PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Walk, Talk and Listen: A pilot randomized controlled trial targeting functional fitness and loneliness in older adults with hearing loss.
AUTHORS	Jones, Charlotte A.; Siever, Jodi; Knuff, Kate; Van Bergen, Colin; Mick, Paul; Little, Jonathan; Jones, Gareth; Murphy, Mary-Ann; Kurtz, Donna; Miller, Harry

VERSION 1 – REVIEW

REVIEWER	Susanne Finnegan University of Warwick, Warwick Clinical Trials Unit
REVIEW RETURNED	28-Aug-2018

GENERAL COMMENTS	This paper presents the results of a pilot RCT targeting functional fitness and loneliness in older adults with hearing loss. This is a very important area of research and this paper describes this pilot RCT very well but some points need clarifying and revising. Abstract: well written and all aspects are clearly described, however, I am slightly confused as one of your objectives appears to be to reduce risk of falls among older adults with HL but I am unsure which of your outcome measures you are specifically using to capture falls risk? And what effect did the intervention have on falls risk? This needs to be clearer. Background: well written but again somewhat confusing as in your objectives there is no mention of falls risk - you need to be consistent as to what your objectives are. Design and methods: Eligibility and baseline assessments were completed by students and research team members after informed consent and prior to randomization and allocation by our statistician - please can you give more detail as to how consent was obtained and the process involved within the manuscript or am I supposed to be looking through the large detailed table at the end of the document for this information? Results: the results do address the research question except for this issue of falls risk. Please clarify which outcome was used to measure falls risk and therefore, how the changes in these outcomes have altered falls risk. Did you measure number of falls during the intervention period? CONSORT - you have not indicated on the checklist on which page each topic has been reported but have then enclosed a large supplementary document with lots of detail so I am unsure which document I am supposed to look at? May I also suggest that you consider using the TIDieR checklist - https://www.bmj.com/content/348/bmj.g1687 or CERT checklist - https://pdfs.semanticscholar.org/920e/a46f0a3d5886331affcf7a62f

	5f2b53c48db.pdf to ensure that you have described your exercise intervention sufficiently.

REVIEWER	Michail Doumas Queen's University Belfast, UK
REVIEW RETURNED	18-Sep-2018

GENERAL COMMENTS	This paper reports the results of a pilot randomised controlled trial assessing improvement in hearing, physical and psychosocial aspects of performance in older adults with hearing loss. Participants were screened for eligibility and tested at baseline for hearing handicap, gait and mobility, and psychosocial factors. Then, they were randomly assigned to two groups. One group (intervention) did Group Audiological Rehabilitation (GAR) with physical exercise, and another group (control) did GAR only for 10 weeks. They were tested again post-intervention. Results showed that exercise improved physical aspects of performance but did not add to the benefits of GAR alone. This is a well-conducted study assessing an intervention targeting hearing loss, which is a relevant and interesting topic in the aging literature. The study was extensive in terms of its measures and as a result the paper is very hard to follow. Furthermore, the theoretical motivation of the study and its outcomes are not clearly written. Below I explain the issues I have with the paper 1. The first is mechanistic. The main idea of the study is that GAR works for people with hearing loss, and the question is whether GAR+physical activity+health education would have a stronger effect in improving physical and mental performance in people in HL. Why would that be, and how would that happen? This is an important link that is missing from the paper. We know that GAR improves performance in people with HL and we know about the beneficial effects of physical exercise. Would their combination improve performance over and above improvement as seen in separate programmes? Why? This is not clear in the present study and as a result it is very hard for me to see the reason to perform this intervention. The authors could try to draw on existing literature on how hearing loss affects posture and balance (e.g. Agmon et al. 2017), and dual-tasking in balance (Bruce et al. 2017). 2. The authors are clear about the exploratory nature of the study, which is fine so it is ok to have many measures to see which ones will be affected by the intervention. However, there has to be some coherence between aims/objectives of the study and outcome measures. This coherence would help the reader to follow the paper from the intro to the results. Here, the authors report far too many demographic and other measures in the paper and in supplementary material and these are very hard to follow, especially because most differences are not significant, so the reader is desperately looking for any evidence for the effectiveness of this programme, mostly in vain. The confusion continues with the abbreviations. I realise that this may be due to word limits, but the use of so many abbreviations, in some cases without explanation is very hard to follow. For example IQR in Table 1 which I guess stands for Inter Quartile Range is not explained anywhere. Simliarly, in the abstract AR is introduced and then GAR is mentioned without explanation. The authors need

	to pay more attention to detail and to remove unnecessary abbreviations. 3. In the introduction, WTL is introduced as a definition, without any link with the previous paragraph. Why is it relevant here and how does it relate to the ideas of the study? 4. The authors need to clarify why did the intervention group receive GAR, a strength and balance training program AND an additional health education program (SHE, which is not described, unless I missed it). Please explain why did the intervention group receive two additional programs compared with the control group. Wouldn't this be a problem in interpreting the source of possible benefits of the intervention? 5. Consistency in terminology is also lacking between the participant-specific outcomes section (page 4, bottom) and Figure 1. In text, authors refer to baseline and end-of-study measures but in the Figure baseline measures are not mentioned (I guess they need to be added to the Completed Health assessment box) and the end of study measures are referred to the figure as follow-up. This type of inconsistency makes the paper very confusing and hard to follow. These and others I may have not spotted need to be corrected.

VERSION 1 – AUTHOR RESPONSE

Reviewer: 1
Reviewer Name: Susanne Finnegan

Institution and Country: The University of Warwick, United Kingdom.

Please state any competing interests or state 'None declared': None declared

Please leave your comments for the authors below
This paper presents the results of a pilot RCT targeting functional fitness and loneliness in older adults with hearing loss. This is a very important area of research and this paper describes this pilot RCT very well but some points need clarifying and revising.
Abstract: well written and all aspects are clearly described, however, I am slightly confused as one of your objectives appears to be to reduce risk of falls among older adults with HL but I am unsure which of your outcome measures you are specifically using to capture falls risk? And what effect did the intervention have on falls risk? This needs to be clearer.

THANK YOU FOR HELPING TO CLARIFY THE OBJECTIVES FOR THIS STUDY.
THE OBJECTIVES NOW READ…."EXAMINE THE FEASIBILITY AND IMPACT OF A GROUP EXERCISE AND SOCIALIZATION/HEALTH EDUCATION INTERVENTION ADDED TO GAR ON PHYSICAL FUNCTION, HEARING-RELATED QUALITY OF LIFE AND LONELINESS AMONG OLDER ADULTS WITH HL".
THE EMPHASIS IS ON PHYSICAL FUNCTION, NOT FALLS.

Background: well written but again somewhat confusing as in your objectives there is no mention of falls risk - you need to be consistent as to what your objectives are.

THANK YOU FOR YOUR CAREFUL AND DETAILED REVIEW OF OUR MANUSCRIPT. YOUR OBSERVATINS HAVE LED TO A MUCH IMPROVED REPRESETNATION OF THE STUDY.
RE: THE BACKGROUND AND OBJECTIVES: THE BACKGROUND AND OBJECTIVES HAVE BEEN RE-WRITTEN TO REFLECT THE ABOVE OBJECTIVES REGARDING LONELINESS AND PHYSICAL FUNCTION.

Design and methods:
Eligibility and baseline assessments were completed by students and research team members after informed consent and prior to randomization and allocation by our statistician - please can you give more detail as to how consent was obtained and the process involved within the manuscript or am I supposed to be looking through the large detailed table at the end of the document for this information?
PLEASE NOTE THE THAT THE FULL PROTOCOL WAS PREVIOUSLY PUBLISHED AND IS REFERENCED IN SEVERAL PLACES IN THE MANUSCRIPT. HOWEVER, WE HAVE ADDED A SENTENCE TO CLARIFY THE CONSENT PROCESS PAGE 4, SECOND PARAGRAPH LINES 8-11.

Results: the results do address the research question except for this issue of falls risk. Please clarify which outcome was used to measure falls risk and therefore, how the changes in these outcomes have altered falls risk. Did you measure number of falls during the intervention period?

YES, THANK YOU. WE HAVE CHANGED THE OUTCOMES TO REFLECT CHANGES IN PHYSICAL FUNCTION RATHER THAN FALLS (AS ABOVE)
YES. WE COLLECTED SELF-REPORTED FALLS FOR THE THREE MONTHS PRIOR TO THE STUDY (PAGE 6 DESCRIBED UNDER BASELINE MEASURES (LINE 5) AND IN TABLE 1. AND DURING THE STUDY PAGE 6 LINE 5 AND IN THE DISCUSSION (PAGE 10) IN THE FIRST PARAGRAPH OF THE RESULTS SECTION.

CONSORT - you have not indicated on the checklist on which page each topic has been reported but have then enclosed a large supplementary document with lots of detail so I am unsure which document I am supposed to look at? May I also suggest that you consider using the TIDieR checklist - https://www.bmj.com/content/348/bmj.g1687 or CERT checklist - https://pdfs.semanticscholar.org/920e/a46f0a3d5886331affcf7a62f5f2b53c4 8db.pdf to ensure that you have described your exercise intervention sufficiently.

THANK YOU, AN OMMISION ON OUR PART BY NOT ADDING THE PAGE NUMBERS TO THE CONSORT TEMPLATE: THIS HAS NOW BEEN RECTIFIED WITH PAGE NUMBERS ADDED. SINCE THE CONSORT DEALS SPECIFICALLY WITH PILOT/FEASIBILITY TRIALS WE FEEL IT STILL THE BEST CHECKLIST. WE HAVE ALSO INCLUDED THE COMPLETED TIDieR TEMPLATE.

Reviewer Name: Michail Doumas

Institution and Country: Queen's University Belfast, UK

Please state any competing interests or state ‘None declared’: None declared

Please leave your comments for the authors below
This paper reports the results of a pilot randomised controlled trial assessing improvement in hearing, physical and psychosocial aspects of performance in older adults with hearing loss. Participants were screened for eligibility and tested at baseline for hearing handicap, gait and mobility, and psychosocial factors. Then, they were randomly assigned to two groups. One group (intervention) did Group Audiological Rehabilitation (GAR) with physical exercise, and another group (control) did GAR only for 10 weeks. They were tested again post-intervention. Results showed that exercise improved physical aspects of performance but did not add to the benefits of GAR alone.

This is a well-conducted study assessing an intervention targeting hearing loss, which is a relevant and interesting topic in the aging literature. The study was extensive in terms of its measures and as a result the paper is very hard to follow. Furthermore, the theoretical motivation of the study and its outcomes are not clearly written. Below I explain the issues I have with the paper

1. The first is mechanistic. The main idea of the study is that GAR works for people with hearing loss, and the question is whether GAR+physical activity+health education would have a stronger effect in improving physical and mental performance in people in HL.
Why would that be, and how would that happen? This is an important link that is missing from the paper. We know that GAR improves performance in people with HL and we know about the beneficial effects of physical exercise. Would their combination improve performance over and above improvement as seen in separate programmes? Why? This is not clear in the present study and as a result it is very hard for me to see the reason to perform this intervention. The authors could try to draw on existing literature on how hearing loss affects posture and balance (e.g. Agmon et al. 2017), and dualtasking in balance (Bruce et al. 2017).

THANK YOU FOR YOUR CAREFUL AND DETAILED REVIEW OF OUR MANUSCRIPT. YOUR OBSERVATINS HAVE LED TO A MUCH IMPROVED REPRESETNATION OF THE STUDY.

THANK YOU FOR HELPING US TO CLARIFY THE RATIONALE FOR THE STUDY AND FOR THE REFERENCES TO THE LITERATURE ON POSTURE AND BALANCE. WE HAVE PRETTY MUCH COMPLETELY RE-WRITTEN THE SECTION ON BACKGROUND AND RATIONAL FOR THE STUDY (PAGE 2). WE APPROACH THE RATIONALE FOR THE INTERVENTION TO THE THEORY OF THE LINK BETWEEN HEARING LOSS-RELATED LONELINESS TO REDUCED PHYSICAL FUNCTION AND THE NEED FOR INTERVENTIONS THAT ADDRESS NOT ONLY THE HEARING-RELATED LONELINESS BUT ALSO THE RELATED PHYSICAL FUNCTION DECLINES.

2. The authors are clear about the exploratory nature of the study, which is fine so it is ok to have many measures to see which ones will be affected by the intervention. However, there has to be some coherence between aims/objectives of the study and outcome measures. This coherence would help the reader to follow the paper from the intro to the results. Here, the authors report far too many demographic and other measures in the paper and in supplementary material and these are very hard to follow, especially because most differences are not significant, so the reader is desperately looking for any evidence for the effectiveness of this programme, mostly in vain. The confusion continues with the abbreviations. I realise that this may be due to word limits, but the use of so many abbreviations, in some cases without explanation is very hard to follow. For example IQR in Table 1 which I guess stands for Inter Quartile Range is not explained anywhere. Simliarly, in the abstract AR is introduced and then GAR is mentioned without explanation. The authors need to pay more attention to detail and to remove unnecessary abbreviations.

THANK YOU AND WE AGREE, PARTICULARLY AS REGARDS THE MOS AND SF-36 DATA WHICH DID NOT ADD TO THE PAPER AND WAS NOT SIGNIFICANT. THIS DATA HAS BEEN REMOVED FROM TABLES ONE AND TWO AND PLACED AS A SUPPLEMENTAL TABLE (IN THE SPIRIT OF MAKING ALL DATA AVAILABLE). WE HAVE INCLUDED ONLY THE KEY RELEVANT DATA AND ABBREVIATIONS, HAVE REDUCED THE OVERALL USE OF ABBREVIATIONS AND HAVE BETTER DEFINED THOSE THAT REMAIN.

3. In the introduction, WTL is introduced as a definition, without any link with the previous paragraph. Why is it relevant here and how does it relate to the ideas of the study?

THANK YOU AGAIN FOR HELPING TO CLARIFY THE RATIONALE OF THE STUDY. THE WTL DEFINITION HAS BEEN REMOVED AND REPLACED WITH A PARAGRAPH ADDRESSING THE BENEFITS OF INTERACTIVE SHARED ACTIVITIES AND EXERCISE AMONG LONELY OLDER ADULTS (PAGE 3 PARAGRAPH 6)

4. The authors need to clarify why did the intervention group receive GAR, a strength and balance training program AND an additional health education program (SHE, which is not described (SEE PROTOCOL MANUSCRIPT:
REFERENCE 25. Lambert J, Ghadry-Tavi R, Knuff K, et al. Targeting functional fitness, hearing and health-related quality of life in older adults with hearing loss: Walk, Talk 'n' Listen, study protocol for a pilot randomized controlled trial. Trials 2017;18(1):47.(
, unless I missed it: Please explain why did the intervention group receive two additional programs compared with the control group. Wouldn't this be a problem in interpreting the source of possible benefits of the intervention?

YOU ARE ABSOLUTLEY CORRECT AND IN A PROPER (NOT PILOT) RCT, EACH OF THESE INTERVENTIONS WOULD BE INCLUDED AS A SEPARATE GROUP (ALONG WITH THE OBVIOUS NEED FOR LONGER POST TRIAL FOLLOW-UP ETC.) DUE TO THE EXPLORATORY NATURE OF THE STUDY LOOKING AT BOTH LONELINESS AND PHYSICAL FUNCTION AND GIVEN THE LITERATURE ON THE EFFECTS OF INTERACTIVE SHARED ACTIVITIES AND PHYSICAL ACTIVITY (AS PER ABOVE #3) IT WAS DECIDED TO COMBINE THE INTERVENTIONS. THIS IS COMMENTED UPON IN THE LIMITATIONS SECTION.

5. Consistency in terminology is also lacking between the participant-specific outcomes section (page 4, bottom) and Figure 1. In text, authors refer to baseline and end-of-study measures but in the Figure baseline measures are not mentioned (I guess they need to be added to the Completed Health assessment box) and the end of study measures are referred to the figure as follow-up. This type of inconsistency makes the paper very confusing and hard to follow. These and others I may have not spotted need to be corrected.

ONCE AGAIN, THANK YOU FOR YOUR CAREFUL REVIEW: WE HAVE INCLUDED THE WORD BASELINE IN THE COMPLETED HEALTH ASSESSMENT BOX IN FIGURE 1 AND, THROUGHOUT THE MANUSCRIPT WE USE BASELINE AND FOLLOW-UP: (DEFINED AS END OF STUDY ON PAGE 4 IN THE FEASIBILITY AND ACCEPTABILITY SECTION) THROUGHOUT.

VERSION 2 – REVIEW

REVIEWER	Susanne Finnegan The University of Warwick, United Kingdom
REVIEW RETURNED	06-Feb-2019

GENERAL COMMENTS	This revision of the paper Walk, Talk and Listen: A pilot randomized controlled trial targeting functional fitness and loneliness in older adults with hearing loss is a much improved version. Overall, your objectives are now much clearer and your methods, results and discussion address the research question sufficiently. There are however, just a few minor points that need final clarification: Abstract/Methods: (line 15 of abstract) you report that participants are over 65 but in the methods section, you report they were over 55 (line 22 of methods) - please clarify. Methods: (line 24) you report that recruitment was from September 2017 to March 2017 - this needs correcting/clarifying Discussion: the third paragraph of the Hearing and health-related quality of life, loneliness and social network section is still slightly confusing and unclear and I feel it is due to the number of abbreviations. For example, line 26 - is AR actually meant to be GAR? If possible can you clarify all the abbreviations throughout the paper - maybe in a table? And there are a few grammatical errors throughout the paper so I recommend a further proof read with this in mind.

VERSION 2 – AUTHOR RESPONSE

• Abstract/Methods: (line 15 of abstract) you report that participants are over 65 but in the methods section, you report they were over 55 (line 22 of methods) - please clarify.

• THANK YOU FOR PICKING THIS UP □

THE METHODS SECTION HAS BEEN CORRECTED TO AGE 65.

• Methods: (line 24) you report that recruitment was from September 2017 to March 2017 – this needs correcting/clarifying

• ONCE AGAIN, THANK YOU FOR YOUR EXCELLENT AND CAREFUL REVIEW. THE INITIAL DATE SHOULD READ (AND NOW DOES READ), JANUARY-FEBRUARY 2016 AND JULY-AUGUST 2016.

• Discussion: the third paragraph of the Hearing and health-related quality of life, loneliness and social network section is still slightly confusing and unclear and I feel it is due to the number of abbreviations. For example, line 26 - is AR actually meant to be GAR? If possible can you clarify all the abbreviations throughout the paper - maybe in a table?

• WE AGREE AND THE WORDING HAS BEEN CLARIFIED. THE ABBREVIATIONS HAVE BEEN REDUCED AND A LIST OF ABBREVIATIONS HAS BEEN ADDED TO THE TITLE PAGE. ALL ABBREVIATIONS IN THE TABLES ARE NOTED AT THE BOTTOM OF EACH TABLE.

• And there are a few grammatical errors throughout the paper so I recommend a further proof read with this in mind.

• WE HAVE REVIEWED THE FULL MANUSCRIPT AND HOPEFULLY CORRECTED ALL THE GRAMMATICAL ERRORS.