Author's response to reviews

Title: Evaluation of a bespoke training to increase uptake by midwifery teams of NICE Guidance for membrane sweeping to reduce induction of labour: a stepped wedge cluster randomised design

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Dear Editor,

TRLS-D-16-00735

Evaluation of a bespoke training to increase uptake by midwifery teams of NICE Guidance for membrane sweeping to reduce induction of labour: a stepped wedge cluster randomised design

We are most grateful for the opportunity to respond to the additional reviewers comments and have done so below. We hope that you will review these and the revised paper and consider the paper suitable for publication.

Reviewer #3: Reviewer's comments

This study assessed the effect of bespoke training on uptake of membrane sweeping by the midwifery teams to reduce induction of labour using stepped wedge cluster randomized design. However this manuscript will require major revision before considering it for publication

Thank you for taking the time to review this paper. We hope that our response and revisions will mean you do consider it suitable for publication.
Abstract:

1) The authors should restructure the abstract section in-line with this format: Background, Methods, Results, and Conclusions

The abstract we have submitted is in line with the format you describe and so no change has been made.

Methods

2) The authors claimed that they used stepped wedge cluster randomized design to assess the outcome. Typically in stepped wedge cluster randomized design the recruited clusters will randomly crossover from pre-intervention phase to intervention phase. It indicates that the duration of pre-intervention and intervention phase for each cluster will not be the same except for cluster that crossed over at the middle of trial. Clusters that crossed over to the intervention phase early in the trial should have a longer intervention phase than pre-intervention phase. In addition, at the early part of a stepped wedge cluster randomized study most of the clusters will be in the pre-intervention phase while at the later part of the study most the clusters would have crossed over to the intervention phase.(1,2) Thus, this paper did not apply "stepped wedge cluster randomized design" as they claimed rather the authors applied "before and after design"

Thank you for highlighting that there is no universally accepted definition of the SW-CRT, but the paper which the reviewer cites (Hemming et al BMJ) uses the following broad definition “The design involves random and sequential crossover of clusters from control to intervention until all clusters are exposed.” Clearly the study reported here does meet the broad definition of the SW-CRT used by the paper the reviewer cited. This is not a before and after design, as we have data on which to estimate temporal trends -and the analysis is adjusted for this. This is of course the key feature of the SW-CRT which means it provides a much higher level of evidence than a simple pre and post study.

3) The authors considered two primary outcomes (proportion of women offered and accepting membrane sweeping and average number of sweeps per woman) in this study. It is important to note that intervention study should not have more than one primary outcome but the outcome can either be a composite outcome or single outcome. The reason provided by the authors that the two outcomes are highly correlated will not justify why the authors considered them as primary outcomes. Moreover the two outcomes are not the same; one is a binary outcome while the other is a continuous outcome. This issue should be addressed

It is not uncommon for studies to have two primary outcomes and as these were pre-specified in the trial protocol they cannot be changed. We have interpreted our findings cautiously - and what is more this study finds no evidence of any effect.

4) The authors should justify why they considered number of women offered and accepting membrane sweeping and average number of sweeps per woman instead of considering the
proportion of ELIGIBLE women who were offered membrane sweeping and accepting membrane sweeping.

We have included all the women eligible for membrane sweeping and report outcomes for those women. We have revisited the abstract to make this point clearer, as we believe this point was within the actual paper.

5) The authors mentioned in their response to the previous reviewer that the primary outcome was "proportion of women offered and accepting membrane sweeping and average number of sweeps per woman" however in the abstract they reported "number of women offered and accepting membrane sweeping and average number of sweeps per woman" as primary outcome. The authors should note that the primary outcome of this study should be "the proportion of ELIGIBLE women who were offered and accepting membrane sweeping"

We report exclusions clearly both in the text and the Consort Flow diagram. The study included all women eligible for membrane sweeping and we could not report outcomes for a very small number (2-3%).

Minor point - can be fixed

6) The authors stated that they followed Hussey and Hughes to estimate the sample size but they did not the intervention effect that they used. Please address this important issue.

We did follow the H and H approach. The intervention effect is reported in the paper in the first two paragraphs on page 9.

7) The authors stated that they used mixed effects Poisson regression model to examined the difference in the proportion of women being swept in before and after the training. I will like to know why the authors considered apply Poisson regression when the outcome is not a count variable.

Poisson regression is an accepted method to estimate relative risks when the outcome is binary. We use robust standard errors to account for the mis-specification of the variances. By oversight we did not mention that we used robust standard errors and this has now been added.

8) The authors claimed that they used mixed effects Poisson regression model but did not report the random effect part of the model in the result table. Kindly provide the results.

We reported ICCs on the proportions scale (as opposed to variances on the log scale).

9) The authors performed sub-group analysis but did not consider it when estimating the sample size. Kindly address this issue.

It is common practice to pre-specify a small number of subgroups without being fully powered for interactions, and this is what we have done.
References


We would be very grateful for your consideration and look forward to hearing from you.

Yours faithfully,

Sara Kenyon

Professor in Evidence Based Maternity Care