Author's response to reviews

Title: Factors influencing the implementation of a lifestyle counseling program in patients with venous leg ulcers: a multiple case study

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Author's response to reviews: see over
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Dear editor

Enclosed is the latest version of our manuscript (MS: 1989861896495770 Determinants of the implementation of a lifestyle counseling program in patients with venous leg ulcers: a multiple case study).

We would like to thank you for the thorough evaluation of our paper. We wrote a point-to-point response to the reviewers’ questions and comments. We highlighted the changes we have made to the manuscript.

With respect to your comments to use terms which are in conformance with qualitative research, we are willing to adjust this. We understand that the term ‘determinants’ might be associated with epidemiological and quantitative research. To avoid misunderstanding we decided to change this term into ‘influencing factors’ throughout the paper.

We have thoroughly checked sentence construction and meaning.

We look forward to your response.

Yours sincerely, on behalf of the co-authors,

Irene van de Glind
Reviewer 1

We thank the reviewer for her positive evaluation of our manuscript and the constructive comments that help us to further improve our paper.

1. I have put some grammatical and wording suggestions in “sticky notes” in the PDF – for example the authors frequently use the word “data” as singular rather than plural.  
   Answer of the authors: Thank you very much for your language corrections. We followed your recommendations and suggestions in our latest version of the manuscript. We have highlighted these changes throughout the paper.

2. There is some stuff about the evidence for Lively Legs that should be in the Background rather than the Methods. The Methods should contain detail about the intervention as delivered but not the history of it and related evidence.  
   Answer of the authors: To improve the structure of the paper we have moved the text about evidence and history of Lively Legs to the Background section. We then revised the Background section to keep the paper concise and readable. See page 3-4, highlighted sentences.

3. I would really like the authors to consider stepping back slightly in the Discussion/Conclusions from Lively Legs and saying something about how the care of people with leg ulcers is organised and the quality of its delivery. For me the strongest message of this paper is that Lively Legs was so difficult to recruit to/implement BECAUSE of the way leg ulcer care is fragmented and issues surrounding that. This raises big questions about the quality of care currently received which could be at least hinted at.  
   Answer of the authors: One important finding of our study is indeed that the implementation of Lively Legs is hindered by the fact that current leg ulcer care is not optimally organized. The findings of this study imply that the quality of care in this patient group could be improved, although we did not measure this. We do hint at it in our implication section by stating that we would like to see further research on process redesign of leg ulcer care, and also in our conclusion, that Lively Legs should be tied into a standardized treatment protocol. However, this message deserves more attention and a more explicit relation to quality of care in our paper. We revised our main results in the Discussion section (page 18-19, highlighted sentences), the Implications (page 21, highlighted sentences) and in the Conclusion (page 22, highlighted sentences). Finally, we added a sentence in our abstract.
Reviewer 2

We thank the reviewer for his positive yet critical evaluation of our manuscript and all comments that further improve our paper.

1. Through the revisions the relatively small sample size regarding patients has been more prominent. What are the implications of having only about 4 patients per trained nurse? This is not described as a limitation, isn’t it a limitation? I also wonder about your description in the abstract where you write that a total of 12 nurses participated in the study. I understand that you trained 12 nurses in the program, but that also other people participated in the study as informants. Why focusing on these 12 nurses?

Answer of the authors:
Although it would have been nice if more patients could have benefitted from the Lively Legs program, we do not think that it is a limitation of our study. The aim of this study was to identify influencing factors for implementation and to understand how and why implementation could succeed in everyday practice. We regarded the number of patients that enrolled in the program an indicator of implementation success and used this to evaluate and understand the implementation in each case. However, implications of a small sample size could be that nurses were not able to master their skills in program delivery. So program adherence could have been affected by this.

Authors’ changes in the manuscript: We have added this implication to the Discussion section of our paper (page 20, highlighted sentences).

Nurses delivered the program, and were key persons in implementing the program. They were trained and were regarded as participants in the study. Other participants were: managers, dermatologists, a general physician, a policy advisor and medical assistants. They were involved, but they did not have a prominent role in program delivery. They did help us to understand the context and surroundings in which care is delivered and in which the Lively Legs program had to be implemented. So their involvement in this study was to identify influencing factors for implementation and to (help) carry out implementation strategies.

Authors’ changes in the manuscript: To avoid misunderstanding, we revised the sentence in our abstract to: “A total of 53 patients enrolled in the Lively Legs program that was delivered by 12 trained nurses.” We have not revised the manuscript, for we think the different roles of participants were already clearly explained (page 7,8,12 and Table 1 and Table 2).

2. In the background section you write that little is known from the literature about what factors are “really important” for facilitation/hindering implementation. Would be good to see in the discussion how you judge your own findings. Did you find the “really important” determinants?

Answer of the authors: Yes, we did find the determinants affecting the implementation of the Lively Legs program. In the background section we argue that
most implementation research only investigates influencing factors beforehand. In this study we follow a small number of implementation trajectories in everyday practice to identify the factors after implementation. When comparing these “true” factors with what people thought beforehand, it appeared that most factors were indeed confirmed – but not all. Moreover, we were able to get a good picture how factors influenced the implementation. We now know why it was difficult to recruit patients and why some nurses succeeded in the implementation and others did not. When re-reading the Discussion section, we think our reflection on this topic should have been more prominent and formulated differently. Therefore, we have revised a few sentences on page 20.

3. On page 6 (bottom lines) you have two sentences that in my opinion do not contribute to strengthening your overview of evidence for the lively legs intervention. “Effects on ulcer healing and pain were not conclusive, but were promising. In Germany, researchers recently developed a nurse-led educational intervention to enhance self care in patients with chronic ulcers [15]. Unfortunately no results have been reported yet.” I think you should take out these sentences.

Answer of the authors: We share your opinion that these sentences do not strengthen the evidence for the program in particular. We added this section in reply to earlier comments of one of the other reviewers that more information is needed on why and for whom an implementation study is interesting. Next to this, one of the other reviewers suggested to move the text about the evidence and history from the Methods to the Background section. Therefore, we comprised and revised the text in the Background section. We think that by doing this, the paragraph now presents an overview of research done on this topic as well as more background information to understand the relevance of the study.

4. On page 8 you state “Next to this, the evaluation makes use of more structured and quantitative methods”. As point 2 this is followed by that you used interviews with open ended questions. I think you should consider a more logical ordering.

Answer of the authors: Thank you for noticing this omission. In the revision of the manuscript we rearranged this paragraph. Point two (interviews with open ended questions) should have been taken out. We deleted this, so the enumeration of more structured and quantitative methods is now logical.

5. On page 10 there is a reference number lacking on line 6. On page 21 there seems to be a redundant “is” in the third line in the second paragraph.

Answer of the authors: Thank you for noticing these mistakes. We corrected them in our latest version of the manuscript.
6. In my previous comments I indicated that I did not get the range in the bottom of table 4. I still have problem with this table. For case 4 you sum up that 15 of 16 strategies were carried out and that the range was 4-14. How can it come that the range does not include the number of strategies carried out?

Answer of the authors: Within the five cases, nine different healthcare organizations participated in this study. In case 2 and case 4 the outpatient clinic and the homecare organization delivered the program to their patients. There were 16 distinct implementation strategies that settings could use. So, in case 4 the outpatient clinic carried out implementation strategies and the homecare organization also carried out implementation strategies. In total 15 different strategies were carried out in case 4, but not all by the same organization. That is the reason that the range does not include the number of total strategies carried out.

Authors' changes in the manuscript: We have put in a note below table 4 to explain the range (page 34).
Reviewer 3

We thank the reviewer for all comments. We used them to further improve our paper.

1. **Page 2: Abstract** – I think that the following sentence is confusing. ‘Analyses focused on qualitative data as the main data source, and comprised of comparing all data (including questionnaires and nurses’ registration) across multiple case studies to draw conclusions from the study as a whole.’ So, it can be read in a variety of ways. Is it that qualitative data was the main focus of the analysis and that findings from this was supported by further quantitative? Keep it simple maybe two separate sentences, so you can divide phases or ideas.

   **Answer of the authors:** We share your opinion that the sentence might be confusing. We changed it to: “Analyses focused on qualitative data as the main data source. All data were compared across multiple cases to draw conclusions from the study as a whole.”

2. **Page 11:** The beginning of this sentence is odd. ‘At last we listed explanations with respect to determinants …’ I think you mean, ‘Finally we listed …’ or ‘We then listed …’ or even, ‘Lastly we listed …’

   **Answer of the authors:** Thank you for this language correction. We changed this in our latest version of the manuscript.

3. **Page 21:** It currently reads ‘On the one hand the framework is gives structure’, it should read ‘On the one hand the framework gives structure’

   **Answer of the authors:** Thank you for noticing this mistake. We have corrected this in the revision.