Author's response to reviews

Title: A pilot randomised controlled trial of negative pressure wound therapy to treat grade III/IV pressure ulcers [ISRCTN69032034].

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Author's response to reviews:

Thank you for considering this manuscript. We have responded to the feedback from the two reviewers and detail our responses below.

We thank Reviewer 1 for taking the time to review this manuscript and note that they do not recommend any changes.

We also thank Reviewer 2 for their comments, which we have addressed below and also within the manuscript.

Comment 1. I found that there was a discrepancy between the primary objective of this project (assess feasibility) and the primary outcome (time to healing of the reference pressure ulcer). I would expect that the primary outcome would be more in line with feasibility assessment, such as rate of recruitment, consent rates, etc. Time to healing could be considered a secondary outcome in this pilot.

Time to healing of the reference ulcer was listed as the primary outcome measure as this measurement would be the primary clinical outcome in a full trial. We do agree with the reviewer that this clinical outcome should not be considered as the primary outcome within this pilot trial, which aims to assess feasibility. This change is reflected on page 2 of the manuscript.

Comment 2. The authors provide recommendations to improve recruitment, data collection, outcome measure selection and trial design for a larger RCT in the Conclusions. However, the authors do not address the issue of how to improve protocol adherence and potential cross-overs, which are significant barriers to feasibility. All 6 of the participants in the treatment group withdrew and received non trial treatment. The authors do not state whether or not this trial would be feasible in their discussion or conclusion. Given the results of this pilot, I would suggest that this may not be feasible unless there are significant changes to the inclusion criteria and/or design. While it may be disappointing to say that a trial is...
not feasible in the current form, it is still important information. Resources are scarce for research and it is vital that funds are used as efficiently as possible; it may not be the best use of funds to make this an international multi-centre study in order to reach target recruitment.

We thank the reviewer for this very useful comment, which provoked discussion amongst the co-authors of this manuscript. We feel that the issues the reviewer has highlighted reflect the pragmatic nature of this trial. Rather than being seen as a failure of the pilot trial, the results instead provide a useful insight into non-compliance to trial treatment in the NPWT group and the associated decision making process of the healthcare provider. It is common for participants to change treatment within wound care trials. We have addressed this on page 23 of the manuscript.

(Discretionary Revision) Under Discussion, in the second paragraph "Recruitment", the second sentence is too long. I would suggest a new sentence at the beginning of "However, this is...".

We agree with the reviewer and have made the suggested alteration (page 19). We have also other made minor alterations, these are indicated by the tracked changes throughout the manuscript. We hope we have addressed the reviewer’s comment satisfactorily and look forward to hearing from you soon.

Yours sincerely,
Professor Nicky Cullum
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