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A study on the effectiveness of a support programme (SUPR) for adult hearing aid users

Submission date
25/01/2016

Recruitment status
No longer recruiting

Registration date
27/01/2016

Overall study status
Completed

Last Edited
23/09/2020

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
Usual hearing health care is mostly restricted to hearing assessment and hearing aid fitting. There is growing evidence showing that to increase everyday communication and wellbeing of hearing-impaired adults, more than hearing aid fitting alone is needed. Training of communication strategies is an example of an intervention that may improve a person's communication in daily life. Recently, an (online) audiologic rehabilitation support program (SUPR) was re-developed in collaboration with hearing care professionals. The main elements are an instruction book including exercises, frequent contact by email with a hearing expert, training modules covering short films with instructions for daily life situations and testimonials consisting of experiences from other peer hearing aid users. The aim of this study is to test the effectiveness of the support programme (SUPR) in hearing-impaired hearing aid users and their communication partners.

Who can participate?
Hearing-impaired hearing aid users, aged 50 and over, including both first-time hearing aid users and experienced hearing aid users, and their communication partners.

What does the study involve?
Hearing aid dispenser shops are randomly allocated to offer their customers either care as usual (hearing aid care) or hearing aid care including the SUPR support programme. Measurements are performed at the start of the study and after 6, 12 and 18 months. The following are assessed: communication strategies and personal adjustment, basic hearing aid handling, actual use of the hearing aid, satisfaction with the hearing care professional service, hearing disability.

What are the possible benefits and risks of participating?
A potential benefit of participation in the support program group is obtaining knowledge on how to deal with hearing impairment in daily life (listening) situations by learning communication strategies. Contributing to the scientific knowledge on the effectiveness of rehabilitation for hearing-impaired adults and their communication partners can also be seen as a benefit of participating. There are no risks associated with participation.

Where is the study run from?
70 hearing aid dispenser shops in the Netherlands

When is the study starting and how long is it expected to run for?
February 2015 to September 2018

Who is funding the study?
AudioNova International B.V. (Netherlands)

Who is the main contact?
Dr Marieke Pronk
Prof Sophia Kramer

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
WC2015-027 2015.335

Study information

Scientific Title
Addition of a SUpport PRogramme (SUPR) to usual hearing aid care as offered by the hearing aid dispenser – What are the effects on coping, hearing aid use and experienced hearing disabilities?

Acronym
SUPR

Study objectives
To study the effectiveness of an online support programme (SUPR) as an addition to usual hearing aid care in older (50 years of age and older) hearing aid users and their communication partners.

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]) has reviewed the study and has confirmed that the Medical Research Involving Human Subjects Act (WMO) does not apply to the study and an official approval of this study by the Medical Ethics Review Committee of VU University Medical Center is not required in this sense (reference number of the application: 2015.335; date of approval initial application: 27/08/2015; date of approval of amendment: 20/01/2016)

Study design
Multicentre interventional cluster randomized controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Other

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
To improve hearing-impaired individuals' communication and personal adjustment to their disability, more than hearing aid fitting alone is needed

Interventions
At the beginning of the study hearing aid dispenser shops will be randomly assigned to offer care as usual (hearing aid care) or hearing aid care including SP. This means that the clusters are defined at the start of the study and the particular hearing aid dispenser shop that the participant visits automatically determines to which group the participant is assigned (Care as Usual or SP). To avoid an unequal distribution of the level of urbanization across the participants of the two groups, shops will be pre-stratified on different levels of urbanization and the randomisation will subsequently be performed within these different strata. The level of urbanization is based on the level of the particular municipality that the shop is localized in. A statistician will perform block randomisation, with blocks of four.

The support programme (SP) is designed to help hearing-impaired individuals use their hearing aid more effectively and to improve communication strategies and personal adjustment, as compared to usual hearing aid care. All participants, including the ones assigned to the control group, are asked to assign a communication partner; a person with whom the participant has regular contact. The communication partner plays an important role in enhancing the motivation of the participant.

Participants who are assigned to the SP arm will be provided with the support programme for a period of six months (two month trial period and four months afterwards) in addition to receiving usual care in the context of hearing aid fitting. The Support Program consists of the Practical Support Book and the following components offered via email:
1. Contact with the hearing aid dispenser, in order to support the user during the first and most crucial trial period of the hearing aid
2. Training modules including:
2.1. Instruction videos with practical information on how to use and maintain a hearing aid
2.2. The educational programme “Horen en Gehoord Worden: Hoe kan het beter”, developed by Kramer et al. (2005). It comprises five short films regarding difficulties experienced by hearing-impaired older persons in everyday life situations. How to improve communication by using certain communication strategies is shown
2.3. Testimonials by hearing-impaired peers, in order to increase acceptation of hearing impairment. In these short films peer hearing aid users share their experiences.

Participants who are assigned to the control group will be provided with usual care in the context of hearing aid fitting.

Intervention Type
Behavioural

Primary outcome measure
Primary outcome measures as of 14/11/2018:
The use of communication strategies, measured with the Communication Profile for the Hearing Impaired (CPHI) at baseline and after 6 (T1), 12 (T2) and 18 (T3) months. Communication strategies are measured using the following three CPHI-subscales: maladaptive behaviours, verbal strategies and non-verbal strategies.

Primary outcome measures as of 31/01/2017:
The use of communication strategies and personal adjustment to hearing impairment, measured with the Communication Profile for the Hearing Impaired (CPHI) at baseline and after 6 (T1), 12 (T2) and 18 (T3) months

Previous primary outcome measures:
Coping with hearing loss, measured with the Communication Profile for the Hearing Impaired (CPHI) at baseline and after 6 (T1), 12 (T2) and 18 (T3) months

Secondary outcome measures

Secondary outcome measures as of 14/11/2018:
1. Personal adjustment to hearing impairment, measured with the Communication Profile for the Hearing Impaired (CPHI), at baseline, and after 6 (T1), 12 (T2) and 18 (T3) months. Personal adjustment is measured using the following three CPHI-subscales: self-acceptance, acceptance of loss, and stress and withdrawal.
2. Self-efficacy of hearing aid use and will be measured by the Basic Handling subscale of the Measure of Audiologic Rehabilitation Self-Efficacy for Hearing Aids (MARS-HA) at baseline, T1, T2 and T3. At baseline it covers the 'expected self-efficacy' of the new hearing aid, while T1, T2 and T3 prompts the 'experienced self-efficacy'. Added 31/01/2017: At T1, T2, and T3, the 5-item subscale Advanced Handling will be additionally administered
3. Actual use of the hearing aid/or use of the 'Alternative Intervention' will be measured with the first item of the International Outcome Inventory – Hearing Aids / International Outcome Inventory – Alternative Interventions questionnaire (IOI-HA/IOI-AI). Hearing aid use/use of the alternative intervention will only be measured at T1, T2 and T3. Furthermore, three questions from the Questionnaire regarding hearing aid usage developed by Laplante-Lévesque and colleagues will be used
4. Efficacy of the hearing aid/alternative intervention will be measured by items of the IOI-HA /IOI-AI questionnaire: benefit (item 2), residual activity limitation (3), satisfaction (4), residual participation restriction (5), impact on others (6) and quality of life (7) of the hearing aid and/or the alternative intervention. In addition to the IOI-AI items, three items of the IOI-HA will be administered in the group of participants who received the Support Program. These are: use (item 1), satisfaction (item 4) and quality of life (item 7). These IOI- items will also only be assessed at T1, T2, and T3
5. Satisfaction with the hearing aid dispensing practice service will be measured by the following question: "How likely is it that you would recommend the service of the hearing aid dispenser practice to other people (family, friends, colleagues)?"
6. Self-reported hearing status will be measured using the following five subscales of the Amsterdam Inventory for Auditory Disability and Handicap (AIADH): Distinction of sounds, Auditory localization, Intelligibility in noise, Intelligibility in quiet, and Detection of sounds. For each item, the A-part inquires about the respondent's ability to hear in a particular listening situation and will be measured at baseline, T1, T2 and T3. The B-part of each item is only asked in case disability is indicated in the A-part, and inquires about the respondent's inconvenience of not being able to hear well in that specific situation. The B-part will be measured at T1, T2, and T3 only.
7, Stage of behaviour change will be measured by the University of Rhode Island Change Assessment- for Hearing health behaviour (URICA) and will be measured at baseline, T1, T2 and T3
8. Emotional response to hearing problems will be measured by using five questions that are inspired by the Hearing Handicap and Disability Inventory (as used by Kramer et al. 2005). It will be administered at baseline, T1, T2, and T3.

Secondary outcomes as of 05/03/2018
1. Self-efficacy of hearing aid use and will be measured by the Basic Handling subscale of the Measure of Audiologic Rehabilitation Self-Efficacy for Hearing Aids (MARS-HA) at baseline, T1, T2 and T3. At baseline it covers the 'expected self-efficacy' of the new hearing aid, while T1, T2 and T3 prompts the 'experienced self-efficacy'. Added 31/01/2017: At T1, T2, and T3, the 5-item subscale Advanced Handling will be additionally administered
2. Actual use of the hearing aid/or use of the 'Alternative Intervention' will be measured with the first item of the International Outcome Inventory – Hearing Aids / International Outcome Inventory – Alternative Interventions questionnaire (IOI-HA/IOI-AI). Hearing aid use/use of the alternative intervention will only be measured at T1, T2 and T3. Furthermore, three questions from the Questionnaire regarding hearing aid usage developed by Laplante-Lévesque and colleagues will be used
3. Efficacy of the hearing aid/alternative intervention will be measured by items of the IOI-HA /IOI-AI questionnaire: benefit (item 2), residual activity limitation (3), satisfaction (4), residual participation restriction (5), impact on others (6) and quality of life (7) of the hearing aid and/or the alternative intervention. These IOI- items will also only be assessed at T1, T2, and T3
4. Satisfaction with the hearing aid dispenser's service will be measured by the Net Promoter Score. It will be measured at baseline, T1, T2 and T3
5. Self-reported hearing status will be measured using the Amsterdam Inventory for Auditory Disability and Handicap (AIADH) and will be measured at baseline, T1, T2 and T3
6, Stage of behaviour change will be measured by the University of Rhode Island Change Assessment- for Hearing health behaviour (URICA) and will be measured at baseline, T1, T2 and T3
7. Emotional response to hearing problems will be measured with the 'emotional response' section from the Hearing Handicap and Disability Inventory at baseline, T1, T2 and T3

Among the communication partners these outcomes will be measured:
1. Third-party disability will be measured with the Significant Other Scale for Hearing Disability (SOS-HEAR) at baseline, T1, T2 and T3
2. Efficacy outcomes of the hearing aid/intervention from the perspective of the significant other will be administered: Use, benefit, residual activity limitation, satisfaction, residual participation restriction, impact on others and quality of life. The 7-item IOI-HA-SO/IOI-AI-SO will be used at T1, T2 and T3

Original secondary outcomes
1. Self-efficacy of hearing aid use and will be measured by the Basic Handling subscale of the Measure of Audiologic Rehabilitation Self-Efficacy for Hearing Aids (MARS-HA) at baseline, T1, T2 and T3. At baseline it covers the 'expected self-efficacy' of the new hearing aid, while T1, T2 and T3 prompts the 'experienced self-efficacy'. Added 31/01/2017: At T1, T2, and T3, the 5-item subscale Advanced Handling will be additionally administered
2. Actual use of the hearing aid/or use of the 'Alternative Intervention' will be measured with the first item of the International Outcome Inventory – Hearing Aids / International Outcome Inventory – Alternative Interventions questionnaire (IOI-HA/IOI-AI). In addition, data-logging within the hearing aid will be used to measure the hearing aid use. Hearing aid use/use of the alternative intervention will only be measured at T1, T2 and T3. Furthermore, three questions from the Questionnaire regarding hearing aid usage developed by Laplante-Lévesque and colleagues will be used
3. Efficacy of the hearing aid/alternative intervention will be measured by items of the IOI-HA /IOI-AI questionnaire: benefit (item 2), residual activity limitation (3), satisfaction (4), residual participation restriction (5), impact on others (6) and quality of life (7) of the hearing aid and/or the alternative intervention. These IOI- items will also only be assessed at T1, T2, and T3
4. Satisfaction with the hearing aid dispenser's service will be measured by the Net Promoter

Score. It will be measured at baseline, T1, T2 and T3
5. Self-reported hearing status will be measured using the Amsterdam Inventory for Auditory Disability and Handicap (AIADH) and will be measured at baseline, T1, T2 and T3
6, Stage of behaviour change will be measured by the University of Rhode Island Change Assessment- for Hearing health behaviour (URICA) and will be measured at baseline, T1, T2 and T3
7. Emotional response to hearing problems will be measured with the 'emotional response' section from the Hearing Handicap and Disability Inventory at baseline, T1, T2 and T3

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Overall study start date
01/02/2015

Completion date
01/09/2018

Eligibility

Key inclusion criteria
1. Are at least 50 years old
2. Are open to the possibility to take up a new hearing aid on one or both ears (at the time of the preparation appointment at the hearing aid dispenser)
3. Purchase a new hearing aid on one or both ears (after the two-month trial period)
4. Have sufficient understanding of the Dutch language (speaking, writing, reading)
5. Have access to a personal computer (desktop, laptop, palmtop, iPad/tablet, smartphone) with an internet connection for the total duration of the study

Participant type(s)
Patient

Age group
Mixed

Sex
Both

Target number of participants
A number of 258 first-time hearing aid users and 311 experienced hearing aid users need to be recruited

Total final enrolment
343

Key exclusion criteria
Hearing aid dispenser clients who:
1. Also receive care at a specialized Audiological Clinic, since this mostly involves people with complex hearing disabilities. This care may overlap and/or interfere with that of the support programme
2. Receive a hearing aid primarily to suppress tinnitus complaints. For these individuals the focus of the rehabilitation is not on restoring communication per se and as such, they are not part of the target group

Date of first enrolment
01/02/2016

Date of final enrolment
01/04/2016

Locations

Countries of recruitment
Netherlands

Study participating centre
Various hearing aid dispenser shops (70 in total)
Netherlands
-

Sponsor information

Organisation
VU University Medical Center Amsterdam (Netherlands)

Sponsor details
De Boelelaan 1118
Amsterdam
Netherlands
1081 HZ

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00q6h8f30

Funder(s)

Funder type
Industry

Funder Name
AudioNova International B.V. (Netherlands)

Results and Publications

Publication and dissemination plan
The protocol will be published in the first half of 2016. Other publications are to be confirmed at a later date.

Intention to publish date
01/04/2020

Individual participant data (IPD) sharing plan
It is not expected that participant level data will be made available because this has not been applied for in the ethics application. Approval has not been sought for the data to be publicly available. Data will be stored on a computer disk at the VU University Medical Center which is locked with a security code only available to members of the SUPR research team. After having received informed consent, data will be archived for a period of 15 years after the study has been completed. After completion, the key file (connecting participant numbers to the names and contact details of the participant) will be destroyed once it is expected that participants do not need to be approached further for the purposes of the study.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	20/06/2017		Yes	No
Results article	results	22/09/2020	23/09/2020	Yes	No