Alleviating **S**pecific **P**hobias **E**xperienced by **C**hildren **T**rial **(ASPECT)**

Qualitative Research Protocol v2

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Table 1

ASPECT Qualitative Research Group Members

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ASPECT Qualitative Project Summary

Cognitive Behavioural Therapy (CBT) is the dominant model of treatment provision for child phobias in the UK. However, the provision of CBT is time consuming, expensive and limited in its availability. Existing therapist resources currently struggle to treat the large numbers of young people needing help with anxiety and phobia problems. Consequently,

there is an urgent need for alternative, evidence-based, low intensity psychological therapies that are able to bridge the gap between those needing treatment and the limited availability of resources. One potential candidate treatment is One Session Treatment (OST), currently being evaluated for clinical and cost-effectiveness in the ASPECT trial. In addition to evaluating these quantitative outcomes, it is important to examine its feasibility and acceptability, from multiple stakeholder perspectives. Greater understanding of OST from the perspective of those receiving the treatment, their parents/guardians, and those delivering OST (i.e., therapists) will aid the interpretation of quantitative trial results, facilitate intervention refinement, and, should OST show non-inferiority to CBT, optimise its implementation and embedding in practice.

Aims and Objectives

The ASPECT process evaluation aims to establish the acceptability of OST to the children taking part in the trial as participants, their parents/guardians, and to the clinicians administering OST.

Qualitative Project Management and Oversight

The ASPECT Qualitative Research Group

A team of researchers lead by Dr Penny Bee (see Table 1) will conduct the qualitative component of the ASPECT trial. Research Assistants will interview a sub-sample of i) trial participants allocated to the intervention arm (children and young people receiving OST), ii) parents/guardians, and the clinicians delivering OST. Research Assistants and a trained PPI representative will conduct the qualitative data analysis, under the supervision of Dr Penny Bee.

Qualitative Research Training

Not all members of the ASPECT Qualitative Research Group have experience using qualitative methodologies with children and young people. Dr Penny Bee will provide training

on the methodologies used in the ASPECT qualitative interviews. The date and format of this training is yet to be finalized.

Communication and Supervision

Dr Penny Bee will supervise the qualitative component and will chair regular meetings of the ASPECT Qualitative Research Group. These meetings will comprise members of the qualitative team outlined in Table 1. Initially, these meetings will be scheduled fortnightly while the process evaluation is in the early stages. However, monthly meetings will be scheduled thereafter and will alternate between teleconference and face-to-face meetings. The content of the Qualitative Research Group meetings will include (but is not restricted to) the following components;

1. Development of a shared coding manual and discussion of emergent themes
2. Revisions to the topic guide to facilitate exploration of emergent themes
3. Discussion of any practical problems
4. Discussion of any distressing issues emerging from the interviews
5. Supervision from Dr Penny Bee regarding qualitative interviewing and coding techniques

Involvement of Other ASPECT Groups

The ASPECT Qualitative Research Group will *not* report findings to ASPECT groups whose members consist of people who are; 1) blind to allocation; 2) delivering a treatment as part of ASPECT; or 3) involved in the analysis of quantitative data. For example, findings relating to the provision/efficacy of OST should not be discussed with the Trial Management Group (TMG) until the end of the trial. However, discussions regarding practical aspects of the qualitative work, including adverse events or safeguarding issues, can be discussed in the first instance with the Trial Manager(s) (Alex Scott and Lucy Tindall).

Study Procedures

Qualitative interview procedure

Each section below details the qualitative interview procedures, namely the identification, approach, and interview of ASPECT participants. Alll documents required can be found in the ASPECT RA Google Drive folder.

Participant identification

Eligible participants are automatically highlighted in Prospect. The Trial Support Officer (TSO) assigned to ASPECT will run a monthly report of eligible participants, and upload this list to a Google Drive qualitative interview tracker, before informing interviewers that they have been assigned a participant to contact. The online tracker will detail the participant's ID number, their geographical location, the interviewer assigned to a given participant, and a number of options designed to allow 'tracking' of each participants through to the eventual outcome (e.g., interviewed, unable to contact, withdrawn etc.). Interviews are expected to keep up-to-date and accurate records of their contacts with qualitative participants using the online tracker.

Participant approach

After receiving a list of eligible participants via the ASPECT TSO, interviewers should contact the parent/guardian of each participant via telephone, and in line with section 3.7, to arrange the interview(s). Interviewers must keep a record of each contact attempt, and the eventual outcome using the Google Drive qualitative interview tracker.

Pre-interview preparation

When the time, date, and location of an interview with the parent/guardian, and/or the young person has been agreed, the interviewer should then prepare for the interview(s). Please ensure each section below is complete before your interview takes place.

Access to an ASPECT encrypted Dictaphone

Interviews with participants must be recorded using an encrypted Dictaphone supplied by the ASPECT team. Please ensure you have access to such a Dictaphone, and that the device has enough storage for your interview. If you do not have access to a Dictaphone, please contact Alex Scott (alex.scott@sheffield.ac.uk), or Lucy Tindall (l.tindall@nhs.net).

The ‘Buddy System’ – letting the team know about your interview

The ‘Buddy System’ is a method of ensuring your safety when interviewing participants in an unfamiliar location (e.g., the participants home). The Buddy System requires you to inform a member of the ASPECT qualitative team (see Table 1) of the date, time, and location of your interview, along with the expected time you will finish your interview, and to input these details onto the online qualitative interview tracker. You must inform your buddy that you have completed your interview and are safe ASAP. Where an interviewer does not contact their buddy at the expected time, the buddy will call the interviewers mobile and check if they are safe.

During the interview

Explaining the qualitative study using information sheets

Firstly, go through the participant information sheets with both the parent/guardian, and the children and young people. This is a good opportunity to explain the study to the participants, and for you to ‘break the ice’ before you begin the formal interview. Take the time to introduce yourself and make the participants feel at ease. If the participants are comfortable with your presence, the interview will likely go better.

Taking consent

Secondly, the interviewer should take informed written consent from; (1) the parent/guardian to be interviewed; (2) the parent/guardian to consent to their child being interviewed; and (3) consent/assent from the young person to be interviewed. Please refer to section 3.5 for the consent procedure.

Recording the interview

Now you are ready to begin the interview. Start the encrypted Dictaphone recording in advance of your interview, and ensure the device is recording. At the end of the interview, ensure you have stopped the device from recording, and that the audio is saved to the device.

After the interview

Leave the interview venue and call your nominated buddy as soon as possible to let them know you are safe.

Data storage and transcription

The audio file of your interview must be uploaded from the encrypted Dictaphone to The University of Sheffield secure drive as soon as possible. As the Dictaphones are encrypted, you will need to use the Dictaphone software supplied with the device to un-encrypt the file. It is recommended that interviewers trial this procedure in advance of the interview, by uploaded a test audio file to the secure drive. The process for uploading files to the secure drive is as follows;

1. First, upload the audio file to a secure computer with an internet connection, and label the file with; (1) the participant's ID number; (2) the role of the interviewee (e.g., parent/guardian, or young person); and (3) the date of the interview.
2. Use your assigned University of Sheffield username and password to log into MUSE, which can be accessed via the University of Sheffield homepage, using the 'log into MUSE' button in the top left of the screen.
3. Click 'My services' □ 'View all services' □ 'UniDrive' □ 'Shared Files' □ 'Uosfstore' □ 'ScHARR' □ 'PR_ASPECT' □ 'General'.
4. To navigate to the folder where audio interview files are stored, click on '10 Qualitative Study Processes' □ '10.5 Qualitative interview audio files'.
5. Then simply upload your audio file to the relevant site folder (e.g., if your interview was with a participant from Humber, upload the audio to folder '01 – Humber NHS Foundation Trust').
6. Update the online qualitative tracker to record that the interview process is complete.

Participant Recruitment and Sampling

The qualitative phase of the ASPECT project will interview three groups of participants; 1) children and young people receiving OST; 2) their parent/guardian; and 3)

clinicians delivering OST. We will use maximum variation sampling to ensure a spread of participants differing in, age, gender, socio-economic background and type of phobia. The final sample size will be determined by data saturation (i.e. the point where no new themes, ideas and/or concepts emerge from the interviews). Based on previous nested qualitative research that has patient acceptability with brief psychological interventions (Lovell et al., 2017), we estimate that we will need to complete a maximum of 25-30 parent, and 25-30 child interviews, along with 15 interviews with clinicians delivering OST.

Eligibility

All children and young people who have received OST, and their parents/guardians who have consented to take part in the qualitative component at baseline will be eligible for inclusion. All clinicians who have delivered OST throughout the trial will be eligible for interview, if they provide consent to do so.

Interview timings and setting

Interviews with children and their parents/guardians will be conducted after participants have completed the final outcome measures at the 6-month follow-up point. Interviews with clinicians delivering OST will take place as soon as their involvement in the trial is complete. Parent interviews and interviews with older children (13 years plus) will be conducted face-to-face, or via the telephone depending upon participant preference. Interviews with younger children (12 years and under) will be conducted face to face. Face to face interviews will be conducted in treatment settings or at participants' homes, depending upon participant preference. With parental consent, we will recruit and interview parents and children separately. Clinician interviews will take place face to face in clinic settings or over the telephone.

Informed Consent

The children and young people taking part in ASPECT and their parent/guardian provided informed consent at baseline to be approached for interview as part of the qualitative phase. Children and young people who received OST, alongside their parent/guardian, will be asked if they would like to take part in the qualitative phase after

their final 6-month follow-up visit. The parent and/or guardian, as well as the children and young people will be give participant information sheets detailing aspects of the qualitative research which they can use to decide if they would like to take part. Informed consent will be taken in person and in writing using age specific consent forms. Parents/guardians will be asked to provide separate consent for themselves to be interviewed, and for their child to be interview. Children and young people will be asked to provide assent to take part and will require parental consent. For interviews involving healthcare professionals and clinicians delivering OST/CBT as part of ASPECT, a consent form (paper and electronic versions) has been ethically approved and will be used to record consent to be interviewed from clinicians.

Interview content and structure

All interviews will be semi-structured, and based on topic guides developed by the research team . Interviews with the parents/guardians of the participants receiving OST will focus on phobia experiences, personal and family impact, perceived treatment need, treatment expectations and treatment engagement and acceptability (e.g. content, delivery mode, format, setting and facilitation). Interviews with the children and young people receiving OST will focus on the same topics, adapted for age and developmental maturity. Face to face interviews with children will draw on the principles of 'draw and write' techniques, whereby children will be offered an opportunity to draw a picture relating to their experiences as a prompt to initiate more in-depth discussion (Angell, Alexander, & Hunt, 2015; McWhirter, 2014). Child interviews will last a maximum of 30 minutes and parent interviews a maximum of 60 minutes as determined by the interviewees. Clinician interviews will also last for a maximum of 60 minutes and focus on their experiences and views of delivering OST, barriers and enablers to its implementation and roll-out, the individual, team and organisational-level supports required and the perceived suitability of OST for the identified client group.

Contact attempts

It is important to consider the number of contact attempts that can be made by the researcher team when trying to either; 1) recruit participants to the qualitative phase; or 2)

follow-up participants to arrange interviews etc. Researchers from the ASPECT team will be limited to three telephone contact attempts. If contact cannot be made, and participants do not respond to messages after three attempts, then the participants will be considered lost-to follow-up and no further attempts will be made.

Data Analysis

All interviews will be digitally recorded using an encrypted digital recorder and transcribed verbatim with participant consent. Analysis will follow a qualitative framework approach (Ritchie, Spencer, Bryman, & Burgess, 1994), a widely used method of analysing primary qualitative data pertaining to health care practices with policy relevance (Dixon-Woods, 2011). Framework analysis permits both deductive and inductive coding, enabling potentially important themes or concepts which have been identified *a priori* to be combined with additional themes emerging de novo. A priori themes will be determined by the literature and through discussion with the ASPECT team. Data coding will be undertaken independently by two trained researchers. We will additionally train a PPI coder (Trilby Breckman) to work alongside these researchers, undertaking independent coding to ensure coding takes account of potential differences in researcher perspectives.

Coders will meet regularly (fortnightly) to develop a shared coding manual and to ensure that all emerging codes remain grounded in the original data. An Excel spreadsheet will be developed which will incorporate preliminary framework themes as column headings and the demographic information related to participants who provided data under each theme. As the constant comparison of new data occurs and the coding team's understandings of the themes under consideration develop, the framework will be amended and re-shaped to enable the introduction of new codes and/or the deletion of redundant, similar or otherwise compromised codes. In this way, a final framework will be achieved that is considered representative of the entire dataset. We will code data from each stakeholder group (children, parents/guardians and clinicians) separately. The final coding manuals, with example entries, will be presented to the TMG and project steering committees to confirm its

validity, coherence and conceptual relevance. Co-applicant Penny Bee from the University of Manchester will supervise the qualitative study and analysis.

Ethical and Practical Considerations

Adverse events

An Adverse Events form will be used to record any untoward occurrence affecting the participant after each therapy session by the therapist and at follow-up by the research assistant. Such an event can be directly related, possibly related or unrelated to the intervention. An occurrence will be recorded if it is suspected to be related to the intervention or an aspect of the research procedures; the therapist can assess relatedness and research assistants may need to seek advice from the Principal Investigator. The occurrence of adverse events during the trial will be monitored by the DMEC and the TSC. All AEs will be assessed for seriousness, and will be recorded as a Serious Adverse Event (SAE) if it;

- Results in death
- Is life-threatening
- Requires hospitalisation or prolongation of existing inpatients hospitalisation
- Results in persistent or significant disability or incapacity

Blinding

All interviews with participants will take place *after* they have completed the 6-month follow-up. Therefore, there is no risk of research assistants being unblinded, as all data has been collected and the participant has completed the study. However, as research assistants are interviewing only those in the OST arm of the trial, there is a chance that (by process of elimination and triangulation with other information) they might suspect the allocation of those still waiting to complete primary outcome assessments in the CBT arm. We will monitor all cases of suspected unblinding and report these at regular intervals to the TMG and trial oversight committees.

Lone Working

Qualitative interviews may be conducted in the participant's own home. To ensure the safety of research staff, all researchers conducting interviews will adhere to a policy on lone working held by the trial sponsor (Leeds and York Partnership NHS Foundation Trust). Furthermore, any researcher conducting qualitative interviews in the participant's home will adhere to a 'buddy system'. This system ensures another member of the team is aware of their whereabouts and inform the relevant people/authorities should contact with the qualitative researcher be lost.

Dealing with distress

Researcher distress

Researchers carrying out interviews could become upset from listening to potentially distressing experiences. However, regular contact between team members will ensure the opportunity to seek support where necessary. A team approach to risk management will be adopted and any concerns will be communicated to the qualitative lead (Dr Penny Bee) in the first instance.

Participant distress

If a participant appears to become distressed, the researcher will follow a number of steps, including:

1. Encourage the participant to take a break from completing forms and answering questions.
2. Acknowledge that talking about problems can be distressing.
3. Offer support by reassuring the participant that they do not need to answer any question(s) that they do not wish to
4. Ask if they would like to continue with the interview or prefer to stop.

If the participants would prefer that the interview be stopped:

1. Finish the interview and offer to return at another time.
2. If the participant withdraws their consent to participate in the entire study then this should be communicated to the study team.

If the interview continues:

1. Take time at the end of the interview to talk informally, and encourage participants to access further support dependant on their level of distress. This may be to visit their GP or mental health service provider or to access support available from the NSPCC/Childline or other appropriate support services.
2. If the participant has any questions or requires reassurance about the research they should be encouraged to contact the research team, University Research Practice and Governance Coordinator, NSPCC or NHS service (contact details will be provided).
3. If the participant still appears to be distressed when the interview is over offer to phone back in a couple of days to ensure the distress has not escalated and to reiterate the sources of support.
4. If the participant becomes more distressed discontinue interview and identify appropriate support.

References

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