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Mobile telephone audio compensation service for hearing impaired users.

Submission date
28/03/2018

Recruitment status
No longer recruiting

Registration date
13/04/2018

Overall study status
Completed

Last Edited
24/01/2020

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
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.

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

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Non randomised study

Study setting(s)
Community

Study type(s)
Quality of life

Participant information sheet
No participant information sheet available

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 measure
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.

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

Overall study start date
31/01/2018

Completion date
31/08/2018

Eligibility

Key inclusion criteria
Individuals with known or suspected hearing impairment

Participant type(s)
All

Age group
Adult

Sex
Both

Target number of participants
50-100

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

Sponsor details
Compass House
Cooil Road
Douglas
Isle of Man
IM2 2QZ
07807 323 021
matthew@goshawk-communications.com

Sponsor type
Industry

Website
http://goshawk-communications.com

Funder(s)

Funder type
Not defined

Funder Name
Goshawk

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal

Intention to publish date
31/07/2019

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?
Results article	results	01/07/2019	24/01/2020	Yes	No