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Support for young people who are distressed by hearing voices

Submission date	Recruitment status	[_] Prospectively registered
02/01/2024	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
11/01/2024	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
19/05/2025	Mental and Behavioural Disorders	[X] Record updated in last year

Plain English summary of protocol

Background and study aims

Voice hearing experiences are commonly reported by children and can sometimes cause distress.

• We have developed and evaluated a coping intervention that seems to work well when delivered to children within Child & Adolescent Mental Health Services (CAMHS).

• We have also developed and evaluated an educational workshop within CAMHS for people who support children who hear voices, e.g., parents/carers.

• We want to explore the feasibility of offering the coping intervention and educational workshop within an intervention package in schools, where children can get earlier access to help.

The aim of this study is to evaluate the feasibility of offering an intervention package in schools that will include:

• 1:1 sessions for the child

• An educational workshop for Plus-1s

• An educational workshop for school staff

This research will help us to make interventions as effective and as accessible as possible. We hope this will help give as many children as possible the best chance of receiving support when they are distressed by hearing voices.

Who can participate?

The participants will include students within secondary schools and some of the people who support them.

What does the study involve?

The study has 4 phases:

• Phase 1 – groups of students, parents/carers and school staff will review and adapt the intervention package.

• Phase 2 – the adapted intervention package will be delivered to a different set of students, people nominated by the students (we call them ‘Plus-1s’) and school staff.

• Phase 3 – data will be collected from the people who received the intervention package in Phase 2. The analysis of this data will generate some findings.

• Phase 4 – the groups of students, parents/carers and school staff and who met in Phase 1 will meet again to review the findings from Phase 3.

What are the possible benefits and risks of participating?
Possible benefits:
• We have good reason to think that most children who receive the coping intervention will benefit, e.g., by being less upset by the voices they hear.
• We also have good reason to think the workshops will enable supporters and school staff to feel more confident about helping children who hear voices.
• However, we have only tested these interventions within CAMHS. That's why we are carrying out this study, to see how the interventions need to be adapted for use in schools and if the interventions can be helpful in schools.
• By taking part, the participants will be helping us to adapt and test these interventions within the school environment.
• Some of the participants will be offered vouchers for taking part in the study.
Possible risks:
• There is a small chance that some of the discussions in the focus groups and intervention sessions/workshops might be upsetting for participants. If this happens, the researchers will help the participants to cope and will arrange any support required.

Where is the study run from?
Sussex Partnership NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
November 2023 to October 2025

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

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
321846

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 54353, NIHR204939, IRAS 321846

Study information

Scientific Title
Support for young people who are distressed by hearing voices: Preliminary evaluation of a psychological intervention package for delivery through Mental Health Support Teams within secondary schools (the ECHOES study)

Acronym
ECHOES

Study objectives
This study will evaluate an intervention package focused upon coping strategies that has the potential to benefit both the young person and the people who support them. Separate elements of this intervention package have been piloted within Child and Adolescent Mental Health Services (CAMHS). As adolescence provides a crucial window of opportunity for early intervention to prevent suffering and disability and improve life trajectories, the intervention package will be offered and evaluated within schools to maximize accessibility.

The study will address the following questions in relation to the intervention package as it is tested and refined on a small scale:
• Is it acceptable to young people, those who support them, and staff and practitioners within secondary schools?
• What is the optimum content, structure and duration?
• Is delivery feasible for the practitioners and what are their requirements for training and supervision?
• What tools can be used to evaluate impact?

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 24/11/2023, North West - Preston Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 207 104 8181; preston.rec@hra.nhs.uk), ref: 23/NW/0334

Study design

Interventional non-randomized

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Hearing voices

Interventions
Phase 1
Volunteers will be recruited from the 13 secondary schools within Thought-Full. We refer to these individuals as 'volunteers' to differentiate them from the 'participants' who will take part in Phase 2. The opportunity to volunteer will be advertised through the usual promotional channels used by Thought-Full: a weekly email sent to all Senior Mental Health Leads (SMHL) in schools and any other key school contacts (e.g., pastoral managers); weekly contact between the SMHL/key contact and the Thought-Full practitioners in the school can also highlight any key messages; working with schools to identify ways to promote to students and parents (e.g. student and parent mail outs; posters; assemblies; etc). Approximately 12 volunteers will be recruited for each of 3 groups: students, parents/carers and school staff. There will be approximately 36 volunteers in total.
All those who express an interest in volunteering will be sent a Participant Information Sheet and have at least 24 hours to review its contents. Prospective volunteers will be invited to a meeting with the Research Assistant where informed assent/consent will be given and eligibility confirmed. Thereafter, the volunteers will be invited to attend the appropriate volunteer meeting. The method for delivering the meetings of the volunteers (online and/or face-to-face) will be influenced by the geographical spread of the volunteers.
Each group of volunteers will have a separate meeting in the first instance, as the power differentials between the groups may inhibit communication and participation. The initial task for each group of volunteers will include: 1) review the content and materials associated with the coping intervention and the psychoeducational workshop and develop an intervention package for delivery within a school environment; and 2) select tools from a range of options for the
assessment of outcomes. A fourth meeting will bring together volunteers from the three groups and explore any differences in views about the development of the intervention package. In the event of different views not being reconciled, these views will be taken to the Lived Experience Advisory Panel (LEAP) who will make a final decision. The work within this phase will culminate in an intervention package that will be delivered in Phase 2. The volunteers in the student and parent/carer groups will each be reimbursed with a £25 voucher after attending each meeting. The volunteers in the school staff group will not be reimbursed as they will be attending in paid time.

Phase 2
Participants will be recruited from a sub-set of selected secondary schools within Thought-Full. Decisions about the schools to be selected will be guided by the capacity of schools (e.g., availability of Thought-Full practitioners) and the needs of the local population (e.g., indices of deprivation, SEN data, ethnicity data and referrals to established emotional wellbeing community services and CAMHS). Students can be referred through the usual Thought-Full processes via self-referral or via parent/school staff; Plus-1s will be nominated by referred

students and the student will provide the Plus-1 with a PIS and ask them with to contact the research team if they wish to participate; and school staff will self-refer. The opportunity to participate will be advertised through the usual promotional channels used by Thought-full (see Phase 1 for details). We can also work with school staff to refer students to the study (with the student's and parent's consent) who they think may be eligible to the study (e.g., run an information session for Heads of Years/pastoral managers). This could support students who may be worried about self-referring. Approximately 32 participants will be recruited to each of the three groups: students, Plus-1s and school staff (see 'Sample size' section below). All those who express an interest in participating will be sent a Participant Information Sheet and have at least 24 hours to review its contents. Each prospective participant will be invited to a meeting with the Research Assistant where informed assent/consent will be given, eligibility will be confirmed, and baseline measures completed. Thereafter, each participant will be offered the appropriate element of the intervention package; the 1:1 coping
intervention for students; the psychoeducation workshop for the Plus-1s; and a separate psychoeducation workshop for the school staff.

Phase 3
After the completion of the intervention, participants will be invited to a final assessment meeting where measures will be completed, and feedback will be sought. The meetings will be facilitated by Sarah Parry and the Research Assistant and will be offered on a 1:1 basis for student participants and as separate focus groups for Plus-1 participants and school staff participants. The meetings will take place either in person or remotely, dependent upon the location, availability and preferences of the participants. The EMHPs and SMHPs who deliver the intervention package will be invited to a separate focus group to reflect upon their experience and will be asked to provide an anonymous written reflection, which will ensure we account for biases inherent in face-to-face qualitative work where the designers of the intervention also evaluate the process. The student participants and Plus-1 participants will be reimbursed with a £20 voucher after attending each of the assessment meetings (baseline assessment and final assessment). The school staff participants will not be reimbursed as they will be attending assessment meetings in paid time.

Phase 4
The three groups of volunteers who worked on Phase 1 will be invited back to revise the intervention package in the light of the learning from Phases 2 and 3. The process will be the same as Phase 1, whereby the groups will meet separately before coming together for a final meeting. Any differences of view that cannot be reconciled will be taken to the LEAP for a final decision. We will maintain contact with the volunteers during the months between Phases 1 and 4
to facilitate ongoing engagement. This contact will take the form of regular updates and newsletters. The volunteers in the student and parent groups will each be reimbursed with a £25 voucher after attending each meeting. The participants in the school staff group will not be reimbursed as they will be attending in paid time.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)

Assessment of feasibility:
1. The number of students, Plus 1s and teaching staff who offer to become participants
2. Amongst the students, Plus 1s and teaching staff offering to be participants, the number and proportion who are found to be eligible
3. The number and proportion of consenting participants who complete an intervention and offer full data sets
4. Feedback from volunteers and participants during Phases 3 and 4 on the content, structure and duration of the interventions
5. Feedback from practitioners during Phase 3 about the feasibility of intervention delivery for the MHST practitioners.
6. Feedback from volunteers during Phase 4 on the tools used to evaluate the impact of the interventions.

Key secondary outcome(s))
Clinical measures of outcome - the selection of outcome measures for use in Phase 2 will be guided by the consultations with volunteers in Phase 1

Completion date
02/10/2025

Eligibility

Key inclusion criteria
Volunteers (Phases 1 and 4):
1. Students – will be students within Years 7-11 (ages ranging from 11-16 years) at one of the 13 schools served by Thought-Full. There will be no criterion related to personal experience of hearing voices and/or mental health problems. The students will need to be willing and able to provide written informed assent. Assent to approach the student's parent/carer will be required for all students. The parent/carer of the students will need to give written informed consent.
2. Parents – will be a parent of a student within Years 7-11 at one of the 13 schools served by Thought-Full. There will no criterion related to the student or the parent having personal experience of hearing voices and/or mental health problems. It will be permitted (but not required) for the parent's child to be a volunteer within the student's group.
3. School staff – will be permanent members of staff at one of the 13 schools served by Thought-Full. There will be no criterion related to the staff having pastoral responsibilities within the school.

Participants (students – Phases 2 and 3):
1. Attending one of the schools selected for participation in Phase 2
2. Within Years 7-11 of the selected schools
3. Willing and able to provide written, informed assent. Assent to approach the student's parent /carer will be required for all students. The parent/carer of the student will need to give written informed consent.
4. Reporting a current voice hearing experience - operationalised by participants having a score of at least 1 on item 1 on the Hamilton Program for Voices Questionnaire (HPSVQ)30 – indicating that the participant has experienced at least one episode of voice-hearing in the past week
5. Reporting that voice hearing experiences are causing distress – operationalised by a score of at least 8 (range from 0–16) on the negative impact scale of the HPSVQ
6. Not a volunteer within this study

Participants (Plus-1s – Phases 2 and 3):
1. Nominated by one of the student participants
2. Aged 16 years or over
3. Willing and able to provide written, informed consent.
4. Not a volunteer within this study
5. Not a student within secondary education.

Participants (school staff – Phases 2 and 3)
1. A member of permanent staff at one of the selected schools
2. Willing and able to provide written, informed consent
3. Not a volunteer within this study

Participant type(s)
Learner/student, Other

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/01/2024

Date of final enrolment
31/07/2025

Locations

Countries of recruitment
United Kingdom

Study participating centre
Sussex Partnership NHS Foundation Trust
Trust Hq
Swandean
Arundel Road
Worthing
United Kingdom
BN13 3EP

Sponsor information

Organisation
Sussex Partnership NHS Foundation Trust

ROR
https://ror.org/05fmrjg27

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF)

Results and Publications

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be 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		04/04/2025	19/05/2025	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes