Reviewer’s report

Title: Reflecting on the methodological challenges of recruiting to a UK-wide multi-centre randomised controlled trial.

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Reviewer: Ursula Bowler

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This paper is relevant to any group embarking on a multi-centre trial. Variability in recruitment across centres despite having received the same level of training and information is something of a mystery. Being able to identify the traits that lead to successful recruitment would have a number of positive outcomes including not wasting time and money training centres who then fail to recruit. Table 1 in the paper demonstrates the variation in recruitment across sites.

There are a few questions I would raise, these may have been undertaken as part of the trial but it is not clear from the paper.

Introduction:
Was the acceptability of the alternative interventions discussed with user groups during the design phase of the trial? If so it would be helpful to know if their feedback was included in the design.

Recruitment of participants:
The paper states ‘gynaecologists completed a trial entry form for all new referrals’ the numbers given in Figure 1 indicate that 2,093 entry forms were completed but only 603 women were eligible. This seems to be a poor use of gynaecologists’ time; with hindsight would the authors recommend a more efficient procedure for the identification of eligible women?

I am not clear why the consent process was carried out over the telephone by someone the woman would not have met, a situation in which it might be easier for her to say no? While being approached by a member of her care team may have been more successful. However I am not familiar with the care path for this condition so accept this may have been the only option.

Facilitators to recruitment:
Several good points have been identified here:

Trial processes were embedded in existing clinical practice
Trial components being familiar to the clinical collaborators
Trial specific staff at the sites to aid recruiting clinicians and the co-ordinating centre.
All strategies other groups would do well to replicate.

Involvement of GPs

A timeline of this strategy set within the trial framework would help understand this paragraph.

It is disappointing to read of the barriers mounted by the PCT RM&G approval process, for a network whose remit is to facilitate research. Have achieved a system for central ethics’ committee approval, and R&D approval co-ordinated through CSP, it is frustrating that another body has emerged who insist on individual approval for each relevant geographical area.

Collaborator and Participant Incentives

It is interesting that a £55.00 incentive to a general training pot was less of an incentive than £5 immediate reward!

Discussion

While I agree with the sentiment that ‘only strategies which are likely to be successful’ should be used, it is hard to identify which strategy will work in which setting. This paper, while discussing some possibilities has not covered all the options, however it is a good starting point which other should build on.

Table 1 shows recruitment by centre – did the authors take the opportunity to visit good recruiting sites to see what they were doing well to share their experiences of what works with the sites who were struggling to recruit? The variation in recruitment from 130 to 0 would suggest there is something else at work here – commitment to / interest in the trial, of the staff at recruiting sites, maybe an area worth exploring but difficult to quantify!

Did the trial hold collaborators’ meeting for the staff at recruiting sites to meet and discuss issues arising from the trial? Peer support may prove beneficial but I have no evidence to back this up.

The authors suggest ensuring adequate funding in the application for incentives; this is not an acceptable research cost for some funding bodies.

I congratulate the authors on their honesty, discussion of the challenges faced by the group will add to the collective knowledge and may assist other groups in designing and running trials more efficiently by avoiding similar pitfalls.

Level of interest: An article of importance in its field

Quality of written English: Acceptable

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

I declare that I have no competing interests