PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	Effectiveness of an online SUpport PRogramme (SUPR) for older hearing aid users: Study protocol for a cluster randomised controlled trial
AUTHORS	Meijerink, Janine; Pronk, Marieke; Paulissen, Bernadettte; Witte, Birgit; Wouden, Bregje; Jansen, Vera; Kramer, Sophia

VERSION 1 - REVIEW

REVIEWER	Carly Meyer The University of Queensland, Australia
REVIEW RETURNED	29-Nov-2016

GENERAL COMMENTS	Thank you for the opportunity to review this Protocol. It is encouraging to see a research protocol for the evaluation of an aural rehabilitation program that will be implemented nation-wide across the Netherlands. The authors clearly communicated how this study will be addressing a gap in the literature – that, despite hearing aids alone not addressing the full range of impacts of hearing loss, there has been no longitudinal research on this scale looking at the benefits of aural rehabilitation on hearing disability. Some minor things to consider in the Introduction include: • Including citations to support the statements on p. 4, line 86 and p. 5, lines 106-109. • Not using the phrase “so-called” as this infers a level of contention (this has been used a number of times throughout the manuscript). • Reporting the sample size of Thoren et al.’s and Ferguson et al.’s study, when describing them on p.7. This will provide context to the comments at the end of the paragraph. • Attending to minor typographical errors e.g., p4, line 20 – double use of “has”. The authors have adhered appropriately to the SPIRIT2013 checklist for reporting clinical trial protocols. However, there are some things I would like further clarification on, including: • Whether or not the Practical Support Book was developed in the context of best practice guidelines for written health information. For further information about this, please refer to Andrea Caposecco’s research. • Whether or not the online support is all asynchronous, meaning that there is no online interaction between the hearing aid dispensers and clients during the trial. If this is the case, have you considered how you might motivate clients to watch the videos if the process evaluation reveals that the dose implemented is low? • Whether there is any capacity to provide patients with DVDs if they do not have access to the Internet?

	• Whether the nominated CP must be 18+ years to participate. Currently, it says there is no inclusion or exclusion criteria. • How the “expected” self-efficacy scale differs from the “experienced” self-efficacy scale (p.17). • How an employee of the headquarters will monitor video watching behaviour (p.22). • Why “Research ethics approval” is rated as N/A in the table when the study protocol has been approved by the Scientific Committee of the EMGO Institute for Health and Care Research. Overall, the study protocol is very comprehensive and the study appears very well designed. I recommend that the Protocol is suitable for publication after minor revision.

REVIEWER	Magdalena Sereda NIHR Nottingham Hearing Biomedical Research Unit, Otology and hearing group, Division of Clinical Neuroscience, School of Medicine, University of Nottingham, United Kingdom
REVIEW RETURNED	02-Dec-2016

GENERAL COMMENTS	This is the protocol for a randomised controlled trial evaluating addition of online support programme to usual hearing aid care. While this seems an interesting study I have struggled to understand what exactly was evaluated. Authors followed SPIRIT 2013 checklist, however some of the elements from the checklist are missing. Specific comments: 1) Title is not clear and not consistent with trial registration. What is being evaluated should be stated (effectiveness as stated in the registration?). 2) Specific objectives and hypotheses are missing, therefore it is difficult to judge if methods used are appropriate. 3) Explanation of the clinical relevance of chosen measures would be strongly recommended. Justification for the choice of primary outcome measure should be included. 4) Sample size calculations are not clear. Different minimum important change is used for first time and previous hearing aid users, however the reasons for that are not clear. 5) Randomisation: sequence generation methods and implementation should be explained in more detail. 6) Blinding: surely some blinding would be possible, e.g. blinding of statistician performing the analysis, researchers etc. Was anyone blinded in the study? 7) The explanation why Data Monitoring Committee was decided not to be needed should be included as this is full scale Randomised Controlled Trial with considerable number of participants and multiple outcome measures. 8) Procedure for obtaining consent from participants should be explained.

	9) Study sponsor should be named. 10) Recruitment status should be stated. 11) Reasons for using cluster randomisation should be explained as in principle randomisation of individual participants seems feasible in this study. 12) Authors stated that the SUPR programme has online elements (p.10 line 242). However, only email is mentioned. It is not clear what was the mode of delivery of online components (i.e. videos). There is also a booklet provided to participants. However, in a few places authors called SUPR and online programme (e.g. p3, line 56) which is misleading. It should be clear that it is a booklet and videos provided by email. 13) p26, line 588: authors stated that the novelty of SUPR is that it is focused on coping which is the main component. However, I am struggling to see what elements of the SUPR, different to the other programmes are focusing on coping. Authors should provide clear definition of coping and highlight the elements of their programme that focus on that aspect and are not present in the other programmes. 14) In page 3 line 56 authors stated that the programme is the first one that was implemented in a hearing aids practice. However, my understanding from reading the methods was that although hearing aids dispensers signposted people to the study patients themselves registered for the participation. In the study of Ferguson et al. (2016) audiologists were actually explaining the use and content of the programme to the potential users. Authors should therefore explain what do they mean by 'implementation in hearing aid practice' and was was novel in their approach. 15) There is an additional inclusion criterion listed in the protocol vs study registration: hearing loss in one or both ears at least 35 dB HL. This deviation should be explained and registration amended accordingly. 16) MARS-HA (Advanced handling subscale) was not mentioned in the study registration. This should be explained and the registration amended accordingly. Minor comments: - p. 10 line 244: 'This takes up to approximately 6 months...' What takes? Should be rephrased/clarified. - p10, line 231/232: 'The book covers four parts, corresponding to four phases.' What phases? Defined on what basis? Should be explained. -what is the reason for performing both intention to treat and per-protocol analysis? This should be explained. -Strategy for analysis of cluster-randomised data should be clearly explained in the statistical analysis plan. More detail about dealing with additional level of dependency in the data should be provided.

	-p 27, line 628/629: Sentence is unclear. How can participants underestimate their hearing impairment because of the stigma? Please explain/rephrase. -p 28, line 639: 'When effects of SUPR turn out to be disappointing...'- unfortunate phrase, please rephrase. -Throughout the manuscript: use of word 'persons', e.g. older persons, hearing-impaired persons, provided for persons etc. Should be: people. -p3, line 67: the older old should be defined.

REVIEWER	Gabrielle Saunders VA RR&D National Center for Rehabilitative Auditory Research
REVIEW RETURNED	04-Dec-2016

GENERAL COMMENTS	Review of evaluating the addition of an outline Support PRogramme (SUPR) to the usual hearing aid care: protocol or a cluster randomized controlled trial. Meijerink, Pronk, Paulissen, Witte, Wouden, Jansen & Kramer. This paper describes the protocol for an RCT to be conducted evaluating the effectiveness of an internet-based auditory rehabilitation intervention on a variety of hearing aid outcomes. The trial is well-designed and should yield important information for the field of audiology. I have a few suggestions for improving the paper. First, there are numerous typos that should be fixed prior to the paper being accepted for publication. There are so many that I will not list them below. In addition, the paper would benefit from editorial input from a native speaker of English because there are a number of grammatically-incorrect phrases and unusually-constructed sentences. Having said that, these only marginally detract from the readability of the paper. In terms of more substantial input I have the following suggestions. **Background.** I think the background could be shortened considerably through editorial changes but the topics addressed are appropriate. Line 104: The most recent MarkeTrak survey (referred to as MT9) shows that olny 3% of hearing aids are unused and that more people are getting hearing aids sooner. This info should replace that stated in the paper. Abrams HB, Kihm J. An Introduction to MarkeTrak IX: A New Baseline for the Hearing Aid Market. Hearing Review. 2015;22(6):16. Line 105: I disagree with the statement that ‘reasons for low uptake are largely known’. I would suggest that many factors have been investigated but always much variance is left unexplained. It would

	be better to omit the above statement and simply note that many factors have been investigated. Parag starting on line 137: I suggest providing reasons for why long term f/u is important. The fact that it has not been done before is not a good reason for doing it now. The authors do provide reasons in the discussion. I would move that info to the background. Conducting the study in multiple dispensing clinics offers more than simply a larger number of subjects – it reflects real world clinical practice. This is a major strength of the study and the authors should make more note of the value of this in the background. **Methods.** Line 235: Provide more information on 'writing down of specific needs' Line 237: I would say 'the client gives feedback' not 'is allowed to give feedback'. Presumably the study team will not prevent participants doing whatever they want! Line 249: To what extent do the videos address the different instructions needed based on hearing aid style? Are there style-specific videos? If not, how will this be dealt with? Line 280: 'to remind them' of what? Finish the sentence please. Line 289 and line 294: Flower coupons and pies seem very nice rewards for participation but this reads a bit strangely in the paper. Can it be rephrased? Line 300: what defines 'intention to take up hearing aids'? At what point is this evaluated? Line 307: Is it possible an enrolled participant will later seek additional care at a specialized audiology clinic? If so, will they then be terminated from the study? Table: It seems to be that the amount of detail provided about the tests in table 1 is greater for some tests than for other tests (e.g. no info is given for self-reported hearing activity while scale info is given self-efficacy while a reference to the test on of hearing aid rehabilitation and SUPR outcome is provided. Please be consistent across tests. Also what is the reference referred on line 56/57 on page 14? Why is the test the only one with a reference cited? Line 384: I wonder whether the authors have considered using a translation of the URICA-Adapted (Saunders et al., 2016)? As noted in that *article 'issues were raised about the relevance of some of the URICA items for assessing hearing health behaviors— especially those that had a psychological undertone. In the present study, the original items of the URICA (McConnaughy et al. 1983) were adapted to be more relevant for hearing health behaviors by*

	reducing the psychological undertones.' Saunders GH, Frederick MT, Silverman SC, Nielsen C, Laplante-Lévesque A. Description of Adults Seeking Hearing Help for the First Time According to Two Health Behavior Change Approaches: Transtheoretical Model (Stages of Change) and Health Belief Model. Ear Hear. 2016 May-Jun;37(3):324-33. Line 437: The tense changes to past in this paragraph, and on line 659 it says 'data collection was done by xxxx.' Is this an error or have the data already been collected? The rest of the paper reads as though this is future work. Line 481: I am unsure as to what '….which questionnaires it reverses to so that data can be merged.' Please clarify Data collected with IOI-HA: Studies in which the IOI-HA has been used show little variability across subjects. Since the IOI-AI scales are identical I would be concerned that the IOI-AI will be an insensitive measure of dose received, satisfaction, and benefit. Is there another measure that could be used instead? Line 526: Shouldn't ALL modifications to the protocol be submitted to VU university ethics committee, not just 'important' ones? Parag beginning line 610: Add to this paragraph that the participants who have access to the internet will be of higher SES and that this may bias the data. Parag beginning 622. I am not sure how this fits into the weaknesses section.

VERSION 1 – AUTHOR RESPONSE

Comments Reviewer 1: Carly Meyer
Thank you for the opportunity to review this Protocol. It is encouraging to see a research protocol for the evaluation of an aural rehabilitation program that will be implemented nation-wide across the Netherlands.

The authors clearly communicated how this study will be addressing a gap in the literature – that, despite hearing aids alone not addressing the full range of impacts of hearing loss, there has been no longitudinal research on this scale looking at the benefits of aural rehabilitation on hearing disability. Some minor things to consider in the Introduction include:

1. Including citations to support the statements on p. 4, line 86 and p. 5, lines 106-109.
Reply: We have now included citations for each of the statements. See p. 4, line 83, and p. 4 and 5, lines 103 to 108.

2. Not using the phrase "so-called" as this infers a level of contention (this has been used a number of

times throughout the manuscript).
Reply: Thank you for noticing. We removed the phrase throughout the MS.

3. Reporting the sample size of Thorén et al.'s and Ferguson et al.'s study, when describing them on p.7. This will provide context to the comments at the end of the paragraph.
Reply: We now added the sample sizes of both studies (see p. 6, lines 143 and 144 and lines 150 and 152).

4. Attending to minor typographical errors e.g., p4, line 20 – double use of "has".
Reply: We have now edited this particular error (see p. 4, line 79) and also thoroughly checked and edited the remaining MS for any other typographical errors.

The authors have adhered appropriately to the SPIRIT2013 checklist for reporting clinical trial protocols. However, there are some things I would like further clarification on, including:

5. Whether or not the Practical Support Book was developed in the context of best practice guidelines for written health information. For further information about this, please refer to Andrea Caposecco's research.
Reply: The Practical Support Booklet was developed by the hearing aid dispenser company. In the last phase of the development process, the VUmc researchers were asked to check one element of the booklet for factual correctness (i.e., the paragraph about the communication strategies).
The purposes of the PSB that the hearing aid company envisaged for the booklet were to: 1) assists clients in getting familiar with their hearing aid, 2) stimulate clients' use of the hearing aid and of the support programme, and 3) guide clients through the various stages (i.e., appointments) of their rehabilitation trajectory. A first version of the booklet was the result of various orientating brainstorm sessions with the different stakeholders involved. Subsequently, a first draft was made and was tested in ten hearing aid dispenser shops for several months. Feedback on the booklet of employees, clients and their partners were collected and sent to the hearing aid dispensing headquarters. In addition, six months after clients received the first draft of the booklet, experiences of a convenient sample of 52 clients were collected using a telephone survey. Furthermore, two focus groups were conducted among hearing impaired people who saw the booklet for the first time. Each group consisted of eight participants who discussed the attractiveness and the usefulness of the booklet. The telephone survey and the focus groups were conducted by a market research bureau.

No specific (scientific) guidelines were followed during development and pilot testing. However, going over the guidelines as provided by Andrea Caposecco et al. (2011), a number of Caposecco's steps were indeed covered during the development process. These are: Meetings were organized with key stake holders (step 1: planning), specific purposes and key objectives for the instruction were defined following this (step 1: planning), short words and sentences were used in the text of the booklet (step 2: design, language), boxes, larger font or indents were used to highlight important information (step 2: design, layout and typography), paragraphs were kept short and expressed only one idea per paragraph (step 2: design, organization), graphics were designed such that the reader would understand all elements in it (step 2 design, graphics), and finally, the material was evaluated with a sample target audience population (step 4: pilot testing and revision).

We now incorporated the above-mentioned information about the development process into the manuscript (see p. 11). It now reads (see lines 264 to 274):
The content and the appearance of the booklet were realised during several months of development by the HAD company. Although no specific guidelines were used for the development of the written health information in the booklet, a number of the subsequent steps that are deemed important by Caposecco et al were taken: 1) interviews with key stakeholders (clients, CPs, HAD practice personnel) were held to specify the booklet's goals and functions, 2) graphics and text were

developed and optimized with regard to their understandability and attractiveness (language difficulty, lay-out, font size, paragraphing), 3) a first complete version of the booklet was pilot-tested in ten HAD practices for several months. Feedback by all key stakeholders was collected, 4) the feedback was incorporated in a new and final version of the booklet (which was used in the study)[47].

6. Whether or not the online support is all asynchronous, meaning that there is no online interaction between the hearing aid dispensers and clients during the trial. If this is the case, have you considered how you might motivate clients to watch the videos if the process evaluation reveals that the dose implemented is low?
Reply: Please first see our reply to comment no. 10. It is unfortunately not possible to motivate specifically those clients who haven't watched the videos due to privacy regulations the HAD practice company has to adhere to. The company is not allowed to determine clients' individual online behavior with regard to opening emails, clicking on the links in the emails, and watching the videos provided in the links. With regard to the measurement of the dose implemented for the process evaluation of the study: The company is only allowed to determine clients' behavior on a group level (i.e., pooling all client data and determining group averages) using Quadia (supplier of online video content) and Google Analytics. As a consequence, these are also the only data that can be used for the process evaluation. This means that we will not be able to discern between study participants' behavior and regular HAD clients' behavior (during the period that the study runs, the HAD practices that do not participate in the study offer SUPR as standard care). We realise that we thereby perhaps incorrectly assume that the study population and regular clients of the practices are similar in their behaviour, but is the best we can do. We added a remark about this limitation to the text of the process evaluation. It now reads (see p.27, lines 564 to 573):
Dose received and implemented: Did the participants open the emails and the videos? If so, did they watch the whole video, or part(s) of it? The video watching behaviour will be determined using Quadia (supplier of online video content) and Google Analytics. Data on the average watching time per video, and how many times a particular video has been opened will be determined. Due to the privacy regulations the HAD company is subject to, the company is only allowed to collect video watching data on a group level (and not on an individual level). As all the HAD practices of the company that do not participate in the study provide SUPR as their standard care at the time of the study, the researchers will not be able to determine specific group averages of the study participants (the averages are based on both study participants and regular HAD clients).

If the process evaluation would reveal that the dose implemented in support programme users generally is low, reminders directed at everybody would currently be the only legal option. However, this method is suboptimal or could perhaps even work counter-effectively (raise irritation). Another option that could be considered for the future would be to obtain each client's consent for monitoring his/her online behavior. Then, tailored reminders would be possible. This option is already considered by the HAD practice company.

7. Whether there is any capacity to provide patients with DVDs if they do not have access to the Internet?
Reply: In the development phase of SUPR, the HAD practice company did consider to additionally provide a DVD version. However, it was decided not to do this for various reasons. Firstly, with a DVD-version, it was considered time-consuming and costly if any updates or other changes to SUPR would have been required (in contrast to an online version). Secondly, it turned out that producing a DVD-version as an additional option was rather expensive. Lastly, the average penetration of the use of internet for the large majority of Dutch older adults and thus for their potential clientele was deemed sufficiently high. The researchers inquired whether there have been any requests for a DVD version by clients so far. It appeared it had been requested only once.

8. Whether the nominated CP must be 18+ years to participate. Currently, it says there is no inclusion

or exclusion criteria.
Reply: The original aim indeed was to only include adult (18+) CPs. We added this in the in- and exclusion criteria section of the MS now (p.14, lines 356 and 357).

9. How the “expected” self-efficacy scale differs from the “experienced” self-efficacy scale(p.17).
Reply: We now explain this (see p. 20 , lines 401-405).

10. How an employee of the headquarters will monitor video watching behaviour (p.22).
Reply: Please see our reply to comment no. 6. In addition, we changed the term “monitor” video watching behaviour to “determine” video watching behaviour (p.27, lines 566 to 573), because we do not warn, control or keep a continuous record of video watching behaviour during the study, but only determine it afterwards.

11. Why “Research ethics approval” is rated as N/A in the table when the study protocol has been approved by the Scientific Committee of the EMGO Institute for Health and Care Research.
Reply: Rating of “Research ethics approval” as N/A was an error. We have now changed this in the checklist (see p. 4, number 24).

We also changed this information in the abstract (see p. 2, lines 46 and 47):
The study was approved by the Dutch Institutional Review Board (IRB) of the VU Medical University Center Amsterdam.

The previous information that was provided here (concerning approval of the scientific soundness of that was given by the Scientific Committee) was correct, but incomplete. In our research institute, scientific soundness is firstly checked by a separate committee (the Scientific Committee). After this, the IRB of our institute weighs the scientific value of the study against the participants’ burden and possible risks. This means, that once the IRB has given its ethical clearance for the study and all the respondent communication (invitation letters, questionnaires, etc.), it indicates both scientific soundness, and an acceptable burden and low (or no risks in the case of our study) for the participants. We therefore decided that stating that the study was approved by the IRB would be sufficient.

Accordingly, we also adjusted the MS text under ‘Ethics approval and consent to participate’. This section now reads (see p. 33 and 34, lines 742 to 746):
Written consent for the SUPR study (reference number: 2015.335) was obtained from the Dutch Institutional Review Board (IRB) of the VU Medical University Center Amsterdam (registered with the US Office for Human Research Protections as IRB00002991; FWA number: FWA00017598). The IRB concluded that Medical Research Involving Human Subjects ACT (WMO) does not apply to this study.

Comments Reviewer 2: Magdalena Sereda
This is the protocol for a randomised controlled trial evaluating the addition of an online support programme to usual hearing aid care. While this seems an interesting study I have struggled to understand what exactly was evaluated. Authors followed SPIRIT 2013 checklist, however some of the elements from the checklist are missing.

Specific comments:

1. Title is not clear and not consistent with trial registration. What is being evaluated should be stated (effectiveness as stated in the registration?).
Reply: Thank you for noticing. We now changed the title of our manuscript into: “Effectiveness of an online SUpport PRogrammme (SUPR) for older hearing aid users: Study protocol for a cluster randomised controlled trial”.

2. Specific objectives and hypotheses are missing, therefore it is difficult to judge if methods used are appropriate.
Reply: We now included more specific objectives and hypotheses in the final part of the introduction. See p. 8, lines 184 to 202.

3. Explanation of the clinical relevance of chosen measures would be strongly recommended. Justification for the choice of primary outcome measure should be included.
Reply: Firstly, please note that the prior use of the term 'coping' throughout our MS may not be interpreted by all readers in the definition that we intend as throughout the literature, different definitions of coping are used. In our definition, coping reflects the underlying constructs captured by the CPHI-subscales: use of maladaptive behaviors, verbal strategies, and non-verbal strategies (together these reflect 'communication strategies'); and self-acceptance, acceptance of loss, and stress & withdrawal (together these reflect 'personal adjustment'). Therefore, we chose to use the terms 'communication strategies' and 'personal adjustment' instead of coping.

We have chosen for the subscales of the CPHI and their underlying constructs as central outcome measures for a number of reasons. This justification is now included in the MS (see p. 20, lines 390 to 393).

4. Sample size calculations are not clear. Different minimum important change is used for first time and previous hearing aid users, however the reasons for that are not clear.
Reply: Lines 515-517 explains the reasons for use of different minimum important change (difference) for first time and experienced hearing aid users: "Given that in a previous study[37] the effect of the programme was larger for first-time than for experienced users, sample sizes should be calculated separately for first-time and experienced users." The term 'minimal important difference' might cause some confusion. We therefore now changed this to 'expected difference' in the sample size calculation section (See p. 25, lines 513, 517, and 526).

5. Randomisation: sequence generation methods and implementation should be explained in more detail.
Reply: We have now explained this in more detail in the randomisation section (see p. 24, lines 492 and 493).

6. Blinding: surely some blinding would be possible, e.g. blinding of statistician performing the analysis, researchers etc. Was anyone blinded in the study?
Reply: Unfortunately blinding of the researchers who will perform the analyses will not be possible. We use different versions of the International Outcome Inventory (IOI), (The International Outcome Inventory – Hearing Aids (IOI-HA) and the equivalent International Outcome Inventory for Alternative Interventions (IOI-AI)) at T1-T3 for participants in the care as usual group and participants in the intervention group. The data files will thus 'give away' which respondents were assigned to which group. We have now explained this in more detail in the discussion section of our manuscript, p. 31, lines 669 to 672.

7. The explanation why Data Monitoring Committee was decided not to be needed should be included as this is full scale Randomised Controlled Trial with considerable number of participants and multiple outcome measures.
Reply: We consulted the IRB of our institute. The SUPR study does not fall under the Research Involving Human Subjects ACT (WMO) and therefore a Data Monitoring Committee to overview the study is not needed. This has now been included in the MS, p. 29, lines 629 to 632.

8. Procedure for obtaining consent from participants should be explained.

Reply: This has now been included. It now reads (see p. 34, lines 747 to749):
Participants' consent will be obtained via the registration website of the study. At this website participants were asked to declare that they were sufficiently informed about the study and agreed on the use of certain data to be collected for the purposes of the study.

9. Study sponsor should be named.
Reply: The sponsor has now been named (i.e., VU University Medical Center, see p. 33, line 735 and 736).

10. Recruitment status should be stated.
Reply: We have now stated the recruitment status (see p. 16, lines 323 and 324). As the recruitment period was finalized in September 2016, we now changed the tense of the sections in the MS about randomisation and recruitment into 'past tense'.

11. Reasons for using cluster randomisation should be explained as in principle randomisation of individual participants seems feasible in this study.
Reply: Cluster randomisation (with the HAD practice as a unit) was chosen because of the risk of contamination in an individual randomisation design. This risk for contamination was considered substantial because individual randomisation would imply that the HAD personnel would potentially have to switch their client approaches (yes/no SUPR) frequently. This would have increased the risk of contamination as the personnel might accidentally refer to or offer SUPR to clients assigned to the Care as Usual group. In addition, there were practical reasons. For instance, as the time between informing the clients about the study, clients' consent to participate in the study and the start of receiving SUPR/Care as Usual was relatively short, it was not feasible for the researchers and the personnel to perform randomisation on an individual level. This information has been added in the study design paragraph of the methods section (see p.9, lines 206 to 212).

12. Authors stated that the SUPR programme has online elements (p .10 line 242). However, only email is mentioned. It is not clear what was the mode of delivery of online components (i.e. videos). There is also a booklet provided to participants. However, in a few places authors called SUPR and online programme (e.g. p3, line 56) which is misleading. It should be clear that it is a booklet and videos provided by email.
Reply: We apologize for the lack of clarity. The links to the videos are provided by email. All content (instruction videos, testimonials of peers and videos of 'Horen en Gehood Worden') can be viewed online on the website of the HAD practice by clicking on the link in the email. For this reason we use the term 'online programme'. We have now explained this in more detail (see p. 11 , lines 277-279).

13. p26, line 588: authors stated that the novelty of SUPR is that it is focused on coping which is the main component. However, I am struggling to see what elements of the SUPR, different to the other programmes are focusing on coping. Authors should provide clear definition of coping and highlight the elements of their programme that focus on that aspect and are not present in the other programmes.
Reply: Please first see our reply under point 3. We now feel that certain elements of the programmes of Thorén and Ferguson, similarly to SUPR, focus on the use of communication strategies and personal adjustment (in the programme of Thorén et al, both the reading material and the online discussion forum cover communication strategies and personal adjustment, and one of the RLOs used in Fergusons' programme covers communication tactics). Therefore we deleted the section in the discussion of the MS in which the elements of SUPR that focus on coping compared to other programmes were described. We have now taken a somewhat different approach in which we highlight that SUPR is unique in implementing the programme on a large scale in the HAD setting in the introduction of the MS (p. 7, lines 176 to 179).

14. In page 3 line 56 authors stated that the programme is the first one that was implemented in a hearing aids practice. However, my understanding from reading the methods was that although hearing aids dispensers signposted people to the study patients themselves registered for the participation. In the study of Ferguson et al. (2016) audiologists were actually explaining the use and content of the programme to the potential users. Authors should therefore explain what do they mean by 'implementation in hearing aid practice' and was was novel in their approach.
Reply: We apologize for the confusion. We wrote that it was the first programme that is implemented in hearing aid dispensing setting. By this, we mean that the support programme is integrated within the hearing care that is offered to clients in the HAD practices. For instance, the timing of the emails with the online content are connected to the timing of certain key appointments with the HAD. Also, the Practical Support Booklet is handed out by the HAD personnel and is used throughout the rehabilitation track.

15) There is an additional inclusion criterion listed in the protocol vs study registration: hearing loss in one or both ears at least 35 dB HL. This deviation should be explained and registration amended accordingly.
Reply: Thank you so much for noticing this difference. This inclusion criterion was not applied during the recruitment, so this criterion was included in the manuscript by mistake. In the Netherlands, a hearing loss of at least 35 dB HL is applied as the minimum hearing loss for which most adults can get the majority of their hearing aid costs reimbursed by their health care insurance. However, for every person with hearing problems who could potentially benefit from a hearing aid, it is always possible to obtain hearing aids, so also if someone for instance has a hearing loss of 25 dB HL (worst ear). These persons could then pay for the aids out of pocket, or sometimes get a reimbursement via their employer. SUPR is suitable for every adult hearing aid user with hearing problems, so also for these persons. We have deleted the criterion from our manuscript now.

16) MARS-HA (Advanced handling subscale) was not mentioned in the study registration. This should be explained and the registration amended accordingly.
Reply: Thank you for noticing. The MARS-HA (advanced handling subscale) was indeed added in a later stage of the study (after the start of administering the baseline questionnaires). We had not realized before that it would be useful to measure these more advanced skills at T1, T2, and T3. As outlined in the introduction now, we hypothesize that SUPR participants will have better handling skills than the Care as Usual participants. The basic handling skills may however show a ceiling effect on the measurements after T0 in both groups (and thus this measure thus may not show any differences). The advanced handling scale might show these differences.
The information in the trial registration will be changed accordingly.

Minor comments:

- p. 10 line 244: 'This takes up to approximately 6 months...' What takes? Should be rephrased/clarified.
Reply: We have now adjusted the text in the paragraph (see p. 11, lines 277 to 282). This now reads: After the intake appointment, the links to the online elements will be sent to the participants via email. There are two emails which offer contact with the HAD practice and eleven emails which contain the links to the various educational videos that are offered (see below). The online part spans a period of up to about six months after the hearing aid purchase. The exact duration of SUPR depends on the duration of the trial period. For example, if a trial period is finalized in three weeks instead of the average four, the total duration of SUPR is one week shorter.

- p10, line 231/232: 'The book covers four parts, corresponding to four phases.' What phases? Defined on what basis? Should be explained.
Reply: This is explained now. The section now reads (see p. 10, lines 249 to 252):

The booklet covers four parts, corresponding to the four key appointments during the trial period (i.e., preparation appointment, intake appointment, control- and/or fine-tuning appointment, and purchase appointment). The information that is provided is synchronized with the topics which are typically discussed during these appointments.

In the section following the section above, the specific content of the four parts is explained. This can now be connected to the four appointments better. See p. 10 and p. 11, lines 252 to 264.

-what is the reason for performing both intention to treat and per-protocol analysis? This should be explained.
Reply: We are aware that the ITT analysis is the widely preferred analysis strategy (see for instance the CONSORT statement)[1]. Per-protocol analysis may introduce biased results for a number of reasons that are associated with selective drop-out (and thus missing values), and with selective non-adherence to the treatment protocol. However, especially when the overall treatment protocol adherence within an intervention group is suboptimal (i.e., dilution due to non-compliance), an ITT analysis yields overly conservative effect sizes (see Gupta, 2011)[2]. The latter may argue for the use of a per-protocol analysis.

1. Moher D, Hopewell S, Schulz KF, et al. CONSORT 2010 Explanation and elaboration: updated guidelines for reporting parallel group randomised trials. BMJ 2010;340:c869. doi:10.1136/bmj.c869
2. Gupta SK. Intention-to-treat concept: A review. Perspect Clin Res 2011;3:109–112.

We have now explained the two approaches in the MS (see p. 25 and p. 26, lines 536 to 543):
In case of substantial missing data, multiple imputation will be applied. The main analysis is intention to treat. Any outcome measure to be collected for participants who discontinue or deviate from intervention protocols will be saved and analyzed according to the intention to treat protocol. In addition, a per-protocol analysis will be performed. A per-protocol analysis includes those participants who completed the intervention originally allocated as described in the study protocol. As a per-protocol analysis can potentially yield biased effects (e.g., see CONSORT statement)[61], great caution will be exerted when interpreting these results. In addition, the report of these findings in future articles will be nuanced explicitly and thoroughly.

-Strategy for analysis of cluster-randomised data should be clearly explained in the statistical analysis plan. More detail about dealing with additional level of dependency in the data should be provided.
Reply: We have now added more details about this in the MS. This section now reads (see p. 25, lines 529 to 532):
For the effect analyses, the groups will be compared on all primary and secondary outcome measures using linear mixed models including the results at T0, T1, T2, and T3. Group, time, and their two-way interaction will be included as fixed effects in the mixed models, with random intercepts for subject and HAD practice. For the covariance matrix, a Variance Component structure will be chosen.

-p 27, line 628/629: Sentence is unclear. How can participants underestimate their hearing impairment because of the stigma? Please explain/rephrase.
Reply: We have now rephrased and explained this section into (see p.32, lines 793 to 703):
At the start of the study, participants might downplay their hearing problems because hearing loss stigma causes them to be reluctant to acknowledge or recognize their hearing problems[70]. We expect that SUPR will have a positive effect on acceptation of hearing loss, and therefore people may report a disability level that is ‘more honest’. This may hold particularly for the first-time HAUs who have never gone through an intensive rehabilitation trajectory before and less so for the experienced users. As such, it is possible that this mechanism will cause an increase in self-reported hearing disability in the intervention group over time. This would counteract the favourable effect that SUPR is expected to create, i.e., a decrease in experienced disability. To examine whether the first-mentioned

mechanism would apply, one of the subscales of the CPHI on acceptation of hearing loss can be used. With this subscale we can examine if acceptance is a mediator between time and hearing status for the intervention group.

-p 28, line 639: 'When effects of SUPR turn out to be disappointing...'- unfortunate phrase, please rephrase.
Reply: We have now rephrased this into (see p. 32, lines 708 to 710):
When no or only small significant effects of SUPR will be found, we may be able to modify the programme based on the results of the process evaluation after the study.

-Throughout the manuscript: use of word 'persons', e.g. older persons, hearing-impaired persons, provided for persons etc. Should be: people.
Reply: Thank you, we have now changed this accordingly.

-p3, line 67: the older old should be defined.
Reply: We have now defined this.

Comments Reviewer 3: Gabrielle Saunders

This paper describes the protocol for an RCT to be conducted evaluating the effectiveness of an internet-based auditory rehabilitation intervention on a variety of hearing aid outcomes. The trial is well-designed and should yield important information for the field of audiology. I have a few suggestions for improving the paper.

First, there are numerous typos that should be fixed prior to the paper being accepted for publication. There are so many that I will not list them below. In addition, the paper would benefit from editorial input from a native speaker of English because there are a number of grammatically-incorrect phrases and unusually-constructed sentences. Having said that, these only marginally detract from the readability of the paper. In terms of more substantial input I have the following suggestions.
Reply: We are very sorry that we did not see the typing errors before submission. We have now made sure that the revised manuscript was thoroughly checked and edited the MS for any other typographical errors. In addition, an employee of Audionova International who is a native speaker of English, has checked the revised manuscript for incorrect phrases and sentences.

Background. I think the background could be shortened considerably through editorial changes but the topics addressed are appropriate.

-Line 104: The most recent MarkeTrak survey (referred to as MT9) shows that only 3% of hearing aids are unused and that more people are getting hearing aids sooner. This info should replace that stated in the paper.
Abrams HB, Kihm J. An Introduction to MarkeTrak IX: A New Baseline for the Hearing Aid Market. Hearing Review. 2015;22(6):16.
Reply: Thank you for referring to this article. We have now changed the information on the use of hearing aids in the introduction (see p. 4, line 101) and replaced reference 23 by the most recent MarkeTrak survey.

-Line 105: I disagree with the statement that ‘reasons for low uptake are largely known’. I would suggest that many factors have been investigated but always much variance is left unexplained. It would be better to omit the above statement and simply note that many factors have been investigated.
Reply: We agree with the reviewer’s comment. We changed the sentence accordingly (see p. 4, line

102).

-Parag starting on line 137: I suggest providing reasons for why long term f/u is important. The fact that it has not been done before is not a good reason for doing it now. The authors do provide reasons in the discussion. I would move that info to the background.
Reply: We agree with the reviewer on this point. We have now moved the reasons for long-term follow-up to the introduction, p. 7 and 8, lines 179 to 182 in the manuscript (and removed it from the discussion).

-Conducting the study in multiple dispensing clinics offers more than simply a larger number of subjects – it reflects real world clinical practice. This is a major strength of the study and the authors should make more note of the value of this in the background.
Reply: We thank the reviewer very much for pointing this out. We have now underlined this as a strength in the MS's background and discussion (see p. 7, lines 176-179 and p. 33, lines 714 to 717).

Methods.
-Line 235: Provide more information on 'writing down of specific needs'
Reply: We have now adapted this sentence and gave an example on p. 10, lines 254 to 257. It now reads:
The client is asked to write down and rank specific communication goals (s)he wishes to reach by the end of the trial period (for example: 'I want to be able to hear the stories of my 10-year old granddaughter Anne when I pick her up from school every Monday'.

-Line 237: I would say 'the client gives feedback' not 'is allowed to give feedback'. Presumably the study team will not prevent participants doing whatever they want!
Reply: We have now changed the sentence in order to make it more clear, p. 11 (lines 259 and 260). It now reads:
In the third part the client and the CP are asked to write down their experiences with the new hearing aid and its settings.

-Line 249: To what extent do the videos address the different instructions needed based on hearing aid style? Are there style-specific videos? If not, how will this be dealt with?
Reply: Participants receive the link to the relevant instruction video depending on their style of hearing aids (i.e., behind-the-ear, in-the-canal, or receiver-in-the-ear). We have now added this information in the methods section of the MS (see p. 12 , lines 384 to 287).

-Line 280: 'to remind them' of what? Finish the sentence please.
Reply: The phone calls are made to remind the hearing aid dispenser practices of the low enrollment numbers (if applicable). We have now explained this process in more detail on p. 13, lines 317-320.

-Line 289 and line 294: Flower coupons and pies seem very nice rewards for participation but this reads a bit strangely in the paper. Can it be rephrased?
Reply: We rephrased 'flower coupons' and 'pies' for 'gift-cards' (see p. 13, lines 329 and 334).

-Line 300: what defines 'intention to take up hearing aids'? At what point is this evaluated?
Reply: We have now clarified this, see p. 14, lines 339 and 341.

-Line 307: Is it possible an enrolled participant will later seek additional care at a specialized audiology clinic? If so, will they then be terminated from the study?
Reply: Yes, this would be a possibility. However, participants who will later seek additional care at a specialized audiology clinic will not be excluded from the study because this would be in conflict with the ITT analysis strategy we plan to use.

-Table: It seems to be that the amount of detail provided about the tests in table 1 is greater for some tests than for other tests (e.g. no info is given for self-reported hearing activity while scale info is given self-efficacy while a reference to the test on of hearing aid rehabilitation and SUPR outcome is provided. Please be consistent across tests. Also what is the reference referred on line 56/57 on page 14? Why is the test the only one with a reference cited?
Reply: We have now adapted our table and made it more consistent. With regard to the questionnaire with a reference cited: We struggled with formulating the outcome measure developed by Laplante-Lévesque et al[55], because it has no specific name. We have now called it 'use questionnaire' as it measures self-reported hearing aid use, and adapted the name in the table.

-Line 384: I wonder whether the authors have considered using a translation of the URICA Adapted (Saunders et al., 2016)? As noted in that article 'issues were raised about the relevance of some of the URICA items for assessing hearing health behaviors— especially those that had a psychological undertone. In the present study, the original items of the URICA (McConnaughy et al. 1983) were adapted to be more relevant for hearing health behaviors by reducing the psychological undertones.'
Saunders GH, Frederick MT, Silverman SC, Nielsen C, Laplante-Lévesque A. Description of Adults Seeking Hearing Help for the First Time According to Two Health Behavior Change Approaches: Transtheoretical Model (Stages of Change) and Health Belief Model. Ear Hear. 2016 May-Jun;37(3):324-33.
Reply: We thank the reviewer for this suggestion. However, the baseline questionnaire was already sent to participants in February 2016 and therefore we did not have a chance to include the adapted items of the URICA questionnaire that the reviewer is referring to (publication in May 2016). We are not sure if this publication could have been accessed online earlier, but if this was the case, we were unfortunately unaware of this. Instead, we used the Dutch validated version of the URICA as it was published by De Jonge et al and we adapted the items for hearing health behaviors following the example by Laplante-Lévesque et al[1, 2]. The version that we used in our study was also used in a previous study that was carried out in our department. Nonetheless, we think that the new version that is suggested by the reviewer is potentially very useful and we would consider to use the adapted items in future research.

1. Jonge de JM, Schaap CPDR, Schippers GM. Motivatie voor verandering: een Nederlandse versie van de University of Rhode Island Change Assessment (URICA_NL) Diagnostiekwijzer: Tijdschrift voor Geestelijke Gezondheidszorg 2002;5
2. Laplante-Lévesque A, Hickson L, Worrall L. Stages of change in adults with acquired hearing impairment seeking help for the first time: application of the transtheoretical model in audiologic rehabilitation. Ear Hear 2013;34:447-57. doi: 10.1097/AUD.0b013e3182772c49

-Line 437: The tense changes to past in this paragraph, and on line 659 it says 'data collection was done by xxxx.' Is this an error or have the data already been collected? The rest of the paper reads as though this is future work.
Reply: We apologize for the confusion. The recruitment period for the SUPR study started in February 2016 and ended in September 2016. Preliminary, HAD practices were randomised to offer care as usual or the intervention. As the recruitment period was finalized in September 2016, we now changed the tense of the sections in the MS about randomisation and recruitment into 'past tense'. As the study (intervention/CaU) and data collection are still ongoing, we will hold on to future sense in the related paragraphs throughout the MS.

-Line 481: I am unsure as to what '…which questionnaires it reverses to so that data can be merged.' Please clarify
Reply: This particular sentence referred to the method of analysis (connecting respondents to the

variables of each of the measurements (T0 to T3)). We now feel, however, that this information is too detailed for the readers and we therefore deleted this sentence as a whole.

-Data collected with IOI-HA: Studies in which the IOI-HA has been used show little variability across subjects. Since the IOI-AI scales are identical I would be concerned that the IOI-AI will be an insensitive measure of dose received, satisfaction, and benefit. Is there another measure that could be used instead?
Reply: Unfortunately, the IOI-HA has already been used as an outcome measure at T1 for a part of the research population. Also we were not aware of alternative skills. However, we decided to additionally include the following question as a measure of satisfaction with the care received: "How likely is it that you would recommend the service of the HAD practice to other people (family, friends, colleagues), see for more information the MS, p.20 and 21, lines 436 to 439. Although we are not aware of the sensitivity of this measure, it might provide more detail on satisfaction.

-Line 526: Shouldn't ALL modifications to the protocol be submitted to VU university ethics committee, not just 'important' ones?
Reply: We removed the word 'important', p. 28, line 595.

-Parag beginning line 610: Add to this paragraph that the participants who have access to the internet will be of higher SES and that this may bias the data.
Reply: This has now been added in this paragraph, p. 31, lines 767-780.

-Parag beginning 622. I am not sure how this fits into the weaknesses section.
Reply: We have now started a new section for these (positive) elements of SUPR on p.30, lines 652 to 657.

VERSION 2 – REVIEW

REVIEWER	Carly Meyer The University of Queensland, Australia
REVIEW RETURNED	17-Feb-2017

GENERAL COMMENTS	**Article review for a revised version of "Effectiveness of an online SUpport PRogramme (SUPR) for older hearing aid users: Study protocol for a cluster randomized controlled trial"** Thank you for the opportunity to review a revised version of this Protocol. I thank the authors for addressing each of my comments comprehensively, I am satisfied with their responses. I appreciate that the authors had a native English speaker check the manuscript for grammatical errors; however, some minor errors remain that should be addressed: • P3, lines 60/63: Consider replacing "online character" with "online nature". • P3, points 3 and 4: These two sentences appear a little contradictory. Could you rephrase slightly? It might help to focus on young-old versus oldest-old. • P3, line 74: Consider substituting "vastly" with "rapidly". • P4, line 83: Substitute "people" with "the person". • P4, para 1: I think your double use of the word "internal" on lines 81 and 83 adds some confusion as you appear to be

	referring to the individual's health condition and personal factors, respectively. Please consider rephrasing • P4, para 2: Within this paragraph the authors have used "significant others" and "communication partners". Could the authors consider using consistent terminology? • P4, last para: The reasons for low HA uptake are indeed numerous. However, I wonder if lines 101-108 could be better integrated? • P5, line 130: Insert "why" to read: "When offered, there are various reasons why adults with hearing impairment …". • P7, line 156: Substitute "Whereas" with "Where". • P7, line 172: Consider substituting "instruction" with "instructional". • P9, line 208: Decapitalise "The" to read: In the case of individual randomisation, the HAD …". • P11, line 265: Consider rephrasing "… were realised during several months of development" as "were developed over the course of several months by the HAD company". • P11, line 268: Insert "into consideration" to read: "… were taken into consideration …". • P11, line 272: insert "and" before the final point (4). • P13, line 331: insert "have" to read: "… for individuals who have already started using a hearing aid". • P13, lines 333-335: This sentence wasn't clear to me, try rephrasing. Also, avoid the use of "&". • Table 1: Will it be possible to reformat the table for publication so that it is easier to read? Perhaps landscape, with repeated column headings, would be best? • P22, line 454: Insert "be" to read: "… will be administered". • P23, line 468: Add plurals where required. • P24, line 500: Avoid the use of "&". • P25, line 517: Substitute "reluctant" with "reluctance". • P31, lines 670-71: Rephrase slightly to read: "…. Administered at T1, T2, and T3 indicates what group each participant was randomised to …". • P32, line 712: Substitute "in" with "for" to read: "… increasing demand for solutions …". Overall, the study protocol is very comprehensive and the study appears very well designed. I recommend that the Protocol is now suitable for publication once the above grammatical errors have been addressed.

REVIEWER	Magdalena Sereda Senior Research Fellow in Tinnitus, NIHR Nottingham Hearing Biomedical Research Unit, Otology and hearing group, Division of Clinical Neuroscience, University of Nottingham, Nottingham, UK
REVIEW RETURNED	11-Feb-2017

GENERAL COMMENTS	The clarity of the manuscript improved greatly after the revision and

	all my comments have been addressed. However, I have some comments to the new sections included in the paper. Major comment: The aims and outcomes paragraph (p8 lines 184-202) lists two primary outcome measures and one main outcome. Using multiple outcome measures in a trial is not advisable (please see CONSORT 2010). Wherever multiple primary outcomes are used this should be reflected in the statistical analysis to account for potential bias. Also, looking closer those two outcomes are covered by only one questionnaire CPHI but two subscales seem to be analysed separately. Is the CPHI primary outcome measure? Are the subscales analysed separately from the outset or is the overall score primary outcome and subscale analysis is performed later? If there are indeed two primary outcome measures it should be acknowledged and the statistical strategies to deal with the bias described. Statement 'main outcome' next to lower third-party disability should be removed as this suggests introduction of the third primary outcome measure, which as I understood was not the case. Minor comments: P 5, line 120: more up to date review than the one by Sweetow is: Henshaw and Ferguson, PLoS One, 2013. P 7, lines 160-164: Provision of hearing aids is country specific and in the UK majority of people would receive hearing aids through audiology service such as Nottingham Audiology Services (free provision) not through dispenser practice (substantial cost for the patient). Therefore, the statement that vast majority of hearing aids are fitted in the dispenser practice is not true for some countries. I understand this is the case in Netherlands and this should be clarified.

VERSION 2 – AUTHOR RESPONSE

Comments reviewer 1: Carly Meyer
Thank you for the opportunity to review a revised version of this Protocol. I thank the authors for addressing each of my comments comprehensively, I am satisfied with their responses.
I appreciate that the authors had a native English speaker check the manuscript for grammatical errors; however, some minor errors remain that should be addressed:

• P3, lines 60/63: Consider replacing “online character” with “online nature”.
Reply: This suggestion was adopted, see p. 3, lines 59 and 62.

• P3, points 3 and 4: These two sentences appear a little contradictory. Could you rephrase slightly? It might help to focus on young-old versus oldest-old.
Reply: We have now clarified points 3 and 4, see p. 3, lines 59-64.

• P3, line 74: Consider substituting “vastly” with “rapidly”.
Reply: This suggestion was adopted, see p. 3, line 73.

• P4, line 83: Substitute “people” with “the person”.
Reply: We have now replaced this, p. 4, line 82.

• P4, para 1: I think your double use of the word “internal” on lines 81 and 83 adds some confusion as you appear to be referring to the individual’s health condition and personal factors, respectively. Please consider rephrasing
Reply: We agree with the reviewer’s comment. The level of impairment in hearing functions and structures (the individual’s health condition), is not an internal personal factor according to the International Classification of Functioning, Disability and Health. Age and coping styles, however, are. We adjusted the text on p. 4, lines 79-83.

• P4, para 2: Within this paragraph the authors have used “significant others” and “communication partners”. Could the authors consider using consistent terminology?
Reply: We are aware of the fact that we use different terminology in this particular paragraph. However, in our definition ‘significant others’ reflect only partners and spouses of hearing-impaired persons whereas a ‘communication partner’ can be any person where a hearing-impaired person communicates with most frequently. Hence, a communication partner can also be a child, or a caregiver. We now clarified the different terms in this paragraph, see p. 4, lines 85-92.

• P4, last para: The reasons for low HA uptake are indeed numerous. However, I wonder if lines 101-108 could be better integrated?
Reply: We have now better integrated these sentences, see p. 4 and 5, lines 99-110.

• P5, line 130: Insert “why” to read: “When offered, there are various reasons why adults with hearing impairment …”.
Reply: This has now been changed accordingly, p.5, line 128.

• P7, line 156: Substitute “Whereas” with “Where”.
Reply: This suggestion was adopted, see p. 6, line 154.

• P7, line 172: Consider substituting “instruction” with “instructional”.
Reply: This suggestion was adopted, p. 7, line 170.

• P9, line 208: Decapitalise “The” to read: In the case of individual randomisation, the HAD …”.
Reply: We edited this particular error, p. 8, line 204.

• P11, line 265: Consider rephrasing “… were realised during several months of development” as “were developed over the course of several months by the HAD company”.
Reply: Thank you for this suggestion. We have adapted the sentence, see p. 11, line 261.

• P11, line 268: Insert “into consideration” to read: “… were taken into consideration …”.
Reply: We have now inserted this, see p. 11, line 264.

• P11, line 272: insert “and” before the final point (4).
Reply: We have now inserted this, see p. 11, line 268.

• P13, line 331: insert “have” to read: “… for individuals who have already started using a hearing aid”.
Reply: We have now inserted this, see p. 13, line 326.

• P13, lines 333-335: This sentence wasn’t clear to me, try rephrasing. Also, avoid the use of “&”.
Reply: We have now clarified the text, see p. 13, lines 328 and 329. We have also checked the remaining MS for any other use of “&”.

• Table 1: Will it be possible to reformat the table for publication so that it is easier to read? Perhaps landscape, with repeated column headings, would be best?
Reply: The table has now repeated column headings, see p. 15-21.

• P22, line 454: Insert “be” to read: “… will be administered”.
Reply: We have now inserted this, see p. 24, line 451.

• P23, line 468: Add plurals where required.
Reply: We have now edited this, see p. 25, line 465.

• P24, line 500: Avoid the use of “&”.
Reply: We replaced “&” with ‘’and”, see p. 26, line 497.

• P25, line 517: Substitute “reluctant” with “reluctance”.
Reply: We have now edited this, see p. 27, line 514.

• P31, lines 670-71: Rephrase slightly to read: “…. Administered at T1, T2, and T3 indicates what group each participant was randomised to …”.
Reply: We have now edited the sentence accordingly, see p. 33, lines 668 and 669.

• P32, line 712: Substitute “in” with “for” to read: “… increasing demand for solutions …”.
Reply: We changed this accordingly, see p. 34, line 710.

Overall, the study protocol is very comprehensive and the study appears very well designed. I recommend that the Protocol is now suitable for publication once the above grammatical errors have been addressed.

Comments reviewer 2: Magdalena Sereda
The clarity of the manuscript improved greatly after the revision and all my comments have been addressed. However, I have some comments to the new sections included in the paper.

Major comment:
• The aims and outcomes paragraph (p8 lines 184-202) lists two primary outcome measures and one main outcome. Using multiple outcome measures in a trial is not advisable (please see CONSORT 2010). Wherever multiple primary outcomes are used this should be reflected in the statistical analysis to account for potential bias. Also, looking closer those two outcomes are covered by only one questionnaire CPHI but two subscales seem to be analysed separately. Is the CPHI primary outcome measure? Are the subscales analysed separately from the outset or is the overall score primary outcome and subscale analysis is performed later? If there are indeed two primary outcome measures it should be acknowledged and the statistical strategies to deal with the bias described. Statement 'main outcome' next to lower third-party disability should be removed as this suggests introduction of the third primary outcome measure, which as I understood was not the case.
Reply: We apologize for the lack of clarity. We intended to use the CPHI as central outcome measure to analyse two outcomes: ‘communication strategies’ and ‘personal adjustment’. Three subscales of the CPHI cover communication strategies: Maladaptive Behaviours, Verbal Strategies, and Non-verbal Strategies, and three subscales cover personal adjustment: Self-acceptance, Acceptance of Loss, and Stress and Withdrawal. It is only possible to calculate scores per subscale and this means that there are six different outcome measures. Unfortunately, multiplicity of analyses creates the risk for false positive findings1. Therefore, we decided to only use the three subscales for communication strategies as the primary outcome measures (i.e., Maladaptive Behaviours, Verbal Strategies, and Non-verbal Strategies).The three subscales related to personal adjustment will then be considered as secondary outcomes measures. We have adjusted the text in the section ‘primary outcome measures

- HAUs' and 'secondary outcome measures - HAUs', see p. 21 and 22, lines 367-392. To adjust for potential bias associated with multiplicity of analyses, statistical significance levels will be set at P< 0.016 (0.05/3). We have now described this in the 'Statistical Analyses' section, p. 27, lines 530 and 531. The statement 'main outcome' has now been deleted, see p. 8, line 198.

1. Moher D, Hopewell S, Schulz KF, et al. CONSORT 2010 Explanation and elaboration: updated guidelines for reporting parallel group randomised trials. BMJ 2010;340:c869. doi:10.1136/bmj.c869

Minor comments:

• P 5, line 120: more up to date review than the one by Sweetow is: Henshaw and Ferguson, PLoS One, 2013.
Reply: Thank you for this suggestion. We are now referring to the updated review of Henshaw and Ferguson.

• P 7, lines 160-164: Provision of hearing aids is country specific and in the UK majority of people would receive hearing aids through audiology service such as Nottingham Audiology Services (free provision) not through dispenser practice (substantial cost for the patient). Therefore, the statement that vast majority of hearing aids are fitted in the dispenser practice is not true for some countries. I understand this is the case in Netherlands and this should be clarified.
Reply: We agree with the reviewer's comment. We have now clarified this, see p.7, line 160-162.

VERSION 3 – REVIEW

REVIEWER	Magdalena Sereda NIHR Nottingham Hearing Biomedical Research Unit, Nottingham, UK
REVIEW RETURNED	10-Mar-2017

GENERAL COMMENTS	All my comments have been addressed.