Author's response to reviews

Title: Improving Primary care Access in Context and Theory (I-ACT trial): A theory informed randomised cluster feasibility trial using a realist perspective

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Author's response to reviews:

Reviewer reports:

Reviewer #1: This interesting manuscript reports the results of a cluster randomised feasibility trial comparing a context sensitive intervention to usual care. The manuscript is written very clearly and it is great to see that the manuscript is in keeping with the CONSORT extension to randomised pilot and feasibility trials (Eldridge et al. 2016). I only have a few very minor comments to make which I think could be addressed very quickly and easily.

Minor comments

would say "cluster randomised" rather than "randomised cluster" when describing the trial design in both the title and throughout the manuscript.

AUTHOR’S RESPONSE

We have changed the title. Nowhere else do we use the term “randomised cluster”
The last sentence of the background section of the abstract is slightly confusing as the reader does not know what the previous research /initial theory is.

AUTHOR’S RESPONSE

We’ve changed the final sentence to read. “Here we report the I-ACT cluster feasibility trial which aims to assess the feasibility of trial design and context-sensitive intervention to improve primary care access for this group and so expand existing theory.”

The target recruitment was 10 participants per practice but only 5 were recruited in the usual car practice - maybe this could be commented on. It appears from the tables that some estimates are calculated on only 3 participants in the usual car arm. The only caution I can see is for the ICC calculation based on the small number of clusters but there is no mention of the caution that should be taken in interpreting estimates based on 3-5 participants.

AUTHOR’S RESPONSE

When reporting the main quantitative findings we have added the statement “but caution is needed because of the small numbers, especially in the usual care arm.”

Often in a feasibility study the data collected is used to inform a future trial - the authors could maybe add a sentence describing what they think the next trial in this area of research should be based on their feasibility.

AUTHOR’S RESPONSE

We have added the following sentence to the discussion “A future trial should test the effectiveness of a support package, including financial support and development meetings, to help practices develop their own service changes. Furthermore, the support manual could be shortened, limiting it to the requirements of the service changes to be developed and examples. A review after six weeks and, if necessary, modification may help practices to optimize their service changes. It is likely that further pilot work would be needed before a definitive trial.”
In the results section under "Baseline characteristics of patients" practice D is mentioned for the first time - it would be better for the reader if it said "the usual care arm, practice D" when D is first mentioned. This is done later so it just needs moved forward.

AUTHOR’S RESPONSE
We have moved this forward as suggested.

In the "Impact of intervention" section the ease of booking appointments is described as most improved in Practice B and C compared to A and usual care. From the tables, A does not improve which isn't made clear by the sentence in the text.

AUTHOR’S RESPONSE
We have amended the text to read. “Ease of booking an appointment scores improved most in Practice B and C, compared to Practice A, which did not improve, and usual care.”

The "Impact of intervention" section does not indicate the uncertainty in the estimates based on the small sample size used.

AUTHOR’S RESPONSE
We have changed two sentences in this section. “Table 5 and 6 show the monthly change and difference in difference for each CMO outcome. Caution is needed interpreting the differences because of the small numbers of observations, especially in the usual care arm” and “Table 7 shows the difference in difference for quality of life, capability and patient activation. Again, caution is needed in interpretation because of the small numbers.”

It is stated that the support manual was rarely used and then in the discussion it states that "practices were able to successfully design and implement their own context-sensitive service changes based on a support manual".
AUTHOR’S RESPONSE We have changed this to “Practices were able to successfully design and implement their own context-sensitive service changes based on development meetings, £1500 grant and, to a lesser extent, the use of a support manual.”

Reviewer #2: This paper has 3 main components:

(A) Development of 3 interventions to improve access to rural primary care for older patients

This description is flimsy; I doubt whether it would help rural practitioners or researchers in this field.

AUTHOR’S RESPONSE

The purpose of this study was to test the feasibility of the intervention (a support package) and study design using a realist perspective, rather than provide definitive evidence of the interventions. We have added more detail to the service changes that the practices developed. For Practice A we have added “The call stacking system could hold up to 100 callers using a cloud based N3 internet connection (high speed broadband connection used in the NHS).”, for Practice B “Signposting is widely used in the NHS to direct patients who contact primary care to the most appropriate service, but it does not often include community transport providers. The charging point was a designated area in reception for patients to park mobility scooters for charging.” and for Practice C “The taxi slots meant that everyday there was an embargoed appointment reserved for patients who relied on taxis. If the slot had not been booked by the day of the appointment, it was released for any patient.”

(B) Cluster randomised feasibility trial to evaluate these 3 interventions against usual care

This trial randomises these 4 interventions between only 4 practices & only 34 patients. It tells us little about the feasibility of a future definitive cluster randomised trial of any combination of the practice-specific interventions under evaluation. Why did the researchers not follow one of several guidelines for pilot & feasibility trials (e.g. Charlesworth et al, 2013)?

AUTHOR’S RESPONSE

We did not have 4 interventions, but rather one intervention - a support package to help practices to develop their own context dependent service changes. We chose this because there is unlikely to be a one-size-fits-all solution for a complex social problem, such as how deprived older people
access their GP surgery. We agree that since this was an experimental trial design, drawing on realist approaches, the study did not entirely align with standard feasibility procedures as this would not have been appropriate. Nevertheless, the aims stated in our manuscript cover many of the items listed in the Charlesworth et al checklist, such as eligibility, recruitment, intervention compliance and data protection. We also tested the feasibility of other items, such as data management processes and trial management, which are not reported here in the interests of space. We have added the following text to the strengths and limitations section “This was an experimental trial design, drawing on realist approaches, and therefore the study did not entirely align with standard feasibility procedures.”

(C) Detailed statistical analysis of this trial.

Detailed statistical analysis of this very weak trial can only draw lessons for analysis of a future definitive trial.

AUTHOR’S RESPONSE

The purpose of the statistical analysis was to learn lessons for a future trial, rather than provide definitive evidence for the intervention. As is standard practice in feasibility studies, have purposefully avoided making too much of the statistical analysis of the data because of the small numbers.

To be constructive, the authors may wish to write separate, but more rigorous, papers about A (e.g. for BJGP Open) & B (e.g. for Pilot & Feasibility Studies).

AUTHOR’S RESPONSE

The purpose of the study was not to develop multiple interventions which could be used by rural practitioners, but rather test the feasibility of the study design (such as recruitment and retention) and support package to facilitate intervention development and implementation. We are not able to draw conclusions about the effectiveness of each individual service change that was developed and implemented. Therefore we would prefer to have the main reporting of the study in one paper rather than splitting the results across a number of different papers, which we believe would put undue emphasis on the individual interventions at the expense of the process of developing and implementing customised practice level interventions.
Reviewer #3: (Associate editor)

After seeing the two reviews gave quite different views of the paper I read it over myself. Generally I think the feasibility trial aspect of the manuscript is well-reported (with a couple of minor comments given below). I did feel some of the more qualitative results were a bit vague and it wasn't clear what the conclusion of the trial was - is a definitive study based on this intervention feasible or is substantial change required (I felt the discussion pointed towards the latter but it should be more explicit).

AUTHOR’S RESPONSE

We have added text to the discussion with more details about what changes should be made before a definitive and clearly state that more pilot work is needed before a definitive trial. “A future trial should test the effectiveness of a support package, including a grant and development meetings, to help practices develop their own service changes. Furthermore, the support manual could be shortened, limiting it to development requirements and examples. A review after six weeks and, if necessary modification, may help practices to optimize their service changes. It is likely that further pilot work would be needed before a definitive trial.”

As a non-expert I do agree with the spirit (if not the wording) of reviewer’s 2 comment on how the description of the development of the interventions could be improved. However that might be best for a separate paper if this paper is to be the main report of the feasibility trial.

AUTHOR’S RESPONSE

Yes, we are keen to have this as the main report of the feasibility study. The main text is already almost 5000 words and we are reluctant to add further in-depth description.

Specific comments:

1) Abstract - "retention was good": could this be more specifically highlighted in the results section? Is retention linked to practice level data (excellent retention), self-report (very good retention) or appointment questionnaires (does not seem good to me but may well be good in this
area). I do not think this is sufficiently clearly reported in the main results either - mention figure 2's loss to follow-up.

AUTHOR’S RESPONSE

There are two separate issues – retention of practices and participants within the study was good because all practices completed the trial, and 91% of participants completed final follow-up. However there was incomplete data collection of the appointment questionnaires (37.3%) which could have been better. We have modified the conclusion of the abstract and the initial paragraph of the discussion to reflect this.

2) In the recruitment section it is stated that 150 then a further 150 patients were invited, so I did not follow how the 1143 participants on page 10 were found. Is the former figure per practice?

AUTHOR’S RESPONSE

The total number of participants invited were 1143. The break down per practice is shown in Supplementary Table 2. Whilst we asked the practice to send out 150 additional letters the practices actually reported sending out the following Practice A 186, Practice B 130, Practice C 88 and Practice D 139. The differences related to the process they used for identifying eligible patients. We have amended the methods section and added a statement into the results to clarify – “In total 1,143 participants were invited from a target of 1,200 because not all practices sent all 150 additional letters (Supplementary Table 2).”

3) Line 348 "given information when the calling" - presumably a typo?

AUTHOR’S RESPONSE

Yes thanks – typo corrected.

4) Figure 2 - 'randomised to intervention' or 'randomised to control' implies individual randomization - would be better 'allocated to intervention cluster' or 'allocated to control cluster'?
AUTHOR’S RESPONSE

Agreed. Figure 2 has been amended.