

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

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| <b>Submission date</b><br>14/10/2015   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol            |
| <b>Registration date</b><br>16/10/2015 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>07/06/2023       | <b>Condition category</b><br>Ear, Nose and Throat | <input type="checkbox"/> 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

## Contact information

### Type(s)

Public

### Contact name

Dr Tamsin Brown

### ORCID ID

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CB21 5EE

### Type(s)

Scientific

**Contact name**

Dr Marina Salorio-Corbetto

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**Additional identifiers**

**Protocol serial number**

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

**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  
United Kingdom  
CB21 5EE

**Study participating centre**

**Chear Ltd.**

30 Fowlmere Road  
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Royston, Herts  
United Kingdom  
SG8 6QS

## **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? |
|--------------------------------------|---------------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a>      | results       | 01/01/2019   | 04/06/2020 | Yes            | No              |
| <a href="#">HRA research summary</a> |               |              | 28/06/2023 | No             | No              |
| <a href="#">Study website</a>        | Study website | 11/11/2025   | 11/11/2025 | No             | Yes             |