Reviewer's report

Title: Meeting the challenges of recruitment to multicentre, community-based, lifestyle-change trials: a case study of the BeWEL trial.

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Reviewer: Peter Bower

Reviewer's report:

Trial recruitment continues to be an issue for teams worldwide and the presentation of detailed case studies about recruitment has the potential to make a useful contribution to the literature. The lead author is a known authority in this area.

This case study provides a good example of using a range of interventions, including those that are evidence-based, to aid a trial experiencing difficulties with recruitment. The case study tracks the impact of these interventions over time, although their effects are assessed in a sequential fashion without strong controls.

The article reads very well, has a clear message about the difficulties encountered and the efforts made to overcome the recruitment problems. Both the local circumstances and wider implications are discussed, and there was an attempt to quantify the impact in terms of the numbers of additional participants recruited for each of the interventions implemented.

It should be noted that there are a large number of case studies in the literature that describe recruitment difficulties, and how these were overcome to enable successful recruitment. The case study does offer clear lessons that trialists can consider when planning and implementing recruitment of participants to their trials.

Major Compulsory Revisions

It would be helpful to have a more detailed section on the exact nature of the original sample size calculation, and the basis of the various parameters that were used. This might be usefully done in a table, and could allow a ready comparison of the parameters estimated and those that were encountered in reality at different points in the trial.

For example, I am not sure of the basis of the 70% estimate which was originally used. This seems to be based on a single study, although estimates of between 22-67% were discussed in the introduction.

The actual consent rate achieved in this study of 49% seems high for a primary care/community-based trial, which typically achieve consent rates of approximately 10-21%.
I think the issue of the basis of the original parameters should be discussed in more detail, both in the Methods and Discussion, as it raises some interesting issues about the basis of such calculations, and how trial teams (and funders) can judge the basis of those calculations. Estimates based on a single study would be considered unreliable in terms of clinical effectiveness, and analogous standards could be used here. The issue seems to be given limited attention when it could be argued that it is fairly critical.

The authors’ suggestions that a 50% threshold be applied is interesting, but seems a little arbitrary. I would be interested in their views on how those estimates can be improved, and the sort of evidential basis that trialists and funders should consider robust. For example, should we be taking more account of the confidence intervals around recruitment estimates, and using the lower bound? Should we require a certain weight of evidence? What are the core issues that would make an estimate from another trial relevant (for example, what is the relative importance of clinical population, context, year, or intervention)? I would encourage the authors to be a little more detailed in their discussion of this issue to maximise the impact of the paper.

The second suggestion about qualitative research is an excellent one, although one potential block is ethics. Should trial teams build this in to ethics applications, to be activated if problems occur? Or does it require a different approach (i.e. being assessed as something other than research?)

Having glanced at Reference 11, it seems to suggest that the response rate was 51% compared to 70% in the paper. Have I misread that? Or was a decision made to inflate the response rate in BEWEL because of other issues or contextual factors?

Can the team give an estimate of the time and cost for telephone reminders? The actual numbers added seem small here and on the face of it, it did not strike me as a cost effective strategy.

Similarly, the same could be done for site visits and home visits. Was there any way of assessing the impact of those on recruitment numbers? My understanding was that repeated on-site visits have not been shown to increase patient recruitment (Liénard, Quinaux et al. 2006).


Minor Essential Revisions

Was there any discussion within the trial team of introducing any of these strategies on a randomised basis? Some of the strategies have evidence, but others do not, and I would be interested to know if randomised introduction was discussed, and if it was, why it was felt to be impractical.
I would be interested in the team’s view of the relative importance of the strategies, if resources meant that they could not do them all. For example, what do they see as the relative importance of telephone follow up and site visits?

It would be useful to link the strategies to the wider theoretical literature. For example, what is the mechanism related to the use of consultant’s names?

The paper cites that 50% of studies fail to achieve their recruitment target. More recent figures by the same research group suggest slightly more positive figures of 45% (Sully, Julious et al. 2013)


Discretionary Revisions

I am not sure of the legitimacy of describing the extension as ‘no cost’, which is a technical term for funders, in terms of the responsibility for payment. The reality is that someone presumably has to pick up these costs – and in this case it might be useful to identify who it was and how much it involved, unless arrangements were put in place to change the funding schedule.

Level of interest: An article whose findings are important to those with closely related research interests

Quality of written English: Acceptable

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:

I am PI on a study on recruitment where the first author is a co-applicant