Author's response to reviews

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

Authors:

Irene M van de Glind (i.vandeglind@iq.umcn.nl)
Maud M Heinen (m.heinen@iq.umcn.nl)
Andrea W Evers (a.evers@mps.umcn.nl)
Michel Wensing (m.wensing@iq.umcn.nl)
Theo van Achterberg (t.vanachterberg@iq.umcn.nl)

Version: 2 Date: 6 March 2012

Author's response to reviews: see over
Nijmegen, March 6th 2012

Dear editor,

Thank you very much for the thorough evaluation of our manuscript. We have provided a point-to-point response to the reviewer’s issues and indicated the changes we have made to the manuscript (MS: 1989861896495770 Determinants of the implementation of a lifestyle counseling program in patients with venous leg ulcers: a multiple case study).

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 and critical evaluation of our manuscript and constructive comments that help us to further improve our paper.

1. Increase the amount of detail about both Lively Legs and the Implementation Strategy. The paper is thin on detail about both Lively Legs and the implementation strategy. Who is the target audience for the paper? It could be leg ulcer specialists who might be interested in implementing Lively Legs or implementation scientists who are interested in the implementation process. I don’t think either constituency will get enough from the paper as it stands because detail is thin. We learn that the authors explored potential determinants of implementation and selected implementation strategies based on the determinants but I am not sure we learned much new about implementation. The report would be enhanced by more in-depth analysis I think; the style is extremely succinct and the fact that there were five cases means we get very little rich detail about them. Description of the Lively Legs Intervention was scant and that is essential context for the interpretation and understanding of its implementation. I was unfamiliar with the intervention but did not learn much from this paper beyond that it “aims at increasing physical activity, leg exercises and adherence with compression therapy…Also … pain management, proper hygiene … foot wear [using] Social Cognitive Theory … Goal Setting Theory …and the Precaution Adoption Process Model”. Motivational interviewing also features and it appears that the intervention is delivered on an individual patient basis rather than in a group but this isn’t clear. I read further using the references provided and learned that the intervention also involves diet and exercise, in other words A BIG, COMPLEX, BROADLY FOCUSED INTERVENTION! Given the huge changes required/expected of the patients (and knowledge and skills required of the nurses) I think readers would benefit from knowing more about the patients and the nurses – we learn almost nothing about them yet this is essential context. Usually venous leg ulcer patients are elderly and have many co-morbidities including those which limit mobility and presumably their ability to engage with this intervention. I do not think there is sufficient detail except at a very meta level; at least as importantly I do not feel there is sufficient contextual information for interpretation.

Answer of the authors:

We have tried to improve the paper by increasing the amount of detail. The reader will get more insight and understanding of the implementation process as well as of the Lively Legs program itself. In our effort to write a concise and clear manuscript, we apparently have removed necessary context information along the way. In our revised manuscript we have tried to resolve this. Firstly, by providing more detail on context in the methods section (in particular the description of the Lively Legs program) and the results section (description of the setting, nurses and patients). Secondly, we have rearranged the results section to highlight the most important qualitative results and underpin these with illustrations and citations.
We would like to add that we believe that scientists and healthcare professionals involved in similar programs for patients with chronic leg ulcers as well as other patient groups may benefit from the results of this implementation study. We think this research offers more insight in implementation problems, and offers possible solutions, for instance redesigning the care process to tie such a program into and facilitating the nurse with sufficient time and autonomy to schedule and coordinate the program.

**Authors’ changes in the manuscript:**

- We provided more detail on context in the background, the methods section (in particular the description of the Lively Legs program) and the results section.
- We have rearranged the results section and added illustrations and citations in the text and in an additional Table (Table 3).

2. More quantitative data needed. I found the data difficult to follow. At one point much of the data (all of it?) will have been qualitative but it appears to have been collapsed and coded into quantitative data. As such it is difficult to get a feel for or interpret. I have read the paper several times but could not really tell you what the “results” are or even how many patients were in each case. Is this a quantitative or a qualitative study? It’s really not clear; it is quantitative in tone but there are few quantitative data reported.

**Answer of the authors:**

This is actually a mixed-methods study. Although qualitative data was the main data source in our analyses, we think that this should have been made clearer in the paper. We may have aggregated the data too much to broad conclusions in our effort to write a concise manuscript. Furthermore, the order in which the measures and methods is presented (first the structured quantitative data, and then qualitative data) is, in hindsight, actually not in line with the study design and relative importance of the used data sources. Considering the fact that the reader may have difficulty in understanding the data, we have shifted the focus and rearranged our methods and results section.

**Authors’ changes in the manuscript:**

- We have changed the order in which we presented measures and data collection in the methods section and in the results section.
- We have explained more prominently the main focus of the study and the way the different data sources were used.
- Next to this, we have added illustrations and citations in the text and in an additional Table (Table 3) in the results section.
3. More required in the Results. For example in the Results section, first paragraph, we learn that it was impossible to collect data for the denominator i.e., the number of potentially eligible patients at each site (which seems unfortunate and tells us something regarding the lack of “central intelligence” regarding this condition – surely a key issue) but that “only the number of participating patients could be retrieved”. There is little quantitative or qualitative data in the paper but we do learn eventually under the heading of “Evaluation” that a total of 53 patients enrolled in the program – this is very few distributed across five case sites and must call into question the cost effectiveness of the exercise. How many patients per site?

**Answer of the authors:**
Indeed, a total of 53 patients enrolled in the program – and it is correct that this number is low as these were distributed across five case sites. The main goal was to identify which determinants hindered and facilitated implementation of Lively Legs in outpatient clinics for dermatology and in homecare. Reaching patients and organizing referrals for the program was actually the most difficult part of the program to implement. This study provided insight into determinants of reach and why patient recruitment succeeded in some cases. We would like to repeat that in our revised manuscript we have emphasized the focus on qualitative data. We think that we improved our manuscript by bringing focus in our paper, and highlight and underpin our main findings with illustrations and citations.

Next to this, we made some changes in the text to resolve confusion about the number of patients per case. We think that our restructuring and refocus on the main qualitative results of the study enhanced the clarity of the data.

**Authors’ changes in the manuscript:**
- We report the number of patients that enrolled in the program earlier in the manuscript.
- We have added a sentence in the methods section to highlight the focus of the study and the way the qualitative and quantitative data was used.

4. **Enhance the discussion with consideration of the volume and quality of the underpinning evidence.** I would question whether we have sufficient data on Lively Legs to warrant implementation anyway. So far as I can see it has been evaluated in only 184 people with 26% dropout, and was only evaluated in dermatology clinics (which helps explain why this study found implementation difficulties beyond the clinics). The RCT found no difference in wearing of compression therapy between the groups, and no difference in “wound time” after adjustment for baseline covariates. There were differences in exercise behaviour but I am not aware of research that shows that exercise improves leg ulcer healing/recurrence (though does improve some physiological measures). So the health benefits of the intervention have not been fully demonstrated and there does not seem to be evidence of cost effectiveness. If research evidence for the health benefits and cost effectiveness of the intervention were more impressive might implementation itself be easier?

**Answer of the authors:**
With regard to your questions on the ‘implementation readiness’ of the program we would like to give you our thoughts on this subject.

The Lively Legs program has shown positive effects on patient behavior (in particular on physical activity and leg exercises). Moreover, in a formal evaluation the
The intervention group had fewer wound days after the initial wound had healed. It was concluded by Heinen et al. (2011) that the program might postpone the occurrence of new leg ulcers. However, evidence is still limited and further clinical studies would be desired. Nevertheless, we think there are good arguments that advocate an exploration of how the program can be implemented.

Firstly, studies from several countries show that the current care practice for venous leg ulcer patients is not satisfying for both patients and health professionals [1-3]. In other words: at the moment there is no structural attention for lifestyle and self-management topics in this patient group. The Lively Legs program offers a method to give structured attention to the prevention and self-management of leg ulcers. Similarly, comparable initiatives were established in Belgium, Germany, the UK and Australia [4-7]. Although evidence is limited, superior initiatives are not available. Secondly, studies (this implementation study and the study by Heinen et al. 2006; Heinen et al. 2011) found that nurses and patients value the program positively. Thirdly, a cost-effectiveness analysis has been performed on data that was collected alongside the trial. From a societal perspective the intervention group had an average of 345 euro less costs over a period of 18 months, including the costs of the intervention. The difference in costs was not significant, but the intervention group had a significantly higher score on quality of life (EQ5D). It was concluded that the intervention was cost-effective in a sense that there is a significant increase in quality of life and no significant difference in costs. In the Netherlands, the main grant provider for scientific research in healthcare (ZonMW) has judged that there was sufficient cost-effectiveness to further explore possibilities for implementing this program in regular care.

**Authors’ changes in the manuscript:**
- In the background section and methods section, we refer to initiatives in other countries more prominently. We also refer to the studies that conclude that current care practices for this patient group should be improved.

5. Reference 14 is repeated as Reference 39.

**Answer of the authors:**
Thank you for your thorough reading of our manuscript. We have changed reference 39 to 14.
Reviewer 2

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

1. The paper would be strengthened if you could describe the principles of this comparison. For example: Did a determinant need to be frequent to be reported as a finding? How frequent? I also would like you to be more explicit on the use of triangulation. What data sources were combined? How?

Answer of the authors:
We have provided a more explicit explanation of how we analyzed the data. We would like to explain that we used the following principles to report determinants:
- Determinants should be apparent in at least three of the five cases (and were regarded even stronger if more than one respondent per case identified the same factor).
- This also meant that a determinant was "counted" when it was a barrier in one case and a facilitator in the other.
- Determinants were divided by type of setting (homecare or outpatient clinic) and by phase (pre or post implementation) to be able to indicate patterns
- At last we listed possible explanations with respect to determinants, for example, we looked at all possible reasons why patient recruitment was problematic in some cases and not in others.

Triangulation was applied as follows:
- The results of the monitor instrument (how many patients enrolled in the program) and the evaluation forms were discussed with respondents in qualitative interviews.
- Observations and field notes were checked in qualitative interviews.
- We compared the results from the barriers and facilitator questionnaire with the findings from interviews afterwards, as respondents filled in the questionnaire after the qualitative interview.

Authors’ changes in the manuscript:
In the methods section we have inserted the above mentioned principles for data analysis and triangulation.

2. Could you link identification of more frequent obstacles to lower extent of guideline implementation? In the results I cannot read that such a comparison is made. On page 18 you claim “by closely following a relatively small number of implementation trajectories, we succeeded in identifying some patterns of influencing factors for implementation”. However, it is not clear for me how you linked determinants to implementation success/failure.

Answer of the authors:
We have tried to improve the paper to strengthen the link between determinants and success/failure.
Determinants were linked to ‘success’ by exploring the explanations of participants if and why they perceived success. This was discussed with open ended questions in the qualitative interviews to evaluate the implementation. From the inventory of
determinants and the explanations of participants, we were able to understand the relation between determinants and perceived success/failure. However, we would like to clarify that we mainly measured perceived success/failure. Relative 'success' was defined by a score that reflected perceived implementation success of participants and by our minimum standard of including one new patient per month in the program. Additionally we looked at adherence to protocol in every case (reported in the additional data file).

We think that adding an extra paragraph in the results section resolves confusion on this topic.

**Authors’ changes in the manuscript:**
We have added an extra paragraph in the results section, called: ‘Linking determinants to perceived implementation success’.

3. In the third paragraph in the discussion section you write that participants were able to identify determinants beforehand and that these mostly were confirmed during and after implementation. I do not really see this repeated measurement approach presented in the results section. Also the following text in the third paragraph is difficult to link to the results section. I think more concrete examples are needed for the reader to understand “how and why determinants were of influence”

**Answer of the authors:**
In our effort to write a concise and manageable paper, some valuable illustrations were apparently lost in aggregation along the way. In the result section we have provided more detail, and we have made a more distinct link to the discussion section. We decided to rearrange the results section to be able to underpin the essential results of our study. Besides highlighting the more qualitative results of our study, we also inserted a table with determinants before and after implementation to reflect the comparison of determinants before and after implementation (Table 3). Next to this, we have added illustrations and citations in the text and in this additional Table (Table 3). During the revision of our manuscript, we realized that these changes indeed highlight one of our main conclusions: that the most hindering and the most facilitating determinants both relate to patient recruitment and some of them were already mentioned in the pre-implementation phase. Therefore we have also added our reflection in the discussion section on the extent to which expected barriers were resolved by implementation strategies.

**Authors’ changes in the manuscript:**
- We have added an additional Table (Table 3) in the results section that present determinants before and after implementation. We have illustrated these with citations to enhance understanding.
- We have inserted illustrations and citations in the text in the result section.
- In the discussion section we added our reflection on the comparison of determinants before and after implementation.
4. You use a framework inspired by Hasson (2007). It is not clear why this specific framework was selected. You write that it addresses determinants but determinants do not seem to be a predominant part of the framework. It would benefit the paper (and the overall issue on use of theory in implementation research) if you in the discussion judge the value of using this framework, what the benefits/disadvantages were.

**Answer of the authors:**

We used the framework of Hasson (2010) to be able to make a distinction between different elements in the evaluation: determinants, implementation success and program adherence. Because data would be collected on each of these areas, the need emerged to organize and order the different elements.

For this purpose the framework of Hasson (2010) sufficed very well. On the one hand the framework is gives structure; on the other hand it is still generic enough to explore how determinants exactly influenced the implementation of this explicit lifestyle program. At the same time, we acknowledge that other frameworks such as these are available and could have been equally suitable.

**Authors’ changes in the manuscript:**
- We inserted our reflection on using the framework of Hasson (2010) in the discussion section.

5. In the methods section I read it as you were developing several implementation strategies that could be used as a “smorgasbord” of participating units. In the results section I find that some strategies were compulsory, others optional depending on obstacles/facilitators at the specific unit. On page 15 you write that one common determinant was the extent to which the implementation program was carried out, which gives me the feeling that you expected all components to be carried out. In Table 3 I see that 3 of 5 units used most of implementation and you describe all strategies as planned in the table. How much of adaption of the implementation program was it to local conditions? This should be made clearer. You also need to explain the bottom line in Table 3, don’t understand that these figures represent range, and particularly case 4?

**Answer of the authors:**

The adaptation of implementation strategies to local conditions was dependent on the choice who would deliver the program and in what way collaboration between organizations was feasible. When this was established in each of the five cases, it appeared from the inventory of determinants before implementation that some settings had specific needs (for instance homecare nurses needed educational materials to hand out to GPs when making agreements) or wishes (for example the wish to publish about this initiative in a local newspaper).
We regarded some implementation strategies as compulsory and equal for all cases. But we also wanted to take into account the differences between the cases, and therefore labeled some strategies as optional.

A range in the extent to which implementation strategies were carried out in each case is possible, because within the cases 1, 2 and 4 multiple healthcare settings delivered the program. We would like to refer to Table 2, which presents the healthcare settings within the cases. In case 4 the program was delivered at an outpatient clinic for dermatology and at two homecare settings. In those two homecare settings less implementation strategies were carried out compared to outpatient clinic; this explains the range.

Authors’ changes in the manuscript:
- In Table 4 we have indicated for each implementation strategy if it was compulsory or optional.
- We added a sentence in the methods section to clarify that strategies could be compulsory or optional.
- Next to this, we changed the order of the text in the paragraph ‘Implementation strategies’ in results section. In the revised manuscript we first report on the compulsory strategies, then on those that were carried out by researchers and at last on the strategies that could be used as desired.

6. I do not get the point of asking study participants how well the programme will be implemented in half a year. For what purpose did you use that information? What are the implications of participants believing that the implementation would be better in half a year? I do not see how this contributes to the paper.

Answer of the authors:
We asked participants to score how well the program will be implemented in half a year, to get an impression of the extent to which they believe the program is or will be embedded in the organization and care delivery. What are the future prospects with respect to program delivery?
Then, by asking why participants thought implementation would be better, equal or less in half a year, we gained understanding in important or meaningful determinants and strategies. We would also like to refer to our answer on your question on how we linked determinants to implementation success/failure.

Authors’ changes in the manuscript:
- We have added a sentence in the methods section to enhance understanding on this topic.

7. Page 19 Implications. I have difficulties in following your reasoning in the implication section. In the first paragraph you state that With less complex interventions it might be sufficient to choose a less extensive method. Is not most implementation interventions complex in nature as they require change of people’s behavior? And what would be a less extensive method than a case study? In the second paragraph under implications you jump to chronic venous insufficiency. I
do not see how that is connected to identification of determinants. And for the third paragraph under implication you state that macro level implementation would be the focus for future research. As it stands I am not sure that this section contributes to the paper, it is too loosely connected to the focus of your paper – identification of determinants of implementation.

**Answer of the authors:**

With regard to your comments on the implication section, we would firstly like to reply to your comment on using a case study method for complex interventions. We have deleted this paragraph from the discussion section, because in hindsight we think this is not one of the main implications that can be derived from our study findings.

Your next comment concerns the connection between our advice to explore the possibilities to expand the patient group to chronic venous insufficiency. In our revised manuscript we have inserted underpinnings for our results on chronic venous insufficiency in the results section.

With respect to your comment that our statement to test macro level implementation strategies is too loosely connected to the results, we would argue that this has not been sufficiently elaborated in the paper. Since we also added more illustrations and citations in our revised manuscript, we decided that the statement to test macro level implementation strategies could better be deleted from the manuscript in order to give more room and foundation to our main study results.

**Authors’ changes in the manuscript:**

- We have deleted our reflection in the discussion section with respect to why a case study is an extensive method.

- We have added our study findings on chronic venous insufficiency in the results section, including illustrations, to give foundation of our statement in the implications section.

- We have deleted the statement to test macro level implementation strategies from the manuscript

8. Page 8. There is word lacking in the following sentence under “Participants responsiveness”: To measure this, patients were given a self-developed evaluation questionnaire with a return envelope at the end of the. 

   Thank you for your thorough reading. We have corrected the sentence in the revised paper.

9. Page 15-16. I found the last paragraph in the results section (page 15) very similar to the introduction paragraph of the discussion section (page 16). I don’t think it is necessary to have information repeated so close to each other.

   We think this comment has resolved itself after we rearranged the result section.
Reviewer 3

We thank the reviewer for the thorough evaluation of our manuscript and constructive comments that have helped us to further improve our paper.

1. Earlier in the paper you note that you are focusing on before, but also during and after implementation’. In the discussion/conclusion, you return to this issue. I’d like to see more of your thoughts and ideas on the value of the focus over time versus an approach that only focuses on pre-implementation phase.

   **Answer of the authors:**
   We would like to refer to our answer to comment 1 of Reviewer 1 and comment 3 of Reviewer 2.

   *In our opinion, a pre-post exploration of determinants is of complementary value to identify facilitators for implementation. This study showed that insight in the real facilitators was not completely gained from participants before implementation took place. However, the evaluation did shed light on meaningful facilitating determinants in particular. We think with this method one can make a better prognosis of what is feasible with respect to implementation in everyday practice. This is even more important as some barriers and contextual factors (for instance competition between healthcare organizations) are not easy to solve with (simple) solutions. Focusing on conditions under which implementation is possible or ‘easier’, might then be a more feasible way to develop an effective implementation strategy for future healthcare settings.*

   In our revised manuscript we have tried to give this topic more attention. We inserted a table with determinants before and after implementation to strengthen this comparison (Table 3). Next to this, we have inserted examples and citations in the text that should illustrate our results. In the discussion we reflect on the extent to which expected barriers were resolved by implementation strategies – and our reflection that this study showed that meaningful facilitators were identified.

   **Authors’ changes in the manuscript:**
   - We have added an additional Table (Table 3) in the results section that present determinants before and after implementation. We have illustrated these with citations to enhance understanding.
   - In the discussion section we added our reflection on the comparison of determinants before and after implementation.

2. Secondly, despite collecting a vast amount of data – both quantitative and qualitative – you seem to present the reader with more information about the specific ‘scores’ people made and offer less focus on the more qualitative aspects. At the moment, we only have access to a gloss of some of the findings. On really key issues, I feel a little more ‘rich description’, drawing on (key extracts) of interview quotes or fieldwork observations might be useful to the reader. I’m not talking about embedding the whole paper with this work, but rather only
focusing on the really central moments (and or, deviant cases – e.g. the nurses that did not ask to take part)

**Answer of the authors:**
We would like to refer to our answer to comment 1 and 2 of Reviewer 1.

**Authors’ changes in the manuscript:**
- We provided more detail on context in the methods section (in particular the description of the Lively Legs program) and the results section.
- We have rearranged the results section and added illustrations and citations in the text and in an additional Table (Table 3).

3. **P8** – It currently reads as ‘To measure this, patients were given a self-developed evaluation questionnaire with a return envelope at the end of the…I take it that last word is missing
   Thank you for your thorough reading. We have corrected the sentence in the revised paper.

4. **P15** – It currently reads as ‘On the other hand, homecare nurses reported that patient recruitment was problematic and they felt they were dependent of GP’s for referrals.’ Should read as ‘dependent on GPs’.
   Thank you for your thorough reading. We have corrected this sentence.

**References** *(all references listed below are also referred to in the manuscript)*