Reviewer's report

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

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Reviewer: Nicky Cullum

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The research addresses the question "which determinants hindered and facilitated implementation of Lively Legs in outpatient clinics for dermatology and in homecare?". This question is novel and well defined. I would however question whether “Lively Legs” is implementation-ready, or at least whether knowledge about its implementation is of interest outside the Netherlands (where they clearly think it IS ripe for implementation).

MAJOR COMPULSORY REVISIONS

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.

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.

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?

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?

MINOR ESSENTIAL REVISION

Reference 14 is repeated as Reference 39.

**Level of interest:** An article of limited interest
Quality of written English: Acceptable

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:
I declare that I have no competing interests.