

# Mobile telephone audio compensation service for hearing impaired users.

<b>Submission date</b> 28/03/2018	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 13/04/2018	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 24/01/2020	<b>Condition category</b> Ear, Nose and Throat	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Current mobile telephone technology reduces the range of sounds transmitted, which is considered to be acceptable to users with normal hearing. However, it's a known issue that hearing impaired individuals can be negatively affected by this. Goshawk is developing a medical device which Goshawk believes can improve the user experience. Previous trials in a laboratory setting showed 70% of users expressed a preference for the Goshawk-processed audio compared to standard mobile phone calls. This study aims to show that using the device in a commercial mobile phone network improves the user experience of mobile telephone calls.

### Who can participate?

Men or women with a known or suspected hearing impairment.

### What does the study involve?

Participants are given access to the Goshawk service, which consists of a web-based hearing assessment tool and a real-time audio compensation service applied to the user's mobile telephone (via the Goshawk SIM). The sound enhancement is based on the user's hearing test results, from the web-based hearing assessment tool.

### What are the possible benefits and risks of participating?

The possible benefits are improved audio quality on mobile telephone calls, resulting in an improved user experience. There are no known side effects to the use of this service, in conjunction with the standard mobile telephones available on the market.

### Where is the study run from?

The study will be run from the Goshawk offices in Compass House, Isle of Man.

### When is the study starting and how long is it expected to run for?

Recruitment for the study has provisionally started. The intervention part of the study is due to commence on 1st May 2018 and is expected to run for 4 to 8 weeks. Recruitment will continue until the target number of users is between 50 and 100.

Who is funding the study?

The study is being funded by a combination of Goshawk, Isle of Man Government Department of Health and Social Care and Manx Telecom.

Who is the main contact?

The main contact for the purposes of the trial registration is the contact in the registration record, Jeff McBride, the Goshawk Quality Representative. E-mail [jeff@mcbridecq.com](mailto:jeff@mcbridecq.com).

## Contact information

### Type(s)

Public

### Contact name

Mr Jeff McBride

### Contact details

c/o Goshawk  
Compass House  
Cooil Road  
Douglas  
Isle of Man  
IM2 2QZ  
07770904371  
[jeff@mcbridecq.com](mailto:jeff@mcbridecq.com)

## Additional identifiers

### Protocol serial number

Goshawk Clinical Protocol 2

## Study information

### Scientific Title

Mobile telephony audio compensation service for use by individuals with sensorineural hearing impairment.

### Acronym

Goshawk Audio Compensation Service

### Study objectives

Use of a mobile telephone is enhanced for users with impaired hearing through the Goshawk device.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Isle of Man Regional Ethics Committee, approval pending

## **Study design**

Single-centre case-controlled study

Interventional study over 4 to 8 weeks, single centre case control study on individuals known or suspected to have hearing impairment to provide evidence that the Goshawk device enhances the users experience of using a mobile telephone

## **Primary study design**

Interventional

## **Study type(s)**

Quality of life

## **Health condition(s) or problem(s) studied**

Hearing impairment

## **Interventions**

Upon commencement of the trial, users will be granted access to the Goshawk product, which delivers real-time audio enhancement over communications networks (initially to mobile telephones, but also applicable to fixed telephony or VoIP applications). Thereafter, any and all calls made using the Goshawk service (via an enabled SIM in their mobile telephone) will be subject to intervention, until the end of the trial (either by normal expiry, or by a user request to leave the trial). The device enhances the user experience of mobile telephone calls

## **Intervention Type**

Device

## **Primary outcome(s)**

User experience measured by an online questionnaire and audibility testing at baseline, at start of service activation, after 4 weeks of use and after deactivation of the service. The audibility test will be conducted by a trial administrator who will conduct verbal testing over the telephone (with the service active), utilising 'Harvard Sentences' (as developed by the IEE, a series of phonetically balanced sentences). The user will be asked to repeat the sentence to the administrator. The first three timepoints will involve testing using 3 of 10 sentences. The last timepoint will use all 10 sentences.

## **Key secondary outcome(s)**

Improved user experience of mobile telephone as measured by call time/frequency increase.

## **Completion date**

31/08/2018

## **Eligibility**

### **Key inclusion criteria**

Individuals with known or suspected hearing impairment

### **Participant type(s)**

All

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**Total final enrolment**

53

**Key exclusion criteria**

Chronic deafness

**Date of first enrolment**

28/03/2018

**Date of final enrolment**

31/05/2018

**Locations****Countries of recruitment**

Isle of Man

**Study participating centre****Goshawk Offices**

Compass House

Cooil Road

Douglas

Isle of Man

IM22QZ

**Sponsor information****Organisation**

Goshawk

**Funder(s)****Funder type**

Not defined

**Funder Name**

Goshawk

## 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-publically available repository access to which can be requested by any interested party.

**IPD sharing plan summary**

Stored in repository

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/07/2019	24/01/2020	Yes	No