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Alleviating specific phobias experienced by children trial (ASPECT)

Submission date
28/11/2016

Recruitment status
No longer recruiting

Registration date
30/11/2016

Overall study status
Completed

Last Edited
19/01/2023

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
A specific phobia is a type of anxiety disorder which causes an overwhelming and unbearable fear and avoidance of whatever is causing the fear (e.g. an animal, situation, activity, etc.). It is estimated that between 5% and 10% of children have a specific phobia which impacts on their everyday lives and lasts for an average of about 20 years. Despite this, fewer than 10% report asking for help with their phobia. Specific phobias can cause distress and considerable problems at home and school and interfere with day-to-day activities. The most common treatment for specific phobias in the UK is Cognitive Behavioural Therapy (CBT), a type of talking therapy that uses different techniques to help people to change unhelpful patterns of thinking around specific phobias. However, CBT usually requires multiple sessions and so it is expensive in terms of time. Additionally, people need to attend several sessions which can result in them not completing them all. A promising alternative to CBT is One Session Treatment (OST). 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. However, OST has not been compared to the routine and most successful treatment for specific phobias, CBT. The aim of this study is to find out whether specific phobias can be successfully treated using OST.

Who can participate?
Children aged between 7 and 16 who have at least one specific phobia.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive Cognitive Behavioural Therapy (CBT). CBT is the most commonly used type of psychological therapy and involves helping people to understand their thought processes and behaviours. CBT is usually the routine choice of treatment for a phobia and typically involves between 6 to 12 hour-long sessions. Those in the second group receive a type of psychological therapy called One Session Treatment (OST). OST uses the same techniques as CBT in that OST tries to help participants understand and change their behaviours. However, instead of taking 6 to 12 hour

long sessions, OST takes only one, 3-hour session to complete. OST is therefore quicker and less time consuming that CBT. Participants in both groups are followed up after six months to find out if the therapy has had any effect on their phobia.

What are the possible benefits and risks of participating?
Through participating in this research participants will receive access to therapy (either OST or a CBT-based therapy) to help them with their phobia. It is hoped that the therapy they receive will be successful in reducing the severity of their phobia and the impact it has on their day-to-day life. All therapies used within this research are safe to use and will be delivered by trained professionals. There are no notable risks involved with participating. All the therapies we are using have been used many times before and are perfectly safe. Additionally, there will be trained research staff on hand and participants will never have to do anything they do not want to.

Where is the study run from?
The study takes place within Improving Access to Psychological Therapy (IAPT) centres and Child and Adolescent Mental Health Services (CAMHS) across North East North Cumbria, Leeds, York, Sheffield and Norfolk (UK)

When is the study starting and how long is it expected to run for?
April 2016 to March 2020

Who is funding the study?
Health Technology Assessment Programme, National Institute for Health Research (UK)

Who is the main contact?
Ms Katie Biggs, c.e.biggs@sheffield.ac.uk

Study website
http://www.sheffield.ac.uk/scharr/sections/dts/ctru/aspect

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA15/38/04

Study information

Scientific 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

Acronym
ASPECT

Study objectives
One Session Treatment (OST) will be shown to be non-inferior to CBT based interventions for specific phobias.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. North East - York Research Ethics Committee, 10/02/2017, ref: 17/NE/0012
2. No pharmaceutical compounds or medical devices are used in this trial, therefore Clinical Trials Authorisation is not required

Study design
Non-inferiority parallel group randomised controlled trial with internal pilot and nested qualitative component

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please contact alex.scott@sheffield.ac.uk (0114 222 0674) for more information.

Health condition(s) or problem(s) studied
Specific phobias

Interventions
Participants will be randomised to either the intervention group or the control group and will be stratified by age and recruitment source using an allocation ratio of 1:1. 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.

Intervention group: Participants randomised to the intervention group will receive One Session Treatment (OST). 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. OST involves a combination of treatment techniques including graduated exposure therapy, participant modelling, reinforcement, psycho-education, cognitive challenges and skills training, consolidated into a single three-hour session.

Control group: Participants allocation to the control group will receive Cognitive Behavioural Therapy (CBT). 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. CBT aims to help a child/young person with specific phobia to
1. Recognise anxious feelings and bodily reactions to anxiety
2. Gradually confront their feared situations until their anxiety subsides
3. Capture and challenge anxious or scary thoughts when faced with a phobic situation or object
4. 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. 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.

Follow-up will take place 6-months after participants have been randomised to receive either OST or CBT. At the follow-up visit, participants will complete the same outcome measures they completed at baseline (e.g. the ADIS, CAIS, RCADS, EQ-5D-Y, CHU-9D, a goal-based outcome measure, and a health utilisation questionnaire).

Intervention Type
Behavioural

Primary outcome measure
The level of fear and avoidance associated with a specific phobia will be assessed using the Behavioural Approach Test (BAT) at baseline and 6 months.

Secondary outcome measures

1. The presence of a specific phobia diagnosis and any accompanying impact of the phobia will be measured using the Anxiety Disorder Interview Schedule (ADIS) at baseline and 6 months
2. The impact of the specific phobia on daily life will be measured using The Child Anxiety Impact Scale (CAIS) at baseline and 6 months
3. The degree of general anxiety and depression will be measured using The Revised Childrens Anxiety and Depression Scale (RCADS) at baseline and 6 months
4. Health related quality of life will be measured using EQ-5D-Y and Child Health Utility-9D (CHU-9D) questionnaires at baseline and 6 months
5. Progress towards a specific goal set by the child and their parent/guardian will be measured using a goal-based outcome measure developed by the study team and based on extant literature at baseline and 6 months
6. Cost effectiveness will be measured using a health resource utilisation questionnaire developed by a health economist and the wider ASPECT research team at baseline and 6 months
7. Fidelity to CBT and OST delivery is measured using the OST Rating Scale and the Cognitive Behavioural Therapy Scale for Children and Young People (CBTS-CYP) at baseline and 6 months.
These outcome measures are not completed by the participants or their parents/guardians. Instead, they are completed as part of routine clinical supervision within Child and Adolescent Mental Health Services (CAMHS) and Improving Access to psychological Therapies services (IAPT).

Overall study start date
01/04/2016

Completion date
01/09/2020

Eligibility

Key inclusion criteria
1. Aged between 7 and 16 years
2. Experience at least one specific phobia as defined by DSM-IV criteria, which will be assessed using the Anxiety Disorder Interview Schedule (ADIS). These criteria are:
2.1. Marked and out of proportion fear to a specific object or situation
2.2. Exposure provokes immediate anxiety
2.3. The phobic situation(s) is avoided where possible
2.4. The avoidance or distress interferes with the person's routine or functioning (e.g. learning, sleep, social activities)
2.5. Present for 6 months or more

Participant type(s)
Mixed

Age group
Child

Lower age limit
7 Years

Upper age limit
16 Years

Sex
Both

Target number of participants
246

Total final enrolment
274

Key exclusion criteria
1. Specific phobias where exposure to the stimulus has the potential to cause harm to the participants, providing the stimulus cannot be safely simulated
2. Specific phobias where exposure therapy is not feasible for the individual child in the context of the study
3. Specific phobias where exposure therapy is not the best first line / available therapy for the individual child'
4. ASPECT will not exclude primarily on the basis of comorbidity; however, as per standard practice, comorbidity will be assessed and monitored by the clinicians and therapists responsible for delivering the therapies. Where comorbidity is likely to impact negatively on the wellbeing of the participants, the participant will be withdrawn from the trial.

Date of first enrolment
01/05/2017

Date of final enrolment
31/01/2020

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
School of Health and Health Related Research
Regent Court
30 Regent Street
Sheffield
United Kingdom
S1 4DA

Sponsor information

Organisation

Leeds and York Partnership NHS Foundation Trust

Sponsor details
First Floor, South Wing
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00n635c12

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication of the results of each phase of the 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, a short summary of the results will be published on the ASPECT study website that can be accessed by all trial participants as well as relevant interest groups, including patient groups. Finally, coverage of findings in the wider media will be ensured by issuing a press release. Towards the end of the trial, 'patient and public involvement (PPI) representatives will organise 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, suggestions will be made to NICE about treatment evidence.

Intention to publish date
01/09/2022

Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	17/08/2018	23/10/2019	Yes	No
Basic results		25/03/2022	25/03/2022	No	No
Results article	Cost-effectiveness	12/08/2022	15/08/2022	Yes	No
Results article	Primary data	01/08/2022	15/08/2022	Yes	No
Results article	Primary data Health Technol Assess	31/10/2022	02/11/2022	Yes	No
Other publications	Qualitative paper	15/09/2022	19/01/2023	Yes	No
Statistical Analysis Plan	version 2		19/01/2023	No	No
HRA research summary			28/06/2023	No	No