Author's response to reviews

Title: Applied public health research - falling through the cracks?

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Author's response to reviews: see over
Dear Dr Norton,

**Re: Applied public health research – falling through the cracks?**

Thank you accepting our paper in principle, and for inviting us to make a final revision.

Please find attached a revised version of the paper with changes highlighted in red, along with a detailed response to each point raised by the reviewer below.

Please do not hesitate to contact me if you require further information. I look forward to hearing from you.

Yours sincerely,

Dr Rebecca K. Simmons  
**Career Development Fellow**
Referee One

1. You talk about ethical objections with withholding a programme from patients who ‘had recently been identified as in need of a tailored exercise programme’. There is an important distinction between a person being identified as needing to become more active, and a person being identified as needing a specific form of intervention which has not been convincingly shown to be an effective means of achieving that end. The arguments surrounding the potential impacts of removing an established service and restarting it as a trial are perhaps more convincing as justifications for not using an RCT.

We acknowledge that the reviewer makes a strong point and have added the following sentence to the appropriate paragraph on page 5:

"However, we were concerned about the ethical implications of removing an established service and restarting it as a trial, as well as enrolling participants in a study in which they would have had to accept a 50% chance of not joining an existing exercise referral scheme, given that they had recently been identified as in need of a tailored exercise programme."

2. ‘In addition, RCTs usually start from an assumption of equipoise — i.e. a position of not knowing which of two competing interventions is more effective, or not knowing whether an intervention is likely to be beneficial or harmful [17] — but in practice, previous research may suggest otherwise. In this case, a recent systematic review based on 18 studies (including six RCTs) has identified that exercise referral has a small but significant effect on increasing physical activity in some people [18].’ I’m not 100% sure I follow your argument here, so some rewording may be useful. Are you saying that this review indicates that equipoise is no longer an issue? If so this is perhaps a little inconsistent with your later comment that equipoise should consider the cost of an intervention. ER schemes may be expensive, and the small impacts demonstrated in (e.g. number to treat of 1 in 17 demonstrated in Williams and colleagues study) may not be sufficient to conclude that equipoise no longer applies.

We acknowledge that this point may have been unclear in the text and have clarified it with the following text:

"In addition, RCTs usually start from an assumption of equipoise — i.e. a position of not knowing which of two competing interventions is more effective, or not knowing whether an intervention is likely to be beneficial or harmful [17] — but this position is not clear with regards to exercise referral schemes. For instance, in a recent systematic review based on 18 studies (including six RCTs), exercise referral was shown to have a small but significant effect on increasing physical activity in some people [18]. While this suggests that equipoise may no longer be an issue, the small effect size and poor quality of many of the studies included in the review, as well as the lack of data on cost-effectiveness, indicates that the situation is not straightforward. Conversely, given that there is evidence for benefit in some people, there may not be enough equipoise to remove an established exercise referral service and restart it as a trial."

3. ‘Methodologically weaker RCTs (for example, those with small numbers of participants, low and differential retention rates, imprecise outcome measures and lack of attention to allocation concealment) should not necessarily “trump” methodologically stronger observational studies [20]. I completely agree with this point, but I think the authors arguments could sometimes be strengthened by avoiding what sometimes reads as a somewhat one-sided attack on RCT methods. For example, whilst the authors cite one study which reported difficulties with wait list control groups to justify their objections to this approach, what about other RCT studies which have used wait list controls without such
difficulties? Is there evidence that the observational study will in fact attract a more representative sample than would an RCT, or would this too suffer selection biases, particularly perhaps where using objective measures of PA, presumably with small subsamples? You comment on the quality of RCTs in the field, but what about the quality of observational studies? Do they suffer similar limitations?

We thank the review for this observation and have tried to balance out our arguments for and against each study design by including the following text:

The limitations of observational studies of exercise referral schemes are well known, including moderate participation rates, lack of long-term follow-up and poor compliance [18]. However, methodologically weaker RCTs... As such, the choice of study design should not be considered the sole criterion of quality. Indeed, the quality of individual studies is now receiving greater emphasis in the formulation of evidence-based guidance than was originally the case [21].