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

Authors:

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Version: 4 Date: 20 August 2012

Author's response to reviews: see over
August 20, 2012

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 evaluating our paper. Below is a point-to-point response to your comments. We highlighted the changes we have made to the manuscript.

We look forward to your response.

Yours sincerely, on behalf of the co-authors,

Irene van de Glind
1. “The program was systematically developed in collaboration with several relevant representatives, and is based on behavioral theories [12-17]”. Further elaboration of this sentence to identify the behavioural items being referred to and who the agents are when the term "several relevant representatives" are being referred to would be helpful.

The development of the Lively Legs program was published in Patient Education and Counseling (Heinen et al., 2006), reference number 11 in the paper.

The program is primarily based on Social Cognitive Theory (Bandura, 1977; Bandura et al., 1977; Bandura and Locke, 2003). Furthermore elements of Goal Setting Theory (Locke and Latham, 2002), the Precaution Adoption Process Model (Weinstein and Sandman, 2008) are included and motivational interviewing (Miller and Rollnick, 2002) is used as a principal technique for discussing health behaviours.

Several representatives were involved in the development of the Lively Legs program. The representatives were divided in two groups. Group one was involved in the development of proximal program objectives (e.g. sufficient exercise and leg exercises, adherence to compression therapy) and determinants of behavior. In this multidisciplinary group the following representatives took part: leg ulcer patients, dermatology nurses, a community nurse, dermatologists, a medical psychologist, a physiotherapist, a dietician, a nurse manager and, an outpatient clinic policy adviser.

The task of group two was to reflect on the program development with respect to translation and dissemination of the program to practice. In this group the following representatives took part: patient organizations, national nursing association, a dietician, a physiotherapist, an outpatient clinic manager, an hospital policy advisor and a nurse specialist. Both groups were organized and led by the researchers (MH, TvA).

Authors’ changes in the manuscript:
We revised the sentence to clarify this issue (page 3):
“The program was systematically developed in collaboration with several representatives (i.e. patients, dermatologists, nurses, a clinical psychologist, a physiotherapist, dietician, hospital management, nursing association and patient organizations) [11], and is based on Social Cognitive Theory, Goal Setting Theory, and the Precaution Adoption Process Model. [12-17]”.

2. Clarification of the type of data used and the questions that were asked would be helpful here "Qualitative data were the main data source to identify influencing factors"

This sentence was found in two places in the article.

Authors’ changes in the manuscript:
We changed the sentence on page 6 as follows:
“however qualitative data (interviews, focusgroups, field notes and observations) were the main data source to identify influencing factors for implementation”.

We changed the sentence on page 8:

Qualitative data (primarily interviews, and secondary field notes and observations) were the main data source to identify influencing factors post implementation.

On page 8 we explained which open ended questions were asked in interviews:

“Open ended questions that were asked during these interviews were: Can you tell me about your experiences with the program? What do you think of the program? What has driven/facilitated the implementation of Lively Legs? What were barriers? Why is that? Are those barriers resolved, and how? What was/is the most important barrier? What is needed to resolve this? What would you do differently next time? What would you advise to others that would want to implement this program?”.

3. There is something about the tense used in this sentence that does not fit with the rest of the tenses used in that section of the paper- could you also clarify what the different methods of recruitment vs patient registration actually are?

“Moreover, recruitment might take a lot of time due to different ways of patient registration, e.g. wound care versus leg ulcers.”

The “different methods of recruitment vs patient registration” refer to the different diagnostic codes that are used to group and identify patients with venous leg ulcers in patient information systems. For example in homecare they only use procedure codes (i.e. wound care or compression therapy) and hospitals use diagnostic and procedure codes. Due to these different methods of coding it is not possible to retrospectively identify and contact patients that are eligible for the Lively Legs program from the patient information systems.

Authors’ changes in the manuscript:

We have changed the sentence (page 13):

“In almost all cases participants stated that it is not clear what would be the best place to recruit as many patients for the program as possible. Moreover, they said that patients could not be easily grouped and identified from patient information systems due to different diagnostic and procedure codes (for example in homecare, venous leg ulcer patients are coded like ‘wound care’ or ‘compression therapy”).”

4. Please identify the nature of the context and contextual influences referred to in this sentence “Furthermore, the context and setting varied between cases and this appeared to be crucial to understand the influencing factors for implementation.”

We used a qualitative approach to look at the context in which the Lively Legs program would be/was implemented. That means that we did not check pre-defined specific/fixed variables. The contextual and setting specific factors that influenced implementation and could be identified and understand, were: the organization of leg ulcer care and the extent to which collaboration between homecare, outpatient clinic
and GP was established, and the extent to which the nurse coordinated the care process.

**Authors’ changes in the manuscript:**
We added these factors to the concerning sentence on page 19:

“Furthermore, the context and setting purposefully varied between cases and this appeared to be crucial to understand the influencing factors for implementation; in particular the influence of the organization of leg ulcer care, the extent to which collaboration between homecare, outpatient clinic and GP was established, and the extent to which the nurse coordinated the care process.”

5. **Program adherence was moderate to good could the authors explain how adherence was judged please?**
We reported program adherence in Additional file 1. Program adherence was measured by assessing frequency, duration and content of counseling sessions. Based on this a coverage score was computed, that is a percentage of the components that are delivered as planned. In the additional file we reported mean scores per case.

For this study, a coverage score of 80% to 100% was regarded as high program adherence; a coverage score between 50% - 80% was regarded as moderate and 50% or less as low program adherence.

In two cases coverage scores were 65%, in one case 73% and in two cases 90%. This explains our conclusion that program adherence was moderate to good.

**Authors’ changes in the manuscript:**
- Page 10: “A coverage score was computed, that is a percentage of the components that are delivered as planned. For this study, a coverage score of 80% to 100% was regarded as high program adherence; a coverage score between 50% - 80% was regarded as moderate and 50% or less as low program adherence.”
- Page 15: *The Lively Legs program was carried out with a moderate to good adherence to protocol (65%-90%). Detailed results on program adherence are described in Additional file 1.*
- We have also added the explanation on how we judged program adherence to the additional data file (see page 2).

6. **Could you expand on the Case study design derived from Yin please**
Yin (2009) defines a case study as “an empirical inquiry that investigates a contemporary phenomenon in depth and within its real-life context” (Yin 2009; p.18). According to Yin (2009) a case study is one way of doing social science research, next to experiments, surveys, epidemiologic or economic research. A case study is in particular appropriate when the “how” or “why” question is being asked about a contemporary set of events, over which the investigator has little or no control, especially when the boundaries between phenomenon and context are not clearly evident.
With respect to our study, the process of implementing a lifestyle program in a healthcare setting could be regarded as an event over which researchers have little control or have difficulties to control this process. Next to this, an implementation process could be considered as a situation in which there will be many more variables of interest than data points, particularly because a lifestyle intervention is a complex intervention (Craig 2009). A case study could be used to explore and describe the relevant variables of interest, and to ‘tell’ the story of what happens. Yin (2009) states that multiple types of data are preferably collected, to be able to enhance construct validity, not to miss any relevant variables of interest.

A multiple case design was chosen for this study, with multiple units of analysis (that is in our study the healthcare settings within the cases), which Yin (2009) refers to as an ‘embedded’ design. The rationale for this is being able to deliberately select cases of contrasting situations and to have more robust findings (instead of having just one case).

Cross-case synthesis was used as analytic technique to analyze the data. This is one of the five techniques Yin distinguishes (2009). This technique treats each individual case study as a separate study and findings are aggregated, using uniform frameworks. Complementary analysis of individual cases is used to identify patterns and explanations.

Authors’ changes in the manuscript:

p. 5: This study used a multiple case study to obtain a picture of how and why implementation is successful in different settings [39]. A case study was defined as “an empirical inquiry that investigates a contemporary phenomenon in depth and within its real-life context” [39; p.18]. This design was chosen, because implementing a lifestyle program in a healthcare setting could be regarded as an event over which researchers can have little control. Next to this, an implementation process could be considered as a situation in which there will be many more variables of interest than data points, particularly because a lifestyle intervention is a complex intervention [32] and boundaries between the implementation process, the lifestyle intervention and context are not always clearly evident. The value of a case study design lies in exploring and describing the relevant variables of interest, and ‘telling’ the story of what happened.

p.10: Cross-case synthesis was used as analytic technique to analyze the data from the multiple cases [39]. Each individual case study was treated as a separate study and findings were aggregated. Complementary analysis of individual cases was used to identify patterns and explanations.

p.20 The strength of using a case study design lies in the opportunity to study the implementation process in various real life settings and collect multiple types of data, enabling to develop an in depth picture [39]. By selecting cases that varied in the way cooperation took place between homecare and outpatient clinic, we were able to obtain a broad picture of everyday practice.