A non-inferiority randomised controlled trial comparing the clinical and cost-effectiveness of one session treatment (OST) with multi-session cognitive behavioural therapy (CBT) in children with specific phobias

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

This protocol has regard for the Health Research Authority (HRA) guidance

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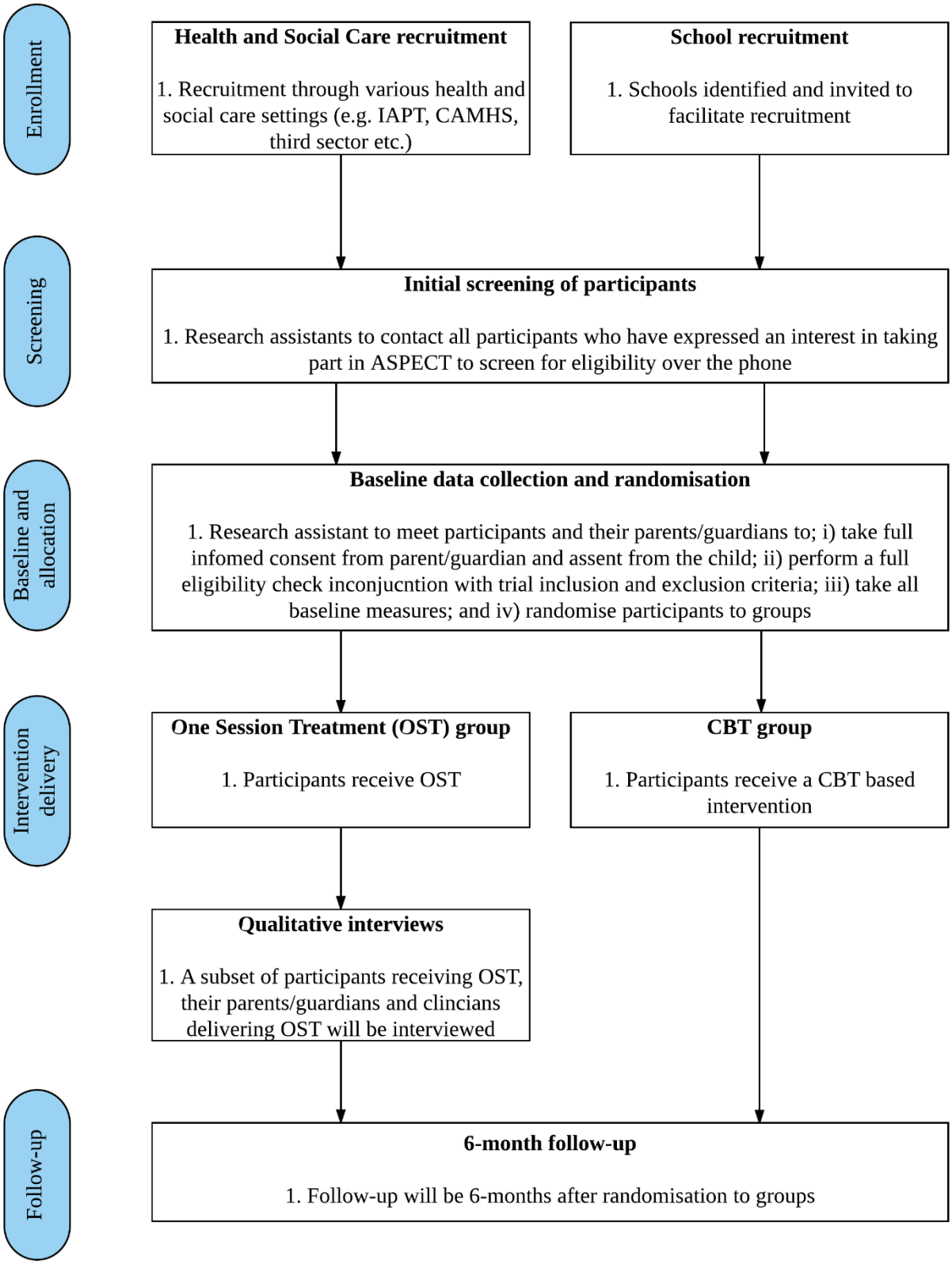
Trial Summary

Trial title	A non-inferiority randomised controlled trial comparing the clinical and cost-effectiveness of one session treatment (OST) with multi-session cognitive behavioural therapy (CBT) in children with specific phobias	
Short title	Alleviating Specific Phobias Experienced by Children Trial (ASPECT)	
Trial design	Non-Inferiority, Parallel Group, Randomised Controlled Trial with internal pilot and nested qualitative component	
Trial participants	Children (aged 7 to 16) with at least one DSM rated specific phobia	
Planned sample size	286	
Follow-up duration	6 months post randomisation	
Planned trial period	4 years	
	Objectives	**Outcome Measures**
Primary	1. To examine the non-inferiority of OST compared to multi-session CBT for treating specific phobias in children.	• Behavioural Approach Test (BAT)
Secondary	1. To investigate the cost-effectiveness of OST compared to CBT.To establish the acceptability (to patients and therapists) of OST.	• The Anxiety Disorder Interview Schedule (ADIS)

	2. To establish the relative impact of the treatments on the child's quality of life, school and social activities, and family functioning. 3. To investigate the acceptability of OST to participants, their parents/guardians and clinicians.	• Child Anxiety Impact Scale (CAIS) • The Revised Children's Anxiety and Depression Scale (RCADS) • A goal based outcome measure • The EQ-5D-Y • The Child Health Utility 9D (CHU9D) • Resource Utilization Questionnaire • Qualitative interviews
Interventions	One Session Treatment (OST) vs. Cognitive Behaviour Therapy (CBT) based interventions	
Method of delivery	A range of health and social care settings across NHS sites including; Children and Young People's Improving Access to Psychological Therapies (CYP-IAPT); Child and Adolescent Mental Health Services (CAMHS); supplementary and third sector organisations; and school based therapists.	

Trial Flow Chart



Abbreviations

ADIS	The Anxiety Disorder and Interview Schedule
AE	Adverse Event
ANCOVA	Analysis of Covariance
BAT	Behavioral Approach Test
CAIS-P	The Child Anxiety Impact Scale
CAMHS	Child and Adolescent Mental Health Services
CA-SUS	Child and Adolescent Service Use Schedule
CBT	Cognitive Behavioural Therapy
CEAC	Cost-Effectiveness Acceptability Curve
CHU9D	Child Health Utility 9D
CI	Chief Investigator
CTRU	Clinical Trials Research Unit
CYP-IAPT	Children and Young People's Improving Access to Psychological Therapies
DMEC	Data Monitoring and Ethics Committee
DSM IV	Diagnostic and Statistical Manual of Mental Disorders, 4th Edition
EQ-5D-Y	EQ-5D Youth version
FSSC-R	The Fear Survey Schedule
GCP	Good Clinical Practice
IAPT	Improving Access to Psychological Therapies
ICC	Intraclass Correlation Coefficient
ISRCTN	International Standard Randomised Controlled Trials Number
ITT	Intention to Treat

LCHT	Leeds Community Healthcare NHS Trust
LYPFT	Leeds and York Partnership NHS Foundation Trust
MHRN	Mental Health Research Network
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NIHR	National Institute for Health Research
OST	One Session Therapy
PI	Principal Investigator
PIS	Participant Information Sheet
PPI	Patient and Public Involvement
QALY	Quality Adjusted Life Years
QOL	Quality of Life
RCT	Randomised Controlled Trial
REC	Research Ethics Committee
SAE	Serious Adverse Event
SD	Standard Deviation
SENCo	Special Education Needs Co-ordinator
SUDS	Subjective Units of Distress
TMG	Trial Management Group
TSC	Trial Steering Committee
WTP	Willingness to Pay

1. Background

1.1.Definitions and Prevalence

A specific phobia is an intense, enduring fear of an identifiable object or situation that leads to anxiety symptoms, distress, and avoidance (American Psychiatric Association, 2000). It is estimated that between 5% and 10% of children have a specific phobia severe enough to impact on their everyday functioning (Kessler et al., 2005), and that the average duration of their phobias is 20 years (Stinson et al., 2007). The mental health, developmental and medical impact of these phobias is significant, with higher rates of health service usage than most other anxiety disorders (Deacon, Lickel, & Abramowitz, 2008), despite the fact that fewer than 10% seek treatment for the phobia itself (Stinson et al., 2007). This can result in considerable academic difficulties (Ialongo, Edelsohn, Werthamerlarsson, Crockett, & Kellam, 1995), personal distress (Ollendick & March, 2004) and interference in day-to-day activities (Ollendick, King, & Muris, 2004).

1.2.Current Treatment Approaches

Interventions based on the principles of Cognitive Behavioural Therapy (CBT, see section 8.1) remain the dominant model of therapy delivery in Children and Young People's Improving Access to Psychological Therapies (CYP-IAPT) for specific phobias (Kendall & Hedtke, 2006; Kendall et al., 2005). Indeed, evidence supporting the efficacy of CBT for anxiety disorders and phobias is robust (Butler, Chapman, Forman, & Beck, 2006; Hofmann, Asnaani, Vonk, Sawyer, & Fang, 2012; Hofmann & Smits, 2008), consequently CBT is often the first choice psychological treatment for these problems. However, there are limitations to the provision of CBT. For example, face-to-face CBT is time consuming (Aschim, Lundevall, Martinsen, & Frich, 2011; Wiebe & Greiver, 2005), is often offered at great cost and, thus, has

limited availability (Cavanagh, 2014; Shapiro, Cavanagh, & Lomas, 2003). As a result, clinical services are moving towards improving patient outcomes by working with low intensity treatments that have the potential to be implemented across the NHS (Bower & Gilbody, 2005; National Collaborating Centre for Mental Health, 2011). One such low intensity alternative to CBT that shows potential is One-Session Treatment (Öst, 1989).

1.3.One-Session Treatment: An Overview

Unlike CBT, OST does not require an extensive treatment period. Instead, a combination of treatment techniques including graduated exposure therapy, participant modelling, reinforcement, psycho-education, cognitive challenges and skills training are consolidated into a single three-hour session, a procedure which has been shown to be clinically effective in children (Ollendick et al., 2009; Öst, Svensson, Hellstrom, & Lindwall, 2001; Ryan, Strege, Oar, & Ollendick, 2016). For example, in one of the largest trials of OST, Ollendick et al. (2009) randomised 196 children (ages 7 to 16) to one of three groups; i) an OST group; ii) an education support group; and iii) a wait-list control group. The authors reported that OST demonstrated superiority over both the education support group and the wait-list control in terms of clinician rated phobia severity, percentage of participants who were diagnosis free, child ratings of anxiety and treatment satisfaction as reported by the children and their parents at post-intervention and a six-month follow-up point. OST, therefore, appears well placed to provide a low intensity alternative to CBT for specific phobias.

2. Study Rationale

CBT is the dominant model of treatment provision in the UK, and more generally. However, as discussed in the previous section, the provision of CBT is time consuming, offered at great cost and is limited in terms of its availability. Indeed, existing therapist resources

struggle at best to treat the existing large numbers of young people in need of help with their anxiety and phobia problems. Consequently, there is great need for evidence based, alternative, low intensity psychological therapies that are able to bridge the gap between those needing treatment and the sparse availability of resources. The present research aims to provide high quality evidence of the non-inferiority of OST when compared to standard CBT in two ways; i) in terms of treatment efficacy; and ii) in terms of economic viability. Furthermore, ASPECT intends to investigate engagement from participants and clinicians alike whilst ensuring the proposed research runs within a pragmatic, 'real-world' setting. A more detailed overview of the aims of ASPECT is outlined below.

2.1.The Non-Inferiority of OST compared to CBT Based Interventions

Although OST has demonstrated efficacy in comparison to an active control group, it is yet to be compared against the primary treatment choice in the UK; CBT. Should OST demonstrate non-inferiority when compared with CBT (i.e. similar or better efficacy) alongside economic advantages, then the evidence in favour of OST for specific phobias would be considerably strengthened.

2.2.How do Clinicians and Patients Engage with OST?

Many training courses across the country already teach OST as an alternative delivery model to multi-session CBT for specific phobias, but the implementation varies in terms of its frequency of use within the services and the practitioners' fidelity to the model. Consequently, we will conduct qualitative interviews with the clinicians delivering OST, as well as the children receiving the intervention and their parents/guardians.

2.3.Can OST be Implemented in the Real World?

Psychological interventions are often trialled in optimal conditions that are most favourable to the intervention. That is, they are tested under tight experimental control that allows the researchers to manipulate aspects of the intervention that may not be possible in a real world setting. For example, a trial testing the impact of a psychological intervention may exclude participants on the basis of comorbidities (i.e. conditions/problems co-occurring with the target problem) that could affect treatment efficacy. ASPECT is a pragmatic trial (i.e. a trial under real conditions within the NHS) which aims to investigate whether OST is an effective, economically viable intervention option for use within care provision across the NHS. Subsequently, the proposed research will be able to distinguish between treatment efficacy (effects under optimal circumstances) and treatment effectiveness (effects under 'real world' clinical settings), an important distinction in extant clinical trials literature (Gartlehner, Hansen, Nissman, Lohr, & Carey, 2006; Nathan, Stuart, & Dolan, 2000).

3. Aims and Objectives

3.1.Primary Objective

To investigate the non-inferiority of OST compared to CBT based interventions for treating specific phobias in children (aged 7 to 16 years old) at a 6 month follow up point. Non-inferiority would be demonstrated if OST is shown to produce similar, or improved, effects on the Behavioural Approach Test (BAT, see section 4.1.1) when compared to CBT.

3.2.Secondary Objectives

In addition to the primary objectives of ASPECT, the proposed research has a number of secondary objectives;

1. We will examine the cost effectiveness of OST, in comparison to CBT. It is hypothesised that OST, when compared with CBT, will be more cost/time effective.
2. ASPECT aims to establish the relative impact of the interventions on the child's quality of life (QoL), school and social life as well as family functioning.
3. ASPECT 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.

4. Outcome Measures

A range of measures will be used throughout ASPECT in order to screen participants and to investigate the primary and secondary objectives (see Table 1 for an overview of outcome measures and time-points).

Table 1

An Overview of Outcome Measures used Throughout ASPECT

Measure	Time points completed	Delivery method	Administered by	Completed by
Screening checklist	Screening	Phone interview	Research assistant	Parent/guardian
Demographics	Screening	Phone interview	Research assistant	Parent/guardian
	Baseline	Face-to-face	Research assistant	Parent/guardian
	Baseline	Face-to-face	Research assistant	Participant
BAT	Baseline	Face-to-face	Research assistant	Participant
	6 months after randomisation	Face-to-face	Research assistant	Participant
ADIS-P	Baseline	Face-to-face	Research assistant	Parent/guardian
	6 months after randomisation	Face-to-face	Research assistant	Parent/guardian
ADIS-C	Baseline	Face-to-face	Research assistant	Participant
	6 months after randomisation	Face-to-face	Research assistant	Participant
CAIS-P	Baseline	Face-to-face	Self-report	Parent/guardian
	6 months after randomisation	Face-to-face	Self-report	Parent/guardian
CAIS-C	Baseline	Face-to-face	Research assistant	Participant
	6 months after randomisation	Face-to-face	Research assistant	Participant

RCADS-P	Baseline	Face-to-face	Research assistant	Participant
	6 months after randomisation	Face-to-face	Research assistant	Participant
RCADS-C	Baseline	Face-to-face	Research assistant	Participant
	6 months after randomisation	Face-to-face	Research assistant	Participant
Goal-based outcome	Baseline	Face-to-face	Research assistant	Participant
	6 months after randomisation	Face-to-face	Research assistant	Participant
CHU-9D	Baseline	Face-to-face	Research assistant	Participant
	6 months after randomisation	Face-to-face	Research assistant	Participant
EQ-5D-Y	Baseline	Face-to-face	Research assistant	Participant
	6 months after randomisation	Face-to-face	Research assistant	Participant
Resource use	Baseline	Face-to-face	Self-report	Parent/guardian
	6 months after randomisation	Face-to-face	Self-report	Parent/guardian
Therapist logs	Ongoing over intervention	NA	self-report	Therapist/clinician
OST integrity scale	Ongoing over intervention	NA	Self-report	Clinical supervisor
CBT fidelity scale	Ongoing over intervention	NA	Self-report	Clinical supervisor

Notes: ADIS = Anxiety Disorder Interview Schedule, BAT = Behavioural Approach Test, CAIS = Child Anxiety Impact Scale, CBT = Cognitive Behavioural Therapy, CHU-9D = Child Health Utility-9D, EQ-5D-Y, OST = One Session Treatment, RCADS = Revised Children's Anxiety and Depression Scale.

4.1.Primary Outcome Measure

4.1.1. The Behavioural Approach Test

The primary outcome measure in this trial will be scores on the Behavioral Approach Test (BAT; Öst, Salkovskis, & Hellstrom, 1991). The BAT is a widely used behavioural outcome measure for the assessment of phobias in children (Ollendick & March, 2004; Öst et al., 2001; Silverman & Ollendick, 2005) and is specific enough to distinguish between multiple phobias. During the BAT, participants are exposed to their phobic stimulus gradually over 10 pre-defined steps which increase in difficulty each time. For example, a child with a distressing phobia of spiders may start the BAT at step 0, standing outside of a room, whilst inside the room is a spider contained in a box. The subsequent steps the child may take are rated as follows; opening the door (step 1), entering the room/passing through the doorway (step 2), entering approximately ¼ of the way into the room (step 3), entering approximately ½-way into the room (step 4), entering approximately ¾ into the room (step 5), stands within approximately 3 feet of the container (step 6), stands within approximately 6 inches of the container (step 7), touches or holds the container (step 8), opens the container (step 9), and holds/lifts the spider for 20 seconds (step 10). The number of steps the participant takes is the main unit of measurement that is recorded for analysis. The BAT also includes a measure of subjective units of distress (SUDS) whereby the participant can indicate their level of fear at both the start of the BAT and at the last step completed (ranging from 0, no fear at all, to 8, very, very much fear).

BATs will be devised by the research team depending on the type of specific phobias encountered, therefore may vary across different phobic stimuli (e.g. a BAT for a spider phobia will differ to a BAT for a fear of small spaces). However, assessments will be standardised according to BAT protocols used in extant literature (Davis et al., 2016a; Davis et al., 2013;

Davis et al., 2016b). The BAT will be completed by trained research assistants who are blind to group allocation and will utilize "low-demand" instructions to minimize demand characteristics (i.e. to not create a situation where a fearful child feels he/she must go further than they normally would). The BAT usually takes 5 to 10 minutes to administer and often involves a level of discomfort for the participant due to the nature of the graded exposures. Similar BATs conducted with children have been found to have good test-retest reliability (Ollendick, Allen, Benoit, & Cowart, 2011; Ollendick et al., 2009) and correlate strongly with other outcome measures of distress and phobia (e.g. Boschen, Veale, Ellison, & Reddell, 2013; Kindt, Brosschot, & Muris, 1996).

4.2.Secondary Outcome Measures

4.2.1. Demographic Information

Demographic information (e.g. age, gender etc.) pertaining to the participants receiving either OST or a CBT, their parents/guardians and the clinicians delivering the interventions will be collected. Demographic information will be collected directly from the participant using a novel demographic information form. Participants will also be asked if they have a treatment preference at baseline, although this will not affect randomisation in any way.

4.2.2. The Anxiety Disorder Interview Schedule (ADIS)

The specific phobia subsection of the Anxiety Disorder Interview Schedule (ADIS; Silverman & Albano, 1996) will be used as an outcome measure at baseline and 6-months after baseline. The ADIS is a semi-structured interview that obtains information from both the participant (child version of the ADIS) and their guardian (parent version) relating to the type specific phobia (e.g. animal/insect, small spaces, blood/injection phobias etc.), the degree of associated fear (rated from 0, 'not at all', to 8, 'very, very much'), whether the phobia causes

avoidance (rated as 'yes' or 'no') and interference with daily life (rated from 0, 'not at all', to 8, 'very, very much'). The ADIS is a routinely used measure in child and adolescent phobia research and has been shown to be a reliable instrument for deriving specific phobia symptoms and experiences in children (Silverman & Albano, 1996; Silverman, Saavedra, & Pina, 2001).

4.2.3. The Child Anxiety Impact Scale (CAIS)

Both the child and parent/guardian versions of the Child Anxiety Impact Scale (CAIS-C/P; Langley, Bergman, McCracken, & Piacentini, 2004) will be used as an outcome measure at baseline and at the 6-months follow-up point. Participants, and their parents, will state to what extent feeling 'nervous, anxious or afraid' has impacted on daily life by indicating on a 4-point scale their agreement, or not, with 27 statements grouped in 3 sub-domains; school activities, social life and home/family life. For example, participants and parents/guardians will indicate to what extent in the previous month their child's phobia impacts on events such as "*getting to school on time in the morning*" and "*making new friends*" on a 4-point scale ranging from 0, 'not at all' to 4, 'very much'. Both the child, and parent versions of the CAIS give a reliable and valid measure of anxiety related functional impairment in school, social, and family domains (Langley et al., 2004; Langley et al., 2014).

4.2.4. The Revised Children's Anxiety and Depression Scale (RCADS)

Both the parent and child versions of the Revised Children's Anxiety and Depression Scale (RCADS-C/P) will be used as an outcome measure at baseline and at the 6-month follow-up point. The RCADS-C/P is a 47 item, self-report scale designed to capture mental health information over 6 sub-domains including; separation anxiety disorder (SAD), social phobia (SP), generalized anxiety disorder (GAD), panic disorder (PD), obsessive compulsive disorder (OCD), and major depressive disorder (MDD). Participants are required to state the frequency of

which statements happen to them on a 4-point scale ranging from 0, 'never', through to 1, 'sometimes', 2, 'often', and 3, 'always'. For example, participants would answer items such as "*I worry about things*", *I have trouble sleeping*" and "*I feel I will make a fool of myself in front of people*". The RCADS is a widely used measure of overall child mental health and has been extensively validated as a reliable and accurate measure (Bouvard & Denis, 2012; Chorpita, Moffitt, & Gray, 2005; Chorpita, Yim, Moffitt, Umemoto, & Francis, 2000; de Ross, Gullone, & Chorpita, 2002).

4.2.5. The EQ-5D-Y

The EQ-5D-Y, originally developed by the EuroQoL group (EuroQol, 1990), is a widely used, generic instrument measuring health-related quality of life (QoL) in children and adolescents. Children and adolescents are able to classify their health on a three-point scale (1, 'no problems', 2, 'some problems' and 3, 'a lot of problems') over five dimensions; mobility (walking about), looking after myself, doing unusual activities, having pain or discomfort, and feeling worried, sad or unhappy. Additionally, the EQ-5D-Y includes a visual analogue scale where participants can indicate their overall health status from 0 (worst imaginable state) to 100 (best imaginable state). All questions refer to the participant's health state 'today'. The EQ-5D-Y has been shown to be a reliable and valid health related QoL instrument for use in children and adolescents (Burstrom, Bartonek, Brostrom, Sun, & Egmar, 2014; Ravens-Sieberer et al., 2010).

4.2.6. The Child Health Utility 9D

The Child Health Utility 9D (CHU-9D) is a health related QoL measure for use with young people (Stevens & Ratcliffe, 2012). The CHU-9D requires children and adolescents to select a sentence from a possible five to describe how they feel in relation to a number of constructs (i.e. sadness, tiredness, pain, etc.) with regards to the current day. For example,

participants will be asked to select one of five statements that best reflects how worried they feel ranging from "*I don't feel worried today*" to "*I feel very worried today*". The CHU-9D is a validated and reliable measure of health related QoL for use in children and adolescents (Ratcliffe, Stevens, Flynn, Brazier, & Sawyer, 2012; Stevens, 2012; Stevens & Ratcliffe, 2012).

4.2.7. A Goal-based Outcome Measure

A goal-based outcome measure is a method of comparing how far a participant feels they have moved towards reaching a specific goal they have set before the intervention has begun. A goal-based outcome measure based on recent guidelines (Law & Jacob, 2013) will be used to set up to three goals at baseline, with progress towards meeting these goals rated on a 10-point scale at the 6-month follow-up point. Progress can range from 0 (i.e. goal not met), to 5 (i.e. half-way to reaching the goal), through to 10 (i.e. goal reached). For example, a participant in the proposed research with a dog phobia may set as their goal that they would like to be able to play in a park they previously saw a dog in. After setting this goal at baseline, they will rate how far they are to achieving this goal at the 6-month follow-up point.

4.2.8. Resource Utilisation Questionnaire

A bespoke resource utilisation questionnaire has been developed by the ASPECT health economist in consultation with clinicians and the wider ASPECT study team. The bespoke questionnaire was based on a previous resource utilisation questionnaire by Barrett, Byford, Chitsabesan, and Kenning (2006) and informed by recent studies conducted by the team that involved mental health of young people (Marshall et al., 2016; Wright et al., 2014). The questionnaire will collect data on the following resource use categories; i) general health and community service use (i.e. appointments with GP's, nurses, social services and educational services); ii) mental health service use (i.e. appointments with a psychiatrist, psychotherapists,

psychologists, CAMHS therapists and other forms of mental health support); iii) hospital-based services, (i.e. visits to A & E, urgent care centres and hospital stays); and iv) days missed from school or training by the child, and days missed by parents/carers from work or studies. The resource utilisation questionnaire will collect data relating to the previous six months and will be completed by the parent, under the supervision of a research assistant.

4.2.9. The Cognitive Behaviour Therapy Scale for Children and Young People (CBTS-CYP)

The most widely used tool for measuring CBT competence with adults is the Cognitive Therapy Scale-Revised (CTS-R, Blackburn et al., 2001); however, its application to children and young people has been questioned (Fuggle, Dunsmuir, & Curry, 2012; Stallard, Myles, & Branson, 2014). Consequently, the proposed research will use the Cognitive Behaviour Therapy Scale for Children and Young People (CBTS-CYP) to assess fidelity to the delivery of CBT for specific phobias. The CBTS-CYP is largely modelled on the CTS-R and utilises the same 7 point Likert scale to rate competence over 14 items assessing the use of goals and assessments, use of behavioural techniques, use of cognitive techniques and ability to facilitate self-discovery and child engagement. Scores over the 14 items are rated from 0, incompetent, through to 6, expert. The CBTS-CYP has demonstrated high face validity and internal reliability with robust convergent validity with the CTS-R (Stallard et al., 2014).

4.2.10. The One Session Treatment Rating Scale (OST-RS)

The proposed trial will use the One Session Treatment Rating Scale (OST-RS) to assess fidelity to the principles of OST delivery. Rater's are asked to indicate how well the therapist delivering OST adhered to core principles of OST over 13 items. For example, the extent to which the therapist delivering OST "*created a good and trustful therapeutic relationship with the*

child" and "*guided the child in the exposure procedure*" are rated from 0, 'not at all', though to 6, 'excellent'. In this case of guiding the child in the exposure procedure, a score of 0, 'not at all', would indicate that the '*therapist never guides the child and gives vague instructions for the exposure*'. Conversely, a score of 6, 'excellent, would indicate that the '*therapist always guides the child through the procedure and makes sure that he/she understands instructions for the exposure*'. The OST-RS will be completed as part of routine clinical supervision after the OST session and was developed for use in a previous RCT of OST with children and young people (Ollendick et al., 2015).

4.2.11. Therapist Logs

As part of the ongoing fidelity and economic evaluation in the proposed trial, clinicians and therapists delivering both OST and CBT will be asked to keep a log of the number, duration and frequency of all sessions they deliver to the participants within the trial period.

5. Study Design and Setting

We will conduct a pragmatic, non-inferiority randomised controlled trial with an internal pilot to compare the clinical effectiveness of OST with multi session CBT. Nested within this trial will be an economic evaluation of both OST and CBT alongside a qualitative investigation of the perceptions and acceptability of OST. Given that ASPECT is a pragmatic trial aiming to reflect actual care provision across the NHS, study settings and health authorities will vary. Multiple research sites across England will be selected to ensure a pragmatic trial according to feasibility of delivering the intervention. For example, we will approach Improving Access to Psychological Therapies (IAPT) and Child and Adolescent Mental Health Services (CAMHS). Furthermore, we will approach supplementary services that often compliment IAPT and CAMHS such as third sector and voluntary organisations, as well as local schools.

6. Eligibility Criteria

A number of inclusion and exclusion criteria must be met before a participant can be considered for inclusion in ASPECT. The restrictions extend to the age of the participants and the specific phobia experienced. As ASPECT is a pragmatic trial, aiming to reflect actual care provision for specific phobias, very few exclusion criteria will be applied. A detailed overview of the inclusion and exclusion criteria for the proposed research can be seen below.

6.1.Inclusion Criteria

In order to be eligible for inclusion in ASPECT, each participant must;

1) Be between the ages of 7 and 16 years of age
2) Experience at least one specific phobia as defined by DSM-IV criteria, which will be assessed using the specific phobia subsection of the Anxiety Disorder Interview Schedule (ADIS). These criteria are; i) marked and out of proportion fear to a specific object or situation; ii) exposure provokes immediate anxiety; iii) the phobic situation(s) is avoided where possible; iv) the avoidance or distress interferes with the person's routine or functioning (e.g. learning, sleep, social activities); v) and present for 6 months or more.

6.2 Exclusion Criteria

The study will include all different types of phobias and potential comorbid conditions, but it will consider - on a case-by-case basis - the exclusion (pre-randomisation) or withdrawal (post-randomisation) of children/young people for whom exposure therapy is potentially: 1) unsafe, 2) not the best first line / best available option:

1) Exposure to the stimulus has the potential to be unsafe or cause harm (e.g. the stimulus cannot be safely simulated or produced, e.g. bees, wasps etc.)

2) Exposure therapy is not the best first line or best available option (the child has other needs that make the therapy currently unsuitable, e.g. psychosis, severe learning disability, suicidality, severe conduct disorder etc.)

7. Study Procedures

7.1.Participant Recruitment

ASPECT will use two methods of participant recruitment; i) from health and social care pathways in the UK; and ii) an active identification process through schools. Each of these two routes are outlined in more detail below.

7.1.1. Recruitment from Health and Social Care

As ASPECT is a pragmatic trial, it is important we implement flexible recruitment from sources that are most likely to deal with specific phobias in children within a given area. Therefore, ASPECT will recruit participants from a range of health and social care settings across several geographical locations in England. For example, ASPECT will recruit from the Improving Access to Psychological Therapies (IAPT) and Children and Adolescent Mental Health Services (CAMHS) care pathways. However, children with specific phobias may also be seen by other services other than IAPT and CAMHS (e.g. third sector and voluntary organisations), therefore we will aim to recruit from these services where appropriate.

The flow of children with specific phobias through health and social care pathways varies across each location. However, most services have an initial point of contact between the child and a member of the health and social care team in that area. For example, in IAPT and CAMHS, a primary mental health worker may conduct an initial clinical assessment of the child before deciding on an appropriate course of action. In third sector organisations, the initial point of contact may be a team member who triages referrals (e.g. social worker, care worker etc.). It is at

these initial points of contact that the child with a specific phobia and their parent/guardian will be informed about ASPECT and asked if they would be interested in taking part. Those that display an interest will be given an ASPECT information pack containing; i) an information sheet about the study; and ii) an expression of interest form. The information sheet will provide further information about the study and what would be expected of the participants alongside contact details for the ASPECT study team (email and phone number). The expression of interest form will require the parent/guardian of the child with a specific phobia to provide contact details and return the form to the ASPECT study team by post. Alternatively, the parent/guardian can email or call the ASPECT team to express an interest in taking part and provide contact details. Alternatively, the interested family could simply return the expression of interest form to the initial point of contact, who can then forward the information to the ASPECT team. After this, a research assistant will contact the potential participant to discuss the study further and perform screening in line with the eligibility criteria over the phone and arrange a date and time for baseline data collection if eligible.

7.1.2. Recruitment from Schools

The ASPECT research team has prior experience recruiting from schools and has established links to education services (Wright et al., 2016; Wright et al., 2014). Consequently, potential schools have already been identified through the Department of Education and local council websites, and a database of all schools in each area has been compiled by the ASPECT research team. Information about the research will be sent to all schools on this database inviting them to participate with instructions to contact the research team if they would like further information, have any questions or would like to express an interest. Follow-up phone calls will be made to any school that has not replied to this initial invitation after two weeks. Further

information about the trial will be provided by the research team via information events, face-to-face meetings, telephone calls, etc. as appropriate. Where a school agrees to take part in ASPECT, school representatives (e.g. head teachers, Special Education Needs Co-ordinators (SENCo), teaching assistants, etc.) will distribute recruitment information packs to all parents of children within the 7 to 16 years age range containing contact details for the research team, information about the study, and an expression of interest form. The expression of interest form will require the parent/guardian of the child with a specific phobia to provide contact details and return the form to the ASPECT study team or to the school. Alternatively, the parent/guardian can email or call the ASPECT team to express an interest in taking part and provide contact details, or simply return the expression of interest form to the school, who can forward this to the ASPECT team. After this, a research assistant will contact the potential participant to discuss the study further and perform screening in line with the eligibility criteria over the phone and arrange a baseline data collection visit if eligible.

7.2.Screening and Eligibility Checks

Research assistants working on ASPECT will contact all families who have expressed an interest in taking part in the trial by telephone to screen participants for eligibility using an eligibility checklist developed by the research team and based on the Anxiety Disorder Interview Schedule (see section 4.2.2). Participants will answer yes or no to 5 items aiming to confirm that the child is within the eligible age ranges for inclusions (7 to 16 years) and is likely to have a DSM rated specific phobia (see section 4.2.2 for more details). These items are;

1. Is your child between the ages of 7 and 16 years old (inclusive)?
2. Does your child have a fear or anxiety in the presence of a specific object or situation?

a. If yes to question 2, please state the object or situation

3. Does your child want to avoid that object or situation when they can?

4. Does this anxiety and avoidance affect your child's life (e.g. does it affect their sleep, school attendance, eating etc.)

5. Has this problem been present for 6 months or longer?

In order to pass this screening process, the parent/guardian will need to answer 'yes' to all questions and will be asked to provide the researcher with information about the nature of their child's phobia. If a child appears eligible for inclusion after the telephone screening, the research assistant will inform the parent/guardian of eligibility, arrange a face-to-face visit in order to take full informed consent, perform a detailed eligibility check (i.e. using both the parent and child version of the ADIS) and take baseline measures. The research team will aim to have obtained informed consent, and completed baseline measures and randomisation within 2 weeks of the initial telephone eligibility screening. Any young person who does not meet the eligibility criteria for study participation and/or does not consent to the trial will be signposted to alternative sources of help relevant to their local area.

7.3.Informed Consent

Full informed consent will be taken at the first face-to-face meeting by the research assistant, which will take place following the initial phone screening. As all participants in this study will be aged 16 or under, consent will be required from both a person with parental responsibility, and the participant themselves if they are deemed competent enough to do so (i.e. they can understand the information given to them about the study, retain the information, be able to relay the information back to the research assistant and can make a decision about participation). Where a child is not deemed competent to give full informed consent, we will take

parental consent and assent from the child. Prior to this meeting, information sheets will have been received by the parents of the children and the children themselves. Two versions of the information sheets will be available based upon age (one for those aged 7 to 11 years and one for those aged 12 to 16). Each potential participant will have had sufficient time to read through the participant information sheet and ask questions, either to the school contact or the ASPECT research team, before deciding whether to take part. All information leaflets and consent forms will be co-developed by the research team and PPI representatives to ensure acceptability amongst participants. If a participant wishes to withdraw from the intervention (i.e. the OST or CBT conditions), we will ask if they are happy to participate in the planned follow up so that their results can be included within an intention to treat analysis (ITT).

7.4.Baseline Data Collection

Baseline data collection will be completed by a trained research assistant, after informed consent has been given, at the location where intervention delivery will take place or another mutually convenient location. We will collect baseline variables from both the children and young people with a specific phobia and their parents/guardians. The specific measures to be completed by children and young people and their parents/guardians are outlined below (and in section 4); however, we estimate that baseline data collection will last approximately one and a half hours (including a break if needed).

7.4.1. Outcomes Completed by Children and Young People

At baseline, children and young people will complete a semi-structured interview about their phobia and a series of self-report questionnaires. The focus will be on the child or young person completing these measures; however, a research assistant and parent/guardian will be on hand to assist should any difficulties arise (e.g. not understanding a question). The specific

phobia subsection of the child version of the Anxiety Disorder Interview Schedule (ADIS-C) will be administered by a research assistant to the child. This is a routinely used standard diagnostic tool that is able to determine the presence and type of specific phobia alongside the level of fear, avoidance and interference with daily life. Children and young people will also complete the child version of the Child Anxiety Impact Scale (CAIS-C), a 27 item self-report questionnaire designed to measure the impact of feeling anxious, nervous or afraid on daily life. The child version of Revised Children's Anxiety and Depression Scale (RCADS-C) will be used in order to capture information relating to any anxiety and depression experienced by the child/young person (see section 4.2.4 for an overview of the RCADS). Two health related measures of quality of life will be completed by the children and young people; the EQ-5D-Y and the Child Health Utility 9D (CHU-9D). In addition, a goal-based outcome will also be completed, which aims to identify specific goals that a child may have that they would like to achieve through participation in the trial. For example, a child with a specific phobia of dogs may choose as a goal, "to be able to play in the local park" and then rate how far away from achieving that goal they currently are (see section 4.2.7 for an overview of the goal-based measure).

The final outcome measure to be taken at baseline will be the Behavioural Approach Test (BAT). The BAT involves graded exposure to the child's phobic stimulus, therefore this has the potential to cause distress to the child. Consequently, a number of steps will be taken to ensure that any distress experienced by the child is limited. For example, there will be a trained research assistant and the parent/guardian of the child present throughout the BAT. Furthermore, an appropriate professional will be present should the phobic stimulus require one (e.g. a phobia of a dog will require an animal handler).

7.4.2. Outcomes Completed by Parents/Guardians

The parents/guardians will complete a range of questionnaires aiming to measure parental perspectives of their child's specific phobia. Parents/guardians will complete the parent version of the specific phobia subsection of the Anxiety Disorder Interview Schedule (ADIS-P), the parent version of the Child Anxiety Impact Scale (CAIS-P) and the parent version of Revised Children's Anxiety and Depression Scale (RCADS-P). These outcome measures will assess the parents view of the severity of their child's phobia, as well as the impact it has on the daily life of their child. In addition to measures assessing their child's phobia, parents will also complete a Resource Utilization questionnaire (see section 4.2.8 for an overview). This outcome will measure the use of health resources (i.e. mental health services, medication etc.) and will form the basis of an economic evaluation of both OST and CBT.

7.5.Randomisation

Allocation to groups will be conducted remotely through a secure web-based program designed by the Sheffield Clinical Trials Unit (CTRU) following consent and completion of the baseline measures. When allocation is made, a member of the study team will inform parents and their designated therapist by phone or email. The ASPECT randomisation allocation ratio will be 1:1 to facilitate equal sample sizes across both the OST and CBT groups. The randomisation schedule will be generated by the trial statistician prior to the start of the study. It is reasonable to assume that both age and phobia severity may impact on outcomes. For example, it is possible that older children may be able to assimilate and apply therapy sessions better than younger children, and thus may lead to better outcomes. Furthermore, baseline symptom severity has been shown to a key moderator of treatment outcomes in children (Ollendick, 2015). It is for these reasons that randomisation will be stratified according to age (7-11 years old vs. 12-16

years old) and symptom severity (mild/moderate vs. severe phobia severity), and will use random permuted blocks of variable size to ensure enough participants are allocated evenly to each arm of the trial within each stratum.

7.6.Blinding

Complete blinding (both single and double blinding) of psychological interventions is often extremely difficult, and, at times, impossible (Boutron, Estellat, & Ravaud, 2005; Boutron et al., 2007; Fergusson, Glass, Waring, & Shapiro, 2004; Sackett, 2004). However, the proposed research will take a number of steps to facilitate blinding the outcome assessor and reduce sources of bias where possible. The research assistants conducting the baseline and follow-up assessments will be independent of the therapists and clinicians delivering the interventions. They will not be informed of, or involved in, group allocation, will not organise or be present during the therapy sessions and will have restricted access to the study database. Participants will be explicitly reminded not to disclose to the research assistant their allocated group. In the event of these procedures being compromised (e.g. a research assistant learning the participant's allocated group), we will record this and where possible arrange for a different outcome assessor in the future. The trial statisticians and health economists will be blind to treatment allocation whilst the trial is ongoing.

7.6.1. Monitoring blinding

We will take all necessary steps (as described above) to ensure that the RAs who collect outcome measures remain blind to the participant's allocation. However, there may still be occasions when the research assistants may guess or become aware of the participant's allocation. To monitor blinding in the proposed research, research assistants collecting the 6-month follow-up data will be asked "d*o you consider that you may have been unblinded*?". If the

answer is yes, the research assistant will be prompted to complete an 'unblinding details' form where they will describe details of the unblinding incident (e.g. suspected allocation and the date, source and method of unblinding) We will report the reasons given by research assistants for potentially knowing or guessing a child's allocation during data collection.

7.7.Withdrawal Criteria

There are a number of reasons as to why participants may withdraw from the research. For example, after a participant has been randomised to receive either OST or CBT, they will have an initial clinical assessment conducted by a clinician/therapist. If the clinician conducting the assessment feels the child should not continue with the trial (e.g. serious comorbidities), then the participant will be withdrawn from the trial. Where withdrawal does occur, it will be clarified if it is from the intervention, follow-up or the study. Where withdrawal is from the intervention, follow-up data will still be collected. Where withdrawal is from follow-up, data will be retained up to the date of withdrawal, unless specifically requested otherwise. The number of withdrawals from treatment and/or follow-up measures will be logged with a summary of their reasons (if offered by the participant).

8. Study Interventions

8.1.Cognitive Behavioural Therapy (CBT) Based Interventions

Cognitive Behavioural Therapy (CBT) is a form of psychological therapy that uses both cognitive and behavioural techniques to help people to change unhelpful thinking patterns and behaviours arising in response to certain situations. Interventions based on the principles of CBT represent the dominant model of therapy delivery for specific phobias, a practice supported by a robust literature attesting to the efficacy of CBT (Butler et al., 2006; Hofmann et al., 2012; Hofmann & Smits, 2008; Kendall & Hedtke, 2006; Kendall et al., 2005). CBT aims to help a

child/young person with specific phobia to; i) recognise anxious feelings and bodily reactions to anxiety; ii) gradually confront their feared situations until their anxiety subsides; iii) capture and challenge anxious or scary thoughts when faced with a phobic situation or object; and iv) develop coping strategies and use anxiety management techniques, especially if distress and physical symptoms become overwhelming and the child cannot stay in the feared situation for the purposes of therapy. CBT based interventions are often delivered in hourly sessions every week. Each session has a specific objective for the child to achieve, supplemented by home-practised tasks between sessions. There is no recommended number of CBT sessions for specific phobias; however, it is often the case that a child receives 6-to-12 sessions of CBT. The actual number of sessions each child receives will be recorded throughout the trial, and fidelity to the principles of CBT will be assessed after each session.

8.2.One Session Treatment (OST)

One Session Treatment (OST) is a variant of CBT based interventions and uses many of the same techniques that CBT uses. However, whereas CBT delivers these techniques weekly through hourly sessions, OST takes a more condensed approach. The proposed research will follow guidelines developed to facilitate the delivery of OST (Davis, Ollendick, & Ost, 2012). OST's main components are an initial 1-hour functional assessment (FA) session and a separate 3-hour rapid exposure therapy (RET) session. During the FA session, the therapist determines any maintaining factors for the phobia (e.g. what the child avoids, what safety behaviours s/he engages in, how friends and family may collude with the phobia). The FA session collects information about the child's catastrophic thoughts (e.g. what do you think may happen if…, what goes through your mind when you…) and generates a fear hierarchy (i.e. a 'ladder' of situations or objects that the child avoids because of their phobia, in the order of the fear or

anxiety evoked by these situations, starting from the least frightening). The therapist uses the FA session to develop an understanding of the onset and course of the phobia and build rapport with the child and their parents. The FA session ends with the therapist presenting the rationale for treatment and discussing with the child what will happen in the 3-hour RET session. At this point, the therapist dispels any misconceptions about exposure therapy and reinforces the message that all the exposure tasks will be graded and negotiated in every step of the way and that nothing will ever happen without the child's permission.

The RET session combines graded exposure, participant modelling, reinforcement and cognitive challenges. The main principle of graded exposure is that the child gradually confronts the situations from their fear hierarchy and remains in each situation until anxiety and fear subsides at least by 50%. Through participant modelling, the therapist first demonstrates how to interact with the phobic object and then helps the child slowly and gradually approach the phobic object (i.e. by first holding the child's hand, then the arm, and gradually removing any physical assistance). Reinforcement from the therapist may take the form of social praise, encouragement, and pats on the back. Finally, the therapist uses the exposure tasks as means for actively eliciting, challenging, and testing catastrophic thoughts associated with the feared situation. It is important that the child maximises, maintains and generalises their gains from RET by practising self-directed exposure tasks at home for the ensuing weeks. Maintenance tasks include a commitment to refrain from avoiding or escaping from the feared object or situation and to deliberately engineer or enter a feared situation every day.

8.3.Intervention Delivery

8.3.1. Treatment Protocols

As OST may be a new concept to therapists taking part in ASPECT, the delivery of OST will follow a treatment protocol based on the work of co-applicant, Thompson Davis (Davis et al., 2012), who will also provide training to clinicians likely to deliver OST at each site. As the proposed trial aims to compare OST to actual CBT delivery across multiple research sites across England, the delivery of CBT will not follow a treatment protocol devised by the research team as such. However, we will undertake an evaluation of the methods and principles of CBT delivery at each site and monitor fidelity to CBT delivery using the CBTS-CYP (Stallard et al., 2014).

8.3.2. Therapy Coaching

Both OST and CBT will be delivered by professionals of an NHS-equivalent level of band 5 or above, who work in different settings (e.g. the NHS, local authorities, schools, voluntary organisations). Therapists may be from varying backgrounds (e.g. primary mental health workers, nurses, social workers, occupational therapists, educational psychologists, counsellors, youth justice workers, youth workers, teachers, teaching assistants). All therapists will be trained in the study's OST protocols, be expected to pass an assessment of therapist competence and will be supervised by experienced therapists. The PI of each area will be responsible for ensuring that all therapists involved in the study receive adequate supervision to minimise inconsistent delivery, therapeutic drift, poor practice or protocol violations. In order to deliver an intervention for ASPECT, therapists must;

- Have completed training in using the study's protocol for OST and are willing to use this protocol to deliver OST.

- Are willing to audio-tape a sample of therapy sessions, subject to participant consent, for use in supervision and for research fidelity checks.
- Are willing to receive supervision and keep a record of each therapy session (duration and content) for each participant.

8.3.3. Timing

Practitioners and services participating in the study will offer OST and CBT as a separate care pathway to minimise delays between baseline assessment and receipt of treatment, especially because delays would be different between the two treatments if CBT were to be delivered as per treatment as usual (CBT more likely to incur waiting lists). Although children who participate in the study will be fast-tracked to receive either OST or CBT for specific phobias according to protocol, this will neither compromise the participating children's access to treatment as usual (TAU) for problems other than specific phobias, nor will it give them an advantage over other children seeking TAU. We will make sure that children, parents, practitioners and service managers understand that OST is not ‘routine care’, and will be delivered in the context of a research study that needs to follow a protocol and be delivered to time; however, the participating children will neither lose their place on the waiting list nor will they jump the queue to receive treatment as usual for problems other than specific phobias. For example, a child with an injection phobia, GAD and OCD who agrees to participate in the study will be fast-tracked to receive either OST or CBT for their injection phobia as per protocol in the context of the research, but s/he can also access CBT for their GAD and OCD concurrently or in tandem as per TAU.

8.4.Modifications/Variations in Delivery

The delivery of both OST and CBT may require variations and modifications to account for differences in the children's clinical and demographic characteristics. Furthermore, modifications may be required to account for parental and child preferences as well as service and practitioner capacity as detailed below.

8.4.1. Childs Age

OST and CBT have to be implemented in a developmentally appropriate way. Younger children (i.e. 7-11 years), as opposed to older children (i.e. 12 to 16 years), may require a slower pace throughout the session (e.g. when moving up the fear hierarchy). Additionally, younger children may feel more comfortable if the treatment session uses imagery and play scenarios such as using 'hero figures' as models of behaviour (e.g. "*what would Superman do?*").

8.4.2. Nature of the Phobia

Depending on the type of phobia that the children experience, the session may need to take place in a clinic with the appropriate feared stimuli brought in, or may take place in a public place (the child's school, a GP surgery, hospital etc.). For some phobias, in-vivo exposure to the feared stimulus will be possible (e.g. a dog or a spider) whereas for others exposure may only be possible by simulation, in imagination, on video/audio tape or in virtual reality (e.g. fake blood or fake vomit, flying or thunder). Some phobias may require adaptations to control physical manifestations of anxiety such as pain and fainting (Oar, Farrell, & Ollendick, 2015). Simulation of specific phobias will occur where it is possible and appropriate to do so and will follow standard procedures in place at each site. Furthermore, intervention delivery taking place outside of the clinic will take place where it is common practice at each site.

8.4.3. Presence of physical problems or disabilities

Some physical problems may be exacerbated by anxiety, or make practice of certain exposure tasks difficult (e.g. cerebral palsy, asthma, epilepsy etc.). In these situations, we will use appropriate techniques (e.g. relaxation or controlled breathing) to prevent adverse physical reactions and we will adapt the environment (e.g. having family members present, having a wheelchair accessible room etc.) to enable exposure tasks to take place.

8.4.4. Presence of Hearing, speech and/or Language barriers

We will work with family members and/or interpreters to deliver the sessions and materials in sign or foreign language where this is possible and appropriate.

8.4.5. Presence of Comorbid Mental Health Problems

The proposed research will not exclude explicitly on the basis of comorbidities. However, there may be occasions when the clinician feels that a comorbid mental health condition may; i) be made worse through trial participation; and/or ii) needs to be treated first as a priority over the specific phobia. At these points the child may be withdrawn from the trial. Those with comorbidities who are able to continue in the trial will receive the OST and CBT interventions as planned. If the child/young person has a care coordinator, we will liaise with them about any specific needs or symptoms that we should consider and/or monitor throughout intervention delivery. Finally, we will write to the GPs of each child taking part in ASPECT to inform them of the child's participation and group allocation.

8.4.6. Presence of intellectual or developmental disabilities, behavioural or attention problems

Some intellectual and developmental disabilities may mean we have to adapt intervention delivery. Where this is likely (e.g. children with ADHD, autism etc.), sessions will be adapted to

help the child complete the exposure tasks. For example, this may involve more frequent breaks, or to have a trusted adult or other things present (e.g. a favourite toy) to comfort the child. The session may even take place at a child's home if this is common practice at the site, necessary and possible. Materials designed for younger children (e.g. with pictures and cartoons) may be used with adolescents who have intellectual disabilities. OST has been successfully delivered before with a child with behavioural problems and developmental disabilities (Davis, Kurtz, Gardner, & Carman, 2007).

8.4.7. Parental or Peer Involvement

Parents can be actively involved in OST and CBT by providing psychoeducation to the children prior to therapy starting, co-facilitating therapy sessions and helping their children maximise gains and prevent setbacks by planning exposure tasks at home. The role of parental involvement in the treatment of anxiety in children and young people is equivocal and does not always lead to improved outcomes (Breinholst, Esbjørn, Reinholdt-Dunne, & Stallard, 2012). Still, younger children may prefer for their parents to be present during therapy sessions especially if they suffer from separation anxiety disorder. Adolescents may prefer that they attend therapy sessions independently of their parents but they may wish to have a friend or a sibling with them. Looked after children/children in care can have another adult (e.g. LAC nurse) to help with treatment and provide follow-up data.

8.4.8. Service and Practitioner Capacity

In some services, practitioners may be able to visit the children in their own home or go out to public places, such as schools, to carry out the exposure tasks. In others services, home visits or therapy in non-clinical areas may not be feasible due to practicalities or liability issues. Also, some services may require or prefer to have two therapists attend home visits (e.g. for

safety) or deliver the 3-hour OST session, whereas others may only be able or prefer to use one therapist.

8.5.Assessment of Fidelity

OST and CBT sessions will be audio-recorded whenever possible following informed consent from the child/parent. A random selection of 15% of participants at each site (or the nearest whole number) will have one therapy session (both OST and CBT) reviewed by a supervisor at quarterly intervals. Supervisors will score the recorded sessions to assess therapist competence and fidelity to OST and CBT delivery using the OST Rating Scale (OST-RS) (Ollendick et al., 2015) and the Cognitive Behaviour Therapy Scale for Children and Young People (CBTS-CYP, Stallard et al., 2014) respectively. These will be used in supervision to improve fidelity to the intervention and address training needs for the therapists as per usual practice.

9. Monitoring of Adverse Events

An Adverse Events form will be used to record any untoward occurrence effecting 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

9.1.Possible Expected Adverse Events

Due to the nature of the interventions offered in the trial, some adverse events can be expected (although unlikely). For example, common physical health problems that are sensitive to high anxiety such as asthma, eczema or gastritis may be exacerbated by aspects of the interventions (i.e. exposure to phobic stimulus). Similarly, participants may be at risk of fainting to exposure to a phobic stimulus (i.e. blood, injury and injection phobias). Furthermore, highly unlikely, but still possible, expected adverse events include exacerbation of heart problems due to increased blood pressure, triggering of fits (epileptic, or not) due to increased anxiety and increased self-harm in those with a history of these problems. Finally, although unlikely, there is a small risk associated with the presence of animals during the outcome assessments and OST intervention session. Related and unexpected (i.e. not listed above) SAEs will be reported to the REC within 15 days of the research team becoming aware of the event. The DMEC/TSC will immediately be informed of all unexpected SAEs thought to be treatment related and all other SAEs at the next scheduled meeting.

10. Data Analysis

10.1. Sample Size Calculation

To our knowledge, no systematic review has examined the effect of CBT on specific phobias as measured by the BAT in children. Consequently, the assumptions for the proposed sample size and non-inferiority margin are based on two separate Cochrane reviews looking at the effects of psychotherapy for those experiencing anxiety. Firstly, Wolitzky-Taylor, Horowitz, Powers, and Telch (2008) conducted a review on studies that used both behavioural measures

and self-report questionnaires on adults with specific phobias and reported an overall, large effect size of $d = 0.81$. However, as the treatment may have a different effect on children, we also examined Reynolds, Wilson, Austin, and Hooper (2012). This review was conducted on studies of children with specific phobias but used self-report questionnaires rather than the BAT. This review also reported a large effect size ($d = 0.85$) for multi session CBT.

Consequently, prior meta-analyses suggest that a standardised mean difference of around 0.8 on the BAT scale is clinically important. Therefore, we set the non-inferiority margin to be half of this at 0.4 (Jones et al 1996). Assuming a correlation of 0.5 between baseline and final BAT measure, we would require 200 participants (100 in each arm) to have 90% power with a 2.5% one-sided significance level to demonstrate non-inferiority of One Session Treatment (OST) compared to cognitive behavioural therapy (CBT). The therapy is delivered by therapists who will see approximately 15 patients each and we anticipate a weak therapist effect (intraclass correlation coefficient (ICC = 0.01)). This clustering will lead to a design effect of 1.14 which increases the number required per arm to 114. We further assume a 20% dropout rate which means 286 (143 per arm) will need to be recruited to the study to demonstrate non-inferiority of OST compared to CBT.

10.2. General Approach to Data Analysis

As this trial is a randomised parallel group non-inferiority trial, data will be analysed and reported according to both CONSORT guidelines (Schulz, Altman, & Moher, 2010) and the non-inferiority trials CONSORT extension (Piaggio et al 2012). Baseline demographic (e.g. age, gender) and outcome measures (e.g. BAT) will be assessed for comparability between groups. Jones, Jarvis, Lewis, and Ebbutt (1996) recommend both per protocol and intention to treat (ITT) analyses for non-inferiority designs. This is because in a comparative trial, where the aim is to

decide if two treatments are different, an ITT analysis is generally conservative, the inclusion of protocol violators and withdrawals will usually make the results from the two treatment groups more similar. However, for an equivalence or non-inferiority trial this effect is no longer conservative, any blurring of the difference between the treatment groups will increase the chance of declaring equivalence. We follow this recommendation with the refinement that the main analysis of the primary outcome will be per protocol (or completers only) with sensitivity analysis on the ITT population (Piaggio et al., 2012). We will require both the 'per protocol' and ITT analyses to demonstrate statistically significant evidence of non-inferiority to declare that the treatment is non-inferior. If the results of the analysis are discrepant (e.g. the ITT rejects the null of inferiority but the 'per protocol' analysis does not, or vice versa) then we will report the conflicting results from both analyses highlighting the inconclusive nature of the results.

10.3. Primary and Secondary Outcome Analysis

The primary outcome (mean BAT score at six months) and the secondary outcomes (ADIS, CAIS, EQ-5D-Y, CHU-9D, RCADS and the goal-based outcome scores) will be compared between groups using mixed effects linear regression with exchangeable correlation to allow for the clustering of outcomes within therapist. The analysis will be conducted controlling for baseline score and stratifying variables (age and baseline phobia severity). The null hypothesis of inferiority will be rejected if the lower limit of the 1-sided 97.5% confidence interval (CI) for the difference is wholly below 0.4 (the range of clinical non-inferiority).

10.4. Missing and/or Spurious Data

We anticipate some dropout/attrition so missing data may be an issue. Case and item missing data will be examined and multiple imputation methods will be used to reduce bias due to any missing responses in both the "per protocol" and the ITT analyses. Where appropriate,

modelling methods that generate robust standard errors in the presence of missing data will be considered.

10.5. Criteria for Early Trial Termination

The internal pilot will run for nine months, at the end of which stop/go criteria will be used to determine the premature termination of the trial. Stop/Go criteria will be based on the feasibility of recruitment and retention, as well as safety outcomes. We anticipate a recruitment rate of 12 children with a specific phobia per month alongside a retention rate of 80% at 6-months follow-up. An overall stopping criterion of 75% of the recruitment target (n = 81) will be set. At this point we expect the six month follow-ups of participants recruited in the first three months (n = 36) and 70% retention (n = 32) of these will be set as stop/go criteria. As the trial exposes children to feared objects, a Data Monitoring and Ethics Committee (DMEC) will review the data at the end of the pilot and every 6 months throughout the trial for safety. The DMEC may advise the TSC if there is evidence of harm due to the interventions or assessments and the trial may be stopped.

10.6. Economic Evaluation

We plan to conduct an economic evaluation from the UK personal and social services perspective. This will take the form of a within-trial cost-effectiveness analysis to determine the incremental cost per unit of quality-adjusted life years (QALYs) of OST compared with CBT in children with specific phobias. Costs will be calculated based on; i) resources required to deliver the interventions; and ii) individual-level use of health and social services and absenteeism from work over the study period. Resource use will be multiplied by unit costs to arrive at total cost in each arm. QALYs will be calculated by measuring health-related quality of life using the self-

reported EuroQol EQ-5D-Y instrument over the study period. Details of the data required for the cost-effectiveness analysis are presented below.

10.6.1. Resource Use

The resources required to deliver the OST intervention will be calculated using bottom-up estimation of the time spent by professionals as well as other resources used (including phobic stimulus acquisition, i.e. animal hire). Individual-level service use data will be based on self-reported use of primary and secondary health care as well as social care. Hence, any additional therapies received in either arm during the trial period will also be recorded and the associated resource use included in the cost-effectiveness analysis. We will also collect data on productivity loss due to absenteeism from work to care for the child. Also, absences of the child/adolescent from school or college over the study period will be recorded. All resource use data will be collected using a bespoke resource utilisation questionnaire developed by the health economist and the project team (see section 4.2.8).

10.6.2. Unit Cost

Unit costs of health and social service use will be obtained from the UK national database of reference costs (Department of Health, 2016) and the Unit Costs of Health and Social Care report produced by the Personal Social Services Research Unit (Curtis & Burns, 2015). The cost of medication will be based on the most recent version of the British National Formulary (BNF) publication (Royal Pharmaceutical Society of Great Britain, 2016).

10.6.3. Effectiveness

Effectiveness will be measured using the EuroQol EQ-5D-Y instrument which measures quality of life on five dimensions (i.e. mobility, self-care, usual activities, pain/discomfort and anxiety/depression). Individual-level responses on the EQ-5D-Y will be used to estimate health-

related quality-of-life (HrQoL) based on a UK population valuation set. Subsequently, an area under the curve approach will be used to calculate quality-adjusted life years (QALYs) for each child. QALY is a utility-based measure, i.e. it measures each person's health state in terms of quality of life dimensions and then weights it on the value or utility of the health state based on UK population preferences (Whitehead & Ali, 2010). The research team has conducted a focused literature search and found only a small number of studies (including RCTs and observational studies) on phobia in this population. However, none of these include long-term longitudinal follow-up; therefore, we found that there is not enough evidence to allow long-term modelling of costs and outcomes. Hence, the analysis will focus on producing robust cost-effectiveness evidence within the trial follow-up period.

10.6.4. Analysis

The primary analysis will be cost-utility analysis conducted over the trial follow-up period. Total costs, including the intervention cost and service utilisation costs, and QALYs will be compared between the intervention and control groups. Unadjusted costs and outcomes will be presented in descriptive analysis using parametric and non-parametric tests. The statistical analysis will compare mean costs and QALYs using a regression model based on an ITT approach. The regression analysis will control for baseline differences in utility (Manca, Hawkins, & Sculpher, 2005) and other baseline characteristics such as age and gender. The specification of the model will follow the approach recommended by Glick, Doshi, Sonnad, and Polsky (2014) which considers the distribution of the dependent variable as well as any correlation between the cost and QALY outcomes. The regression coefficient on treatment will then represent the difference in mean cost and mean QALYs between groups. A Bootstrap method will be used to produce confidence intervals around the cost and QALY differences due

to the likely skewness in the distribution of regression residuals (Hoch, Briggs, & Willan, 2002). To present this in the UK decision-making context, the results will be in the conventional form of a cost-effectiveness acceptability curve (CEAC). CEAC presents the probability of the intervention being cost-effective over a range of willingness-to-pay (WTP) thresholds per QALY (Fenwick, O'Brien, & Briggs, 2004). The higher the probability, the more likely it is that the treatment is cost-effective at the particular WTP threshold.

10.6.5. Sensitivity Analysis

The following sensitivity analyses will be conducted; i) a cost-utility analysis using the CHU9D instrument instead of EQ-5D; ii) a cost-effectiveness analysis using a phobia-specific measure instead of a utility-based measure; and iii) cost-utility analysis from a health services perspective.

10.7. Qualitative Analysis

In addition to the planned quantitative analysis, the proposed research will conduct a qualitative investigation to examine the acceptability of OST.

10.7.1. Method

We will invite a sub-sample of trial participants to participate in interviews and use maximum variation sampling to ensure a spread of participants differing in, age, gender, socio-economic background and type of phobia. We will seek written consent (and assent where appropriate) to interview a sample of; i) children receiving OST; ii) their parents/guardians; and iii) clinicians delivering OST across all study sites. With parental consent, we will recruit and interview parents and children separately. The final sample size for the remaining qualitative components of ASPECT (i.e. patients engaging in treatment and professionals delivering treatments) and treatment engagement interviews) 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., in press), we estimate that we will need to complete a maximum of 30 parent and 25 child interviews and 15 interviews with clinicians. Participant recruitment and data collection will be undertaken by an ASPECT researcher who will be unblinded to trial allocation.

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 for parents will focus on phobia experiences, personal and family impact, perceived treatment need, treatment expectations and treatment acceptability (e.g. content, delivery mode, format, setting and facilitation). Child interviews 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, the individual and organisational support required and the perceived suitability OST for the identified client group.

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.

Clinician interviews will take place face to face in clinic settings or over the telephone when their involvement in the trial is complete.

10.7.2. Analysis

All interviews will be digitally recorded and transcribed verbatim, with participant consent. Analysis will follow a qualitative framework approach (Ritchie, Spencer, Bryman, & Burgess, 1994), a widely used method of analyzing 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.

Data coding will be undertaken independently by two trained researchers. We will additionally train a PPI (parent representative) coder to work alongside these researchers, and to ensure coding takes account of potential differences in perspective. Coders will meet regularly to develop a shared coding manual and to ensure that all emerging codes remain grounded in original data. An Excel spread sheet 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 professionals) 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.

10.7.3. Ethical Considerations

The key ethical issues for the qualitative aspect of the study include confidentiality, participant anonymity, and informed consent to participate in research. Whilst the risk is small, there is a small possibility that participants might become distressed by disclosures about their own experiences during interviews and there may be disclosures relating to professional practice. A distress policy will be developed in consultation with the advisory team and a clinical lead will be identified to seek advice and guidance from should the need arise. The information sheets will provide potential participants with information about the study, including the potential benefits and risks of taking part and information on anonymity and confidentiality.

11. Data Management

11.1. Data Collection Tools

The content of all validated measures used in this trial will not change; however, the Clinical Trials Research Unit (CTRU) will reformat the outcome measures in order to standardize their appearance and layout where possible. All measures are patient reported and will form the basis of all source data during this trial.

11.2. Data Handling and record keeping

Trial data will be extracted from source documents and entered onto the CTRU's in-house data management system (Prospect). Prospect stores data in a PostgreSQL database on virtual servers hosted by Corporate Information and Computing Services (CiCS) at the University of Sheffield. The database uses industry standard techniques to provide security; including password authentication and encryption using SSL/TLS. Access to Prospect is

controlled by usernames and encrypted passwords. A comprehensive privilege management feature ensures only the minimum amount of data required is available to each individual to complete their tasks. The system has a full electronic audit trail and is regularly backed up. Output for analysis will be generated in a format, and at intervals, to be agreed between Sheffield CTRU and the CI. Participant names and contact details will be collected and entered on the Prospect database. Access to these personal details will be restricted to users with appropriate privileges only. All users who do not require access to identifiable data will only identify data by a unique participant ID number, and no patient identifiable data will be transferred from the database to the statistician. All data will be collected and retained in accordance with the Data Protection Act 1998 and CTRU standard operating procedures (SOPs).

11.3. Data Access and Quality Assurance

The sponsor will permit monitoring and audits by the relevant authorities, including the HRA. The CI will also allow monitoring and audits by these bodies and the sponsor, providing direct access to source data and documents, including the database. The CTRU data management system incorporates quality control to validate study data. Validation reports will be run regularly to check the study data for completeness, accuracy and consistency. Discrepancies will be generated and managed to resolution. The central study team will work with research assistants to ensure the quality of data provided. Data monitoring and audits will be conducted in accordance with the CTRU SOPs.

11.4. Archiving

Study documentation and data will be archived at a suitable time following database lock. All essential study documents will be retained as part of the Trial Master File (TMF) and

individual site files. After notification of study completion, all documentation and study data will be stored securely for five years and will be accessible for inspections and audits.

12. Monitoring, Audit and Inspection

Trial monitoring procedures and site monitoring will be undertaken at a level appropriate to a risk assessment performed by the Sponsor and the CTRU according to CTRU SOPs, and significant findings will be presented to the appropriate oversight committee. Three committees will be established to govern the conduct of this study;

1. A Trial Steering Committee (TSC)
2. An independent Data Monitoring and Ethics Committee (DMEC)
3. A Trial Management Group (TMG)

These committees will function in accordance with Sheffield CTRU SOPs. The TSC will consist of an independent chair, an independent subject specialist, an independent clinical academic, an independent statistician and a patient representative. The Committee will meet approximately every 6 months from the start of the trial. The DMEC will consist of an independent chair, an independent statistician, and an independent ethics specialist experienced in research with children and families. The TMG will comprise of the co-applicants and the two trial managers who will be jointly supervised by the CI, the Director of the Sheffield CTRU and a lead trial manager in the CTRU. Meeting attendance of the co-applicants will depend on the agenda and relevance to their role.

13. Ethical and Regulatory Considerations

13.1. Health Research Authority (HRA) Review and Reports

We will seek ethical approval in line with NHS Research Ethics Committee (REC) and HRA guidance. No pharmaceutical compounds or medical devices are used in this trial, therefore

Clinical Trials Authorisation is not required. Separate research governance approval will be required from each of the areas in which participants are to be recruited. Changes to study documents will be reviewed and approved in line with HRA requirements and annual reports will be sent to the HRA.

13.2. Peer Review

The proposed trial has been previously peer reviewed in line with National Institute for Health Research (NIHR) Health Technology Assessment (HTA) funding process.

13.3. Public and Patient Involvement (PPI)

We are committed to the involvement of patient and public representative at all stages of the proposed research. The original research proposal was developed in consultation with the phobia charity 'Triumph Over Phobia', with their development manager, Trilby Breckman, named as a co-applicant on ASPECT. We have also engaged with the York Youth Council, who are a group of young people aged 11-18, who come from all over the city to make a positive difference to young people in York. In addition to commenting on study documentation, the York Youth Council have provided input on the methodology of the trial and the potential impact of the therapy on the community. We will continue to work with these groups throughout ASPECT and incorporate suggestions and feedback where appropriate and possible. Finally, we recognise the need for independent qualitative data analysis, and will train a PPI representative to assist with the qualitative data analysis. The PPI representative will be reimbursed for their time, commensurate with current INVOLVE guidelines.

13.4. Protocol, GCP and Regulatory Compliance

Non-compliance with Good Clinical Practice and protocol deviations will be monitored and recorded by the ASPECT study team in accordance with standard operating procedures.

13.5. Financial and Competing Interests

Co-applicant, Dr. Thompson Davis, has published a practical reference and training guide for One Session Treatment which will form the basis of the OST delivered in the proposed trial (Davis et al., 2012). There are no other financial and/or competing interest to declare.

13.6. Indemnity and Insurance

To meet the potential legal liability for harm to participants arising from the design, conduct and management of the research, NHS employees will be covered by NHS indemnity and university employees will be covered by their institutions insurance. Participants will be treated in the NHS, or in services already treating NHS patients and will be covered by NHS indemnity.

14. Dissemination Policy

The research team has a strong track record of successful dissemination of work funded by the NIHR and other funding bodies. We will begin to consider our dissemination strategy at an early stage of the project. We will aim to publish the results of each phase of our study in high profile mainstream and specialist science journals, such as the *British Journal of Psychiatry*, the *Journal of Child Psychology and Psychiatry*, and *Clinical Child Psychology*. Presentations of study findings will be taken to relevant research conferences, local research symposia and seminars for CAMHS, child health and educational professionals. In addition, the Triumph Over Phobia and members of service user groups will be consulted in the development of methods and dissemination which will be effective in reaching families of children with specific phobias. Additionally, we will publish a short summary of the results on the ASPECT study website that can be accessed by all trial participants as well as relevant interest groups, including patient groups. Finally, we will aim to ensure coverage of our findings in the wider media by issuing a

press release. Towards the end of the trial, our PPI representatives will organize a meeting with stakeholders including parents and professionals working with young people with anxiety disorders to specifically discuss the dissemination of the study findings and put together a dissemination plan. This will be presented at the trial management group and any additional dissemination plans will be added. Depending on findings, we will make suggestions to NICE about treatment evidence.

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