Non-CTIMP Study Protocol

An Evaluation of an ACT and PBS Group for Parents and Education Staff of Children and Young People with an Intellectual Disability

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CONTENTS

LIST OF ABBREVIATIONS

ACCORD	Academic and Clinical Central Office for Research & Development - Joint office for The University of Edinburgh and Lothian Health Board
ACT	Acceptance and Commitment Therapy
AE	Adverse Event
ASD	Autism Spectrum Disorder
CI	Chief Investigator
CB	Challenging Behaviour
CBI	Copenhagen Burnout Inventory
CBSES	Challenging Behaviour Self Efficacy Scale
ComPACT	Comprehensive Assessment of Acceptance and Commitment Therapy Processes
CRF	Case Report Form
CYP-ID	Children and Young People with an Intellectual/Learning Disability
DASS-21	Depression Anxiety and Stress Scale (21 item version)
GCP	Good Clinical Practice
ICH	International Conference on Harmonisation
ID	Intellectual Disability
PI	Principal Investigator
PBS	Positive Behaviour Support
QA	Quality Assurance
RCT	Randomised Controlled Trial
REC	Research Ethics Committee
SAE	Serious Adverse Event
SAR	Serious Adverse Reaction
SOP	Standard Operating Procedure
SUSAR	Suspected Unexpected Serious Adverse Reaction
TAU	Treatment As Usual
WEM	Workshop Evaluation Measure

1 INTRODUCTION

1.1 BACKGROUND

The Scottish Mental Health Strategy 2017-2027 (Scottish Government, 2017) emphasises the need to improve the supports surrounding children, including focusing upon the quality of parent-child relationships, the school environment and provision of tier one and two mental health services. The strategy identifies that children and young people with intellectual disability (CYP-ID) and autism spectrum disorder (ASD) have the highest rates of mental health difficulties. Furthermore, up to 60% of CYP-ID present with challenging behaviour (CB; Adams & Allen, 2001)

Challenging Behaviour

CB is defined as "behaviour that puts the individual or others at risk and/or could lead to the limitation of an individual's access to their community" (British Psychological Society, 2018, p. 2). CBs, which can include aggression, self-injury and disruptive behaviours, have a significant impact on the child, their family and the services that support them (Fox et al., 2002). Positive behaviour support (PBS) is widely accepted to be the best practice model to support CB (British Psychological Society, 2018). PBS aims to improve quality of life of individuals with intellectual disability in a values-based and person-centred manner (see Carr et al., 2002 for a review).

Stress and Distress in Parents and Teachers

However, PBS can be very demanding for the systems around young people to implement, especially in a consistent manner. Parents of children with an ID have been shown to have significantly higher rates of parenting stress and mental health difficulties (Hassall et al., 2005; Olsson & Hwaang, 2001), it is key that they are also provided with appropriate support so that they can implement the intensive PBS plans and have close, high-quality relationships with their children.

Furthermore, teaching is amongst the occupations with the lowest levels of job satisfaction and highest stress levels (Johnson et al., 2005). Indeed, this appears to be an even greater issue within schools for CYP-ID, where a relationship between child behaviour difficulties and emotional exhaustion has been identified (Hastings & Brown, 2002). Considering that all education staff "have a responsibility to support the mental, emotional, social and physical wellbeing of pupils" (Scottish Government, 2017, p.13), they also require appropriate support and intervention to be able to do so, in the context of the high levels of stress they experience.

Acceptance and Mindfulness-based Interventions

Positively, there is a developing evidence base for the effectiveness of acceptance and mindfulness-based interventions for reducing the psychological stress and distress experienced by support staff, parents and teachers. Acceptance and Commitment Therapy (ACT), a third-wave of cognitive and behavioural therapies, was developed by Hayes, Strosahl and Wilson (1999). ACT supports individuals to live life based on their values, to willingly experience difficult emotions and to be able to step back and 'defuse' from difficult thoughts, with the aim to increase psychological flexibility (Blackledge & Hayes, 2006). Psychological flexibility is defined as "the capacity to persist or to change behaviour in a way that includes conscious and open contact with thoughts and feelings, appreciates what the situation affords, and serves one's goals and values" (McCracken & Morley, 2014, p.225). Mindfulness is a core process within ACT but is also practiced within mindfulness-based

cognitive therapy and mindfulness-based stress reduction, which both also have well-developed evidence bases (see Gu et al., 2015).

ACT has often been described as a particularly appropriate intervention for parents and staff working with CYP-ID, given that their appraisal of the difficulties they face may often be realistic and thus perhaps less amenable to traditional cognitive behavioural strategies (Blackledge & Hayes, 2006). Recent meta-analyses of ACT have identified a developing evidence base for many psychological presentations, where ACT is superior to treatment as usual (TAU) and equivalent to cognitive-behavioural therapy (see A-Tjak et al., 2015; Öst, 2014).

Support Staff

The evidence base for acceptance and mindfulness-based interventions for supporting systems around people with ID is most well-developed for support staff of adults with ID. A recent systematic review concluded that there is sufficient evidence for short term benefits for mindfulness-based interventions with paid support staff (Ó Donnchadha, 2018). However, the review identified that only three of the eight studies were of adequate quality, with others notably limited due to small sample sizes, and lack of appropriate follow-up and appropriate controls. Of note within the high-quality studies is an ACT group workshop intervention for support staff, with a randomised waitlist control design and six-week follow-up (McConachie et al., 2014). The results demonstrated a significant reduction in psychological distress in the ACT condition, with an increased effect for those with higher levels of distress at baseline. This study highlights the potential utility for this 'dosage' of ACT within this population.

Teachers

Within a teacher population, a relatively small RCT of an ACT workshop for early years education staff working with CYP-ID demonstrated improvements in teacher's self-reported self-efficacy, willingness to experience emotion and mindfulness, although was not reported to improve ratings of depression (Biglan et al., 2013). While the study did not provide an active control with which to compare the ACT intervention, it provides preliminary evidence for the effectiveness and acceptability of ACT workshops with teachers working in special education environments.

Parents

Considering the provision of ACT to parents with CYP-ID, Blackledge and Hayes (2006) conducted an uncontrolled small study of a two-day ACT group workshop for parents of children with autism. The results identified significant improvements in depression and psychological distress both after the group and at a three-month follow-up. However, the changes could not be reliably attributed to the intervention in the absence of appropriate controls. Furthermore, Reid and colleagues (2016) qualitatively evaluated an ACT group for parents of children and young people with severe ID and challenging behaviour. The group was delivered in a workshop format with two days of four-hour groups. Themes identified from interviews suggested that participants had felt that they were at a "crunch point" (Reid et al., 2016, p.9) before the intervention, that they had liked the focus on their own wellbeing and the group format. The authors acknowledged that they were unsure about the applicability of the group to parents of children with less severe ID, and highlighted that quantitative analysis was needed to measure changes in parents' distress. Interestingly, this ACT intervention was delivered in the context of a service where PBS was also being provided. While the ACT intervention was not evaluated in this context, this is suggestive of the close link between the two interventions and how they may each increase the others effectiveness.

The role for Positive Behavioural Support

Therefore, there is an argument for strengthening the ties between ACT and PBS when providing interventions to families. Dunlap and Fox (2007) have argued that a key feature of PBS plans is the development of a parent-professional partnership, where parents function as collaborators in the development and implementation of the plan. This shift from the 'expert model' is of such significance because it is largely parents and teachers that implement PBS plans, and thus it is important that they have a high level of perceived self-efficacy for managing challenging behaviour. Where parents and teachers have been involved in the PBS process and their development of self-efficacy for managing challenging behavior has been supported, the intervention is more likely to socially valid and implemented (Dunlap & Fox, 2007; Dunlap et al., 2001; Gore et al., 2013). However, research suggests that parents describe rarely experiencing partnership with professionals (Wodehouse & McGill, 2009). It is proposed that where professionals are the only ones to hold knowledge of PBS, this power imbalance is likely to remain (Proctor, 2008). Moreover, the recent NICE guidelines for the management of CB advises that families should be provided with "skills training and emotional support, or information about these, to help them take part in and support interventions for the person with a learning disability and behaviour that challenges" (2015, p.60).

Interestingly, some work has begun on including PBS instruction in third-wave interventions within this population. Singh and colleagues (2014) completed a multiple baseline design study with three mothers of children with ASD who were displaying high levels of challenging behaviours. The mothers all previously had PBS plans that they had stopped implementing due to the associated stress this had caused. On completion of an eight-week mindfulness-based PBS programme (MBPBS), the results identified statistically significant reductions in maternal stress and significant reductions in recorded incidents of challenging behaviour. This work was extended with a RCT with support staff of adults with ID, comparing MBPBS with TAU, applied behavioural analysis training (Singh et al., 2016). The findings identified that the MBPBS condition was significantly more effective than TAU in reducing staff stress, and reducing challenging behaviours, emergency medications and staff turnover.

Current Study

Considering the currently available research, it appears that there is a developing evidence base for ACT and mindfulness-based interventions for parents, teachers and support staff, and for mindfulness-based PBS for parents and support staff. However, it appears that there is yet to be a quantitatively evaluated parent ACT workshop or combined ACT and PBS-based intervention. ACT and PBS are theoretically paired well together, in the context of their values focus and emphasis on increasing quality of life in a meaningful way. Given that parents and teachers both appear in need of access to these psychological interventions to support them in their distress and in their implementation of PBS, in this study, parents and teachers of CYP-ID will participate in a mixed methods study evaluating the effectiveness and mechanisms of an ACT and PBS based group workshop. The workshop format should fit well within tier one and two mental health services and provide a sustainable way to systemically improving the wellbeing of children and young people with IDs and the caregivers around them.

Quantitative Research Questions

- Is an ACT and PBS based group workshop ("the intervention") effective in reducing the psychological distress experienced by parents and teachers who work with children with IDs?
- Is the intervention effective in increasing parents and education staff self-efficacy in managing children's challenging behaviour?
- Is the intervention effective in reducing education staff's self-reported experience of burnout?
- Is there a significant change in the parents and education staff Acceptance and Commitment Therapy processes?

Qualitative Research Question

- In which contexts and through which mechanisms does the group work to achieve these outcomes?

Study Hypotheses

- The intervention will be effective in significantly reducing the psychological distress self-reported by parents and teachers who work with children with IDs.
- The intervention will be effective in significantly increasing parents and education staff self-reported self-efficacy in managing children's challenging behaviour.
- The intervention will be effective in significantly reducing education staff's self-reported experience of burnout.

Study Risks and Benefits

The study will aim to ensure that all participants have capacity to give informed consent and that they are not pressured into participating. Confidentiality will be maintained where appropriate, with safeguarding measures in place to safely manage any disclosures that occur during the study. It is possible that by participating in the group, focus group or completing the study questionnaires, that participants may experience some distress. This will be safely managed by signposting participants and communicating with their GP as appropriate. However, participants also may benefit from the therapeutic group and consequently experience a reduction in psychological distress and a possible improvement in their child's wellbeing. Participants may also derive some satisfaction from their involvement in the research.

2 STUDY OBJECTIVES

2.1 OBJECTIVES

2.1.1 Primary Objective

- To evaluate whether an ACT and PBS based workshop ("the intervention") is effective in reducing the psychological distress experienced by parents and education staff who work with children with Intellectual Disability.

2.1.2 Secondary Objectives

- To evaluate whether the intervention is effective in increasing education staff and parents' self-efficacy in managing children's challenging behaviour.
- To evaluate whether the intervention is effective in reducing the self-reported burnout of education staff.
- To examine in which contexts and through which mechanisms the group works to achieve these outcomes.

2.2 ENDPOINTS

2.2.1 Primary Endpoint

The primary outcome measure is the short form version of the Depression Anxiety and Stress Questionnaire (DASS-21).

2.2.2 Secondary Endpoints

The secondary outcome measures are as follows:

- The Challenging Behaviour Self-Efficacy Scale (CBSES)

- Copenhagen Burnout Inventory (CBI) (Education staff only)
- Comprehensive Assessment of Acceptance and Commitment Therapy Processes (ComPACT)
- Workshop Evaluation Measure (WEM)

3 STUDY DESIGN

- The study has a mixed-methods design and draws upon a realist evaluation framework. The mixed methods approach allows the utilisation both quantitative and qualitative approaches to gain a greater level of detail than either one methodology would allow for individually, and for the results to support a firmer conclusion if the differing methodologies corroborate each other. The realist evaluation approach is a relatively new framework for research and aims to answer "what works for whom in what circumstances" (Pawson & Manzano-Santaella, 2012, p.177). Realist evaluation tends to critique randomised controlled trials and other evaluations as overly focused on aggregate outcomes which evaluate interventions in a binary way as successful or unsuccessful. Realist evaluation suggests that it might be more helpful to consider the context in which the intervention has been implemented and how this has interacted with mechanisms to produce the outcomes observed. This framework has been chosen to guide the mixed-methods approach in this study as it is particularly relevant given the complexity of delivering psychological interventions in this population, and the many factors that may influence their effectiveness.
- Participants may be involved in the study for a period of approximately six months, due to the expectation that they may need to wait for a group appropriate to them to begin. Participants will be actively involved in the group for nine weeks, with three weeks of group sessions, and a focus group six weeks after this.
- The study will take place in NHS Lothian buildings, schools or in community facilities.

4 STUDY POPULATION

4.1 NUMBER OF PARTICIPANTS

- We will aim to recruit approximately 40 participants to the study (10 participants allocated to four groups).
- Number of sites involved: 8 (LD-CAMHS and up to 7 schools for children with special educational needs).
- Length of recruitment period: Estimated at approximately six to eight months.

4.2 INCLUSION CRITERIA

- Parent or Guardian of a Child aged 5-18 with a diagnosis of an Intellectual Disability/Learning Disability and experience of challenging behaviour.
- OR an employee working in a school for children with additional support needs, directly working with children with diagnosed Intellectual/Learning Disabilities.
- Must speak English fluently.
- Must be able to provide informed consent.

4.3 EXCLUSION CRITERIA

- Temporary staff members (contract remaining of less than six months).
- Parents or Education Staff aged less than 18 years old.

- Parents or Education staff that have a diagnosis of an ID, such that they would not be able to understand the group materials or questionnaires and complete them independently.
- Individuals who are not able to provide informed consent.

4.4 CO-ENROLMENT

Participants' direct care team or school are likely to be aware of whether they are participating in other research. However, participants will additionally be routinely verbally asked about this during their discussion with study researchers, the direct care team or school. Where other studies are observational and questionnaire-based only in nature, this will be permitted. However, participants will not be permitted to take part in other intervention research during the duration of the study.

5 PARTICIPANT SELECTION AND ENROLMENT

5.1 IDENTIFYING PARTICIPANTS

LD-CAMHS clinicians (members of the direct care team) will directly identify potential participants from patients currently on their caseloads. This may involve the patient file being reviewed by the clinician to ensure that the parents would meet the study inclusion criteria, and/or a telephone call or face to face discussion with potential participants. Clinicians will record their communication with potential participants, regarding the study, within the clinical notes. This will allow other clinicians within their care team to know if parents have already been approached.

Schools will identify current staff members that may benefit from participating in the study. This may involve a review of staff files to identify whether they meet study inclusion criteria (e.g. that have employment contract of sufficient duration) but will not involve any review of their medical records. Schools may distribute study information sheets to staff members and ask them to discuss it with a named member of staff if interested in participating or may discuss with individual staff members who meet study criteria. Schools will also distribute information sheets to parents or guardians of children who attend the school, who meet the study criteria. This may involve review of files regarding the child/parent that the school may hold (but not their medical files).

Flyers advertising the study, its group locations and times will be placed in the LD-CAMHS building and in school buildings (should the relevant management authorities wish to do so) and may be distributed to participants also. The flyers will serve to heighten awareness of the research study and as a reminder of the next group dates available.

The direct care team and school staff will be informed of the study, and inclusion and exclusion criteria through meetings, emails and telephone calls as appropriate.

5.2 CONSENTING PARTICIPANTS

The process of taking informed consent will be LD-CAMHS clinicians or senior education staff members providing the potential participant with the participant information sheet and discussing this with them. The participant information sheets for the study provide clear, easy to understand information to support potential participants making an informed decision where they are aware of the possible risks and benefits to participating. Considering the suggested heritability of milder forms of ID, it will be important to ensure that participants, particularly parents, have the capacity to give informed consent. This will be based on the referring clinician/school staff's judgement, as the individuals who will know the potential participants best. Potential participants will then take a minimum of 24hours to decide whether to participate in the study or not, to try to reduce any pressure they may feel regarding their participation. Should participants decide to take part in the study, they will be asked to return their completed

contact details form to their clinician or senior education staff member who discussed the study with them. It will be made clear that by completing and returning the form, they are consenting to these details being passed to the study research team who will contact them to discuss the study. When the study research team receive the contact details form, they will telephone the participant to discuss any questions they may have and to discuss their availability to attend a group. Before the beginning of the first group session, participants will complete the study consent form with the study researchers on an individual basis. This will ensure that the study research team can make sure that participants are fully informed about their decision to participate in the study.

5.2.1 Withdrawal of Study Participants

Participants are free to withdraw from the study at any point or a participant can be withdrawn by the Investigator. If withdrawal occurs, the primary reason for withdrawal will be documented in the participant's case report form, if possible. The participant will have the option of withdrawal from

(i) all aspects of the trial but continued use of data collected up to that point
(ii) all aspects of the trial with removal of all previously collected data

Participants who do not attend one or more of the group sessions will be welcome to attend the remaining sessions if they so wish but will be excluded from any relevant analyses. Participants may take part in the focus group if they have attended at least one group session.

6 STUDY ASSESSMENTS

6.1 STUDY ASSESSMENTS

Participants will complete measures at three time points: before the first group session, after the last group session and before the focus group approximately six weeks after the last group session.

6.2 LONG TERM FOLLOW UP ASSESSMENTS

Participants will be invited to take part in an hour-long focus group approximately six weeks after the therapeutic group has ended. This focus group will be facilitated by a researcher, who may be LD-CAMHS clinician, to reduce the impact of a social desirability bias in participants' responses. Parents and education staff will attend separate focus groups. There will be no further follow-up after the focus group. Participants will be asked to complete the follow-up measures just before the focus group takes place. If participants do not attend the focus group, questionnaires will be posted to their home address with a return envelope provided, or they may return them to their LD-CAMHS clinician or participating school.

7 DATA COLLECTION

7.1 MEASURES

Demographic Data

A questionnaire will ask participants:

- their child's age, gender and diagnoses,
- their own age and gender,
- their attained education level and occupational status,

- whether the parent or education staff member has attended any relevant training or psychoeducation groups,
- whether the person is the primary caregiver for the child and if there is another significant caregiver available to the child (if a parent; e.g. second residential parent, non-residential parent, residential grandparent)
- number of years they have been in their role (if education staff).

Depression Anxiety and Stress Scale -21 item (DASS-21)

The DASS-21 is the short form measure of the Depression Anxiety and Stress Scale (Lovibond & Lovibond, 1995). The DASS-21 is widely used and has normative data available derived from a UK population sample (Henry & Crawford, 2005). The DASS-21 has three subscales of depression, anxiety and stress, with an underlying general factor of psychological distress (Henry & Crawford, 2005). The scale has been shown to have excellent internal reliability (α =0.93) and good convergent validity (Henry & Crawford, 2005). The DASS-21 has been chosen above the General Health Questionnaire-12 due to the criticism levelled at it regarding the possible impact of response bias on its psychometric integrity (Hankins, 2008) and as its suggested factors of anxiety/depression, social dysfunction and loss of confidence are not what is hoped to be captured by a measure of psychological distress in this study (Romppel et al., 2013).

Copenhagen Burnout Inventory (CBI; Borritz et al., 2006; for Education Staff only).

The CBI is a nineteen-item measure consisting of three subscales of personal, client-related and work-related burnout. Burnout has been conceptualised as emotional, mental and physical exhaustion related to chronically high levels of emotional demand at work (Schaufeli & Greenglass, 2001). Burnout is included within this study for education staff as it is thought that burnout may capture a different aspect of the impact of the demands of working in a school for children with special educational needs beyond a measurement of psychological distress, and as burnout may feel more acceptable for education staff to report than psychological distress. The measure was developed in response to criticism of the Maslach Burnout Inventory, and has been validated for use with a general Danish workforce sample and samples of teachers from New Zealand and Italy (Borritz et al., 2006; Fiorilli et al., 2015; Milfont et al., 2008). The measure has been shown to have good internal reliability and construct validity (Borritz et al., 2006; Mifont et al., 2008).

Challenging Behaviour Self-Efficacy Scale (CBSES)

Hastings and Brown (2002a) developed the CBSES as a five-item measure of self-efficacy related to managing challenging behaviours, with items such as “How confident are you in dealing with the challenging behaviours of the child/children you care for”. The measure is scored with a seven-point likert scale. In a sample of parents of children with autism and challenging behaviour, there was excellent internal reliability for mothers (α =0.94) and fathers (α =0.92). The measure has since been subject to a confirmatory factor analysis with Korean and US samples (Oh & Kozub, 2010), which identified a one factor model with adequate model fit and excellent internal reliability.

Comprehensive Assessment of Acceptance and Commitment Therapy Processes (ComPACT)

ComPACT is a recently developed 23 item ACT process measure (Francis et al., 2016). The measure was developed by consensus from experts, with an item pool derived from 11 other ACT process measures. It was developed due to the lack of a questionnaire that measured all aspects of ACT. For example, the Acceptance and Action Questionnaire (AAQ-II) has been argued to capture experiential avoidance and to neglect committed action (Francis et al., 2016). The ComPACT measure has demonstrated adequate internal consistency and good convergent and concurrent validity (Francis et al., 2016).

Workshop Evaluation Measure (WEM)

A brief measure will be devised on the basis of a previous social validity measure for an ACT based workshop (Bethay et al., 2013), with items such as “I have been consistently practicing the techniques and principles that I learned in the workshop” and “the workshop was interesting

and enjoyable", rated on a seven point Likert scale ranging from completely disagree to completely agree. Open-ended items such as "what was the most helpful part of the workshop?" and "what was the least helpful part of the workshop?" will additionally be included to allow participants to flexibly express their experience of the intervention. This measure will be completed at the end of the third workshop session. Finally, all of these measures are free to use, and it is estimated that it will take participants up to fifteen minutes to complete this questionnaire battery.

The following table details when participants will complete each questionnaire.

Participant Type	Group Session 1	Group Session 3	Focus Group/Postal
Parents	• Demographics • DASS-21 • CBSES • ComPACT	• DASS-21 • CBSES • ComPACT • WEM	• DASS-21 • CBSES • ComPACT
Education Staff	• Demographics • DASS-21 • CBI • CBSES • ComPACT	• DASS-21 • CBI • CBSES • ComPACT • WEM	• DASS-21 • CBI • CBSES • ComPACT

7.2 SOURCE DATA DOCUMENTATION

Source documents are those in which information is recorded and documented for the first time.

Source	Data
Paper consent form	Participant written informed consent
Paper participant contact information sheet	Participant contact details and GP contact details
Medical notes – paper and electronic (Trak)	Note from direct care team clinician recording date of provision of participant information sheet, and relevant information regarding participation in the study.
School files/notes – paper and/or electronic	Note from education staff recording date of provision of participant information sheet and relevant information regarding participation in the study.
Audio file on an NHS audio recorder	Audio recording of focus groups
Paper questionnaires	Questionnaire data
Electronic database	Electronic Anonymised Questionnaire Data

Electronic word files	Anonymised transcripts of focus groups

8 STATISTICS AND DATA ANALYSIS

8.1 SAMPLE SIZE CALCULATION

Power calculations were performed utilising G-Power 3.1 (Faul et al., 2007). The statistical analysis was set to be a with a within-between interaction, with two groups and three measurement points. The alpha level was set to 0.05 and power to 0.80, as per convention (Cunningham & McCrum-Gardner, 2007). The effect size previously reported for psychological distress in a similar study (McConachie et al., 2014) was medium to large. To be conservative, the power calculation for this study was performed with a medium effect size (f=0.25), which suggested a total sample size of 28 participants. Therefore, this study will aim to have four groups with ten participants each. This would mean recruiting 40 participants, with the expectation that 12 would be lost to attrition.

8.2 PROPOSED ANALYSES

Summary Measures Reported

The mean, standard deviation and range of the demographic variables and dependent variables will be reported. The percentage of missing data across the measures will also be reported.

Methods of Analysis

Regarding quantitative data, the statistical analysis will be completed using SPSS software. Data will be explored to ensure that test assumptions are met. Each dependent variable will then be analysed with repeated measures analyses of variance (ANOVA) with a within-between interaction, with significant effects further evaluated appropriately.

Regarding qualitative data, the focus group interview transcripts will be analysed with thematic analysis, as per Braun and Clarke (2006).

Management of Missing Data

Should the level of missing data be minimal (<5%), the data will be assumed to be missing at random and a suitable method of imputation (most likely multiple imputation due to the small sample size) will be used to manage this appropriately.

Should a higher level of missing data occur, the missing data will be analysed to examine whether it is missing at random or not. A suitable method of imputation will then be used.

9 ADVERSE EVENTS

Should multiple participants present with high levels of persistent distress that appear to be related to participating in the group, this will be reviewed by the Chief investigator and researchers.

10 OVERSIGHT ARRANGEMENTS

10.1 INSPECTION OF RECORDS

Investigators and institutions involved in the study will permit trial related monitoring and audits on behalf of the sponsor, REC review, and regulatory inspection(s). In the event of audit or monitoring, the Investigator agrees to allow the representatives of the sponsor direct access to

all study records and source documentation. In the event of regulatory inspection, the Investigator agrees to allow inspectors direct access to all study records and source documentation. Consent for this will be included in the Participant Consent Form.

10.2 RISK ASSESSMENT

A study specific risk assessment will be performed by representatives of the co-sponsors, ACCORD monitors and the QA group, in accordance with ACCORD governance and sponsorship SOPs. Input will be sought from the Chief Investigator or designee. The outcomes of the risk assessment will form the basis of the monitoring plans and audit plans. The risk assessment outcomes will also indicate which risk adaptions (delete if no adaptations were possible) could be incorporated into to trial design.

10.3 STUDY MONITORING AND AUDIT

The ACCORD Sponsor Representative will assess the study to determine if an independent risk assessment is required. If required, the independent risk assessment will be carried out by the ACCORD Quality Assurance Group to determine if an audit should be performed before/during/after the study and, if so, at what frequency.

Risk assessment, if required, will determine if audit by the ACCORD QA group is required. Should audit be required, details will be captured in an audit plan. Audit of Investigator sites, study management activities and study collaborative units, facilities and 3rd parties may be performed.

11 GOOD CLINICAL PRACTICE

11.1 ETHICAL CONDUCT

The study will be conducted in accordance with the principles of the International Conference on Harmonisation Tripartite Guideline for Good Clinical Practice (ICH GCP).

Before the study can commence, all required approvals will be obtained and any conditions of approvals will be met.

11.2 INVESTIGATOR RESPONSIBILITIES

The Investigator is responsible for the overall conduct of the study at the site and compliance with the protocol and any protocol amendments. In accordance with the principles of ICH GCP, the following areas listed in this section are also the responsibility of the Investigator. Responsibilities may be delegated to an appropriate member of study site staff.

11.2.1 Informed Consent

The Investigator will be responsible for ensuring informed consent is obtained before any protocol specific procedures are carried out. The decision of a participant to participate in clinical research is voluntary and will be based on a clear understanding of what is involved. Participants will receive adequate oral and written information – appropriate Participant Information and Informed Consent Forms will be provided. The oral explanation to the participant will be performed by LD-CAMHS clinicians or senior members of education staff, and will cover all the elements specified in the Participant Information Sheet and Consent Form.

The participant will be given every opportunity to clarify any points they do not understand and, if necessary, ask for more information. In particular, the participant will have the opportunity to ask questions after they have been provided with an oral explanation of the study and Participant Information Sheet, and the contact details of a study researcher will be included on the Participant Information Sheet, should they have any further questions. The participant will be given a minimum of 24 hours to consider the information before deciding whether or not they wish to provide consent to take part. It will be emphasised to the

participant that they may withdraw their consent to participate at any time without loss of benefits to which they otherwise would be entitled.

The participant will be informed and agree to their medical records being inspected by representatives of the sponsor(s).

The Investigator or delegated member of the trial team and the participant will sign and date the Informed Consent Form(s) to confirm that consent has been obtained. The participant will receive a copy of this document and a copy filed in the Investigator Site File (ISF) and participant's LD-CAMHS notes (if applicable).

11.2.2 Study Site Staff

The Investigator will be familiar with the protocol and the study requirements. It will be the Investigator's responsibility to ensure that all staff assisting with the study are adequately informed about the protocol and their trial related duties.

11.2.3 Investigator Documentation

The Principal Investigator will ensure that the required documentation is available in local Investigator Site files ISFs.

11.2.4 GCP Training

All researchers will be encouraged to undertake GCP training in order to understand the principles of GCP. GCP training status for all investigators will be indicated in their respective CVs.

11.2.5 Confidentiality

Participants' confidentiality will be maintained by ensuring that any identifiable information collected during the study is not accessible by any non-NHS staff, with the identifiable information kept within NHS Lothian. Participants will be informed in the participant information sheet that all information is confidential, but that their GP will be notified that they are participating in the study and that should the researchers become aware that there is a risk of harm to the participant or to someone else their GP and other relevant professionals will be notified (e.g. Police Scotland; Social Work Services). We will manage the identification of suicidal ideation or other significant mental health difficulties in participants by providing the participant with suitable contact numbers for support after the group session and notifying their GP by phone. In instances where child protection concerns are identified, the Clinical Supervisor and relevant NHS Child Protection Liaison will be consulted as soon as possible, and Social Work Services contacted by phone as per NHS Lothian child protection guidelines if appropriate. In the unlikely event of the researcher being made aware of a serious crime, Police Scotland will be contacted by phone should this be deemed to be in the public interest, as per confidentiality/data protection guidelines.

While given the group setting it may be difficult to ensure confidentiality is maintained by other participants, the importance of this will be emphasised at the beginning of each group and will be part of the "group rules".

Participants will complete paper measures, which will be transported from the data collection site to the NHS site in the locked boot of a car, which is insured for business use. All identifiable data will be held only within the NHS. Participants will be allocated a unique code to identify their data. Hard copies of participant consent forms and decode sheet (where the participant unique code identifiers will be recorded) will be kept in a separate locked cabinet from the hard copies of the participant questionnaires. Participants will be provided with questionnaire packs with a front sheet asking their name. Once the questionnaires are received back, the participants' unique code will be recorded on the questionnaires and the front sheet securely shredded. This is as we do not expect participants to know or remember their unique code when completing questionnaires. Therefore, the stored questionnaire data will be anonymous.

Identifiable electronic data (e.g. database of participants, audio recordings of the focus groups) will be held within a limited access folder on networked NHS servers, which are backed up regularly. Only the researcher and the clinical supervisor will have access to this folder. The anonymised database of questionnaire data and anonymised focus group transcripts will be held within the University of Edinburgh's One Drive, a secure, password protected, regularly backed-up server that the university recommends for storing active research data. The anonymised data will be saved onto the researcher's University of Edinburgh One Drive server via the researcher's nhs.net email address, which is accessible outside of the NHS computer network. This anonymized data will only be accessed by the researcher and Academic Supervisor and a vpn will be used when accessing this data for security purposes. On completion of the study, all identifiable data will be securely deleted or shredded within three months. The anonymised data will be kept within the university for a period of ten years in the University Data Store, a data server designed to store archived research data, with a further review every five years after this if appropriate, as per university research handbook guidelines. The researcher, academic supervisor and clinical supervisor will all be named custodians of this data.

11.2.6 Data Protection

All Investigators and study site staff involved with this study will comply with the requirements of the Data Protection Act 2018 with regard to the collection, storage, processing and disclosure of personal information and will uphold the Act's core principles. Access to collated participant data will be restricted to individuals from the research team treating the participants, representatives of the sponsor(s) and representatives of regulatory authorities.

Computers used to collate the data will have limited access measures via user names and passwords. The audio-recorders used to record the focus groups will be NHS encrypted and password protected.

Published results will not contain any personal data that could allow identification of individual participants.

12 STUDY CONDUCT RESPONSIBILITIES

12.1 PROTOCOL AMENDMENTS

Any changes in research activity, except those necessary to remove an apparent, immediate hazard to the participant in the case of an urgent safety measure, must be reviewed and approved by the Chief Investigator.

Amendments will be submitted to a sponsor representative for review and authorisation before being submitted in writing to the appropriate REC, and local R&D for approval prior to participants being enrolled into an amended protocol.

12.2 MANAGEMENT OF PROTOCOL NON-COMPLIANCE

Prospective protocol deviations, i.e. protocol waivers, will not be approved by the sponsors and therefore will not be implemented, except where necessary to eliminate an immediate hazard to study participants. If this necessitates a subsequent protocol amendment, this should be submitted to the REC, and local R&D for review and approval if appropriate.

Protocol deviations will be recorded in a protocol deviation log and logs will be submitted to the sponsors every 3 months. Each protocol violation will be reported to the sponsor within 3 days of becoming aware of the violation. All protocol deviation logs and violation forms should be emailed to QA@accord.scot

Deviations and violations are non-compliance events discovered after the event has occurred. Deviation logs will be maintained for each site in multi-centre studies. An alternative frequency of deviation log submission to the sponsors may be agreed in writing with the sponsors.

12.3 SERIOUS BREACH REQUIREMENTS

A serious breach is a breach which is likely to effect to a significant degree:

(a) the safety or physical or mental integrity of the participants of the trial; or

(b) the scientific value of the trial.

If a potential serious breach is identified by the Chief investigator, Principal Investigator or delegates, the co-sponsors (seriousbreach@accord.scot) must be notified within 24 hours. It is the responsibility of the co-sponsors to assess the impact of the breach on the scientific value of the trial, to determine whether the incident constitutes a serious breach and report to research ethics committees as necessary.

12.4 STUDY RECORD RETENTION

All study documentation will be kept for 10 years from the protocol defined end of study point. When the minimum retention period has elapsed, study documentation will not be destroyed without permission from the sponsor.

12.5 END OF STUDY

The end of study is defined as the last participant's last visit.

The Investigators or the co-sponsor(s) have the right at any time to terminate the study for clinical or administrative reasons.

The end of the study will be reported to the REC, and R+D Office(s) and co-sponsors within 90 days, or 15 days if the study is terminated prematurely. The Investigators will inform participants of the premature study closure and ensure that the appropriate follow up is arranged for all participants involved. End of study notification will be reported to the co-sponsors via email to resgov@accord.scot.

A summary report of the study will be provided to the REC within 1 year of the end of the study.

12.6 CONTINUATION OF TREATMENT FOLLOWING THE END OF STUDY

There is no planned continued provision of the intervention after the study has concluded. The intervention will not be further provided to participants as participants will be considered to have completed the intervention, and as they will continue to receive their treatment as usual from their care providers, if applicable.

12.7 INSURANCE AND INDEMNITY

The co-sponsors are responsible for ensuring proper provision has been made for insurance or indemnity to cover their liability and the liability of the Chief Investigator and staff.

The following arrangements are in place to fulfil the co-sponsors' responsibilities:

- The Protocol has been designed by the Chief Investigator and researchers employed by the University and collaborators. The University has insurance in place (which includes no-fault compensation) for negligent harm caused by poor protocol design by the Chief Investigator and researchers employed by the University.
- Sites participating in the study will be liable for clinical negligence and other negligent harm to individuals taking part in the study and covered by the duty of care owed to them by the sites concerned. The co-sponsors require individual sites participating in the study to arrange for their own insurance or indemnity in respect of these liabilities.

- Sites which are part of the United Kingdom's National Health Service will have the benefit of NHS Indemnity.

13 REPORTING, PUBLICATIONS AND NOTIFICATION OF RESULTS

13.1 AUTHORSHIP POLICY

Ownership of the data arising from this study resides with the study team.

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