Author’s response to reviews

Title: Risk factors for foot ulceration in adults with end-stage renal disease on dialysis: study protocol for a prospective observational cohort study

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To the Editor
Journal of Foot and Ankle Research

We are submitting our revised protocol manuscript (following the second round of peer-review) for consideration in the Journal of Foot and Ankle Research: ‘Risk factors for foot ulceration in adults with end-stage renal disease on dialysis: study protocol for a prospective observational cohort study’. Study ID: 5082525681576459. We thank reviewer one for their further comments and suggested amendments.

In response to the reviewer’s comments, our second round of responses are included on the following page and the corresponding changes have been made to the manuscript (amended manuscript uploaded). There were only two issues that required our attention (under Minor essential revisions). We appreciate the opportunity to resubmit our revised manuscript to the Journal of Foot and Ankle Research for consideration and look forward to your reply when convenient.

Kind regards,

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Reviewer 1

The authors have addressed all of the concerns I raised in the first review and have significantly strengthened the statistical section of the protocol.

**1. I only have one Minor Essential Revision:**
One point that was addressed by the authors in their response, that I still feel should be amended within the text, is the issue of mortality. It appears, based on the response, that they will be collecting the foot ulcer outcome data from medical records even if the patient has died during the study period, and therefore will able to be included in the analysis (?). This is an important point to clarify as part of the protocol if this is the case. Mortality should also be mentioned as a potential limitation in this specific patient population and how it will be addressed in the relevant sections.

**Author response:**
Thank you for your valuable suggestion. To clarify, we will review hospital medical records of participants that died during the study period. Data will be collected for the primary and secondary outcomes up until the date of death. Therefore, these participants will be able to be included in the analysis.

With regard to mortality (as mentioned in the previous response document), it is unlikely that the mortality rate will exceed 20% (prospective sample size estimation allows for 20% loss to follow-up). However, as suggested, we agree that it is important to mention mortality as a potential limitation and how we will address this issue if it occurs.

**Changes to the manuscript:**

1. We have reworded the ‘Methods/Design – Secondary outcomes’ section by:
   - Stating that medical records will be reviewed for the primary and secondary outcomes for those that die during the study period (page 20, paragraph 2, lines 14-16).

2. We have also reworded the ‘Discussion’ section by:
   - Stating that “as this cohort is made up of severely ill participants, mortality and loss to follow-up due to comorbidities could be potentially higher than the expected 20%. If this is exceeded, we will address this issue by using imputation techniques for missing data in regression models” (page 26, final paragraph, lines 14-17).