ISRCTN34766613 https://doi.org/10.1186/ISRCTN34766613

Specific phobias in children with learning disabilities (SPIRIT)

Submission date
17/05/2021

Recruitment status
No longer recruiting

Registration date
05/07/2021

Overall study status
Completed

Last Edited
07/10/2024

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
A large number of children with learning disabilities have significant fears or phobias. These can, for example, include a severe fear of dogs or other animals, visiting the dentist, or having an injection. There is good evidence that talking psychological therapies are an effective treatment for fears, but many of these treatments have not been tested for use with people who have learning disabilities.

Aims: We will work with young people with learning disabilities, carers and family members, and therapists to adapt an existing treatment for dog phobia in adolescents with severe learning disability. We will also complete a feasibility study to try out our treatment and get feedback from participants and their families. We will also collect information about what treatment people are currently receiving, and test out some measures.

Who can participate?
Young people (age 5 – 15 years) with learning disabilities, carers and family members.

What does the study involve?
In the first phase, we will change an existing treatment together with young people with learning disabilities, parents, carers and therapists. We will use action research methods to both change our treatment and examine several possible outcome measures for use in the feasibility study. We will describe the treatments and supports (Treatment as Usual; TAU) that young people are receiving by completing a UK survey of parents who have a child who has a learning disability and a phobia, along with interviews with health professionals who work with children with learning disabilities.

In the second phase, we will complete a study of our treatment with up to 20 participants who will receive the treatment plus TAU. We will interview parents and therapists about their experiences of taking part in the study. This will allow us to understand the acceptability and experience of receiving the treatment.

Patient and Public Involvement
We want young people with learning disabilities, carers, and family members, involved in our

study. They will be part of the project steering group that is in charge of the study. The Foundation for People with Learning Disabilities will also help with this study. They will help us prepare our paperwork, find people to be in the study, and tell people about the study and what we find out.

What are the possible benefits and risks of participating?
Benefits:
While we do not know whether the treatment is likely to be beneficial for children and adolescents with moderate to severe learning disabilities, there is a possibility that the treatment may result in an improvement of symptoms associated with specific phobia. The aim of this study is to try out the treatment and seek feedback from participants and their families to decide if a larger trial is needed.

Risks:
Since the treatment involves exposure-based elements, there is a risk of temporary distress to the participants. This will be minimised by carefully planning the treatment. The study has been categorised as low risk.

Where is the study run from?
The University of Warwick (UK) with help from the Foundation for People with Learning Disabilities, University of Reading, University of East Anglia, Evelina London, and Cardiff University

When is the study starting and how long is it expected to run for?
From January 2021 to March 2023

Who is funding the study?
National Institute for Health Research (NIHR) (UK).

Who is the main contact?
Dr Magdalena Apanasionok (Study manager)
SPIRIT@warwick.ac.uk

Contact information

Type(s)
Public

Contact name
Dr Magdalena Apanasionok

ORCID ID
http://orcid.org/0000-0002-3861-3801

Contact details
Centre for Educational Development, Appraisal and Research (CEDAR)
University of Warwick
Coventry
United Kingdom

CV4 8UW
No telephone contact available
SPIRIT@warwick.ac.uk

Type(s)
Scientific

Contact name
Prof Kylie Gray

ORCID ID
http://orcid.org/0000-0001-6518-4240

Contact details
Centre for Educational Development, Appraisal and Research (CEDAR)
University of Warwick
Coventry
United Kingdom
CV4 8UW
No telephone contact available
SPIRIT@warwick.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
295630

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 48695, IRAS 295630

Study information

Scientific Title
Specific phobias in children with learning disabilities (SPIRIT): An adaptation and feasibility study

Acronym
SPIRIT

Study objectives
To examine the feasibility of conducting a definitive trial of the SPIRIT intervention to treat specific phobia in children and adolescents with moderate to severe intellectual disabilities.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 26/04/2021, Edgbaston Research Ethics Committee (3rd Floor Barlow House; Minshull Street; Manchester M1 3DZ; +44 (0)20 7104 8112; edgbaston.rec@hra.nhs.uk), ref: 21/WM/0072

Study design
Interventional non-randomized trial

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Learning disorders - child

Interventions
Phase 1a (Intervention Adaptation)
We will establish an Intervention Adaptation Group (IAG) comprised of 6 to 8 key stakeholders who will be representatives from our PPI partners, family members, people with autism and/or intellectual disabilities, and clinicians, along with members of the research team. This group will be led by the Chief Investigator. We will use coproduction, and working together with stakeholders, we will use action research over a series of five meetings over four months to: define the needs and problems that are to be addressed for children with moderate to severe intellectual disabilities, define the intervention objectives, with reference to the likely barriers, adapt the existing manualised intervention, develop a logic model, develop a fidelity checklist, based on approaches that have been successful in our recent LD trials within UK NHS settings, advise on recruitment pathways, establish how to measure outcomes and consider the challenges or barriers to our evaluation plan, including likely to solutions.
Feedback will be sought at each meeting, and following reflection, subsequent refinements will be made to the manual and fidelity checklist by the research team which will be presented to the IAG at the next meeting leading to a final version. This will ensure that our approach is problem-focused and cyclical, allowing for repeated episodes of reflection and action during and between meetings (Leykum, Pugh, Lanham, Harmon, & McDaniel, 2009). We will make use of our existing intervention that was previously developed for the treatment of dog phobia amongst adolescents with severe learning disabilities and limited communication skills (Williams et al., 2018; Burton et al., 2017), and adapt it for use with children and adolescents who have moderate to severe intellectual disabilities and with phobia related to any specific stimulus, as defined by the DSM-5 (Animal, Natural Environment, Blood-injection injury, Situational, Other). The outcomes from Phase 1 will be: an adapted intervention manual that can be tested within a

feasibility study, a fidelity checklist, and candidate outcome measures for use within our feasibility study.

Phase 1b (TAU Survey) Design
This will be an online survey of parents of children (aged 5 to 15 years) with specific phobia and moderate to severe learning disabilities living in the United Kingdom to characterise TAU. Our survey will include questions that are informed by the Template for Intervention Description and Replication (TIDieR) checklist. The TIDieR checklist is used to provide a description of an intervention, including the use of any associated materials. Who, how and where an intervention is delivered is also described as well as the associated dose and modifications. Our online survey will be delivered using Qualtrics. Setting. We will utilise our existing Midlands and wider UK networks of schools, support groups, charities, our PPI partner (the Foundation for People with Learning Disabilities) to disseminate the online survey to parents of children and adolescents throughout England, Wales, Northern Ireland, and Scotland. We will also use our existing LD health professional networks, together with the local NIHR Clinical Research Network. We aim to recruit minimum of 50 parents.

Phase 1b (TAU Interviews) Design
We will also conduct a series of telephone interviews with Learning Disability professionals, service providers, and commissioners. The interviews questions will mirror those in the parent survey, adapted for service providers.
Setting. We will utilise the Child and Adolescent Intellectual Disability Psychiatry Network in the UK to recruit the LD professionals for the interview. We may also recruit from similar clinical psychology networks of which co-applicants are members. We will also work with the Research in Developmental Neuropsychiatry (RADiANT) consortium of NHS providers to recruit professionals for the interviews. RADiANT is a consortium of NHS service providers which works in collaboration with academics in a number of universities. It seeks advice from service users, patients, families, charities, community leaders and a range of statutory bodies and organisations. RADiANT focuses on mental health and behavioural issues associated with five developmental conditions- intellectual disabilities, autism, attention deficit hyperactivity disorder, epilepsy and acquired brain injury. It is hosted by Hertfordshire Partnership University NHS Foundation Trust (HPFT), and multiple NHS Trusts are partners who have committed to actively supporting and taking part in research studies within the aforementioned five developmental conditions, including the lead NHS Trust for the current application, Coventry and Warwickshire Partnership NHS Trust. Worcestershire Health and Care NHS Trust are an additional partner in this project and a full member of RADiANT (https://radiant.nhs.uk). We aim to recruit 25 learning disability professionals.
Descriptive statistics will be used to analyse the results of the parent survey, and the interview data will be managed and analysed using NVivo.

Phase 2 (Feasibility Study) Design
We will make use of our existing treatment manual, which will have been adapted within Phase 1 of the current study, and complete a feasibility study to model the exposure-based intervention and determine its acceptability and feasibility for stakeholders including service users, parents and clinicians who are delivering the intervention in according with the MRC Framework for developing and assessing the feasibility of complex interventions (Medical Research Council, 2006; O'Cathain et al., 2019). Further refinements to the manual are anticipated as a result.
We will include a single-arm non-randomised feasibility study of exposure-based intervention plus TAU for the treatment of specific phobias amongst children with moderate to severe intellectual disabilities, and the use of qualitative and quantitative research methods to help address key components of feasibility. Recruitment will be open to participants aged 5 to 15 years with moderate to severe intellectual disabilities who have specific phobias within England

and their parent carers. The intervention is a parent skills training intervention. We anticipate that the adapted intervention will consist of two parts: a parent/carer skills training group workshop (over 1 day), and weekly therapist support telephone calls with individual parents for up to 7 weeks. Therapists will receive training in the intervention.
Participants will be assessed at three times points: screening, assessment within 4-weeks before the commencement of the intervention, and assessment within 4-weeks of the completion of the intervention. Additional components of feasibility (e.g. acceptability) will be assessed using semi-structured interviews and qualitative analysis.

Setting. The study will take place within NHS child learning disabilities services, and/or specialist LD or mainstream child and adolescent mental health services in England (Coventry and Warwickshire Partnership NHS Trust; Worcestershire Health and Care NHS Trust. We will use a multi-point recruitment strategy incorporating specialist community teams for children with intellectual disabilities, advocacy and family support groups, mental health teams, the voluntary and charitable sector, special education settings, self-referral, and through our PPI partners associated networks, specifically the Foundation for People with Learning Disabilities. We aim to recruit up to 20 children and adolescents with their parent carers. The steps in the pathway for the feasibility study are as follows:
1. All participants who provide consent will be screened by research staff to ensure they meet the eligibility criteria for the study
2. Following baseline assessment, participants who meet eligibility criteria will be assigned to receive the behavioural intervention plus TAU
3. Participants will then be assessed using our outcome measures within 4-weeks following the completion of the intervention
4. A subsample of participants and their parents and therapists will be asked to take part in semi-structured interviews following the intervention process to further ascertain acceptability and the experience of the intervention the study pathway, and procedures, consent, and associated factors to create a description of factors that promote or challenge the implementation of the intervention, recognising that those with severe intellectual disabilities may not be able to take part in these interviews, meaning that we will have to rely on parents
5. Through the Study Steering Committee, make a recommendation to the funders for their consideration as to whether a future clinical trial is feasible. This decision will be made by the funder once the study results are available.

Intervention Type
Behavioural

Primary outcome measure
1. Accrual rate recorded as the number of eligible participants who consent to participate in the study per month over 7 months.
2. Attrition rate recorded as the number of participants who consent to participate that remain in the study until the end of follow up
3. Response rate recorded as the number of completed assessments per measure at baseline and follow-up (within 4 weeks of completion of the intervention)
4. Therapist adherence to the intervention manual measured with fidelity ratings after the parent skills training workshop and after each telephone support session
5. Acceptability of the intervention and associated study procedures to parents, therapists and participants assessed using semi-structured interviews after the intervention is complete (between November 2021 and March 2022)

Secondary outcome measures

There are no secondary outcome measures

Overall study start date
02/01/2021

Completion date
31/03/2023

Eligibility

Key inclusion criteria
Phase 2:
1. Aged 5 - 15 years
2. Existing diagnosis of moderate to severe LD, confirmed at screening
3. Suspected/diagnosed specific phobia (DSM-5), confirmed at screening
4. Parent/carer able to participate in the intervention

Participant type(s)
Patient

Age group
Child

Lower age limit
5 Years

Upper age limit
15 Years

Sex
Both

Target number of participants
Planned Sample Size: 115; UK Sample Size: 115

Total final enrolment
97

Key exclusion criteria
Phase 2:
1. Currently receiving another psychological therapy for anxiety
2. Screening indicates anxiety behaviours are likely associated with a physical health condition (e.g. dental problems)
3. No consent obtained to take part in the research

Date of first enrolment
01/07/2021

Date of final enrolment
30/09/2022

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Coventry And Warwickshire Partnership NHS Trust
Wayside House
Wilsons Lane
Coventry
United Kingdom
CV6 6NY

Study participating centre
Worcestershire Health And Care NHS Trust
Unit 2 Kings Court
Charles Hastings Way
Worcester
United Kingdom
WR5 1JR

Sponsor information

Organisation
Coventry and Warwickshire Partnership NHS Trust

Sponsor details
1st Floor, Caludon Centre
Clifford Bridge Road
Coventry
England
United Kingdom
CV2 2TE
+44 (0)2476932430
Kay.Wright@covwarkpt.nhs.uk

Sponsor type
Hospital/treatment centre

Website
https://www.covwarkpt.nhs.uk/

ROR
https://ror.org/01gh80505

Funder(s)

Funder type
Government

Funder Name
NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC); Grant Codes: NIHR130177

Funder Name
National Institute for Health Research (NIHR) (UK)

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
We will write articles which are published in a journal, which will be read by professionals. The protocol will be submitted for publication in a peer-reviewed journal. The Foundation for People with Learning Disabilities will also help us to tell people about the study by writing about it in their newsletter and talking about it in a podcast. They will also talk about what the study found out with young people, parents, carers, and professionals through social media and their website. We will also put information about our study on our website. Together with the Foundation for People with Learning Disabilities, young people, and parents we will have a seminar to talk about the study. We will also talk about the study at conferences.

Intention to publish date
01/07/2023

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a non-publicly available repository (University of Warwick and NHS servers). It may be placed in the public domain as required by either the funder or a peer review journal in an anonymised format.

IPD sharing plan summary

Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Results article		01/10/2024	07/10/2024	Yes	No