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Improving mental health support for children with unusual sensory experiences through a new talking therapy and parent training program

Submission date
29/05/2024

Recruitment status
Recruiting

Registration date
14/06/2024

Overall study status
Ongoing

Last Edited
09/07/2024

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims

Distressing sensory experiences, such as hearing voices, seeing visions, or feeling presences others don't, are often associated with emerging signs of psychosis. Consequently, these experiences are surrounded by stigma, which can make young people and their parents very anxious. It is this anxiety that often leads young people and families to seek help from children's mental health services. Very few of these children will receive a diagnosis of early-onset psychosis, but the anxiety surrounding distressing sensory experiences can cause difficulties for the young person in their day-to-day lives, schooling, and relationships. Anxiety about distressing sensory experiences can make the symptoms more frightening and harder to ignore, which is why it is so important children and families can access timely support. In the UK, there are currently no specialist interventions for these children, even though around half of children in mental health services report distressing sensory experiences, some of whom desperately need tailored support. Many mental health practitioners feel ill-equipped to offer psychological therapies for distressing sensory experiences due to a lack of national clinical guidelines and child-centred research to inform their approach. Therefore, parents, carers and young people can spend years trying to find help. Delayed access to support increases anxiety further, exacerbates family stress and often worsens the original symptoms. Parents have explained: "There is a massive gap in services with zero services being available for someone experiencing voices so young". Without suitable support, the overall well-being of the family can decrease rapidly, reducing their ability to cope.

Building upon the extensive research of the team to date and national stakeholder consultations, this study will trial a new approach to supporting young people and their parents to learn new information and coping skills, which aim to improve their overall well-being and reduce future risks to their mental health. This study aims to evaluate the feasibility and acceptability of conducting a future larger-scale definitive efficacy and cost-effectiveness trial of brief psychological therapy for young people (8-15 years old) with distressing sensory experiences, with an accompanying parent-training programme.

Who can participate?
Young people aged 8-15 years old experiencing distressing sensory experiences and their parent (s)

What does the study involve?
The study has two parts. Firstly, the researchers will ask children and their parents to take part in a short talking therapy intervention and parent-training programme to develop skills and understanding of their distressing sensory experiences. Another group of children will join the study and receive the care that would usually be provided. This intervention will be based in Child and Adolescent Mental Health Services to help children and parents when they initially seek help. Secondly, the children, parents/carers and practitioners who take part will be invited to give detailed feedback about their participation to see what difference the intervention makes, learning from their insights.

What are the possible benefits and risks of participating?
Benefits
1. Improved Understanding and Coping Skills:
Children will learn to understand and manage their distressing sensory experiences, which can reduce anxiety and improve their daily lives.
2. Enhanced Support for Parents:
Parents will gain skills and knowledge through the parent-training program, helping them better support their children.
3. Reduced Anxiety and Stress:
Early and appropriate intervention can help reduce anxiety and stress for both children and their families.
4. Better Day-to-Day Functioning:
With improved coping mechanisms, children may experience fewer disruptions in their schooling, relationships, and overall daily activities.
5. Timely Access to Specialized Care:
Participation in the study provides access to a specialized intervention that is currently unavailable in typical NHS services.
6. Contributing to Future Services:
By providing feedback, participants will help shape future mental health services, ensuring that other children and families receive better support in the future.
7. Overall Family Wellbeing:
Improved mental health support can enhance the overall wellbeing of the family, helping them cope more effectively with distressing sensory experiences.

Risk
1. The proposed intervention offers a novel, tailored and theoretically informed approach to support children already in CAMHS and receiving non-tailored talking therapy. Compared to normal standard practice, the proposed intervention should pose less risk as its development has been theoretically informed and co-produced throughout six years of primary and secondary research, and co-production.
2. Due to the brief nature of the proposed intervention, the frequency of risk should be lower than current practice, which is non-tailored, not standardised, and variable in quality and length.
3. A dedicated trial therapist and highly trained research team will ensure that the intervention is delivered and evaluated to the highest quality, with participant care in mind at all times.

This trial is categorised as Type A = No higher than the risk of standard medical care.

Where is the study run from?
The University of Manchester (UK)

When is the study starting and how long is it expected to run for?
February 2024 to August 2026

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

Who is the main contact?
Dr Sarah Parry, sarah.parry@manchester.ac.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
327343

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 55761, IRAS 327343

Study information

Scientific Title
Improving access to psychological therapies for children with distressing sensory experiences: the feasibility and acceptability of the ChUSE trial, a novel child-focused and parent intervention

Acronym

ChUSE

Study objectives
1. Is the ChUSE intervention acceptable to children/young people with unusual sensory experiences?
2. Is the ChUSE intervention acceptable to parents/carers of children with unusual sensory experiences?
3. Is the ChUSE parent training program acceptable to parents/carers of children with unusual sensory experiences?

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 02/05/2024, Health Research Authority/ Health and Care Research Wales (19 Cowbridge Rd E, Cardiff, CF11 9AB, United Kingdom; +44 (0)2920 230457; healthandcareresearch@wales.nhs.uk), ref: 24/WM/0054

Study design
Feasibility multicentre single-blind parallel-group randomized controlled trial with a nested process evaluation

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Distressing sensory experiences (DSE)

Interventions
The trial will be a single-blind parallel-group RCT with two arms:
1. Brief psychological intervention involving four sessions of talking therapy for the children /young people with distressing sensory experiences, and the optional offer of a three-session parent training program, plus treatment as usual (TAU)
2. TAU alone

The psychological intervention will include the following:
Session 1: Psychoeducation, normalisation, externalisation techniques
Session 2: Multisensory coping strategies based on compassion-focused therapy skills
Session 3: Cognitive appraisal, coping skills practice, simple self-formulation training.
Session 4: Compassion-focused reflection and coping skills consolidation.

The parent program will include:
Session 1:
1. Psychoeducation, normalisation and re-appraisal
2. Therapist-guided, scenario-based, problem-solving Q&A
3. Homework: reading a brief psychoeducation guide

Session 2:
1. Introduction to compassion-focused coping strategies
2. Self-kind self-talk and containment
3. Homework: skills practice

Session 3:
1. Therapist-guided compassionate reflection upon coping skills practice
2. Consolidation of new knowledge and skills

Randomisation will be independent and concealed, via an online pseudo-random list hosted by sealedenvelope.com with random permuted blocks of varying sizes.

Key outcomes will be assessed at baseline (T0), end of intervention (3 months post-randomisation; T1) at which point participants will also be invited to take part in qualitative interviews, and 6 months post-randomisation (T2).

Intervention Type
Behavioural

Primary outcome(s)
The principal feasibility outcomes will be:
1. Trial recruitment measured using study data to calculate the number of family units recruited and randomised per month
2. Trial retention measured using study data to calculate % of participants retained at each assessment point
3. Treatment engagement measured using study data to calculate the number of sessions attended by CYP and parents/carers allocated to the ChUSE intervention + TAU and TAU arm of the trial) at the end of the study
4. ChUSE intervention treatment fidelity measured using study data to calculate the extent to which the trial therapist can deliver the ChUSE intervention with high levels of treatment fidelity) at the end of the study
5. The safety of the ChUSE intervention for young people and parents/caregivers measured using information collected via detailed Adverse Event (AE) forms (e.g., number of AE and SAE related and unrelated to trial procedures and interventions) at the end of the study
6. The uptake of the parent training programme measured using treatment engagement data (i. e., number of parents who accept the PTP offer and number of sessions attended parents /carers) at the end of the study
7. The feasibility of collecting key outcome measures to inform the selection and data collection procedures for the future definitive trial measured using the completeness (i.e. % of missing responses and reasons for missingness) of the aforementioned and below outcome measures at the end of the study

Key secondary outcome(s))
The following secondary outcome measures will be evaluated at baseline, T1 (three months), and T2 (six months) using a range of self-report measures collected from both children and young people (CYP) and their parents/guardians:

The ‘promise of efficacy’ of the ChUSE intervention and the necessary parameters to inform a sample size calculation for a future efficacy trial.

Measures for CYP:
1. Symptom Level measured using:
1.1. Manchester Voices Inventory for Children (MAVIC)
1.2. Unusual Experiences Questionnaire (UEQ)
1.3. Brief Self-compassion Scale

2. Health-related quality of life outcomes measured using:
2.1. Stirling Children's Wellbeing Scale
2.2. EQ-5D-Y
2.3. KidCOPE scale
2.4. Child Health Utility Instrument (CHU-9D)
2.5. Strengths and Difficulties Questionnaire Self-Report version for 11-17 year olds

Measures for parents/guardians:
1. Health-related quality of life outcomes measured using:
1.1. SDQ-parent version
1.2. Adult Wellbeing Scale (parents/carers)
1.3. Parental Stress Scale (PSS), an 18-item questionnaire assessing parents' feelings about their parenting role, exploring positive [e.g. demands on resources, feelings of stress]
1.4. Coping Health Inventory for Parents (CHIP)
1.5. EQ-5D

Completion date
31/08/2026

Eligibility

Key inclusion criteria
Young people and their parent/parent pair (i.e., children and parent/carer dyads) will be eligible if:
1. The child is aged 8-15-years-old and self-identifies as experiencing DSE: due to the current lack of sensitivity of diagnostic or clinical threshold assessments of DSEs, young people who have been referred to CAMHS will automatically be considered eligible for inclusion if they report the presence of DSEs, which will be confirmed by the MAVIC
2. The child is currently under the care of CAMHS
3. At least one parent, primary carer or legal guardian provides consent for trial participation, and in line with Health Research Authority guidance for Research Involving Children, the child provides assent for inclusion into the trial

Participant type(s)
Carer, Service user

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
8 years

Upper age limit
99 years

Sex
All

Key exclusion criteria
Children and parent/carer dyads will be excluded when:
1. Young people unable to engage in conversational English, as the intervention and trial assessments are currently only available in English. If a parent is unable to take part in the PTP, the young person can still engage in the young person's ChUSE intervention.
2. The child experiences a mental health crisis requiring inpatient hospital admission at the time of study enrolment. The intervention is designed to be accessed as an early intervention on an outpatient basis, so those accessing inpatient CAMHS services will not be eligible for inclusion as they may have urgent clinical needs.
3. The child is already enrolled in another mental health clinical trial involving the provision of an active psychological treatment, as concomitant trial participation may be excessively burdensome and influence outcome assessment.

Date of first enrolment
01/09/2024

Date of final enrolment
31/01/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Greater Manchester Mental Health NHS Foundation Trust
Prestwich Hospital
Bury New Road
Prestwich
Manchester
United Kingdom
M25 3BL

Study participating centre
Manchester University NHS Foundation Trust
Cobbett House
Oxford Road

Manchester
United Kingdom
M13 9WL

Study participating centre
Pennine Care NHS Foundation Trust
225 Old Street
Ashton-under-lyne
United Kingdom
OL6 7SR

Sponsor information

Organisation
Greater Manchester Mental Health NHS Foundation Trust

ROR
https://ror.org/05sb89p83

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care 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

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

IPD sharing plan summary

Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes