACT aims to increase psychological flexibility which is defined as; "contacting the present moment as a conscious human being, and, based on what that situation affords, acting in accordance with one's chosen values" (Hayes, Strosahl, Bunting, Twohig & Wilson, 2004). ACT research has shown psychological flexibility to have a mediating effect reducing symptomology, both later in the therapy process or at longer term follow-up. ACT comprises of six core processes: (1) being in the present moment (focusing attention, without judgement, on present internal and external experiences); (2) values (identified qualities that are important to the individual); (3) committed action (changes in behavior in accordance with identified values); (4) self as context (the content of experience, is distinct from the 'self') and (5) defusion (a strategy to create emotional distance from language and cognitions); (6) acceptance (being fully open to your experiences without defense or judgment) (Hayes, Luoma, Bond, Masuda & Lillis, 2006). Through the combination and interaction of these core processes, there is an increase in psychological flexibility and decrease experience of psychopathology through decreasing cognitive fusion, experiential avoidance and maladaptive behaviors and increasing mindfulness, acceptance and committed behavior in line with values.

Acceptance and Commitment Therapy and ASD

There have been over one hundred randomized control trials (RCTs) supporting the efficacy of ACT for different types of distress and severity (A-Tjak *et al*., 2015; Swain, Hancock, Hainsworth & Bowman, 2013). A literature base for third wave behavioral therapies is developing. Leonie, Cortie and Cavagnola (2015) reviewed and considered future research, for third generation behavioral therapies for neurodevelopmental disorders (NDD). This review highlighted ACT and mindfulness-based CBT having the most potential to be adapted for intervention for people with NDD, due to the behavioral elements included in the treatments. These results are supported by Pahnke, Lundgren, Hursti & Hirvikoski (2014), who conducted an ACT based group, for students with ASD. Results indicated that levels of stress, hyperactivity and emotional distress were reduced in the treatment group, compared to classes as unusual; results were maintained or improved at a 2 month follow up. ACT aims to increase psychological flexibility which is underdeveloped in this population (D'Cruz *et al*., 2013; Geurts, Corbett and Solomon, 2009). It also gives a clear conceptual framework of the combined process of ACT, and how these together improve psychological flexibility. Therefore, this therapy compared to other third wave behavioural therapies appears to possess the most potential to improve psychological distress within this population. To date

few studies have been conducted investigating ACT interventions within an adult ASD population.

Why guided self-help?

In the UK there are significant waiting lists and access to psychological therapy is limited. As a consequence, to this people who would benefit from effective treatment continue to struggle with depression, anxiety and stress. Evidence for effective forms of alternative psychological interventions is required. Emerging evidence suggests that self-help and guided self-help ACT interventions produce significant small to medium effect sizes, in comparison to control conditions on measures of; acceptance/mindfulness, depression and anxiety (Cavanagh, Strauss, Forder & Jones, 2014). ACT self-help delivered by bibliotherapy (self-help workbooks), specifically targeting anxiety has shown promising effectiveness in an international sample (Ritzert *et al.*, 2016). There are also small effect sizes for the effectiveness of ACT bibliotherapy for depression, anxiety and psychological flexibility (French, Golijani-Moghaddan & Schroder, 2017). Bibliotherapies have been shown to be a cost effective, easily assessable option for people who experience psychological distress (Newman, Erickson, Przeworski & Dzus, 2003).

Rationale for the present study

Throughout this research the term Autistic Spectrum Disorder will be used. Although ASD is the correct diagnostic term, this also includes adults who have an intellectual disability. For this study all the adults with ASD who do not have an intellectual disability will be the sample population.

STUDY OBJECTIVES AND PURPOSE

PURPOSE

This research will indicate if guided ACT self-help facilitates increased psychological flexibility for adults with ASD, which is known to be less developed in people with ASD. Psychological flexibility mediates the experience of psychological distress (Hayes *et al*., 2006), for example depression, anxiety and stress; which are known to be highly prevalent in this population (Lecavalier, 2006). Currently there are mixed results in relation to effectiveness of CBT (Weston *et al*., 2016); no study has measured the effectiveness of ACT to increase psychological flexibility in an adult ASD population and determine if this mediates a reduction in psychological distress.

This research will add knowledge about how ACT guided self-help can be adapted for adults with ASD. It will give results on how effective ACT guided self-help is in supporting adults with ASD, to increase psychological flexibility and reduce psychological distress. If guided ACT self-help intervention is effective; this will help increase access and availability of psychological intervention for people with ASD, specifically in relation to associated difficulties in social communication and interaction.

PRIMARY OBJECTIVE

To examine whether an ACT bibliotherapy intervention for adults with a diagnosis of ASD who experience psychological distress increases psychological flexibility.

SECONDARY OBJECTIVE(S)

To examine whether psychological flexibility mediates changes in; personally-identified therapeutic goals, increasing psychological wellbeing and decreasing anxiety, stress and depression.

OUTCOME MEASURES/ENDPOINTS

PRIMARY OUTCOME MEASURE/ENDPOINT

To examine whether an ACT bibliotherapy intervention for adults with a diagnosis of ASD who experience psychological distress increases psychological flexibility.

Psychological distress will be measured by the depression, anxiety and stress scale (DASS) and psychological flexibility will be measured by the CompACT to measure psychological flexibility.

The full versions of the DASS will be administered as a screening questionnaire, weekly during the baseline phase, weekly during the intervention phase, two-week post intervention phase and one-month post intervention phase.

Full versions of the CompACT will be administered at the pre-intervention phase, two week and one-month post intervention phase.

The short form CompACT will be administered every three days during the baseline and intervention phase.

SECONDARY ENDPOINTS/OUTCOMES

To examine whether psychological flexibility mediates changes in; personally identified therapeutic goals, increasing psychological wellbeing and decreasing anxiety, stress and depression.

Wellbeing will be measured by the World Health Organisation Quality of Life Scale (WHOQOL-BREF) and the Personal Questionnaire (PQ).

The WHOQOL-BREF will be administered during the pre-intervention phase, , two-week post intervention and one month post intervention.

Personally, identified therapeutic goals will be identified by the personal questionnaire, which will be developed during the pre-intervention meeting; administered weekly during the baseline and intervention phase, two week and four weeks post intervention.

During the two-week follow-up the change questionnaire will be administered.

TABLE OF ENDPOINTS/OUTCOMES

Stage	Frequency	Measures
Screening		• DASS (21)
Pre-Intervention	Data collected within one week of consenting to take part.	• CompACT • WHOQOL-BREF • Personal Questionnaire
Baseline (two weeks with option to extend to three weeks if required)	Data collected every three days	• CompACT (short form)
	Data collected weekly	• DASS (21) • WHOQOL-BREF
Intervention (eight-ten weeks)	Data collected every three days	• CompACT (short form) •
	Data Collected weekly	• DASS • WHOQOL-BREF
Two week post intervention	Data collected which one week of sending.	• DASS • CompACT • WHOQOL-BREF • Personal Questionnaire • Change Questionaire
One month follow up	Data collected within one week of sending.	• DASS • CompACT • WHOQOL-BREF • Personal Questionnaire

STUDY DESIGN

This is a repeated measures design, using a single case experimental design. Each participant with be asked to complete weekly measures and shortened measure every three days, please see above table for the measures and timeframes. Weekly data collection will last for approximately 9 weeks, with a two- and four-week follow-up.

DATA ANALYSIS

SCED data will be predominantly analysed using visual analysis. Data will be plotted onto graphs to analyse the direction of the data (trend), the “magnitude” (level) (Gast, 2005) and the variability of the data (stability) (Lane & Gast, 2014). To find out if change from pre and post scores is reliable, a Reliable Change Index (RCI) will be conducted. To determine if any change is clinically significant, a Clinically Significant Criterion (CSC) will be conducted (Jacobson, Follette & Revenstorf, 1984). The data will be analysed at the University of Lincoln and Students home (via secured sites). The data will be analysed using Excel software. No interim analysis if planned for safety, efficacy, or management purposes.

STUDY SETTING

Participants will be recruited from Nottingham City Autism Service (NCAS). The initial appointment to collect consent to participate in the research will be competed remotely via Microsoft Teams or over the telephone All the data will be collected via Qualtrics online, the participants will complete the bibliotherapy at their home and weekly telephone calls will be made to the participants at a designated time convenient to them.

SELECTION OF PARTICIPANTS

ELIGIBILITY CRITERIA

Inclusion Criteria

1. 18+ years old with a formal diagnosis of Autistic Spectrum Disorder, without a diagnosis if an Intellectual Disability.
2. To be over the age of 18 years.
3. Accessing Nottingham City Autism Service
4. Experiencing elevated anxiety, and / or stress, and /or depression and meet the clinical threshold or moderate on the Depression, Anxiety and Stress Scale.
5. Access to the internet via an electronic device (to complete electronic measures).
6. Agreement and knowledge of the time commitment for the completion of the intervention, competition of measure and change questionnaire at the end of the study.

Exclusion Criteria

1. Unable to communicate fluently in English (justification: the cost of hiring an interpreter).
2. Unable to read English (justification: participant will be unable to read and engage in the bibliotherapy)
3. Adults who are currently accessing psychological therapy. If participants start psychological therapy during the study, they will be removed from the study (justification: unable to separate out effects of research intervention from psychological therapy intervention).
4. If they have a co-morbid diagnosis of intellectual disability (justification: may have different needs regarding therapy adaptations.
5. No access to mobile or internet (justification: unable to complete measures).

Sampling

Participants will be recruited from the Nottingham City Autism Service (NCAS) within Nottingham Healthcare NHS Foundation Trust. This is an appropriate service for recruitment as it is an ASD diagnostic service for adults, without an intellectual disability. The study will be advertised through clinical staff within the diagnostic team talking to appropriate clients. Clients experiencing stress, or anxiety, or depression will be initially identified through clinical interviews and observations as part of the diagnostic process. The client will be asked to complete the depression, anxiety and stress scale (DASS). If the clinical cut off for moderate, severe or very severe anxiety (10+), or depression (14+) or stress (19+) is met then the client will meet the inclusion criteria.

It will be explained verbally and in writing that entry into the study is entirely voluntary and that their treatment as usual (TAU) will not be affected by their decision. It will also be explained in writing (information sheet) and verbally that each participant can withdraw at any time. Participants have the right to withdraw their data up to two weeks after their final data is collected. Consent will be obtained on entry to the study to ensure all data collected is retained for seven years, to allow for replicability and final analysis.

Size of sample

To ensure robust internal validity there must be replicability in results at least three times (Kratochwill *et al.*, 2010). Therefore, a minimum of three participants are required; sampling will continue until six participants have consented to the research; this is in line with publishing standards (Smith, 2012). Taking attrition into account 6-8 participants will be recruited. Based upon the service evaluation statistics for 2016-2017, Nottingham City Autism Service (NCAS) received 85 referrals per year for support (clients who have an existing diagnosis) and 268 referrals per year for ASD diagnostic assessment; from this figure 75 people received a diagnosis of ASD. This gives an estimated sample pool of 160 people diagnosed with ASD, within NCAS per year. The service has experienced a year on year referral increase, indicating that the 2018/19 sample pool will be larger than 160 people.

Sampling technique

Opportunity sampling will be implemented, clients who meet the inclusion criteria and are accessing Nottingham City Autism Service will be asked to take part.

RECRUITMENT

There are three points with the service pathway at which clients could be identified by the patient's usual care team to take part in this research; 1) Initial appointment for clients with existing ASD diagnosis; 2) following diagnostic assessment and receipt of ASD diagnosis; 3) post diagnostic group 4) identified via support telephone calls provided by NCAS.

The patient's usual care team will identify patients who meet the inclusion criteria and verbally discuss with them about the study. If the patient is interested in the study, will be sent an information sheet via e-mail and be asked to complete an online consent to be contacted form. This form is not to consent to participant in the research but to consent to be contact by the researcher (Megan Mellor) for more information.

The researcher (Megan Mellor) will then contact the client via their chosen communication preference (e-mail or phone) within two weeks and send the Depress, Anxiety and Stress Scale (DASS) screening measure to be completed. If the client's scores meet inclusion criteria then they will be contacted and asked if they would like to take part in the study, a date will be arranged to speak with the researcher (Megan Mellor) over the phone or via Microsoft Teams, to find more about the study.. If the clients scores do not meet inclusion criteria, then they will be contacted and informed that they are unable to take part in the study and referred to NCAS for further support (if required). During the initial researcher contact if the client continues to be interested in participation, they will be invited to arrange a time and date to speak with the researcher (Megan Mellor) via the phone or Microsoft Teams.

During the initial telephone/ online meeting information will be given about the research and an opportunity for the client to ask questions. The intervention will not delay any other identified treatment and is an addition to what the service currently delivers.

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.

If the client consents to take part in the research, then they will sent a consent form to complete via Qualtrics). If the client consents during this meeting, the personal questionnaire can be developed between the participant and researcher. Following the meeting the participant will be sent the pre-intervention measures (CompACT WHOQOL-BREF, Personal Questionnaire electronically to complete.

Participant Payment

Participants will be given £20.00 Amazon electronic voucher to participate in the study. Participants who wish to withdraw from the study can do so after the first session without losing any monetary rewards.

CONSENT

All participants will be contacted initially by their usual care team. Capacity to consent will be accessed at this point. However, the clients accessing the service are over eighteen years, do not have an Intellectual Disability (Learning Disability) and are not accessing the service for support related to specific mental health problems; as this is an autism assessment service, not a mental health service.

All participants shall provide informed consent, via completion of the informed consent form via Qualtrics. The completion of the Informed Consent Form (ICF) will provide consent and the date the form is completed will be logged electronically.

The recruiting Investigator will explain the details of the study and provide a Participant Information Sheet (and any other study related literature), ensuring that the participant has enough time to consider participating or not. Opportunity will be given to the participant to ask any questions they may have has concerning study participation.

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.

Informed consent will be collected from each participant before they undergo any study interventions related to the study.

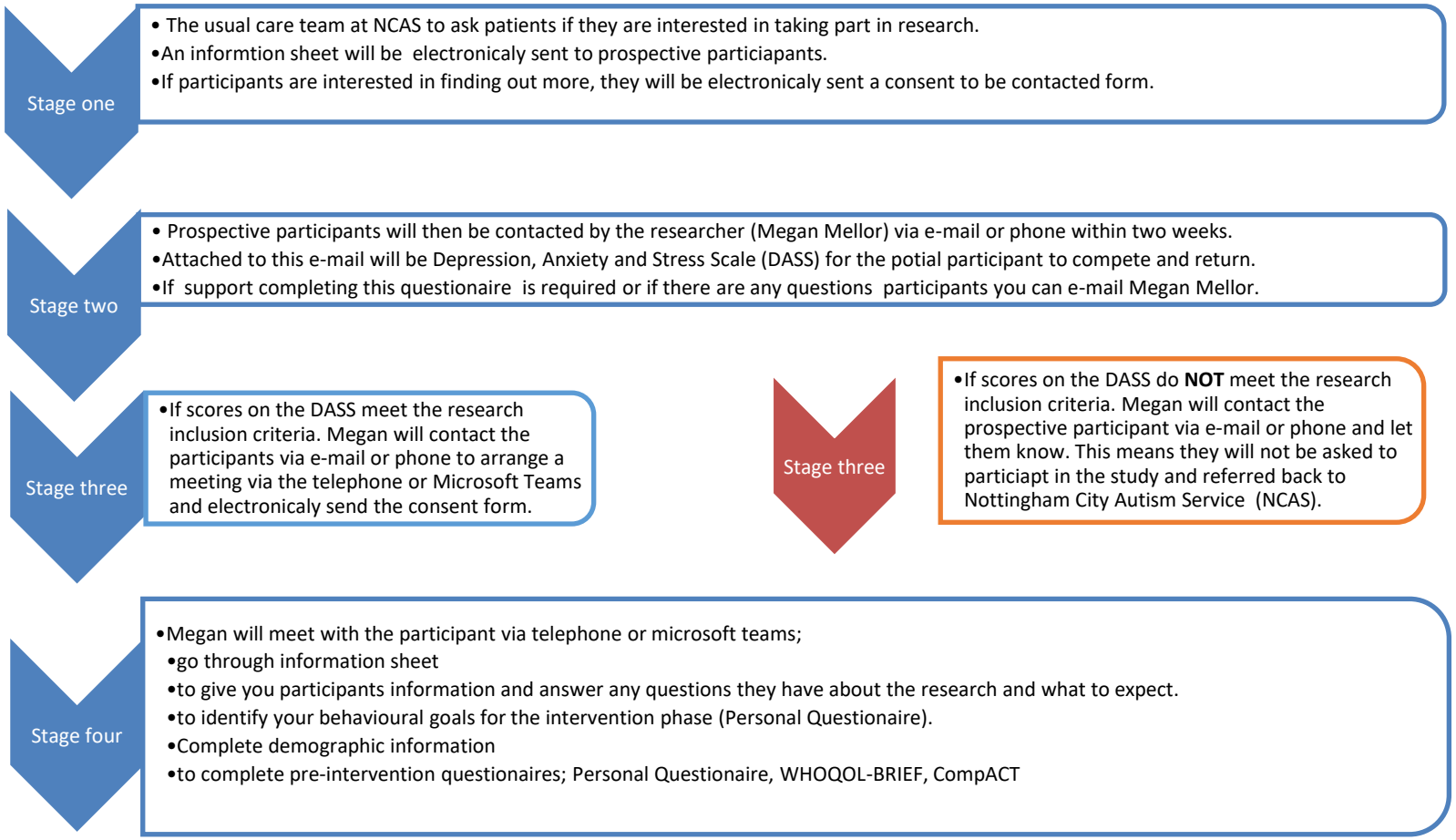
One copy of the ICF will be sent to the participant electronically, one will be kept by the Investigator, and a third will be sent electronical to NCAS and retained in the participant's medical records.

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 Consent form which will be signed by the participant.

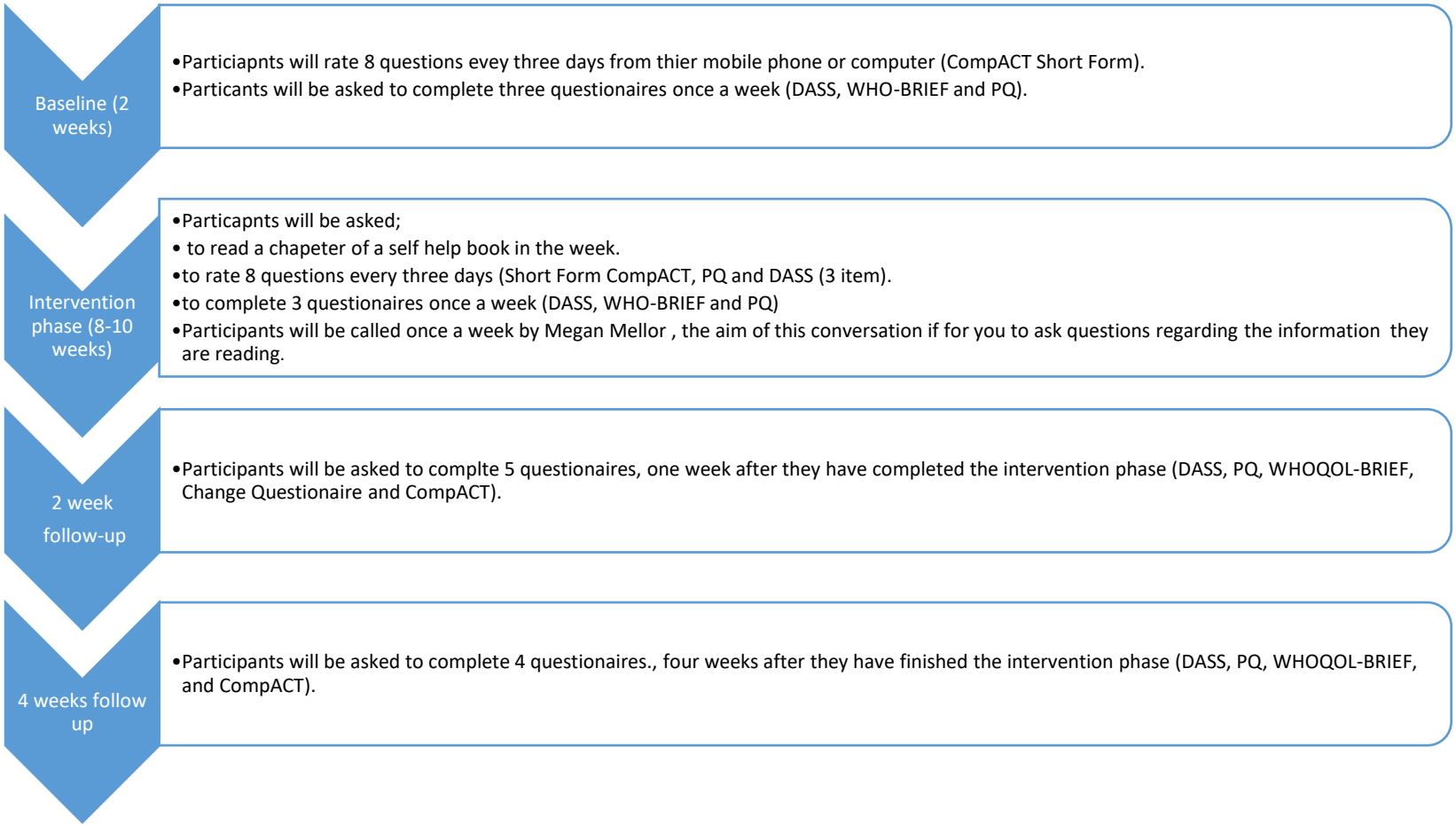
STUDY PROCEDURES/REGIMEN

STUDY FLOWCHART

Flow chart of the four stages before starting the intervention phase



Flow chart of the four stages from baseline phase, intervention phase, one week and two months post intervention



STUDY REGIMEN

Recruitment and screening: Participants will be identified by their usual care team and verbally informed about the research, sent an information sheet and asked if they consent to be contacted by the researcher for more information. They will be sent an electronic consent to be contacted by the researcher form. They will be contacted within two weeks either over phone or via e-mail (which ever they specified on the consent to be contacted form). A screening measure (DASS) will be sent via e-mail to be completed. If the participant meets the inclusion criteria, then they will be contacted and invited to arrange a telephone call or Microsoft Teams meeting with the researcher for an initial meeting at NCAS. During the meeting the prospective participant will go through the information sheet, send out the consent form, clients will have the opportunity to ask any questions about the study, identify behavioural goals for the personal questionnaire and complete the pre intervention questionnaires (Depression, Anxiety and Stress Scale (DASS); Personal Questionnaire, WHOQOL-BRIEF, CompACT.

All measures and forms administered via Qualtrics and all contact with the researcher will be over the phone or via Microsoft Teams.

Baseline phase: This will last two weeks, with an option to extend to three weeks if required (If three or more stable baseline points have not been met within two weeks) participants will complete rate eight questions every three days from their mobile phone or computer (Short Form ComptACT. Participants will be asked to complete two questionnaires once a week (DASS, WHO-BRIEF).

Intervention Phase: This phase will last from 8-10 weeks, dependent on if the participant requires an additional two weeks due to personal circumstances. They are required to read a section of a self-help book 'Get out of your mind and into your life' (Hayes 2005) in the week. Each chapter will be either e-mailed and/or posted to the participant on a weekly basis. The participant will receive a full copy of the book following the completion of the intervention phase. To rate 9 questions every three day (Short Form CompACT,); complete two questionnaires once a week (DASS and WHO-BRIEF). Participants will be called once a week by Megan Mellor, the aim of this conversation if for them to ask questions regarding the information they are reading and exercises they are completing. All telephone calls will follow a set structure and be recorded for fidelity checking.

Two-weeks follow-up: OTwo weeks following the completion of the intervention phase. Participants will be asked to complete five questionnaires (DASS, PQ, WHOQOL-BRIEF, Change Questionnaire and CompACT) via Qualtrics.

Four week follow-up: Participants will be asked to complete four questionnaires, four weeks after they have finished the intervention phase (DASS, PQ, WHOQOL-BRIEF, CompACT).

SCHEDULE OF PROCEDURES

Procedures	Visits (insert visit numbers as appropriate)					
	Screening	**Initial meeting at NCAS**	**Baseline (2 weeks)**	**Intervention (8-10 weeks)**	**2-week follow-up**	**4week follow-up**
Consent to be contact by the researcher	x					
Informed consent		x				
Demographics		x				
Pre-Intervention questionnaire		x				
Developing Personal Questionnaire		x				
Completion of baseline questionnaires			x			
Reading a chapter of the bibliotherapy each week				x		
Every other day completion of measures				x		
Completion of weekly measures				x		
Engaging in weekly telephone calls				x		
Completion of follow-up questionnaires and change questionaire					x	
Completion of follow-up questionnaires						x

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.

Participants may withdraw from the study or be withdrawn from the study at any time. It will also be explained that data cannot be withdrawn following two weeks of the last data

collection. Participants who wish to withdraw will be asked to consent for primary outcome data to be collected at the end of follow up. This will support with the planned analysis and replicability of the study. Participants will not be accepted as lost to follow up unless enough attempted contact has been made via phone calls and letters. This will include two attempted telephone calls across four days, with messages left asking them to call back, and one letter if they have not responded within a week.

Participants can be withdrawn from the study by the primary researcher if they stop adhering to the protocol, not completing the bibliotherapy, or are unable to complete the reading within the three-week extension period. The remainder of the bibliotherapy will be provided following withdrawal, if the participant desires.

Following the withdrawal of a participant, a new participant will be recruited, time permitting. There are not anticipated safety reasons for terminating participants from the study.

ETHICAL AND REGULATORY CONSIDERATIONS

ASSESSMENT AND MANAGEMENT OF RISK

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 researcher will discuss this with the CI and where appropriate reported accordingly. If any risk to self or others is reported during the research, alongside discussing this with the CI this will be reported to the client's clinical team at Nottingham City Autism Service and the Nottinghamshire Health Care NHS safeguarding procedures and risk management procedures will be adhered to.

To date no research has been found highlighting a detrimental or negative impact of ACT therapy. However, participants who identify values by which they are not living to may experience some distress. Any participants experiencing distress directly associated with the ACT chapters and exercises will be provided with support via weekly telephone calls from the researcher.

ADVERSE EVENTS

Due to the nature of this study, no adverse events are anticipated, and no adverse event data will be collected.

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

This study design and protocol has been reviewed by Research tutors on the Trent Doctorate in Clinical Psychology.

PUBLIC & PATIENT INVOLVEMENT

Design of the research: Service users (not taking part in the research) will have the opportunity to input into adaptations of the bibliotherapy.

Undertaking the research: Service users will be actively involved in participant of the research.

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.

Deviations from the 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 General Data Protection Regulation (GDPR) 2016/079 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 study records, other study related 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 five years 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

The Chief Investigator and the co-investigator Dr Anna Tickle and student Megan Mellor will have access to the final data set.

DISSEMINATION POLICY

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

The research will be disseminated via Megan Mellor's research thesis. All participants will be e-mailed an electronic of the research report and any published work resulting for the research data.

Authorship eligibility guidelines and any intended use of professional writers

The final study report will be written in accordance with the Trent Doctorate and Clinical Psychology guidelines. Any journal papers resulting from this study will be written in accordance with the selected journal. All researchers named on this protocol will be named authors of ant publications resulting from the data collected in this study.

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