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Exploring interventions over the watchful waiting period for children with hearing loss secondary to chronic otitis media with effusion ('glue ear')

Submission date
14/10/2015

Recruitment status
No longer recruiting

Registration date
16/10/2015

Overall study status
Completed

Last Edited
07/06/2023

Condition category
Ear, Nose and Throat

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

Plain English summary of protocol

Background and study aims
Glue ear, or chronic otitis media with effusion (OME) is a medical condition often seen in childhood where the middle ear becomes filled with fluid. The main symptom is hearing loss. Children with OME are at risk of educational and communication difficulties, self-esteem and behavioural problems, and lower quality of life when compared to other children. The current guidelines for care, as established by NICE, are that these children are monitored with 'watchful waiting' and advice until grommets (also known as 'ventilation tubes') are inserted or hearing aids considered. Our hypothesis is that transmission of speech aided by a wireless bone-conduction headset (a headset designed so that sound is conducted through the bones of the skull) connected to a wireless Bluetooth microphone during the waiting time for the insertion of grommets improves speech and language and other developmental outcomes. The aim of this study is to measure the differences in speech, language, and quality of life between a group of children given a bone-conduction headset while waiting for grommet insertion, and a group of children that are not.

Who can participate?
Children aged 3-6 with glue ear and waiting for treatment with grommets.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in group 1 (study group) are given a bone-conduction headset paired with a Bluetooth microphone. Those in group 2 (control group) are given listening-based electronic games as an alternative activity. Each child's speech and language development, quality of life and listening skills are measured before the start of the study and after treatment (between six and nine months later).

What are the possible benefits and risks of participating?
Benefits to participants include having access to more information about their hearing, since they will have a more thorough hearing test (such as determining listening levels in a noisy

environment) and a speech and language assessment. They will all have web-based access to resources and information about glue ear which they would not otherwise have. They will all have petrol costs reimbursed and a small gift for each child participating will be given (under the value of £5 per child). Additionally , those children in the control group of the study will have access to computer games/apps which have been made to aid development of listening and auditory processing skills. Those children in the study group will benefit from wearing a bone conduction headset which will be linked to a microphone that can be worn by their teacher, or their parent, or their speech and language therapist, for up to 4 hours a day. They will benefit from having access to clear speech sounds which will be transferred through the child's cheekbones to the inner part of the child's ear, by-passing the middle part of the ear which is affected by the glue ear. The risks would be if the child found the device uncomfortable or felt there was a stigma attached to wearing it, or if the child managed to self adjust the hidden volume button and make sounds too loud.

Where is the study run from?
Cambridgeshire Community Services (CCS) and Chear Ltd. (an independent organisation for assessment and management of hearing)

When is the study starting and how long is it expected to run for?
October 2015 to October 2016

Who is funding the study?
1. Health Education,East of England
2. British Society of Audiology Applied Research Grant in Honour of Stuart Gatehouse
3. Cambridge Hearing Trust

Who is the main contact?
1. Tamsin Brown (public)
2. Dr Marina Salorio-Corbetto (scientific)
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Contact information

Type(s)
Public

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Additional identifiers

Study information

Scientific Title
Exploring interventions over the watchful waiting period for children with hearing loss secondary to chronic otitis media with effusion ('glue ear'): a single-centre interventional randomised controlled trial.

Study objectives
Transmission of speech aided by a wireless bone-conduction headphone connected to a wireless Bluetooth microphone during the waiting time for the insertion of grommets improves speech and language and other developmental outcomes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Black Country NRES Committee, 13/01/2016, ref: 15/WM/0438

Study design
Single-centre interventional randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Chronic otitis media with effusion

Interventions
1. Study group: Participants (children) will wear a bone-conduction headset paired with a Bluetooth microphone. The microphone can be worn by a parent or a teacher. Children are

expected to wear the device for four hours daily.
2. Control group: Participants will be presented with an alternative activity in order to control for performance bias. The activity is the use of listening-based electronic games (applications).

Groups are blinded as to which is the control and the experimental condition.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Bone-conduction headset paired with a Bluetooth microphone

Primary outcome(s)
Speech and Language Development: DIFFERENTIAL SCORE (before/after) obtained from the outcomes of Preschool-age CELF (Clinical Evaluation of Language Fundamentals) and STAP (South Tyneside assessment of Phonology). The examiner is blinded as to which condition was assigned to each participant.

"Before" and "after" are the timepoints at the start of the study (before the intervention) and at the end of the study (for most children between six and nine months after the beginning of the intervention).
The data will be tested to check the assumptions of ANOVA (analysis of variance). If these assumptions (normal distribution and homogeneity of variance) are met then a one-way ANOVA with factor group and variate "differential score" will be performed for each outcome measure. If the assumptions of ANOVA are not met, a non-parametric test will be used. Data will be summarised by creating graphs. The scientist who will carry out the statistical analysis will remain blinded to the identity of the groups until the statistical analysis has been completed.

Key secondary outcome(s))
Other measures: DIFFERENTIAL SCORE (before/after) obtained from the outcomes of the questionnaires (Strengths and Difficulties [quality of life], Conners [Attention Deficit and Hyperactivity Disorder], ABEL (Auditory Behaviour in Everyday Life) [Listening skills].

"Before" and "after" are the timepoints at the start of the study (before the intervention) and at the end of the study (for most children between six and nine months after the beginning of the intervention). Statistical analysis will be accomplished as described for the primary outcome measure.

Completion date
30/09/2018

Eligibility

Key inclusion criteria
1. Aged 3 to 6 years
2. Diagnosed with non-infected chronic otitis media waiting for grommet insertion
3. Hearing loss should be 25 dB or more at three AC test frequencies. Unaided BC thresholds should be 10 dB or better

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
3 years

Upper age limit
6 years

Sex
All

Total final enrolment
19

Key exclusion criteria
1. Cleft palate
2. Risk factors for or diagnosis of sensorineural hearing loss, unrelated speech and/or language and/or communication disorders
3. Non-English dominant language, as this could affect the typical course of speech and language development, introducing a source of variability not related to middle-ear pathology

Date of first enrolment
15/10/2015

Date of final enrolment
28/02/2018

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Cambridgeshire Community Services (CCS)
Block 13, Ida Darwin Hospital
Fulbourn
Cambridge
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Study participating centre
Chear Ltd.
30 Fowlmere Road
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Sponsor information

Organisation
Cambridge Hearing Trust

Organisation
Health Enterprise East

Organisation
British Society of Audiology

ROR
https://ror.org/0597vc250

Organisation
Health Education East of England

Funder(s)

Funder type
Government

Funder Name
Health Education East of England, HEEoE

Funder Name
British Society of Audiology Applied Research Grant in Honour of Stuart Gatehouse

Funder Name
Cambridge Hearing Trust

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Marina Salorio-Corbetto Marina@chears.co.uk.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2019	04/06/2020	Yes	No
HRA research summary			28/06/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes