ISRCTN93742150 https://doi.org/10.1186/ISRCTN93742150

Effectiveness of the HEAR-aware smartphone app for hearing-impaired adults aged 50+ years who are not ready for a hearing aid

Submission date
28/04/2021

Recruitment status
No longer recruiting

Registration date
03/05/2021

Overall study status
Completed

Last Edited
24/07/2024

Condition category
Ear, Nose and Throat

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

Plain English summary of protocol

Background and study aims
An alarming two-thirds of adults aged 50+ years with hearing impairment who could benefit from hearing aids do not want any, leaving these adults with no support. To fill this gap, the HEAR-aware smartphone app may be offered as an alternative. The goal of the HEAR-aware smartphone app is to help adults with hearing loss self-manage their hearing problems. The app provides educational content tailored to a person's readiness to take action on their hearing and to a person's acoustic environment and associated challenges. The Hear-aware app may increase users' readiness to take some form of action on their hearing loss. The study's findings should help to improve audiological rehabilitation for adults with hearing loss who are not ready for hearing aids.

Who can participate?
Adults with hearing loss who are 50 years and over and do not want a hearing aid.

What does the study involve?
Participants will be randomly assigned to either the app group or the control group. Participants in the app group will be asked to use the HEAR-aware app for a period of 4 weeks. Participants in the control group will receive no support (usual care). Measurements will be taken immediately before the 4 weeks of app use, directly after it and 4 weeks later. Measurements in the control group will be carried out at the same time as the app group., including readiness to take action, self-reported hearing disability, coping with hearing loss, prior hearing help-seeking, health-related quality of life, attitudes on hearing loss and hearing aids and self-efficacy of hearing help seeking.

What are the possible benefits and risks of participating?
Participants in the app group will obtain knowledge on how to cope with hearing loss in daily life and in particular in (listening) situations that they encounter and receive tailored information on how to improve these listening situations. Both groups contribute to the scientific knowledge

on the effectiveness of aural rehabilitation other than hearing aids and this may be considered a benefit of participating. There are no risks associated with participation other than spending time filling out questionnaires.

Where is the study run from?
Amsterdam UMC – VU University Medical Center (Netherlands)

When is the study starting and how long is it expected to run for?
May 2021 to December 2021

Who is funding the study?
1. Schoonenberg HoorSupport (Netherlands)
2. Sonova AG (Switzerland)
3. The PPP Allowance (Netherlands)

Who is the main contact?
Prof. dr. S.E. Kramer
se.kramer@amsterdamumc.nl

Contact information

Type(s)
Scientific

Contact name
Prof Sophia E. Kramer

ORCID ID
https://orcid.org/0000-0002-0451-8179

Contact details
Dept. of Otolaryngology - Head and Neck Surgery
Section Ear & Hearing, Room PK2Y144
PO Box 7057
Amsterdam
Netherlands
1007 MB
+31 (0)204440969
se.kramer@amsterdamumc.nl

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
2021.0153

Study information

Scientific Title
How effective is the HEAR-aware smartphone app to increase readiness to take action of hearing-impaired adults aged 50+ years: a randomised controlled trial comparing the intervention group (4 weeks of HEAR-Aware app use) and the control group (no support)

Acronym
HearAware

Study objectives
The increase in participants' readiness to take action on their hearing will be higher in the HEAR-aware app group compared to the control group immediately after 1 month of app use and 4 weeks later.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Institutional Review Board of the VU University Medical Center (official name: the Medical Ethics Review Committee of VU University Medical Center; registered under IRB00002991 [OHRP] and FWA00017598 [FWA]) located at De Boelelaan 1109, Postbox 7057, 1081 HV Amsterdam has reviewed the study and has confirmed that the Medical Research Involving Human Subjects Act (WMO) does not apply to the study. Official approval of this study by the Medical Ethics Review Committee of VU University Medical Center is not required in this sense. Date of decision letter 26/04/2021, ref: 2021.0153

Study design
Single-center randomized controlled trial

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Readiness to take action on hearing loss

Interventions
Participants will be randomized at an individual level using Castor EDC. Castor EDC uses the standard method of variable block randomization. The researchers use random block sizes of 4 and 6 as these are considered most suitable for their sample size. Due to the fact that participants in the intervention group will receive the app while the control group will receive no intervention, blinding of participants is not possible. Also, the two groups will receive a partly different set of questionnaires. In addition, the researchers will have to facilitate the app download for the intervention group.

The intervention group will receive self-management support via the Hear-Aware app on their smartphone during a period of 4 weeks. Three times a day (at 9.30 am, 1 pm, and 7:30 pm), a

push notification will show up including an invitation to do a short multiple-choice survey. The user is asked to enter listening situations that were (past), are (current) or will be (future) difficult for them given their hearing loss. Depending on the listening situation they enter, acoustic labels are selected activating the app to offer educational snippets matching the reported listening situation. Snippets can be instructions, strategies, tips offered through written text, video, a sound fragment, or a combination of these. The length may vary (2-10 min. reading/watching time), but most are shorter than 5 min. Every released snippet is stored in the user's Personal Library, and can always be re-accessed. In total, 118 snippets are available, of which 81 can be released in response to a survey, and 37 are already available when starting up the app (i.e., making up the standard library). One snippet can cover multiple themes. The possible themes are:
1. Background knowledge on hearing
2. Communication strategies
3. Coping with impaired hearing
4. Understanding by loved ones
5. Hearing at work
6. Assistive listening devices - to be used without hearing aids
7. Hearing aids
8. Assistive listening devices- to be used with hearing aids
9. Fun

The control arm receives no intervention (usual care).

Intervention Type
Behavioural

Primary outcome(s)
Readiness to take action is measured using the Stages of Change measurement The Line, a discrete 11-point scale ranging from 0 (not ready at all) to 10 (highly ready) at baseline (T0), immediately after 4 weeks of app use (T1) and 4 weeks later (T2). The Line is generic in nature and does not specify what 'taking action on hearing' is. As the HEARaware app targets various target behaviors (e.g., communication strategies use, taking up hearing aids), Stages of Change will be measured both generically and specifically for these target behaviors.

Key secondary outcome(s))
1. Self-reported hearing disability measured using the Amsterdam Inventory for Auditory Disability and Handicap at T0, T1 and T2
2. Coping measured using the Communication Profile for the Hearing Impaired (CPHI) at T0, T1 and T2
3. Prior hearing help-seeking steps taken measured by asking whether or not participants have ever taken helpseeking steps (yes/no) (e.g. having visited a HAD/general practitioner/Ear Nose, and Throat doctor for a hearing test, performed a screening selftest) at T0, T1 and T2
4. Health-related quality of life measured using the EQ5D at T0, T1 and T2
5. Attitudes on hearing loss and hearing aids measured using the Attitude Questionnaire at T0, T1 and T2
6. Self-efficacy of hearing help-seeking measured using the SelfEfficacy of Hearing HelpSeeking Scale (SEHHS) at T0, T1 and T2

Completion date
31/12/2021

Eligibility

Key inclusion criteria
1. Age 50 years or older
2. Minimum pure tone threshold of 35 dB HL (hearing level) averaged across 1, 2, and 4 kHz in at least one ear
3. Visited a hearing aid dispensing practice for a hearing test appointment or a subsequent intake appointment in the past 1.5 years, but decided to not pursue a hearing aid trajectory
4. Does not (yet) want a hearing aid
5. Never tried a hearing aid before
6. Owns an email account, smartphone (iPhone iOS 10 and higher, i.e. iPhone 5 or newer; Android 4.4 or higher, i.e., phone bought in 2015 or newer), and uses apps
7. Is fluent in Dutch
8. Is willing to use the app regularly (on a daily basis)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Other

Lower age limit
50 years

Sex
All

Total final enrolment
87

Key exclusion criteria
1. Main complaint is tinnitus (and not hearing impairment). The HEAR-aware app does not have tinnitus coping as its main focus
2. Patient is referred to and enrolled in care through a multidisciplinary audiological center. The app has overlapping content with care provided in such a center

Date of first enrolment
06/05/2021

Date of final enrolment
16/09/2021

Locations

Countries of recruitment
Netherlands

Study participating centre
Hearing Aid Dispensing HAD practice Schoonenberg Hoorsupport
Dordrecht
Netherlands
3319 CH

Sponsor information

Organisation
VU University Medical Center

ROR
https://ror.org/00q6h8f30

Funder(s)

Funder type
Industry

Funder Name
Schoonenberg HoorSupport (Netherlands)

Funder Name
Sonova AG (Switzerland)

Funder Name
The PPP Allowance made available by Health~Holland, Top Sector Life Sciences & Health

Results and Publications

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		04/06/2024	24/07/2024	Yes	No
Protocol article		18/09/2020	30/04/2021	Yes	No
Other publications	Feasibility of the HEAR-aware App sub study	06/09/2023	30/01/2024	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes