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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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3 1 **Evaluating the addition of an online Support Programme (SUPR) to usual hearing aid care:**
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5 2 **protocol for a cluster randomized controlled trial**
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3 27 **ABSTRACT**
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5 28 **Background:** An educational Support Programme called SUPR was developed for hearing aid users
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7 (HAUs) and their communication partners (CPs) offering care beyond hearing aid fitting. SUPR
8
9 teaches its users communication strategies and hearing aid handling skills, and offers peer
10
11 testimonials. Ultimately, its main aim is to improve coping strategies (i.e., application of favourable
12
13 communication strategies, and personal adjustment).
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16
17 33 **Methods/design:** Using a cluster randomized controlled trial-design, 70 Dutch hearing aid dispenser
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19 practices were randomized into hearing aid fitting (care as usual, 34 practices) and hearing aid fitting
20
21 including SUPR (36 practices). The aim is to recruit a total of 569 older (aged 50+) first-time (n=258)
22
23 and experienced (n=311) HAUs and their CPs. SUPR consists of a Practical Support Book and online
24
25 material offered via email over a period of 6-7 months. The book provides practical information on
26
27 hearing aids, advice on communication strategies, and home exercises. The online material consists
28
29 of educational videos on hearing aid functionality and usage, communication strategies, and peer
30
31 testimonials. Lastly, noncommittal email contact with the dispenser chain is offered. Every HAU is
32
33 asked to assign a CP who is advised to be involved intensively. Effect measurements will occur at
34
35 baseline, and at 6, 12, and 18 months follow-up via online questionnaires. The primary outcome for
36
37 HAUs will be coping with hearing impairment as measured by the subscales of the Communication
38
39 Profile for the Hearing Impaired. The primary outcome for CPs will be third-party disability
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41 (Significant Other Scale for Hearing Disability). A process evaluation will be performed.
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46 46 **Ethics and dissemination:** This study protocol was approved by the Scientific Committee of the
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48 EMGO Institute for Health and Care Research. This intervention could contribute to lowering the
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50 hearing impairment burden in our ageing society. The results will be disseminated through peer-
51
52 reviewed publications and scientific conferences.
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55 50 Trial registration: ISRCTN77340339; Pre-Results.
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3 51 **Keywords:** Hearing loss, 'coping with hearing impairment', intervention, cluster randomized
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5 52 controlled trial, hearing aids, communication, communication strategies, internet
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11 55 **STRENGTHS AND LIMITATIONS**

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14 56 - This is the first study to evaluate the effects of an online Support Programme (SUPR) for hearing aid
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16 57 users that is implemented in a hearing aid dispensing practice setting.

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19 58 - SUPR is a multifaceted educational intervention, including a Practical Support Book, online elements
20
21 59 via email, and noncommittal email contact with the dispenser chain, focusing on personal
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23 60 adjustment and communication strategies.

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27 61 - The SUPR study is a large scale study, involving hearing-impaired participants and their
28
29 62 communication partners from 70 hearing aid dispensing practices all over the Netherlands.

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32 63 - The online character of the programme suits the current and future developments in the increasing
33
34 64 internet use among older persons and can reach out to those with reduced (physical) access to
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36 65 health care.

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39 66 - Nonetheless, the online character might yield a selective sample of older persons (especially among
40
41 67 the older old), that is included in the study and for whom SUPR will be suitable.

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44 68 - Another limitation of the study is that the design does not allow the blinding of participants and
45
46 69 researchers for intervention allocation. This could lead to performance bias.

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49 70 - The findings of the study will potentially contribute to improvement of hearing health care services
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51 71 for hearing-impaired persons and their communication partners.

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3 74 **BACKGROUND**
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5 75 Hearing impairment is one of the most prevalent chronic health conditions affecting older adults. It
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7 76 was ranked fifth in the top 25 of global causes for years lived with disability in 2013[1]. Due to the
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9 77 overall aging of the population[2], the prevalence of hearing impairment is increasing vastly,
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11 78 imposing a great burden on individuals and society.
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16 80 Hearing impairment essentially leads to the inability to communicate effectively, which in turn can
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18 81 result in a cascade of effects leading to poor psychosocial outcomes such as social isolation[3],
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20 82 loneliness[4, 5], distress[6], depression[6, 7], and work-related fatigue[8]. It has also has been
21
22 83 associated with accelerated cognitive decline[9] and falls[10]. The limitations in daily life activities
23
24 84 and restrictions in social and societal participation that a person experiences depend on aspects that
25
26 85 are both internal (such as the level of impairment in hearing functions and structures) and external
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28 86 (such as availability of hearing aids, care facilities, and social support) to a person. In addition,
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30 87 internal so-called 'personal factors' including age and coping are important factors that can influence
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32 88 psychosocial outcomes[11].
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37 90 Significant others can also be negatively affected by the hearing impairment of their loved ones.
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39 91 Partners and spouses generally experience frustration and embarrassment, for example in
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41 92 challenging social communication settings[12]. Communication difficulties in background noise, the
42
43 93 partner's frequent request to repeat, and the need to act as an interpreter may cause irritation,
44
45 94 embarrassment, and tension in the relationship[12]. In a systematic review conducted by Kamil *et al*
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47 95 it was found that communication partners (CPs) of persons with hearing impairment experience
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49 96 decreased social functioning, poorer quality of life and more participation restriction than CPs of
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51 97 normally hearing individuals[13].
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3 99 The usual care provided for persons with hearing impairment is often restricted to the assessment of
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5 100 hearing loss and the provision and fitting of hearing aids[14]. Hearing aid use has positive effects on
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7 101 quality of life, social and emotional wellbeing, and may reduce depressive complaints[15-17], and
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9 102 possibly even cognitive decline[18]. Despite this abundant evidence, the uptake and use of hearing
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11 103 aids is low. It is estimated that around one third of the adults who would benefit from hearing aids
12
13 104 own them[19-21] and 12-20% of the owners never uses them[22,23]. Reasons for low uptake and use
14
15 105 are largely known[24-26] and include low perceived need of amplification reflected in low self-
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17 106 reported hearing disability and limited acceptance of hearing loss. In addition, low expectations of
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19 107 hearing aid benefits, limited gain in noisy situations, low overall sound quality, other perceived
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21 108 barriers to use hearing aids such as hearing aid stigma, high costs and, need for regular hearing aid
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23 109 care and maintenance, are factors adding to low uptake and use. Finally, lack of social support or
24
25 110 social pressure to get a hearing aid are factors negatively influencing hearing aid use.
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31 112 Because the factors leading to low use are numerous and their interplay is complex, it has often been
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33 113 argued that hearing health care should offer more than hearing aids alone to improve daily life
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35 114 communication and wellbeing of hearing-impaired adults[27]. This argument is in line with the
36
37 115 biopsychosocial approach of health that is receiving increasing attention in the field of audiology:
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39 116 Experienced hearing disability (i.e., activity limitations and participation restrictions) is the outcome
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41 117 of a complex interaction between an individual and his/her contextual factors[28-30].
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46 119 Various interventions have been proposed to complement hearing aid fitting. Examples are
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48 120 communication programmes aimed at improving speech perception and/or communication
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50 121 management[31]. These include speech perception training, communication management training
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52 122 and social support[27, 32, 33]. For reviews, see Barker *et al*, Sweetow *et al*, and Wong *et al*[34-36].
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54 123 Examples of effective programmes are the Home Education programme[37] and the Active
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56 124 Communication Education (ACE) group programme[38]. Both programmes consist of modules on
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3 125 everyday communication situations, aiming to improve the use of communication strategies,
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5 126 personal adjustment to living with hearing impairment, quality of life, development of problem-
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7 127 solving skills and to decrease the level of experienced hearing disability. These programmes showed
8
9 128 an improvement in communication strategies[37] and communicative participation restrictions and
10
11 129 activity limitations[38]. Kramer *et al* found that the effects of the Home Education programme were
12
13 130 larger for first-time HAUs, as compared to experienced HAUs. Further, the study had a relatively
14
15 131 small sample size (n=48) and the participants were all patients of a specialized tertiary Audiology
16
17 132 Centre, limiting the generalizability of the results. In general, only a small number of hearing aid
18
19 133 applicants with relatively complex hearing problems receive hearing care through a tertiary clinic.
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21
22 134 The vast majority of hearing aids are fitted in a dispenser practice. A study on the effectiveness of the
23
24 135 Home Education programme in a dispenser practice setting is therefore needed.
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29 137 For the evaluation of their programmes, both Kramer *et al*[37] and Hickson *et al*[38] used a total
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31 138 follow-up period of six months. A review study by Hawkins *et al* showed that on the short term (i.e.,
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33 139 up to six months), counselling-based adult group rehabilitation programmes may generally reduce
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35 140 self-perception of hearing disability and enable better use of communication strategies and hearing
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37 141 aids[39]. Unfortunately, there is limited evidence for the long-term effects of these programmes[39].
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42 143 Communication training programmes, whether or not combined with hearing aid fitting, are rarely
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44 144 offered in hearing health care[27, 32]. When offered, there are various reasons for adults with
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46 145 hearing impairment to not pursue communication training programmes, such as for example living in
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48 146 a rural area, lack of time, and no easy access[32]. Due to the paradigm shift in health care from the
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50 147 traditional doctor-centric model to a more patient-centered model combined with increasingly
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52 148 pervasive use of e-health methods and technology, the typical barriers causing the low use of (group)
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54 149 communication training programmes can be overcome[40, 41, 42].
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3 151 Recently, a number of studies have been published reporting on the development and evaluation of
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5 152 online communication programmes. Thorén *et al* developed such a programme[43]. It included
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7 153 reading material on hearing anatomy, hearing aids, communication strategies, assistive listening
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9 154 devices, and guidelines for CPs. In addition, the intervention included weekly email contact with an
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11 155 audiologist, problem solving exercises and online peer discussion on personal experiences with
12
13 156 hearing loss. Thorén *et al* studied the effectiveness of the programme using a randomized controlled
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15 157 trial-design in which the intervention group received the online programme while the control
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17 158 participants were offered access to an internet discussion forum or were placed on a waiting list[43].
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19 159 The researchers found reduced symptoms of depression[44] and a significant decrease of activity
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21 160 limitations and participation restrictions in the intervention group compared to the controls at five
22
23 161 weeks directly after the intervention, and at three-months follow-up[43]. Ferguson *et al* investigated
24
25 162 the use of short interactive videos (reusable learning objects, RLOs)[45]. RLOs were delivered via DVD
26
27 163 for TV, computer and the internet and covered practical and psychosocial issues which are relevant
28
29 164 for audiologic rehabilitation. The intervention group received seven RLOs plus usual clinical services
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31 165 including hearing aid fitting and counseling. They were compared to a control group who received
32
33 166 clinical services only and were placed on a waiting list. Participants in the intervention group had
34
35 167 significantly better hearing aid skills and better knowledge on psychosocial issues than the control
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37 168 group after 6-weeks follow-up. Whereas the online education programme of Thorén *et al* was
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39 169 evaluated in a sample of adults who were recruited by local advertisements and articles and were
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41 170 wearing a hearing aid for at least one year[43], Ferguson *et al* evaluated their RLOs in a small sample
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43 171 of patients of the audiology service of the Nottingham University Hospitals NHS Trust. Patients were
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45 172 adults who had been referred to the clinic by their family doctor[45].
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52 174 To the best of our knowledge, there is no study available evaluating the effectiveness of an online
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54 175 communication training programme that is implemented on a large scale in a hearing aid dispensing
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56 176 setting. This paper reports on the design of such a study. It addresses the different steps that will be
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3 177 taken to evaluate an online intervention programme for hearing-impaired adults and their CPs. The
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5 178 programme is based on the Home Education programme mentioned earlier[37]. A remake was
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7 179 created so that it would be applicable for use over the internet and would be a more up-to-date
8
9 180 version of the one developed in 1995. Also, the programme was expanded with extra elements,
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11 181 including instruction videos on how to operate and maintain hearing aids, testimonials of peers,
12
13 182 through emails which are sent every other week. The main focus of SUPR is on improving the use of
14
15 183 communication strategies and personal adjustment to hearing loss, which within the field of
16
17 184 audiology, are sometimes summarized as 'coping'[46]. More details of the online SUPR
18
19 185 PRogramme – further referred to as SUPR - are provided in the sections below.
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24 187 The study will determine the effectiveness of SUPR as part of standard hearing aid dispensing care by
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26 188 comparing it to hearing aid fitting only. Its effectiveness will be studied both in first-time and
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28 189 experienced HAUs and their CPs.
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34 35 192 **METHODS**

36 37 193 **Study design**

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39 194 A cluster randomized controlled trial with an 18-month follow-up period will be performed. Dutch
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41 195 hearing aid dispensing practices (henceforth: HAD practices) and consequently all clients in these
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43 196 practices will be randomly assigned to one of two groups. The control group will receive care as usual
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45 197 (CaU) which is hearing aid fitting only, while the intervention group will receive hearing aid fitting
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47 198 supplemented with SUPR.
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51 52 200 **Care as Usual**

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54 201 CaU starts with a so-called preparation appointment during which a screening pure-tone audiogram
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56 202 (only air conduction) is administered by the hearing aid dispenser. If the hearing loss in one or both
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3 203 ears is at least 35 decibel (dB) hearing level (HL) (averaged over the three frequencies 1, 2, and 4 kHz)
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5 204 in one or both ears, someone is considered potentially eligible for hearing aid fitting and more
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7 205 comprehensive audiometry is required. If the client is interested in hearing aids, his/her general
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9 206 wishes and goals are discussed after which the client is provided with the Amsterdam Inventory for
10
11 207 Auditory Disability and Handicap (AIADH; Kramer *et al*[47]). Clients are asked to complete it at home
12
13 208 and bring it along to the next appointment. The AIADH assesses activity limitations and participation
14
15 209 restrictions due to hearing impairment. During the next appointment, i.e., the so-called intake
16
17 210 appointment, comprehensive audiometry (air and bone conduction, and speech audiometry) are
18
19 211 performed by the hearing aid dispenser. The results of all tests, the AIADH, and the wishes of the
20
21 212 client determine what type of hearing aid may be best suited for this person. The appropriate
22
23 213 hearing aids will be selected and fitted directly (if available in the HAD practice) or in a subsequent
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25 214 fitting appointment. Fitting is followed by a trial period of up to four weeks mostly, during which a
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27 215 person can try out the hearing aid and decide whether or not to purchase it. Depending on the
28
29 216 client's needs, tuning or other follow-up appointments are scheduled during the trial period but also
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31 217 after the device has been purchased.
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37 219 The hearing aid dispenser will invite first-time HAUs to participate in the study at the end of their
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39 220 preparation appointment. Experienced HAUs will also be invited at the end of their preparation or at
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41 221 the end of their intake appointment, if they did not require a preparation appointment. See 'Study
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43 222 population & recruitment' for further details.
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48 224 **Intervention: SUPR**

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50 225 SUPR consists of a Practical Support Paper Book and online material. The Practical Support Book will
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52 226 be handed out at the end of the preparation appointment (first-time HAUs, experienced HAUs) or
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54 227 the intake appointment (experienced HAUs). After the intake appointment, the online elements will
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56 228 be sent out to the participants by email.
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5 230 The aim of the Practical Support Book is to help the client to become familiar with their hearing aid.

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7 231 The book is intended to be used until the end of the trial period. The book covers four parts,

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9 232 corresponding to four phases. The information provided is synchronized with the issues typically

10
11 233 discussed during visits to the HAD practices in the trial period. The first part outlines the process of

12
13 234 getting a hearing aid and includes an introduction to the hearing aid dispenser and an explanation of

14
15 235 the pure tone audiogram. The client is asked to write down specific needs. The second part revolves

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17 236 around the type and choice of the new hearing aid. Information about how to operate and manage

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19 237 the device is provided as well. In the third part the client is allowed to give feedback on experiences

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21 238 with the new hearing aid and the settings. This information will be used for further refinement of the

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23 239 fitting. The final section of the book provides information on assistive listening devices,

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25 240 reimbursement of costs and more detailed information on the audiogram and the hearing aids.

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31 242 **Online Elements**

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33 243 The online part of the programme consists of email contact with the dispenser during the trial period

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35 244 followed by a series of training modules. This takes up to approximately six months after the hearing

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37 245 aid purchase. The exact time depends on the duration of the trial period. For example, if a trial

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39 246 period is finalized in three weeks instead of the average four, the total duration of SUPR is one week

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41 247 shorter.

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46 249 The following online components are provided: 1) Training modules on hearing aid handling skills:

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48 250 Three short instruction videos with practical information on the use and maintenance of hearing aids.

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50 251 2) Training modules on communication strategies and personal adjustment: Remake (modernized

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52 252 version) of the home educational programme "*Horen en Gehoord Worden: Hoe kan het beter*", as

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54 253 developed by Kramer *et al*[37]. It comprises five short videos showing the difficulties that a hearing-

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56 254 impaired person can experience in everyday life situations. The typical reactions in these situations

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3 255 are shown and a trainer illustrates how communication could be improved by using communication
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5 256 strategies (for both the hearing-impaired person and his/her CP). 3) Testimonials by hearing-
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7 257 impaired peers who are sharing their experiences with hearing aids.
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11 259 Participants in both the CaU and the intervention group will be asked to invite a CP to participate in
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13 260 the study. Having a CP who is willing to participate is not obligatory though.
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16 262 **Measurements**

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18 263 For all participants four measurements will take place: at baseline (after the preparation
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20 264 appointment, but before the actual hearing aid fitting) (T0), six months after the hearing aid
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22 265 purchase (T1), one year after the hearing aid purchase (T2), and eighteen months after the hearing
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24 266 aid purchase (T3). Measurements at T3 serve to determine the long-term effects of SUPR, i.e., one
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26 267 year after its completion. Data will be collected using online questionnaires through NetQ Premium,
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28 268 which is an online survey programme. Email-reminders will be sent within a week after the first
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30 269 invitation-email, and another two weeks after the first reminder, if necessary.
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34 271 **Study population & recruitment**

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37 272 Hearing aid dispensers will invite clients to participate in the study. They will hand out a package with
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39 273 information including an invitation letter, a selection form outlining the in- and exclusion criteria, a
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41 274 brochure about the study, and an envelope with an information letter and brochure for the CP. All
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43 275 interested participants will be asked to enrol themselves for the study by signing in on a registration
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45 276 webpage. Every month there will be an assessment to determine – for each HAD practice - the
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47 277 number of clients that were invited (number of envelopes that were handed out) and the number of
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49 278 participants that enrolled themselves. If the enrolment numbers will be low in comparison to other
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51 279 HAD practices, a phone call will be made to the specific HAD practice to identify underlying reasons
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53 280 and to remind them. Moreover, throughout the recruitment period, the headquarters of the HAD
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3 281 practice will organize motivational conference calls for HAD practices that did not yet reach the
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5 282 required number of the target. Finally, if enrolment ratings keep lagging behind, employees of the
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7 283 headquarters will invite clients who recently had a preparation appointment but were not invited, by
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9 284 calling them and subsequently sending the study material by email.
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14 286 **Incentives**

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16 287 After completing the T0 questionnaire, all participants will be offered a voucher of EUR 50 to spend
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18 288 on a hearing aid or EUR 25 to spend on other articles of the HAD practice if they decide not to
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20 289 purchase a hearing aid. CPs will be offered a flower coupon. In addition, participants in the control
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22 290 group will be offered a shortened version of SUPR after eighteen months. For them, SUPR will be
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24 291 slightly adjusted such that it becomes suitable for individuals who already started using a hearing aid.
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29 293 In addition to the motivational procedures described under Study population & recruitment, HAD
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31 294 practices will be (see under 'Sample size calculation') offered movie tickets and pies for the entire
32
33 295 team once the total number of participants is recruited.
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37 297 **Inclusion criteria**

38
39 298 The following inclusion criteria for the hearing aid candidates will be applied:
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41 299 1) Age 50 years or older. 2) Hearing loss in one or both ears is at least 35 dB HL (averaged over 1, 2,
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43 300 and 4 kHz). 3) Intention to take up one or two new hearing aid(s). This can be their first hearing aid
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45 301 (i.e., first-time HAUs), or a replacement hearing aid (i.e., experienced HAUs). Clients who do not
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47 302 purchase a hearing aid after the trial period will be considered drop-outs. 4) Sufficient understanding
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49 303 of the Dutch language. 5) Access to a personal computer with an internet connection for the total
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51 304 duration of the study.
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57 306 **Exclusion criteria**
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307 The following hearing aid candidates will be excluded: 1) Candidates who receive additional care at a
 308 specialized Audiology Clinic. In the Netherlands, an Audiology Clinic offers elaborate,
 309 multidisciplinary and specialized, tertiary health care and is aimed at people with complex hearing
 310 problems. This care may overlap and/or interfere with that of SUPR. 2) Candidates that will receive a
 311 hearing aid primarily to suppress tinnitus complaints. For these individuals the focus of the
 312 rehabilitation is not on restoring communication per se, and as such, they are not part of the target
 313 group of SUPR.

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

316

317 Outcome measures

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

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

TIMEPOINT	Outcome measurements	Allocation of HAD practices	Enrolment	Post-Allocation & Enrolment			
		-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						

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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 -URICA - maintenance	x	x	x	x
Emotional response	HHDI (Emotional response subscale)		x	x	x
<hr/>					
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

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

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3 327 Communication Partner, SOS-HEAR: Significant Other Scale for Hearing Disability, IOI-HA-SO:
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5 328 International Outcome Inventory Significant Other– Hearing Aids, IOI-AI-SO: International Outcome
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7 329 Inventory Significant Other– Alternative Interventions.
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9 330

10 331 Primary outcome measure – HAU

11 332 - *Coping with hearing impairment* will be measured using the reliable and validated Dutch 35-item

12 333 version of the Communication Profile for the Hearing Impaired (CPHI)[49, 50]). It covers two sections.

13 334 The first addresses communication strategies and has three subscales (Maladaptive Behaviors,

14 335 Verbal Strategies and Non-verbal Strategies) each consisting of statements for which the respondent

15 336 has to indicate how often (s)he applies this strategy. An example: “I avoid conversations with

16 337 strangers, because of my hearing loss” (subscale maladaptive behaviour). The five answer options

17 338 range from ‘almost never’ to ‘almost always’. Scores are averaged per subscale and range from 1

18 339 (low) to 5 (high). The second section deals with Personal Adjustment and also has three subscales:

19 340 Self-acceptance, Acceptance of Loss, Stress & Withdrawal. An example item of the latter subscale is:

20 341 “I feel very tensed, because of my hearing loss”. The five answer options range from ‘totally disagree’

21 342 to ‘totally agree’. Averaged scores per subscale range from 1 (low) to 5 (high). Because of reverse

22 343 scaling, some items need to be recoded. After recoding the item scores, low scores indicate poor

23 344 coping. In addition to the subscale scores, a total score of the summed six subscales scores can be

24 345 calculated.
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347 Secondary outcome measures - HAU

348 - *Self-efficacy of hearing aid handling* will be measured by the Basic Handling subscale of the

349 Measure of Audiologic Rehabilitation Self-Efficacy for Hearing Aids (MARS-HA). The English version of

350 this 7-item subscale has good psychometric quality[51]. Scores can range from 0% to 100%, with

351 lower scores representing less certainty in one’s capability of handling a hearing aid. At T1, T2 and T3,

352 the 5-item subscale Advanced Handling will be added. Dutch versions of the subscales were created

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2
3 353 through a rigorous translation process using the forward-backward method[52]. At T0 the 'Expected
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5 354 Self-Efficacy' scale will be administered, whereas at T1, T2 and T3 the 'Experienced Self-Efficacy'
6
7 355 subscale will be used instead.

8
9 356 - *Hearing aid rehabilitation and SUPR outcome*. The International Outcome Inventory – Hearing Aids
10
11 357 (IOI-HA) and the equivalent International Outcome Inventory for Alternative Interventions
12
13 358 questionnaire (IOI-AI) will be used to assess the outcome of hearing aid rehabilitation and SUPR
14
15 359 respectively[53]. The Dutch version of IOI-HA has shown to have good test-retest reliability and
16
17 360 validity[54]. The first item determines the frequency of hearing aid use / the use of the alternative
18
19 361 intervention, respectively "How many hours per day on average have you been using your hearing
20
21 362 aid(s) in the last two weeks?" and "How often have you used the learnt communication strategies on
22
23 363 an average day in the last two weeks?". Answer options are 'none', 'less than 1 hour a day', '1-4
24
25 364 hours a day', '4-8 hours a day' and 'more than 8 hours a day'. Hearing aid use will additionally be
26
27 365 measured by data-logging and three questions from a questionnaire developed by Laplante-Lévesque
28
29 366 *et al*[55]. The latter questionnaire was translated into Dutch, using a forward-backward method[52].
30
31 367 The remaining six items of the IOI-HA/IOI-AI questionnaire cover: benefit, residual activity limitation,
32
33 368 satisfaction with the hearing aid(s)/SUPR, remaining personal restrictions, impact on others, and
34
35 369 quality of life.

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38
39 370 - *Satisfaction with the hearing aid dispenser service*. Satisfaction will be measured by one question:
40
41 371 "How likely is it that you would recommend the service of the HAD practice to other people (family,
42
43 372 friends, colleagues)?" It is scored on a visual analogue scale running from 0 (=not at all likely) to 10
44
45 373 (=extremely likely).

46
47
48 374 - *Self-reported activity limitations and participation restrictions* are measured using the reliable and
49
50 375 validated original (Dutch) version of the Amsterdam Inventory for Auditory Disability and Handicap
51
52 376 (AIADH)[47, 56]. It contains 28 questions regarding everyday listening situations. An example is: "Do
53
54 377 you immediately look into the right direction when somebody calls you in the street"? The 4-point
55
56 378 response scale covers: 'almost never' (1), 'sometimes' (2), 'often' (3) and 'almost always' (4). When
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3 379 the participant answers the question with 'almost never' or 'sometimes', he or she is directed to
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5 380 question b which is about the inconvenience of not being able to hear well in that specific situation.
6
7 381 Answer options are: 'no (1)', 'a little' (2), 'very handicapped'(3), 'extremely handicapped'(4). Hence,
8
9 382 the total score can range from 28-112 with higher scores indicating greater participation restriction.

10
11 383 - *Stage of behaviour change* will be measured by the validated Dutch 24-item version of the
12
13 384 University of Rhode Island Change Assessment (URICA)[57]. Formulations of items were adjusted
14
15 385 such that they applied to hearing problems. The inventory contains 24 statements regarding
16
17 386 attitudes and behaviours assessing an individual's stage of behaviour change. At T0 the following
18
19 387 stages will be assessed: precontemplation (does not intend to take action in the foreseeable future,
20
21 388 e.g., "As far as I'm concerned, I don't have any problems with my hearing that need changing"),
22
23 389 contemplation (intends to change in the next six months and is aware of the pros and cons of
24
25 390 changing), and action (has made specific modifications in his/her lifestyle towards healthy
26
27 391 behaviour). At T1, T2, and T3 the maintenance stage (can maintain the changes in new behaviour)
28
29 392 will be added. The five response options range from 'fully disagree' (score 1) to 'fully agree' (score 5).
30
31 393 Summed scores for each subscale will be calculated. In addition the composite 'readiness score '
32
33 394 (adding the contemplation, action and maintenance scores and subtracting the precontemplation
34
35 395 score) and the composite 'committed action score' (subtracting the contemplation stage score from
36
37 396 the action stage score) will be calculated[57]. The higher the composite scores, the further the
38
39 397 respondents are along the stages of change.

40
41 398 - *Emotional response to hearing problems*. The Hearing Handicap and Disability Inventory (HHDI) will
42
43 399 be used[58]. The purpose of the inventory is to identify the individual's problems caused by hearing
44
45 400 loss. Only the section 'emotional response' will administered. It contains five statements each with
46
47 401 five response options: 'yes!' (4), 'yes' (3), 'more or less' (2), 'no' (1) and 'no!' (0). An example is "I find
48
49 402 it difficult to accept that I am hearing impaired". Lower scores indicate better outcomes.
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57 404 Secondary outcome measures - CP
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3 405 - *Third-party disability* will be measured using the Significant Other Scale for Hearing Disability (SOS-
4 HEAR)[12]. This questionnaire was translated into Dutch for the purposes of this study following a
5 406 forward-backward method[52]. The 27-item questionnaire addresses the problems and limitations
6 407 experienced by the CP. An example item is: "Because of my partner's hearing difficulties I have to
7 408 repeat myself often". For each item the CP has to indicate how much of a problem it is for him/her:
8 409 'no problem' (0); 'a mild problem' (1), 'a moderate problem' (2), 'a severe problem' (3), 'a complete
9 410 problem' (4). Higher scores indicate greater difficulties.
10 411

11 412 - *The outcomes of the hearing aid rehabilitation / alternative intervention as viewed from the*
12 413 *perspective of the CP* will be administered with the 7-item IOI-HA-SO/IOI-AI-SO and covers use,
13 414 benefit, residual activity limitation, satisfaction, residual participation restriction, impact on others,
14 415 and quality of life [59].
15 416

16 417 Baseline measurement- Demographical characteristics

17 418 - Gender (male/female)

18 419 - Age (in years)

19 420 - Marital status (married/cohabiting/widow or widower/divorced/single, never married)

20 421 - Living situation (living together with my partner/living together with my partner and children/living
21 422 together without my partner but with one or more family members/living alone (own room) or in a
22 423 care institution/living alone, independently or nursing home/other, namely...)

23 424 - Level of education (no completed education/lower general education, elementary education or a
24 425 part of it/lower general secondary education/vocational education/secondary education/technical
25 426 and vocational education/higher professional education/higher general education/scientific
26 427 education/other, namely...)

27 428 - Occupational status (yes/no)

28 429 - Country of birth (The Netherlands/other, namely...)

29 430 - Country of birth father (The Netherlands/other, namely...)

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3 431 - Country of birth mother (The Netherlands/other, namely...)
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5 432 - Hearing loss in each ear, in dB HL (averaged over 1, 2, and 4 kHz) as retrieved from the pure-tone
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7 433 audiogram as provided by the hearing aid dispenser.
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11 435 **Randomisation**

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13 436 HAD practices will be randomly assigned to offer CaU or the intervention. To avoid an unequal
14
15 437 distribution of HAD practices with regard to level of urbanisation, HAD practices were pre-stratified
16
17 438 (HAD practices located in a relatively rural area versus in an urban area) and randomisation occurred
18
19 439 within these two strata. A statistician performed block randomisation, with blocks of four HAD
20
21 440 practices. 34 HAD practices were assigned to CaU and 36 HAD practices to the intervention group.
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23 441 The recruitment procedure and period will be the same for all 70 included HAD practices (the total
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25 442 list of included HAD practices are available on request from the research team).
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30 444 **Sample size calculation**

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32 445 Sample size calculations are based on the expected effects of the intervention on the primary
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34 446 outcome: coping with hearing impairment (CPHI). Demorest & Erdman indicated that the minimal
35
36 447 important difference on the subscales of the CPHI varies from 0.67 (Maladaptive Behaviour) to 0.95
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38 448 (Self-Acceptance)[60]. Given that in a previous study[37] the effect of the programme was larger for
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40 449 first-time than for experienced users, we calculated sample sizes separately for first-time and
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42 450 experienced users. For first-time HAUs, we based our sample size calculations on a minimal
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44 451 important difference of 0.67 between the intervention and the CaU group. Calculations in PASS 12
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46 452 (Tests for Two Means in a Cluster-Randomized Design; Intraclass correlation coefficient: 0.01;
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48 453 alpha: 0.05; power: 0.80) shows, that when 70 HAD practices are included (of which half will offer
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50 454 SUPR and half CaU), the number of first-time HAUs to include in the analyses is two per dispenser
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52 455 HAD practice. For the experienced users sample size calculation we chose an expected minimal
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54 456 important difference of 0.4 between the intervention and CaU group. The number of experienced
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3 457 HAUs (power: 0.80) to include is then three per HAD practice. We expected the proportion of drop-
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5 458 out or loss to follow-up across the study to be 20%. This includes loss to follow-up for a range of
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7 459 reasons: no motivation anymore, reluctant to purchase a hearing aid after a successful trial, sickness,
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9 460 death etc. Taking the loss to follow-up and the proportion of clients that normally purchase a hearing
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11 461 aid into account results in a total (rounded) number of four first-time HAUs per HAD practice and five
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13 462 experienced HAUs per HAD practice to be recruited.
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17 18 464 **Statistical analyses**

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20 465 To check the comparability between the groups (CaU or intervention group) at baseline, baseline
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22 466 characteristics of the participants will be compared using the Chi Square test (for categorical
23
24 467 variables), the independent samples *t*-test (for normally distributed continuous variables) and the
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26 468 Mann-Whitney test (for non-normally distributed continuous variables). Comparability will be
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28 469 checked for all demographic variables and all primary and secondary outcomes.
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33 471 For the effect analyses, the groups will be compared on all primary and secondary outcome
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35 472 measures using linear mixed models including the results at T0, T1, T2 and T3. If a significant effect is
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37 473 found, an independent samples *t*-test will be used and a Bonferroni correction will be administered
38
39 474 in case of multiple comparisons. Type of HAU (first-time or experienced) will be tested as an effect
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41 475 modifier for potential subgroup differences. The main analysis is intention to treat and additionally a
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43 476 per protocol analysis will be performed. A per protocol analysis is restricted to participants who
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45 477 complete the entire study as described in the study protocol. Any outcome measure to be collected
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47 478 for participants who discontinue or deviate from intervention protocols will be saved and analyzed
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49 479 according to the intention to treat protocol. In case of substantial missing data, multiple imputation
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51 480 will be applied. Items of all questionnaires will have a unique code. It will be evident from the code
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53 481 which questionnaire it reverses to (T0-T3) so that data can be merged. To promote data quality range
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55 482 checks for data values will be performed.
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5 484 **Process evaluation**

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7 485 The process of implementing SUPR into the care of the HAD practices in the intervention arm will be
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9 486 evaluated. The main aims of this evaluation are to gain insight into 1) the circumstances in which the
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11 487 intervention was implemented, 2) (non-) compliance with the intervention, and 3) the professionals'
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13 488 and clients' appraisal of the intervention.
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18 490 The process evaluation will be carried out according to the framework as proposed by Linnan *et*
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20 491 *al*[61]. It covers seven parameters: recruitment, reach, fidelity, dose delivered, dose received and
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22 492 implemented, satisfaction, and perceived benefit[62]. A brief description of each of the parameters is
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24 493 given below.
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29 495 - Recruitment refers to the procedures applied to approach and attract potential participants. The
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31 496 hearing aid dispensers will be asked to provide this information.

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33 497 - Response. This is the proportion of people participating relative to the number of people invited.

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35 498 - Fidelity relates to the question of whether the intervention was provided as intended. The team
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37 499 that is responsible for the email contact will be asked to provide a written report on this.

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39 500 - Dose delivered: This concerns the question of whether the elements (emails) of the intervention
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41 501 were sent out correctly (correct content) and on time?

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43 502 - Dose received and implemented: Did the participants open the emails and the videos? If so, did
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45 503 they watch the whole video, or part(s) of it? Information on implementation of the knowledge that
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47 504 participants learnt from SUPR will be deduced from the IOI-AI questionnaire (item on use) on T1. An
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49 505 employee of the headquarters of the hearing aid dispenser chain will monitor the video watching
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51 506 behaviour.
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3 507 - Satisfaction: Satisfaction of the participant with SUPR will be evaluated using the IOI-AI
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5 508 questionnaire (item satisfaction) on T1. The hearing aid dispensers will be asked to answer the
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7 509 question: How would you rate your satisfaction with SUPR?
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10 510 - Benefit: Information on the experienced benefit of the participant will be obtained from the IOI-AI
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12 511 questionnaire (item benefit) on T1. The hearing aid dispensers will be asked to answer the question:
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14 512 How would you rate the perceived benefit from SUPR for your clients' ability to improve in
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16 513 communication?
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20 515 Additionally, focus group discussions with participants from the intervention group will be organized
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22 516 to gain insight into the reasons for using the knowledge of SUPR in their daily lives or not. At least
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24 517 two focus groups will be organized. The exact number will depend on data saturation. Heterogeneity
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26 518 in age, gender, educational level, severity of hearing impairment, and stage of behaviour change (at
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28 519 baseline) within the groups will be strived for. Given the difficulties hearing-impaired individuals
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30 520 might have with group conversations, the focus groups will have a maximum size of six participants
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32 521 each.
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36 524 **ETHICS AND DISSEMINATION**

37 525 **Protocol amendments, confidentiality and dissemination policy**

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39 526 Any important future protocol modifications will be submitted to the VU University Medical Center
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41 527 Medical Ethical Committee. Directly upon approval, the modification will be corresponded to the trial
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43 528 registry.
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47 530 Personal information about enrolled participants will only be shared with employees of the
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49 531 headquarters of the HAD practices who signed a privacy declaration. This exchange of personal
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51 532 information is only done to collect data within the framework of the study (e.g., to collect audiogram
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3 533 data, hearing aid purchase status, use of SUPR). Any exchanged data and personal information will be
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5 534 protected with a password.

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9 536 VU University Medical Center has all property rights on the final results of the trial and is entitled to
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11 537 publish the results. The sponsor is not entitled to publish the results without written confirmation of
12
13 538 the VU University Medical Center. These agreements are secured in a contract. For specific author
14
15 539 contributions for the current paper, see 'Authors contributions'.

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20 541 Findings of the study will be published in academic journals and presented at scientific conferences.
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22 542 and will be communicated within the national and international media. A short report of the findings
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24 543 of the study will be sent to the participants for those who are interested. The results will be
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26 544 communicated within the hearing aid dispenser chain.

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30 31 546 **Data collection forms and data storage**

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33 547 Data collection forms and procedures for data management are available on request. All data that
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35 548 will be collected are digital and will be stored on a computer disk at the VU University Medical Center
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37 549 that is locked with a security code which is only available to members of the SUPR research team.

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39 550 According to Good Clinical Practice guidelines and after having received informed consent, data will
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41 551 be archived for a period of fifteen years after finalizing the study. After finalization, the key file
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43 552 (connecting participant numbers to the names and contact details of the participant) will be
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45 553 destroyed once it is expected that participants do not need to be approached any more for the
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47 554 purposes of the study. We will perform double data entry of a selection of the audiograms and the
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49 555 baseline AIADH data for quality purposes.

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53 54 55 557 **Monitoring**

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3 558 The study is subjected to local regulations and its quality is monitored by the research institute's (i.e.,
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5 559 EMGO⁺) Quality Committee. This committee is responsible for developing, implementing and
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7 560 maintaining a system for quality assurance and control for all research within the institute. Due to
8
9 561 the nature of the study, the formation of a Clinical Trial Data Monitoring Committee was not deemed
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11 562 necessary.
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15 565 **DISCUSSION**

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18 566 Like in most parts in the world, usual care for adults with hearing impairment in the Netherlands is
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20 567 mostly restricted to audiological assessment and hearing aid fitting. This type of care is for a large
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22 568 part provided by commercial hearing aid dispensers. Communication programmes aimed at training
23
24 569 in communication strategies and personal adjustment to hearing impairment, and hearing aid
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26 570 handling skills are not provided on a large scale in standard hearing health care settings, despite the
27
28 571 growing evidence showing that including such programmes may decrease communication problems
29
30 572 and improve coping[27, 33]. Likewise, despite the fact that including CPs in the rehabilitation process
31
32 573 is increasingly recognized within audiology as a prerequisite for successful rehabilitation[12], CPs are
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34 574 not yet part of standard hearing health care. In the current study, these elements (i.e., a
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36 575 communication programme and involvement of a CP) are part of a programme called SUPR that is
37
38 576 incorporated in regular hearing aid dispensing care and that will be tested for its effectivity. SUPR's
39
40 577 prior aims are to improve older hearing aid owners' communication strategies and personal
41
42 578 adjustment (together referred to as coping) and decrease their CPs' third-party disability. To our
43
44 579 knowledge, similar online support programmes for HAU that are implemented on a large scale in
45
46 580 hearing aid dispenser settings are not available yet.
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51 582 Thorén *et al* and Ferguson *et al* found positive short-term effects for their online interventions in the
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53 583 domains of participation restrictions and activity limitations and knowledge on hearing aids and
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3 584 communication strategies, respectively[43, 45]. Main topics of the online programme of Thóren *et al*
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5 585 covered knowledge about hearing anatomy, hearing aids, communication strategies, and guidelines
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7 586 for significant others[43]. The programme of Ferguson *et al* did include some communication
8
9 587 strategies, but the focus of the programme was on hearing aids[45]. Although coping elements were
10
11 588 an important focus in the programme of Thorén *et al*[43], in the SUPR study coping is the main
12
13 589 component, which is thereby unique. Another major advantage of the current study is that it uses a
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15 590 long-term follow-up design of eighteen months. Such a long follow-up has thus far not been applied
16
17 591 in similar studies. As was already raised by Kramer *et al*, Barker *et al* and Wong *et al* more research
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19 592 on treatment efficacy in the long(er)-term is essential because it is possible that some short-term
20
21 593 effects may disappear and other effects can arise[34, 36-37]. Barker *et al* and Wong *et al* also advised
22
23 594 to conduct large and appropriately powered studies[34, 36]. The latter has been taken into account
24
25 595 in the sample size calculation. The aim thus is that SUPR will be a large-scale study with an inclusion
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27 596 of 70 HAD practices across the Netherlands with ambitious numbers of first time and experienced
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29 597 HAU's to be recruited (i.e.258 and 311 in total, respectively).
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35 599 A few limitations to the design need to be considered. Unfortunately it is not possible to perform a
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37 600 double-blinded, randomised, controlled trial due to the nature of the intervention study. Participants
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39 601 will be aware that the general aim of the SUPR study is to evaluate a support programme and know
40
41 602 that they are either part of the group that receives care as usual or SUPR. Nevertheless, we will
42
43 603 attempt to minimize the provision of information on the content of SUPR to participants of the CaU
44
45 604 group. These participants only know that SUPR is a support programme aimed to improve
46
47 605 communication, but for instance do not know what the intervention further entails. This way, we
48
49 606 aimed to prevent that they would independently seek access to SUPR (which would cause
50
51 607 contamination) and that their knowledge of the care they were missing out on would affect their
52
53 608 responses in the questionnaires. We also attempted to prevent this by offering the programme to
54
55 609 the CaU-participants for free after the study.
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3 610 SUPR is an online intervention, it is thus essential that people have access to a device with an
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5 611 internet connection. The requirement to be online to participate in the study may be an issue for the
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7 612 older population (74+). The probability that we are targeting a selected group when offering care
8
9 613 online needs discussion. It is known however that the use of internet among older adults is already
10
11 614 substantial among the relatively young-old (i.e., 55-74 years)[63]. Amongst the young-old, weekly
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13 615 internet use has increased from 70% in 2010 to 83% in 2015 in the Netherlands and will most
14
15 616 probably keep rising in the future[64]. The non-use of internet among the older olds (74+) has
16
17 617 decreased from 66% in 2012 to 50% in 2015[65]. Furthermore, it is known that the older persons
18
19 618 who do use the internet, generally use it more for health-related tasks or information than for
20
21 619 personal tasks [66]. Also, persons with hearing loss are more likely to use the internet than people in
22
23 620 the general population (OR=1.74, 95% CI 1.23-3.17)[66]. We are therefore confident that our
24
25 621 participants will be open to using SUPR.
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29 622 Finally, it is known that for those who are at risk for isolation or those who have reduced access to
30
31 623 health care, internet can be a practical tool to have direct access to health services [67]. Other
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33 624 elements that can add to the effectiveness of online support programmes as SUPR are that it can be
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35 625 (partly or mainly) provided in a visual mode (images, written text, subtitles), the volume can be
36
37 626 controlled, background noises can be relatively easily eliminated, and online support programmes
38
39 627 provide the opportunity to tailor intervention elements.
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42 628 At the start of the study, participants might underestimate their hearing impairment caused by the
43
44 629 stigma on hearing impairment[68]. We expect that SUPR may have a positive effect on acceptance
45
46 630 and therefore people will be more honest on their report of hearing disability. As such, it is possible
47
48 631 that we will observe an increase in self-reported hearing disability in the intervention group over
49
50 632 time, whereas SUPR is expected to result in a decrease in experienced disability. To examine this, we
51
52 633 can use one of the subscales of the CPHI on acceptance of hearing loss. With this subscale we can
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54 634 examine if acceptance is a mediator between time and hearing status for the intervention group.
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3 636 This study aims to perform a process evaluation, as is strongly recommended in all randomized
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5 637 controlled trial research. A process evaluation provides insight into reasons for the demonstrated
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7 638 (absence of) effectiveness of the intervention, and might offer information concerning the
8
9 639 generalizability of the study results. When effects of SUPR turn out to be disappointing, we may be
10
11 640 able to modify the programme based on the results of the process evaluation after the study.
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16 642 In the future, it is expected that there will be an increasing demand in solutions for hearing health
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18 643 conditions due to the ageing population and thus increased prevalence of hearing problems. SUPR is
19
20 644 especially developed for use on a large scale basis in HAD practices. Demonstrating its effectiveness
21
22 645 will be a great step forward in our attempts to further improving health care services for persons
23
24 646 with hearing impairment.
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30 31 649 **ACKNOWLEDGEMENTS**

32
33 650 We would like to acknowledge Schoonenberg Hoorcomfort (AudioNova) for their contribution to the
34
35 651 development of the SUPR study.
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41 42 654 **FOOTNOTES**

43 44 655 **Contributors**

45
46 656 SEK developed the first version of the study design, in collaboration with BP and VJ. MP and SK
47
48 657 developed the study design further and wrote up the first draft of study protocol. BvdW, FJM, MP,
49
50 658 SEK, and VJ worked on the design further, and facilitated the practical implementation of the study.
51
52 659 BIW provided statistical and methodological advice. Data collection was done by BvdW and FJM,
53
54 660 assisted by VJ, and supervised by SEK and MP. FJM wrote the final version of the manuscript. SEK and
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3 661 MP supervised the writing process and MP, SEK, BP, BIW, VJ, and BvdW gave critical comments on
4
5 662 several drafts of the manuscript.
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9 664 **Funding**

10
11 665 The SUPR study is funded by Audionova International. The study design was developed by SEK in
12
13 666 collaboration with BP and VJ. VJ supported the practical implementation of the study. Audionova
14
15 667 International had no role in data analysis and interpretation of data.
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20 669 **Competing interests**

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22 670 VJ is an employee at Schoonenberg Hoorcomfort. BP is an employee at AudioNova.
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26 672 **Ethics approval and consent to participate**

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29 673 The Medical Research Involving Human Subjects ACT (WMO) does not apply to this study and an
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31 674 official approval by the Medical Ethics Review Committee of the VU University Medical Center is not
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33 675 required. The Medical Ethics Review Committee of the VU University Medical Center is registered
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35 676 with the US Office for Human Research Protections (OHRP) as IRB00002991. The FWA number
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37 677 assisted to VU University Medical Center is FWA00017598.

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39 678 An informed consent procedure will be followed prior to participants' enrolment for the study on the
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41 679 registration website.
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46 681 **Abbreviations**

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48 682 SUPR: Support Programme, CaU: care as usual, CP: communication partner, HAU: hearing aid users,
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50 683 HAD practices: hearing aid dispensing practices, AIADH: Amsterdam Inventory for Auditory Disability
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52 684 and Handicap, CPHI: Communication Profile for the Hearing Impaired, MARS-HA: Measure of
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54 685 Audiologic Rehabilitation Self-Efficacy for Hearing Aids, IOI-HA: International Outcome Inventory –
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56 686 Hearing Aids, IOI-AI: International Outcome Inventory – Alternative Interventions, URICA: University

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3 687 of Rhode Island Change Assessment- for Hearing health behaviour, HHDI: Hearing Handicap and
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5 688 Disability Inventory, SOS-HEAR: Significant Other Scale for Hearing Disability, IOI-HA-SO: International
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7 689 Outcome Inventory Significant Other- Hearing Aids, IOI-AI-SO: International Outcome Inventory
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10 690 Significant Other- Alternative Interventions.

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16 693 **REFERENCES**

- 17 694 1. Vos T, Barber RM, Bell B, et al. Global, regional, and national incidence, prevalence, and
18 695 years lived with disability for 301 acute and chronic diseases and injuries in 188 countries,
19 696 1990-2013: a systematic analysis for the Global Burden of Disease Study 2013. *Lancet*
20 697 2015;386:743-800. doi: 10.1016/S0140-6736(15)60692-4
21
22 698 2. United Nations, Department of Economic and Social Affairs, Population Division. World
23 699 population ageing 2015. New York: United Nations 2015.
24
25 700 3. Weinstein BE, Sirow LW, Moser S. Relating hearing aid use to social and emotional loneliness
26 701 in older adults. *Am J Audiol* 2016;25:54-61. doi: 10.1044/2015_AJA-15-0055
27
28 702 4. Pronk M, Deeg DJ, Smits C, et al. Prospective effects of hearing status on loneliness and
29 703 depression in older persons: Identification of subgroups. *Int J Audiol* 2011;50:887-96. doi:
30 704 10.3109/14992027.2011.599871
31
32 705 5. Strawbridge WJ, Wallhagen MI, Shema SJ, et al. Negative consequences of hearing
33 706 impairment in old age a longitudinal analysis. *Gerontologist* 2000;40:320-6. doi:
34 707 10.1093/geront/40.3.320
35
36 708 6. Nachtegaal J, Smit JH, Smits C, et al. The association between hearing status and
37 709 psychosocial health before the age of 70 years: results from an internet-based national
38 710 survey on hearing. *Ear Hear* 2009;30:302-12. doi: 10.1097/AUD.0b013e31819c6e01
39
40 711 7. Saito H, Nishiwaki Y, Michikawa T, et al. Hearing handicap predicts the development of
41 712 depressive symptoms after 3 Years in older community-dwelling Japanese. *J Am Geriatr*
42 713 2010;58:93-7. doi: 10.1111/j.1532-5415.2009.02615.x
43
44 714 8. Nachtegaal J, Festen JM, Kramer SE. Hearing ability in working life and its relationship with
45 715 sick leave and self-reported work productivity. *Ear Hear* 2012;33:94-103. doi:
46 716 10.1097/AUD.0b013e318228033e
47
48 717 9. Lin FR, Yaffe K, Xia J, et al. Hearing loss and cognitive decline in older adults. *JAMA Intern*
49 718 *Med* 2013;173:293-9. doi: 10.1001/jamainternmed.2013.1868
50
51
52
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55
56
57
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- 1
2
3 719 10. Jiam NT, Li C, and Agrawal Y. Hearing loss and falls: A systematic review and meta-analysis.
4 720 *Laryngoscope* 2016;126:2587-96.
5
6 721 11. World Health Organization. International Classification of Functioning, Disability and Health.
7 722 Geneva: World Health Organization 2001.
8
9 723 12. Scarinci N, Worrall L, Hickson L. The effect of hearing impairment in older people on the
10 724 spouse: development and psychometric testing of the significant other scale for hearing
11 725 disability (SOS-HEAR). *Int J Audiol* 2009;48:671-83. doi: 10.1080/14992020902998409
12
13 726 13. Kamil RJ, Lin FR. The effects of hearing impairment in older adults on CPs: a systematic
14 727 review. *J Am Acad Audiol* 2015;26:155-82. doi: 10.3766/jaaa.26.2.6
15
16 728 14. Jennings MB, Shaw L. Impact of hearing loss in the workplace: raising questions about
17 729 partnerships with professionals. *Work* 2008;30:289-95.
18
19 730 15. Chisolm TH, Johnson CE, Danhauer JL, et al. A systematic review of health-related quality of
20 731 life and hearing aids: final report of the American Academy of Audiology Task Force On the
21 732 Health-Related Quality of Life Benefits of Amplification in Adults. *J Am Acad Audiol*
22 733 2007;18:151-83.
23
24 734 16. Mulrow CD, Tuley MR, Aguilar C. Sustained benefits of hearing aids. *J Speech Hear Res.*
25 735 1992;35:1402-5. doi:10.1044/jshr.3506.1402
26
27 736 17. Acar B, Yurekli MF, Babademez MA, et al. Effects of hearing aids on cognitive functions and
28 737 depressive signs in elderly people. *Arch Gerontol Geriatr* 2011;52:250-2. doi:
29 738 10.1016/j.archger.2010.04.013
30
31 739 18. Amieva H, Ouvrard C, Giulioli C, et al. Self-reported hearing loss, hearing aids, and cognitive
32 740 decline in elderly adults: A 25-Year study. *J Am Geriatr Soc* 2015;63:2099-104. doi:
33 741 10.1111/jgs.13649
34
35 742 19. Chia EM, Wang JJ, Rochtchina E, et al. Hearing impairment and health-related quality of life:
36 743 the Blue Mountains Hearing Study. *Ear Hear* 2007;28:187-95. doi:
37 744 10.1097/AUD.0b013e31803126b6
38
39 745 20. Hartley D, Rochtchina E, Newall P, et al. Use of hearing aids and assistive listening devices in
40 746 an older Australian population. *J Am Acad Audiol* 2010;21:642-53. doi: 10.3766/jaaa.21.10.4.
41
42 747 21. Smits C, Kramer SE, Houtgast T. Speech reception thresholds in noise and self-reported
43 748 hearing disability in a general adult population. *Ear Hear* 2006;27:538-49. doi:
44 749 10.1097/01.aud.0000233917.72551.cf
45
46 750 22. Gates GA, Cooper JC Jr, Kannel WB et al. Hearing in the Elderly: The Framingham Cohort,
47 751 1983-1985: Part 1. Basic Audiometric Test Results. *Ear Hear* 1990;11:247-56.
48
49 752 23. Kochkin S. MarkeTrak VIII: Consumer satisfaction with hearing aids is slowly increasing. *Hear*
50 753 *J.* 2010;63:19-20. doi: 10.1097/01.HJ.0000366912.40173.76
51
52
53
54
55
56
57
58
59
60

- 1
2
3 754 24. Knudsen LV, Oberg M, Nielsen C, et al. Factors influencing help seeking, hearing aid uptake,
4 755 hearing aid use and satisfaction with hearing aids: A review of the literature. *Trends Amplif*
5 756 2010;14:127-54. doi: 10.1177/1084713810385712
6
7
8 757 25. Meyer C, Hickson L. What factors influence help-seeking for hearing impairment and hearing
9 758 aid adoption in older adults? *Int J Audiol* 2012;51:66-74. doi:
10 759 10.3109/14992027.2011.611178
11
12 760 26. McCormack A, Fortnum H. Why do people fitted with hearing aids not wear them? *Int J*
13 761 *Audiol* 2013;52:360-8. doi: 10.3109/14992027.2013.769066
14
15
16 762 27. Boothroyd A. Adult aural rehabilitation: What is it and does it work? *Trends Amplif*
17 763 2007;11:63-71. doi: 10.1177/1084713807301073
18
19 764 28. Hickson L, Scarinci N. Older adults with acquired hearing impairment: applying the ICF in
20 765 rehabilitation. *Semin Speech Lang* 2007;28:283-90. doi: 10.1055/s-2007-986525
21
22 766 29. Granberg S, Swanepoel de W, Englund U, et al. The ICF core sets for hearing loss project:
23 767 International expert survey on functioning and disability of adults with hearing loss using the
24 768 international classification of functioning, disability, and health (ICF). *Int J Audiol* 2014;
25 769 53:497-506. doi: 10.3109/14992027.2014.900196
26
27
28 770 30. Granberg S, Pronk M, Swanepoel de W, et al. The ICF core sets for hearing loss project:
29 771 Functioning and disability from the patient perspective. *Int J Audiol* 2014;53:777-86. doi:
30 772 10.3109/14992027.2014.938370
31
32
33 773 31. Gagné JP, Jennings MB. Audiologic rehabilitation intervention services for adults with
34 774 acquired hearing impairment. In: Valente M, Hosford-Dunn H, Roeser RJ, eds. *Audiology:*
35 775 *Treatment*. New York: Thieme Medical Publishers 2008:370-99.
36
37
38 776 32. Laplante-Lévesque A, Hickson L, Worrall L. Factors influencing rehabilitation decisions of
39 777 adults with acquired hearing impairment. *Int J Audiol* 2010;49:497-507. doi:
40 778 10.3109/14992021003645902
41
42
43 779 33. Kiessling J, Pichora-Fuller MK, Gatehouse S, et al. Candidature for and delivery of
44 780 audiological services: Special needs of older people. *Int J Audiol* 2003;42 Suppl 2S92-101.
45
46
47 781 34. Barker F, Mackenzie E, Elliott L, et al. Interventions to improve hearing aid use in adult
48 782 auditory rehabilitation. *Cochrane Database Syst Rev* 2016;8 doi:
49 783 10.1002/14651858.CD010342.pub3.
50
51
52 784 35. Sweetow R, Palmer CV. Efficacy of individual auditory training in adults: A systematic review
53 785 of the evidence. *J Am Acad Audiol* 2005;16:494-504.
54
55
56 786 36. Wong L, Hickson L. Evidence-based practice in audiology: Evaluating interventions for
57 787 children and adults with hearing impairment. San Diego, CA: Plural Publishing 2012.
58
59
60

- 1
2
3 788 37. Kramer SE, Allessie GH, Dondorp AW et al. A home education program for older adults with
4 789 hearing impairment and their significant others: A randomized trial evaluating short- and
5 790 long-term effects. *Int J Audiol* 2005;44:255-64.
6 791
7 791 38. Hickson L, Worrall L, Scarinci N. A randomized controlled trial evaluating the active
8 792 communication education program for older people with hearing impairment. *Ear Hear*
9 793 2007;28:212-30. doi: 10.1097/AUD.0b013e31803126c8
10 794
11 794 39. Hawkins DB. Effectiveness of counseling-based adult group aural rehabilitation programs: A
12 795 systematic review of the evidence. *J Am Acad Audiol* 2005;16:485-93.
13 796
14 796 40. Hickson L. Defining a paradigm shift. *Semin Hear* 2012;33:3-8. doi: 10.1055/s-0032-1304722
15 797
16 797 41. Lusic I, Mason P. Paradigm shift: The new world of hearing health care delivery. *ASHA Lead*
17 798 2012;17:36-7. doi:10.1044/leader.FTR2.17092012.36
18 799
19 799 42. Tognola G, Paglialonga A, Chiaramello E, et al. eHealth for hearing—new views and apps
20 800 practicalities. *EJBI*. 2015;11:37-49.
21 801
22 801 43. Thorén ES, Öberg M, Wänström G, et al. A randomized controlled trial evaluating the effects
23 802 of online rehabilitative intervention for adult hearing-aid users. *Int J Audiol* 2014;53:452-61.
24 803 doi: 10.3109/14992027.2014.892643
25 804
26 804 44. Thorén E, Svensson M, Törnqvist A, et al. Rehabilitative online education versus internet
27 805 discussion group for hearing aid users: a randomized controlled trial. *J Am Acad Audiol*
28 806 2011;22:274-85. doi: 10.3766/jaaa.22.5.4.
29 807
30 807 45. Ferguson M, Brandreth M, Brassington W, et al. A randomized controlled trial to evaluate
31 808 the benefits of a multimedia educational program for first-time hearing aid users. *Ear Hear*
32 809 2016;37:123-36. doi: 10.1097/AUD.0000000000000237
33 810
34 810 46. Gomez RG, Madey SF. Coping-with-hearing-loss model for older adults. *J Gerontol B Psychol*
35 811 *Sci Soc Sci* 2001;56:223-5. doi: 10.1093/geronb/56.4.P223
36 812
37 812 47. Kramer SE, Kapteyn TS, Festen JM, et al. Factors in subjective hearing disability. *Audiology*
38 813 1995;34:311-20.
39 814
40 814 48. Chan AW, Tetzlaff JM, Altman DG, et al. SPIRIT 2013 Statement: Defining standard protocol
41 815 items for clinical trials. *Ann Intern Med* 2013;158:200-7. doi: 10.7326/0003-4819-158-3-
42 816 201302050-00583.
43 817
44 817 49. Demorest ME, Erdman SA. Development of the communication profile for the hearing
45 818 impaired. *J Speech Hear Disord* 1987;52:129-43. doi:10.1044/jshd.5202.129
46 819
47 819 50. Mekkink LB, Knol DL, van Nispen RM, et al. Improving the quality and applicability of the
48 820 Dutch scales of the Communication Profile for the Hearing Impaired using item response
49 821 theory. *J Speech Lang Hear Res* 2010;53:556-71. doi: 10.1044/1092-4388(2010/09-0035)

- 1
2
3 822 51. West RL, Smith SL. Development of a hearing aid self-efficacy questionnaire. *Int J Audiol*
4 823 2007;46:759-71. doi: 10.1080/14992020701545898
5
6 824 52. Beaton DE, Bombardier C, Guillemin F, et al. Guidelines for the process of Cross-Cultural
7 825 Adaption of Self-Report Measures. *Spine* 2000;25:3186-91.
8
9 826 53. Kozlowski L, Almeida G, Ribas A. Level of user satisfaction with hearing AIDS and
10 827 environment: the international outcome inventory for hearing AIDS. *Int Arch*
11 828 *Otorhinolaryngol* 2014;18:229-34. doi: 10.1055/s-0033-1363782
12
13 829 54. Kramer SE, Goverts ST, Dreschler WA, et al. International Outcome Inventory for Hearing
14 830 Aids (IOI-HA): results from The Netherlands. *Int J Audiol* 2002;41:36-41. doi:
15 831 10.3109/14992020209101310
16
17 832 55. Laplante-Lévesque A, Nielsen C, Jensen LD, et al. Patterns of hearing aid usage predict
18 833 hearing aid use amount (data logged and self-reported) and overreport. *J Am Acad Audiol*
19 834 2014;25:187-98. doi: 10.3766/jaaa.25.2.7
20
21 835 56. Meijer AG, Wit HP, TenVergert EM, et al. Reliability and validity of the (modified) Amsterdam
22 836 Inventory for Auditory Disability and Handicap. *Int J Audiol* 2003;42:220-6. doi:
23 837 10.1111/j.1365-2273.2004.00844
24
25 838 57. Laplante-Lévesque A, Hickson L, Worrall L. Stages of change in adults with acquired hearing
26 839 impairment seeking help for the first time: application of the transtheoretical model in
27 840 audiologic rehabilitation. *Ear Hear* 2013;34:447-57. doi: 10.1097/AUD.0b013e3182772c49
28
29 841 58. van den Brink RHS. Attitude and illness behavior in hearing impaired elderly (Unpublished
30 842 doctoral thesis). Rijks University of Groningen 1995.
31
32 843 59. Noble W. Extending the IOI to significant others and to nonhearing aid-based interventions.
33 844 *Int J Audiol* 2002;41:27-9. doi: 10.3109/14992020209101308
34
35 845 60. Demorest ME, Erdman SA. Retest stability of the communication profile for the hearing
36 846 impaired. *Ear Hear* 1988;9:237-42. doi: 10.1097/00003446-198810000-00002
37
38 847 61. Linnan L, Steckler A. Process evaluation for public health interventions and research. 1st ed.
39 848 San Francisco CA: Jossey-Bass 2002.
40
41 849 62. Gussenhoven AH, Singh AS, Goverts ST, et al. A process evaluation of implementing a
42 850 vocational enablement protocol for employees with hearing difficulties in clinical practice.
43 851 *Int J Audiol* 2015;54:507-17. doi: 10.3109/14992027.2015.1009642
44
45 852 63. UNECE Statistical Database. 2015. <http://w3.unec.org/PXWeb/en>. Accessed 20 June 2016
46
47 853 64. Gell NM, Rosenberg DE, Demiris G et al. Patterns of technology use among older adults with
48 854 and without disabilities. *Gerontologist* 2015;55:412-21. doi: 10.1093/geront/gnt166
49
50 855 65. Centraal Bureau voor Statistiek (CBS). 2016. [https://www.cbs.nl/nl-nl/nieuws/2016/22/acht-](https://www.cbs.nl/nl-nl/nieuws/2016/22/acht-procent-van-de-nederlanders-nooit-op-internet)
51
52 856 procent-van-de-nederlanders-nooit-op-internet. Accessed 26 Sep 2016.
53
54
55
56
57
58
59
60

- 1
2
3 857 66. Thorén ES, Öberg M, Wänström G, et al. Internet access and use in adults with hearing loss. *J*
4 858 *Med Internet Res* 2013;15:e91. doi: 10.2196/jmir.2221
5
6 859 67. Swanepoel dW, Hall JW, III. A systematic review of telehealth applications in audiology.
7 860 *Telemed J E Healt* 2010;16:181-200. doi: 10.1089/tmj.2009.0111
8
9 861 68. Wallhagen MI. The stigma of hearing loss. *Gerontologist* 2010;50:66-75. doi:
10 862 10.1093/geront/gnp107
11
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For peer review only



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

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49**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

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3	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
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6	Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	11,12
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8 **Methods: Assignment of interventions (for controlled trials)**

9 Allocation:

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12	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
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18	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
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22	Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	20
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25	Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	3
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28		17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/A
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32 **Methods: Data collection, management, and analysis**

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34	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
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39		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
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3	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
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7	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
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10		20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	21,22
11				
12		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
13				
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16	Methods: Monitoring			
17				
18	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
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23		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
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26	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
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29	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
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33	Ethics and dissemination			
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35	Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	N/A
36				
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38	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
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3	Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	29
4				
5				
6		26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
7				
8				
9	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
10				
11				
12	Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	29
13				
14				
15	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
16				
17				
18	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
19				
20				
21	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
22				
23				
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25				
26		31b	Authorship eligibility guidelines and any intended use of professional writers	28,29
27				
28		31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	N/A
29				
30	Appendices			
31				
32	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)
33				
34				
35				
36	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.
37				
38				

*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](https://creativecommons.org/licenses/by-nc-nd/3.0/)" license.

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For peer review only

Communicatiepartner Toestemmingspagina

versie 5 dd 03-12-2015

SUPR

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

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

SUPR

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

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

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2016-015012.R1
Article Type:	Protocol
Date Submitted by the Author:	26-Jan-2017
Complete List of Authors:	Meijerink, Janine; Amsterdam Public Health research institute, VU University Medical Centre, Amsterdam, Department of Otolaryngology - Head and Neck Surgery, section Ear & Hearing Pronk, Marieke; Amsterdam Public Health research institute, VU University Medical Centre, Amsterdam, Department of Otolaryngology - Head and Neck Surgery, section Ear & Hearing Paulissen, Bernadette; AudioNova International Witte, Birgit; VU University Medical Center, Department of Epidemiology and Biostatistics Wouden, Bregje; Amsterdam Public Health research institute, VU University Medical Centre, Department of Otolaryngology - Head and Neck Surgery, section Ear & Hearing Jansen, Vera; Schoonenberg Kramer, Sophia; Amsterdam Public Health research institute, VU University Medical Centre, Amsterdam, Department of Otolaryngology - Head and Neck Surgery, section Ear & Hearing
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

SCHOLARONE™
Manuscripts

26 January 2017 – Protocol version 2

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3 1 **Effectiveness of an online SUpport PRogramme (SUPR) for older hearing aid users: Study protocol**
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5 2 **for a cluster randomised controlled trial**

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9 4 Janine F.J. Meijerink^{1*}, Marieke Pronk¹, Bernadette Paulissen², Birgit I. Witte³, Bregje van der
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11 5 Wouden¹, Vera Jansen⁴, Sophia E. Kramer¹

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52 24 Word count: 8,528

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3 27 **ABSTRACT**

4
5 28 **Background:** An educational Support Programme called SUPR has been developed for hearing aid
6
7 29 users (HAUs) and their communication partners (CPs) offering care beyond hearing aid fitting. SUPR
8
9 30 teaches its users communication strategies, hearing aid handling skills, and offers peer testimonials.
10
11 31 Ultimately, its main aim is to improve communication strategies and personal adjustment.

12
13 32 **Methods/design:** Using a cluster randomised controlled trial-design, 70 Dutch hearing aid dispenser
14
15 33 practices were randomised into hearing aid fitting (care as usual, 34 practices) and hearing aid fitting
16
17 34 including SUPR (36 practices). The aim was to recruit a total of 569 older (aged 50+) first-time
18
19 35 (n=258) and experienced (n=311) HAUs and their CPs. SUPR consists of a Practical Support Booklet
20
21 36 and online material offered via email over a period of 6-7 months. The booklet provides practical
22
23 37 information on hearing aids, advice on communication strategies, and home exercises. The online
24
25 38 material consists of educational videos on hearing aid functionality and usage, communication
26
27 39 strategies, and peer testimonials. Finally, noncommittal email contact with the dispenser is offered.
28
29 40 Every HAU is asked to assign a CP who is advised to be involved intensively. Effect measurements will
30
31 41 occur at baseline and at 6, 12, and 18-months follow-up via online questionnaires. The primary
32
33 42 outcome for HAUs will be the use of communication strategies and personal adjustment with hearing
34
35 43 impairment as measured by the subscales of the Communication Profile for the Hearing Impaired.
36
37 44 The primary outcome for CPs will be third-party disability (Significant Other Scale for Hearing
38
39 45 Disability). A process evaluation will be performed.

40
41 46 **Ethics and dissemination:** The study was approved by the Dutch Institutional Review Board (IRB) of
42
43 47 the VU Medical University Center Amsterdam. This intervention could contribute to lowering the
44
45 48 hearing impairment burden in our ageing society. The results will be disseminated through peer-
46
47 49 reviewed publications and scientific conferences.

48
49 50 **Trial registration:** ISRCTN77340339; Pre-Results.

50
51 51 **Keywords:** Hearing loss, personal adjustment to hearing impairment, communication strategies,
52
53 52 intervention, cluster randomised controlled trial, hearing aids, communication, internet.

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3 534
5 54 **STRENGTHS AND LIMITATIONS**

6
7 55 - This is the first study to evaluate the effects of an online educational Support Programme (SUPR)
8
9 56 for hearing aid users that is implemented in a hearing aid dispensing (HAD) practice setting on a large
10
11 57 scale.

12
13 58 - Hearing-impaired participants and their communication partners (CPs) originating from 70 HAD
14
15 59 practices located all across the Netherlands will be included.

16
17 60 - The online character of the programme suits the current and future developments in the increasing
18
19 61 internet use among older people and can reach out to those with reduced (physical) access to health
20
21 62 care.

22
23 63 - The online character might however reach a selective sample of older people (especially among the
24
25 64 oldest old, 75+), willing or able to adopt the intervention (i.e., only those with access to and willing to
26
27 65 use the internet for this purpose).

28
29 66 - The study design does not allow the blinding of participants and researchers for intervention
30
31 67 allocation. This could potentially lead to performance bias.

32
33 68 - The findings of the study will potentially contribute to improvement of hearing health care services
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35 69 for hearing-impaired people and their CPs.

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41 7042 71 **BACKGROUND**

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44 72 Hearing impairment is one of the most prevalent chronic health conditions affecting older adults. It
45
46 73 was ranked fifth in the top 25 of global causes for years lived with disability in 2013[1]. Due to the
47
48 74 overall aging of the population[2], the prevalence of hearing impairment is increasing vastly,
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50 75 imposing a great burden on individuals and society.

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57 77 Hearing impairment essentially leads to the inability to communicate effectively which in turn can
58
59 78 result in a cascade of effects leading to poor psychosocial outcomes such as loneliness[3-5],
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3 79 distress[6], depression[6, 7], and work-related fatigue[8]. It has also been associated with
4
5 80 accelerated cognitive decline[9] and falls[10]. The limitations on daily life activities and restrictions in
6
7 81 social and societal participation that people experience depend on aspects that are both internal
8
9 82 (such as the level of impairment in hearing functions and structures) and external (such as availability
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11 83 of hearing aids, care facilities, and social support) to people[11]. In addition, internal 'personal
12
13 84 factors' including age and applied coping strategies are important factors which can influence
14
15 85 psychosocial outcomes[11].
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20 87 Significant others can also be negatively affected by the hearing impairment of their loved ones.
21
22 88 Partners and spouses generally experience frustration and embarrassment, for example in
23
24 89 challenging social communication settings[12]. Communication difficulties in background noise, the
25
26 90 partner's frequent request to repeat, and the need to act as an interpreter may cause irritation and
27
28 91 tension within a relationship[12]. In a systematic review conducted by Kamil *et al* it was found that
29
30 92 communication partners (CPs) of people with hearing impairment experience decreased social
31
32 93 functioning, poorer quality of life, and more participation restrictions than CPs of normally hearing
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34 94 individuals[13].
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40 96 The usual care provided for people with hearing impairment is often restricted to the assessment of
41
42 97 hearing loss and the fitting of hearing aids[14]. Hearing aid use has positive effects on quality of life,
43
44 98 social and emotional wellbeing, and may reduce depressive complaints[15-17], and possibly even
45
46 99 cognitive decline[18]. Despite this abundant evidence on positive health effects, the uptake and use
47
48 100 of hearing aids is low. It is estimated that around one third of the adults who would benefit from
49
50 101 hearing aids own them[19-21] and 3-20% of these owners never use them[22,23]. Reasons for low
51
52 102 uptake and use have been investigated and include low perceived need of amplification reflected in
53
54 103 low self-reported hearing disability[24-26] and limited acceptance of hearing loss[24]. In addition,
55
56 104 low expectations of hearing aid benefits[24, 25], limited gain in noisy situations[25, 26], and low
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3 105 overall sound quality[26], add to low uptake and use. Other perceived barriers include stigma[25,
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5 106 26], high monetary costs[26], and the need for regular hearing aid care and maintenance[26]. Finally,
6
7 107 lack of social support or social pressure to get a hearing aid are factors having a negative impact on
8
9 108 hearing aid use[25, 26].

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14 110 Because the factors leading to low use are numerous and their interplay is complex, it has often been
15
16 111 argued that hearing health care should offer more than hearing aids alone to improve everyday
17
18 112 communication and wellbeing of hearing-impaired adults[27]. This argument is in line with the
19
20 113 biopsychosocial approach of health which is receiving increasing attention in the field of audiology:
21
22 114 Experienced hearing disability (i.e., activity limitations and participation restrictions) is the outcome
23
24 115 of a complex interaction between an individual and his/her contextual factors[28-30].
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29 117 Various interventions have been proposed in the past to complement hearing aid fitting. Examples
30
31 118 are communication programmes aimed at improving speech perception and/or communication
32
33 119 management[31]. These programmes include speech perception training, communication
34
35 120 management training, and social support[27, 32, 33]. For reviews, see Barker *et al*, Sweetow *et al*,
36
37 121 and Wong *et al*[34-36]. Examples of effective programmes are the Home Education programme[37]
38
39 122 and the Active Communication Education (ACE) group programme[38]. Both programmes consist of
40
41 123 modules on everyday communication situations, aiming to improve the use of communication
42
43 124 strategies, personal adjustment to living with hearing impairment, quality of life, development of
44
45 125 problem-solving skills, and to decrease the level of experienced hearing disability. These programmes
46
47 126 showed an improvement in communication strategies[37] and communicative participation
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49 127 restrictions and activity limitations[38].
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55 129 Communication training programmes, whether combined with hearing aid fitting or not, are rarely
56
57 130 offered in hearing health care[27, 32]. When offered, there are various reasons adults with hearing
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3 131 impairment would choose not to pursue communication training programmes; they could live in a
4
5 132 rural area, have a lack of time, or no easy access[32]. The paradigm shift in health care from the
6
7 133 traditional doctor-centric model to a more patient-centered model, combined with increasingly
8
9 134 pervasive use of e-health methods and technology, means that the typical barriers causing the low
10
11 135 use of (group) communication training programmes can now be overcome[39-41].
12
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15
16 137 A number of studies have recently been published reporting on the development and evaluation of
17
18 138 online communication programmes. Thorén *et al* developed such a programme[42] which included
19
20 139 reading material on hearing anatomy, hearing aids, communication strategies, assistive listening
21
22 140 devices, and guidelines for CPs. In addition, the intervention included weekly email contact with an
23
24 141 audiologist, problem solving exercises, and online peer discussion on personal experiences with
25
26 142 hearing loss. Thorén *et al* studied the effectiveness of the programme using a randomised controlled
27
28 143 trial-design in which the intervention group ($n=38$) received the online programme while the control
29
30 144 participants ($n=38$) were offered access to an internet discussion forum or were placed on a waiting
31
32 145 list[42]. The researchers found reduced symptoms of depression[43] and a significant decrease of
33
34 146 activity limitations and participation restrictions in the intervention group compared to the controls
35
36 147 at five weeks directly after the intervention and at three-months follow-up[42]. Ferguson *et al*
37
38 148 investigated the use of short interactive videos (reusable learning objects, RLOs)[44]. RLOs were
39
40 149 delivered via DVD for TV, computer, and the internet and covered practical and psychosocial issues
41
42 150 which are relevant for audiological rehabilitation. The intervention group ($n=103$) received seven RLOs
43
44 151 plus usual clinical services including hearing aid fitting and counseling. They were compared to a
45
46 152 control group ($n=100$) who received clinical services only and were placed on a waiting list.
47
48 153 Participants in the intervention group had significantly better hearing aid skills and better knowledge
49
50 154 on psychosocial issues than the control group after 6-weeks follow-up.
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3 156 Whereas the online education programme of Thorén *et al* was evaluated in a sample of adults who
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5 157 were recruited by local advertisements and articles and were wearing a hearing aid for at least one
6
7 158 year[42], Ferguson *et al* evaluated their RLOs in a small sample of patients of the audiology service of
8
9 159 the Nottingham University Hospitals NHS Trust. Patients were adults who had been referred to the
10
11 160 clinic by their family doctor[44]. The participants in the study of Kramer *et al* mentioned earlier, were
12
13 161 all patients of a specialized tertiary Audiology Centre, limiting the generalizability of the results[37].
14
15 162 In general, only a small number of hearing aid applicants with relatively complex hearing problems
16
17 163 receive hearing care through a tertiary clinic. The vast majority of hearing aids are fitted in a
18
19 164 dispenser practice.
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23

24 166 To the best of our knowledge, there is no study available evaluating the effectiveness of an online
25
26 167 communication training programme that is implemented on a large scale in a hearing aid dispensing
27
28 168 (HAD) practice setting. This paper reports on the design of such a study. It addresses the different
29
30 169 steps that will be taken to evaluate an online SUpport PRogramme (SUPR) for hearing-impaired
31
32 170 adults and their CPs. SUPR is based on the Home Education programme developed by Kramer *et*
33
34 171 *al*[37]. The original version developed in 1995 has been updated so that it would be applicable for
35
36 172 use over the internet. SUPR has also been expanded with extra elements including instruction videos
37
38 173 on how to operate and maintain hearing aids and peer testimonials. All elements will be sent about
39
40 174 bi-weekly via email.
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46 176 This study aimed to involve seventy HAD practices, of which half will offer the training programme.
47
48 177 This large number of practices not only contributes to a large sample size (and therefore statistical
49
50 178 power), it also reflects real world clinical practice and thus contributes to the external validity of the
51
52 179 future results. The study will include an 18-month follow-up. As was mentioned earlier by Kramer *et*
53
54 180 *al*, Barker *et al*, and Wong *et al* more research on treatment efficacy in the long(er)-term is essential
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3 181 because it is possible that some short-term effects may disappear and other effects can arise[34, 36-
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5 182 37].
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8
9 184 The aim of this study is to determine the effectiveness of SUPR as part of standard HAD care among
10
11 185 older hearing aid users (HAUs) and their CPs. Based on the active elements included in SUPR, we
12
13 186 hypothesize that older HAUs who receive SUPR in addition to hearing aid fitting will show the
14
15 187 following favourable effects at 18-months follow-up when compared to HAUs who receive hearing
16
17 188 aid fitting only:

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19
20 189 - More use of favourable and less use of unfavourable communication strategies (primary outcome
21
22 190 measure).
23

24 191 - Better personal adjustment to hearing impairment (primary outcome measure).
25

26 192 - Higher self-efficacy of hearing aid handling, higher hearing aid use, less activity limitations and
27
28 193 participation restrictions, less handicap and disability, better self-reported intervention outcomes,
29
30 194 higher readiness to do something about their hearing, and higher satisfaction with HAD services
31
32 195 (secondary outcome measures).
33

34
35 196 These effects will be studied both in first-time and experienced HAUs.
36

37 197 - Consistent with the findings by Kramer *et al*[37], we hypothesize that effects on all outcomes will be
38
39 198 larger in first-time HAUs than in experienced HAUs.
40

41 199 With regard to the CPs, we hypothesize that CPs who receive SUPR - as compared to CPs whose loved
42
43 200 ones only receive hearing aid fitting - will show the following favourable effects:
44

45
46 201 - Lower third-party disability (main outcome).
47

48 202 - Better self-reported intervention outcomes.
49

50 203

51 52 204 **METHODS**

53 54 55 205 **Study design** 56 57 58 59 60

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3 206 A cluster randomised controlled trial with an 18-month follow-up period will be performed. Cluster
4
5 207 randomisation (with the HAD practice as a unit) was chosen over individual randomisation because
6
7 208 the latter would hold a high risk of contamination. In case of individual randomisation, The HAD
8
9 209 personnel would have to switch between approaches (SUPR/CaU) frequently and could accidentally
10
11 210 refer to or offer SUPR to clients assigned to the CaU group. In addition, as the time between
12
13 211 informing the clients about the study, receiving clients' consent and the start of SUPR/CaU was
14
15 212 relatively short, performing randomisation on an individual level was not feasible. Dutch HAD
16
17 213 practices and consequently all clients in these practices were randomly assigned to one of two
18
19 214 groups. The control group received care as usual (CaU) which is hearing aid fitting only, while the
20
21 215 intervention group received hearing aid fitting supplemented with SUPR.
22
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26 217 **Care as Usual**

28
29 218 CaU starts with a preparation appointment during which a screening pure-tone audiogram (only air
30
31 219 conduction) is administered by the hearing aid dispenser. If the hearing loss in one or both ears is at
32
33 220 least 35 decibel (dB) hearing level (HL) (averaged over the three frequencies 1, 2, and 4 kHz) in one or
34
35 221 both ears, someone is considered potentially eligible for hearing aid fitting and more comprehensive
36
37 222 audiometry is required. If the client is interested in hearing aids, his/her general wishes and goals are
38
39 223 discussed after which the Amsterdam Inventory for Auditory Disability and Handicap (AIADH; Kramer
40
41 224 *et al*[45]) is handed out. Clients are asked to complete the AIADH at home and bring it along to the
42
43 225 next appointment. The AIADH assesses hearing activity limitations and participation restrictions.
44
45 226 Clients are asked to assign a CP and involve them throughout the rehabilitation (e.g., bring them to
46
47 227 appointments). During the next appointment, i.e., the intake appointment, comprehensive
48
49 228 audiometry (air and bone conduction, and speech audiometry) are performed. The results of all tests,
50
51 229 the AIADH, and the wishes of the client determine what type of hearing aid may be best suited for
52
53 230 this person. The appropriate hearing aids will be selected and fitted directly (if available in the HAD
54
55 231 practice) or in a subsequent fitting appointment. Fitting is followed by a trial period which usually
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3 232 lasts up to four weeks, during which people can try out the hearing aid and decide whether or not to
4
5 233 purchase it. Depending on the client's needs, fine-tuning or other follow-up appointments are
6
7 234 scheduled. These can be scheduled during the trial period but also after the device has been
8
9 235 purchased.

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11 236

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13
14 237 **Intervention: SUPR**

15
16 238 SUPR consists of a Practical Support Booklet and online elements. In addition, clients are asked to
17
18 239 assign a CP who is involved actively in the programme (see below).

19
20 240

21
22 241 **Practical Support Booklet**

23
24 242 The Practical Support Booklet will be handed out at the end of the preparation appointment (first-
25
26 243 time HAUs, experienced HAUs) or the intake appointment (experienced HAUs). The aims of the
27
28 244 Practical Support Booklet are to: 1) assist clients and CPs in getting familiar with their hearing aid, 2)
29
30 245 stimulate clients' use of the hearing aid and clients' and CPs' use of communication strategies, and 3)
31
32 246 guide clients and their CPs through the various stages (i.e., appointments) of the rehabilitation
33
34 247 trajectory. Although the theoretical elements of the booklet can also be used as a reference *after* the
35
36 248 purchase of the hearing aid, the booklet's focus is on the period between the first HAD appointment
37
38 249 and the end of the trial period. The booklet covers four parts, corresponding to the four key
39
40 250 appointments during the trial period (i.e., preparation appointment, intake appointment, control-
41
42 251 and/or fine-tuning appointment, and purchase appointment). The information that is provided is
43
44 252 synchronized with the topics which are typically discussed during these appointments. The first part
45
46 253 outlines the process of getting a hearing aid and includes an introduction to the hearing aid
47
48 254 dispenser's care and an explanation about the pure tone audiogram. The client is asked to write
49
50 255 down and rank specific communication goals (s)he wishes to reach by the end of the trial period (for
51
52 256 example: 'I want to be able to hear the stories of my 10-year old granddaughter Anne when I pick her
53
54 257 up from school every Monday'. The second part revolves around the types of hearing aids available
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3 258 and the client's hearing aid preferences. Information about how to operate and maintain the device
4
5 259 is provided as well. In the third part the client and the CP are asked to write down their experiences
6
7 260 with the new hearing aid and its settings. This information will be used for further refinement of the
8
9 261 fitting. The final section of the booklet provides information on assistive listening devices,
10
11 262 reimbursement of costs, more information on the audiogram, types of hearing loss, and the types of
12
13 263 hearing aids (e.g. behind-the-ear and in-the-canal). In addition, an overview of the most important
14
15 264 communication strategies that clients and their CP can apply is provided. The content and the
16
17 265 appearance of the booklet were realised during several months of development by the HAD
18
19 266 company. Although no specific guidelines were used for the development of the written health
20
21 267 information in the booklet, a number of the subsequent steps that are deemed important by
22
23 268 Caposecco *et al* were taken: 1) interviews with key stakeholders (clients, CPs, HAD practice
24
25 269 personnel) were held to specify the booklet's goals and functions, 2) graphics and text were
26
27 270 developed and optimized with regard to their understandability and attractiveness (language
28
29 271 difficulty, lay-out, font size, paragraphing), 3) a first complete version of the booklet was pilot-tested
30
31 272 in ten HAD practices for several months. Feedback by all key stakeholders was collected, 4) the
32
33 273 feedback was incorporated in a new and final version of the booklet (which was used in the
34
35 274 study)[46].
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276 **Online Elements**

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

283

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3 284 The educational videos consist of: 1) Training modules on hearing aid handling skills. These comprise
4
5 285 of three short instruction videos with practical information on the use and maintenance of hearing
6
7 286 aids. Participants receive the link to the relevant instruction video depending on their style of hearing
8
9 287 aids (i.e., behind-the-ear, in-the-canal, or receiver-in-the-ear). 2) Training modules on
10
11 288 communication strategies and personal adjustment. This is a remake (i.e., a modernized version) of
12
13 289 the home educational programme "*Horen en Gehoord Worden: Hoe kan het beter*", as developed by
14
15 290 Kramer *et al*[37]. It comprises five short videos showing the difficulties that hearing-impaired people
16
17 291 can experience in everyday listening situations. The typical reactions by both the hearing-impaired
18
19 292 people and his/her social environment to these situations are shown, and a trainer illustrates how
20
21 293 communication could be improved by using communication strategies (for both hearing-impaired
22
23 294 people and his/her CP). 3) Three testimonials by hearing-impaired peers who share their experiences
24
25 295 with hearing aids.
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31 297 **Measurements**

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33 298 For all participants four measurements will take place: at baseline (after the preparation
34
35 299 appointment, but before the actual hearing aid fitting) (T0), six months after the hearing aid
36
37 300 purchase (T1), one year after the hearing aid purchase (T2), and eighteen months after the hearing
38
39 301 aid purchase (T3). Measurements at T3 serve to determine the long-term effects of SUPR, i.e., one
40
41 302 year after its completion. Data will be collected using online questionnaires through NetQ Premium,
42
43 303 which is an online survey programme. Email-reminders will be sent within a week after the first
44
45 304 invitation-email and another week after the first reminder, if necessary.
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51 306 **Study population & recruitment**

52
53 307 The following procedures were followed during the recruitment period (February 2016 to September
54
55 308 2016). Hearing aid dispensers invited clients to participate in the study. First-time HAUs were invited
56
57 309 at the end of their preparation appointment. Experienced HAUs were invited at the end of their
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3 310 preparation or at the end of their intake appointment, if they did not require a preparation
4
5 311 appointment. Hearing aid dispensers handed out an information package including an invitation
6
7 312 letter, a selection form outlining the in- and exclusion criteria, a brochure about the study, and an
8
9 313 envelope with an information letter and brochure for the CP. All interested participants were asked
10
11 314 to enrol themselves for the study by subscribing on a registration webpage and signing the online
12
13 315 consent from there. Every month the number of clients who were invited (number of envelopes that
14
15 316 was handed out) and were enrolled (number of online subscriptions) per HAD practice were
16
17 317 determined. When enrolment numbers for a particular HAD practice were relatively low, a phone call
18
19 318 was made to the specific HAD practice to notify them of their current number of enrolments, to
20
21 319 identify possible underlying reasons, and to motivate them to reach the required target. Throughout
22
23 320 the recruitment period, the HAD headquarters organized motivational conference calls for the HAD
24
25 321 practices that had not yet reached their target. Finally, when enrolment ratings continued to be
26
27 322 behind target, employees of the headquarters directly invited potentially eligible clients who were
28
29 323 not invited by the HAD practice personnel, via a telephone call. The study material was then sent via
30
31 324 email.
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326 **Incentives**

327 After completing the T0 questionnaire, all participants will be offered a voucher of EUR 50 to spend
328 on a hearing aid or EUR 25 to spend on other articles of the HAD practice if they decide not to
329 purchase a hearing aid. CPs will be offered a gift card. In addition, participants in the control group
330 will be offered a shortened version of SUPR after eighteen months. For them, SUPR will be slightly
331 adjusted such that it becomes suitable for individuals who already started using a hearing aid.
332

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

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5 337 **Inclusion criteria**

7 338 The following inclusion criteria for the hearing aid candidates were applied:

9 339 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
11 340 follow-up appointment). This hearing aid could be their first (i.e., first-time HAUs), or a replacement
13 341 hearing aid (i.e., experienced HAUs). Clients who did not purchase a hearing aid after the trial period
15 342 were considered drop-outs. 3) Sufficient understanding of the Dutch language. 4) Access to a
17 343 personal computer with internet access and owner of an email account for the total duration of the
19 344 study.
21

22 345

24 346 **Exclusion criteria**

26 347 The following hearing aid candidates were excluded: 1) Candidates who received additional care at a
28 348 specialized Audiology Clinic. In the Netherlands, an Audiology Clinic offers elaborate,
30 349 multidisciplinary and specialized, tertiary health care and is aimed at people with complex hearing
32 350 problems. This care may overlap and/or interfere with that of SUPR. 2) Candidates that received a
34 351 hearing aid primarily to suppress tinnitus complaints. For these individuals the focus of the
36 352 rehabilitation is not on restoring communication per se, and as such, they were not part of the target
38 353 group of SUPR.
40

41 354

43 355 Although all participants were encouraged to assign a CP, it was not obligatory for them to assign one
45 356 in order to participate in the study. For the CPs, the only inclusion criterion applied was that they
47 357 should be 18 years or older.
49

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52 359 **Outcome measures**

54 360 An overview of all outcome measures and measurements over time is presented in Table 1[47].
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362 **Table 1 Spirit flow diagram. Schedule of enrolment, interventions, and assessments**

		Allocation	Enrolment	Post-Allocation & Enrolment			
		of HAD practices					
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					
INTERVENTIONS:							
	Care as Usual (Hearing aid fitting)	x	—————			x	
	Intervention (Hearing aid fitting + SUPR)	x	—————			x	
ASSESSMENTS:							
	Demographic variables						

1					
2					
3	Gender				x
4					
5					
6					
7	Age				x
8					
9					
10					
11	Marital status				x
12					
13					
14					
15	Living situation				x
16					
17					
18					
19	Level of				x
20	education				
21					
22					
23					
24	Occupational				x
25					
26	status				
27					
28					
29					
30	Country of birth				x
31					
32	participant				
33					
34					
35					
36	Country of birth				x
37					
38	participant's				
39	parents				
40					
41					
42					
43					
44	Primary				
45					
46	outcome				
47					
48	measure HAUs				
49					
50					
51					
52	The use of	CPHI			x
53					x
54	communication				x
55					x
56	strategies and				
57					
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personal

adjustment

Secondary

outcome

measures –

HAUs

Self-efficacy of -MARS-HA - x x x x

hearing aid Basic handling

handling subscale

-MARS-HA - x x x

Advanced

handling

subscale

Self-reported -IOI-HA (items x x x

intervention 2-7)/IOI-AI (all 7

outcomes items)

Self-reported -IOI-HA (item 1) x x x

hearing aid use -Use

questionnaire x x x

Objective -Data-logging x x x

hearing aid use

Satisfaction 'How likely is it x x x x

with the that you would

hearing aid recommend the

dispenser service of the

1						
2						
3	service	HAD practice to				
4		other people				
5		(family, friends,				
6		colleagues?)’				
7						
8						
9						
10	Self-reported	AIADH	x	x	x	x
11						
12	activity					
13						
14	limitations and					
15						
16	participation					
17						
18	restrictions					
19						
20	Hearing status	Pure tone	x			
21		audiogram				
22						
23						
24	Readiness to do	-URICA -	x	x	x	x
25						
26	something	Precontemplati				
27						
28	about one’s	on/				
29						
30	hearing	Contemplation/				
31						
32	problems	Action stages				
33						
34		-URICA -		x	x	x
35						
36		Maintenance				
37						
38		stage				
39						
40	Emotional	HHDI -		x	x	x
41						
42	response	Emotional				
43						
44		response				
45						
46		subscale				
47						
48	<hr/>					
49	Secondary					
50	outcome					
51						
52	measures – CP					
53						
54						
55						
56	Third-party	SOS-HEAR	x	x	x	x
57						
58						
59						
60						

For peer review only

1
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3 disability

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6
7 Self-reported IOI-HA-SO/IOI- x x x

8 intervention AI-SO

9 outcomes from

10 the perspective

11 of the CP

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15
16 363 Abbreviations: HAD practice: hearing aid dispensing practice, SUPR: Support PRogramme, HAU:

17 364 hearing aid user, CPHI: Communication Profile for the Hearing Impaired, MARS-HA: Measure of

18 365 Audiologic Rehabilitation Self-Efficacy for Hearing Aids, IOI-HA: International Outcome Inventory –

19 366 Hearing Aids, IOI-AI: International Outcome Inventory – Alternative Interventions, AIADH:

20 367 Amsterdam Inventory for Auditory Disability and Handicap, URICA: University of Rhode Island Change

21 368 Assessment- for Hearing health behaviour, HHDI: Hearing Handicap and Disability Inventory, CP:

22 369 Communication Partner, SOS-HEAR: Significant Other Scale for Hearing Disability, IOI-HA-SO:

23 370 International Outcome Inventory Significant Other– Hearing Aids, IOI-AI-SO: International Outcome

24 371 Inventory Significant Other– Alternative Interventions.

25 372

26 373 Primary outcome measure – HAUs

27 374 - *The use of communication strategies and personal adjustment with hearing impairment* will be

28 375 measured using the reliable and validated Dutch 35-item version of the Communication Profile for

29 376 the Hearing Impaired (CPHI)[48, 49]). Communication strategies are measured using the following

30 377 subscales: Maladaptive Behaviours, Verbal Strategies, and Non-verbal Strategies. Each subscale

31 378 consists of statements for which the respondent has to indicate how often (s)he applies this strategy.

32 379 An example: “I avoid conversations with strangers, because of my hearing loss” (subscale

33 380 Maladaptive Behaviour). The five response options range from ‘almost never’ to ‘almost always’.

34 381 Scores are averaged per subscale and range from 1 to 5. High scores indicate favourable strategies

35 382 whereas low scores indicate unfavourable strategies. The second section of the CPHI deals with

1
2
3 383 personal adjustment and also contains three subscales: Self-acceptance, Acceptance of Loss, and
4
5 384 Stress & Withdrawal. An example item of the latter subscale is: "I feel very tense because of my
6
7 385 hearing loss". The five response options range from 'totally disagree' to 'totally agree'. Some items
8
9 386 were recoded because of reverse scaling. After recoding the item scores, average scores per subscale
10
11 387 can be calculated, with low scores indicating poor personal adjustment and high scores indicating
12
13 388 good personal adjustment.

14
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16 389

17
18 390 We have chosen for the subscales of the CPHI as central outcome measures for the following
19
20 391 reasons. Firstly, the subscales are purported to measure the constructs that are acted upon by the
21
22 392 core active element of the intervention (i.e., the revised home education programme). Secondly, the
23
24 393 CPHI has proven to have very good validity and reliability in the target population of this study[49].
25

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29 395 Secondary outcome measures - HAUs

30
31 396 - *Self-efficacy of hearing aid handling* will be measured by the Basic Handling subscale of the
32
33 397 Measure of Audiologic Rehabilitation Self-Efficacy for Hearing Aids (MARS-HA). The English version of
34
35 398 this 7-item subscale has good psychometric quality[50]. Scores can range from 0% to 100%, with
36
37 399 lower scores representing less certainty in one's capability of handling a hearing aid. At T1, T2, and
38
39 400 T3, the 5-item subscale Advanced Handling will be additionally administered. Dutch versions of the
40
41 401 scales were created using the forward-backward method[51]. At T0 'expected self-efficacy' will be
42
43 402 administered, whereas at T1, T2, and T3 'experienced self-efficacy' will be determined as the new
44
45 403 hearing aids will have been fitted by then. For measurement of 'expected self-efficacy', all MARS-HA-
46
47 404 items start with 'I think I can ...', whereas for measurement of 'experienced' self-efficacy all items
48
49 405 start with 'I can... '.

50
51
52 406 - *Hearing aid use*. Self-reported use will be measured using the first item of the International
53
54 407 Outcome Inventory – Hearing Aids (IOI-HA) ("How many hours per day on average have you been
55
56 408 using your hearing aid(s) in the last two weeks?"). Response options are 'none', 'less than 1 hour a

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2
3 409 day', '1-4 hours a day', '4-8 hours a day', and 'more than 8 hours a day'[52]. Self-reported hearing aid
4
5 410 use will additionally be measured by three questions from the use questionnaire developed by
6
7 411 Laplante-Lévesque *et al*[53]. The latter questionnaire was translated into Dutch, using the forward-
8
9 412 backward method[51]. Hearing aid use will also be measured objectively via data-logging.

10
11 413 - *Self-reported intervention outcomes (hearing aid rehabilitation and SUPR outcome)*. The
12
13 414 International Outcome Inventory – Hearing Aids (IOI-HA; items 2-7) and the equivalent International
14
15 415 Outcome Inventory for Alternative Interventions questionnaire (IOI-AI; all 7 items) will be used to
16
17 416 assess the outcome of hearing aid rehabilitation and SUPR respectively[52]. The Dutch version of IOI-
18
19 417 HA has a good test-retest reliability and validity[54]. The first item of the IOI-AI determines the
20
21 418 frequency of the use of the alternative intervention, i.e., "How often have you used the learnt
22
23 419 communication strategies on an average day in the last two weeks?". Response options are 'never'
24
25 420 (1), 'rarely' (2), 'sometimes' (3), 'often' (4), and 'almost always' (5). Items 2-7 of the IOI-HA/IOI-AI
26
27 421 questionnaire cover: benefit, residual activity limitation, satisfaction with the hearing aid(s)/SUPR,
28
29 422 residual participation restriction, impact on others, and quality of life.

30
31 423 - *Satisfaction with the HAD practice service*. Satisfaction will be measured by the following question:
32
33 424 "How likely is it that you would recommend the service of the HAD practice to other people (family,
34
35 425 friends, colleagues)?" It is scored on a visual analogue scale running from 0 (=not at all likely) to 10
36
37 426 (=extremely likely).

38
39 427 - *Self-reported activity limitations and participation restrictions* are measured using the reliable and
40
41 428 validated original (Dutch) version of the Amsterdam Inventory for Auditory Disability and Handicap
42
43 429 (AIADH)[45, 55]. It contains 28 questions regarding everyday listening situations. An example is: "Do
44
45 430 you immediately look into the right direction when somebody calls you in the street"? The 4-point
46
47 431 response scale covers: 'almost never' (1), 'sometimes' (2), 'often' (3) and 'almost always' (4). When
48
49 432 the participant answers the question with 'almost never' or 'sometimes', he or she is directed to
50
51 433 question b which is about the inconvenience of not being able to hear well in that specific situation.
52
53 434 Response options are: 'no' (1), 'a little' (2), 'very handicapped' (3), and 'extremely handicapped' (4).
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3 435 Hence, the total score can range from 28-112 with higher scores indicating greater participation
4
5 436 restriction.

6
7 437 - *Readiness to do something about one's hearing problems* will be measured by the validated Dutch
8
9 438 24-item version of the University of Rhode Island Change Assessment (URICA)[56]. Formulations of
10
11 439 items were adjusted such that they applied to hearing problems. The inventory contains 24
12
13 440 statements regarding attitudes and behaviours assessing an individual's stage of behaviour change.
14
15 441 At T0 the scores on the following stages will be assessed: pre-contemplation (does not intend to take
16
17 442 action in the foreseeable future, e.g., "As far as I'm concerned, I don't have any problems with my
18
19 443 hearing that need changing"), contemplation (intends to change in the next six months and is aware
20
21 444 of the pros and cons of changing), and action (has made specific modifications in his/her lifestyle
22
23 445 towards healthy behaviour). At T1, T2, and T3 the maintenance stage (can maintain the changes in
24
25 446 new behaviour) will be added. The five response options range from 'fully disagree' (score 1) to 'fully
26
27 447 agree' (score 5). Summed scores for each subscale will be calculated. In addition the composite
28
29 448 'readiness score' (adding the contemplation, action and maintenance scores and subtracting the pre-
30
31 449 contemplation score) and the composite 'committed action score' (subtracting the contemplation
32
33 450 stage score from the action stage score) will be calculated[56]. The higher the composite scores, the
34
35 451 further the respondents are along the stages of change.

36
37
38 452 - *Emotional response to hearing problems*. The Hearing Handicap and Disability Inventory (HHDI) will
39
40 453 be used[57]. The purpose of the inventory is to identify the individual's problems caused by hearing
41
42 454 loss. Only the section 'emotional response' will administered. It contains five statements each with
43
44 455 five response options: 'yes!' (4), 'yes' (3), 'more or less' (2), 'no' (1) and 'no!' (0). An example is: "I
45
46 456 find it difficult to accept that I am hearing impaired". Lower scores indicate better outcomes.
47
48
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52 458 Secondary outcome measures - CP

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54
55 459 - *Third-party disability* will be measured using the Significant Other Scale for Hearing Disability (SOS-
56
57 460 HEAR)[12]. This questionnaire was translated into Dutch for the purposes of this study following a
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2
3 461 forward-backward method[51]. The 27-item questionnaire addresses the problems and limitations
4
5 462 experienced by the CP. An example item is: "Because of my partner's hearing difficulties I have to
6
7 463 repeat myself often". For each item the CP has to indicate how much of a problem it is for him/her:
8
9 464 'no problem' (0), 'a mild problem' (1), 'a moderate problem' (2), 'a severe problem' (3), 'a complete
10
11 465 problem' (4). Higher scores indicate greater difficulties.

12
13
14 466 - *Hearing aid rehabilitation and SUPR outcome as viewed from the perspective of the CP* will be
15
16 467 administered with the 7-item IOI-HA-SO/IOI-AI-SO and covers use, benefit, residual activity
17
18 468 limitation, satisfaction, residual participation restriction, impact on others, and quality of life[58].

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20 469

21
22 470 Baseline measurement- Demographical characteristics

23
24 471 - Gender (male/female)

25
26 472 - Age (in years)

27
28 473 - Marital status (married/cohabiting/widow or widower/divorced/single, never married)

29
30 474 - Living situation (living together with my partner/living together with my partner and children/living
31
32 475 together without my partner but with one or more family members/living alone (own room) or in a
33
34 476 care institution/living alone, independently or nursing home/other, namely...)

35
36 477 - Level of education (no completed education/lower general education, elementary education or a
37
38 478 part of it/lower general secondary education/vocational education/secondary education/technical
39
40 479 and vocational education/higher professional education/higher general education/scientific
41
42 480 education/other, namely...)

43
44 481 - Occupational status (yes/no)

45
46 482 - Country of birth (The Netherlands/other, namely...)

47
48 483 - Country of birth father (The Netherlands/other, namely...)

49
50 484 - Country of birth mother (The Netherlands/other, namely...)

51
52 485 - Hearing loss in each ear, in dB HL (averaged over 1, 2, and 4 kHz) as retrieved from the pure-tone
53
54 486 audiogram as provided by the hearing aid dispenser.

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5 488 **Randomisation**

6
7 489 HAD practices were randomly assigned to offer CaU or the intervention. To avoid an unequal
8
9 490 distribution of HAD practices with regard to level of urbanisation, HAD practices were pre-stratified
10
11 491 (HAD practices located in a relatively rural area versus in an urban area) and randomisation occurred
12
13 492 within these two strata. A statistician performed block randomisation of the HAD practices in the
14
15 493 statistical software R, with random permutation in blocks of size four and with a fixed seed. 34 HAD
16
17 494 practices were assigned to CaU and 36 HAD practices to the intervention group. The recruitment
18
19 495 procedure and period was the same for all 70 included HAD practices (the total list of included HAD
20
21 496 practices are available on request from the research team).
22
23

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27 498 **Sample size calculation**

28
29 499 Sample size calculations are based on the expected effects of the intervention on the primary
30
31 500 outcome: coping with hearing impairment (CPHI). Demorest & Erdman indicated that the expected
32
33 501 difference on the subscales of the CPHI varies from 0.67 (Maladaptive Behaviour) to 0.95 (Self-
34
35 502 Acceptance)[59]. Given that in a previous study[37] the effect of the programme was larger for first-
36
37 503 time than for experienced users, we calculated sample sizes separately for first-time and experienced
38
39 504 users. For first-time HAU, we based our sample size calculations on an expected difference of 0.67
40
41 505 between the intervention and the CaU group. Note that the subscale with the smallest minimal
42
43 506 importance difference (i.e., Maladaptive Behaviour) was used in the calculation, as finding a
44
45 507 significant difference on this measure requires the largest number of participants. Calculations in
46
47 508 PASS 12 (Tests for Two Means in a Cluster-Randomised Design; Intraclass correlation coefficient:
48
49 509 0.01; alpha: 0.05; power: 0.80) shows, that when 70 HAD practices are included (of which half will
50
51 510 offer SUPR and half will offer CaU), the number of first-time HAUs to include in the analyses is two
52
53 511 per HAD practice. For the sample size calculation of the experienced users we chose an expected
54
55 512 difference of 0.4 between the intervention and CaU group. The expected difference was set lower
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3 513 than for first-time HAUs as Kramer *et al* had previously found generally smaller effects for
4
5 514 experienced users than for first-time users[37]. With a difference of 0.4 the number of experienced
6
7 515 HAUs (power: 0.80) to include is three per HAD practice. We expected the proportion of drop-out or
8
9 516 loss to follow-up across the study to be 20%. This includes loss to follow-up for a range of reasons: no
10
11 517 motivation anymore, reluctant to purchase a hearing aid after a successful trial, sickness, death etc.
12
13 518 Taking the loss to follow-up and the proportion of clients that normally purchase a hearing aid into
14
15 519 account results in a total (rounded) number of four first-time HAUs per HAD practice and five
16
17 520 experienced HAUs per HAD practice to be recruited.
18
19
20
21

521

522 **Statistical analyses**

523 To check the comparability between the groups (CaU or intervention group) at baseline, baseline
524 characteristics of the participants will be compared using the Chi Square test (for categorical
525 variables), the independent samples *t*-test (for normally distributed continuous variables) and the
526 Mann-Whitney test (for non-normally distributed continuous variables). Comparability will be
527 checked for all demographic variables and all primary and secondary outcomes.
528

529

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

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

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3 539 addition, a per-protocol analysis will be performed. A per-protocol analysis includes those
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5 540 participants who completed the intervention originally allocated as described in the study protocol.
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7 541 As a per-protocol analysis can potentially yield biased effects (e.g., see CONSORT statement)[60],
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9 542 great caution will be exerted when interpreting these results. In addition, the report of these findings
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11 543 in future articles will be nuanced explicitly and thoroughly.
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16 545 **Process evaluation**

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18 546 The process of implementing SUPR into the HAD care in the intervention arm will be evaluated. The
19
20 547 main aim of this evaluation is to gain insight into 1) the circumstances in which the intervention was
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22 548 implemented, 2) (non-) compliance with the intervention, and 3) the professionals' and clients'
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24 549 appraisal of the intervention.
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29 551 The process evaluation will be carried out according to the framework as proposed by Linnan *et*
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31 552 *al*[61]. It covers seven parameters: recruitment, reach, fidelity, dose delivered, dose received and
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33 553 implemented, satisfaction, and perceived benefit[62]. A brief description of each of the parameters is
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35 554 given below.
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39 556 - Recruitment refers to the procedures applied to approach and attract potential participants. The
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41 557 hearing aid dispensers will be asked to provide this information.

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43 558 - Reach. This is the proportion of people participating relative to the number of people invited.

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45 559 - Fidelity relates to the question of whether the intervention was provided as intended. The team
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47 560 that is responsible for the email contact will be asked to provide a written report on this.

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49 561 - Dose delivered: 1) Did the personnel of the HAD practice hand out the Practical Support Booklet at
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51 562 the end of the preparation appointment? 2) Did the personnel of the HAD headquarters send out the
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53 563 emails correctly (correct content) and on time.
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3 564 - Dose received and implemented: 1) Did the participants receive and use the Practical Support
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5 565 Booklet? 2) Did the participants open the emails and the videos? If so, did they watch the whole
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7 566 video, or part(s) of it? The video watching behaviour will be determined using Quadia (supplier of
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9 567 online video content) and Google analytics. Data on the average watching time per video, and how
10
11 568 many times a particular video has been opened will be determined. Due to the privacy regulations
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13 569 the HAD company is subject to, the company is only allowed to collect video watching data on a
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15 570 group level (and not on an individual level). As all the HAD practices of the company that do not
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17 571 participate in the study provide SUPR as their standard care at the time of the study, the researchers
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19 572 will not be able to determine specific group averages of the study participants (the averages are
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21 573 based on both study participants and regular HAD clients). Information on implementation of the
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23 574 knowledge that participants learnt from SUPR will be deduced from the IOI-AI questionnaire (item on
24
25 575 use) on T1. If participants received and used the Practical Support Booklet will be measured by a
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27 576 questionnaire.

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31 577 - Satisfaction: Satisfaction of the participant with SUPR will be evaluated using the IOI-AI
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33 578 questionnaire (item satisfaction) on T1. The hearing aid dispensers will be asked to answer the
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35 579 question: How would you rate your satisfaction with SUPR?

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37 580 - Benefit: Information on the experienced benefit of the participant will be obtained from the IOI-AI
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39 581 questionnaire (item benefit) on T1. The hearing aid dispensers will be asked to answer the question:
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41 582 How would you rate the perceived benefit from SUPR for your clients' ability to improve in
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43 583 communication?
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48 585 Additionally, focus group discussions with participants from the intervention group will be organized
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50 586 to gain insight into the reasons for using the knowledge of SUPR in their daily lives or not. A minimum
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52 587 of two focus groups will be organized. The exact number will depend on data saturation.
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54 588 Heterogeneity in age, gender, educational level, severity of hearing impairment, and stage of
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56 589 behaviour change (at baseline) within the groups will be strived for. Given the difficulties hearing-
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3 590 impaired individuals might have with group conversations, the focus groups will have a maximum
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5 591 size of six participants each.

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9 593 **ETHICS AND DISSEMINATION**

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11 594 **Protocol amendments, confidentiality and dissemination policy**

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13 595 Any future protocol modifications will be submitted to the VU University Medical Center Medical
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15 596 Ethical Committee. Directly upon approval, the modification will be corresponded to the trial
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17 597 registry.

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22 599 Personal information about enrolled participants will only be shared with employees of the
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24 600 headquarters of the HAD practices who signed a privacy declaration. This exchange of personal
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26 601 information will only occur in order to collect data within the framework of the study (e.g., to collect
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28 602 audiogram data, hearing aid purchase status, and use of SUPR). Any exchanged data and personal
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30 603 information will be password protected.

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35 605 VU University Medical Center has all property rights on the final results of the trial and is entitled to
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37 606 publish the results. The funder is not entitled to publish the results without written consent of the
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39 607 VU University Medical Center. These agreements are secured in a contract. For specific author
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41 608 contributions for the current paper, see 'Authors contributions'.

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46 610 Findings of the study will be published in scientific journals and presented at scientific conferences,
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48 611 and will be communicated within the national and international media. A short report of the study
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50 612 findings will be sent to interested participants. The results will be communicated within the hearing
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52 613 aid dispenser company.

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57 615 **Data collection forms and data storage**

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3 616 Data collection forms and procedures for data management are available on request. All data will be
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5 617 collected digitally and will be stored on a computer disk at the VU University Medical Center which is
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7 618 locked with a security code only available to members of the SUPR research team. According to Good
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9 619 Clinical Practice guidelines and after having received informed consent, data will be archived for a
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11 620 period of fifteen years after finalizing the study. After finalization, the key file (connecting participant
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13 621 numbers to the names and contact details of the participant) will be destroyed once it is expected
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15 622 that participants do not need to be approached further for the purposes of the study. We will
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17 623 perform double data entry of a selection of the audiograms and the baseline AIADH data for quality
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19 624 purposes.
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24 626 **Monitoring**

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26 627 The study is subjected to local regulations and its quality is monitored by the research institutes (i.e.,
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28 628 EMGO⁺) Quality Committee. This committee is responsible for developing, implementing, and
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30 629 maintaining a system for quality assurance and control for all research within the institute. Due to
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32 630 the decision of the Dutch Institutional Review Board (IRB) of the VU Medical University Center
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34 631 Amsterdam that the study does not fall under the Research Involving Human Subjects Act (WMO),
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36 632 the formation of a Clinical Trial Data Monitoring Committee was not deemed necessary.
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41 634 **DISCUSSION**

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43 635 Like in most parts in the world, usual care for adults with hearing impairment in the Netherlands is
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45 636 mostly restricted to audiological assessment and hearing aid fitting. This type of care is in the large
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47 637 part provided by commercial hearing aid dispensers. Communication programmes aimed at
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49 638 improving the use of favourable communication strategies, increasing personal adjustment to
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51 639 hearing impairment, and improving hearing aid handling skills are not provided on a large scale in
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53 640 standard hearing health care settings. This is undesirable, as there is a growing body of evidence
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55 641 showing that offering such programmes can effectively decrease communication problems and
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3 642 associated negative health outcomes[27, 33, 38, 42]. Likewise, despite the fact that including CPs in
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5 643 the rehabilitation process is increasingly recognized within audiology as a prerequisite for successful
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7 644 rehabilitation[12], CPs are not yet part of standard hearing health care. In the current study, these
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9 645 elements (i.e., a communication programme and involvement of a CP) are part of a programme
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11 646 called SUPR that is incorporated in regular hearing aid dispensing care and that will be tested for its
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13 647 effectiveness. SUPR's primary aims are to improve older hearing aid owners' communication
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15 648 strategies and personal adjustment and decrease their CPs' third-party disability. To our knowledge,
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17 649 similar online support programmes for HAUAs that are implemented on a large scale in hearing aid
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19 650 dispenser settings are not yet available.
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24 652 A strength of the SUPR programme is that for those who are at risk for isolation or those who have
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26 653 reduced access to health care, the internet can be a practical tool providing direct access to health
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28 654 services[63]. Other elements that can add to the effectiveness of online support programmes as
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30 655 SUPR are that it can (partly or mainly) be provided in a visual mode (images, written text, subtitles),
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32 656 the volume can be controlled, background noises can be relatively easily eliminated, and online
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34 657 support programmes provide the opportunity to tailor intervention elements.
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39 659 A few limitations to the design need to be considered. Unfortunately it is not possible to perform a
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41 660 double-blinded, randomised, controlled trial due to the nature of the intervention study. Blinding of
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43 661 the participants is not possible as they will be informed about the general aim of the SUPR study (i.e.
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45 662 to evaluate a support programme) and know that they are either part of the group that receives CaU
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47 663 or SUPR. Nevertheless, we will attempt to minimize the provision of information on the content of
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49 664 SUPR to participants of the CaU group. The participants only know that SUPR is a support programme
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51 665 aimed to 'improve communication', but for instance do not know what the intervention further
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53 666 entails. This way, we aimed to prevent that they would independently seek access to SUPR (which
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55 667 would cause contamination) and that their knowledge of the care they were missing out on would
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3 668 affect their responses in the questionnaires. We further attempted to prevent contamination by
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5 669 offering the programme to the CaU-participants for free after completing the study. Blinding the
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7 670 researchers during the effect analysis is also not possible as the IOI measure that is administered on
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9 671 T1, T2, and T3 indicates in what group each participant was randomised (IOI-HA only: CaU group; IOI-
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11 672 AI: intervention group).

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17 674 SUPR is an online intervention, it is thus essential that people have access to a device with internet
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19 675 access and an email account. Participants who have access to the internet will most likely be of high
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21 676 SES and this might bias the data. The fact that the support programme as such reaches a selective
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23 677 part of the dispenser's clientele requires further discussion. Consistent with findings from Choi *et al*
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25 678 and Fox *et al* who compared non-internet users and users, it is possible that the older people
26
27 679 participating in the SUPR study generally have a somewhat higher socioeconomic status and are
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29 680 somewhat younger than the average clientele of the dispenser[64, 65]. With regard to age however,
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31 681 it should be noted amongst the young-old the weekly internet use has increased from 70% in 2010 to
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33 682 83% in 2015 in the Netherlands and will most probably keep rising in the future[66]. This suggests
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35 683 that the large majority of the younger-old can currently already be reached with SUPR and this will
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37 684 improve even more in the future. The non-use of internet among the older olds (74+) currently still is
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39 685 substantial, although this proportion also has decreased strongly in the past few years (66% in 2012
40
41 686 to 50% in 2015[67]). Furthermore, it is encouraging that older internet users, generally use it more
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43 687 for health-related tasks or information than for personal tasks[68]. In addition, people with hearing
44
45 688 loss are more likely to use the internet than people in the general population (OR=1.74, 95% CI 1.23-
46
47 689 3.17)[69]. Baring these developments in mind, we are confident that the large majority of the older
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49 690 HAs who can potentially benefit from SUPR will be increasingly eligible and open to using SUPR to
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51 691 improve their hearing health.

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3 693 At the start of the study, participants might downplay their hearing problems because hearing loss
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5 694 stigma causes them to be reluctant to acknowledge or recognize their hearing problems[70]. We
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7 695 expect that SUPR will have a positive effect on acceptance of hearing loss, and therefore people may
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9 696 report a disability level that is 'more honest'. This may hold particularly for the first-time HAUs who
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11 697 have never gone through an intensive rehabilitation trajectory before and less so for the experienced
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13 698 users. As such, it is possible that this mechanism will cause an increase in self-reported hearing
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15 699 disability in the intervention group over time. This would counteract the favourable effect that SUPR
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17 700 is expected to create, i.e., a decrease in experienced disability. To examine whether the first-
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19 701 mentioned mechanism would apply, one of the subscales of the CPHI on acceptance of hearing loss
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21 702 can be used[48]. With this subscale we can examine if acceptance is a mediator between time and
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23 703 hearing status for the intervention group.
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29 705 This study aims to perform a process evaluation, as is strongly recommended in all randomised
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31 706 controlled trial research. A process evaluation provides insight into reasons for the demonstrated
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33 707 (absence of) effectiveness of the intervention and might offer information concerning the
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35 708 generalizability of the study results. When no or only small significant effects of SUPR will be found,
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37 709 we may be able to modify the programme based on the results of the process evaluation after the
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39 710 study.
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44 712 In the future, it is expected that there will be an increasing demand in solutions for hearing health
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46 713 conditions due to the ageing population and thus increased prevalence of hearing problems. SUPR is
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48 714 especially developed for use on a large scale basis in HAD practices. The large number of practices
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50 715 that are involved in the study not only contributes to a large sample size (and statistical power), it
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52 716 also reflects real world clinical practice. This will potentially make a strong case for the extrapolation
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54 717 of the study's results. Demonstrating the programmes effectiveness would be a great step forward
55
56 718 improving health care services for people with hearing impairment.
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5 720 **ACKNOWLEDGEMENTS**6
7 721 We would like to acknowledge Schoonenberg Hoorcomfort (AudioNova International) for their
8
9 722 contribution to the development of the SUPR study design and the writing of this paper.10
11 72312
13 724 **FOOTNOTES**14
15 725 **Contributors**16
17 726 SEK developed the first version of the study design in collaboration with BP and VJ. MP and SK
18
19 727 developed the study design further and wrote up the first draft of the study protocol. BvdW, JFJM,
20
21 728 MP, SEK, and VJ worked on the design further and facilitated the practical implementation of the
22
23 729 study. BIW provided statistical and methodological advice. Data collection will be done by BvdW and
24
25 730 JFJM, assisted by VJ, and supervised by SEK and MP. JFJM wrote the final version of the manuscript.
26
27 731 SEK and MP supervised the writing process and MP, SEK, BP, BIW, VJ, and BvdW gave critical
28
29 732 comments on several drafts of the manuscript.
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31 73332
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35 735 The SUPR study is funded by Audionova International and is sponsored by the VU University Medical
36
37 736 Centre. Audionova International will have no role in the data analysis and/or the interpretation of
38
39 737 the data.
40
41 73842
43 739 **Competing interests**44
45 740 VJ is an employee at Schoonenberg Hoorcomfort. BP is an employee at AudioNova International.
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47 74148
49 742 **Ethics approval and consent to participate**50
51 743 Written consent for the SUPR study (reference number: 2015.335) was obtained from the Dutch
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53 744 Institutional Review Board (IRB) of the VU Medical University Center Amsterdam (registered with the
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3 745 US Office for Human Research Protections as IRB00002991; FWA number: FWA00017598). The IRB
4
5 746 concluded that Medical Research Involving Human Subjects ACT (WMO) does not apply to this study.
6
7 747 Participants' consent will be obtained via the registration website of the study. At this website
8
9 748 participants were asked to declare that they were sufficiently informed about the study and agreed
10
11 749 on the use of certain data to be collected for the purposes of the study.
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15 16 751 **Abbreviations**

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18 752 SUPR: SUpport PRogramme, CaU: care as usual, CP: communication partner, HAU: hearing aid users,
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20 753 HAD practices: hearing aid dispensing practices, AIADH: Amsterdam Inventory for Auditory Disability
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22 754 and Handicap, CPHI: Communication Profile for the Hearing Impaired, MARS-HA: Measure of
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24 755 Audiologic Rehabilitation Self-Efficacy for Hearing Aids, IOI-HA: International Outcome Inventory –
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26 756 Hearing Aids, IOI-AI: International Outcome Inventory – Alternative Interventions, URICA: University
27
28 757 of Rhode Island Change Assessment for Hearing health behaviour, HHDI: Hearing Handicap and
29
30 758 Disability Inventory, SOS-HEAR: Significant Other Scale for Hearing Disability, IOI-HA-SO: International
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32 759 Outcome Inventory Significant Other – Hearing Aids, IOI-AI-SO: International Outcome Inventory
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34 760 Significant Other – Alternative Interventions.
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38 39 762 **REFERENCES**

- 40
41 763 1. Vos T, Barber RM, Bell B, et al. Global, regional, and national incidence, prevalence, and years
42
43 764 lived with disability for 301 acute and chronic diseases and injuries in 188 countries, 1990-2013:
44
45 765 a systematic analysis for the Global Burden of Disease Study 2013. *Lancet* 2015;386:743-800. doi:
46
47 766 10.1016/S0140-6736(15)60692-4
48
49
50 767 2. United Nations, Department of Economic and Social Affairs, Population Division. World
51
52 768 population ageing 2015. New York: United Nations 2015.
53
54
55 769 3. Weinstein BE, Sirow LW, Moser S. Relating hearing aid use to social and emotional loneliness in
56
57 770 older adults. *Am J Audiol* 2016;25:54-61. doi: 10.1044/2015_AJA-15-0055
58
59
60

- 1
2
3 771 4. Pronk M, Deeg DJ, Smits C, et al. Prospective effects of hearing status on loneliness and
4
5 772 depression in older persons: Identification of subgroups. *Int J Audiol* 2011;50:887-96. doi:
6
7 773 10.3109/14992027.2011.599871
8
9 774 5. Strawbridge WJ, Wallhagen MI, Shema SJ, et al. Negative consequences of hearing impairment in
10
11 775 old age: A longitudinal analysis. *Gerontologist* 2000;40:320-6. doi: 10.1093/geront/40.3.320
12
13 776 6. Nachtegaal J, Smit JH, Smits C, et al. The association between hearing status and psychosocial
14
15 777 health before the age of 70 years: results from an internet-based national survey on hearing. *Ear*
16
17 778 *Hear* 2009;30:302-12. doi: 10.1097/AUD.0b013e31819c6e01
18
19 779 7. Saito H, Nishiwaki Y, Michikawa T, et al. Hearing handicap predicts the development of
20
21 780 depressive symptoms after 3 Years in older community-dwelling Japanese. *J Am Geriatr*
22
23 781 2010;58:93-7. doi: 10.1111/j.1532-5415.2009.02615.x
24
25 782 8. Nachtegaal J, Festen JM, Kramer SE. Hearing ability in working life and its relationship with sick
26
27 783 leave and self-reported work productivity. *Ear Hear* 2012;33:94-103. doi:
28
29 784 10.1097/AUD.0b013e318228033e
30
31 785 9. Lin FR, Yaffe K, Xia J, et al. Hearing loss and cognitive decline in older adults. *JAMA Intern Med*
32
33 786 2013;173:293-9. doi: 10.1001/jamainternmed.2013.1868
34
35 787 10. Jiam NT, Li C, and Agrawal Y. Hearing loss and falls: A systematic review and meta-analysis.
36
37 788 *Laryngoscope* 2016;126:2587-96.
38
39 789 11. World Health Organization. International Classification of Functioning, Disability and Health.
40
41 790 Geneva: World Health Organization 2001.
42
43 791 12. Scarinci N, Worrall L, Hickson L. The effect of hearing impairment in older people on the spouse:
44
45 792 development and psychometric testing of the significant other scale for hearing disability (SOS-
46
47 793 HEAR). *Int J Audiol* 2009;48:671-83. doi: 10.1080/14992020902998409
48
49 794 13. Kamil RJ, Lin FR. The effects of hearing impairment in older adults on CPs: a systematic review. *J*
50
51 795 *Am Acad Audiol* 2015;26:155-82. doi: 10.3766/jaaa.26.2.6
52
53
54
55
56
57
58
59
60

- 1
2
3 796 14. Jennings MB, Shaw L. Impact of hearing loss in the workplace: raising questions about
4
5 797 partnerships with professionals. *Work* 2008;30:289-95.
6
7 798 15. Chisolm TH, Johnson CE, Danhauer JL, et al. A systematic review of health-related quality of life
8
9 799 and hearing aids: final report of the American Academy of Audiology Task Force On the Health-
10
11 800 Related Quality of Life Benefits of Amplification in Adults. *J Am Acad Audiol* 2007;18:151-83.
12
13 801 16. Mulrow CD, Tuley MR, Aguilar C. Sustained benefits of hearing aids. *J Speech Hear Res.*
14
15 802 1992;35:1402-5. doi:10.1044/jshr.3506.1402
16
17 803 17. Acar B, Yurekli MF, Babademez MA, et al. Effects of hearing aids on cognitive functions and
18
19 804 depressive signs in elderly people. *Arch Gerontol Geriatr* 2011;52:250-2. doi:
20
21 805 10.1016/j.archger.2010.04.013
22
23 806 18. Amieva H, Ouvrard C, Giulioli C, et al. Self-reported hearing loss, hearing aids, and cognitive
24
25 807 decline in elderly adults: A 25-Year study. *J Am Geriatr Soc* 2015;63:2099-104. doi:
26
27 808 10.1111/jgs.13649
28
29 809 19. Chia EM, Wang JJ, Rochtchina E, et al. Hearing impairment and health-related quality of life: the
30
31 810 Blue Mountains Hearing Study. *Ear Hear* 2007;28:187-95. doi: 10.1097/AUD.0b013e31803126b6
32
33 811 20. Hartley D, Rochtchina E, Newall P, et al. Use of hearing aids and assistive listening devices in an
34
35 812 older Australian population. *J Am Acad Audiol* 2010;21:642-53. doi: 10.3766/jaaa.21.10.4.
36
37 813 21. Smits C, Kramer SE, Houtgast T. Speech reception thresholds in noise and self-reported hearing
38
39 814 disability in a general adult population. *Ear Hear* 2006;27:538-49. doi:
40
41 815 10.1097/01.aud.0000233917.72551.cf
42
43 816 22. Gates GA, Cooper JC Jr, Kannel WB et al. Hearing in the Elderly: The Framingham Cohort, 1983-
44
45 817 1985: Part 1. Basic Audiometric Test Results. *Ear Hear* 1990;11:247-56.
46
47 818 23. Abrams HB, Kihm J. An introduction to MarkeTrak IX: A New Baseline for the Hearing Aid Market.
48
49 819 *Hearing Review* 2015;22:16.
50
51
52
53
54
55
56
57
58
59
60

- 1
2
3 820 24. Knudsen LV, Oberg M, Nielsen C, et al. Factors influencing help seeking, hearing aid uptake,
4
5 821 hearing aid use and satisfaction with hearing aids: A review of the literature. *Trends Amplif*
6
7 822 2010;14:127-54. doi: 10.1177/1084713810385712
8
9 823 25. Meyer C, Hickson L. What factors influence help-seeking for hearing impairment and hearing aid
10
11 824 adoption in older adults? *Int J Audiol* 2012;51:66-74. doi: 10.3109/14992027.2011.611178
12
13 825 26. McCormack A, Fortnum H. Why do people fitted with hearing aids not wear them? *Int J Audiol*
14
15 826 2013;52:360-8. doi: 10.3109/14992027.2013.769066
16
17 827 27. Boothroyd A. Adult aural rehabilitation: What is it and does it work? *Trends Amplif* 2007;11:63-
18
19 828 71. doi: 10.1177/1084713807301073
20
21 829 28. Hickson L, Scarinci N. Older adults with acquired hearing impairment: applying the ICF in
22
23 830 rehabilitation. *Semin Speech Lang* 2007;28:283-90. doi: 10.1055/s-2007-986525
24
25 831 29. Granberg S, Swanepoel de W, Englund U, et al. The ICF core sets for hearing loss project:
26
27 832 International expert survey on functioning and disability of adults with hearing loss using the
28
29 833 international classification of functioning, disability, and health (ICF). *Int J Audiol* 2014; 53:497-
30
31 834 506. doi: 10.3109/14992027.2014.900196
32
33 835 30. Granberg S, Pronk M, Swanepoel de W, et al. The ICF core sets for hearing loss project:
34
35 836 Functioning and disability from the patient perspective. *Int J Audiol* 2014;53:777-86. doi:
36
37 837 10.3109/14992027.2014.938370
38
39 838 31. Gagné JP, Jennings MB. Audiologic rehabilitation intervention services for adults with acquired
40
41 839 hearing impairment. In: Valente M, Hosford-Dunn H, Roeser RJ, eds. *Audiology: Treatment*. New
42
43 840 York: Thieme Medical Publishers 2008:370-99.
44
45 841 32. Laplante-Lévesque A, Hickson L, Worrall L. Factors influencing rehabilitation decisions of adults
46
47 842 with acquired hearing impairment. *Int J Audiol* 2010;49:497-507. doi:
48
49 843 10.3109/14992021003645902
50
51 844 33. Kiessling J, Pichora-Fuller MK, Gatehouse S, et al. Candidature for and delivery of audiological
52
53 845 services: Special needs of older people. *Int J Audiol* 2003;42 Suppl 2S92-101.
54
55
56
57
58
59
60

- 1
2
3 846 34. Barker F, Mackenzie E, Elliott L, et al. Interventions to improve hearing aid use in adult auditory
4
5 847 rehabilitation. *Cochrane Database Syst Rev* 2016;8 doi: 10.1002/14651858.CD010342.pub3.
6
7 848 35. Sweetow R, Palmer CV. Efficacy of individual auditory training in adults: A systematic review of
8
9 849 the evidence. *J Am Acad Audiol* 2005;16:494-504.
10
11 850 36. Wong L, Hickson L. Evidence-based practice in audiology: Evaluating interventions for children
12
13 851 and adults with hearing impairment. San Diego, CA: Plural Publishing 2012.
14
15 852 37. Kramer SE, Allessie GH, Dondorp AW et al. A home education program for older adults with
16
17 853 hearing impairment and their significant others: A randomized trial evaluating short- and long-
18
19 854 term effects. *Int J Audiol* 2005;44:255-64.
20
21 855 38. Hickson L, Worrall L, Scarinci N. A randomized controlled trial evaluating the active
22
23 856 communication education program for older people with hearing impairment. *Ear Hear*
24
25 857 2007;28:212-30. doi: 10.1097/AUD.0b013e31803126c8
26
27 858 39. Hickson L. Defining a paradigm shift. *Semin Hear* 2012;33:3-8. doi: 10.1055/s-0032-1304722
28
29 859 40. Lusic I, Mason P. Paradigm shift: The new world of hearing health care delivery. *ASHA Lead*
30
31 860 2012;17:36-7. doi:10.1044/leader.FTR2.17092012.36
32
33 861 41. Tognola G, Paglialonga A, Chiaramello E, et al. eHealth for hearing—new views and apps
34
35 862 practicalities. *EJBI* 2015;11:37-49.
36
37 863 42. Thorén ES, Öberg M, Wänström G, et al. A randomized controlled trial evaluating the effects of
38
39 864 online rehabilitative intervention for adult hearing-aid users. *Int J Audiol* 2014;53:452-61. doi:
40
41 865 10.3109/14992027.2014.892643
42
43 866 43. Thorén E, Svensson M, Törnqvist A, et al. Rehabilitative online education versus internet
44
45 867 discussion group for hearing aid users: a randomized controlled trial. *J Am Acad Audiol*
46
47 868 2011;22:274-85. doi: 10.3766/jaaa.22.5.4.
48
49 869 44. Ferguson M, Brandreth M, Brassington W, et al. A randomized controlled trial to evaluate the
50
51 870 benefits of a multimedia educational program for first-time hearing aid users. *Ear Hear*
52
53 871 2016;37:123-36. doi: 10.1097/AUD.0000000000000237
54
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3 872 45. Kramer SE, Kapteyn TS, Festen JM, et al. Factors in subjective hearing disability. *Audiology*
4
5 873 1995;34:311-20.
6
7 874 46. Caposecco A, Hickson L, Meyer C. Assembly and insertion of a self-fitting hearing aid: Design of
8
9 875 effective instruction materials. *Trends Amplif* 2011;15:184-95. doi: 10.1177/1084713811430837
10
11 876 47. Chan AW, Tetzlaff JM, Altman DG, et al. SPIRIT 2013 Statement: Defining standard protocol items
12
13 877 for clinical trials. *Ann Intern Med* 2013;158:200-7. doi: 10.7326/0003-4819-158-3-201302050-
14
15 878 00583.
16
17
18 879 48. Demorest ME, Erdman SA. Development of the communication profile for the hearing impaired.
19
20 880 *J Speech Hear Disord* 1987;52:129-43. doi:10.1044/jshd.5202.129
21
22 881 49. Mokkink LB, Knol DL, van Nispen RM, et al. Improving the quality and applicability of the Dutch
23
24 882 scales of the Communication Profile for the Hearing Impaired using item response theory. *J*
25
26 883 *Speech Lang Hear Res* 2010;53:556-71. doi: 10.1044/1092-4388(2010/09-0035)
27
28
29 884 50. West RL, Smith SL. Development of a hearing aid self-efficacy questionnaire. *Int J Audiol*
30
31 885 2007;46:759-71. doi: 10.1080/14992020701545898
32
33 886 51. Beaton DE, Bombardier C, Guillemin F, et al. Guidelines for the process of Cross-Cultural
34
35 887 Adaption of Self-Report Measures. *Spine* 2000;25:3186-91.
36
37 888 52. Kozlowski L, Almeida G, Ribas A. Level of user satisfaction with hearing AIDS and environment:
38
39 889 the international outcome inventory for hearing AIDS. *Int Arch Otorhinolaryngol* 2014;18:229-34.
40
41 890 doi: 10.1055/s-0033-1363782
42
43
44 891 53. Laplante-Lévesque A, Nielsen C, Jensen LD, et al. Patterns of hearing aid usage predict hearing aid
45
46 892 use amount (data logged and self-reported) and overreport. *J Am Acad Audiol* 2014;25:187-98.
47
48 893 doi: 10.3766/jaaa.25.2.7
49
50 894 54. Kramer SE, Goverts ST, Dreschler WA, et al. International Outcome Inventory for Hearing Aids
51
52 895 (IOI-HA): results from The Netherlands. *Int J Audiol* 2002;41:36-41. doi:
53
54 896 10.3109/14992020209101310
55
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2
3 897 55. Meijer AG, Wit HP, TenVergert EM, et al. Reliability and validity of the (modified) Amsterdam
4
5 898 Inventory for Auditory Disability and Handicap. *Int J Audiol* 2003;42:220-6. doi: 10.1111/j.1365-
6
7 899 2273.2004.00844
- 8
9 900 56. Laplante-Lévesque A, Hickson L, Worrall L. Stages of change in adults with acquired hearing
10
11 901 impairment seeking help for the first time: application of the transtheoretical model in audiologic
12
13 902 rehabilitation. *Ear Hear* 2013;34:447-57. doi: 10.1097/AUD.0b013e3182772c49
- 14
15 903 57. van den Brink RHS. Attitude and illness behavior in hearing impaired elderly (Unpublished
16
17 904 doctoral thesis). Rijks University of Groningen 1995.
- 18
19 905 58. Noble W. Extending the IOI to significant others and to nonhearing aid-based interventions. *Int J*
20
21 906 *Audiol* 2002;41:27-9. doi: 10.3109/14992020209101308
- 22
23 907 59. Demorest ME, Erdman SA. Retest stability of the communication profile for the hearing
24
25 908 impaired. *Ear Hear* 1988;9:237-42. doi: 10.1097/00003446-198810000-00002
- 26
27 909 60. Moher D, Hopewell S, Schulz KF, et al. CONSORT 2010 Explanation and elaboration: updated
28
29 910 guidelines for reporting parallel group randomised trials. *BMJ* 2010;340:c869.
30
31 911 doi:10.1136/bmj.c869
- 32
33 912 61. Linnan L, Steckler A. Process evaluation for public health interventions and research. 1st ed. San
34
35 913 Francisco CA: Jossey-Bass 2002.
- 36
37 914 62. Gussenhoven AH, Singh AS, Goverts ST, et al. A process evaluation of implementing a vocational
38
39 915 enablement protocol for employees with hearing difficulties in clinical practice. *Int J Audiol*
40
41 916 2015;54:507-17. doi: 10.3109/14992027.2015.1009642
- 42
43 917 63. Swanepoel dW, Hall JW, III. A systematic review of telehealth applications in audiology. *Telemed J*
44
45 918 *E Healt* 2010;16:181-200. doi: 10.1089/tmj.2009.0111
- 46
47 919 64. Choi NG, DiNitto DM. Internet use among older adults: association with health needs,
48
49 920 psychological capital, and social capital. *J Med Internet Res* 2013;15:e97. doi: 10.2196/jmir.2333
- 50
51 921 65. Fox S. Digital Divisions. PEW Internet & American Life Project. Washington, DC 2005.
- 52
53 922 66. UNECE Statistical Database. 2015. <http://w3.unece.org/PXWeb/en>. Accessed 20 June 2016
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3 923 67. Centraal Bureau voor Statistiek (CBS). 2016. <https://www.cbs.nl/nl-nl/nieuws/2016/22/acht->
4
5 924 [procent-van-de-nederlanders-nooit-op-internet](#). Accessed 26 Sep 2016.
6
7 925 68. Gell NM, Rosenberg DE, Demiris G et al. Patterns of technology use among older adults with and
8
9 926 without disabilities. *Gerontologist* 2015;55:412-21. doi: 10.1093/geront/gnt166
10
11 927 69. Thorén ES, Öberg M, Wänström G, et al. Internet access and use in adults with hearing loss. *J*
12
13 928 *Med Internet Res* 2013;15:e91. doi: 10.2196/jmir.2221
14
15 929 70. Martin KA, Leary MR, Rejeski WJ. Self-presentational concerns in older adults: Implications for
16
17 930 health and well-being. *Basic Appl Soc Psych* 2000;22:169-79. doi:
18
19 931 10.1207/S15324834BASP2203_5
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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.

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- 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).

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Heeft u een communicatiepartner gekozen voor HoorSupport/het onderzoek?

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- 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						

1					
2					
3	Gender				x
4					
5					
6					
7	Age				x
8					
9					
10					
11	Marital status				x
12					
13					
14					
15	Living situation				x
16					
17					
18					
19	Level of				x
20	education				
21					
22					
23					
24					
25	Occupational				x
26	status				
27					
28					
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31					
32	Country of birth				x
33	participant				
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37					
38	Country of birth				x
39	participant's				
40	parents				
41					
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47	Primary				
48	outcome				
49	measure HAU's				
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55	The use of	CPHI			
56	communication		x	x	x
57	strategies and				x
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personal

adjustment

Secondary

outcome

measures –

HAUs

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

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

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3 disability

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7 Self-reported IOI-HA-SO/IOI-

x

x

x

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9 intervention AI-SO

10 outcomes from

11 the perspective

12 of the CP

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17 Abbreviations: HAD practice: hearing aid dispensing practice, SUPR: Support PRogramme, HAU:
18 hearing aid user, CPHI: Communication Profile for the Hearing Impaired, MARS-HA: Measure of
19 Audiologic Rehabilitation Self-Efficacy for Hearing Aids, IOI-HA: International Outcome Inventory –
20 Hearing Aids, IOI-AI: International Outcome Inventory – Alternative Interventions, AIADH:
21 Amsterdam Inventory for Auditory Disability and Handicap, URICA: University of Rhode Island Change
22 Assessment- for Hearing health behaviour, HHDI: Hearing Handicap and Disability Inventory, CP:
23 Communication Partner, SOS-HEAR: Significant Other Scale for Hearing Disability, IOI-HA-SO:
24 International Outcome Inventory Significant Other– Hearing Aids, IOI-AI-SO: International Outcome
25 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	1-32
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

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2				
3	Introduction			
4				
5	Background and	6a	Description of research question and justification for undertaking the trial, including summary of relevant	3-8
6	rationale		studies (published and unpublished) examining benefits and harms for each intervention	
7				
8		6b	Explanation for choice of comparators	3-8
9				
10	Objectives	7	Specific objectives or hypotheses	8
11				
12	Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group),	
13			allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	9
14				
15				
16	Methods: Participants, interventions, and outcomes			
17				
18	Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will	8-12
19			be collected. Reference to where list of study sites can be obtained	
20				
21	Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and	14
22			individuals who will perform the interventions (eg, surgeons, psychotherapists)	
23				
24	Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be	8-11
25			administered	
26				
27		11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose	N/A
28			change in response to harms, participant request, or improving/worsening disease)	
29				
30		11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence	12, 13, 27
31			(eg, drug tablet return, laboratory tests)	
32				
33		11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	12,13
34				
35	Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood	19-23
36			pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg,	
37			median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen	
38			efficacy and harm outcomes is strongly recommended	
39				
40	Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for	12,13, 15-19
41			participants. A schematic diagram is highly recommended (see Figure)	
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3 Sample size 14 Estimated number of participants needed to achieve study objectives and how it was determined, including 24, 25
4 clinical and statistical assumptions supporting any sample size calculations

5
6 Recruitment 15 Strategies for achieving adequate participant enrolment to reach target sample size 13
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8 **Methods: Assignment of interventions (for controlled trials)**
9

10 Allocation:

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12 Sequence generation 16a Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any 24
13 factors for stratification. To reduce predictability of a random sequence, details of any planned restriction
14 (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants
15 or assign interventions
16

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18 Allocation concealment mechanism 16b Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, 20
19 opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned
20
21

22 Implementation 16c Who will generate the allocation sequence, who will enrol participants, and who will assign participants to 9, 24
23 interventions
24

25 Blinding (masking) 17a Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome 30, 31
26 assessors, data analysts), and how
27

28 17b If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's N/A
29 allocated intervention during the trial
30
31

32 **Methods: Data collection, management, and analysis**
33

34 Data collection methods 18a Plans for assessment and collection of outcome, baseline, and other trial data, including any related 15-23
35 processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of
36 study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known.
37 Reference to where data collection forms can be found, if not in the protocol
38

39 18b Plans to promote participant retention and complete follow-up, including list of any outcome data to be 13, 25
40 collected for participants who discontinue or deviate from intervention protocols
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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



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2				
3	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
4				
5				
6		26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
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9	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
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12	Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	33
13				
14				
15	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
16				
17				
18	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
19				
20				
21	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
22				
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24				
25				
26		31b	Authorship eligibility guidelines and any intended use of professional writers	28, 33
27				
28		31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	N/A
29				
30	Appendices			
31				
32	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)
33				
34				
35				
36	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.
37				
38				

*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](https://creativecommons.org/licenses/by-nc-nd/3.0/)" 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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3 1 **Effectiveness of an online SUpport PRogramme (SUPR) for older hearing aid users: Study protocol**
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5 2 **for a cluster randomised controlled trial**

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3 27 **ABSTRACT**
4

5 28 **Background:** An educational Support Programme called SUPR has been developed for hearing aid
6
7 29 users (HAUs) and their communication partners (CPs) offering care beyond hearing aid fitting. SUPR
8
9 30 teaches its users communication strategies, hearing aid handling skills, and personal adjustment to
10
11 31 hearing impairment.
12

13 32 **Methods/design:** Using a cluster randomised controlled trial-design, 70 Dutch hearing aid dispenser
14
15 33 practices were randomised into hearing aid fitting (care as usual, 34 practices) and hearing aid fitting
16
17 34 including SUPR (36 practices). The aim was to recruit a total of 569 older (aged 50+) first-time
18
19 35 (n=258) and experienced (n=311) HAUs and their CPs. SUPR consists of a Practical Support Booklet
20
21 36 and online material offered via email over a period of 6-7 months. The booklet provides practical
22
23 37 information on hearing aids, advice on communication strategies, and home exercises. The online
24
25 38 material consists of educational videos on hearing aid functionality and usage, communication
26
27 39 strategies, and peer testimonials. Finally, noncommittal email contact with the dispenser is offered.
28
29 40 Every HAU is asked to assign a CP who is advised to be involved intensively. Effect measurements for
30
31 41 HAUs and their CPs will occur at baseline and at 6, 12, and 18-months follow-up via online
32
33 42 questionnaires. The primary outcomes for HAUs will be the use of communication strategies as
34
35 43 measured by the subscales of the Communication Profile for the Hearing Impaired. A process
36
37 44 evaluation will be performed.
38
39

40 45 **Ethics and dissemination:** The study was approved by the Dutch Institutional Review Board (IRB) of
41
42 46 the VU Medical University Center Amsterdam. This intervention could contribute to lowering the
43
44 47 hearing impairment burden in our ageing society. The results will be disseminated through peer-
45
46 48 reviewed publications and scientific conferences.
47
48

49 49 **Trial registration:** ISRCTN77340339; Pre-Results.
50

51 50 **Keywords:** Hearing loss, communication strategies, personal adjustment to hearing impairment,
52
53 51 intervention, cluster randomised controlled trial, hearing aids, communication, internet.
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3 53 **STRENGTHS AND LIMITATIONS**
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5 54 - This is the first study to evaluate the effects of an online educational Support Programme (SUPR)
6
7 55 for hearing aid users that is implemented in a hearing aid dispensing (HAD) practice setting on a large
8
9 56 scale.

10
11 57 - Hearing-impaired participants and their communication partners (CPs) originating from 70 HAD
12
13 58 practices located all across the Netherlands will be included.

14
15 59 - The online nature of the programme suits the current and future developments in the increasing
16
17 60 internet use among the young-old (55-74) and can reach out to those with reduced (physical) access
18
19 61 to health care.

20
21 62 - The online nature might however reach a selective sample, especially among the oldest old (75+),
22
23 63 who are willing or able to adopt the intervention (i.e., only those with access to and willing to use the
24
25 64 internet for this purpose).

26
27 65 - The study design does not allow the blinding of participants and researchers for intervention
28
29 66 allocation. This could potentially lead to performance bias.

30
31 67 - The findings of the study will potentially contribute to improvement of hearing health care services
32
33 68 for hearing-impaired people and their CPs.

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39 70 **BACKGROUND**
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41 71 Hearing impairment is one of the most prevalent chronic health conditions affecting older adults. It
42
43 72 was ranked fifth in the top 25 of global causes for years lived with disability in 2013[1]. Due to the
44
45 73 overall aging of the population[2], the prevalence of hearing impairment is increasing rapidly,
46
47 74 imposing a great burden on individuals and society.

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51
52 76 Hearing impairment essentially leads to the inability to communicate effectively which in turn can
53
54 77 result in a cascade of effects leading to poor psychosocial outcomes such as loneliness[3-5],
55
56 78 distress[6], depression[6, 7], and work-related fatigue[8]. It has also been associated with
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3 79 accelerated cognitive decline[9] and falls[10]. The limitations on daily life activities and restrictions in
4
5 80 social and societal participation that people experience depend on aspects that are both internal
6
7 81 (such as age and applied coping styles) and external (such as availability of hearing aids, care
8
9 82 facilities, and social support) to the person[11]. In addition, the level of impairment in hearing
10
11 83 functions and structures is an important factor which can influence psychosocial outcomes[11].
12

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15
16 85 Partners and spouses can also be negatively affected by the hearing impairment of their loved ones.
17
18 86 They generally experience frustration and embarrassment, for example in challenging social
19
20 87 communication settings[12]. Communication difficulties in background noise, the partner's frequent
21
22 88 request to repeat, and the need to act as an interpreter may cause irritation and tension within a
23
24 89 relationship[12]. In a systematic review conducted by Kamil *et al* it was found that communication
25
26 90 partners (CPs, i.e. spouses, partners, close family members, neighbours, or caregivers) of people with
27
28 91 hearing impairment experience decreased social functioning, poorer quality of life, and more
29
30 92 participation restrictions than CPs of normally hearing individuals[13].
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35 94 The usual care provided for people with hearing impairment is often restricted to the assessment of
36
37 95 hearing loss and the fitting of hearing aids[14]. Hearing aid use has positive effects on quality of life,
38
39 96 social and emotional wellbeing, and may reduce depressive complaints[15-17], and possibly even
40
41 97 cognitive decline[18]. Despite this abundant evidence on positive health effects, the uptake and use
42
43 98 of hearing aids is low. It is estimated that around one third of the adults who would benefit from
44
45 99 hearing aids own them[19-21] and 3-20% of these owners never use them[22,23]. Reasons for low
46
47
48 100 uptake and use have been investigated and include low perceived need of amplification reflected in
49
50 101 low self-reported hearing disability[24-26], limited acceptance of hearing loss[24], low expectations
51
52 102 of hearing aid benefits[24, 25], limited gain in noisy situations[25, 26], and low overall sound
53
54 103 quality[26]. Other perceived barriers include stigma[25, 26], high monetary costs[26], and the need
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3 104 for regular hearing aid care and maintenance[26]. Finally, lack of social support or social pressure to
4
5 105 get a hearing aid are factors having a negative impact on hearing aid use[25, 26].
6
7 106

8
9 107 Given this broad spectrum of factors affecting hearing aid uptake and use, it has often been argued
10
11 108 that hearing health care should not be restricted to the provision of hearing aids alone, but cover
12
13 109 more than that to improve hearing aid success, everyday communication, and wellbeing of hearing-
14
15 110 impaired adults[27]. This argument is in line with the biopsychosocial approach of health which is
16
17 111 receiving increasing attention in the field of audiology: Experienced hearing disability (i.e., activity
18
19 112 limitations and participation restrictions) is the outcome of a complex interaction between an
20
21 113 individual and his/her contextual factors[28-30].
22
23 114

24
25 115 Various interventions have been proposed in the past to complement hearing aid fitting. Examples
26
27 116 are communication programmes aimed at improving speech perception and/or communication
28
29 117 management[31]. These programmes include speech perception training, communication
30
31 118 management training, and social support[27, 32, 33]. For reviews, see Barker *et al*, Henshaw *et al*,
32
33 119 and Wong *et al*[34-36]. Examples of effective programmes are the Home Education programme[37]
34
35 120 and the Active Communication Education (ACE) group programme[38]. Both programmes consist of
36
37 121 modules on everyday communication situations, aiming to improve the use of communication
38
39 122 strategies, personal adjustment to living with hearing impairment, quality of life, development of
40
41 123 problem-solving skills, and to decrease the level of experienced hearing disability. These programmes
42
43 124 showed an improvement in communication strategies[37] and communicative participation
44
45 125 restrictions and activity limitations[38].
46
47 126

48
49 127 Communication training programmes, whether combined with hearing aid fitting or not, are rarely
50
51 128 offered in hearing health care[27, 32]. When offered, there are various reasons why adults with
52
53 129 hearing impairment would choose not to pursue communication training programmes; they could
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2
3 130 live in a rural area, have a lack of time, or no easy access[32]. The paradigm shift in health care from
4
5 131 the traditional doctor-centric model to a more patient-centered model, combined with increasingly
6
7 132 pervasive use of e-health methods and technology, means that the typical barriers causing the low
8
9 133 use of (group) communication training programmes can now be overcome[39-41].
10

11
12 134

13
14 135 A number of studies have recently been published reporting on the development and evaluation of
15
16 136 online communication programmes. Thorén *et al* developed such a programme[42] which included
17
18 137 reading material on hearing anatomy, hearing aids, communication strategies, assistive listening
19
20 138 devices, and guidelines for CPs. In addition, the intervention included weekly email contact with an
21
22 139 audiologist, problem solving exercises, and online peer discussion on personal experiences with
23
24 140 hearing loss. Thorén *et al* studied the effectiveness of the programme using a randomised controlled
25
26 141 trial-design in which the intervention group ($n=38$) received the online programme while the control
27
28 142 participants ($n=38$) were offered access to an internet discussion forum or were placed on a waiting
29
30 143 list[42]. The researchers found reduced symptoms of depression[43] and a significant decrease of
31
32 144 activity limitations and participation restrictions in the intervention group compared to the controls
33
34 145 at five weeks directly after the intervention and at three-months follow-up[42]. Ferguson *et al*
35
36 146 investigated the use of short interactive videos (reusable learning objects, RLOs)[44]. RLOs were
37
38 147 delivered via DVD for TV, computer, and the internet and covered practical and psychosocial issues
39
40 148 which are relevant for audiological rehabilitation. The intervention group ($n=103$) received seven RLOs
41
42 149 plus usual clinical services including hearing aid fitting and counseling. They were compared to a
43
44 150 control group ($n=100$) who received clinical services only and were placed on a waiting list.
45
46 151 Participants in the intervention group had significantly better hearing aid skills and better knowledge
47
48 152 on psychosocial issues than the control group after 7-weeks follow-up.
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54 154 Where the online education programme of Thorén *et al* was evaluated in a sample of adults who
55
56 155 were recruited by local advertisements and articles and were wearing a hearing aid for at least one
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1
2
3 156 year[42], Ferguson *et al* evaluated their RLOs in a small sample of patients of the audiology service of
4
5 157 the Nottingham University Hospitals NHS Trust. Patients were adults who had been referred to the
6
7 158 clinic by their family doctor[44]. The participants in the study of Kramer *et al* mentioned earlier, were
8
9 159 all patients of a specialized tertiary Audiology Centre, limiting the generalizability of the results[37].
10
11 160 In the Netherlands, only a small number of hearing aid applicants receive hearing care through a
12
13 161 tertiary clinic, i.e., only those with relatively complex hearing problems. The vast majority of hearing
14
15 162 aids are fitted in a dispenser practice.
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19

20 164 To the best of our knowledge, there is no study available evaluating the effectiveness of an online
21
22 165 communication training programme that is implemented on a large scale in a hearing aid dispensing
23
24 166 (HAD) practice setting. This paper reports on the design of such a study. It addresses the different
25
26 167 steps that will be taken to evaluate an online Support Programme (SUPR) for hearing-impaired
27
28 168 adults and their CPs. SUPR is based on the Home Education programme developed by Kramer *et*
29
30 169 *al*[37]. The original version developed in 1995 has been updated so that it would be applicable for
31
32 170 use over the internet. SUPR has also been expanded with extra elements including instructional
33
34 171 videos on how to operate and maintain hearing aids and peer testimonials. All elements will be sent
35
36 172 about bi-weekly via email.
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40 173
41
42 174 This study aimed to involve seventy HAD practices, of which half will offer the training programme.
43
44 175 This large number of practices not only contributes to a large sample size (and therefore statistical
45
46 176 power), it also reflects real world clinical practice and thus contributes to the external validity of the
47
48 177 future results. The study will include an 18-month follow-up. As was mentioned earlier by Kramer *et*
49
50 178 *al*, Barker *et al*, and Wong *et al* more research on treatment efficacy in the long(er)-term is essential
51
52 179 because it is possible that some short-term effects may disappear and other effects can arise[34, 36-
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54 180 37].
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3 182 The aim of this study is to determine the effectiveness of SUPR as part of standard HAD care among
4
5 183 older hearing aid users (HAUs) and their CPs. Based on the active elements included in SUPR, we
6
7 184 hypothesize that older HAUs who receive SUPR in addition to hearing aid fitting will show the
8
9 185 following favourable effects at 18-months follow-up when compared to HAUs who receive hearing
10
11 186 aid fitting only:

12
13 187 - More use of favourable and less use of unfavourable communication strategies (primary outcome
14
15 188 measures).

16
17 189 - Better personal adjustment to hearing impairment, higher self-efficacy of hearing aid handling,
18
19 190 higher hearing aid use, less activity limitations and participation restrictions, less handicap and
20
21 191 disability, better self-reported intervention outcomes, higher readiness to do something about their
22
23 192 hearing, and higher satisfaction with HAD services (secondary outcome measures).

24
25 193 These effects will be studied both in first-time and experienced HAUs.

26
27 194 - Consistent with the findings by Kramer *et al*[37], we hypothesize that effects on all outcomes will be
28
29 195 larger in first-time HAUs than in experienced HAUs.

30
31 196 With regard to the CPs, we hypothesize that CPs who receive SUPR - as compared to CPs whose loved
32
33 197 ones only receive hearing aid fitting - will show the following favourable effects:

34
35 198 - Lower third-party disability and better self-reported intervention outcomes.

36
37 199

38 39 200 **METHODS**

40 41 201 **Study design**

42
43 202 A cluster randomised controlled trial with an 18-month follow-up period will be performed. Cluster
44
45 203 randomisation (with the HAD practice as a unit) was chosen over individual randomisation because
46
47 204 the latter would hold a high risk of contamination. In case of individual randomisation, the HAD
48
49 205 personnel would have to switch between approaches (SUPR/CaU) frequently and could accidentally
50
51 206 refer to or offer SUPR to clients assigned to the CaU group. In addition, as the time between
52
53 207 informing the clients about the study, receiving clients' consent and the start of SUPR/CaU was
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3 208 relatively short, performing randomisation on an individual level was not feasible. Dutch HAD
4
5 209 practices and consequently all clients in these practices were randomly assigned to one of two
6
7 210 groups. The control group received care as usual (CaU) which is hearing aid fitting only, while the
8
9 211 intervention group received hearing aid fitting supplemented with SUPR.
10

11 212

13 213 **Care as Usual**

14
15 214 CaU starts with a preparation appointment during which a screening pure-tone audiogram (only air
16
17 215 conduction) is administered by the hearing aid dispenser. If the hearing loss in one or both ears is at
18
19 216 least 35 decibel (dB) hearing level (HL) (averaged over the three frequencies 1, 2, and 4 kHz) in one or
20
21 217 both ears, someone is considered potentially eligible for hearing aid fitting and more comprehensive
22
23 218 audiometry is required. If the client is interested in hearing aids, his/her general wishes and goals are
24
25 219 discussed after which the Amsterdam Inventory for Auditory Disability and Handicap (AIADH; Kramer
26
27 220 *et al*[45]) is handed out. Clients are asked to complete the AIADH at home and bring it along to the
28
29 221 next appointment. The AIADH assesses hearing activity limitations and participation restrictions.
30
31 222 Clients are asked to assign a CP and involve them throughout the rehabilitation (e.g., bring them to
32
33 223 appointments). During the next appointment, i.e., the intake appointment, comprehensive
34
35 224 audiometry (air and bone conduction, and speech audiometry) are performed. The results of all tests,
36
37 225 the AIADH, and the wishes of the client determine what type of hearing aid may be best suited for
38
39 226 this person. The appropriate hearing aids will be selected and fitted directly (if available in the HAD
40
41 227 practice) or in a subsequent fitting appointment. Fitting is followed by a trial period which usually
42
43 228 lasts up to four weeks, during which people can try out the hearing aid and decide whether or not to
44
45 229 purchase it. Depending on the client's needs, fine-tuning or other follow-up appointments are
46
47 230 scheduled. These can be scheduled during the trial period but also after the device has been
48
49 231 purchased.
50

51 232

53 233 **Intervention: SUPR**

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2
3 234 SUPR consists of a Practical Support Booklet and online elements. In addition, clients are asked to
4
5 235 assign a CP who is involved actively in the programme (see below).
6

7 236

8
9 237 **Practical Support Booklet**

10
11 238 The Practical Support Booklet will be handed out at the end of the preparation appointment (first-
12
13 239 time HAUs, experienced HAUs) or the intake appointment (experienced HAUs). The aims of the
14
15 240 Practical Support Booklet are to: 1) assist clients and CPs in getting familiar with their hearing aid, 2)
16
17 241 stimulate clients' use of the hearing aid and clients' and CPs' use of communication strategies, and 3)
18
19 242 guide clients and their CPs through the various stages (i.e., appointments) of the rehabilitation
20
21 243 trajectory. Although the theoretical elements of the booklet can also be used as a reference *after* the
22
23 244 purchase of the hearing aid, the booklet's focus is on the period between the first HAD appointment
24
25 245 and the end of the trial period. The booklet covers four parts, corresponding to the four key
26
27 246 appointments during the trial period (i.e., preparation appointment, intake appointment, control-
28
29 247 and/or fine-tuning appointment, and purchase appointment). The information that is provided is
30
31 248 synchronized with the topics which are typically discussed during these appointments. The first part
32
33 249 outlines the process of getting a hearing aid and includes an introduction to the hearing aid
34
35 250 dispenser's care and an explanation about the pure tone audiogram. The client is asked to write
36
37 251 down and rank specific communication goals (s)he wishes to reach by the end of the trial period (for
38
39 252 example: 'I want to be able to hear the stories of my 10-year old granddaughter Anne when I pick her
40
41 253 up from school every Monday'. The second part revolves around the types of hearing aids available
42
43 254 and the client's hearing aid preferences. Information about how to operate and maintain the device
44
45 255 is provided as well. In the third part the client and the CP are asked to write down their experiences
46
47 256 with the new hearing aid and its settings. This information will be used for further refinement of the
48
49 257 fitting. The final section of the booklet provides information on assistive listening devices,
50
51 258 reimbursement of costs, more information on the audiogram, types of hearing loss, and the types of
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53 259 hearing aids (e.g. behind-the-ear and in-the-canal). In addition, an overview of the most important
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3 260 communication strategies that clients and their CP can apply is provided. The content and the
4
5 261 appearance of the booklet were developed over the course of several months by the HAD company.
6
7 262 Although no specific guidelines were used for the development of the written health information in
8
9 263 the booklet, a number of the subsequent steps that are deemed important by Caposecco *et al* were
10
11 264 taken into consideration: 1) interviews with key stakeholders (clients, CPs, HAD practice personnel)
12
13 265 were held to specify the booklet's goals and functions, 2) graphics and text were developed and
14
15 266 optimized with regard to their understandability and attractiveness (language difficulty, lay-out, font
16
17 267 size, paragraphing), 3) a first complete version of the booklet was pilot-tested in ten HAD practices
18
19 268 for several months. Feedback by all key stakeholders was collected, and 4) the feedback was
20
21 269 incorporated in a new and final version of the booklet (which was used in the study)[46].
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270

271 **Online Elements**

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

278

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

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2
3 286 can experience in everyday listening situations. The typical reactions by both the hearing-impaired
4
5 287 people and his/her social environment to these situations are shown, and a trainer illustrates how
6
7 288 communication could be improved by using communication strategies (for both hearing-impaired
8
9 289 people and his/her CP). 3) Three testimonials by hearing-impaired peers who share their experiences
10
11 290 with hearing aids.
12

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14 291

15 16 292 **Measurements**

17
18 293 For all participants four measurements will take place: at baseline (after the preparation
19
20 294 appointment, but before the actual hearing aid fitting) (T0), six months after the hearing aid
21
22 295 purchase (T1), one year after the hearing aid purchase (T2), and eighteen months after the hearing
23
24 296 aid purchase (T3). Measurements at T3 serve to determine the long-term effects of SUPR, i.e., one
25
26 297 year after its completion. Data will be collected using online questionnaires through NetQ Premium,
27
28 298 which is an online survey programme. Email-reminders will be sent within a week after the first
29
30 299 invitation-email and another week after the first reminder, if necessary.
31
32

33 300

34 35 301 **Study population and recruitment**

36
37 302 The following procedures were followed during the recruitment period (February 2016 to September
38
39 303 2016). Hearing aid dispensers invited clients to participate in the study. First-time HAU were invited
40
41 304 at the end of their preparation appointment. Experienced HAU were invited at the end of their
42
43 305 preparation or at the end of their intake appointment, if they did not require a preparation
44
45 306 appointment. Hearing aid dispensers handed out an information package including an invitation
46
47 307 letter, a selection form outlining the in- and exclusion criteria, a brochure about the study, and an
48
49 308 envelope with an information letter and brochure for the CP. All interested participants were asked
50
51 309 to enrol themselves for the study by subscribing on a registration webpage and signing the online
52
53 310 consent from there. Every month the number of clients who were invited (number of envelopes that
54
55 311 was handed out) and were enrolled (number of online subscriptions) per HAD practice were
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1
2
3 312 determined. When enrolment numbers for a particular HAD practice were relatively low, a phone call
4
5 313 was made to the specific HAD practice to notify them of their current number of enrolments, to
6
7 314 identify possible underlying reasons, and to motivate them to reach the required target. Throughout
8
9 315 the recruitment period, the HAD headquarters organized motivational conference calls for the HAD
10
11 316 practices that had not yet reached their target. Finally, when enrolment ratings continued to be
12
13 317 behind target, employees of the headquarters directly invited potentially eligible clients who were
14
15 318 not invited by the HAD practice personnel, via a telephone call. The study material was then sent via
16
17 319 email.
18
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21
22 321 **Incentives**

23
24 322 After completing the T0 questionnaire, all participants will be offered a voucher of EUR 50 to spend
25
26 323 on a hearing aid or EUR 25 to spend on other articles of the HAD practice if they decide not to
27
28 324 purchase a hearing aid. CPs will be offered a gift card. In addition, participants in the control group
29
30 325 will be offered a shortened version of SUPR after eighteen months. For them, SUPR will be slightly
31
32 326 adjusted such that it becomes suitable for individuals who have already started using a hearing aid.
33
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36
37 328 Employees of the HAD practices will be offered gift cards once the total number of participants is
38
39 329 recruited (see 'Sample size calculation' section).
40

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43
44 331 **Inclusion criteria**

45
46 332 The following inclusion criteria for the hearing aid candidates were applied:
47
48 333 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
49
50 334 follow-up appointment). This hearing aid could be their first (i.e., first-time HAUs), or a replacement
51
52 335 hearing aid (i.e., experienced HAUs). Clients who did not purchase a hearing aid after the trial period
53
54 336 were considered drop-outs. 3) Sufficient understanding of the Dutch language. 4) Access to a
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3 337 personal computer with internet access and owner of an email account for the total duration of the
4
5 338 study.

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8
9 340 **Exclusion criteria**

10
11 341 The following hearing aid candidates were excluded: 1) Candidates who received additional care at a
12
13 342 specialized Audiology Clinic. In the Netherlands, an Audiology Clinic offers elaborate,
14
15 343 multidisciplinary and specialized, tertiary health care and is aimed at people with complex hearing
16
17 344 problems. This care may overlap and/or interfere with that of SUPR. 2) Candidates that received a
18
19 345 hearing aid primarily to suppress tinnitus complaints. For these individuals the focus of the
20
21 346 rehabilitation is not on restoring communication per se, and as such, they were not part of the target
22
23 347 group of SUPR.
24
25

26
27 348

28
29 349 Although all participants were encouraged to assign a CP, it was not obligatory for them to assign one
30
31 350 in order to participate in the study. For the CPs, the only inclusion criterion applied was that they
32
33 351 should be 18 years or older.
34

35
36 352

37 353 **Outcome measures**

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39 354 An overview of all outcome measures and measurements over time according to Standard Protocol
40
41 355 Items; Recommendations for Interventional Trials (SPIRIT) is attached (see online supplementary
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43 356 appendix 1)[47]
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3 357 Primary outcome measures – HAUs

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5 358 - *The use of communication strategies* will be measured using the reliable and validated Dutch 35-
6
7 359 item version of the Communication Profile for the Hearing Impaired (CPHI)[48, 49]). Communication
8
9 360 strategies are measured using the following subscales: Maladaptive Behaviours, Verbal Strategies,
10
11 361 and Non-verbal Strategies. Each subscale consists of statements for which the respondent has to
12
13 362 indicate how often (s)he applies this strategy. An example: “I avoid conversations with strangers,
14
15 363 because of my hearing loss” (subscale Maladaptive Behaviour). The five response options range from
16
17 364 ‘almost never’ to ‘almost always’. Scores are averaged per subscale and range from 1 to 5. Some
18
19 365 items were recoded because of reverse scaling. High scores indicate favourable strategies whereas
20
21 366 low scores indicate unfavourable strategies.
22
23
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26
27 368 We have chosen for the Communication Strategies subscales of the CPHI as central outcome
28
29 369 measures for the following reasons. Firstly, the subscales are purported to measure the constructs
30
31 370 that are acted upon by the core active element of the intervention (i.e., the revised home education
32
33 371 programme). Secondly, the CPHI has proven to have very good validity and reliability in the target
34
35 372 population of this study[49].
36

37
38 373

39 374 Secondary outcome measures – HAUs

40
41 375 - *Personal adjustment to hearing impairment* will also be measured using the reliable and validated
42
43 376 Dutch 35-item version of the Communication Profile for the Hearing Impaired (CPHI)[48, 49]). This
44
45 377 second section of the CPHI deals with personal adjustment and also contains three subscales: Self-
46
47 378 acceptance, Acceptance of Loss, and Stress and Withdrawal. An example item of the latter subscale
48
49 379 is: “I feel very tense because of my hearing loss”. The five response options range from ‘totally
50
51 380 disagree’ (1) to ‘totally agree’ (5). All items were recoded because of reverse scaling. After recoding
52
53 381 the item scores, average scores per subscale can be calculated, with low scores indicating poor
54
55 382 personal adjustment and high scores indicating good personal adjustment.
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3 383 - *Self-efficacy of hearing aid handling* will be measured by the Basic Handling subscale of the
4
5 384 Measure of Audiologic Rehabilitation Self-Efficacy for Hearing Aids (MARS-HA). The English version of
6
7 385 this 7-item subscale has good psychometric quality[50]. Scores can range from 0% to 100%, with
8
9 386 lower scores representing less certainty in one's capability of handling a hearing aid. At T1, T2, and
10
11 387 T3, the 5-item subscale Advanced Handling will be additionally administered. Dutch versions of the
12
13 388 scales were created using the forward-backward method[51]. At T0 'expected self-efficacy' will be
14
15 389 administered, whereas at T1, T2, and T3 'experienced self-efficacy' will be determined as the new
16
17 390 hearing aids will have been fitted by then. For measurement of 'expected self-efficacy', all MARS-HA-
18
19 391 items start with 'I think I can ...', whereas for measurement of 'experienced' self-efficacy all items
20
21 392 start with 'I can...'.
22
23

24 393 - *Hearing aid use*. Self-reported use will be measured using the first item of the International
25
26 394 Outcome Inventory – Hearing Aids (IOI-HA) ("How many hours per day on average have you been
27
28 395 using your hearing aid(s) in the last two weeks?"). Response options are 'none', 'less than 1 hour a
29
30 396 day', '1-4 hours a day', '4-8 hours a day', and 'more than 8 hours a day'[52]. Self-reported hearing aid
31
32 397 use will additionally be measured by three questions from the use questionnaire developed by
33
34 398 Laplante-Lévesque *et al*[53]. The latter questionnaire was translated into Dutch, using the forward-
35
36 399 backward method[51]. Hearing aid use will also be measured objectively via data-logging.
37
38

39 400 - *Self-reported intervention outcomes (hearing aid rehabilitation and SUPR outcome)*. The
40
41 401 International Outcome Inventory - Hearing Aids (IOI-HA; items 2-7) and the equivalent International
42
43 402 Outcome Inventory for Alternative Interventions questionnaire (IOI-AI; all 7 items) will be used to
44
45 403 assess the outcome of hearing aid rehabilitation and SUPR respectively[52]. The Dutch version of IOI-
46
47 404 HA has a good test-retest reliability and validity[54]. The first item of the IOI-AI determines the
48
49 405 frequency of the use of the alternative intervention, i.e., "How often have you used the learnt
50
51 406 communication strategies on an average day in the last two weeks?". Response options are 'never'
52
53 407 (1), 'rarely' (2), 'sometimes' (3), 'often' (4), and 'almost always' (5). Items 2-7 of the IOI-HA/IOI-AI
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3 408 questionnaire cover: benefit, residual activity limitations, satisfaction with the hearing aid(s)/SUPR,
4
5 409 residual participation restrictions, impact on others, and quality of life.

6
7 410 - *Satisfaction with the HAD practice service*. Satisfaction will be measured by the following question:

8
9 411 “How likely is it that you would recommend the service of the HAD practice to other people (family,
10
11 412 friends, colleagues)?” It is scored on a visual analogue scale running from 0 (=not at all likely) to 10
12
13 413 (=extremely likely).

14
15 414 - *Self-reported activity limitations and participation restrictions* are measured using the reliable and
16
17 415 validated original (Dutch) version of the Amsterdam Inventory for Auditory Disability and Handicap
18
19 416 (AIADH)[45, 55]. It contains 28 questions regarding everyday listening situations. An example is: “Do
20
21 417 you immediately look into the right direction when somebody calls you in the street”? The 4-point
22
23 418 response scale covers: ‘almost never’ (1), ‘sometimes’ (2), ‘often’ (3) and ‘almost always’ (4). When
24
25 419 the participant answers the question with ‘almost never’ or ‘sometimes’, he or she is directed to
26
27 420 question b which is about the inconvenience of not being able to hear well in that specific situation.
28
29 421 Response options are: ‘no’ (1), ‘a little’ (2), ‘very handicapped’ (3), and ‘extremely handicapped’ (4).
30
31 422 Hence, the total score can range from 28-112 with higher scores indicating greater participation
32
33 423 restrictions.

34
35 424 - *Readiness to do something about one’s hearing problems* will be measured by the validated Dutch
36
37 425 24-item version of the University of Rhode Island Change Assessment (URICA)[56]. Formulations of
38
39 426 items were adjusted such that they applied to hearing problems. The inventory contains 24
40
41 427 statements regarding attitudes and behaviours assessing an individual’s stage of behaviour change.
42
43 428 At T0 the scores on the following stages will be assessed: pre-contemplation (does not intend to take
44
45 429 action in the foreseeable future, e.g., “As far as I’m concerned, I don’t have any problems with my
46
47 430 hearing that need changing”), contemplation (intends to change in the next six months and is aware
48
49 431 of the pros and cons of changing), and action (has made specific modifications in his/her lifestyle
50
51 432 towards healthy behaviour). At T1, T2, and T3 the maintenance stage (can maintain the changes in
52
53 433 new behaviour) will be added. The five response options range from ‘fully disagree’ (score 1) to ‘fully
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3 434 agree' (score 5). Summed scores for each subscale will be calculated. In addition the composite
4
5 435 'readiness score' (adding the contemplation, action and maintenance scores and subtracting the pre-
6
7 436 contemplation score) and the composite 'committed action score' (subtracting the contemplation
8
9 437 stage score from the action stage score) will be calculated[56]. The higher the composite scores, the
10
11 438 further the respondents are along the stages of change.

12
13 439 - *Emotional response to hearing problems*. The Hearing Handicap and Disability Inventory (HHDI) will
14
15 440 be used[57]. The purpose of the inventory is to identify the individual's problems caused by hearing
16
17 441 loss. Only the section 'emotional response' will be administered. It contains five statements each
18
19 442 with five response options: 'yes!' (4), 'yes' (3), 'more or less' (2), 'no' (1) and 'no!' (0). An example is:
20
21 443 "I find it difficult to accept that I am hearing impaired". Lower scores indicate better outcomes.
22
23 444

24
25
26 445 Secondary outcome measures - CP

27
28 446 - *Third-party disability* will be measured using the Significant Other Scale for Hearing Disability (SOS-
29
30 447 HEAR)[12]. This questionnaire was translated into Dutch for the purposes of this study following a
31
32 448 forward-backward method[51]. The 27-item questionnaire addresses the problems and limitations
33
34 449 experienced by the CP. An example item is: "Because of my partner's hearing difficulties I have to
35
36 450 repeat myself often". For each item the CP has to indicate how much of a problem it is for him/her:
37
38 451 'no problem' (0), 'a mild problem' (1), 'a moderate problem' (2), 'a severe problem' (3), 'a complete
39
40 452 problem' (4). Higher scores indicate greater difficulties.
41
42

43
44 453 - *Hearing aid rehabilitation and SUPR outcome as viewed from the perspective of the CP* will be
45
46 454 administered with the 7-item IOI-HA-SO/IOI-AI-SO and covers use, benefit, residual activity
47
48 455 limitations, satisfaction, residual participation restrictions, impact on others, and quality of life[58].
49
50

51 456

52 457 Baseline measurement - Demographical characteristics

53
54 458 - Gender (male/female)

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56 459 - Age (in years)
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3 460 - Marital status (married/cohabiting/widow or widower/divorced/single, never married)
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5 461 - Living situation (living together with my partner/living together with my partner and children/living
6
7 462 together without my partner but with one or more family members/living alone (own room) or in a
8
9 463 care institution/living alone, independently or nursing home/other, namely...)
10
11 464 - Level of education (no completed education/lower general education, elementary education or a
12
13 465 part of it/lower general secondary education/vocational education/secondary education/technical
14
15 466 and vocational education/higher professional education/higher general education/scientific
16
17 467 education/other, namely...)
18
19 468 - Occupational status (yes/no)
20
21 469 - Country of birth (The Netherlands/other, namely...)
22
23 470 - Country of birth father (The Netherlands/other, namely...)
24
25 471 - Country of birth mother (The Netherlands/other, namely...)
26
27 472 - Hearing loss in each ear, in dB HL (averaged over 1, 2, and 4 kHz) as retrieved from the pure-tone
28
29 473 audiogram as provided by the hearing aid dispenser.
30
31
32

33 474

35 475 **Randomisation**

36
37 476 HAD practices were randomly assigned to offer CaU or the intervention. To avoid an unequal
38
39 477 distribution of HAD practices with regard to level of urbanisation, HAD practices were pre-stratified
40
41 478 (HAD practices located in a relatively rural area versus in an urban area) and randomisation occurred
42
43 479 within these two strata. A statistician performed block randomisation of the HAD practices in the
44
45 480 statistical software R, with random permutation in blocks of size four and with a fixed seed. 34 HAD
46
47 481 practices were assigned to CaU and 36 HAD practices to the intervention group. The recruitment
48
49 482 procedure and period was the same for all 70 included HAD practices (the total list of included HAD
50
51 483 practices are available on request from the research team).
52
53

54 484

57 485 **Sample size calculation**

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3 486 Sample size calculations are based on the expected effects of the intervention on the primary
4
5 487 outcomes: communication strategies (CPHI). Demorest and Erdman indicated that the expected
6
7 488 difference on the subscales of the CPHI varies from 0.67 (Maladaptive Behaviour) to 0.95 (Self-
8
9 489 Acceptance)[59]. Given that in a previous study[37] the effect of the programme was larger for first-
10
11 490 time than for experienced users, we calculated sample sizes separately for first-time and experienced
12
13 491 users. For first-time HAUs, we based our sample size calculations on an expected difference of 0.67
14
15 492 between the intervention and the CaU group. Note that the subscale with the smallest minimal
16
17 493 importance difference (i.e., Maladaptive Behaviour) was used in the calculation, as finding a
18
19 494 significant difference on this measure requires the largest number of participants. Calculations in
20
21 495 PASS 12 (Tests for Two Means in a Cluster-Randomised Design; Intraclass correlation coefficient:
22
23 496 0.01; alpha: 0.05; power: 0.80) shows, that when 70 HAD practices are included (of which half will
24
25 497 offer SUPR and half will offer CaU), the number of first-time HAUs to include in the analyses is two
26
27 498 per HAD practice. For the sample size calculation of the experienced users we chose an expected
28
29 499 difference of 0.4 between the intervention and CaU group. The expected difference was set lower
30
31 500 than for first-time HAUs as Kramer *et al* had previously found generally smaller effects for
32
33 501 experienced users than for first-time users[37]. With a difference of 0.4 the number of experienced
34
35 502 HAUs (power: 0.80) to include is three per HAD practice. We expected the proportion of drop-out or
36
37 503 loss to follow-up across the study to be 20%. This includes loss to follow-up for a range of reasons: no
38
39 504 motivation anymore, reluctance to purchase a hearing aid after a successful trial, sickness, death etc.
40
41 505 Taking the loss to follow-up and the proportion of clients that normally purchase a hearing aid into
42
43 506 account results in a total (rounded) number of four first-time HAUs per HAD practice and five
44
45 507 experienced HAUs per HAD practice to be recruited.
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509 **Statistical analyses**

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

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2
3 512 variables), the independent samples *t*-test (for normally distributed continuous variables) and the
4
5 513 Mann-Whitney test (for non-normally distributed continuous variables). Comparability will be
6
7 514 checked for all demographic variables and all primary and secondary outcomes.
8

9 515

10
11 516 For the effect analyses, the groups will be compared on all primary and secondary outcome
12
13 517 measures using linear mixed models including the results at T0, T1, T2, and T3. Group, time, and their
14
15 518 two-way interaction will be included as fixed effects in the mixed models, with random intercepts for
16
17 519 subject and HAD practice. For the covariance matrix, a Variance Component structure will be chosen.
18

19
20 520 To adjust for potential bias associated with multiplicity of analyses, statistical significance levels will
21
22 521 be set at $P < 0.016$ ($0.05/3$). If a significant effect is found, an independent samples *t*-test will be used
23
24 522 and a Bonferroni correction will be administered in case of multiple comparisons. Type of HAU (first-
25
26 523 time or experienced) will be tested as an effect modifier for potential subgroup differences.
27

28
29 524 In case of substantial missing data, multiple imputation will be applied. The main analysis is intention
30
31 525 to treat. Any outcome measure to be collected for participants who discontinue or deviate from
32
33 526 intervention protocols will be saved and analyzed according to the intention to treat protocol. In
34
35 527 addition, a per-protocol analysis will be performed. A per-protocol analysis includes those
36
37 528 participants who completed the intervention originally allocated as described in the study protocol.
38
39 529 As a per-protocol analysis can potentially yield biased effects (e.g., see CONSORT statement)[60],
40
41 530 great caution will be exerted when interpreting these results. In addition, the report of these findings
42
43 531 in future articles will be nuanced explicitly and thoroughly.
44

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46 532

47 48 533 **Process evaluation**

49
50 534 The process of implementing SUPR into the HAD care in the intervention arm will be evaluated. The
51
52 535 main aims of this evaluation are to gain insight into 1) the circumstances in which the intervention
53
54 536 was implemented, 2) (non-) compliance with the intervention, and 3) the professionals' and clients'
55
56 537 appraisal of the intervention.
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5 539 The process evaluation will be carried out according to the framework as proposed by Linnan *et*
6
7 540 *al*[61]. It covers seven parameters: recruitment, reach, fidelity, dose delivered, dose received and
8
9 541 implemented, satisfaction, and perceived benefit[62]. A brief description of each of the parameters is
10
11 542 given below.

12
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15
16 544 - Recruitment refers to the procedures applied to approach and attract potential participants. The
17
18 545 hearing aid dispensers will be asked to provide this information.

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20 546 - Reach. This is the proportion of people participating relative to the number of people invited.

21
22 547 - Fidelity relates to the question of whether the intervention was provided as intended. The team
23
24 548 that is responsible for the email contact will be asked to provide a written report on this.

25
26 549 - Dose delivered: 1) Did the personnel of the HAD practice hand out the Practical Support Booklet at
27
28 550 the end of the preparation appointment? 2) Did the personnel of the HAD headquarters send out the
29
30 551 emails correctly (correct content) and on time.

31
32 552 - Dose received and implemented: 1) Did the participants receive and use the Practical Support
33
34 553 Booklet? 2) Did the participants open the emails and the videos? If so, did they watch the whole
35
36 554 video, or part(s) of it? The video watching behaviour will be determined using Quadia (supplier of
37
38 555 online video content) and Google analytics. Data on the average watching time per video, and how
39
40 556 many times a particular video has been opened will be determined. Due to the privacy regulations
41
42 557 the HAD company is subject to, the company is only allowed to collect video watching data on a
43
44 558 group level (and not on an individual level). As all the HAD practices of the company that do not
45
46 559 participate in the study provide SUPR as their standard care at the time of the study, the researchers
47
48 560 will not be able to determine specific group averages of the study participants (the averages are
49
50 561 based on both study participants and regular HAD clients). Information on implementation of the
51
52 562 knowledge that participants learnt from SUPR will be deduced from the IOI-AI questionnaire (item on
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2
3 563 use) on T1. If participants received and used the Practical Support Booklet will be measured by a
4
5 564 questionnaire.

6
7 565 - Satisfaction: Satisfaction of the participant with SUPR will be evaluated using the IOI-AI
8
9 566 questionnaire (item satisfaction) on T1. The hearing aid dispensers will be asked to answer the
10
11 567 question: How would you rate your satisfaction with SUPR?

12
13 568 - Benefit: Information on the experienced benefit of the participant will be obtained from the IOI-AI
14
15 569 questionnaire (item benefit) on T1. The hearing aid dispensers will be asked to answer the question:
16
17 570 How would you rate the perceived benefit from SUPR for your clients' ability to improve in
18
19 571 communication?
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24 573 Additionally, focus group discussions with participants from the intervention group will be organized
25
26 574 to gain insight into the reasons for using the knowledge of SUPR in their daily lives or not. A minimum
27
28 575 of two focus groups will be organized. The exact number will depend on data saturation.
29
30 576 Heterogeneity in age, gender, educational level, severity of hearing impairment, and stage of
31
32 577 behaviour change (at baseline) within the groups will be strived for. Given the difficulties hearing-
33
34 578 impaired individuals might have with group conversations, the focus groups will have a maximum
35
36 579 size of six participants each.
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40 581 **ETHICS AND DISSEMINATION**

41 582 **Protocol amendments, confidentiality and dissemination policy**

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43 583 Any future protocol modifications will be submitted to the VU University Medical Center Medical
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45 584 Ethical Committee. Directly upon approval, the modification will be corresponded to the trial
46
47 585 registry.
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53 587 Personal information about enrolled participants will only be shared with employees of the
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55 588 headquarters of the HAD practices who signed a privacy declaration. This exchange of personal
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3 589 information will only occur in order to collect data within the framework of the study (e.g., to collect
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5 590 audiogram data, hearing aid purchase status, and use of SUPR). Any exchanged data and personal
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7 591 information will be password protected.
8

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10
11 593 VU University Medical Center has all property rights on the final results of the trial and is entitled to
12
13 594 publish the results. The funder is not entitled to publish the results without written consent of the
14
15 595 VU University Medical Center. These agreements are secured in a contract. For specific author
16
17 596 contributions for the current paper, see 'Authors contributions'.
18

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21
22 598 Findings of the study will be published in scientific journals and presented at scientific conferences,
23
24 599 and will be communicated within the national and international media. A short report of the study
25
26 600 findings will be sent to interested participants. The results will be communicated within the hearing
27
28 601 aid dispenser company.
29

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32 33 603 **Data collection forms and data storage**

34
35 604 Data collection forms and procedures for data management are available on request. All data will be
36
37 605 collected digitally and will be stored on a computer disk at the VU University Medical Center which is
38
39 606 locked with a security code only available to members of the SUPR research team. According to Good
40
41 607 Clinical Practice guidelines and after having received informed consent, data will be archived for a
42
43 608 period of fifteen years after finalizing the study. After finalization, the key file (connecting participant
44
45 609 numbers to the names and contact details of the participant) will be destroyed once it is expected
46
47 610 that participants do not need to be approached further for the purposes of the study. We will
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49 611 perform double data entry of a selection of the audiograms and the baseline AIADH data for quality
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51 612 purposes.
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55 56 57 614 **Monitoring**

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3 615 The study is subjected to local regulations and its quality is monitored by the research institutes (i.e.,
4
5 616 EMGO⁺) Quality Committee. This committee is responsible for developing, implementing, and
6
7 617 maintaining a system for quality assurance and control for all research within the institute. Due to
8
9 618 the decision of the Dutch Institutional Review Board (IRB) of the VU Medical University Center
10
11 619 Amsterdam that the study does not fall under the Research Involving Human Subjects Act (WMO),
12
13 620 the formation of a Clinical Trial Data Monitoring Committee was not deemed necessary.
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18 622 **DISCUSSION**

19
20 623 Like in most parts in the world, usual care for adults with hearing impairment in the Netherlands is
21
22 624 mostly restricted to audiological assessment and hearing aid fitting. This type of care is in the large
23
24 625 part provided by commercial hearing aid dispensers. Communication programmes aimed at
25
26 626 improving the use of favourable communication strategies, increasing personal adjustment to
27
28 627 hearing impairment, and improving hearing aid handling skills are not provided on a large scale in
29
30 628 standard hearing health care settings. This is undesirable, as there is a growing body of evidence
31
32 629 showing that offering such programmes can effectively decrease communication problems and
33
34 630 associated negative health outcomes[27, 33, 38, 42]. Likewise, despite the fact that including CPs in
35
36 631 the rehabilitation process is increasingly recognized within audiology as a prerequisite for successful
37
38 632 rehabilitation[12], CPs are not yet part of standard hearing health care. In the current study, these
39
40 633 elements (i.e., a communication programme and involvement of a CP) are part of a programme
41
42 634 called SUPR that is incorporated in regular hearing aid dispensing care and that will be tested for its
43
44 635 effectiveness. SUPR's primary aims are to improve older hearing aid owners' communication
45
46 636 strategies and personal adjustment and decrease their CPs' third-party disability. To our knowledge,
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48 637 similar online support programmes for HAU that are implemented on a large scale in hearing aid
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50 638 dispenser settings are not yet available.
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3 640 A strength of the SUPR programme is that for those who are at risk for isolation or those who have
4
5 641 reduced access to health care, the internet can be a practical tool providing direct access to health
6
7 642 services[63]. Other elements that can add to the effectiveness of online support programmes as
8
9 643 SUPR are that it can (partly or mainly) be provided in a visual mode (images, written text, subtitles),
10
11 644 the volume can be controlled, background noises can be relatively easily eliminated, and online
12
13 645 support programmes provide the opportunity to tailor intervention elements.
14
15
16 646

17
18 647 A few limitations to the design need to be considered. Unfortunately it is not possible to perform a
19
20 648 double-blinded, randomised, controlled trial due to the nature of the intervention study. Blinding of
21
22 649 the participants is not possible as they will be informed about the general aim of the SUPR study (i.e.
23
24 650 to evaluate a support programme) and know that they are either part of the group that receives CaU
25
26 651 or SUPR. Nevertheless, we will attempt to minimize the provision of information on the content of
27
28 652 SUPR to participants of the CaU group. The participants only know that SUPR is a support programme
29
30 653 aimed to 'improve communication', but for instance do not know what the intervention further
31
32 654 entails. This way, we aimed to prevent that they would independently seek access to SUPR (which
33
34 655 would cause contamination) and that their knowledge of the care they were missing out on would
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36 656 affect their responses in the questionnaires. We further attempted to prevent contamination by
37
38 657 offering the programme to the CaU-participants for free after completing the study. Blinding the
39
40 658 researchers during the effect analysis is also not possible as the IOI measure that is administered at
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42 659 T1, T2, and T3 indicates what group each participant was randomised to (IOI-HA only: CaU group; IOI-
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44 660 AI: intervention group).
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50 662 SUPR is an online intervention, it is thus essential that people have access to a device with internet
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52 663 access and an email account. Participants who have access to the internet will most likely be of high
53
54 664 SES and this might bias the data. The fact that the support programme as such reaches a selective
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56 665 part of the dispenser's clientele requires further discussion. Consistent with findings from Choi *et al*
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3 666 and Fox *et al* who compared non-internet users and users, it is possible that the older people
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5 667 participating in the SUPR study generally have a somewhat higher socioeconomic status and are
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7 668 somewhat younger than the average clientele of the dispenser[64, 65]. With regard to age however,
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9 669 it should be noted amongst the young-old (55-74) the weekly internet use has increased from 70% in
10
11 670 2010 to 83% in 2015 in the Netherlands and will most probably keep rising in the future[66]. This
12
13 671 suggests that the large majority of the younger-old can currently already be reached with SUPR and
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15 672 this will improve even more in the future. The non-use of internet among the older olds (75+)
16
17 673 currently still is substantial, although this proportion also has decreased strongly in the past few
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19 674 years (66% in 2012 to 50% in 2015[67]). Furthermore, it is encouraging that older internet users,
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21 675 generally use it more for health-related tasks or information than for personal tasks[68]. In addition,
22
23 676 people with hearing loss are more likely to use the internet than people in the general population
24
25 677 (OR=1.74, 95% CI 1.23-3.17)[69]. Baring these developments in mind, we are confident that the large
26
27 678 majority of the older HAUs who can potentially benefit from SUPR will be increasingly eligible and
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29 679 open to using SUPR to improve their hearing health.
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35 681 At the start of the study, participants might downplay their hearing problems because hearing loss
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37 682 stigma causes them to be reluctant to acknowledge or recognize their hearing problems[70]. We
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39 683 expect that SUPR will have a positive effect on acceptance of hearing loss, and therefore people may
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41 684 report a disability level that is 'more honest'. This may hold particularly for the first-time HAUs who
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43 685 have never gone through an intensive rehabilitation trajectory before and less so for the experienced
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45 686 users. As such, it is possible that this mechanism will cause an increase in self-reported hearing
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47 687 disability in the intervention group over time. This would counteract the favourable effect that SUPR
48
49 688 is expected to create, i.e., a decrease in experienced disability. To examine whether the first-
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51 689 mentioned mechanism would apply, one of the subscales of the CPHI on acceptance of hearing loss
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53 690 can be used[48]. With this subscale we can examine if acceptance is a mediator between time and
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55 691 hearing status for the intervention group.
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5 693 This study aims to perform a process evaluation, as is strongly recommended in all randomised
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7 694 controlled trial research. A process evaluation provides insight into reasons for the demonstrated
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9 695 (absence of) effectiveness of the intervention and might offer information concerning the
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11 696 generalizability of the study results. When no or only small significant effects of SUPR will be found,
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13 697 we may be able to modify the programme based on the results of the process evaluation after the
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15 698 study.

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20 700 In the future, it is expected that there will be an increasing demand for solutions for hearing health
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22 701 conditions due to the ageing population and thus increased prevalence of hearing problems. SUPR is
23
24 702 especially developed for use on a large scale basis in HAD practices. The large number of practices
25
26 703 that are involved in the study not only contributes to a large sample size (and statistical power), it
27
28 704 also reflects real world clinical practice. This will potentially make a strong case for the extrapolation
29
30 705 of the study's results. Demonstrating the programmes effectiveness would be a great step forward
31
32 706 improving health care services for people with hearing impairment.

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40
41 710 contribution to the development of the SUPR study design and the writing of this paper.

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45 46 712 **FOOTNOTES**

47 48 713 **Contributors**

49
50 714 SEK developed the first version of the study design in collaboration with BP and VJ. MP and SK
51
52 715 developed the study design further and wrote up the first draft of the study protocol. BvdW, JFJM,
53
54 716 MP, SEK, and VJ worked on the design further and facilitated the practical implementation of the
55
56 717 study. BIW provided statistical and methodological advice. Data collection will be done by BvdW and
57
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2
3 718 JFJM, assisted by VJ, and supervised by SEK and MP. JFJM wrote the final version of the manuscript.
4
5 719 SEK and MP supervised the writing process and MP, SEK, BP, BIW, VJ, and BvdW gave critical
6
7 720 comments on several drafts of the manuscript.
8

9 721

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14
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16
17 725 the data.
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19 726

20 21 727 **Competing interests**

22
23 728 VJ is an employee at Schoonenberg Hoorcomfort. BP is an employee at AudioNova International.
24
25 729

26 27 730 **Ethics approval and consent to participate**

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29 731 Written consent for the SUPR study (reference number: 2015.335) was obtained from the Dutch
30
31 732 Institutional Review Board (IRB) of the VU Medical University Center Amsterdam (registered with the
32
33 733 US Office for Human Research Protections as IRB00002991; FWA number: FWA00017598). The IRB
34
35 734 concluded that Medical Research Involving Human Subjects ACT (WMO) does not apply to this study.
36
37 735 Participants' consent will be obtained via the registration website of the study. At this website
38
39 736 participants were asked to declare that they were sufficiently informed about the study and agreed
40
41 737 on the use of certain data to be collected for the purposes of the study.
42
43 738

44 45 739 **Data sharing statement**

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47 740 It is not expected that participant level data will be made available because this has not been applied
48
49 741 for in the ethics application. Approval has not been sought for the data to be publicly available.
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51 742

52 53 743 **Abbreviations**

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3 744 SUPR: SUpport PRogramme, CaU: care as usual, CP: communication partner, HAU: hearing aid users,
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5 745 HAD practices: hearing aid dispensing practices, AIADH: Amsterdam Inventory for Auditory Disability
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7 746 and Handicap, CPHI: Communication Profile for the Hearing Impaired, MARS-HA: Measure of
8
9 747 Audiologic Rehabilitation Self-Efficacy for Hearing Aids, IOI-HA: International Outcome Inventory -
10
11 748 Hearing Aids, IOI-AI: International Outcome Inventory - Alternative Interventions, URICA: University
12
13 749 of Rhode Island Change Assessment for Hearing health behaviour, HHDI: Hearing Handicap and
14
15 750 Disability Inventory, SOS-HEAR: Significant Other Scale for Hearing Disability, IOI-HA-SO: International
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17 751 Outcome Inventory Significant Other - Hearing Aids, IOI-AI-SO: International Outcome Inventory
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19 752 Significant Other - Alternative Interventions.
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754 **REFERENCES**

- 25
26
27 755 1. Vos T, Barber RM, Bell B, et al. Global, regional, and national incidence, prevalence, and years
28
29 756 lived with disability for 301 acute and chronic diseases and injuries in 188 countries, 1990-2013:
30
31 757 a systematic analysis for the Global Burden of Disease Study 2013. *Lancet* 2015;386:743-800. doi:
32
33 758 10.1016/S0140-6736(15)60692-4
34
35 759 2. United Nations, Department of Economic and Social Affairs, Population Division. World
36
37 760 population ageing 2015. New York: United Nations 2015.
38
39 761 3. Weinstein BE, Sirow LW, Moser S. Relating hearing aid use to social and emotional loneliness in
40
41 762 older adults. *Am J Audiol* 2016;25:54-61. doi: 10.1044/2015_AJA-15-0055
42
43 763 4. Pronk M, Deeg DJ, Smits C, et al. Prospective effects of hearing status on loneliness and
44
45 764 depression in older persons: Identification of subgroups. *Int J Audiol* 2011;50:887-96. doi:
46
47 765 10.3109/14992027.2011.599871
48
49 766 5. Strawbridge WJ, Wallhagen MI, Shema SJ, et al. Negative consequences of hearing impairment in
50
51 767 old age: A longitudinal analysis. *Gerontologist* 2000;40:320-6. doi: 10.1093/geront/40.3.320
52
53
54
55
56
57
58
59
60

- 1
2
3 768 6. Nachtegaal J, Smit JH, Smits C, et al. The association between hearing status and psychosocial
4
5 769 health before the age of 70 years: results from an internet-based national survey on hearing. *Ear*
6
7 770 *Hear* 2009;30:302-12. doi: 10.1097/AUD.0b013e31819c6e01
8
9
10 771 7. Saito H, Nishiwaki Y, Michikawa T, et al. Hearing handicap predicts the development of
11
12 772 depressive symptoms after 3 Years in older community-dwelling Japanese. *J Am Geriatr Soc*
13
14 773 2010;58:93-7. doi: 10.1111/j.1532-5415.2009.02615.x
15
16 774 8. Nachtegaal J, Festen JM, Kramer SE. Hearing ability in working life and its relationship with sick
17
18 775 leave and self-reported work productivity. *Ear Hear* 2012;33:94-103. doi:
19
20 776 10.1097/AUD.0b013e318228033e
21
22 777 9. Lin FR, Yaffe K, Xia J, et al. Hearing loss and cognitive decline in older adults. *JAMA Intern Med*
23
24 778 2013;173:293-9. doi: 10.1001/jamainternmed.2013.1868
25
26
27 779 10. Jiam NT, Li C, and Agrawal Y. Hearing loss and falls: A systematic review and meta-analysis.
28
29 780 *Laryngoscope* 2016;126:2587-96.
30
31 781 11. World Health Organization. International Classification of Functioning, Disability and Health.
32
33 782 Geneva: World Health Organization 2001.
34
35 783 12. Scarinci N, Worrall L, Hickson L. The effect of hearing impairment in older people on the spouse:
36
37 784 development and psychometric testing of the significant other scale for hearing disability (SOS-
38
39 785 HEAR). *Int J Audiol* 2009;48:671-83. doi: 10.1080/14992020902998409
40
41
42 786 13. Kamil RJ, Lin FR. The effects of hearing impairment in older adults on communication partners: a
43
44 787 systematic review. *J Am Acad Audiol* 2015;26:155-82. doi: 10.3766/jaaa.26.2.6
45
46 788 14. Jennings MB, Shaw L. Impact of hearing loss in the workplace: raising questions about
47
48 789 partnerships with professionals. *Work* 2008;30:289-95.
49
50 790 15. Chisolm TH, Johnson CE, Danhauer JL, et al. A systematic review of health-related quality of life
51
52 791 and hearing aids: final report of the American Academy of Audiology Task Force On the Health-
53
54 792 Related Quality of Life Benefits of Amplification in Adults. *J Am Acad Audiol* 2007;18:151-83.
55
56
57
58
59
60

- 1
2
3 793 16. Mulrow CD, Tuley MR, Aguilar C. Sustained benefits of hearing aids. *J Speech Hear Res*
4
5 794 1992;35:1402-5. doi:10.1044/jshr.3506.1402
6
7 795 17. Acar B, Yurekli MF, Babademez MA, et al. Effects of hearing aids on cognitive functions and
8
9 796 depressive signs in elderly people. *Arch Gerontol Geriatr* 2011;52:250-2. doi:
10
11 797 10.1016/j.archger.2010.04.013
12
13 798 18. Amieva H, Ouvrard C, Giulioli C, et al. Self-reported hearing loss, hearing aids, and cognitive
14
15 799 decline in elderly adults: A 25-Year study. *J Am Geriatr Soc* 2015;63:2099-104. doi:
16
17 800 10.1111/jgs.13649
18
19 801 19. Chia EM, Wang JJ, Rochtchina E, et al. Hearing impairment and health-related quality of life: the
20
21 802 Blue Mountains Hearing Study. *Ear Hear* 2007;28:187-95. doi: 10.1097/AUD.0b013e31803126b6
22
23 803 20. Hartley D, Rochtchina E, Newall P, et al. Use of hearing aids and assistive listening devices in an
24
25 804 older Australian population. *J Am Acad Audiol* 2010;21:642-53. doi: 10.3766/jaaa.21.10.4
26
27 805 21. Smits C, Kramer SE, Houtgast T. Speech reception thresholds in noise and self-reported hearing
28
29 806 disability in a general adult population. *Ear Hear* 2006;27:538-49. doi:
30
31 807 10.1097/01.aud.0000233917.72551.cf
32
33 808 22. Gates GA, Cooper JC Jr, Kannel WB, et al. Hearing in the Elderly: The Framingham Cohort, 1983-
34
35 809 1985: Part 1. Basic Audiometric Test Results. *Ear Hear* 1990;11:247-56.
36
37 810 23. Abrams HB, Kihm J. An introduction to MarkeTrak IX: A New Baseline for the Hearing Aid Market.
38
39 811 *Hearing Review* 2015;22:16.
40
41 812 24. Knudsen LV, Oberg M, Nielsen C, et al. Factors influencing help seeking, hearing aid uptake,
42
43 813 hearing aid use and satisfaction with hearing aids: A review of the literature. *Trends Amplif*
44
45 814 2010;14:127-54. doi: 10.1177/1084713810385712
46
47 815 25. Meyer C, Hickson L. What factors influence help-seeking for hearing impairment and hearing aid
48
49 816 adoption in older adults? *Int J Audiol* 2012;51:66-74. doi: 10.3109/14992027.2011.611178
50
51 817 26. McCormack A, Fortnum H. Why do people fitted with hearing aids not wear them? *Int J Audiol*
52
53 818 2013;52:360-8. doi: 10.3109/14992027.2013.769066
54
55
56
57
58
59
60

- 1
2
3 819 27. Boothroyd A. Adult aural rehabilitation: What is it and does it work? *Trends Amplif* 2007;11:63-
4
5 820 71. doi: 10.1177/1084713807301073
6
7 821 28. Hickson L, Scarinci N. Older adults with acquired hearing impairment: applying the ICF in
8
9 822 rehabilitation. *Semin Speech Lang* 2007;28:283-90. doi: 10.1055/s-2007-986525
10
11 823 29. Granberg S, Swanepoel de W, Englund U, et al. The ICF core sets for hearing loss project:
12
13 824 International expert survey on functioning and disability of adults with hearing loss using the
14
15 825 international classification of functioning, disability, and health (ICF). *Int J Audiol* 2014;53:497-
16
17 826 506. doi: 10.3109/14992027.2014.900196
18
19
20 827 30. Granberg S, Pronk M, Swanepoel de W, et al. The ICF core sets for hearing loss project:
21
22 828 Functioning and disability from the patient perspective. *Int J Audiol* 2014;53:777-86. doi:
23
24 829 10.3109/14992027.2014.938370
25
26
27 830 31. Gagné JP, Jennings MB. Audiologic rehabilitation intervention services for adults with acquired
28
29 831 hearing impairment. In: Valente M, Hosford-Dunn H, Roeser RJ, eds. *Audiology: Treatment*. New
30
31 832 York: Thieme Medical Publishers 2008:370-99.
32
33 833 32. Laplante-Lévesque A, Hickson L, Worrall L. Factors influencing rehabilitation decisions of adults
34
35 834 with acquired hearing impairment. *Int J Audiol* 2010;49:497-507. doi:
36
37 835 10.3109/14992021003645902
38
39
40 836 33. Kiessling J, Pichora-Fuller MK, Gatehouse S, et al. Candidature for and delivery of audiological
41
42 837 services: Special needs of older people. *Int J Audiol* 2003;42 Suppl 2S92-101.
43
44 838 34. Barker F, Mackenzie E, Elliott L, et al. Interventions to improve hearing aid use in adult auditory
45
46 839 rehabilitation. *Cochrane Database Syst Rev* 2016;8 doi: 10.1002/14651858.CD010342.pub3
47
48 840 35. Henshaw H, Ferguson MA. Efficacy of Individual Computer-Based Auditory Training for People
49
50 841 with Hearing Loss: A Systematic Review of the Evidence. *PLoS ONE* 2013;8:e62836.
51
52 842 doi:10.1371/journal.pone.0062836
53
54 843 36. Wong L, Hickson L. Evidence-based practice in audiology: Evaluating interventions for children
55
56 844 and adults with hearing impairment. San Diego, CA: Plural Publishing 2012.
57
58
59
60

- 1
2
3 845 37. Kramer SE, Allessie GH, Dondorp AW, et al. A home education program for older adults with
4
5 846 hearing impairment and their significant others: A randomized trial evaluating short- and long-
6
7 847 term effects. *Int J Audiol* 2005;44:255-64.
8
9 848 38. Hickson L, Worrall L, Scarinci N. A randomized controlled trial evaluating the active
10
11 849 communication education program for older people with hearing impairment. *Ear Hear*
12
13 850 2007;28:212-30. doi: 10.1097/AUD.0b013e31803126c8
14
15
16 851 39. Hickson L. Defining a paradigm shift. *Semin Hear* 2012;33:3-8. doi: 10.1055/s-0032-1304722
17
18 852 40. Lusic I, Mason P. Paradigm shift: The new world of hearing health care delivery. *ASHA Lead*
19
20 853 2012;17:36-7. doi:10.1044/leader.FTR2.17092012.36
21
22 854 41. Tognola G, Paglialonga A, Chiaramello E, et al. eHealth for hearing—new views and apps
23
24 855 practicalities. *EJBI* 2015;11:37-49.
25
26 856 42. Thorén ES, Öberg M, Wänström G, et al. A randomized controlled trial evaluating the effects of
27
28 857 online rehabilitative intervention for adult hearing-aid users. *Int J Audiol* 2014;53:452-61. doi:
29
30 858 10.3109/14992027.2014.892643
31
32 859 43. Thorén E, Svensson M, Törnqvist A, et al. Rehabilitative online education versus internet
33
34 860 discussion group for hearing aid users: a randomized controlled trial. *J Am Acad Audiol*
35
36 861 2011;22:274-85. doi: 10.3766/jaaa.22.5.4
37
38 862 44. Ferguson M, Brandreth M, Brassington W, et al. A randomized controlled trial to evaluate the
39
40 863 benefits of a multimedia educational program for first-time hearing aid users. *Ear Hear*
41
42 864 2016;37:123-36. doi: 10.1097/AUD.0000000000000237
43
44 865 45. Kramer SE, Kapteyn TS, Festen JM, et al. Factors in subjective hearing disability. *Audiology*
45
46 866 1995;34:311-20.
47
48 867 46. Caposecco A, Hickson L, Meyer C. Assembly and insertion of a self-fitting hearing aid: Design of
49
50 868 effective instruction materials. *Trends Amplif* 2011;15:184-95. doi: 10.1177/1084713811430837
51
52
53
54
55
56
57
58
59
60

- 1
2
3 869 47. Chan AW, Tetzlaff JM, Altman DG, et al. SPIRIT 2013 Statement: Defining standard protocol items
4
5 870 for clinical trials. *Ann Intern Med* 2013;158:200-7. doi: 10.7326/0003-4819-158-3-201302050-
6
7 871 00583
8
9 872 48. Demorest ME, Erdman SA. Development of the communication profile for the hearing impaired.
10
11 873 *J Speech Hear Disord* 1987;52:129-43. doi:10.1044/jshd.5202.129
12
13 874 49. Morkink LB, Knol DL, van Nispen RM, et al. Improving the quality and applicability of the Dutch
14
15 875 scales of the Communication Profile for the Hearing Impaired using item response theory. *J*
16
17 876 *Speech Lang Hear Res* 2010;53:556-71. doi: 10.1044/1092-4388(2010/09-0035)
18
19 877 50. West RL, Smith SL. Development of a hearing aid self-efficacy questionnaire. *Int J Audiol*
20
21 878 2007;46:759-71. doi: 10.1080/14992020701545898
22
23 879 51. Beaton DE, Bombardier C, Guillemin F, et al. Guidelines for the process of Cross-Cultural
24
25 880 Adaption of Self-Report Measures. *Spine* 2000;25:3186-91.
26
27 881 52. Kozlowski L, Almeida G, Ribas A. Level of user satisfaction with hearing AIDS and environment:
28
29 882 the international outcome inventory for hearing AIDS. *Int Arch Otorhinolaryngol* 2014;18:229-34.
30
31 883 doi: 10.1055/s-0033-1363782
32
33 884 53. Laplante-Lévesque A, Nielsen C, Jensen LD, et al. Patterns of hearing aid usage predict hearing aid
34
35 885 use amount (data logged and self-reported) and overreport. *J Am Acad Audiol* 2014;25:187-98.
36
37 886 doi: 10.3766/jaaa.25.2.7
38
39 887 54. Kramer SE, Goverts ST, Dreschler WA, et al. International Outcome Inventory for Hearing Aids
40
41 888 (IOI-HA): results from The Netherlands. *Int J Audiol* 2002;41:36-41. doi:
42
43 889 10.3109/14992020209101310
44
45 890 55. Meijer AG, Wit HP, TenVergert EM, et al. Reliability and validity of the (modified) Amsterdam
46
47 891 Inventory for Auditory Disability and Handicap. *Int J Audiol* 2003;42:220-6. doi: 10.1111/j.1365-
48
49 892 2273.2004.00844
50
51
52
53
54
55
56
57
58
59
60

- 1
2
3 893 56. Laplante-Lévesque A, Hickson L, Worrall L. Stages of change in adults with acquired hearing
4
5 894 impairment seeking help for the first time: application of the transtheoretical model in audiologic
6
7 895 rehabilitation. *Ear Hear* 2013;34:447-57. doi: 10.1097/AUD.0b013e3182772c49
8
9 896 57. van den Brink RHS. Attitude and illness behavior in hearing impaired elderly (Unpublished
10
11 897 doctoral thesis). Rijks University of Groningen 1995.
12
13 898 58. Noble W. Extending the IOI to significant others and to nonhearing aid-based interventions. *Int J*
14
15 899 *Audiol* 2002;41:27-9. doi: 10.3109/14992020209101308
16
17 900 59. Demorest ME, Erdman SA. Retest stability of the communication profile for the hearing
18
19 901 impaired. *Ear Hear* 1988;9:237-42. doi: 10.1097/00003446-198810000-00002
20
21 902 60. Moher D, Hopewell S, Schulz KF, et al. CONSORT 2010 Explanation and elaboration: updated
22
23 903 guidelines for reporting parallel group randomised trials. *Int J Surg* 2012;10:28-55 doi:
24
25 904 10.1016/j.ijvsu.2011.10.001
26
27 905 61. Linnan L, Steckler A. Process evaluation for public health interventions and research. 1st ed. San
28
29 906 Francisco CA: Jossey-Bass 2002.
30
31 907 62. Gussenhoven AH, Singh AS, Goverts ST, et al. A process evaluation of implementing a vocational
32
33 908 enablement protocol for employees with hearing difficulties in clinical practice. *Int J Audiol*
34
35 909 2015;54:507-17. doi: 10.3109/14992027.2015.1009642
36
37 910 63. Swanepoel dW, Hall JW, III. A systematic review of telehealth applications in audiology. *Telemed J*
38
39 911 *E Healt* 2010;16:181-200. doi: 10.1089/tmj.2009.0111
40
41 912 64. Choi NG, DiNitto DM. Internet use among older adults: association with health needs,
42
43 913 psychological capital, and social capital. *J Med Internet Res* 2013;15:e97. doi: 10.2196/jmir.2333
44
45 914 65. Fox S. Digital Divisions. PEW Internet & American Life Project. Washington, DC 2005.
46
47 915 66. UNECE Statistical Database. 2015. <http://w3.unece.org/PXWeb/en>. Accessed 20 June 2016
48
49 916 67. Centraal Bureau voor Statistiek (CBS). 2016. [https://www.cbs.nl/nl-nl/nieuws/2016/22/acht-](https://www.cbs.nl/nl-nl/nieuws/2016/22/acht-procent-van-de-nederlanders-nooit-op-internet)
50
51 917 [procent-van-de-nederlanders-nooit-op-internet](https://www.cbs.nl/nl-nl/nieuws/2016/22/acht-procent-van-de-nederlanders-nooit-op-internet). Accessed 26 Sep 2016.
52
53
54
55
56
57
58
59
60

- 1
2
3 918 68. Gell NM, Rosenberg DE, Demiris G, et al. Patterns of technology use among older adults with and
4
5 919 without disabilities. *Gerontologist* 2015;55:412-21. doi: 10.1093/geront/gnt166
6
7 920 69. Thorén ES, Öberg M, Wänström G, et al. Internet access and use in adults with hearing loss. *J*
8
9 921 *Med Internet Res* 2013;15:e91. doi: 10.2196/jmir.2221
10
11 922 70. Martin KA, Leary MR, Rejeski WJ. Self-presentational concerns in older adults: Implications for
12
13 923 health and well-being. *Basic Appl Soc Psych* 2000;22:169-79. doi:
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15 924 10.1207/S15324834BASP2203_5
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Appendix 1 Spirit flow diagram. Schedule of enrolment, interventions, and assessments

		Allocation	Enrolment	Post-Allocation and Enrolment			
		of HAD practices					
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					
INTERVENTIONS:							
Care as Usual (Hearing aid fitting)		x	—————			x	
Intervention (Hearing aid fitting + SUPR)		x	—————			x	

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

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

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3 subscales
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6 *Secondary*

7 *outcome*

8 *measures -*

9 *HAUs*

		Allocation	Enrolment	Post-Allocation and Enrolment			
		of HAD practices					
TIMEPOINT	Outcome	-T2	-T1	T0	T1	T2	T3
	measurements			(Baseline)	(6 months)	(12 months)	(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

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Self-reported	-IOI-HA (item 1)				x	x	x
hearing aid use	-Use questionnaire				x	x	x
Objective	-Data-logging				x	x	x
		Allocation	Enrolment	Post-Allocation and Enrolment			
		of HAD practices					
TIMEPOINT	Outcome	-T2	-T1	T0	T1	T2	T3
	measurements			(Baseline)	(6 months)	(12 months)	(18 months)
Self-reported	-IOI-HA (items				x	x	x
intervention	2-7)/IOI-AI (all 7						
outcomes	items)						
Satisfaction	“How likely is it			x	x	x	x
with the	that you would						
hearing aid	recommend the						
dispenser	service of the						
service	HAD practice to						
	other people						
	(family, friends,						

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colleagues?)"

Self-reported	AIADH			x	x	x	x
activity							
limitations and							
participation							
restrictions							

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

Emotional response	HHDI - Emotional response subscale	x	x	x	x
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Secondary

outcome

measures - CP

Third-party disability	SOS-HEAR	x	x	x	x
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Self-reported intervention	IOI-HA-SO/IOI-AI-SO		x	x	x
----------------------------	---------------------	--	---	---	---

outcomes from the perspective of the CP

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.



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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	1-36
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

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2
3 **Introduction**
4

5 Background and	6a	Description of research question and justification for undertaking the trial, including summary of relevant	3-8
6 rationale		studies (published and unpublished) examining benefits and harms for each intervention	
7			
8	6b	Explanation for choice of comparators	3-8
9			
10 Objectives	7	Specific objectives or hypotheses	8
11			
12 Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group),	8, 9
13		allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	
14			
15			
16 Methods: Participants, interventions, and outcomes			
17			
18 Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will	8-12
19		be collected. Reference to where list of study sites can be obtained	
20			
21 Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and	13,14
22		individuals who will perform the interventions (eg, surgeons, psychotherapists)	
23			
24 Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be	8-12
25		administered	
26			
27	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose	N/A
28		change in response to harms, participant request, or improving/worsening disease)	
29			
30	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence	12, 13, 31
31		(eg, drug tablet return, laboratory tests)	
32			
33	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	12,13
34			
35 Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood	21,25
36		pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg,	
37		median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen	
38		efficacy and harm outcomes is strongly recommended	
39			
40			
41 Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for	12,13, 15-21
42		participants. A schematic diagram is highly recommended (see Figure)	
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3 Sample size 14 Estimated number of participants needed to achieve study objectives and how it was determined, including 26, 27
4 clinical and statistical assumptions supporting any sample size calculations

5
6 Recruitment 15 Strategies for achieving adequate participant enrolment to reach target sample size 13
7

8 **Methods: Assignment of interventions (for controlled trials)**
9

10 Allocation:

11
12 Sequence generation 16a Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any 26
13 factors for stratification. To reduce predictability of a random sequence, details of any planned restriction
14 (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants
15 or assign interventions
16

17
18 Allocation concealment mechanism 16b Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, 26
19 opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned
20
21

22 Implementation 16c Who will generate the allocation sequence, who will enrol participants, and who will assign participants to 9, 26
23 interventions
24

25 Blinding (masking) 17a Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome 32, 33
26 assessors, data analysts), and how
27

28 17b If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's N/A
29 allocated intervention during the trial
30
31

32 **Methods: Data collection, management, and analysis**
33

34 Data collection methods 18a Plans for assessment and collection of outcome, baseline, and other trial data, including any related 12, 15-25
35 processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of
36 study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known.
37 Reference to where data collection forms can be found, if not in the protocol
38

39 18b Plans to promote participant retention and complete follow-up, including list of any outcome data to be 27, 28
40 collected for participants who discontinue or deviate from intervention protocols
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3	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
4				
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6				
7	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
8				
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10		20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	27, 28
11				
12		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
13				
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15				
16	Methods: Monitoring			
17				
18	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
19				
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23		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
24				
25				
26	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
27				
28				
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
30				
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33	Ethics and dissemination			
34				
35	Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	35, 36
36				
37				
38	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
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3	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
4				
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6		26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
7				
8				
9	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
10				
11				
12	Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	35
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15	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
16				
17				
18	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
19				
20				
21	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
22				
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26		31b	Authorship eligibility guidelines and any intended use of professional writers	35
27				
28		31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	N/A
29				
30	Appendices			
31				
32	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)
33				
34				
35				
36	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.
37				
38				

39 *It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items.
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 42