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Evaluating the addition of an online SUpport PRogramme (SUPR) to usual hearing aid care: protocol for a cluster randomized controlled trial

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ABSTRACT

Background: An educational SUpport PRogramme called SUPR was developed for hearing aid users (HAUs) and their communication partners (CPs) offering care beyond hearing aid fitting. SUPR teaches its users communication strategies and hearing aid handling skills, and offers peer testimonials. Ultimately, its main aim is to improve coping strategies (i.e., application of favourable communication strategies, and personal adjustment).

Methods/design: Using a cluster randomized controlled trial-design, 70 Dutch hearing aid dispenser practices were randomized into hearing aid fitting (care as usual, 34 practices) and hearing aid fitting including SUPR (36 practices). The aim is to recruit a total of 569 older (aged 50+) first-time (n=258) and experienced (n=311) HAUs and their CPs. SUPR consists of a Practical Support Book and online material offered via email over a period of 6-7 months. The book provides practical information on hearing aids, advice on communication strategies, and home exercises. The online material consists of educational videos on hearing aid functionality and usage, communication strategies, and peer testimonials. Lastly, noncommittal email contact with the dispenser chain is offered. Every HAU is asked to assign a CP who is advised to be involved intensively. Effect measurements will occur at baseline, and at 6, 12, and 18 months follow-up via online questionnaires. The primary outcome for HAUs will be coping with hearing impairment as measured by the subscales of the Communication Profile for the Hearing Impaired. The primary outcome for CPs will be third-party disability (Significant Other Scale for Hearing Disability). A process evaluation will be performed.

Ethics and dissemination: This study protocol was approved by the Scientific Committee of the EMGO Institute for Health and Care Research. This intervention could contribute to lowering the hearing impairment burden in our ageing society. The results will be disseminated through peer-reviewed publications and scientific conferences.

Trial registration: ISRCTN77340339; Pre-Results.

Keywords: Hearing loss, 'coping with hearing impairment', intervention, cluster randomized controlled trial, hearing aids, communication, communication strategies, internet

STRENGHTS AND LIMITATIONS

- This is the first study to evaluate the effects of an online SUpport Programme (SUPR) for hearing aid users that is implemented in a hearing aid dispensing practice setting.

- SUPR is a multifaceted educational intervention, including a Practical Support Book, online elements via email, and noncommittal email contact with the dispenser chain, focusing on personal adjustment and communication strategies.

- The SUPR study is a large scale study, involving hearing-impaired participants and their communication partners from 70 hearing aid dispensing practices all over the Netherlands.

- The online character of the programme suits the current and future developments in the increasing internet use among older persons and can reach out to those with reduced (physical) access to health care.

- Nonetheless, the online character might yield a selective sample of older persons (especially among the older old), that is included in the study and for whom SUPR will be suitable.

- Another limitation of the study is that the design does not allows the blinding of participants and researchers for intervention allocation. This could lead to performance bias.

- The findings of the study will potentially contribute to improvement of hearing health care services for hearing-impaired persons and their communication partners.

BACKGROUND

Hearing impairment is one of the most prevalent chronic health conditions affecting older adults. It was ranked fifth in the top 25 of global causes for years lived with disability in 2013[1]. Due to the overall aging of the population[2], the prevalence of hearing impairment is increasing vastly, imposing a great burden on individuals and society.

Hearing impairment essentially leads to the inability to communicate effectively, which in turn can result in a cascade of effects leading to poor psychosocial outcomes such as social isolation[3], loneliness[4, 5], distress[6], depression[6, 7], and work-related fatigue[8]. It has also has been associated with accelerated cognitive decline[9] and falls[10]. The limitations in daily life activities and restrictions in social and societal participation that a person experiences depend on aspects that are both internal (such as the level of impairment in hearing functions and structures) and external (such as availability of hearing aids, care facilities, and social support) to a person. In addition, internal so-called 'personal factors' including age and coping are important factors that can influence psychosocial outcomes[11].

Significant others can also be negatively affected by the hearing impairment of their loved ones. Partners and spouses generally experience frustration and embarrassment, for example in challenging social communication settings[12]. Communication difficulties in background noise, the partner's frequent request to repeat, and the need to act as an interpreter may cause irritation, embarrassment, and tension in the relationship[12]. In a systematic review conducted by Kamil *et al* it was found that communication partners (CPs) of persons with hearing impairment experience decreased social functioning, poorer quality of life and more participation restriction than CPs of normally hearing individuals[13].

The usual care provided for persons with hearing impairment is often restricted to the assessment of hearing loss and the provision and fitting of hearing aids[14]. Hearing aid use has positive effects on quality of life, social and emotional wellbeing, and may reduce depressive complaints[15-17], and possibly even cognitive decline[18]. Despite this abundant evidence, the uptake and use of hearing aids is low. It is estimated that around one third of the adults who would benefit from hearing aids own them[19-21] and 12-20% of the owners never uses them[22,23]. Reasons for low uptake and use are largely known[24-26] and include low perceived need of amplification reflected in low self-reported hearing disability and limited acceptation of hearing loss. In addition, low expectations of hearing aid benefits, limited gain in noisy situations, low overall sound quality, other perceived barriers to use hearing aids such as hearing aid stigma, high costs and, need for regular hearing aid care and maintenance, are factors adding to low uptake and use. Finally, lack of social support or social pressure to get a hearing aid are factors negatively influencing hearing aid use.

Because the factors leading to low use are numerous and their interplay is complex, it has often been argued that hearing health care should offer more than hearing aids alone to improve daily life communication and wellbeing of hearing-impaired adults[27]. This argument is in line with the biopsychosocial approach of health that is receiving increasing attention in the field of audiology: Experienced hearing disability (i.e., activity limitations and participation restrictions) is the outcome of a complex interaction between an individual and his/her contextual factors[28-30].

Various interventions have been proposed to complement hearing aid fitting. Examples are communication programmes aimed at improving speech perception and/or communication management[31]. These include speech perception training, communication management training and social support[27, 32, 33]. For reviews, see Barker *et al*, Sweetow *et al*, and Wong *et al*[34-36]. Examples of effective programmes are the Home Education programme[37] and the Active Communication Education (ACE) group programme[38]. Both programmes consist of modules on

everyday communication situations, aiming to improve the use of communication strategies, personal adjustment to living with hearing impairment, quality of life, development of problem-solving skills and to decrease the level of experienced hearing disability. These programmes showed an improvement in communication strategies[37] and communicative participation restrictions and activity limitations[38]. Kramer *et al* found that the effects of the Home Education programme were larger for first-time HAUs, as compared to experienced HAUs. Further, the study had a relatively small sample size (n=48) and the participants were all patients of a specialized tertiary Audiology Centre, limiting the generalizability of the results. In general, only a small number of hearing aid applicants with relatively complex hearing problems receive hearing care through a tertiary clinic. The vast majority of hearing aids are fitted in a dispenser practice. A study on the effectiveness of the Home Education programme in a dispenser practice setting is therefore needed.

For the evaluation of their programmes, both Kramer *et al*[37] and Hickson *et al*[38] used a total follow-up period of six months. A review study by Hawkins *et al* showed that on the short term (i.e., up to six months), counselling-based adult group rehabilitation programmes may generally reduce self-perception of hearing disability and enable better use of communication strategies and hearing aids[39]. Unfortunately, there is limited evidence for the long-term effects of these programmes[39].

Communication training programmes, whether or not combined with hearing aid fitting, are rarely offered in hearing health care[27, 32]. When offered, there are various reasons for adults with hearing impairment to not pursue communication training programmes, such as for example living in a rural area, lack of time, and no easy access[32]. Due to the paradigm shift in health care from the traditional doctor-centric model to a more patient-centered model combined with increasingly pervasive use of e-health methods and technology, the typical barriers causing the low use of (group) communication training programmes can be overcome[40, 41, 42].

Recently, a number of studies have been published reporting on the development and evaluation of online communication programmes. Thorén *et al* developed such a programme[43]. It included reading material on hearing anatomy, hearing aids, communication strategies, assistive listening devices, and guidelines for CPs. In addition, the intervention included weekly email contact with an audiologist, problem solving exercises and online peer discussion on personal experiences with hearing loss. Thorén *et al* studied the effectiveness of the programme using a randomized controlled trial-design in which the intervention group received the online programme while the control participants were offered access to an internet discussion forum or were placed on a waiting list[43]. The researchers found reduced symptoms of depression[44] and a significant decrease of activity limitations and participation restrictions in the intervention group compared to the controls at five weeks directly after the intervention, and at three-months follow-up[43]. Ferguson *et al* investigated the use of short interactive videos (reusable learning objects, RLOs)[45]. RLOs were delivered via DVD for TV, computer and the internet and covered practical and psychosocial issues which are relevant for audiologic rehabilitation. The intervention group received seven RLOs plus usual clinical services including hearing aid fitting and counseling. They were compared to a control group who received clinical services only and were placed on a waiting list. Participants in the intervention group had significantly better hearing aid skills and better knowledge on psychosocial issues than the control group after 6-weeks follow-up. Whereas the online education programme of Thorén *et al* was evaluated in a sample of adults who were recruited by local advertisements and articles and were wearing a hearing aid for at least one year[43], Ferguson *et al* evaluated their RLOs in a small sample of patients of the audiology service of the Nottingham University Hospitals NHS Trust. Patients were adults who had been referred to the clinic by their family doctor[45].

To the best of our knowledge, there is no study available evaluating the effectiveness of an online communication training programme that is implemented on a large scale in a hearing aid dispensing setting. This paper reports on the design of such a study. It addresses the different steps that will be

taken to evaluate an online intervention programme for hearing-impaired adults and their CPs. The programme is based on the Home Education programme mentioned earlier[37]. A remake was created so that it would be applicable for use over the internet and would be a more up-to-date version of the one developed in 1995. Also, the programme was expanded with extra elements, including instruction videos on how to operate and maintain hearing aids, testimonials of peers, through emails which are sent every other week. The main focus of SUPR is on improving the use of communication strategies and personal adjustment to hearing loss, which within the field of audiology, are sometimes summarized as 'coping'[46]. More details of the online SUpport PRogramme – further referred to as SUPR - are provided in the sections below.

The study will determine the effectiveness of SUPR as part of standard hearing aid dispensing care by comparing it to hearing aid fitting only. Its effectiveness will be studied both in first-time and experienced HAUs and their CPs.

METHODS

Study design

A cluster randomized controlled trial with an 18-month follow-up period will be performed. Dutch hearing aid dispensing practices (henceforth: HAD practices) and consequently all clients in these practices will be randomly assigned to one of two groups. The control group will receive care as usual (CaU) which is hearing aid fitting only, while the intervention group will receive hearing aid fitting supplemented with SUPR.

Care as Usual

CaU starts with a so-called preparation appointment during which a screening pure-tone audiogram (only air conduction) is administered by the hearing aid dispenser. If the hearing loss in one or both

ears is at least 35 decibel (dB) hearing level (HL) (averaged over the three frequencies 1, 2, and 4 kHz) in one or both ears, someone is considered potentially eligible for hearing aid fitting and more comprehensive audiometry is required. If the client is interested in hearing aids, his/her general wishes and goals are discussed after which the client is provided with the Amsterdam Inventory for Auditory Disability and Handicap (AIADH; Kramer *et al*[47]). Clients are asked to complete it at home and bring it along to the next appointment. The AIADH assesses activity limitations and participation restrictions due to hearing impairment. During the next appointment, i.e., the so-called intake appointment, comprehensive audiometry (air and bone conduction, and speech audiometry) are performed by the hearing aid dispenser. The results of all tests, the AIADH, and the wishes of the client determine what type of hearing aid may be best suited for this person. The appropriate hearing aids will be selected and fitted directly (if available in the HAD practice) or in a subsequent fitting appointment. Fitting is followed by a trial period of up to four weeks mostly, during which a person can try out the hearing aid and decide whether or not to purchase it. Depending on the client's needs, tuning or other follow-up appointments are scheduled during the trial period but also after the device has been purchased.

The hearing aid dispenser will invite first-time HAUs to participate in the study at the end of their preparation appointment. Experienced HAUs will also be invited at the end of their preparation or at the end of their intake appointment, if they did not require a preparation appointment. See 'Study population & recruitment' for further details.

Intervention: SUPR

SUPR consists of a Practical Support Paper Book and online material. The Practical Support Book will be handed out at the end of the preparation appointment (first-time HAUs, experienced HAUs) or the intake appointment (experienced HAUs). After the intake appointment, the online elements will be sent out to the participants by email.

The aim of the Practical Support Book is to help the client to become familiar with their hearing aid. The book is intended to be used until the end of the trial period. The book covers four parts, corresponding to four phases. The information provided is synchronized with the issues typically discussed during visits to the HAD practices in the trial period. The first part outlines the process of getting a hearing aid and includes an introduction to the hearing aid dispenser and an explanation of the pure tone audiogram. The client is asked to write down specific needs. The second part revolves around the type and choice of the new hearing aid. Information about how to operate and manage the device is provided as well. In the third part the client is allowed to give feedback on experiences with the new hearing aid and the settings. This information will be used for further refinement of the fitting. The final section of the book provides information on assistive listening devices, reimbursement of costs and more detailed information on the audiogram and the hearing aids.

Online Elements

The online part of the programme consists of email contact with the dispenser during the trial period followed by a series of training modules. This takes up to approximately six months after the hearing aid purchase. The exact time depends on the duration of the trial period. For example, if a trial period is finalized in three weeks instead of the average four, the total duration of SUPR is one week shorter.

The following online components are provided: 1) Training modules on hearing aid handling skills: Three short instruction videos with practical information on the use and maintenance of hearing aids. 2) Training modules on communication strategies and personal adjustment: Remake (modernized version) of the home educational programme *"Horen en Gehoord Worden: Hoe kan het beter",* as developed by Kramer *et al*[37]. It comprises five short videos showing the difficulties that a hearing-impaired person can experience in everyday life situations. The typical reactions in these situations

are shown and a trainer illustrates how communication could be improved by using communication strategies (for both the hearing-impaired person and his/her CP). 3) Testimonials by hearing-impaired peers who are sharing their experiences with hearing aids.

Participants in both the CaU and the intervention group will be asked to invite a CP to participate in the study. Having a CP who is willing to participate is not obligatory though.

Measurements

For all participants four measurements will take place: at baseline (after the preparation appointment, but before the actual hearing aid fitting) (T0), six months after the hearing aid purchase (T1), one year after the hearing aid purchase (T2), and eighteen months after the hearing aid purchase (T3). Measurements at T3 serve to determine the long-term effects of SUPR, i.e., one year after its completion. Data will be collected using online questionnaires through NetQ Premium, which is an online survey programme. Email-reminders will be sent within a week after the first invitation-email, and another two weeks after the first reminder, if necessary.

Study population & recruitment

Hearing aid dispensers will invite clients to participate in the study. They will hand out a package with information including an invitation letter, a selection form outlining the in- and exclusion criteria, a brochure about the study, and an envelope with an information letter and brochure for the CP. All interested participants will be asked to enrol themselves for the study by signing in on a registration webpage. Every month there will be an assessment to determine – for each HAD practice - the number of clients that were invited (number of envelopes that were handed out) and the number of participants that enrolled themselves. If the enrolment numbers will be low in comparison to other HAD practices, a phone call will be made to the specific HAD practice to identify underlying reasons and to remind them. Moreover, throughout the recruitment period, the headquarters of the HAD

practice will organize motivational conference calls for HAD practices that did not yet reach the required number of the target. Finally, if enrolment ratings keep lagging behind, employees of the headquarters will invite clients who recently had a preparation appointment but were not invited, by calling them and subsequently sending the study material by email.

Incentives

After completing the T0 questionnaire, all participants will be offered a voucher of EUR 50 to spend on a hearing aid or EUR 25 to spend on other articles of the HAD practice if they decide not to purchase a hearing aid. CPs will be offered a flower coupon. In addition, participants in the control group will be offered a shortened version of SUPR after eighteen months. For them, SUPR will be slightly adjusted such that it becomes suitable for individuals who already started using a hearing aid.

In addition to the motivational procedures described under Study population & recruitment, HAD practices will be (see under 'Sample size calculation') offered movie tickets and pies for the entire team once the total number of participants is recruited.

Inclusion criteria

The following inclusion criteria for the hearing aid candidates will be applied: 1) Age 50 years or older. 2) Hearing loss in one or both ears is at least 35 dB HL (averaged over 1, 2, and 4 kHz). 3) Intention to take up one or two new hearing aid(s). This can be their first hearing aid (i.e., first-time HAUs), or a replacement hearing aid (i.e., experienced HAUs). Clients who do not purchase a hearing aid after the trial period will be considered drop-outs. 4) Sufficient understanding of the Dutch language. 5) Access to a personal computer with an internet connection for the total duration of the study.

Exclusion criteria

The following hearing aid candidates will be excluded: 1) Candidates who receive additional care at a specialized Audiology Clinic. In the Netherlands, an Audiology Clinic offers elaborate, multidisciplinary and specialized, tertiary health care and is aimed at people with complex hearing problems. This care may overlap and/or interfere with that of SUPR. 2) Candidates that will 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 of SUPR.

No in- or exclusion criteria will be applied for CPs.

Outcome measures

An overview of all outcome measures and measurements over time is presented in Table 1.

Table 1 Spirit flow diagram [48]. Schedule of enrolment, interventions, and assessments

		Allocation of HAD practices	Enrolmbent	Post-Allocation & Enrolment			
TIMEPOINT	Outcome measurements	–T2	-T1	T0 (Baseline)	T1 (6 months)	T2 (12 months)	T3 (18 months)
ENROLMENT: Eligibility screen			x				
Informed consent			x				
Allocation		x					
INTER-VENTIONS: Care as Usual (Hearing aid fitting)		x	———	———	x		
Intervention (Hearing aid fitting + SUPR)		x	———	———	x		
ASSESSMENTS: Baseline							

measurements					
Gender		x			
Age		x			
Marital status		x			
Living situation		x			
Level of education		x			
Occupational status		x			
Country of birth participant		x			
Country of birth participant's parents		x			
Hearing loss	Pure-tone audiogram	x			
Primary outcome measure HAUs					
Coping with hearing impairment	CPHI subscales	x	x	x	x
Secondary outcome measures – HAUs					
Self-efficacy of basic hearing aid handling	MARS-HA (Basic handling subscale)	x	x	x	x
Self-efficacy of advanced hearing aid handling	MARS-HA (Advanced handling subscale)		x	x	x
Hearing aid rehabilitation and SUPR outcome	-IOI-HA/IOI-AI -Data-logging -Question-naire on hearing aid use by Laplante-Lévesque et al.(items 13-14-15)		x x x	x x x	x x x

Satisfaction with the hearing aid dispenser service	'How likely is it that you would recommend the service of the HAD practice to other people (family, friends, colleagues?)'	x	x	x	x
Self-reported hearing activity limitations and participation restrictions	AIADH	x	x	x	x
Hearing status	Pure tone audiogram	x			
Stage of behaviour change	-URICA – precontemplation/contemplation/action	x	x	x	x
	-URICA - maintenance		x	x	x
Emotional response	HHDI (Emotional response subscale)		x	x	x
Secondary outcome measures – CP					
Third-party disability	SOS-HEAR	x	x	x	x
Efficacy of hearing aid/alternative intervention	IOI-HA-SO/IOI-AI-SO		x	x	x

Abbreviations: HAD Practice: hearing aid dispensing practice, SUPR: Support PRogramme, HAU: hearing aid user, CPHI: Communication Profile for the Hearing Impaired, MARS-HA: Measure of Audiologic Rehabilitation Self-Efficacy for Hearing Aids, IOI-HA: International Outcome Inventory – Hearing Aids, IOI-AI: International Outcome Inventory – Alternative Interventions, AIADH: Amsterdam Inventory for Auditory Disability and Handicap, URICA: University of Rhode Island Change Assessment- for Hearing health behaviour, HHDI: Hearing Handicap and Disability Inventory, CP:

Communication Partner, SOS-HEAR: Significant Other Scale for Hearing Disability, IOI-HA-SO: International Outcome Inventory Significant Other– Hearing Aids, IOI-AI-SO: International Outcome Inventory Significant Other– Alternative Interventions.

Primary outcome measure – HAUs

- *Coping with hearing impairment* will be measured using the reliable and validated Dutch 35-item version of the Communication Profile for the Hearing Impaired (CPHI)[49, 50]). It covers two sections. The first addresses communication strategies and has three subscales (Maladaptive Behaviors, Verbal Strategies and Non-verbal Strategies) each consisting of statements for which the respondent has to indicate how often (s)he applies this strategy. An example: "I avoid conversations with strangers, because of my hearing loss" (subscale maladaptive behaviour). The five answer options range from 'almost never' to 'almost always'. Scores are averaged per subscale and range from 1 (low) to 5 (high). The second section deals with Personal Adjustment and also has three subscales: Self-acceptance, Acceptance of Loss, Stress & Withdrawal. An example item of the latter subscale is: "I feel very tensed, because of my hearing loss". The five answer options range from 'totally disagree' to 'totally agree'. Averaged scores per subscale range from 1 (low) to 5 (high). Because of reverse scaling, some items need to be recoded. After recoding the item scores, low scores indicate poor coping. In addition to the subscale scores, a total score of the summed six subscales scores can be calculated.

Secondary outcome measures - HAUs

- *Self-efficacy of hearing aid handling* will be measured by the Basic Handling subscale of the Measure of Audiologic Rehabilitation Self-Efficacy for Hearing Aids (MARS-HA). The English version of this 7-item subscale has good psychometric quality[51]. Scores can range from 0% to 100%, with lower scores representing less certainty in one's capability of handling a hearing aid. At T1, T2 and T3, the 5-item subscale Advanced Handling will be added. Dutch versions of the subscales were created

through a rigorous translation process using the forward-backward method[52]. At T0 the 'Expected Self-Efficacy' scale will be administered, whereas at T1, T2 and T3 the 'Experienced Self-Efficacy' subscale will be used instead.

- *Hearing aid rehabilitation and SUPR outcome*. The International Outcome Inventory – Hearing Aids (IOI-HA) and the equivalent International Outcome Inventory for Alternative Interventions questionnaire (IOI-AI) will be used to assess the outcome of hearing aid rehabilitation and SUPR respectively[53]. The Dutch version of IOI-HA has shown to have good test-retest reliability and validaty[54]. The first item determines the frequency of hearing aid use / the use of the alternative intervention, respectively "How many hours per day on average have you been using your hearing aid(s) in the last two weeks?" and "How often have you used the learnt communication strategies on an average day in the last two weeks?". Answer options are 'none', 'less than 1 hour a day', '1-4 hours a day', '4-8 hours a day' and 'more than 8 hours a day'. Hearing aid use will additionally be measured by data-logging and three questions from a questionnaire developed by Laplante-Lévesque *et al*[55]. The latter questionnaire was translated into Dutch, using a forward-backward method[52]. The remaining six items of the IOI-HA/IOI-AI questionnaire cover: benefit, residual activity limitation, satisfaction with the hearing aid(s)/SUPR, remaining personal restrictions, impact on others, and quality of life.

- *Satisfaction with the hearing aid dispenser service.* Satisfaction will be measured by one question: "How likely is it that you would recommend the service of the HAD practice to other people (family, friends, colleagues)?" It is scored on a visual analogue scale running from 0 (=not at all likely) to 10 (=extremely likely).

- *Self-reported activity limitations and participation restrictions* are measured using the reliable and validated original (Dutch) version of the Amsterdam Inventory for Auditory Disability and Handicap (AIADH)[47, 56]. It contains 28 questions regarding everyday listening situations. An example is: "Do you immediately look into the right direction when somebody calls you in the street"? The 4-point response scale covers: 'almost never' (1), 'sometimes' (2), 'often' (3) and 'almost always' (4). When

the participant answers the question with 'almost never' or 'sometimes', he or she is directed to question b which is about the inconvenience of not being able to hear well in that specific situation. Answer options are: 'no (1)', 'a little' (2), 'very handicapped'(3), 'extremely handicapped'(4). Hence, the total score can range from 28-112 with higher scores indicating greater participation restriction.

- *Stage of behaviour change* will be measured by the validated Dutch 24-item version of the University of Rhode Island Change Assessment (URICA)[57]. Formulations of items were adjusted such that they applied to hearing problems. The inventory contains 24 statements regarding attitudes and behaviours assessing an individual's stage of behaviour change. At T0 the following stages will be assessed: precontemplation (does not intend to take action in the foreseeable future, e.g., "As far as I'm concerned, I don't have any problems with my hearing that need changing"), contemplation (intends to change in the next six months and is aware of the pros and cons of changing), and action (has made specific modifications in his/her lifestyle towards healthy behaviour). At T1, T2, and T3 the maintenance stage (can maintain the changes in new behaviour) will be added. The five response options range from 'fully disagree' (score 1) to 'fully agree' (score 5). Summed scores for each subscale will be calculated. In addition the composite 'readiness score ' (adding the contemplation, action and maintenance scores and substracting the precontemplation score) and the composite 'committed action score' (subtracting the contemplation stage score from the action stage score) will be calculated[57]. The higher the composite scores, the further the respondents are along the stages of change.

- *Emotional response to hearing problems*. The Hearing Handicap and Disability Inventory (HHDI) will be used[58]. The purpose of the inventory is to identify the individual's problems caused by hearing loss. Only the section 'emotional response' will administered. It contains five statements each with five response options: 'yes!' (4), 'yes' (3), 'more or less' (2), 'no' (1) and 'no!' (0). An example is "I find it difficult to accept that I am hearing impaired". Lower scores indicate better outcomes.

Secondary outcome measures - CP

- *Third-party disability* will be measured using the Significant Other Scale for Hearing Disability (SOS-HEAR)[12]. This questionnaire was translated into Dutch for the purposes of this study following a forward-backward method[52]. The 27-item questionnaire addresses the problems and limitations experienced by the CP. An example item is: "Because of my partner's hearing difficulties I have to repeat myself often". For each item the CP has to indicate how much of a problem it is for him/her: 'no problem' (0); 'a mild problem' (1), 'a moderate problem' (2), 'a severe problem' (3), 'a complete problem' (4). Higher scores indicate greater difficulties.

- *The outcomes of the hearing aid rehabilitation / alternative intervention as viewed from the perspective of the CP* will be administered with the 7-item IOI-HA-SO/IOI-AI-SO and covers use, benefit, residual activity limitation, satisfaction, residual participation restriction, impact on others, and quality of life [59].

Baseline measurement- Demographical characteristics

- Gender (male/female)
- Age (in years)
- Marital status (married/cohabiting/widow or widower/divorced/single, never married)
- Living situation (living together with my partner/living together with my partner and children/living together without my partner but with one or more family members/living alone (own room) or in a care institution/living alone, independently or nursing home/other, namely…)
- Level of education (no completed education/lower general education, elementary education or a part of it/lower general secondary education/vocational education/secondary education/technical and vocational education/higher professional education/higher general education/scientific education/other, namely…)
- Occupational status (yes/no)
- Country of birth (The Netherlands/other, namely…)
- Country of birth father (The Netherlands/other, namely…)

- Country of birth mother (The Netherlands/other, namely…)

- Hearing loss in each ear, in dB HL (averaged over 1, 2, and 4 kHz) as retrieved from the pure-tone audiogram as provided by the hearing aid dispenser.

Randomisation

HAD practices will be randomly assigned to offer CaU or the intervention. To avoid an unequal distribution of HAD practices with regard to level of urbanisation, HAD practices were pre-stratified (HAD practices located in a relatively rural area versus in an urban area) and randomisation occurred within these two strata. A statistician performed block randomisation, with blocks of four HAD practices. 34 HAD practices were assigned to CaU and 36 HAD practices to the intervention group. The recruitment procedure and period will be the same for all 70 included HAD practices (the total list of included HAD practices are available on request from the research team).

Sample size calculation

Sample size calculations are based on the expected effects of the intervention on the primary outcome: coping with hearing impairment (CPHI). Demorest & Erdman indicated that the minimal important difference on the subscales of the CPHI varies from 0.67 (Maladaptive Behaviour) to 0.95 (Self-Acceptance)[60]. Given that in a previous study[37] the effect of the programme was larger for first-time than for experienced users, we calculated sample sizes separately for first-time and experienced users. For first-time HAUs, we based our sample size calculations on a minimal important difference of 0.67 between the intervention and the CaU group. Calculations in PASS 12 (Tests for Two Means in a Cluster-Randomized Design; Intracluster correlation coefficient: 0.01; alpha: 0.05; power: 0.80) shows, that when 70 HAD practices are included (of which half will offer SUPR and half CaU), the number of first-time HAUs to include in the analyses is two per dispenser HAD practice. For the experienced users sample size calculation we chose an expected minimal important difference of 0.4 between the intervention and CaU group. The number of experienced

HAUs (power: 0.80) to include is then three per HAD practice. We expected the proportion of drop-out or loss to follow-up across the study to be 20%. This includes loss to follow-up for a range of reasons: no motivation anymore, reluctant to purchase a hearing aid after a successful trial, sickness, death etc. Taking the loss to follow-up and the proportion of clients that normally purchase a hearing aid into account results in a total (rounded) number of four first-time HAUs per HAD practice and five experienced HAUs per HAD practice to be recruited.

Statistical analyses

To check the comparability between the groups (CaU or intervention group) at baseline, baseline characteristics of the participants will be compared using the Chi Square test (for categorical variables), the independent samples *t*-test (for normally distributed continuous variables) and the Mann-Whitney test (for non-normally distributed continuous variables). Comparability will be checked for all demographic variables and all primary and secondary outcomes.

For the effect analyses, the groups will be compared on all primary and secondary outcome measures using linear mixed models including the results at T0, T1, T2 and T3. If a significant effect is found, an independent samples *t*-test will be used and a Bonferroni correction will be administered in case of multiple comparisons. Type of HAU (first-time or experienced) will be tested as an effect modifier for potential subgroup differences. The main analysis is intention to treat and additionally a per protocol analysis will be performed. A per protocol analysis is restricted to participants who complete the entire study as described in the study protocol. Any outcome measure to be collected for participants who discontinue or deviate from intervention protocols will be saved and analyzed according to the intention to treat protocol. In case of substantial missing data, multiple imputation will be applied. Items of all questionnaires will have a unique code. It will be evident from the code which questionnaire it reverses to (T0-T3) so that data can be merged. To promote data quality range checks for data values will be performed.

Process evaluation

The process of implementing SUPR into the care of the HAD practices in the intervention arm will be evaluated. The main aims of this evaluation are to gain insight into 1) the circumstances in which the intervention was implemented, 2) (non-) compliance with the intervention, and 3) the professionals' and clients' appraisal of the intervention.

The process evaluation will be carried out according to the framework as proposed by Linnan *et al*[61]. It covers seven parameters: recruitment, reach, fidelity, dose delivered, dose received and implemented, satisfaction, and perceived benefit[62]. A brief description of each of the parameters is given below.

- Recruitment refers to the procedures applied to approach and attract potential participants. The hearing aid dispensers will be asked to provide this information.
- Response. This is the proportion of people participating relative to the number of people invited.
- Fidelity relates to the question of whether the intervention was provided as intended. The team that is responsible for the email contact will be asked to provide a written report on this.
- Dose delivered: This concerns the question of whether the elements (emails) of the intervention were sent out correctly (correct content) and on time?
- Dose received and implemented: Did the participants open the emails and the videos? If so, did they watch the whole video, or part(s) of it? Information on implementation of the knowledge that participants learnt from SUPR will be deduced from the IOI-AI questionnaire (item on use) on T1. An employee of the headquarters of the hearing aid dispenser chain will monitor the video watching behaviour.

- Satisfaction: Satisfaction of the participant with SUPR will be evaluated using the IOI-AI questionnaire (item satisfaction) on T1. The hearing aid dispensers will be asked to answer the question: How would you rate your satisfaction with SUPR?

- Benefit: Information on the experienced benefit of the participant will be obtained from the IOI-AI questionnaire (item benefit) on T1. The hearing aid dispensers will be asked to answer the question: How would you rate the perceived benefit from SUPR for your clients' ability to improve in communication?

Additionally, focus group discussions with participants from the intervention group will be organized to gain insight into the reasons for using the knowledge of SUPR in their daily lives or not. At least two focus groups will be organized. The exact number will depend on data saturation. Heterogeneity in age, gender, educational level, severity of hearing impairment, and stage of behaviour change (at baseline) within the groups will be strived for. Given the difficulties hearing-impaired individuals might have with group conversations, the focus groups will have a maximum size of six participants each.

ETHICS AND DISSEMINATION

Protocol amendments, confidentiality and dissemination policy

Any important future protocol modifications will be submitted to the VU University Medical Center Medical Ethical Committee. Directly upon approval, the modification will be corresponded to the trial registry.

Personal information about enrolled participants will only be shared with employees of the headquarters of the HAD practices who signed a privacy declaration. This exchange of personal information is only done to collect data within the framework of the study (e.g., to collect audiogram

data, hearing aid purchase status, use of SUPR). Any exchanged data and personal information will be protected with a password.

VU University Medical Center has all property rights on the final results of the trial and is entitled to publish the results. The sponsor is not entitled to publish the results without written confirmation of the VU University Medical Center. These agreements are secured in a contract. For specific author contributions for the current paper, see 'Authors contributions´.

Findings of the study will be published in academic journals and presented at scientific conferences. and will be communicated within the national and international media. A short report of the findings of the study will be sent to the participants for those who are interested. The results will be communicated within the hearing aid dispenser chain.

Data collection forms and data storage

Data collection forms and procedures for data management are available on request. All data that will be collected are digital and will be stored on a computer disk at the VU University Medical Center that is locked with a security code which is only available to members of the SUPR research team. According to Good Clinical Practice guidelines and after having received informed consent, data will be archived for a period of fifteen years after finalizing the study. After finalization, 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 any more for the purposes of the study. We will perform double data entry of a selection of the audiograms and the baseline AIADH data for quality purposes.

Monitoring

The study is subjected to local regulations and its quality is monitored by the research institute's (i.e., EMGO+) Quality Committee. This committee is responsible for developing, implementing and maintaining a system for quality assurance and control for all research within the institute. Due to the nature of the study, the formation of a Clinical Trial Data Monitoring Committee was not deemed necessary.

DISCUSSION

Like in most parts in the world, usual care for adults with hearing impairment in the Netherlands is mostly restricted to audiological assessment and hearing aid fitting. This type of care is for a large part provided by commercial hearing aid dispensers. Communication programmes aimed at training in communication strategies and personal adjustment to hearing impairment, and hearing aid handling skills are not provided on a large scale in standard hearing health care settings, despite the growing evidence showing that including such programmes may decrease communication problems and improve coping[27, 33]. Likewise, despite the fact that including CPs in the rehabilitation process is increasingly recognized within audiology as a prerequisite for successful rehabilitation[12], CPs are not yet part of standard hearing health care. In the current study, these elements (i.e., a communication programme and involvement of a CP) are part of a programme called SUPR that is incorporated in regular hearing aid dispensing care and that will be tested for its effectivity. SUPR's prior aims are to improve older hearing aid owners' communication strategies and personal adjustment (together referred to as coping) and decrease their CPs' third-party disability. To our knowledge, similar online support programmes for HAUs that are implemented on a large scale in hearing aid dispenser settings are not available yet.

Thorén *et al* and Ferguson *et al* found positive short-term effects for their online interventions in the domains of participation restrictions and activity limitations and knowledge on hearing aids and

communication strategies, respectively[43, 45]. Main topics of the online programme of Thóren *et al* covered knowledge about hearing anatomy, hearing aids, communication strategies, and guidelines for significant others[43]. The programme of Ferguson *et al* did include some communication strategies, but the focus of the programme was on hearing aids[45]. Although coping elements were an important focus in the programme of Thorén *et al*[43], in the SUPR study coping is the main component, which is thereby unique. Another major advantage of the current study is that it uses a long-term follow-up design of eighteen months. Such a long follow-up has thus far not been applied in similar studies. As was already raised by Kramer *et al*, Barker *et al* and Wong *et al* more research on treatment efficacy in the long(er)-term is essential because it is possible that some short-term effects may disappear and other effects can arise[34, 36-37]. Barker *et al* and Wong *et al* also advised to conduct large and appropriately powered studies[34, 36]. The latter has been taken into account in the sample size calculation. The aim thus is that SUPR will be a large-scale study with an inclusion of 70 HAD practices across the Netherlands with ambitious numbers of first time and experienced HAUs to be recruited (i.e.258 and 311 in total, respectively).

A few limitations to the design need to be considered. Unfortunately it is not possible to perform a double-blinded, randomised, controlled trial due to the nature of the intervention study. Participants will be aware that the general aim of the SUPR study is to evaluate a support programme and know that they are either part of the group that receives care as usual or SUPR. Nevertheless, we will attempt to minimize the provision of information on the content of SUPR to participants of the CaU group. These participants only know that SUPR is a support programme aimed to improve communication, but for instance do not know what the intervention further entails. This way, we aimed to prevent that they would independently seek access to SUPR (which would cause contamination) and that their knowledge of the care they were missing out on would affect their responses in the questionnaires. We also attempted to prevent this by offering the programme to the CaU-participants for free after the study.

SUPR is an online intervention, it is thus essential that people have access to a device with an internet connection. The requirement to be online to participate in the study may be an issue for the older population (74+). The probability that we are targeting a selected group when offering care online needs discussion. It is known however that the use of internet among older adults is already substantial among the relatively young-old (i.e., 55-74 years)[63]. Amongst the young-old, weekly internet use has increased from 70% in 2010 to 83% in 2015 in the Netherlands and will most probably keep rising in the future[64]. The non-use of internet among the older olds (74+) has decreased from 66% in 2012 to 50% in 2015[65]. Furthermore, it is known that the older persons who do use the internet, generally use it more for health-related tasks or information than for personal tasks [66]. Also, persons with hearing loss are more likely to use the internet than people in the general population (OR=1.74, 95% CI 1.23-3.17)[66]. We are therefore confident that our participants will be open to using SUPR.

Finally, it is known that for those who are at risk for isolation or those who have reduced access to health care, internet can be a practical tool to have direct access to health services [67]. Other elements that can add to the effectiveness of online support programmes as SUPR are that it can be (partly or mainly) provided in a visual mode (images, written text, subtitles), the volume can be controlled, background noises can be relatively easily eliminated, and online support programmes provide the opportunity to tailor intervention elements.

At the start of the study, participants might underestimate their hearing impairment caused by the stigma on hearing impairment[68]. We expect that SUPR may have a positive effect on acceptation and therefore people will be more honest on their report of hearing disability. As such, it is possible that we will observe an increase in self-reported hearing disability in the intervention group over time, whereas SUPR is expected to result in a decrease in experienced disability. To examine this, we can use one of the subscales of the CPHI on acceptation of hearing loss. With this subscale we can examine if acceptance is a mediator between time and hearing status for the intervention group.

This study aims to perform a process evaluation, as is strongly recommended in all randomized controlled trial research. A process evaluation provides insight into reasons for the demonstrated (absence of) effectiveness of the intervention, and might offer information concerning the generalizability of the study results. When effects of SUPR turn out to be disappointing, we may be able to modify the programme based on the results of the process evaluation after the study.

In the future, it is expected that there will be an increasing demand in solutions for hearing health conditions due to the ageing population and thus increased prevalence of hearing problems. SUPR is especially developed for use on a large scale basis in HAD practices. Demonstrating its effectiveness will be a great step forward in our attempts to further improving health care services for persons with hearing impairment.

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FOOTNOTES

Contributors

SEK developed the first version of the study design, in collaboration with BP and VJ. MP and SK developed the study design further and wrote up the first draft of study protocol. BvdW, FJM, MP, SEK, and VJ worked on the design further, and facilitated the practical implementation of the study. BIW provided statistical and methodological advice. Data collection was done by BvdW and FJM, assisted by VJ, and supervised by SEK and MP. FJM wrote the final version of the manuscript. SEK and

MP supervised the writing process and MP, SEK, BP, BIW, VJ, and BvdW gave critical comments on several drafts of the manuscript.

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The SUPR study is funded by Audionova International. The study design was developed by SEK in collaboration with BP and VJ. VJ supported the practical implementation of the study. Audionova International had no role in data analysis and interpretation of data.

Competing interests

VJ is an employee at Schoonenberg Hoorcomfort. BP is an employee at AudioNova.

Ethics approval and consent to participate

The Medical Research Involving Human Subjects ACT (WMO) does not apply to this study and an official approval by the Medical Ethics Review Committee of the VU University Medical Center is not required. The Medical Ethics Review Committee of the VU University Medical Center is registered with the US Office for Human Research Protections (OHRP) as IRB00002991. The FWA number assisted to VU University Medical Center is FWA00017598.

An informed consent procedure will be followed prior to participants' enrolment for the study on the registration website.

Abbreviations

SUPR: SUpport PRogramme, CaU: care as usual, CP: communication partner, HAU: hearing aid users, HAD practices: hearing aid dispensing practices, AIADH: Amsterdam Inventory for Auditory Disability and Handicap, CPHI: Communication Profile for the Hearing Impaired, MARS-HA: Measure of Audiologic Rehabilitation Self-Efficacy for Hearing Aids, IOI-HA: International Outcome Inventory – Hearing Aids, IOI-AI: International Outcome Inventory – Alternative Interventions, URICA: University

of Rhode Island Change Assessment- for Hearing health behaviour, HHDI: Hearing Handicap and Disability Inventory, SOS-HEAR: Significant Other Scale for Hearing Disability, IOI-HA-SO: International Outcome Inventory Significant Other– Hearing Aids, IOI-AI-SO: International Outcome Inventory Significant Other– Alternative Interventions.

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SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	2
	2b	All items from the World Health Organization Trial Registration Data Set	1-28
Protocol version	3	Date and version identifier	1
Funding	4	Sources and types of financial, material, and other support	29
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	29
	5b	Name and contact information for the trial sponsor	1
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	17
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	N/A

Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4-8
	6b	Explanation for choice of comparators	4-8
Objectives	7	Specific objectives or hypotheses	8
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	8
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	8-11
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	12-13
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	8-11
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	N/A
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	11-12
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	13
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	13-20
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	13-15

Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	20,21
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	11,12
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	20
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	20
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	20
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	3
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/A
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	13-20
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	21

Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	21,22
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	21,22
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	21,22
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	21
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	24,25
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	N/A
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	24,25
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	24,25
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	N/A
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	24,25

Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	29
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	23,24
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	29
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	23,24
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	24
	31b	Authorship eligibility guidelines and any intended use of professional writers	28,29
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	N/A
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Appendix 1 and 2 (uploaded as additional files)
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A.

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

Communicatiepartner Toestemmingspagina versie 5 dd 03-12-2015

Comment [b1]: Wanneer men de link opent dan verschijnt deze website

SUPR

Een onderzoek naar de effectiviteit van HoorSupport

Respondentnummer:	
Volledige achternaam:	
E-mailadres:	
Achternaam slechthorende naaste:	

Door deel te nemen geef ik te kennen voldoende te zijn geïnformeerd over het doel en de inhoud van het onderzoek. Het doel van dit onderzoek is om te bepalen of HoorSupport de communicatie van iemand met hoorproblemen verbetert (met zijn/haar communicatiepartner). Dit wordt gemeten met behulp van vragenlijsten.

• Ik weet dat ik in totaal vier keer een vragenlijst ontvang over mijn ervaringen met de slechthorendheid van mijn naaste.

• Ik ben ervan op de hoogte dat verzamelde gegevens zullen worden gebruikt voor wetenschappelijk onderzoek, zonder vermelding van mijn naam en andere persoonlijke gegevens.

• Ik ben ervan op de hoogte dat ik mijn deelname op ieder moment mag en kan beëindigen.Wanneer ik besluit te stoppen zullen de tot dan toe verzamelde gegevens gebruikt worden voor het onderzoek, tenzij ik anders aangeef.

• Ik geef toestemming om mijn gegevens nog 15 jaar na dit onderzoek te bewaren.

Slechthorende Toestemmingspagina versie 5 dd 03-12-2015

Comment [b1]: Wanneer men de link opent dan verschijnt deze website (let op er zijn 2 pagina's)

SUPR

Een onderzoek naar de effectiviteit van HoorSupport

Respondentnummer:	
Cliëntnummer:	
Volledige achternaam:	
Emailadres:	
Achternaam communicatie partner:	

Door deel te nemen geef ik te kennen voldoende te zijn geïnformeerd over het doel en de inhoud van het onderzoek. Het doel van dit onderzoek is om te bepalen of HoorSupport de communicatie van iemand met hoorproblemen verbetert (met zijn/haar communicatiepartner). Dit wordt gemeten met behulp van vragenlijsten.

• Ik weet dat ik in totaal drie keer een vragenlijst ontvang over mijn communicatie en gehoorklachten.

• Ik ben ervan op de hoogte dat verzamelde gegevens zullen worden gebruikt voor wetenschappelijk onderzoek, zonder vermelding van mijn naam en andere persoonlijke gegevens.

• Ik ben ervan op de hoogte dat ik mijn deelname op ieder moment mag en kan beëindigen. Wanneer ik besluit te stoppen zullen de tot dan toe verzamelde gegevens gebruikt worden voor het onderzoek, tenzij ik anders aangeef.

• Ik geef toestemming om mijn gegevens nog 15 jaar na dit onderzoek te bewaren.

Slechthorende Toestemmingspagina versie 5 dd 03-12-2015

- Met mijn deelname geef ik automatisch aan akkoord te gaan met het gebruik van mijn toonaudiogram en de antwoorden op de Amsterdamse Vragenlijst welke zijn afgenomen tijdens afspraken bij de audicien (Schoonenberg).

Heeft u een communicatiepartner gekozen voor HoorSupport/het onderzoek?

Comment [b2]: Na de toestemmingspagina opent een korte vragenlijst.

  - Ja (hierbij opent de volgende vraag)
  - Nee (hierbij wijzen wij de persoon erop dat het voor HoorSupport en/of het onderzoek erg nuttig kan zijn om een communicatiepartner te kiezen. De persoon wordt vriendelijk verzocht het aanwijzen van een CP nog eens te overwegen.)

- Heeft u deze communicatiepartner de envelop gegeven met daarin de uitnodiging voor het onderzoek?
  - Ja (hierbij opent de volgende vraag)
  - Nee (hierbij wijzen wij de persoon erop dat het voor het onderzoek erg nuttig kan zijn om de gekozen communicatiepartner uit te nodigen)

- Weet u of diegene mee wil doen?
  - Ja, hij/zij wil ook meedoen aan het onderzoek
  - Nee, hij/zij wil niet meedoen aan het onderzoek
  - Weet ik niet

BMJ Open

Effectiveness of an online SUpport PRogramme (SUPR) for older hearing aid users: Study protocol for a cluster randomised controlled trial

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Primary Subject Heading:	Ear, nose and throat/otolaryngology
Secondary Subject Heading:	Evidence based practice
Keywords:	Cluster randomized controlled trial, Hearing aids, Internet, Communication programs hearing loss, Communication strategies, Personal adjustment to hearing impairment

26 January 2017 – Protocol version 2

Effectiveness of an online SUpport PRogramme (SUPR) for older hearing aid users: Study protocol for a cluster randomised controlled trial

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ABSTRACT

Background: An educational SUpport PRogramme called SUPR has been developed for hearing aid users (HAUs) and their communication partners (CPs) offering care beyond hearing aid fitting. SUPR teaches its users communication strategies, hearing aid handling skills, and offers peer testimonials. Ultimately, its main aim is to improve communication strategies and personal adjustment.

Methods/design: Using a cluster randomised controlled trial-design, 70 Dutch hearing aid dispenser practices were randomised into hearing aid fitting (care as usual, 34 practices) and hearing aid fitting including SUPR (36 practices). The aim was to recruit a total of 569 older (aged 50+) first-time (n=258) and experienced (n=311) HAUs and their CPs. SUPR consists of a Practical Support Booklet and online material offered via email over a period of 6-7 months. The booklet provides practical information on hearing aids, advice on communication strategies, and home exercises. The online material consists of educational videos on hearing aid functionality and usage, communication strategies, and peer testimonials. Finally, noncommittal email contact with the dispenser is offered. Every HAU is asked to assign a CP who is advised to be involved intensively. Effect measurements will occur at baseline and at 6, 12, and 18-months follow-up via online questionnaires. The primary outcome for HAUs will be the use of communication strategies and personal adjustment with hearing impairment as measured by the subscales of the Communication Profile for the Hearing Impaired. The primary outcome for CPs will be third-party disability (Significant Other Scale for Hearing Disability). A process evaluation will be performed.

Ethics and dissemination: The study was approved by the Dutch Institutional Review Board (IRB) of the VU Medical University Center Amsterdam. This intervention could contribute to lowering the hearing impairment burden in our ageing society. The results will be disseminated through peer-reviewed publications and scientific conferences.

Trial registration: ISRCTN77340339; Pre-Results.

Keywords: Hearing loss, personal adjustment to hearing impairment, communication strategies, intervention, cluster randomised controlled trial, hearing aids, communication, internet.

STRENGHTS AND LIMITATIONS

- This is the first study to evaluate the effects of an online educational SUpport PRogramme (SUPR) for hearing aid users that is implemented in a hearing aid dispensing (HAD) practice setting on a large scale.
- Hearing-impaired participants and their communication partners (CPs) originating from 70 HAD practices located all across the Netherlands will be included.
- The online character of the programme suits the current and future developments in the increasing internet use among older people and can reach out to those with reduced (physical) access to health care.
- The online character might however reach a selective sample of older people (especially among the oldest old, 75+), willing or able to adopt the intervention (i.e., only those with access to and willing to use the internet for this purpose).
- The study design does not allow the blinding of participants and researchers for intervention allocation. This could potentially lead to performance bias.
- The findings of the study will potentially contribute to improvement of hearing health care services for hearing-impaired people and their CPs.

BACKGROUND

Hearing impairment is one of the most prevalent chronic health conditions affecting older adults. It was ranked fifth in the top 25 of global causes for years lived with disability in 2013[1]. Due to the overall aging of the population[2], the prevalence of hearing impairment is increasing vastly, imposing a great burden on individuals and society.

Hearing impairment essentially leads to the inability to communicate effectively which in turn can result in a cascade of effects leading to poor psychosocial outcomes such as loneliness[3-5],

distress[6], depression[6, 7], and work-related fatigue[8]. It has also been associated with accelerated cognitive decline[9] and falls[10]. The limitations on daily life activities and restrictions in social and societal participation that people experience depend on aspects that are both internal (such as the level of impairment in hearing functions and structures) and external (such as availability of hearing aids, care facilities, and social support) to people[11]. In addition, internal 'personal factors' including age and applied coping strategies are important factors which can influence psychosocial outcomes[11].

Significant others can also be negatively affected by the hearing impairment of their loved ones. Partners and spouses generally experience frustration and embarrassment, for example in challenging social communication settings[12]. Communication difficulties in background noise, the partner's frequent request to repeat, and the need to act as an interpreter may cause irritation and tension within a relationship[12]. In a systematic review conducted by Kamil *et al* it was found that communication partners (CPs) of people with hearing impairment experience decreased social functioning, poorer quality of life, and more participation restrictions than CPs of normally hearing individuals[13].

The usual care provided for people with hearing impairment is often restricted to the assessment of hearing loss and the fitting of hearing aids[14]. Hearing aid use has positive effects on quality of life, social and emotional wellbeing, and may reduce depressive complaints[15-17], and possibly even cognitive decline[18]. Despite this abundant evidence on positive health effects, the uptake and use of hearing aids is low. It is estimated that around one third of the adults who would benefit from hearing aids own them[19-21] and 3-20% of these owners never use them[22,23]. Reasons for low uptake and use have been investigated and include low perceived need of amplification reflected in low self-reported hearing disability[24-26] and limited acceptance of hearing loss[24]. In addition, low expectations of hearing aid benefits[24, 25], limited gain in noisy situations[25, 26], and low

overall sound quality[26], add to low uptake and use. Other perceived barriers include stigma[25, 26], high monetary costs[26], and the need for regular hearing aid care and maintenance[26]. Finally, lack of social support or social pressure to get a hearing aid are factors having a negative impact on hearing aid use[25, 26].

Because the factors leading to low use are numerous and their interplay is complex, it has often been argued that hearing health care should offer more than hearing aids alone to improve everyday communication and wellbeing of hearing-impaired adults[27]. This argument is in line with the biopsychosocial approach of health which is receiving increasing attention in the field of audiology: Experienced hearing disability (i.e., activity limitations and participation restrictions) is the outcome of a complex interaction between an individual and his/her contextual factors[28-30].

Various interventions have been proposed in the past to complement hearing aid fitting. Examples are communication programmes aimed at improving speech perception and/or communication management[31]. These programmes include speech perception training, communication management training, and social support[27, 32, 33]. For reviews, see Barker *et al*, Sweetow *et al*, and Wong *et al*[34-36]. Examples of effective programmes are the Home Education programme[37] and the Active Communication Education (ACE) group programme[38]. Both programmes consist of modules on everyday communication situations, aiming to improve the use of communication strategies, personal adjustment to living with hearing impairment, quality of life, development of problem-solving skills, and to decrease the level of experienced hearing disability. These programmes showed an improvement in communication strategies[37] and communicative participation restrictions and activity limitations[38].

Communication training programmes, whether combined with hearing aid fitting or not, are rarely offered in hearing health care[27, 32]. When offered, there are various reasons adults with hearing

impairment would choose not to pursue communication training programmes; they could live in a rural area, have a lack of time, or no easy access[32]. The paradigm shift in health care from the traditional doctor-centric model to a more patient-centered model, combined with increasingly pervasive use of e-health methods and technology, means that the typical barriers causing the low use of (group) communication training programmes can now be overcome[39-41].

A number of studies have recently been published reporting on the development and evaluation of online communication programmes. Thorén *et al* developed such a programme[42] which included reading material on hearing anatomy, hearing aids, communication strategies, assistive listening devices, and guidelines for CPs. In addition, the intervention included weekly email contact with an audiologist, problem solving exercises, and online peer discussion on personal experiences with hearing loss. Thorén *et al* studied the effectiveness of the programme using a randomised controlled trial-design in which the intervention group (*n*=38) received the online programme while the control participants (*n*=38) were offered access to an internet discussion forum or were placed on a waiting list[42]. The researchers found reduced symptoms of depression[43] and a significant decrease of activity limitations and participation restrictions in the intervention group compared to the controls at five weeks directly after the intervention and at three-months follow-up[42]. Ferguson *et al* investigated the use of short interactive videos (reusable learning objects, RLOs)[44]. RLOs were delivered via DVD for TV, computer, and the internet and covered practical and psychosocial issues which are relevant for audiologic rehabilitation. The intervention group (*n*=103) received seven RLOs plus usual clinical services including hearing aid fitting and counseling. They were compared to a control group (*n*=100) who received clinical services only and were placed on a waiting list. Participants in the intervention group had significantly better hearing aid skills and better knowledge on psychosocial issues than the control group after 6-weeks follow-up.

Whereas the online education programme of Thorén *et al* was evaluated in a sample of adults who were recruited by local advertisements and articles and were wearing a hearing aid for at least one year[42], Ferguson *et al* evaluated their RLOs in a small sample of patients of the audiology service of the Nottingham University Hospitals NHS Trust. Patients were adults who had been referred to the clinic by their family doctor[44]. The participants in the study of Kramer *et al* mentioned earlier, were all patients of a specialized tertiary Audiology Centre, limiting the generalizability of the results[37]. In general, only a small number of hearing aid applicants with relatively complex hearing problems receive hearing care through a tertiary clinic. The vast majority of hearing aids are fitted in a dispenser practice.

To the best of our knowledge, there is no study available evaluating the effectiveness of an online communication training programme that is implemented on a large scale in a hearing aid dispensing (HAD) practice setting. This paper reports on the design of such a study. It addresses the different steps that will be taken to evaluate an online SUpport PRogramme (SUPR) for hearing-impaired adults and their CPs. SUPR is based on the Home Education programme developed by Kramer *et al*[37]. The original version developed in 1995 has been updated so that it would be applicable for use over the internet. SUPR has also been expanded with extra elements including instruction videos on how to operate and maintain hearing aids and peer testimonials. All elements will be sent about bi-weekly via email.

This study aimed to involve seventy HAD practices, of which half will offer the training programme. This large number of practices not only contributes to a large sample size (and therefore statistical power), it also reflects real world clinical practice and thus contributes to the external validity of the future results. The study will include an 18-month follow-up. As was mentioned earlier by Kramer *et al*, Barker *et al,* and Wong *et al* more research on treatment efficacy in the long(er)-term is essential

because it is possible that some short-term effects may disappear and other effects can arise[34, 36-37].

The aim of this study is to determine the effectiveness of SUPR as part of standard HAD care among older hearing aid users (HAUs) and their CPs. Based on the active elements included in SUPR, we hypothesize that older HAUs who receive SUPR in addition to hearing aid fitting will show the following favourable effects at 18-months follow-up when compared to HAUs who receive hearing aid fitting only:

- More use of favourable and less use of unfavourable communication strategies (primary outcome measure).
- Better personal adjustment to hearing impairment (primary outcome measure).
- Higher self-efficacy of hearing aid handling, higher hearing aid use, less activity limitations and participation restrictions, less handicap and disability, better self-reported intervention outcomes, higher readiness to do something about their hearing, and higher satisfaction with HAD services (secondary outcome measures).

These effects will be studied both in first-time and experienced HAUs.

- Consistent with the findings by Kramer *et al*[37], we hypothesize that effects on all outcomes will be larger in first-time HAUs than in experienced HAUs.

With regard to the CPs, we hypothesize that CPs who receive SUPR - as compared to CPs whose loved ones only receive hearing aid fitting - will show the following favourable effects:

- Lower third-party disability (main outcome).
- Better self-reported intervention outcomes.

METHODS

Study design

A cluster randomised controlled trial with an 18-month follow-up period will be performed. Cluster randomisation (with the HAD practice as a unit) was chosen over individual randomisation because the latter would hold a high risk of contamination. In case of individual randomisation, The HAD personnel would have to switch between approaches (SUPR/CaU) frequently and could accidentally refer to or offer SUPR to clients assigned to the CaU group. In addition, as the time between informing the clients about the study, receiving clients' consent and the start of SUPR/CaU was relatively short, performing randomisation on an individual level was not feasible. Dutch HAD practices and consequently all clients in these practices were randomly assigned to one of two groups. The control group received care as usual (CaU) which is hearing aid fitting only, while the intervention group received hearing aid fitting supplemented with SUPR.

Care as Usual

CaU starts with a preparation appointment during which a screening pure-tone audiogram (only air conduction) is administered by the hearing aid dispenser. If the hearing loss in one or both ears is at least 35 decibel (dB) hearing level (HL) (averaged over the three frequencies 1, 2, and 4 kHz) in one or both ears, someone is considered potentially eligible for hearing aid fitting and more comprehensive audiometry is required. If the client is interested in hearing aids, his/her general wishes and goals are discussed after which the Amsterdam Inventory for Auditory Disability and Handicap (AIADH; Kramer *et al*[45]) is handed out. Clients are asked to complete the AIADH at home and bring it along to the next appointment. The AIADH assesses hearing activity limitations and participation restrictions. Clients are asked to assign a CP and involve them throughout the rehabilitation (e.g., bring them to appointments). During the next appointment, i.e., the intake appointment, comprehensive audiometry (air and bone conduction, and speech audiometry) are performed. The results of all tests, the AIADH, and the wishes of the client determine what type of hearing aid may be best suited for this person. The appropriate hearing aids will be selected and fitted directly (if available in the HAD practice) or in a subsequent fitting appointment. Fitting is followed by a trial period which usually

lasts up to four weeks, during which people can try out the hearing aid and decide whether or not to purchase it. Depending on the client's needs, fine-tuning or other follow-up appointments are scheduled. These can be scheduled during the trial period but also after the device has been purchased.

Intervention: SUPR

SUPR consists of a Practical Support Booklet and online elements. In addition, clients are asked to assign a CP who is involved actively in the programme (see below).

Practical Support Booklet

The Practical Support Booklet will be handed out at the end of the preparation appointment (first-time HAUs, experienced HAUs) or the intake appointment (experienced HAUs). The aims of the Practical Support Booklet are to: 1) assist clients and CPs in getting familiar with their hearing aid, 2) stimulate clients' use of the hearing aid and clients' and CPs' use of communication strategies, and 3) guide clients and their CPs through the various stages (i.e., appointments) of the rehabilitation trajectory. Although the theoretical elements of the booklet can also be used as a reference *after* the purchase of the hearing aid, the booklet's focus is on the period between the first HAD appointment and the end of the trial period. The booklet covers four parts, corresponding to the four key appointments during the trial period (i.e., preparation appointment, intake appointment, control- and/or fine-tuning appointment, and purchase appointment). The information that is provided is synchronized with the topics which are typically discussed during these appointments. The first part outlines the process of getting a hearing aid and includes an introduction to the hearing aid dispenser's care and an explanation about the pure tone audiogram. The client is asked to write down and rank specific communication goals (s)he wishes to reach by the end of the trial period (for example: 'I want to be able to hear the stories of my 10-year old granddaughter Anne when I pick her up from school every Monday'. The second part revolves around the types of hearing aids available

and the client's hearing aid preferences. Information about how to operate and maintain the device is provided as well. In the third part the client and the CP are asked to write down their experiences with the new hearing aid and its settings. This information will be used for further refinement of the fitting. The final section of the booklet provides information on assistive listening devices, reimbursement of costs, more information on the audiogram, types of hearing loss, and the types of hearing aids (e.g. behind-the-ear and in-the-canal). In addition, an overview of the most important communication strategies that clients and their CP can apply is provided. The content and the appearance of the booklet were realised during several months of development by the HAD company. Although no specific guidelines were used for the development of the written health information in the booklet, a number of the subsequent steps that are deemed important by Caposecco *et al* were taken: 1) interviews with key stakeholders (clients, CPs, HAD practice personnel) were held to specify the booklet's goals and functions, 2) graphics and text were developed and optimized with regard to their understandability and attractiveness (language difficulty, lay-out, font size, paragraphing), 3) a first complete version of the booklet was pilot-tested in ten HAD practices for several months. Feedback by all key stakeholders was collected, 4) the feedback was incorporated in a new and final version of the booklet (which was used in the study)[46].

Online Elements

After the intake appointment, the links to the online elements will be sent to the participants via email. There are two emails which offer contact with the HAD practice and eleven emails which contain the links to the various educational videos that are offered (see below). The online part spans a period of up to about six months after the hearing aid purchase. The exact duration of SUPR depends on the duration of the trial period. For example, if a trial period is finalized in three weeks instead of the average four, the total duration of SUPR is one week shorter.

The educational videos consist of: 1) Training modules on hearing aid handling skills. These comprise of three short instruction videos with practical information on the use and maintenance of hearing aids. Participants receive the link to the relevant instruction video depending on their style of hearing aids (i.e., behind-the-ear, in-the-canal, or receiver-in-the-ear). 2) Training modules on communication strategies and personal adjustment. This is a remake (i.e., a modernized version) of the home educational programme *"Horen en Gehoord Worden: Hoe kan het beter",* as developed by Kramer *et al*[37]. It comprises five short videos showing the difficulties that hearing-impaired people can experience in everyday listening situations. The typical reactions by both the hearing-impaired people and his/her social environment to these situations are shown, and a trainer illustrates how communication could be improved by using communication strategies (for both hearing-impaired people and his/her CP). 3) Three testimonials by hearing-impaired peers who share their experiences with hearing aids.

Measurements

For all participants four measurements will take place: at baseline (after the preparation appointment, but before the actual hearing aid fitting) (T0), six months after the hearing aid purchase (T1), one year after the hearing aid purchase (T2), and eighteen months after the hearing aid purchase (T3). Measurements at T3 serve to determine the long-term effects of SUPR, i.e., one year after its completion. Data will be collected using online questionnaires through NetQ Premium, which is an online survey programme. Email-reminders will be sent within a week after the first invitation-email and another week after the first reminder, if necessary.

Study population & recruitment

The following procedures were followed during the recruitment period (February 2016 to September 2016). Hearing aid dispensers invited clients to participate in the study. First-time HAUs were invited at the end of their preparation appointment. Experienced HAUs were invited at the end of their

preparation or at the end of their intake appointment, if they did not require a preparation appointment. Hearing aid dispensers handed out an information package including an invitation letter, a selection form outlining the in- and exclusion criteria, a brochure about the study, and an envelope with an information letter and brochure for the CP. All interested participants were asked to enrol themselves for the study by subscribing on a registration webpage and signing the online consent from there. Every month the number of clients who were invited (number of envelopes that was handed out) and were enrolled (number of online subscriptions) per HAD practice were determined. When enrolment numbers for a particular HAD practice were relatively low, a phone call was made to the specific HAD practice to notify them of their current number of enrolments, to identify possible underlying reasons, and to motivate them to reach the required target. Throughout the recruitment period, the HAD headquarters organized motivational conference calls for the HAD practices that had not yet reached their target. Finally, when enrolment ratings continued to be behind target, employees of the headquarters directly invited potentially eligible clients who were not invited by the HAD practice personnel, via a telephone call. The study material was then sent via email.

Incentives

After completing the T0 questionnaire, all participants will be offered a voucher of EUR 50 to spend on a hearing aid or EUR 25 to spend on other articles of the HAD practice if they decide not to purchase a hearing aid. CPs will be offered a gift card. In addition, participants in the control group will be offered a shortened version of SUPR after eighteen months. For them, SUPR will be slightly adjusted such that it becomes suitable for individuals who already started using a hearing aid.

In addition to the motivational procedures described under Study population & recruitment, HAD practices will be (see under 'sample size calculation') offered gift cards for the entire team once the total number of participants is recruited.

Inclusion criteria

The following inclusion criteria for the hearing aid candidates were applied: 1) Age 50 years or older. 2) Is willing to try out one or two new hearing aid(s) (i.e., agreed to plan a follow-up appointment). This hearing aid could be their first (i.e., first-time HAUs), or a replacement hearing aid (i.e., experienced HAUs). Clients who did not purchase a hearing aid after the trial period were considered drop-outs. 3) Sufficient understanding of the Dutch language. 4) Access to a personal computer with internet access and owner of an email account for the total duration of the study.

Exclusion criteria

The following hearing aid candidates were excluded: 1) Candidates who received additional care at a specialized Audiology Clinic. In the Netherlands, an Audiology Clinic offers elaborate, multidisciplinary and specialized, tertiary health care and is aimed at people with complex hearing problems. This care may overlap and/or interfere with that of SUPR. 2) Candidates that received 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 were not part of the target group of SUPR.

Although all participants were encouraged to assign a CP, it was not obligatory for them to assign one in order to participate in the study. For the CPs, the only inclusion criterion applied was that they should be 18 years or older.

Outcome measures

An overview of all outcome measures and measurements over time is presented in Table 1[47].

362 **Table 1 Spirit flow diagram. Schedule of enrolment, interventions, and assessments**

		Allocation of HAD practices	Enrolment	Post-Allocation & Enrolment			
TIMEPOINT	Outcome measurements	–T2	-T1	T0 (Baseline)	T1 (6 months)	T2 (12 months)	T3 (18 months)
ENROLMENT:							
Eligibility screen			**x**				
Informed consent			**x**				
Allocation		**x**					
INTER-VENTIONS:							
Care as Usual (Hearing aid fitting)		**x**	———	———	———	———	**x**
Intervention (Hearing aid fitting + SUPR)		**x**	———	———	———	———	**x**
ASSESSMENTS:							
Demographic variables							

Gender		x			
Age		x			
Marital status		x			
Living situation		x			
Level of education		x			
Occupational status		x			
Country of birth participant		x			
Country of birth participant's parents		x			
Primary outcome measure HAUs					
The use of communication strategies and	CPHI	x	x	x	x

personal adjustment					
Secondary outcome measures – HAUs					
Self-efficacy of hearing aid handling	-MARS-HA - Basic handling subscale	x	x	x	x
	-MARS-HA - Advanced handling subscale		x	x	x
Self-reported intervention outcomes	-IOI-HA (items 2-7)/IOI-AI (all 7 items)		x	x	x
Self-reported hearing aid use	-IOI-HA (item 1)		x	x	x
	-Use questionnaire		x	x	x
Objective hearing aid use	-Data-logging		x	x	x
Satisfaction with the hearing aid dispenser	'How likely is it that you would recommend the service of the	x	x	x	x

service	HAD practice to other people (family, friends, colleagues?)'				
Self-reported activity limitations and participation restrictions	AIADH	x	x	x	x
Hearing status	Pure tone audiogram	x			
Readiness to do something about one's hearing problems	-URICA - Precontemplation/ Contemplation/ Action stages	x	x	x	x
	-URICA - Maintenance stage		x	x	x
Emotional response	HHDI - Emotional response subscale		x	x	x
Secondary outcome measures – CP					
Third-party	SOS-HEAR	x	x	x	x

disability					
Self-reported intervention outcomes from the perspective of the CP	IOI-HA-SO/IOI-AI-SO	x	x	x	

Abbreviations: HAD practice: hearing aid dispensing practice, SUPR: Support PRogramme, HAU: hearing aid user, CPHI: Communication Profile for the Hearing Impaired, MARS-HA: Measure of Audiologic Rehabilitation Self-Efficacy for Hearing Aids, IOI-HA: International Outcome Inventory – Hearing Aids, IOI-AI: International Outcome Inventory – Alternative Interventions, AIADH: Amsterdam Inventory for Auditory Disability and Handicap, URICA: University of Rhode Island Change Assessment- for Hearing health behaviour, HHDI: Hearing Handicap and Disability Inventory, CP: Communication Partner, SOS-HEAR: Significant Other Scale for Hearing Disability, IOI-HA-SO: International Outcome Inventory Significant Other– Hearing Aids, IOI-AI-SO: International Outcome Inventory Significant Other– Alternative Interventions.

Primary outcome measure – HAUs

- *The use of communication strategies and personal adjustment with hearing impairment* will be measured using the reliable and validated Dutch 35-item version of the Communication Profile for the Hearing Impaired (CPHI)[48, 49]). Communication strategies are measured using the following subscales: Maladaptive Behaviours, Verbal Strategies, and Non-verbal Strategies. Each subscale consists of statements for which the respondent has to indicate how often (s)he applies this strategy. An example: "I avoid conversations with strangers, because of my hearing loss" (subscale Maladaptive Behaviour). The five response options range from 'almost never' to 'almost always'. Scores are averaged per subscale and range from 1 to 5. High scores indicate favourable strategies whereas low scores indicate unfavourable strategies. The second section of the CPHI deals with

personal adjustment and also contains three subscales: Self-acceptance, Acceptance of Loss, and Stress & Withdrawal. An example item of the latter subscale is: "I feel very tense because of my hearing loss". The five response options range from 'totally disagree' to 'totally agree'. Some items were recoded because of reverse scaling. After recoding the item scores, average scores per subscale can be calculated, with low scores indicating poor personal adjustment and high scores indicating good personal adjustment.

We have chosen for the subscales of the CPHI as central outcome measures for the following reasons. Firstly, the subscales are purported to measure the constructs that are acted upon by the core active element of the intervention (i.e., the revised home education programme). Secondly, the CPHI has proven to have very good validity and reliability in the target population of this study[49].

Secondary outcome measures - HAUs

- *Self-efficacy of hearing aid handling* will be measured by the Basic Handling subscale of the Measure of Audiologic Rehabilitation Self-Efficacy for Hearing Aids (MARS-HA). The English version of this 7-item subscale has good psychometric quality[50]. Scores can range from 0% to 100%, with lower scores representing less certainty in one's capability of handling a hearing aid. At T1, T2, and T3, the 5-item subscale Advanced Handling will be additionally administered. Dutch versions of the scales were created using the forward-backward method[51]. At T0 'expected self-efficacy' will be administered, whereas at T1, T2, and T3 'experienced self-efficacy' will be determined as the new hearing aids will have been fitted by then. For measurement of 'expected self-efficacy', all MARS-HA-items start with 'I think I can …', whereas for measurement of 'experienced' self-efficacy all items start with 'I can… '.

- *Hearing aid use*. Self-reported use will be measured using the first item of the International Outcome Inventory – Hearing Aids (IOI-HA) ("How many hours per day on average have you been using your hearing aid(s) in the last two weeks?"). Response options are 'none', 'less than 1 hour a

day', '1-4 hours a day', '4-8 hours a day', and 'more than 8 hours a day'[52]. Self-reported hearing aid use will additionally be measured by three questions from the use questionnaire developed by Laplante-Lévesque *et al*[53]. The latter questionnaire was translated into Dutch, using the forward-backward method[51]. Hearing aid use will also be measured objectively via data-logging.

- *Self-reported intervention outcomes (hearing aid rehabilitation and SUPR outcome)*. The International Outcome Inventory – Hearing Aids (IOI-HA; items 2-7) and the equivalent International Outcome Inventory for Alternative Interventions questionnaire (IOI-AI; all 7 items) will be used to assess the outcome of hearing aid rehabilitation and SUPR respectively[52]. The Dutch version of IOI-HA has a good test-retest reliability and validaty[54]. The first item of the IOI-AI determines the frequency of the use of the alternative intervention, i.e., "How often have you used the learnt communication strategies on an average day in the last two weeks?". Response options are 'never' (1), 'rarely' (2), 'sometimes' (3), 'often' (4), and 'almost always' (5). Items 2-7 of the IOI-HA/IOI-AI questionnaire cover: benefit, residual activity limitation, satisfaction with the hearing aid(s)/SUPR, residual participation restriction, impact on others, and quality of life.

- *Satisfaction with the HAD practice service.* Satisfaction will be measured by the following question: "How likely is it that you would recommend the service of the HAD practice to other people (family, friends, colleagues)?" It is scored on a visual analogue scale running from 0 (=not at all likely) to 10 (=extremely likely).

- *Self-reported activity limitations and participation restrictions* are measured using the reliable and validated original (Dutch) version of the Amsterdam Inventory for Auditory Disability and Handicap (AIADH)[45, 55]. It contains 28 questions regarding everyday listening situations. An example is: "Do you immediately look into the right direction when somebody calls you in the street"? The 4-point response scale covers: 'almost never' (1), 'sometimes' (2), 'often' (3) and 'almost always' (4). When the participant answers the question with 'almost never' or 'sometimes', he or she is directed to question b which is about the inconvenience of not being able to hear well in that specific situation. Response options are: 'no' (1), 'a little' (2), 'very handicapped' (3), and 'extremely handicapped' (4).

Hence, the total score can range from 28-112 with higher scores indicating greater participation restriction.

- *Readiness to do something about one's hearing problems* will be measured by the validated Dutch 24-item version of the University of Rhode Island Change Assessment (URICA)[56]. Formulations of items were adjusted such that they applied to hearing problems. The inventory contains 24 statements regarding attitudes and behaviours assessing an individual's stage of behaviour change. At T0 the scores on the following stages will be assessed: pre-contemplation (does not intend to take action in the foreseeable future, e.g., "As far as I'm concerned, I don't have any problems with my hearing that need changing"), contemplation (intends to change in the next six months and is aware of the pros and cons of changing), and action (has made specific modifications in his/her lifestyle towards healthy behaviour). At T1, T2, and T3 the maintenance stage (can maintain the changes in new behaviour) will be added. The five response options range from 'fully disagree' (score 1) to 'fully agree' (score 5). Summed scores for each subscale will be calculated. In addition the composite 'readiness score' (adding the contemplation, action and maintenance scores and subtracting the pre-contemplation score) and the composite 'committed action score' (subtracting the contemplation stage score from the action stage score) will be calculated[56]. The higher the composite scores, the further the respondents are along the stages of change.

- *Emotional response to hearing problems***.** The Hearing Handicap and Disability Inventory (HHDI) will be used[57]. The purpose of the inventory is to identify the individual's problems caused by hearing loss. Only the section 'emotional response' will administered. It contains five statements each with five response options: 'yes!' (4), 'yes' (3), 'more or less' (2), 'no' (1) and 'no!' (0). An example is: "I find it difficult to accept that I am hearing impaired". Lower scores indicate better outcomes.

Secondary outcome measures - CP

- *Third-party disability* will be measured using the Significant Other Scale for Hearing Disability (SOS-HEAR)[12]. This questionnaire was translated into Dutch for the purposes of this study following a

forward-backward method[51]. The 27-item questionnaire addresses the problems and limitations experienced by the CP. An example item is: "Because of my partner's hearing difficulties I have to repeat myself often". For each item the CP has to indicate how much of a problem it is for him/her: 'no problem' (0), 'a mild problem' (1), 'a moderate problem' (2), 'a severe problem' (3), 'a complete problem' (4). Higher scores indicate greater difficulties.

- *Hearing aid rehabilitation and SUPR outcome as viewed from the perspective of the CP* will be administered with the 7-item IOI-HA-SO/IOI-AI-SO and covers use, benefit, residual activity limitation, satisfaction, residual participation restriction, impact on others, and quality of life[58].

Baseline measurement- Demographical characteristics

- Gender (male/female)
- Age (in years)
- Marital status (married/cohabiting/widow or widower/divorced/single, never married)
- Living situation (living together with my partner/living together with my partner and children/living together without my partner but with one or more family members/living alone (own room) or in a care institution/living alone, independently or nursing home/other, namely…)
- Level of education (no completed education/lower general education, elementary education or a part of it/lower general secondary education/vocational education/secondary education/technical and vocational education/higher professional education/higher general education/scientific education/other, namely…)
- Occupational status (yes/no)
- Country of birth (The Netherlands/other, namely…)
- Country of birth father (The Netherlands/other, namely…)
- Country of birth mother (The Netherlands/other, namely…)
- Hearing loss in each ear, in dB HL (averaged over 1, 2, and 4 kHz) as retrieved from the pure-tone audiogram as provided by the hearing aid dispenser.

Randomisation

HAD practices were randomly assigned to offer CaU or the intervention. To avoid an unequal distribution of HAD practices with regard to level of urbanisation, HAD practices were pre-stratified (HAD practices located in a relatively rural area versus in an urban area) and randomisation occurred within these two strata. A statistician performed block randomisation of the HAD practices in the statistical software R, with random permutation in blocks of size four and with a fixed seed**.** 34 HAD practices were assigned to CaU and 36 HAD practices to the intervention group. The recruitment procedure and period was the same for all 70 included HAD practices (the total list of included HAD practices are available on request from the research team).

Sample size calculation

Sample size calculations are based on the expected effects of the intervention on the primary outcome: coping with hearing impairment (CPHI). Demorest & Erdman indicated that the expected difference on the subscales of the CPHI varies from 0.67 (Maladaptive Behaviour) to 0.95 (Self-Acceptance)[59]. Given that in a previous study[37] the effect of the programme was larger for first-time than for experienced users, we calculated sample sizes separately for first-time and experienced users. For first-time HAUs, we based our sample size calculations on an expected difference of 0.67 between the intervention and the CaU group. Note that the subscale with the smallest minimal importance difference (i.e., Maladaptive Behaviour) was used in the calculation, as finding a significant difference on this measure requires the largest number of participants. Calculations in PASS 12 (Tests for Two Means in a Cluster-Randomised Design; Intracluster correlation coefficient: 0.01; alpha: 0.05; power: 0.80) shows, that when 70 HAD practices are included (of which half will offer SUPR and half will offer CaU), the number of first-time HAUs to include in the analyses is two per HAD practice. For the sample size calculation of the experienced users we chose an expected difference of 0.4 between the intervention and CaU group. The expected difference was set lower

than for first-time HAUs as Kramer *et al* had previously found generally smaller effects for experienced users than for first-time users[37]. With a difference of 0.4 the number of experienced HAUs (power: 0.80) to include is three per HAD practice. We expected the proportion of drop-out or loss to follow-up across the study to be 20%. This includes loss to follow-up for a range of reasons: no motivation anymore, reluctant to purchase a hearing aid after a successful trial, sickness, death etc. Taking the loss to follow-up and the proportion of clients that normally purchase a hearing aid into account results in a total (rounded) number of four first-time HAUs per HAD practice and five experienced HAUs per HAD practice to be recruited.

Statistical analyses

To check the comparability between the groups (CaU or intervention group) at baseline, baseline characteristics of the participants will be compared using the Chi Square test (for categorical variables), the independent samples *t*-test (for normally distributed continuous variables) and the Mann-Whitney test (for non-normally distributed continuous variables). Comparability will be checked for all demographic variables and all primary and secondary outcomes.

For the effect analyses, the groups will be compared on all primary and secondary outcome measures using linear mixed models including the results at T0, T1, T2, and T3. Group, time, and their two-way interaction will be included as fixed effects in the mixed models, with random intercepts for subject and HAD practice. For the covariance matrix, a Variance Component structure will be chosen. If a significant effect is found, an independent samples *t*-test will be used and a Bonferroni correction will be administered in case of multiple comparisons. Type of HAU (first-time or experienced) will be tested as an effect modifier for potential subgroup differences.

In case of substantial missing data, multiple imputation will be applied. The main analysis is intention to treat. Any outcome measure to be collected for participants who discontinue or deviate from intervention protocols will be saved and analyzed according to the intention to treat protocol. In

addition, a per-protocol analysis will be performed. A per-protocol analysis includes those participants who completed the intervention originally allocated as described in the study protocol. As a per-protocol analysis can potentially yield biased effects (e.g., see CONSORT statement)[60], great caution will be exerted when interpreting these results. In addition, the report of these findings in future articles will be nuanced explicitly and thoroughly.

Process evaluation

The process of implementing SUPR into the HAD care in the intervention arm will be evaluated. The main aim of this evaluation is to gain insight into 1) the circumstances in which the intervention was implemented, 2) (non-) compliance with the intervention, and 3) the professionals' and clients' appraisal of the intervention.

The process evaluation will be carried out according to the framework as proposed by Linnan *et al*[61]. It covers seven parameters: recruitment, reach, fidelity, dose delivered, dose received and implemented, satisfaction, and perceived benefit[62]. A brief description of each of the parameters is given below.

- Recruitment refers to the procedures applied to approach and attract potential participants. The hearing aid dispensers will be asked to provide this information.
- Reach. This is the proportion of people participating relative to the number of people invited.
- Fidelity relates to the question of whether the intervention was provided as intended. The team that is responsible for the email contact will be asked to provide a written report on this.
- Dose delivered: 1) Did the personnel of the HAD practice hand out the Practical Support Booklet at the end of the preparation appointment? 2) Did the personnel of the HAD headquarters send out the emails correctly (correct content) and on time.

- Dose received and implemented: 1) Did the participants receive and use the Practical Support Booklet? 2) Did the participants open the emails and the videos? If so, did they watch the whole video, or part(s) of it? The video watching behaviour will be determined using Quadia (supplier of online video content) and Google analytics. Data on the average watching time per video, and how many times a particular video has been opened will be determined. Due to the privacy regulations the HAD company is subject to, the company is only allowed to collect video watching data on a group level (and not on an individual level). As all the HAD practices of the company that do not participate in the study provide SUPR as their standard care at the time of the study, the researchers will not be able to determine specific group averages of the study participants (the averages are based on both study participants and regular HAD clients). Information on implementation of the knowledge that participants learnt from SUPR will be deduced from the IOI-AI questionnaire (item on use) on T1. If participants received and used the Practical Support Booklet will be measured by a questionnaire.

- Satisfaction: Satisfaction of the participant with SUPR will be evaluated using the IOI-AI questionnaire (item satisfaction) on T1. The hearing aid dispensers will be asked to answer the question: How would you rate your satisfaction with SUPR?

- Benefit: Information on the experienced benefit of the participant will be obtained from the IOI-AI questionnaire (item benefit) on T1. The hearing aid dispensers will be asked to answer the question: How would you rate the perceived benefit from SUPR for your clients' ability to improve in communication?

Additionally, focus group discussions with participants from the intervention group will be organized to gain insight into the reasons for using the knowledge of SUPR in their daily lives or not. A minimum of two focus groups will be organized. The exact number will depend on data saturation. Heterogeneity in age, gender, educational level, severity of hearing impairment, and stage of behaviour change (at baseline) within the groups will be strived for. Given the difficulties hearing-

impaired individuals might have with group conversations, the focus groups will have a maximum size of six participants each.

ETHICS AND DISSEMINATION

Protocol amendments, confidentiality and dissemination policy

Any future protocol modifications will be submitted to the VU University Medical Center Medical Ethical Committee. Directly upon approval, the modification will be corresponded to the trial registry.

Personal information about enrolled participants will only be shared with employees of the headquarters of the HAD practices who signed a privacy declaration. This exchange of personal information will only occur in order to collect data within the framework of the study (e.g., to collect audiogram data, hearing aid purchase status, and use of SUPR). Any exchanged data and personal information will be password protected.

VU University Medical Center has all property rights on the final results of the trial and is entitled to publish the results. The funder is not entitled to publish the results without written consent of the VU University Medical Center. These agreements are secured in a contract. For specific author contributions for the current paper, see 'Authors contributions'.

Findings of the study will be published in scientific journals and presented at scientific conferences, and will be communicated within the national and international media. A short report of the study findings will be sent to interested participants. The results will be communicated within the hearing aid dispenser company.

Data collection forms and data storage

Data collection forms and procedures for data management are available on request. All data will be collected digitally and 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. According to Good Clinical Practice guidelines and after having received informed consent, data will be archived for a period of fifteen years after finalizing the study. After finalization, 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. We will perform double data entry of a selection of the audiograms and the baseline AIADH data for quality purposes.

Monitoring

The study is subjected to local regulations and its quality is monitored by the research institutes (i.e., EMGO^{+}) Quality Committee. This committee is responsible for developing, implementing, and maintaining a system for quality assurance and control for all research within the institute. Due to the decision of the Dutch Institutional Review Board (IRB) of the VU Medical University Center Amsterdam that the study does not fall under the Research Involving Human Subjects Act (WMO), the formation of a Clinical Trial Data Monitoring Committee was not deemed necessary.

DISCUSSION

Like in most parts in the world, usual care for adults with hearing impairment in the Netherlands is mostly restricted to audiological assessment and hearing aid fitting. This type of care is in the large part provided by commercial hearing aid dispensers. Communication programmes aimed at improving the use of favourable communication strategies, increasing personal adjustment to hearing impairment, and improving hearing aid handling skills are not provided on a large scale in standard hearing health care settings. This is undesirable, as there is a growing body of evidence showing that offering such programmes can effectively decrease communication problems and

associated negative health outcomes[27, 33, 38, 42]. Likewise, despite the fact that including CPs in the rehabilitation process is increasingly recognized within audiology as a prerequisite for successful rehabilitation[12], CPs are not yet part of standard hearing health care. In the current study, these elements (i.e., a communication programme and involvement of a CP) are part of a programme called SUPR that is incorporated in regular hearing aid dispensing care and that will be tested for its effectiveness. SUPR's primary aims are to improve older hearing aid owners' communication strategies and personal adjustment and decrease their CPs' third-party disability. To our knowledge, similar online support programmes for HAUs that are implemented on a large scale in hearing aid dispenser settings are not yet available.

A strength of the SUPR programme is that for those who are at risk for isolation or those who have reduced access to health care, the internet can be a practical tool providing direct access to health services[63]. Other elements that can add to the effectiveness of online support programmes as SUPR are that it can (partly or mainly) be provided in a visual mode (images, written text, subtitles), the volume can be controlled, background noises can be relatively easily eliminated, and online support programmes provide the opportunity to tailor intervention elements.

A few limitations to the design need to be considered. Unfortunately it is not possible to perform a double-blinded, randomised, controlled trial due to the nature of the intervention study. Blinding of the participants is not possible as they will be informed about the general aim of the SUPR study (i.e. to evaluate a support programme) and know that they are either part of the group that receives CaU or SUPR. Nevertheless, we will attempt to minimize the provision of information on the content of SUPR to participants of the CaU group. The participants only know that SUPR is a support programme aimed to 'improve communication', but for instance do not know what the intervention further entails. This way, we aimed to prevent that they would independently seek access to SUPR (which would cause contamination) and that their knowledge of the care they were missing out on would

affect their responses in the questionnaires. We further attempted to prevent contamination by offering the programme to the CaU-participants for free after completing the study. Blinding the researchers during the effect analysis is also not possible as the IOI measure that is administered on T1, T2, and T3 indicates in what group each participant was randomised (IOI-HA only: CaU group; IOI-AI: intervention group).

SUPR is an online intervention, it is thus essential that people have access to a device with internet access and an email account. Participants who have access to the internet will most likely be of high SES and this might bias the data. The fact that the support programme as such reaches a selective part of the dispenser's clientele requires further discussion. Consistent with findings from Choi *et al* and Fox *et al* who compared non-internet users and users, it is possible that the older people participating in the SUPR study generally have a somewhat higher socioeconomic status and are somewhat younger than the average clientele of the dispenser[64, 65]. With regard to age however, it should be noted amongst the young-old the weekly internet use has increased from 70% in 2010 to 83% in 2015 in the Netherlands and will most probably keep rising in the future[66]. This suggests that the large majority of the younger-old can currently already be reached with SUPR and this will improve even more in the future. The non-use of internet among the older olds (74+) currently still is substantial, although this proportion also has decreased strongly in the past few years (66% in 2012 to 50% in 2015[67]). Furthermore, it is encouraging that older internet users, generally use it more for health-related tasks or information than for personal tasks[68]. In addition, people with hearing loss are more likely to use the internet than people in the general population (OR=1.74, 95% CI 1.23-3.17)[69]. Baring these developments in mind, we are confident that the large majority of the older HAUs who can potentially benefit from SUPR will be increasingly eligible and open to using SUPR to improve their hearing health.

At the start of the study, participants might downplay their hearing problems because hearing loss stigma causes them to be reluctant to acknowledge or recognize their hearing problems[70]. We expect that SUPR will have a positive effect on acceptation of hearing loss, and therefore people may report a disability level that is 'more honest'. This may hold particularly for the first-time HAUs who have never gone through an intensive rehabilitation trajectory before and less so for the experienced users. As such, it is possible that this mechanism will cause an increase in self-reported hearing disability in the intervention group over time. This would counteract the favourable effect that SUPR is expected to create, i.e., a decrease in experienced disability. To examine whether the first-mentioned mechanism would apply, one of the subscales of the CPHI on acceptation of hearing loss can be used[48]. With this subscale we can examine if acceptance is a mediator between time and hearing status for the intervention group.

This study aims to perform a process evaluation, as is strongly recommended in all randomised controlled trial research. A process evaluation provides insight into reasons for the demonstrated (absence of) effectiveness of the intervention and might offer information concerning the generalizability of the study results. When no or only small significant effects of SUPR will be found, we may be able to modify the programme based on the results of the process evaluation after the study.

In the future, it is expected that there will be an increasing demand in solutions for hearing health conditions due to the ageing population and thus increased prevalence of hearing problems. SUPR is especially developed for use on a large scale basis in HAD practices. The large number of practices that are involved in the study not only contributes to a large sample size (and statistical power), it also reflects real world clinical practice. This will potentially make a strong case for the extrapolation of the study's results. Demonstrating the programmes effectiveness would be a great step forward improving health care services for people with hearing impairment.

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FOOTNOTES

Contributors

SEK developed the first version of the study design in collaboration with BP and VJ. MP and SK developed the study design further and wrote up the first draft of the study protocol. BvdW, JFJM, MP, SEK, and VJ worked on the design further and facilitated the practical implementation of the study. BIW provided statistical and methodological advice. Data collection will be done by BvdW and JFJM, assisted by VJ, and supervised by SEK and MP. JFJM wrote the final version of the manuscript. SEK and MP supervised the writing process and MP, SEK, BP, BIW, VJ, and BvdW gave critical comments on several drafts of the manuscript.

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Competing interests

VJ is an employee at Schoonenberg Hoorcomfort. BP is an employee at AudioNova International.

Ethics approval and consent to participate

Written consent for the SUPR study (reference number: 2015.335) was obtained from the Dutch Institutional Review Board (IRB) of the VU Medical University Center Amsterdam (registered with the

US Office for Human Research Protections as IRB00002991; FWA number: FWA00017598). The IRB concluded that Medical Research Involving Human Subjects ACT (WMO) does not apply to this study. Participants' consent will be obtained via the registration website of the study. At this website participants were asked to declare that they were sufficiently informed about the study and agreed on the use of certain data to be collected for the purposes of the study.

Abbreviations

SUPR: SUpport PRogramme, CaU: care as usual, CP: communication partner, HAU: hearing aid users, HAD practices: hearing aid dispensing practices, AIADH: Amsterdam Inventory for Auditory Disability and Handicap, CPHI: Communication Profile for the Hearing Impaired, MARS-HA: Measure of Audiologic Rehabilitation Self-Efficacy for Hearing Aids, IOI-HA: International Outcome Inventory – Hearing Aids, IOI-AI: International Outcome Inventory – Alternative Interventions, URICA: University of Rhode Island Change Assessment for Hearing health behaviour, HHDI: Hearing Handicap and Disability Inventory, SOS-HEAR: Significant Other Scale for Hearing Disability, IOI-HA-SO: International Outcome Inventory Significant Other – Hearing Aids, IOI-AI-SO: International Outcome Inventory Significant Other – Alternative Interventions.

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SUPR

Een onderzoek naar de effectiviteit van HoorSupport

Respondentnummer:	
Volledige achternaam:	
E-mailadres:	
Achternaam slechthorende naaste:	

Door deel te nemen geef ik te kennen voldoende te zijn geïnformeerd over het doel en de inhoud van het onderzoek. Het doel van dit onderzoek is om te bepalen of HoorSupport de communicatie van iemand met hoorproblemen verbetert (met zijn/haar communicatiepartner). Dit wordt gemeten met behulp van vragenlijsten.

• Ik weet dat ik in totaal vier keer een vragenlijst ontvang over mijn ervaringen met de slechthorendheid van mijn naaste.

• Ik ben ervan op de hoogte dat verzamelde gegevens zullen worden gebruikt voor wetenschappelijk onderzoek, zonder vermelding van mijn naam en andere persoonlijke gegevens.

• Ik ben ervan op de hoogte dat ik mijn deelname op ieder moment mag en kan beëindigen.Wanneer ik besluit te stoppen zullen de tot dan toe verzamelde gegevens gebruikt worden voor het onderzoek, tenzij ik anders aangeef.

• Ik geef toestemming om mijn gegevens nog 15 jaar na dit onderzoek te bewaren.

SUPR

Een onderzoek naar de effectiviteit van HoorSupport

Respondentnummer:	
Cliëntnummer:	
Volledige achternaam:	
Emailadres:	
Achternaam communicatie partner:	

Door deel te nemen geef ik te kennen voldoende te zijn geïnformeerd over het doel en de inhoud van het onderzoek. Het doel van dit onderzoek is om te bepalen of HoorSupport de communicatie van iemand met hoorproblemen verbetert (met zijn/haar communicatiepartner). Dit wordt gemeten met behulp van vragenlijsten.

• Ik weet dat ik in totaal drie keer een vragenlijst ontvang over mijn communicatie en gehoorklachten.

• Ik ben ervan op de hoogte dat verzamelde gegevens zullen worden gebruikt voor wetenschappelijk onderzoek, zonder vermelding van mijn naam en andere persoonlijke gegevens.

• Ik ben ervan op de hoogte dat ik mijn deelname op ieder moment mag en kan beëindigen. Wanneer ik besluit te stoppen zullen de tot dan toe verzamelde gegevens gebruikt worden voor het onderzoek, tenzij ik anders aangeef.

• Ik geef toestemming om mijn gegevens nog 15 jaar na dit onderzoek te bewaren.

Slechthorende Toestemmingspagina versie 5 dd 03-12-2015

- Met mijn deelname geef ik automatisch aan akkoord te gaan met het gebruik van mijn toonaudiogram en de antwoorden op de Amsterdamse Vragenlijst welke zijn afgenomen tijdens afspraken bij de audicien (Schoonenberg).

Heeft u een communicatiepartner gekozen voor HoorSupport/het onderzoek?

- Ja (hierbij opent de volgende vraag)
- Nee (hierbij wijzen wij de persoon erop dat het voor HoorSupport en/of het onderzoek erg nuttig kan zijn om een communicatiepartner te kiezen. De persoon wordt vriendelijk verzocht het aanwijzen van een CP nog eens te overwegen.)

- Heeft u deze communicatiepartner de envelop gegeven met daarin de uitnodiging voor het onderzoek?
  - Ja (hierbij opent de volgende vraag)
  - Nee (hierbij wijzen wij de persoon erop dat het voor het onderzoek erg nuttig kan zijn om de gekozen communicatiepartner uit te nodigen)

- Weet u of diegene mee wil doen?
  - Ja, hij/zij wil ook meedoen aan het onderzoek
  - Nee, hij/zij wil niet meedoen aan het onderzoek
  - Weet ik niet

Table 1 Spirit flow diagram. Schedule of enrolment, interventions, and assessments

		Allocation of HAD practices	Enrolment	Post-Allocation & Enrolment			
TIMEPOINT	Outcome measurements	–T2	-T1	T0 (Baseline)	T1 (6 months)	T2 (12 months)	T3 (18 months)
ENROLMENT:							
Eligibility screen			x				
Informed consent			x				
Allocation		x					
INTER-VENTIONS:							
Care as Usual (Hearing aid fitting)		x	———	———	———	———	x
Intervention (Hearing aid fitting + SUPR)		x	———	———	———	———	x
ASSESSMENTS:							
Demographic variables							

Gender		x			
Age		x			
Marital status		x			
Living situation		x			
Level of education		x			
Occupational status		x			
Country of birth participant		x			
Country of birth participant's parents		x			
Primary outcome measure HAUs					
The use of communication strategies and	CPHI	x	x	x	x

personal adjustment					
Secondary outcome measures – HAUs					
Self-efficacy of hearing aid handling	-MARS-HA - Basic handling subscale	x	x	x	x
	-MARS-HA - Advanced handling subscale		x	x	x
Self-reported intervention outcomes	-IOI-HA (items 2-7)/IOI-AI (all 7 items)		x	x	x
Self-reported hearing aid use	-IOI-HA (item 1)		x	x	x
	-Use questionnaire		x	x	x
Objective hearing aid use	-Data-logging		x	x	x
Satisfaction with the hearing aid dispenser	'How likely is it that you would recommend the service of the	x	x	x	x

service	HAD practice to other people (family, friends, colleagues?)'				
Self-reported activity limitations and participation restrictions	AIADH	x	x	x	x
Hearing status	Pure tone audiogram	x			
Readiness to do something about one's hearing problems	-URICA - Precontemplation/ Contemplation/ Action stages	x	x	x	x
	-URICA - Maintenance stage		x	x	x
Emotional response	HHDI - Emotional response subscale		x	x	x
Secondary outcome measures – CP					
Third-party	SOS-HEAR	x	x	x	x

disability				
Self-reported intervention outcomes from the perspective of the CP	IOI-HA-SO/IOI-AI-SO	**x**	**x**	**x**

Abbreviations: HAD practice: hearing aid dispensing practice, SUPR: Support PRogramme, HAU: hearing aid user, CPHI: Communication Profile for the Hearing Impaired, MARS-HA: Measure of Audiologic Rehabilitation Self-Efficacy for Hearing Aids, IOI-HA: International Outcome Inventory – Hearing Aids, IOI-AI: International Outcome Inventory – Alternative Interventions, AIADH: Amsterdam Inventory for Auditory Disability and Handicap, URICA: University of Rhode Island Change Assessment- for Hearing health behaviour, HHDI: Hearing Handicap and Disability Inventory, CP: Communication Partner, SOS-HEAR: Significant Other Scale for Hearing Disability, IOI-HA-SO: International Outcome Inventory Significant Other– Hearing Aids, IOI-AI-SO: International Outcome Inventory Significant Other– Alternative Interventions.

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	2
	2b	All items from the World Health Organization Trial Registration Data Set	1-32
Protocol version	3	Date and version identifier	1
Funding	4	Sources and types of financial, material, and other support	33
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1, 33
	5b	Name and contact information for the trial sponsor	1
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	33
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	29

Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	3-8
	6b	Explanation for choice of comparators	3-8
Objectives	7	Specific objectives or hypotheses	8
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	9
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	8-12
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	14
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	8-11
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	N/A
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	12, 13, 27
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	12,13
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	19-23
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	12,13, 15-19

Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	24, 25
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	13
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	24
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	20
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	9, 24
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	30, 31
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/A
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	15-23
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	13, 25

Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	28, 29
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	25, 26
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	25, 26
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	25, 26
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	29
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	N/A
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	29
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	N/A
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	33, 34
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	28

Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	33, 34
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	28, 29
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	33
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	28
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	28
	31b	Authorship eligibility guidelines and any intended use of professional writers	28, 33
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	N/A
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Appendix 1 and 2 (uploaded as additional files)
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A.

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

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Effectiveness of an online SUpport PRogramme (SUPR) for older hearing aid users: Study protocol for a cluster randomised controlled trial

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9 March 2017 – Protocol version 3

Effectiveness of an online SUpport PRogramme (SUPR) for older hearing aid users: Study protocol for a cluster randomised controlled trial

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ABSTRACT

Background: An educational SUpport PRogramme called SUPR has been developed for hearing aid users (HAUs) and their communication partners (CPs) offering care beyond hearing aid fitting. SUPR teaches its users communication strategies, hearing aid handling skills, and personal adjustment to hearing impairment.

Methods/design: Using a cluster randomised controlled trial-design, 70 Dutch hearing aid dispenser practices were randomised into hearing aid fitting (care as usual, 34 practices) and hearing aid fitting including SUPR (36 practices). The aim was to recruit a total of 569 older (aged 50+) first-time (n=258) and experienced (n=311) HAUs and their CPs. SUPR consists of a Practical Support Booklet and online material offered via email over a period of 6-7 months. The booklet provides practical information on hearing aids, advice on communication strategies, and home exercises. The online material consists of educational videos on hearing aid functionality and usage, communication strategies, and peer testimonials. Finally, noncommittal email contact with the dispenser is offered. Every HAU is asked to assign a CP who is advised to be involved intensively. Effect measurements for HAUs and their CPs will occur at baseline and at 6, 12, and 18-months follow-up via online questionnaires. The primary outcomes for HAUs will be the use of communication strategies as measured by the subscales of the Communication Profile for the Hearing Impaired. A process evaluation will be performed.

Ethics and dissemination: The study was approved by the Dutch Institutional Review Board (IRB) of the VU Medical University Center Amsterdam. This intervention could contribute to lowering the hearing impairment burden in our ageing society. The results will be disseminated through peer-reviewed publications and scientific conferences.

Trial registration: ISRCTN77340339; Pre-Results.

Keywords: Hearing loss, communication strategies, personal adjustment to hearing impairment, intervention, cluster randomised controlled trial, hearing aids, communication, internet.

STRENGHTS AND LIMITATIONS

- This is the first study to evaluate the effects of an online educational SUpport PRogramme (SUPR) for hearing aid users that is implemented in a hearing aid dispensing (HAD) practice setting on a large scale.
- Hearing-impaired participants and their communication partners (CPs) originating from 70 HAD practices located all across the Netherlands will be included.
- The online nature of the programme suits the current and future developments in the increasing internet use among the young-old (55-74) and can reach out to those with reduced (physical) access to health care.
- The online nature might however reach a selective sample, especially among the oldest old (75+), who are willing or able to adopt the intervention (i.e., only those with access to and willing to use the internet for this purpose).
- The study design does not allow the blinding of participants and researchers for intervention allocation. This could potentially lead to performance bias.
- The findings of the study will potentially contribute to improvement of hearing health care services for hearing-impaired people and their CPs.

BACKGROUND

Hearing impairment is one of the most prevalent chronic health conditions affecting older adults. It was ranked fifth in the top 25 of global causes for years lived with disability in 2013[1]. Due to the overall aging of the population[2], the prevalence of hearing impairment is increasing rapidly, imposing a great burden on individuals and society.

Hearing impairment essentially leads to the inability to communicate effectively which in turn can result in a cascade of effects leading to poor psychosocial outcomes such as loneliness[3-5], distress[6], depression[6, 7], and work-related fatigue[8]. It has also been associated with

accelerated cognitive decline[9] and falls[10]. The limitations on daily life activities and restrictions in social and societal participation that people experience depend on aspects that are both internal (such as age and applied coping styles) and external (such as availability of hearing aids, care facilities, and social support) to the person[11]. In addition, the level of impairment in hearing functions and structures is an important factor which can influence psychosocial outcomes[11].

Partners and spouses can also be negatively affected by the hearing impairment of their loved ones. They generally experience frustration and embarrassment, for example in challenging social communication settings[12]. Communication difficulties in background noise, the partner's frequent request to repeat, and the need to act as an interpreter may cause irritation and tension within a relationship[12]. In a systematic review conducted by Kamil *et al* it was found that communication partners (CPs, i.e. spouses, partners, close family members, neighbours, or caregivers) of people with hearing impairment experience decreased social functioning, poorer quality of life, and more participation restrictions than CPs of normally hearing individuals[13].

The usual care provided for people with hearing impairment is often restricted to the assessment of hearing loss and the fitting of hearing aids[14]. Hearing aid use has positive effects on quality of life, social and emotional wellbeing, and may reduce depressive complaints[15-17], and possibly even cognitive decline[18]. Despite this abundant evidence on positive health effects, the uptake and use of hearing aids is low. It is estimated that around one third of the adults who would benefit from hearing aids own them[19-21] and 3-20% of these owners never use them[22,23]. Reasons for low uptake and use have been investigated and include low perceived need of amplification reflected in low self-reported hearing disability[24-26], limited acceptance of hearing loss[24], low expectations of hearing aid benefits[24, 25], limited gain in noisy situations[25, 26], and low overall sound quality[26]. Other perceived barriers include stigma[25, 26], high monetary costs[26], and the need

for regular hearing aid care and maintenance[26]. Finally, lack of social support or social pressure to get a hearing aid are factors having a negative impact on hearing aid use[25, 26].

Given this broad spectrum of factors affecting hearing aid uptake and use, it has often been argued that hearing health care should not be restricted to the provision of hearing aids alone, but cover more than that to improve hearing aid success, everyday communication, and wellbeing of hearing-impaired adults[27]. This argument is in line with the biopsychosocial approach of health which is receiving increasing attention in the field of audiology: Experienced hearing disability (i.e., activity limitations and participation restrictions) is the outcome of a complex interaction between an individual and his/her contextual factors[28-30].

Various interventions have been proposed in the past to complement hearing aid fitting. Examples are communication programmes aimed at improving speech perception and/or communication management[31]. These programmes include speech perception training, communication management training, and social support[27, 32, 33]. For reviews, see Barker *et al*, Henshaw *et al*, and Wong *et al*[34-36]. Examples of effective programmes are the Home Education programme[37] and the Active Communication Education (ACE) group programme[38]. Both programmes consist of modules on everyday communication situations, aiming to improve the use of communication strategies, personal adjustment to living with hearing impairment, quality of life, development of problem-solving skills, and to decrease the level of experienced hearing disability. These programmes showed an improvement in communication strategies[37] and communicative participation restrictions and activity limitations[38].

Communication training programmes, whether combined with hearing aid fitting or not, are rarely offered in hearing health care[27, 32]. When offered, there are various reasons why adults with hearing impairment would choose not to pursue communication training programmes; they could

live in a rural area, have a lack of time, or no easy access[32]. The paradigm shift in health care from the traditional doctor-centric model to a more patient-centered model, combined with increasingly pervasive use of e-health methods and technology, means that the typical barriers causing the low use of (group) communication training programmes can now be overcome[39-41].

A number of studies have recently been published reporting on the development and evaluation of online communication programmes. Thorén *et al* developed such a programme[42] which included reading material on hearing anatomy, hearing aids, communication strategies, assistive listening devices, and guidelines for CPs. In addition, the intervention included weekly email contact with an audiologist, problem solving exercises, and online peer discussion on personal experiences with hearing loss. Thorén *et al* studied the effectiveness of the programme using a randomised controlled trial-design in which the intervention group (*n*=38) received the online programme while the control participants (*n*=38) were offered access to an internet discussion forum or were placed on a waiting list[42]. The researchers found reduced symptoms of depression[43] and a significant decrease of activity limitations and participation restrictions in the intervention group compared to the controls at five weeks directly after the intervention and at three-months follow-up[42]. Ferguson *et al* investigated the use of short interactive videos (reusable learning objects, RLOs)[44]. RLOs were delivered via DVD for TV, computer, and the internet and covered practical and psychosocial issues which are relevant for audiologic rehabilitation. The intervention group (*n*=103) received seven RLOs plus usual clinical services including hearing aid fitting and counseling. They were compared to a control group (*n*=100) who received clinical services only and were placed on a waiting list. Participants in the intervention group had significantly better hearing aid skills and better knowledge on psychosocial issues than the control group after 7-weeks follow-up.

Where the online education programme of Thorén *et al* was evaluated in a sample of adults who were recruited by local advertisements and articles and were wearing a hearing aid for at least one

year[42], Ferguson *et al* evaluated their RLOs in a small sample of patients of the audiology service of the Nottingham University Hospitals NHS Trust. Patients were adults who had been referred to the clinic by their family doctor[44]. The participants in the study of Kramer *et al* mentioned earlier, were all patients of a specialized tertiary Audiology Centre, limiting the generalizability of the results[37]. In the Netherlands, only a small number of hearing aid applicants receive hearing care through a tertiary clinic, i.e., only those with relatively complex hearing problems. The vast majority of hearing aids are fitted in a dispenser practice.

To the best of our knowledge, there is no study available evaluating the effectiveness of an online communication training programme that is implemented on a large scale in a hearing aid dispensing (HAD) practice setting. This paper reports on the design of such a study. It addresses the different steps that will be taken to evaluate an online SUpport PRogramme (SUPR) for hearing-impaired adults and their CPs. SUPR is based on the Home Education programme developed by Kramer *et al*[37]. The original version developed in 1995 has been updated so that it would be applicable for use over the internet. SUPR has also been expanded with extra elements including instructional videos on how to operate and maintain hearing aids and peer testimonials. All elements will be sent about bi-weekly via email.

This study aimed to involve seventy HAD practices, of which half will offer the training programme. This large number of practices not only contributes to a large sample size (and therefore statistical power), it also reflects real world clinical practice and thus contributes to the external validity of the future results. The study will include an 18-month follow-up. As was mentioned earlier by Kramer *et al*, Barker *et al,* and Wong *et al* more research on treatment efficacy in the long(er)-term is essential because it is possible that some short-term effects may disappear and other effects can arise[34, 36-37].

The aim of this study is to determine the effectiveness of SUPR as part of standard HAD care among older hearing aid users (HAUs) and their CPs. Based on the active elements included in SUPR, we hypothesize that older HAUs who receive SUPR in addition to hearing aid fitting will show the following favourable effects at 18-months follow-up when compared to HAUs who receive hearing aid fitting only:

- More use of favourable and less use of unfavourable communication strategies (primary outcome measures).
- Better personal adjustment to hearing impairment, higher self-efficacy of hearing aid handling, higher hearing aid use, less activity limitations and participation restrictions, less handicap and disability, better self-reported intervention outcomes, higher readiness to do something about their hearing, and higher satisfaction with HAD services (secondary outcome measures).

These effects will be studied both in first-time and experienced HAUs.

- Consistent with the findings by Kramer *et al*[37], we hypothesize that effects on all outcomes will be larger in first-time HAUs than in experienced HAUs.

With regard to the CPs, we hypothesize that CPs who receive SUPR - as compared to CPs whose loved ones only receive hearing aid fitting - will show the following favourable effects:

- Lower third-party disability and better self-reported intervention outcomes.

METHODS

Study design

A cluster randomised controlled trial with an 18-month follow-up period will be performed. Cluster randomisation (with the HAD practice as a unit) was chosen over individual randomisation because the latter would hold a high risk of contamination. In case of individual randomisation, the HAD personnel would have to switch between approaches (SUPR/CaU) frequently and could accidentally refer to or offer SUPR to clients assigned to the CaU group. In addition, as the time between informing the clients about the study, receiving clients' consent and the start of SUPR/CaU was

relatively short, performing randomisation on an individual level was not feasible. Dutch HAD practices and consequently all clients in these practices were randomly assigned to one of two groups. The control group received care as usual (CaU) which is hearing aid fitting only, while the intervention group received hearing aid fitting supplemented with SUPR.

Care as Usual

CaU starts with a preparation appointment during which a screening pure-tone audiogram (only air conduction) is administered by the hearing aid dispenser. If the hearing loss in one or both ears is at least 35 decibel (dB) hearing level (HL) (averaged over the three frequencies 1, 2, and 4 kHz) in one or both ears, someone is considered potentially eligible for hearing aid fitting and more comprehensive audiometry is required. If the client is interested in hearing aids, his/her general wishes and goals are discussed after which the Amsterdam Inventory for Auditory Disability and Handicap (AIADH; Kramer *et al*[45]) is handed out. Clients are asked to complete the AIADH at home and bring it along to the next appointment. The AIADH assesses hearing activity limitations and participation restrictions. Clients are asked to assign a CP and involve them throughout the rehabilitation (e.g., bring them to appointments). During the next appointment, i.e., the intake appointment, comprehensive audiometry (air and bone conduction, and speech audiometry) are performed. The results of all tests, the AIADH, and the wishes of the client determine what type of hearing aid may be best suited for this person. The appropriate hearing aids will be selected and fitted directly (if available in the HAD practice) or in a subsequent fitting appointment. Fitting is followed by a trial period which usually lasts up to four weeks, during which people can try out the hearing aid and decide whether or not to purchase it. Depending on the client's needs, fine-tuning or other follow-up appointments are scheduled. These can be scheduled during the trial period but also after the device has been purchased.

Intervention: SUPR

SUPR consists of a Practical Support Booklet and online elements. In addition, clients are asked to assign a CP who is involved actively in the programme (see below).

Practical Support Booklet

The Practical Support Booklet will be handed out at the end of the preparation appointment (first-time HAUs, experienced HAUs) or the intake appointment (experienced HAUs). The aims of the Practical Support Booklet are to: 1) assist clients and CPs in getting familiar with their hearing aid, 2) stimulate clients' use of the hearing aid and clients' and CPs' use of communication strategies, and 3) guide clients and their CPs through the various stages (i.e., appointments) of the rehabilitation trajectory. Although the theoretical elements of the booklet can also be used as a reference *after* the purchase of the hearing aid, the booklet's focus is on the period between the first HAD appointment and the end of the trial period. The booklet covers four parts, corresponding to the four key appointments during the trial period (i.e., preparation appointment, intake appointment, control- and/or fine-tuning appointment, and purchase appointment). The information that is provided is synchronized with the topics which are typically discussed during these appointments. The first part outlines the process of getting a hearing aid and includes an introduction to the hearing aid dispenser's care and an explanation about the pure tone audiogram. The client is asked to write down and rank specific communication goals (s)he wishes to reach by the end of the trial period (for example: 'I want to be able to hear the stories of my 10-year old granddaughter Anne when I pick her up from school every Monday'. The second part revolves around the types of hearing aids available and the client's hearing aid preferences. Information about how to operate and maintain the device is provided as well. In the third part the client and the CP are asked to write down their experiences with the new hearing aid and its settings. This information will be used for further refinement of the fitting. The final section of the booklet provides information on assistive listening devices, reimbursement of costs, more information on the audiogram, types of hearing loss, and the types of hearing aids (e.g. behind-the-ear and in-the-canal). In addition, an overview of the most important

communication strategies that clients and their CP can apply is provided. The content and the appearance of the booklet were developed over the course of several months by the HAD company. Although no specific guidelines were used for the development of the written health information in the booklet, a number of the subsequent steps that are deemed important by Caposecco *et al* were taken into consideration: 1) interviews with key stakeholders (clients, CPs, HAD practice personnel) were held to specify the booklet's goals and functions, 2) graphics and text were developed and optimized with regard to their understandability and attractiveness (language difficulty, lay-out, font size, paragraphing), 3) a first complete version of the booklet was pilot-tested in ten HAD practices for several months. Feedback by all key stakeholders was collected, and 4) the feedback was incorporated in a new and final version of the booklet (which was used in the study)[46].

Online Elements

After the intake appointment, the links to the online elements will be sent to the participants via email. There are two emails which offer contact with the HAD practice and eleven emails which contain the links to the various educational videos that are offered (see below). The online part spans a period of up to about six months after the hearing aid purchase. The exact duration of SUPR depends on the duration of the trial period. For example, if a trial period is finalized in three weeks instead of the average four, the total duration of SUPR is one week shorter.

The educational videos consist of: 1) Training modules on hearing aid handling skills. These comprise of three short instruction videos with practical information on the use and maintenance of hearing aids. Participants receive the link to the relevant instruction video depending on their style of hearing aids (i.e., behind-the-ear, in-the-canal, or receiver-in-the-ear). 2) Training modules on communication strategies and personal adjustment. This is a remake (i.e., a modernized version) of the home educational programme *"Horen en Gehoord Worden: Hoe kan het beter",* as developed by Kramer *et al*[37]. It comprises five short videos showing the difficulties that hearing-impaired people

can experience in everyday listening situations. The typical reactions by both the hearing-impaired people and his/her social environment to these situations are shown, and a trainer illustrates how communication could be improved by using communication strategies (for both hearing-impaired people and his/her CP). 3) Three testimonials by hearing-impaired peers who share their experiences with hearing aids.

Measurements

For all participants four measurements will take place: at baseline (after the preparation appointment, but before the actual hearing aid fitting) (T0), six months after the hearing aid purchase (T1), one year after the hearing aid purchase (T2), and eighteen months after the hearing aid purchase (T3). Measurements at T3 serve to determine the long-term effects of SUPR, i.e., one year after its completion. Data will be collected using online questionnaires through NetQ Premium, which is an online survey programme. Email-reminders will be sent within a week after the first invitation-email and another week after the first reminder, if necessary.

Study population and recruitment

The following procedures were followed during the recruitment period (February 2016 to September 2016). Hearing aid dispensers invited clients to participate in the study. First-time HAUs were invited at the end of their preparation appointment. Experienced HAUs were invited at the end of their preparation or at the end of their intake appointment, if they did not require a preparation appointment. Hearing aid dispensers handed out an information package including an invitation letter, a selection form outlining the in- and exclusion criteria, a brochure about the study, and an envelope with an information letter and brochure for the CP. All interested participants were asked to enrol themselves for the study by subscribing on a registration webpage and signing the online consent from there. Every month the number of clients who were invited (number of envelopes that was handed out) and were enrolled (number of online subscriptions) per HAD practice were

determined. When enrolment numbers for a particular HAD practice were relatively low, a phone call was made to the specific HAD practice to notify them of their current number of enrolments, to identify possible underlying reasons, and to motivate them to reach the required target. Throughout the recruitment period, the HAD headquarters organized motivational conference calls for the HAD practices that had not yet reached their target. Finally, when enrolment ratings continued to be behind target, employees of the headquarters directly invited potentially eligible clients who were not invited by the HAD practice personnel, via a telephone call. The study material was then sent via email.

Incentives

After completing the T0 questionnaire, all participants will be offered a voucher of EUR 50 to spend on a hearing aid or EUR 25 to spend on other articles of the HAD practice if they decide not to purchase a hearing aid. CPs will be offered a gift card. In addition, participants in the control group will be offered a shortened version of SUPR after eighteen months. For them, SUPR will be slightly adjusted such that it becomes suitable for individuals who have already started using a hearing aid.

Employees of the HAD practices will be offered gift cards once the total number of participants is recruited (see 'Sample size calculation' section).

Inclusion criteria

The following inclusion criteria for the hearing aid candidates were applied: 1) Age 50 years or older. 2) Is willing to try out one or two new hearing aid(s) (i.e., agreed to plan a follow-up appointment). This hearing aid could be their first (i.e., first-time HAUs), or a replacement hearing aid (i.e., experienced HAUs). Clients who did not purchase a hearing aid after the trial period were considered drop-outs. 3) Sufficient understanding of the Dutch language. 4) Access to a

personal computer with internet access and owner of an email account for the total duration of the study.

Exclusion criteria

The following hearing aid candidates were excluded: 1) Candidates who received additional care at a specialized Audiology Clinic. In the Netherlands, an Audiology Clinic offers elaborate, multidisciplinary and specialized, tertiary health care and is aimed at people with complex hearing problems. This care may overlap and/or interfere with that of SUPR. 2) Candidates that received 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 were not part of the target group of SUPR.

Although all participants were encouraged to assign a CP, it was not obligatory for them to assign one in order to participate in the study. For the CPs, the only inclusion criterion applied was that they should be 18 years or older.

Outcome measures

An overview of all outcome measures and measurements over time according to Standard Protocol Items; Recommendations for Interventional Trials (SPIRIT) is attached (see online supplementary appendix 1)[47]

Primary outcome measures – HAUs

- *The use of communication strategies* will be measured using the reliable and validated Dutch 35-item version of the Communication Profile for the Hearing Impaired (CPHI)[48, 49]). Communication strategies are measured using the following subscales: Maladaptive Behaviours, Verbal Strategies, and Non-verbal Strategies. Each subscale consists of statements for which the respondent has to indicate how often (s)he applies this strategy. An example: "I avoid conversations with strangers, because of my hearing loss" (subscale Maladaptive Behaviour). The five response options range from 'almost never' to 'almost always'. Scores are averaged per subscale and range from 1 to 5. Some items were recoded because of reverse scaling. High scores indicate favourable strategies whereas low scores indicate unfavourable strategies.

We have chosen for the Communication Strategies subscales of the CPHI as central outcome measures for the following reasons. Firstly, the subscales are purported to measure the constructs that are acted upon by the core active element of the intervention (i.e., the revised home education programme). Secondly, the CPHI has proven to have very good validity and reliability in the target population of this study[49].

Secondary outcome measures – HAUs

- *Personal adjustment to hearing impairment* will also be measured using the reliable and validated Dutch 35-item version of the Communication Profile for the Hearing Impaired (CPHI)[48, 49]). This second section of the CPHI deals with personal adjustment and also contains three subscales: Self-acceptance, Acceptance of Loss, and Stress and Withdrawal. An example item of the latter subscale is: "I feel very tense because of my hearing loss". The five response options range from 'totally disagree' (1) to 'totally agree' (5). All items were recoded because of reverse scaling. After recoding the item scores, average scores per subscale can be calculated, with low scores indicating poor personal adjustment and high scores indicating good personal adjustment.

- *Self-efficacy of hearing aid handling* will be measured by the Basic Handling subscale of the Measure of Audiologic Rehabilitation Self-Efficacy for Hearing Aids (MARS-HA). The English version of this 7-item subscale has good psychometric quality[50]. Scores can range from 0% to 100%, with lower scores representing less certainty in one's capability of handling a hearing aid. At T1, T2, and T3, the 5-item subscale Advanced Handling will be additionally administered. Dutch versions of the scales were created using the forward-backward method[51]. At T0 'expected self-efficacy' will be administered, whereas at T1, T2, and T3 'experienced self-efficacy' will be determined as the new hearing aids will have been fitted by then. For measurement of 'expected self-efficacy', all MARS-HA-items start with 'I think I can …', whereas for measurement of 'experienced' self-efficacy all items start with 'I can… '.

- *Hearing aid use*. Self-reported use will be measured using the first item of the International Outcome Inventory – Hearing Aids (IOI-HA) ("How many hours per day on average have you been using your hearing aid(s) in the last two weeks?"). Response options are 'none', 'less than 1 hour a day', '1-4 hours a day', '4-8 hours a day', and 'more than 8 hours a day'[52]. Self-reported hearing aid use will additionally be measured by three questions from the use questionnaire developed by Laplante-Lévesque *et al*[53]. The latter questionnaire was translated into Dutch, using the forward-backward method[51]. Hearing aid use will also be measured objectively via data-logging.

- *Self-reported intervention outcomes (hearing aid rehabilitation and SUPR outcome)*. The International Outcome Inventory - Hearing Aids (IOI-HA; items 2-7) and the equivalent International Outcome Inventory for Alternative Interventions questionnaire (IOI-AI; all 7 items) will be used to assess the outcome of hearing aid rehabilitation and SUPR respectively[52]. The Dutch version of IOI-HA has a good test-retest reliability and validaty[54]. The first item of the IOI-AI determines the frequency of the use of the alternative intervention, i.e., "How often have you used the learnt communication strategies on an average day in the last two weeks?". Response options are 'never' (1), 'rarely' (2), 'sometimes' (3), 'often' (4), and 'almost always' (5). Items 2-7 of the IOI-HA/IOI-AI

questionnaire cover: benefit, residual activity limitations, satisfaction with the hearing aid(s)/SUPR, residual participation restrictions, impact on others, and quality of life.

- *Satisfaction with the HAD practice service.* Satisfaction will be measured by the following question: "How likely is it that you would recommend the service of the HAD practice to other people (family, friends, colleagues)?" It is scored on a visual analogue scale running from 0 (=not at all likely) to 10 (=extremely likely).

- *Self-reported activity limitations and participation restrictions* are measured using the reliable and validated original (Dutch) version of the Amsterdam Inventory for Auditory Disability and Handicap (AIADH)[45, 55]. It contains 28 questions regarding everyday listening situations. An example is: "Do you immediately look into the right direction when somebody calls you in the street"? The 4-point response scale covers: 'almost never' (1), 'sometimes' (2), 'often' (3) and 'almost always' (4). When the participant answers the question with 'almost never' or 'sometimes', he or she is directed to question b which is about the inconvenience of not being able to hear well in that specific situation. Response options are: 'no' (1), 'a little' (2), 'very handicapped' (3), and 'extremely handicapped' (4). Hence, the total score can range from 28-112 with higher scores indicating greater participation restrictions.

- *Readiness to do something about one's hearing problems* will be measured by the validated Dutch 24-item version of the University of Rhode Island Change Assessment (URICA)[56]. Formulations of items were adjusted such that they applied to hearing problems. The inventory contains 24 statements regarding attitudes and behaviours assessing an individual's stage of behaviour change. At T0 the scores on the following stages will be assessed: pre-contemplation (does not intend to take action in the foreseeable future, e.g., "As far as I'm concerned, I don't have any problems with my hearing that need changing"), contemplation (intends to change in the next six months and is aware of the pros and cons of changing), and action (has made specific modifications in his/her lifestyle towards healthy behaviour). At T1, T2, and T3 the maintenance stage (can maintain the changes in new behaviour) will be added. The five response options range from 'fully disagree' (score 1) to 'fully

agree' (score 5). Summed scores for each subscale will be calculated. In addition the composite 'readiness score' (adding the contemplation, action and maintenance scores and subtracting the pre-contemplation score) and the composite 'committed action score' (subtracting the contemplation stage score from the action stage score) will be calculated[56]. The higher the composite scores, the further the respondents are along the stages of change.

- *Emotional response to hearing problems*. The Hearing Handicap and Disability Inventory (HHDI) will be used[57]. The purpose of the inventory is to identify the individual's problems caused by hearing loss. Only the section 'emotional response' will be administered. It contains five statements each with five response options: 'yes!' (4), 'yes' (3), 'more or less' (2), 'no' (1) and 'no!' (0). An example is: "I find it difficult to accept that I am hearing impaired". Lower scores indicate better outcomes.

Secondary outcome measures - CP

- *Third-party disability* will be measured using the Significant Other Scale for Hearing Disability (SOS-HEAR)[12]. This questionnaire was translated into Dutch for the purposes of this study following a forward-backward method[51]. The 27-item questionnaire addresses the problems and limitations experienced by the CP. An example item is: "Because of my partner's hearing difficulties I have to repeat myself often". For each item the CP has to indicate how much of a problem it is for him/her: 'no problem' (0), 'a mild problem' (1), 'a moderate problem' (2), 'a severe problem' (3), 'a complete problem' (4). Higher scores indicate greater difficulties.

- *Hearing aid rehabilitation and SUPR outcome as viewed from the perspective of the CP* will be administered with the 7-item IOI-HA-SO/IOI-AI-SO and covers use, benefit, residual activity limitations, satisfaction, residual participation restrictions, impact on others, and quality of life[58].

Baseline measurement - Demographical characteristics

- Gender (male/female)

- Age (in years)

- Marital status (married/cohabiting/widow or widower/divorced/single, never married)
- Living situation (living together with my partner/living together with my partner and children/living together without my partner but with one or more family members/living alone (own room) or in a care institution/living alone, independently or nursing home/other, namely…)
- Level of education (no completed education/lower general education, elementary education or a part of it/lower general secondary education/vocational education/secondary education/technical and vocational education/higher professional education/higher general education/scientific education/other, namely…)
- Occupational status (yes/no)
- Country of birth (The Netherlands/other, namely…)
- Country of birth father (The Netherlands/other, namely…)
- Country of birth mother (The Netherlands/other, namely…)
- Hearing loss in each ear, in dB HL (averaged over 1, 2, and 4 kHz) as retrieved from the pure-tone audiogram as provided by the hearing aid dispenser.

Randomisation

HAD practices were randomly assigned to offer CaU or the intervention. To avoid an unequal distribution of HAD practices with regard to level of urbanisation, HAD practices were pre-stratified (HAD practices located in a relatively rural area versus in an urban area) and randomisation occurred within these two strata. A statistician performed block randomisation of the HAD practices in the statistical software R, with random permutation in blocks of size four and with a fixed seed**.** 34 HAD practices were assigned to CaU and 36 HAD practices to the intervention group. The recruitment procedure and period was the same for all 70 included HAD practices (the total list of included HAD practices are available on request from the research team).

Sample size calculation

Sample size calculations are based on the expected effects of the intervention on the primary outcomes: communication strategies (CPHI). Demorest and Erdman indicated that the expected difference on the subscales of the CPHI varies from 0.67 (Maladaptive Behaviour) to 0.95 (Self-Acceptance)[59]. Given that in a previous study[37] the effect of the programme was larger for first-time than for experienced users, we calculated sample sizes separately for first-time and experienced users. For first-time HAUs, we based our sample size calculations on an expected difference of 0.67 between the intervention and the CaU group. Note that the subscale with the smallest minimal importance difference (i.e., Maladaptive Behaviour) was used in the calculation, as finding a significant difference on this measure requires the largest number of participants. Calculations in PASS 12 (Tests for Two Means in a Cluster-Randomised Design; Intracluster correlation coefficient: 0.01; alpha: 0.05; power: 0.80) shows, that when 70 HAD practices are included (of which half will offer SUPR and half will offer CaU), the number of first-time HAUs to include in the analyses is two per HAD practice. For the sample size calculation of the experienced users we chose an expected difference of 0.4 between the intervention and CaU group. The expected difference was set lower than for first-time HAUs as Kramer *et al* had previously found generally smaller effects for experienced users than for first-time users[37]. With a difference of 0.4 the number of experienced HAUs (power: 0.80) to include is three per HAD practice. We expected the proportion of drop-out or loss to follow-up across the study to be 20%. This includes loss to follow-up for a range of reasons: no motivation anymore, reluctance to purchase a hearing aid after a successful trial, sickness, death etc. Taking the loss to follow-up and the proportion of clients that normally purchase a hearing aid into account results in a total (rounded) number of four first-time HAUs per HAD practice and five experienced HAUs per HAD practice to be recruited.

Statistical analyses

To check the comparability between the groups (CaU or intervention group) at baseline, baseline characteristics of the participants will be compared using the Chi Square test (for categorical

variables), the independent samples *t*-test (for normally distributed continuous variables) and the Mann-Whitney test (for non-normally distributed continuous variables). Comparability will be checked for all demographic variables and all primary and secondary outcomes.

For the effect analyses, the groups will be compared on all primary and secondary outcome measures using linear mixed models including the results at T0, T1, T2, and T3. Group, time, and their two-way interaction will be included as fixed effects in the mixed models, with random intercepts for subject and HAD practice. For the covariance matrix, a Variance Component structure will be chosen. To adjust for potential bias associated with multiplicity of analyses, statistical significance levels will be set at $P< 0.016$ (0.05/3). If a significant effect is found, an independent samples *t*-test will be used and a Bonferroni correction will be administered in case of multiple comparisons. Type of HAU (first-time or experienced) will be tested as an effect modifier for potential subgroup differences.

In case of substantial missing data, multiple imputation will be applied. The main analysis is intention to treat. Any outcome measure to be collected for participants who discontinue or deviate from intervention protocols will be saved and analyzed according to the intention to treat protocol. In addition, a per-protocol analysis will be performed. A per-protocol analysis includes those participants who completed the intervention originally allocated as described in the study protocol. As a per-protocol analysis can potentially yield biased effects (e.g., see CONSORT statement)[60], great caution will be exerted when interpreting these results. In addition, the report of these findings in future articles will be nuanced explicitly and thoroughly.

Process evaluation

The process of implementing SUPR into the HAD care in the intervention arm will be evaluated. The main aims of this evaluation are to gain insight into 1) the circumstances in which the intervention was implemented, 2) (non-) compliance with the intervention, and 3) the professionals' and clients' appraisal of the intervention.

The process evaluation will be carried out according to the framework as proposed by Linnan *et al*[61]. It covers seven parameters: recruitment, reach, fidelity, dose delivered, dose received and implemented, satisfaction, and perceived benefit[62]. A brief description of each of the parameters is given below.

- Recruitment refers to the procedures applied to approach and attract potential participants. The hearing aid dispensers will be asked to provide this information.
- Reach. This is the proportion of people participating relative to the number of people invited.
- Fidelity relates to the question of whether the intervention was provided as intended. The team that is responsible for the email contact will be asked to provide a written report on this.
- Dose delivered: 1) Did the personnel of the HAD practice hand out the Practical Support Booklet at the end of the preparation appointment? 2) Did the personnel of the HAD headquarters send out the emails correctly (correct content) and on time.
- Dose received and implemented: 1) Did the participants receive and use the Practical Support Booklet? 2) Did the participants open the emails and the videos? If so, did they watch the whole video, or part(s) of it? The video watching behaviour will be determined using Quadia (supplier of online video content) and Google analytics. Data on the average watching time per video, and how many times a particular video has been opened will be determined. Due to the privacy regulations the HAD company is subject to, the company is only allowed to collect video watching data on a group level (and not on an individual level). As all the HAD practices of the company that do not participate in the study provide SUPR as their standard care at the time of the study, the researchers will not be able to determine specific group averages of the study participants (the averages are based on both study participants and regular HAD clients). Information on implementation of the knowledge that participants learnt from SUPR will be deduced from the IOI-AI questionnaire (item on

use) on T1. If participants received and used the Practical Support Booklet will be measured by a questionnaire.

- Satisfaction: Satisfaction of the participant with SUPR will be evaluated using the IOI-AI questionnaire (item satisfaction) on T1. The hearing aid dispensers will be asked to answer the question: How would you rate your satisfaction with SUPR?

- Benefit: Information on the experienced benefit of the participant will be obtained from the IOI-AI questionnaire (item benefit) on T1. The hearing aid dispensers will be asked to answer the question: How would you rate the perceived benefit from SUPR for your clients' ability to improve in communication?

Additionally, focus group discussions with participants from the intervention group will be organized to gain insight into the reasons for using the knowledge of SUPR in their daily lives or not. A minimum of two focus groups will be organized. The exact number will depend on data saturation. Heterogeneity in age, gender, educational level, severity of hearing impairment, and stage of behaviour change (at baseline) within the groups will be strived for. Given the difficulties hearing-impaired individuals might have with group conversations, the focus groups will have a maximum size of six participants each.

ETHICS AND DISSEMINATION

Protocol amendments, confidentiality and dissemination policy

Any future protocol modifications will be submitted to the VU University Medical Center Medical Ethical Committee. Directly upon approval, the modification will be corresponded to the trial registry.

Personal information about enrolled participants will only be shared with employees of the headquarters of the HAD practices who signed a privacy declaration. This exchange of personal

information will only occur in order to collect data within the framework of the study (e.g., to collect audiogram data, hearing aid purchase status, and use of SUPR). Any exchanged data and personal information will be password protected.

VU University Medical Center has all property rights on the final results of the trial and is entitled to publish the results. The funder is not entitled to publish the results without written consent of the VU University Medical Center. These agreements are secured in a contract. For specific author contributions for the current paper, see 'Authors contributions'.

Findings of the study will be published in scientific journals and presented at scientific conferences, and will be communicated within the national and international media. A short report of the study findings will be sent to interested participants. The results will be communicated within the hearing aid dispenser company.

Data collection forms and data storage

Data collection forms and procedures for data management are available on request. All data will be collected digitally and 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. According to Good Clinical Practice guidelines and after having received informed consent, data will be archived for a period of fifteen years after finalizing the study. After finalization, 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. We will perform double data entry of a selection of the audiograms and the baseline AIADH data for quality purposes.

Monitoring

The study is subjected to local regulations and its quality is monitored by the research institutes (i.e., EMGO+) Quality Committee. This committee is responsible for developing, implementing, and maintaining a system for quality assurance and control for all research within the institute. Due to the decision of the Dutch Institutional Review Board (IRB) of the VU Medical University Center Amsterdam that the study does not fall under the Research Involving Human Subjects Act (WMO), the formation of a Clinical Trial Data Monitoring Committee was not deemed necessary.

DISCUSSION

Like in most parts in the world, usual care for adults with hearing impairment in the Netherlands is mostly restricted to audiological assessment and hearing aid fitting. This type of care is in the large part provided by commercial hearing aid dispensers. Communication programmes aimed at improving the use of favourable communication strategies, increasing personal adjustment to hearing impairment, and improving hearing aid handling skills are not provided on a large scale in standard hearing health care settings. This is undesirable, as there is a growing body of evidence showing that offering such programmes can effectively decrease communication problems and associated negative health outcomes[27, 33, 38, 42]. Likewise, despite the fact that including CPs in the rehabilitation process is increasingly recognized within audiology as a prerequisite for successful rehabilitation[12], CPs are not yet part of standard hearing health care. In the current study, these elements (i.e., a communication programme and involvement of a CP) are part of a programme called SUPR that is incorporated in regular hearing aid dispensing care and that will be tested for its effectiveness. SUPR's primary aims are to improve older hearing aid owners' communication strategies and personal adjustment and decrease their CPs' third-party disability. To our knowledge, similar online support programmes for HAUs that are implemented on a large scale in hearing aid dispenser settings are not yet available.

A strength of the SUPR programme is that for those who are at risk for isolation or those who have reduced access to health care, the internet can be a practical tool providing direct access to health services[63]. Other elements that can add to the effectiveness of online support programmes as SUPR are that it can (partly or mainly) be provided in a visual mode (images, written text, subtitles), the volume can be controlled, background noises can be relatively easily eliminated, and online support programmes provide the opportunity to tailor intervention elements.

A few limitations to the design need to be considered. Unfortunately it is not possible to perform a double-blinded, randomised, controlled trial due to the nature of the intervention study. Blinding of the participants is not possible as they will be informed about the general aim of the SUPR study (i.e. to evaluate a support programme) and know that they are either part of the group that receives CaU or SUPR. Nevertheless, we will attempt to minimize the provision of information on the content of SUPR to participants of the CaU group. The participants only know that SUPR is a support programme aimed to 'improve communication', but for instance do not know what the intervention further entails. This way, we aimed to prevent that they would independently seek access to SUPR (which would cause contamination) and that their knowledge of the care they were missing out on would affect their responses in the questionnaires. We further attempted to prevent contamination by offering the programme to the CaU-participants for free after completing the study. Blinding the researchers during the effect analysis is also not possible as the IOI measure that is administered at T1, T2, and T3 indicates what group each participant was randomised to (IOI-HA only: CaU group; IOI-AI: intervention group).

SUPR is an online intervention, it is thus essential that people have access to a device with internet access and an email account. Participants who have access to the internet will most likely be of high SES and this might bias the data. The fact that the support programme as such reaches a selective part of the dispenser's clientele requires further discussion. Consistent with findings from Choi *et al*

and Fox *et al* who compared non-internet users and users, it is possible that the older people participating in the SUPR study generally have a somewhat higher socioeconomic status and are somewhat younger than the average clientele of the dispenser[64, 65]. With regard to age however, it should be noted amongst the young-old (55-74) the weekly internet use has increased from 70% in 2010 to 83% in 2015 in the Netherlands and will most probably keep rising in the future[66]. This suggests that the large majority of the younger-old can currently already be reached with SUPR and this will improve even more in the future. The non-use of internet among the older olds (75+) currently still is substantial, although this proportion also has decreased strongly in the past few years (66% in 2012 to 50% in 2015[67]). Furthermore, it is encouraging that older internet users, generally use it more for health-related tasks or information than for personal tasks[68]. In addition, people with hearing loss are more likely to use the internet than people in the general population (OR=1.74, 95% CI 1.23-3.17)[69]. Baring these developments in mind, we are confident that the large majority of the older HAUs who can potentially benefit from SUPR will be increasingly eligible and open to using SUPR to improve their hearing health.

At the start of the study, participants might downplay their hearing problems because hearing loss stigma causes them to be reluctant to acknowledge or recognize their hearing problems[70]. We expect that SUPR will have a positive effect on acceptation of hearing loss, and therefore people may report a disability level that is 'more honest'. This may hold particularly for the first-time HAUs who have never gone through an intensive rehabilitation trajectory before and less so for the experienced users. As such, it is possible that this mechanism will cause an increase in self-reported hearing disability in the intervention group over time. This would counteract the favourable effect that SUPR is expected to create, i.e., a decrease in experienced disability. To examine whether the first-mentioned mechanism would apply, one of the subscales of the CPHI on acceptation of hearing loss can be used[48]. With this subscale we can examine if acceptance is a mediator between time and hearing status for the intervention group.

This study aims to perform a process evaluation, as is strongly recommended in all randomised controlled trial research. A process evaluation provides insight into reasons for the demonstrated (absence of) effectiveness of the intervention and might offer information concerning the generalizability of the study results. When no or only small significant effects of SUPR will be found, we may be able to modify the programme based on the results of the process evaluation after the study.

In the future, it is expected that there will be an increasing demand for solutions for hearing health conditions due to the ageing population and thus increased prevalence of hearing problems. SUPR is especially developed for use on a large scale basis in HAD practices. The large number of practices that are involved in the study not only contributes to a large sample size (and statistical power), it also reflects real world clinical practice. This will potentially make a strong case for the extrapolation of the study's results. Demonstrating the programmes effectiveness would be a great step forward improving health care services for people with hearing impairment.

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FOOTNOTES

Contributors

SEK developed the first version of the study design in collaboration with BP and VJ. MP and SK developed the study design further and wrote up the first draft of the study protocol. BvdW, JFJM, MP, SEK, and VJ worked on the design further and facilitated the practical implementation of the study. BIW provided statistical and methodological advice. Data collection will be done by BvdW and

JFJM, assisted by VJ, and supervised by SEK and MP. JFJM wrote the final version of the manuscript. SEK and MP supervised the writing process and MP, SEK, BP, BIW, VJ, and BvdW gave critical comments on several drafts of the manuscript.

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Competing interests

VJ is an employee at Schoonenberg Hoorcomfort. BP is an employee at AudioNova International.

Ethics approval and consent to participate

Written consent for the SUPR study (reference number: 2015.335) was obtained from the Dutch Institutional Review Board (IRB) of the VU Medical University Center Amsterdam (registered with the US Office for Human Research Protections as IRB00002991; FWA number: FWA00017598). The IRB concluded that Medical Research Involving Human Subjects ACT (WMO) does not apply to this study. Participants' consent will be obtained via the registration website of the study. At this website participants were asked to declare that they were sufficiently informed about the study and agreed on the use of certain data to be collected for the purposes of the study.

Data sharing statement

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.

Abbreviations

SUPR: SUpport PRogramme, CaU: care as usual, CP: communication partner, HAU: hearing aid users, HAD practices: hearing aid dispensing practices, AIADH: Amsterdam Inventory for Auditory Disability and Handicap, CPHI: Communication Profile for the Hearing Impaired, MARS-HA: Measure of Audiologic Rehabilitation Self-Efficacy for Hearing Aids, IOI-HA: International Outcome Inventory - Hearing Aids, IOI-AI: International Outcome Inventory - Alternative Interventions, URICA: University of Rhode Island Change Assessment for Hearing health behaviour, HHDI: Hearing Handicap and Disability Inventory, SOS-HEAR: Significant Other Scale for Hearing Disability, IOI-HA-SO: International Outcome Inventory Significant Other - Hearing Aids, IOI-AI-SO: International Outcome Inventory Significant Other - Alternative Interventions.

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Appendix 1 Spirit flow diagram. Schedule of enrolment, interventions, and assessments

		Allocation of HAD practices	Enrolment	Post-Allocation and Enrolment			
TIMEPOINT	Outcome measurements	-T2	-T1	T0 (Baseline)	T1 (6 months)	T2 (12 months)	T3 (18 months)
ENROLMENT:							
Eligibility screen			x				
Informed consent			x				
Allocation		x					
INTER-VENTIONS:							
Care as Usual (Hearing aid fitting)		x	———	———	———	———	x
Intervention (Hearing aid fitting + SUPR)		x	———	———	———	———	x

		Allocation of HAD practices	Enrolment	Post-Allocation and Enrolment			
TIMEPOINT	Outcome measurements	-T2	-T1	T0 (Baseline)	T1 (6 months)	T2 (12 months)	T3 (18 months)
ASSESSMENTS:							
Demographic variables							
Gender				**x**			
Age				**x**			
Marital status				**x**			
Living situation				**x**			
Level of education				**x**			
Occupational status				**x**			
Country of birth participant				**x**			

		Allocation of HAD practices	Enrolment	Post-Allocation and Enrolment			
TIMEPOINT	Outcome measurements	-T2	-T1	T0 (Baseline)	T1 (6 months)	T2 (12 months)	T3 (18 months)
Country of birth participant's parents				**x**			
Hearing status	Pure tone audiogram			**x**			
Primary outcome measures - HAUs							
The use of communication strategies	CPHI - Maladaptive Behaviours, Verbal Strategies, and Non-verbal Strategies			**x**	**x**	**x**	**x**

	subscales						
Secondary outcome measures - HAUs							
		Allocation of HAD practices	Enrolment	Post-Allocation and Enrolment			
TIMEPOINT	Outcome measurements	-T2	-T1	T0 (Baseline)	T1 (6 months)	T2 (12 months)	T3 (18 months)
Personal adjustment to hearing impairment	CPHI - Self-acceptance, Acceptance of Loss, and Stress and Withdrawal subscales			**x**	**x**	**x**	**x**
Self-efficacy of hearing aid handling	-MARS-HA - Basic handling subscale			**x**	**x**	**x**	**x**
	-MARS-HA - Advanced handling subscale				**x**	**x**	**x**

Self-reported hearing aid use	-IOI-HA (item 1)				**x**	**x**	**x**
	-Use questionnaire				**x**	**x**	**x**
Objective hearing aid use	-Data-logging				**x**	**x**	**x**

		Allocation of HAD practices	Enrolment	Post-Allocation and Enrolment			
TIMEPOINT	Outcome measurements	-T2	-T1	T0 (Baseline)	T1 (6 months)	T2 (12 months)	T3 (18 months)
Self-reported intervention outcomes	-IOI-HA (items 2-7)/IOI-AI (all 7 items)				**x**	**x**	**x**
Satisfaction with the hearing aid dispenser service	"How likely is it that you would recommend the service of the HAD practice to other people (family, friends,			**x**	**x**	**x**	**x**

	colleagues?)"						
Self-reported activity limitations and participation restrictions	AIADH			**x**	**x**	**x**	**x**

		Allocation of HAD practices	Enrolment	Post-Allocation and Enrolment			
TIMEPOINT	Outcome measurements	-T2	-T1	T0 (Baseline)	T1 (6 months)	T2 (12 months)	T3 (18 months)
Readiness to do something about one's hearing problems	-URICA - Precontemplation/ Contemplation/ Action stages			**x**	**x**	**x**	**x**
	-URICA - Maintenance stage				**x**	**x**	**x**

Emotional response	HHDI - Emotional response subscale	x	x	x	x
Secondary outcome measures - CP					
Third-party disability	SOS-HEAR	x	x	x	x
Self-reported intervention outcomes from the perspective of the CP	IOI-HA-SO/IOI-AI-SO		x	x	x

Abbreviations: HAD practice: hearing aid dispensing practice, SUPR: Support PRogramme, HAU: hearing aid user, CPHI: Communication Profile for the Hearing Impaired, MARS-HA: Measure of Audiologic Rehabilitation Self-Efficacy for Hearing Aids, IOI-HA: International Outcome Inventory -Hearing Aids, IOI-AI: International Outcome Inventory - Alternative Interventions, AIADH: Amsterdam Inventory for Auditory Disability and Handicap, URICA: University of Rhode Island Change Assessment - for Hearing health behaviour, HHDI: Hearing Handicap and Disability Inventory, CP: Communication Partner, SOS-HEAR: Significant Other Scale for Hearing Disability, IOI-HA-SO: International Outcome Inventory Significant Other - Hearing Aids, IOI-AI-SO: International Outcome Inventory Significant Other - Alternative Interventions.

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	2
	2b	All items from the World Health Organization Trial Registration Data Set	1-36
Protocol version	3	Date and version identifier	1
Funding	4	Sources and types of financial, material, and other support	35
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1, 35
	5b	Name and contact information for the trial sponsor	1
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	35
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	31

Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	3-8
	6b	Explanation for choice of comparators	3-8
Objectives	7	Specific objectives or hypotheses	8
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	8, 9
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	8-12
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	13,14
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	8-12
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	N/A
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	12, 13, 31
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	12,13
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	21,25
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	12,13, 15-21

Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	26, 27
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	13
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	26
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	26
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	9, 26
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	32, 33
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/A
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	12, 15-25
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	27, 28

Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	30,31
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	27, 28
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	27, 28
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	27, 28
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	31
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	N/A
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	N/A
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	N/A
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	35, 36
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	30

Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	35, 36
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	30, 31
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	35
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	30
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	30
	31b	Authorship eligibility guidelines and any intended use of professional writers	35
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	N/A
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Appendix 1 and 2 (uploaded as additional files)
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A.

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.