Reviewer’s report

Title: Home management of lower limb lymphoedema with an intermittent pneumatic compression device: A Feasibility Study

Version: 0 Date: 08 Jan 2019

Reviewer: Daniel Gow

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I found this manuscript to be concise and very to-the-point regarding the purpose, design, results, and discussion. However, on certain points I feel it was too concise and lacking detail. I've commented below on areas that could be elaborated further to better explain or document the study. There are also a small number of grammatical or formatting issues, noted first.

Page 3, line 44: no period at end of "...successful lymphoedema management [4,5]"

Page 13, line 24: no period at end of "...and viscoelastic properties [24]".

Page 13, line 37: no closing single-quote for the full spelling of the Lymph-ICF-LL questionnaire; though it's not clear that you necessarily need an opening single-quote.

Both Table 1 and 2, in the lymphoedema stage row, 100% for stage II and 0% for stage III, but "(0)" in all cases for the number of participants.

Figure 3 shows that 3 subjects were lost to follow-up in the control arm before the 3 month follow-up, but then has n=8 at the 3-month follow-up.

Page 4 identifies differences in IPC modality (proximal-distal vs distal-proximal, equivalency to manual lymph drainage technique). In the study design, could you clarify how the IPC device chosen in this pilot study works? Furthermore, it might be useful to comment on how the results of a larger study would or would not be generalizable depending on the nature of the device used. Also, you note that there is lack of consensus for treatment parameters using IPC; how was that overcome or addressed by this study, and in the next study?

Page 6 notes that limb volume measurements were taken at baseline by an RN with experience in this area; how was this accuracy maintained at the follow-up visits?

Also, Table 1 provides a comparison of demographics between control and intervention. With only 20 participants total, it does not seem that this study is sufficiently powered to have statistically significant outcomes or differences in participants, thus the p-values are not surprising, but nor are they relevant. Later, on page 10, the table of mean leg volume differences does not show p-values for comparison of means. I would suggest being consistent about this, either including or excluding them.
This also speaks to the manuscript not commenting on why 20 was the sample size for this study, or whether 20 would be sufficient/insufficient to show any statistical significance in outcomes. It's clearly stated that the objective of this study is feasibility, not treatment effect, but the choice of sample size and consequent power of the study should be commented on, if at least to inform how large a larger study would need to be to show significant treatment effect.

Page 8: could you comment on the pathophysiological difference between Stage II and Stage III lymphoedema and how this might impact the analysis of study outcomes with respect to use of the IPC device? It's explained in the Discussion how recruitment bias may have affected the demographics of the participants, but not whether IPC may be more or less feasible or acceptable for an individual with stage II vs stage III lymphoedema, thereby affecting the recruitment, retention, and analysis of a larger study that does include individuals at stage III.

Page 10: the mean leg volume differences table and analysis is confusing. Is this reporting an increase or decrease in volume over time? As in, between the 3 month and 6 month follow-ups, across the Control group, was there a mean leg volume increase of 128.42 mL? There appears to be a very wide variation in volume change (again, on trends, considering that 5 of the 6 confidence intervals cross 0). If you could, please clarify further what these results are reporting and their significance.

Also, a table for the QOL scores would be helpful. The study design also only notes the QOL questionnaire being completed at baseline, not at the 3 and 6-month follow-ups, yet here it was clearly was being completed at follow-up. It should be clarified in the study design when the questionnaire was being completed.

Page 12: to address participant apathy in the control group, consequent to not receiving an IPC device, you suggest using a cross-over design and five week intervals. Considering that five weeks is less than the 3 month follow-up interval in this study, and not in accordance with the general follow-up schedule at the lymphoedema clinic, could you clarify why 5 weeks would be appropriate for the next study design (especially if 3-4 weeks is more common in clinical practice when MLD is the treatment modality)?

Furthermore, how will shortening the IPC intervention period to 3-4 weeks affect longer-term analysis? Would you still attempt 3 and 6-month follow-ups to assess for long-term impact on lymphoedema after a short-term intervention? How generalizable and clinically useful would the results of the next study be if the intervention period is shortened, for the sake of reducing participant burden?

Page 13: additional outcome measures important to participants were identified, including subjective 'limb heaviness' and 'tightness'. However, to address this, the use of the Myoton Pro is suggested and it is explained how it collects objective data. How will the next study address the subjective outcome measures?

Regarding Intervention Feasibility, it might also be useful to clarify here (as opposed to above under Study Feasibility) how the next study would try to ensure, or at least assess, proper use of the IPC device, considering that lack of this was a drawback in this study.
Page 14: although this is a feasibility study and thus not intended to draw conclusions about the effectiveness of the intervention itself, I think it would be worth in the Discussion section either (a) commenting on any trends noted in the analysis of study outcomes, or (b) explicitly stating why there is no comment on any potential trends that speak to the effectiveness of the intervention. Furthermore, considering that next study will be looking for effectiveness of the intervention, how does this study inform the nature of the intervention for that next study (e.g.: choice and modality of the IPC device itself, frequency of use, comparison to MLD and otherwise standard of care).

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