ISRCTN13818722 https://doi.org/10.1186/ISRCTN13818722

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)
marina@chears.co.uk

Study website
https://hearglueear.wordpress.com

Contact information

Type(s)
Public

Contact name
Dr Tamsin Brown

ORCID ID
http://orcid.org/0000-0003-0745-8877

Contact details
Community Child Health
Block 13, Ida Darwin Hospital
Fulbourn

Cambridge
United Kingdom
CB21 5EE

Type(s)
Scientific

Contact name
Dr Marina Salorio-Corbetto

Contact details
Chear Ltd.
30 Fowlmere Road
Shepreth
Royston, Herts
United Kingdom
SG8 6QS
+44(0)1783263333
marina@chears.co.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

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

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Treatment

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

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 measure
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.

Secondary outcome measures
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.

Overall study start date
01/11/2014

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

Age group
Child

Lower age limit
3 Years

Upper age limit
6 Years

Sex
Both

Target number of participants
30

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
England

United Kingdom

Study participating centre
Cambridgeshire Community Services (CCS)
Block 13, Ida Darwin Hospital
Fulbourn
Cambridge
United Kingdom
CB21 5EE

Study participating centre
Chear Ltd.
30 Fowlmere Road
Shepreth
Royston, Herts
United Kingdom
SG8 6QS

Sponsor information

Organisation
Cambridge Hearing Trust

Sponsor details
34 Butchers Hill
Ickleton

Saffron Walden
United Kingdom
CB10 1SR

Sponsor type
Charity

Organisation
Health Enterprise East

Sponsor details
Milton Hall
Ely Road, Milton
Cambridge
United Kingdom
CB24 6WZ
+44 (0)1223 928040
enquiries@hee.co.uk

Sponsor type
Other

Website
http://www.hee.org.uk

Organisation
British Society of Audiology

Sponsor details
80 Brighton Road
Reading
United Kingdom
RG6
+44 (0)118 966 0622
bsa@thebsa.org.uk

Sponsor type
Charity

Website
www.thebsa.org.uk

ROR
https://ror.org/0597vc250

Organisation
Health Education East of England

Sponsor details
2-4 Victoria House
Capital Park
Fulbourn
Cambridge
England
United Kingdom
CB21 5XB
+44(0)1223 597500
midlandsandeast.comms@nhs.net

Sponsor type
Hospital/treatment centre

Website
www.eoe.hee.nhs.uk

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

Publication and dissemination plan
We intend to publish at the end of the trial in a well known medical peer reviewed journal. Additionally as part of the funding agreement with the BSA (British Society of Audiology) we, as the team agreed to present at a BSA conference or national meeting. We also intend to do this at the BAPA (British Association of Paediatricians in Audiology) annual conference.

Intention to publish date
31/12/2016

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