

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

<b>Submission date</b> 28/04/2021	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 03/05/2021	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 24/07/2024	<b>Condition category</b> Ear, Nose and Throat	<input type="checkbox"/> 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

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## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

### EudraCT/CTIS number

Nil known

### IRAS number

### ClinicalTrials.gov number

Nil known

## Secondary identifying numbers

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

## Secondary study design

Randomised controlled trial

## Study setting(s)

Home

## Study type(s)

Other

## 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

## 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 measure

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.

### Secondary outcome measures

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

**Overall study start date**

03/05/2021

**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

**Age group**

Other

**Lower age limit**

50 Years

**Sex**

Both

**Target number of participants**

84

**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

**Sponsor details**

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**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.amsterdamumc.nl>

**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

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

Intention to publish date  
01/10/2024

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?
<a href="#">Protocol article</a>		18/09/2020	30/04/2021	Yes	No
<a href="#">Other publications</a>	Feasibility of the HEAR-aware App sub study	06/09/2023	30/01/2024	Yes	No
<a href="#">Results article</a>		04/06/2024	24/07/2024	Yes	No