Author's response to reviews

Title: Efficacy of a pressure-sensing mattress cover system on reducing interface pressure: Study protocol for a parallel two-group randomized trial design

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The cover letter is attached; however, the system asked us to provide a response to the reviewers too, so I've copied and pasted the letter here as well.

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Enclosure
August 7, 2015
Dr. Doug Altman
Dr. Curt Furberg
Dr. Jeremy Grimshaw
Editors-in-Chief
Trials
Re: Resubmission of MS: 1909557830162465 - Efficacy of a pressure-sensing mattress cover system on reducing interface pressure: Study protocol for a parallel two-group randomized trial

Dear Drs. Altman, Furberg and Grimshaw,

Thank you for the opportunity to resubmit our manuscript “Efficacy of a
pressure-sensing mattress cover system on reducing interface pressure: Study protocol for a parallel two-group randomized trial design”. We revised the manuscript as per the referee’s suggested revisions. Below, we listed each revision request in bold, followed by our response, and made the corresponding changes to the manuscript.

1. You have outlined randomisation really clearly now – thanks. I am not sure that the details about allocation concealment are clear. Could you just clarify that the person actioning the randomisation – that is the person allocating people to groups - will be independent? This detail is important for risk of bias assessments.

We included the following under “Blinding” on page 21 to clarify that allocation will occur independently:

“Allocation will be independently undertaken, and…”

2. You now state While pressure ulcer incidence may be of primary clinical interest, interface pressure measurements are quantifiable and are recognized to be a major risk factor for pressure ulcer development, while the actual incidence of pressure ulcers may be dependent on too many risk factors which are beyond the scope of this study design

I think this last sentence just needs to be reconsidered/revised – this is an RCT so all known and unknown risk factors for PU should be balanced between the two groups. This means that I don’t understand what point is being made.

We amended the sentence under “Primary outcome” on page 17 to the following:

While pressure ulcer incidence may be of primary clinical interest, interface pressure measurements are quantifiable and are recognized to be a major risk factor for pressure ulcer development. For the purposes of this trial, we would like to focus on interface pressure as the primary outcome, as using pressure ulcer incidence as a primary outcome would likely involve many other factors that would influence the development of pressure ulcers, requiring a much higher sample size than what this single-site study will be appropriate for.

Finally a point that is not related to a requested amendment (discretionary amendment)

I disagree that the assessment of clinical features such as the presence of skin changes and pressure ulcers is an objective outcome – I think it has a subjective element.

The study you quote defines objective and subjective assessments in the following way

“We classified outcomes in two ways: firstly, as objectively or subjectively assessed, and, secondly, as all cause mortality or other outcomes. The definition of objective and subjective outcomes was based on the extent to which outcome assessment could be influenced by investigators’ judgment. Objectively
assessed outcomes included all cause mortality, measures based on a recognised laboratory procedure (such as measurement of haemoglobin concentrations), other objective measures (such as preterm birth), and surgical or instrumental outcomes (all of these were concerned with childbirth, such as caesarean section or instrumental delivery). Note that such surgical outcomes (classified as objectively assessed) depend on doctors’ decisions, which could, in the absence of blinding, be affected by knowledge of the intervention received.

Subjectively assessed outcome measures included patient reported outcomes, physician assessed disease outcomes (such as vascular events, pyelonephritis, or respiratory distress syndrome), measures combined from several outcomes, and withdrawals or study dropouts.”

The study then goes on to conclude that:

In trials with subjective outcomes effect estimates were exaggerated when there was inadequate or unclear allocation concealment (ratio of odds ratios 0.69 (95% CI 0.59 to 0.82)) or lack of blinding (0.75 (0.61 to 0.93)).

I think the outcome you describe would be classed as subjective based on the definition that the paper uses so I would not quote this paper in the context you have. I agree that assessment for the primary outcome will be more objective.

If you think it is objective then I think it is fine to say and I am not asking for any amendments as this is a difficult area and the protocol can be published with your view – that is fine. I think the main thing is to be really clear whether blinding is taking place and this is done well.

I just wanted to take this opportunity to point out other might disagree with your view so in SRs that include this study it could be rated as high risk of bias for outcome assessment of clinical features. The use of photographs for blinded outcome assessment of clinical features or independent assessors if possible might mitigate this.

We decided not to make an amendment, but we would like to thank you for bringing this to our attention and your insight on this point.

(End of comments)

Thank you once again for providing us with the opportunity to resubmit our manuscript again, and we look forward to your response at your earliest convenience.

Kind regards,

Holly Wong (on behalf of our team)