Author’s response to reviews

Title: Facilitating Implementation of Research Evidence (FIRE): an international cluster randomised controlled trial to evaluate two models of facilitation informed by the Promoting Action in Research Implementation in Health Services (PARIHS) framework.

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Author’s response to reviews:

Editors comments

We would recommend that you address the analysis concerns raised by reviewer 1. In doing so, you may also wish to consider what the implications are for the two related manuscripts; especially as neither set of reviewers asked to see the summary findings manuscript. We would also like you to reflect more on whether facilitation. Reviewer 2 asks how was the topic determined? Some reflection on intervention selection and development is warranted especially as there is a suspicion that lack of participant buy in may be more to do with the 'juice not being worth the squeeze'.

Response: Thank-you for your helpful comments.

We have addressed the concerns of reviewer 1 below.

We have added a supplementary file to explain the intervention more fully in this paper so this paper stands alone. (It is also fully explained in the two linked papers)

We have clarified how the topic was determined.

We have addressed possible lack of buy-in in the discussion.

Reviewer 1

This is a major major accomplishment and represents the summary of what was undoubtedly a huge amount of work. I found it interesting to read and congratulate the authors and team on their ambitious and important work.

Response: Thank-you.

Reviewer 1:

The order of subtitles in the methods section is not the usual approach to reporting cluster trials, which usually follows closer to the Equator checklist (helpfully appended by the authors). The editors can decide if this matters much to them.
Response: We have revised this so it followed more closely with the checklist (CONSORT in Supplementary file 4). We have not marked this reordering with track changes as it was moving text, not revising it, and the resultant track changes made it difficult to read.

Reviewer 1:

Intervention description could be more clear in terms of understanding specifically what the expected active ingredients / components of the interventions were and how they differed. I gather this has been reported elsewhere? Maybe a table or figure might be helpful for readers of this paper? Maybe supplementary materials?

Response: We have added a supplementary file 1 which contains a full description.

Reviewer 1: Most importantly: Analysis - the description of the linear regression model is not clear enough for my liking. How did it adjust for clustering? Seems there could be four levels here… is there a need to adjust for physician or just home? And what about country? Repeated measures is not usually managed this way either in a trial - or maybe it's just not clear to me what was done.

Response: We have rewritten this section to make it clearer and address the reviewers helpful comments. This is highlighted in yellow in the findings section.

Plus, in a three-arm trial, some adjustment for multiple comparisons is usual.

Reviewer 1: I think maybe a statistician should look at this.

Given what happened with England (only one control site) it may be impossible in England to distinguish site from effects. A post-hoc sensitivity analysis dropping England might be warranted here.

Response: Although this is a three arm trial the analysis of the primary outcome does not carry out multiple comparisons so no adjustment has been included in the paper.

The study was not powered with the intention of investigating country within arm effects, so thus do not include such a sensitivity analysis. However, we have checked the impact on the results of dropping England from the analysis and this does not change the conclusions with regard to the interventions.
Reviewer 1:

Results

Table 1 - appears to not be adjusted for clustering?

I fear that Table 2 through 7 need to be reworked. The key in a trial is to contrast intervention versus control (controlling for covariates per a priori statistical plan, usually including baseline value for outcome, stratification factors in allocation, etc).

The current approach to presenting results makes it difficult to see that this is what was done? I also do not see any ICCs reported.

Response: Table 1 has been revised to make it clear how we adjusted for clustering.

We have revised tables 2-7 to make the contrast between intervention and control clearer, and have revised the tables so that percentage compliance with the guidance is more clearly presented.

We have also included ICCs p13

Reviewer 1:

Alberta Context Tool section - this feels like a potentially important effect modifier, but I’m not sure it is analysed as such here. This section mixes methods and results and discussion. I’ll leave it to the editors to decide how important it is to reorganize this.

Response: The ACT is a measure of organisational context, used with individual healthcare providers to measure their perceptions of context. So we analysed the data to give us a view on the contextual factors that might have hindered or facilitated knowledge translation, consistent with the purpose of ACT.

We have divided the ACT section and moved it into Methods, results and discussions as relevant.

Reviewer 1:

Discussion

Although incontinence is no doubt important overall, maybe professionals in nursing homes who were being asked to make changes simply didn't feel the 'juice was worth the squeeze' in this area? If adverse events are so uncommon already, maybe they understood that all those extra
processes would be unlikely to significantly further reduce this? This is conjecture though as I could not identify actual rates of outcomes like dermatitis or UTI (this is stated as low).

Response: The incontinence guidance suggested that if the guidance was followed, incontinence in this group of residents could be avoided or reduced. Thus although adverse events like UTIs were uncommon, the residents in the study experienced incontinence. The changes were to try and promote continence in this group rather than a focus on reducing what were fairly rare adverse events.

So in relation to “was the juice worth the squeeze” – at a long term care setting level they had chosen to do this, but it may be for individual staff within each setting, this wasn’t necessarily their top priority.

We have added this point to the discussion.

The number of UTIs is included in the text.

Reviewer 2 Comments

Overall a very well written article with a nice introduction to set the stage as well as a good methods section. Response: Thank-you.

Reviewer 2:

The authors do refer frequently to a process paper which details the intervention and possibly other information as well which may be important to include in this paper as well. It should be able to stand alone. Whilst I understand it is hard to fit it all in, I think a greater depth of detail about the settings is important- for example, given this was a cross-country study- what are the major differences/similarities in terms of health system- is long term care this a publicly funded in all countries?

Response: We have provided more details in a concise manner. We have included more details on the intervention in a supplementary file.

We have added information confirming that all sites had publicly funded places. (p8)

The training of the facilitators is covered in detail in linked paper by Rycroft-Malone et al and Harvey et al.