

PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Effectiveness of a nurse-supported self-management programme for dual sensory impaired older adults in long-term care: a cluster randomised controlled trial
AUTHORS	Roets-Merken, Lieve; Zuidema, Sytse; Vernooij-Dassen, Myrra; Teerenstra, Steven; Hermesen, Pieter; Kempen, Gertrudis; Graff, Maud

VERSION 1 – REVIEW

REVIEWER	Christine Kovach University of Wisconsin-Milwaukee United States of America
REVIEW RETURNED	12-Mar-2017

GENERAL COMMENTS	<p>There are many methodological strengths to this paper. Here are suggestions for improving the quality of the manuscript:</p> <p>1. Grammar needs to be edited throughout the paper. Paragraphs need to have a topic sentence and then internal consistency regarding the topic. Currently multiple paragraphs ramble from one point to another. Shorten some of the long sentences. Overall this paper is very hard to read and understand due to language and grammar issues.</p> <p>2. The background should describe the theoretical frameworks for the study and justify the variables under consideration. The lack of the theoretical explanation leads to other issues. The authors begin with the problem of dual-sensory impairment. This is actually the target population. The fact that the DV is social participation suggests that this is the main problem trying to be influenced by the intervention. Yet it is not the central focus of the paper. Hence the logic for the study is not clear or justified. Why is self-management such a salient variable related to the DV? This needs to be more clearly explained. Why is social participation as an outcome variable necessary? Based on Socioemotional selectivity theory older adults often decrease their social network and want more control and choice over both the size and constitution of their network. Do you account for preferences for more or less social participation? All of these problems can be cleared up with theory, explanation, and citing evidence that provides explanations and rationales for your study hypotheses and variables.</p> <p>3. The components of the intervention are not adequately described. A table describing components of the theory that inform each component of the intervention would be helpful.</p>
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	<p>4. Treatment fidelity testing should be more clearly explained.</p> <p>5. The data collection points were very far apart and not justified. This is a limitation of the study and should be described in limitations. Also relying on this one measurement of the DV is a limitation.</p> <p>6. State the use of the nurse variables and justify these in the background to the study.</p> <p>7. There should be a brief mention of checking assumptions for the data analytical approach and if there were any issues with skew etc.</p> <p>8. The sentence "In summary, this study demonstrates that the nurse supported SMP DSI was successful in addressing IADL problems in DSI older adults" is an overstatement. The main focus was to address social participation, so this finding should be discussed with more caution. This could simply be a spurious finding. I cannot connect IADL problems to the intervention components to the outcomes. Hence, this seems like an overstatement.</p>
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REVIEWER	Adam Gordon University of Nottingham, UK
REVIEW RETURNED	22-Mar-2017

GENERAL COMMENTS	<p>Thank you for the opportunity to review this publication which summarises the findings of a high quality, well designed, excellently conducted cluster-randomised controlled trial of a self-management programme for dual sensory impaired adults living in a Dutch nursing home setting.</p> <p>I have very little to suggest by way of modifications but I think the authors might help the less well initiated reader to work out the clinical implications of their study by addressing the limitations regarding generalisability as follows. The difficulties with recruitment due to the shifting demography of the Dutch long-term care population are important. The population will, I suspect, get more cognitively impaired and dependent over time, thus the proportion of the population who receive care in this setting using this resource intensive (and potentially costly but as yet uncoded) intervention is likely to be small. I struggle to imagine that it will be cost-effective in a long-term care setting. This is important in terms of generalisability to the Dutch population but also internationally. 75-80% of the UK care home population are cognitively impaired and the median MMSE is 11/30. UK care homes are much smaller than Dutch nursing homes - if this is unlikely to be cost effective in Dutch homes, it is unlikely to have any place in UK care homes. So what, therefore, is the lesson? That this works but is unlikely to be implementable in the real world of long-term care, where resources are significantly constrained? Or do the authors want to speculate on other care settings where the insights from this study might be applied?</p>
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REVIEWER	Julie Schneider Menzies Centre for Health Policy Sydney Medical School (Public Health) University of Sydney Australia
REVIEW RETURNED	26-Mar-2017

GENERAL COMMENTS	<p>Thank you to the authors for completing this study which is ambitious and well written. DSI in older age is a topic slowly growing in awareness. As the authors correctly note, very few RCTs have been conducted targeting this population. The majority of literature in the DSI field focuses on prevalence/incidence of dual loss, association of dual loss with negative impacts, and (rarely) interventions intended to improve hearing aid or service use for example (Schneider et al 2014; Vreeken et al 2013; 2015) rather than daily life/ psychosocial/participation outcomes directly. Therefore the current study does make a strong contribution to the field and documents an innovative model of intervention.</p> <p>Authors appear to have followed well the CONSORT guidelines and the article is well presented. Extra care to include additional details throughout the manuscript could add to the rigour. I appreciate that related papers from the same study are published/being published, however I believe each article should stand alone so the reader does not feel it necessary to locate all resources to get a complete picture of the study details.</p> <p>Specific feedback/suggestions are noted below:</p> <p>Methods</p> <p>p. 7 – when introducing the Activity Card Sort instrument you reference [17] rather than a source more directly about the instrument, perhaps add citation for Baum C, Edwards D (2001)? When providing more detail about ACS (p. 11), it may be wise to mention features like test-retest reliability of the instrument etc if available?</p> <p>You refer to your study protocol and attach a copy as a supplementary file, however I note there is not a lot of detail provided about the choice / rationale for use of different outcome measures. Are these areas being investigated because they are typically seen to benefit from self management interventions for example? Or are they included because they are known areas of concern identified among older people with DSI in the literature? Are the instruments chosen well tested in the literature with robust features?</p> <p>p. 8, line 94 - When discussing inclusion criteria take care to be specific in your language e.g., is visual impairment measured with both eyes open? Pure tone audiometry measured across what frequencies? (I eventually located it from the results tables, but you could note PTA1-4hz (subscript) in brackets in the text to be clear for the reader for example). Notably this is a moderate (or worse) criteria - is there a particular reason you did not include mild hearing loss levels in your definition of DSI? Is there any reason why those with milder forms of loss would not benefit from 'self management' interventions?</p> <p>What is 'usual care' in LTC facilities? Are you able to provide some additional information to give the reader a clearer view of this (and therefore greater understanding of the extent the intervention differs from it). E.g., is there is a 'standard practice' guideline that nurses follow in delivering 'usual care' in LTC facilities? Or can this be inferred from job descriptions of nurses etc?</p>
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	<p>Supplementary file 1 outlines the assessment procedure used to detect potentially eligible participants but it is not clear what score determined eligibility using the SDSL scale. Please add a sentence about this in file 1 to increase transparency of methods. Direct the reader to supplementary file when introducing the screening on p. 13 and or add reference for Roetz-Merken et al 2014 article.</p> <p>p. 11 In data analysis you mention that clustering was taken account of, but little detail is offered about processes applied. (I am not a statistician nor experienced in cluster RCT analysis, so I was not sure whether this brief explanation alone is adequate?).</p> <p>p. 12 At the end of the data analysis section you introduce comparing the treatment delivery findings to themes identified in a separate qualitative study (and cite a publication not yet available to the reader). I question whether reference to this paper is warranted here. I believe the results can stand alone and the inclusion of it here (and p. 14 para 1 and in the discussion p. 22) may unintentionally confuse the reader. Introduction to it some point in discussion (e.g., around where you do in p.23) could be appropriate however, that is, rather than using it to present your findings just acknowledge it in interpreting them in relation to wider literature.</p> <p>Results</p> <p>p. 14 – you cite reference [35] but I think you mean [33]? Numbers were small and less than planned in the protocol paper. It is also disappointing that >2/3 of potential participants in care homes (n = 525) were deemed unsuitable for the study. This reflects the age and setting targeted and the changes you mention on p. 23 re: LTC admission criteria (although that took place after trial commenced - assuming after allocation of clusters?). Perhaps a pilot study when developing your SMP-DSI intervention may have been advisable to better gauge implementation feasibility. Alternatively, a less stringent criteria of sensory loss e.g., including mild hearing loss within DSI definitions could potentially have boosted numbers slightly. What are the implications of these limitations and challenges for future work if others aspire to also test intervenes with elders with DSI? Would you advise trialing a similar intervention model among community-living older persons? Could this allow an 'early intervention' focus and potentially reduce the level of comorbidities and frailty (hence exclusions) among potential participants or would it be too logistically challenging?</p> <p>Table 1 – baseline characteristics. Were the differences between groups explored statistically? If so, use the words 'no statistically significant differences' were found rather than 'no large differences'. If any statistically significant differences were found please indicate these in the table for the readers convenience (bold/notation). Particularly with small sample cluster studies it is not uncommon for imbalances between the groups to be seen.</p> <p>Table 2 – perhaps bold the significant result to allow easy location given a lot of data are presented in this one table.</p> <p>Reference list</p> <p>Couple of errors noted:</p> <p>Reference 4 – should be updated to be more complete as this article was published in 2016, 71(1)117-23</p> <p>Reference 5 - includes an error as first author is Gopinath B.</p> <p>Congratulations on your interesting project.</p>
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REVIEWER	Robert Wellman Kaiser Permanente Washington Health Research Institute
REVIEW RETURNED	03-May-2017

GENERAL COMMENTS	<p>The authors present an interesting study of a nurse-led intervention for improving outcomes for elderly adults with DSI in care facilities in the Netherlands. However, difficulty in study recruitment and public policy hampered the success of the study. The following issues should be addressed to make the manuscript stronger:</p> <p>1) Make sure that the description of the primary outcome is consistent throughout, e.g., in the methods section the primary outcome is listed as "social participation, and the ACS," whereas in the data collection section the ACS and the HHQ are discussed as primary outcomes, and then in the analysis section HHQ is referred to as a supportive (secondary) outcome.</p> <p>2) In my eyes, Table 1 shows several variables that could be considered to be imbalanced between control and intervention patients. I don't think this is surprising given the clinic-level randomization, but these factors need to be adjusted for, especially if they are thought to be associated with the study outcomes (which I assume some of them are). Otherwise, there needs to be more justification as to why only diabetes was considered for adjustment or effect modification.</p> <p>3) Given concerns about power here, I think you would be better served to fit a model with the change from baseline as the outcome while adjusting for baseline. As opposed to the longitudinal model that I think you fit (baseline appears as the first of two longitudinal measures, correct?) the change score outcome with baseline adjustment should have more power given the precision gained from adjusting for baseline score.</p> <p>4) It's strange to me that the randomization was done in blocks here, but the nature of the blocks is not described. The only information is that the block sizes were 8, 7, 2, 5, 4 and 2. Were the blocks based on some kind of factor (geography, size)? Why were those sizes chosen and why is the total split uneven?</p> <p>5) It would be beneficial to talk more about what usual care entailed and whether you collected notes or follow up information (other than outcomes) from the usual care nurses as well. From table 1 it also looks like the control nurses had a fair bit less experience than the intervention nurses. I don't see mention of this being controlled for.</p> <p>6) I find table 2 difficult to understand. It's a bit hard to relate the baseline and unadjusted estimates to the Estimates from the repeated measures model. For example the unadjusted 9-month change in the UC group appears to be 1.6 for ACS overall, but the adjusted estimate is -2.7 I think; it's totally in a different direction. If that's the right comparison then I redouble my comments about potential confounding.</p> <p>7) I find the conclusions regarding feasibility and acceptability of the intervention to be fairly subjective in tone.</p>
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VERSION 1 – AUTHOR RESPONSE

Reviewer 1

There are many methodological strengths to this paper. Here are suggestions for improving the quality of the manuscript.

1. Grammar needs to be edited throughout the paper. Paragraphs need to have a topic sentence and then internal consistency regarding the topic. Currently multiple paragraphs ramble from one point to another. Shorten some of the long sentences. Overall this paper is very hard to read and understand due to language and grammar issues.

Re: We have rephrased several parts of the background and methods sections. See underneath, points 2 and 4.

2. The background should describe the theoretical frameworks for the study and justify the variables under consideration. The lack of the theoretical explanation leads to other issues. The authors begin with the problem of dual-sensory impairment. This is actually the target population. The fact that the DV is social participation suggests that this is the main problem trying to be influenced by the intervention. Yet it is not the central focus of the paper. Hence the logic for the study is not clear or justified. Why is self-management such a salient variable related to the DV? This needs to be more clearly explained. Why is social participation as an outcome variable necessary? Based on Socioemotional selectivity theory older adults often decrease their social network and want more control and choice over both the size and constitution of their network. Do you account for preferences for more or less social participation? All of these problems can be cleared up with theory, explanation, and citing evidence that provides explanations and rationales for your study hypotheses and variables.

Re: Thank you for your comments and recommendations. We rearranged the background section, adding linkages between DSI, participation, health and self-management. Page 6, lines 49-56; p. 7, lines 68-83; page 8-9, lines 106-117.

3. The components of the intervention are not adequately described. A table describing components of the theory that inform each component of the intervention would be helpful.

Re: We have added a table (new Table 1) with the key features of the intervention. Page 12.

4. Treatment fidelity testing should be more clearly explained.

Re: In the Methods section (data collection), we added a more detailed description of how we evaluated treatment delivery and adherence. Pages 15-16, lines 251-255.

5. The data collection points were very far apart and not justified. This is a limitation of the study and should be described in limitations. Also relying on this one measurement of the DV is a limitation.

Re: In the Methods section, we have added that we chose for a more extended data collection period as nurses showed to need more time to become familiar with the intervention. Page 15, lines 237-240.

6. State the use of the nurse variables and justify these in the background to the study.

Re: We have added that nurses taught very little about how best to provide this type of support when at school or at work.²⁴ This in turn can lead to less pleasure in their work and a higher rate of job loss.²⁵ And: As the training programme may influence the job satisfaction of the participating nurses, we added job satisfaction as an outcome for the nurses. Page 8, lines 94-96, p. 9, lines 116-117.

7. There should be a brief mention of checking assumptions for the data analytical approach and if there were any issues with skew etc.

Re: In the results section, we rephrased/added: Table 2 presents the baseline characteristics of the intervention and control group. Control for potential confounders showed no relevant change in the intervention estimate, i.e. the differences in baseline characteristics did not confound the intervention effect. Page 19, lines 331-335.

8. The sentence "In summary, this study demonstrates that the nurse supported SMP DSI was successful in addressing IADL problems in DSI older adults" is an overstatement. The main focus was to address social participation, so this finding should be discussed with more caution. This could simply be a spurious finding. I cannot connect IADL problems to the intervention components to the outcomes. Hence, this seems like an overstatement.

Re: Research on the concept of social participation identifies IADL is a domain of social participation (Levasseur M, Richard L, Gauvin L, Raymond E. Inventory and analysis of definitions of social participation found in the aging literature: proposed taxonomy of social activities. *Soc Sci Med*. 2010;71(12):2141-9). The ACS is in line with this, one of its domains is IADL (Baum CM, Edwards D. Activity Card Sort, second edition. Bethesda (MD): AOTA Press; Pittsburgh; 2008). To avoid the impression of overstatement, we rephrased the sentence. Page 28, lines 436-438.

Reviewer 2

Comment: I have very little to suggest by way of modifications but I think the authors might help the less well initiated reader to work out the clinical implications of their study by addressing the limitations regarding generalisability as follows.

The difficulties with recruitment due to the shifting demography of the Dutch long-term care population are important. The population will, I suspect, get more cognitively impaired and dependent over time, thus the proportion of the population who receive care in this setting using this resource intensive (and potentially costly but as yet uncoded) intervention is likely to be small. I struggle to imagine that it will be cost-effective in a long-term care setting. This is important in terms of generalisability to the Dutch population but also internationally. 75-80% of the UK care home population are cognitively impaired and the median MMSE is 11/30. UK care homes are much smaller than Dutch nursing homes - if this is unlikely to be cost effective in Dutch homes, it is unlikely to have any place in UK care homes. So what, therefore, is the lesson? That this works but is unlikely to be implementable in the real world of long-term care, where resources are significantly constrained? Or do the authors want to speculate on other care settings where the insights from this study might be applied?

Re: Thank you for your comments and suggestions. In the discussion, we have added some thoughts on the clinical implications of the study. Page 28, lines 426-435.

Reviewer 3

Comment: Thank you to the authors for completing this study which is ambitious and well written. DSI in older age is a topic slowly growing in awareness. As the authors correctly note, very few RCTs have been conducted targeting this population. The majority of literature in the DSI field focuses on prevalence/incidence of dual loss, association of dual loss with negative impacts, and (rarely) interventions intended to improve hearing aid or service use for example (Schneider et al 2014; Vreeken et al 2013; 2015) rather than daily life/ psychosocial/participation outcomes directly. Therefore the current study does make a strong contribution to the field and documents an innovative model of intervention.

Authors appear to have followed well the CONSORT guidelines and the article is well presented. Extra care to include additional details throughout the manuscript could add to the rigour. I appreciate that related papers from the same study are published/being published, however I believe each article should stand alone so the reader does not feel it necessary to locate all resources to get a complete picture of the study details.

Re: Thank you for your comments and thoughts. We agree and made some changes in the abstract and in the results.

Methods p. 7 – when introducing the Activity Card Sort instrument you reference [17] rather than a source more directly about the instrument, perhaps add citation for Baum C, Edwards D (2001)? When providing more detail about ACS (p. 11), it may be wise to mention features like test-retest reliability of the instrument etc. if available?

Re: We have added the reference Baum CM, Edwards D. Activity Card Sort, second edition. AOTA Press; Pittsburgh; 2008, as you suggested. Page 9, line 130. We also added a second validation study of Poerbodipoero SJ, et al.: The construct validity of the Dutch version of the activity card sort. Disabil Rehabil. 2016;38(19):1943-51. doi: 10.3109/09638288.2015.1107779. Page 14, line 224.

Comment: You refer to your study protocol and attach a copy as a supplementary file, however I note there is not a lot of detail provided about the choice /rationale for use of different outcome measures. Are these areas being investigated because they are typically seen to benefit from self management interventions for example? Or are they included because they are known areas of concern identified among older people with DSI in the literature? Are the instruments chosen well tested in the literature with robust features?

Re: The literature search showed a lack of robust validated sensory-specific as well as self-management outcome measures. Therefore, a focus group of DSI older persons and experienced healthcare professionals discussed and analyzed different outcome instruments aiming at autonomy, participation, self-efficacy and (generic and sensory-specific) quality of life, all used in published controlled and/or validation studies. The focus group assigned autonomy and participation as primary outcome candidates. As we could not find a robust validated autonomy measure, we assigned the 'best' among them as a secondary outcome measure (PAQ). Of the participation measures, the focus group judged the ACS as the 'best' instrument, because they felt endorsed by its focus on actual activities ('do you' in contrast to 'can you'), and by its comparison of these actual activities with the previous life style of the person (earlier, did you...). As there was some doubt as to whether the ACS may overlook the hearing and listening factor in participation, the HHQ was added as additional participation instrument.

p. 8, line 94 - When discussing inclusion criteria take care to be specific in your language e.g., is visual impairment measured with both eyes open? Pure tone audiometry measured across what frequencies? (I eventually located it from the results tables, but you could note PTA1-4hz (subscript) in brackets in the text to be clear for the reader for example). Notably this is a moderate (or worse) criteria - is there a particular reason you did not include mild hearing loss levels in your definition of DSI? Is there any reason why those with milder forms of loss would not benefit from 'self management' interventions?

Re: In line with the Snellen-instruction, we measured visual acuity with one eye covered. In table 2 we added 'best eye'. Page 20, table 2. We have added the different frequencies we have measured. Page 10, lines 142-143.

The reason why we chose a minimum of 40dB was based on the findings of the validation study (SDSL screening tool) to this intervention study where we observed that the older adults and the LTC professionals often denied the occurrence of a mild hearing loss.

As this study was an intervention study, it was essential that the older participants were aware of their hearing problems, and that they felt free and motivated to cooperate and give their consent for participation.

Comment: What is 'usual care' in LTC facilities? Are you able to provide some additional information to give the reader a clearer view of this (and therefore greater understanding of the extent the intervention differs from it). E.g., is there is a 'standard practice' guideline that nurses follow in delivering 'usual care' in LTC facilities? Or can this be inferred from job descriptions of nurses etc.?

Re: In the background section, we have added information on usual care in LTC. Pages 7-8, lines 86-91.

Comment: Supplementary file 1 outlines the assessment procedure used to detect potentially eligible participants but it is not clear what score determined eligibility using the SDSL scale. Please add a sentence about this in file 1 to increase transparency of methods. Direct the reader to supplementary file when introducing the screening on p. 13 and or add reference for Roets-Merken et al 2014 article.

Re: In the supplementary file, we have added the cut-off score, and in the manuscript we have added the reference to the SDSL publication, page 18, line 305.

p. 11 In data analysis you mention that clustering was taken account of, but little detail is offered about processes applied. (I am not a statistician nor experienced in cluster RCT analysis, so I was not sure whether this brief explanation alone is adequate?).

Re: The full sentence on page 16, lines 266-268, the reviewer refers to is "Older adults' outcomes were analyzed using a linear mixed model accounting for clustering of older adults within LTC homes (random effect for home) and repeated measurements (random effect for an older adult within a home)." For data-analysts, this provides sufficient detail to replicate the analysis because all major statistical packages provide a procedure to analyze linear mixed models with a random effect for home and a random effect for elderly nested within homes. So we chose not to add additional information on these analyses.

p. 12 At the end of the data analysis section you introduce comparing the treatment delivery findings to themes identified in a separate qualitative study (and cite a publication not yet available to the reader). I question whether reference to this paper is warranted here. I believe the results can stand alone and the inclusion of it here (and p. 14 para 1 and in the discussion p. 22) may unintentionally confuse the reader.

Introduction to it some point in discussion (e.g., around where you do in p.23) could be appropriate however, that is, rather than using it to present your findings just acknowledge it in interpreting them in relation to wider literature.

Re: We agree and have moved the text to the discussion section: page 25, lines 366-372.

Results p. 14 – you cite reference [35] but I think you mean [33]?

Re: We have rephrased the sentence and made a comparison with the study of Leontjevas. Page 25, lines 363-366.

Comment: Numbers were small and less than planned in the protocol paper. It is also disappointing that >2/3 of potential participants in care homes (n = 525) were deemed unsuitable for the study. This reflects the age and setting targeted and the changes you mention on p. 23 re: LTC admission criteria (although that took place after trial commenced – assuming after allocation of clusters?). Perhaps a pilot study when developing your SMP-DSI intervention may have been advisable to better gauge implementation feasibility. Alternatively, a less stringent criteria of sensory loss e.g., including mild hearing loss within DSI definitions could potentially have boosted numbers slightly. What are the implications of these limitations and challenges for future work if others aspire to also test intervenes with elders with DSI? Would you advise trialling a similar intervention model among community-living older persons? Could this allow an 'early intervention' focus and potentially reduce the level of comorbidities and frailty (hence exclusions) among potential participants or would it be too logistically challenging?

Re: We have added some thoughts on the implications for practice and research in the discussion section. Page 28, lines 426-435.

Table 1 – baseline characteristics. Were the differences between groups explored statistically? If so, use the words 'no statistically significant differences' were found rather than 'no large differences'. If any statistically significant differences were found please indicate these in the table for the readers convenience (bold/notation). Particularly with small sample cluster studies it is not uncommon for imbalances between the groups to be seen.

Re: Conform the CONSORT 2010 guidelines, difference between groups at baseline were not statistically tested (de Boer MR, et al. Testing for baseline differences in randomized controlled trials: an unhealthy research behavior that is hard to eradicate. *Int J Behav Nutr Phys Act.* 015;12:4; Moher D, Hopewell S, et al. CONSORT 2010 explanation and elaboration: updated guidelines for reporting parallel group randomised trials. *BMJ.* 2010;340:c869). In fact, there is little value in using a small p-value as indication for a non-random difference, because the randomisation (we have no indications in the process that the randomisation blind was broken) implies that differences at baseline are due to chance regardless of the p-value of a statistical test.

Comment: As authors we discussed for the relevant outcomes which baseline covariates may be potential confounders. We controlled for gender, average hearing loss, visual acuity, physical and mental health and for nurses' education level, but did not find a relevant change in the intervention effect estimate, i.e. no confounding. Apart from that, as planned in the study protocol, we looked if mood (CES-D) was an effect modifier. As reported, no significant effect was found.

Table 2 –(new table 3, LRM) perhaps bold the significant result to allow easy location given a lot of data are presented in this one table.

Re: We have marked the significant result in table 3. Page 22.

Reviewer 4

The authors present an interesting study of a nurse-led intervention for improving outcomes for elderly adults with DSI in care facilities in the Netherlands. However, difficulty in study recruitment and public policy hampered the success of the study. The following issues should be addressed to make the manuscript stronger.

1) Make sure that the description of the primary outcome is consistent throughout, e.g., in the methods section the primary outcome is listed as "social participation, and the ACS," whereas in the data collection section the ACS and the HHQ are discussed as primary outcomes, and then in the analysis section HHQ is referred to as a supportive (secondary) outcome.

Re: We rephrased the related sentences, page 4, lines 12-13, page 14, line 229, lines 225-227.

2) In my eyes, Table 1 (new table 2, LRM) shows several variables that could be considered to be imbalanced between control and intervention patients. I don't think this is surprising given the clinic-level randomization, but these factors need to be adjusted for, especially if they are thought to be associated with the study outcomes (which I assume some of them are). Otherwise, there needs to be more justification as to why only diabetes depressive feelings (LRM) was considered for adjustment or effect modification.

Re: As authors we discussed for the relevant outcomes which baseline covariates may be potential confounders. We controlled for gender, average hearing loss, visual acuity, physical and mental health (and recently, motivated by your suggestion), for nurses' education level, but did not find a relevant change in the intervention estimate, i.e. no confounding. Apart from that, as planned in the study protocol, we looked if mood (CES-D) was an effect modifier. As reported, no significant effect was found. Page 19, lines 332-335; page 21, lines 348-350.

3) Given concerns about power here, I think you would be better served to fit a model with the change from baseline as the outcome while adjusting for baseline. As opposed to the longitudinal model that I think you fit (baseline appears as the first of two longitudinal measures, correct?) the change score outcome with baseline adjustment should have more power given the precision gained from adjusting for baseline score.

Re: We agree with your suggestion that the most powerful analysis should be done and we explain now that we have in fact already implemented this, because:

a) fitting a model for change from baseline as outcome with baseline as a independent variable is mathematically equivalent to
b) fitting a model for the outcome with baseline as a independent variable (ancova), while this is in turn equivalent to
c) fitting a repeated measures model with the baseline as the first of the two repeated measures. This is explained in section 4 of Van Breukelen GJ. ANCOVA versus change from baseline: more power in randomized studies, more bias in nonrandomized studies [corrected]. J Clin Epidemiol. 2006;59(9):920-5). Cit: "It is much less known that ANCOVA is equivalent to testing the group by time interaction γ_3 in the reduced model (2), which is obtained by assuming that $\gamma_1 = 0$. So ANCOVA assumes that there is no group difference at pretest [15]."). The latter is the model we fitted. In conclusion, we believe that our analyses address your point.

4) It's strange to me that the randomization was done in blocks here, but the nature of the blocks is not described. The only information is that the block sizes were 8, 7, 2, 5, 4 and 2. Were the blocks based on some kind of factor (geography, size)? Why were those sizes chosen and why is the total split uneven?

Re: We have added in the text that the LTC homes were recruited in blocks due to planning and availability of coaches. These blocks had different number of homes. Also, to avoid contamination sometimes some homes in a wave had to have equal randomisation allocation which forced that randomisation ratio to be different from 1:1 in each wave. Therefore, the randomisation ratio was adapted per wave to maintain as much as possible similar number of homes in each treatment group, but in the end some imbalance in allocation was inevitable. Page 10, lines 155-156

5) It would be beneficial to talk more about what usual care entailed and whether you collected notes or follow up information (other than outcomes) from the usual care nurses as well. From table 1 it also looks like the control nurses had a fair bit less experience than the intervention nurses. I don't see mention of this being controlled for.

Re: In the background section, we have added information on usual care. Pages 7-8, lines 86-91. As described above (point 2), we controlled for several baseline characteristics. Regarding nurses' information: during the screening period we noticed that many nurses were unaware of the occurrence of DSI among their clients, nor of its impact (as expected and described in the background). Therefore, by identifying eligible DSI older adults, we risked to alter nurses' (un)awareness and therefore also their usual behaviour. To minimize a bias, our contacts with the usual care nurses was as low profile as possible. Nevertheless, as we collected and reported on the perceptions of the nurses in the intervention group, we were able to get a thorough insight in nurses' initial perceptions which we presume, as the clusters were randomised, comparable with those of the usual care nurses (doi:10.1136/bmjopen-2016-013122).

6) I find table 2 (new table 3, LRM) difficult to understand. It's a bit hard to relate the baseline and unadjusted estimates to the Estimates from the repeated measures model. For example the unadjusted 9-month change in the UC group appears to be 1.6 for ACS overall, but the adjusted estimate is -2.7 I think; it's totally in a different direction. If that's the right comparison then I redouble my comments about potential confounding.

Re: Thank your for your perceptivity: we omitted the direction of the unadjusted mean differences. We corrected the data in the table, so that a negative difference corresponds to a decrease. There is actually another reason why estimates are different. Because the data is assumed to be correlated (clustering of seniors within homes and repeated measures within seniors) and this is supported by the magnitude and statistical significance of the random effects, the best fitting correlation (covariance) structure is imposed on the data and this makes adjusted estimates that result from the linear mixed model always different from the raw change from baseline scores. Page 22-23, table 3.

7) I find the conclusions regarding feasibility and acceptability of the intervention to be fairly subjective in tone.

Re: We rephrased the sentence. Page 28, lines 444-446.

VERSION 2 – REVIEW

REVIEWER	Adam Gordon University of Nottingham UK
REVIEW RETURNED	04-Aug-2017

GENERAL COMMENTS	<p>Of the peer reviewers listed, I raised the fewest concerns but I am not convinced that my concerns have been addressed in any meaningful way by the authors' adjustments to the manuscript.</p> <p>I asked them to attend to issues of generalizability, with a particular view towards considering the differing contextual factors and populations cared for in long term care internationally. The authors have not addressed that.</p> <p>I asked the authors to consider that the proportion of cognitively intact patients cared for in long-term care settings (certainly in the UK and, almost certainly in the Netherlands given recent policy shifts in that country) will dwindle over time. So is long term care the right setting for the intervention? They have not addressed this question.</p> <p>I asked them to consider issues of implementability and the cost- and resource-effectiveness of an intervention of this type given numerous competing issues in multimorbid and frail care recipients that require attention by health and social care staff. They have not addressed this issue.</p> <p>It may be that the authors feel unable to address the above issues but I would present an inability to do so as part of their limitations if they are unable to consider them. Until they can, I would not be in the slightest way inclined to take the intervention forward in practice (although I might be interested to research it further).</p> <p>I feel, therefore, unable to recommend this for progress to publication at this time as none of my concerns as raised at initial peer-review have been directly addressed.</p>
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REVIEWER	Julie Schneider Menzi's Centre for Health Policy Sydney Medical School (Public Health) University of Sydney Australia
REVIEW RETURNED	23-Sep-2017

GENERAL COMMENTS	<p>Thank you to the authors for your responses to reviewer feedback. You have adjusted the paper well. The background reads more easily and the justification for the study is clearer to the audience. You have addressed all the issues I raised in my earlier review, either within the article or your letter of response. Thank you.</p> <p>I have only two small comments in reviewing the paper again.</p> <p>1. I continue to feel frustrated that the reader doesn't obtain a good understanding of the nature of 'usual care' through the paper (and just how different it is to the intervention developed and implemented in the study). Although you have added an overview description of usual care p. 7, this indicates that 'participation' is one of 4 government defined priority domains in LTC service provision, therefore nurses should be facilitating this in usual care.</p>
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	<p>But just HOW participation is facilitated by staff in usual care remains a bit of a mystery. Are there any papers/qualitative studies about nurse-resident interactions you can summarise for the reader to assist them to have a clearer understanding? I find myself making assumptions that nurses are perhaps more accustomed to 'doing for' residents rather than 'doing with' residents as is the problem solving interaction approach of your SMP-DSI. (Likely due to staff shortages and a need to be time-efficient, or of having only received basic training that is more oriented to serving physical care needs?). If there is literature about usual care interactions between nurses and residents that could be added, I believe it would enhance your paper and strengthen the rationale for designing your intervention. However, I appreciate it may be difficult to describe or know the intricacies of 'usual care' interactions - perhaps it can only be gleaned from the reflections of the nurses themselves in your qualitative paper.</p> <p>2. In the discussion section (p. 24, para 2) - The finding about the SMP-DSI having less success addressing problems that required interactive/behavioural involvement of others is a really important one. You make some nice observations about this finding. A further consideration I believe is that residents may feel concerned about burdening others by requiring interactive support for participation. Particularly if they perceive nurses are very time-poor or stretched in their roles, or if they perceive that when they take up more time, other residents go without. (Within unpublished qualitative work done with community-dwelling older persons with DSI, we have seen this sense of burden can impact even the extent participants were comfortable to reach out to family members for support). How can this be addressed at a practical level? Is it beyond the scope of the nurses' role? Could a volunteer program of 1:1 support be possible in LTC facilities? Personally, I believe the challenges of DSI emerge in the interactive space and therefore can be best overcome through interactive support (as technological solutions are supportive but cannot eliminate communication-participation limitations entirely). In a similar way to the concept of communication guide support (that is funded in some countries to facilitate community participation for those with deafblindness), one on one communicative support for elders with DSI has potential to impact participation and quality of life outcomes, dependent as you note, on the sense of 'partnership' and trust between parties being achieved. I am not asking you to add more to the paper regarding this point, I'm just sharing thoughts and observations that your work provokes.</p> <p>Thank you for the opportunity to review this interesting work. Congratulations again on your study which makes a strong contribution to literature within the DSI field.</p>
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VERSION 2 – AUTHOR RESPONSE

Reviewer: 2

Reviewer Name: Adam Gordon

Of the peer reviewers listed, I raised the fewest concerns but I am not convinced that my concerns have been addressed in any meaningful way by the authors' adjustments to the manuscript.

I asked them to attend to issues of generalizability, with a particular view towards considering the differing contextual factors and populations cared for in long term care internationally. The authors have not addressed that.

Comment: I asked the authors to consider that the proportion of cognitively intact patients cared for in long-term care settings (certainly in the UK and, almost certainly in the Netherlands given recent policy shifts in that country) will dwindle over time. So is long term care the right setting for the intervention? They have not addressed this question.

I asked them to consider issues of implementability and the cost- and resource-effectiveness of an intervention of this type given numerous competing issues in multimorbid and frail care recipients that require attention by health and social care staff. They have not addressed this issue.

It may be that the authors feel unable to address the above issues but I would present an inability to do so as part of their limitations if they are unable to consider them. Until they can, I would not be in the slightest way inclined to take the intervention forward in practice (although I might be interested to research it further).

I feel, therefore, unable to recommend this for progress to publication at this time as none of my concerns as raised at initial peer-review have been directly addressed.

Response to reviewer 2

We apologize for responding insufficiently to your concerns. We feel that we attended to the issues of generalizability in the Discussion, where we suggested considering the differing contextual factors regarding (international) populations in long-term care. We also have responded to the issues of cost effectiveness, resource effectiveness, and of implementability, and whether the current long-term care is the right setting for the intervention. We have included our responses below:

Response towards the cost and resource effectiveness:

Page 25, lines 361-363:

“Another limitation was that we did not calculate the cost-effectiveness of the intervention. Future research should review costs, based on resource and time calculations, involved in the evaluation.”

Response towards the generalizability and contextual factors:

Page 26-27, lines 382-413:

First, the generalizability of the SMP-DSI intervention itself to other care organizations or healthcare systems has been challenged. The performance of the SMP-DSI requires qualitative conditions, such as partnership and connectedness, which are not obviously present in usual care. The SMP-DSI is an intervention that fits in the (inter)nationally changing focus in healthcare from physical health to social health, from taking care of the care recipient and aiming at physical wellbeing, to care offering psychosocial support aiming at social wellbeing. However, as such psychosocial interventions are still scarce, a great deal of its implementability, strengths and barriers, remain unexplored. The findings of nurses' changing perceptions in our study illustrated the cultural clash that occurs when both aims meet each other. Regarding generalizability of the SMP-DSI, the strength of this study is in the identification of those psychosocial intervention elements that were shown to be working elements. This demonstrated that the combination of longitudinal, ongoing nurse – older adult interactions with self-reflective coaching was an important positive working element to take these cultural hurdles.

Second, the SMP-DSI requires mental capacities in executive functioning that probably makes the intervention difficult to implement among older adults suffering from moderate to severe cognitive impairment. Yet the increasing DSI population with cognitive impairment in LTC reaffirms the need to develop psychosocial support for these care dependent older adults. Findings from this study such as the need of client-aligning attitudes and skills among nurses, and the problems identified by the DSI older adults with no or only mild cognitive problems, may offer researchers and program developers opportunities to develop observational and behavioral tools aimed at providing support to cognitive impaired DSI older adults.

Finally, the SMP-DSI was developed as an empowering instrument for care dependent DSI older adults, whether they were community dwellers or LTC-residents. As home care organizations were not able to meet our inclusion criterion that familiar nurses could meet the older adults at least twice a week, the SMP-DSI could not be tested among community dwelling DSI older adults. However, taking the findings on the relevance and feasibility of the SMP-DSI in LTC into account, we recommend implementing and testing the SMP-DSI in home dwelling environments in a lower once-a-week meeting frequency of the familiar nurse with the older adult, which would possibly be more implementable and might be feasible in home dwelling environments. Another option is to involve voluntary welfare professionals who visit these DSI older adults at home, and who have been coached in the SMP-DSI method by trained coaches (e.g. nurses or other care or welfare professionals). However, this should be investigated in future research.

Reviewer 3

Reviewer Name: Julie Schneider

Comment: Thank you to the authors for your responses to reviewer feedback. You have adjusted the paper well. The background reads more easily and the justification for the study is clearer to the audience. You have addressed all the issues I raised in my earlier review, either within the article or your letter of

response. Thank you.

I have only two small comments in reviewing the paper again.

1. I continue to feel frustrated that the reader doesn't obtain a good understanding of the nature of 'usual care' through the paper (and just how different it is to the intervention developed and implemented in the study). Although you have added an overview description of usual care p. 7, this indicates that 'participation' is one of 4 government defined priority domains in LTC service provision, therefore nurses should be facilitating this in usual care. But just HOW participation is facilitated by staff in usual care remains a bit of a mystery. Are there any papers/qualitative studies about nurse-resident interactions you can summarise for the reader to assist them to have a clearer understanding? I find myself making assumptions that nurses are perhaps more accustomed to 'doing for' residents rather than 'doing with' residents as is the problem solving interaction approach of your SMP-DSI. (Likely due to staff shortages and a need to be time-efficient, or of having only received basic training that is more oriented to serving physical care needs?). If there is literature about usual care interactions between nurses and residents that could be added, I believe it would enhance your paper and strengthen the rationale for designing your intervention. However, I appreciate it may be difficult to describe or know the intricacies of 'usual care' interactions - perhaps it can only be gleaned from the reflections of the nurses themselves in your qualitative paper.

2. In the discussion section (p. 24, para 2) - The finding about the SMP-DSI having less success addressing problems that required interactive/behavioural involvement of others is a really important one. You make some nice observations about this finding. A further consideration I believe is that residents may feel concerned about burdening others by requiring interactive support for participation. Particularly if they perceive nurses are very time-poor or stretched in their roles, or if they perceive that when they take up more time, other residents go without. (Within unpublished qualitative work done with community-dwelling older persons with DSI, we have seen this sense of burden can impact even the extent participants were comfortable to reach out to family members for support). How can this be addressed at a practical level? Is it beyond the scope of the nurses' role? Could a volunteer program of 1:1 support be possible in LTC facilities? Personally, I believe the challenges of DSI

emerge in the interactive space and therefore can be best overcome through interactive support (as technological solutions are supportive but cannot eliminate communication-participation limitations entirely). In a similar way to the concept of communication guide support (that is funded in some countries to facilitate community participation for those with deafblindness), one on one communicative support for elders with DSI has potential to impact participation and quality of life outcomes, dependent as you note, on the sense of 'partnership' and trust between parties being achieved. I am not asking you to add more to the paper regarding this point, I'm just sharing thoughts and observations that your work provokes.

Thank you for the opportunity to review this interesting work. Congratulations again on your study which makes a strong contribution to literature within the DSI field.

Response to reviewer 3

Thank you for your comments. We have added information on the usual care interactions, page 7, lines 77-80:

"Nurses in usual care have two mediating roles in social participation: by bringing residents together, based on the rationale that proximity creates automatic opportunities for contact and participation; and by scheduling volunteers who support the older adults with their hobbies.²³". Indeed, the guidelines of the Professional Association Nurses and Nurse Assistants describe that organizing activities aiming at participation is not a responsibility of the nurses (rather a responsibility of family members, volunteers, or of social workers specially trained to organize activities for the older adults). Your thoughts about interactive support are very interesting. Based on two findings in our qualitative studies, we believe that, apart from interactions with other relevant persons, older adults long for alignment with those persons who offer daily care: (1) the older adults showed their relief and enthusiasm when they observed that the nurse really wanted to discuss and search for solutions together, and (2) almost every problem identified by the older adults in the cRCT were targeting daily-life problems in LTC.

Our data do not provide sufficient information about a possible concern of the older adults towards burdening others when nurses spent effort or time with them. However, several older adults mentioned that their problem was caused by not being able to understand what the nurse meant, due to her speaking too quickly or her rapid disappearance from the room. These observations bring us back to the need for partnership and interaction. Yes, we agree, there is still a lot to explore when discussing how to support frail DSI older adults.

VERSION 3 – REVIEW

REVIEWER	Julie Schneider Menzies Centre for Health Policy Sydney Medical School (Public Health) University of Sydney Australia
REVIEW RETURNED	15-Nov-2017
GENERAL COMMENTS	Thank you to the authors for adding further information regarding usual care in response to one of my previous comments. I think the article is reading well and that this version incorporates a stronger discussion, acknowledging limitations and considering 'lessons learned' and implications in more detail. This has improved the manuscript in my view.