Reviewer’s report

Title: Recruitment challenges in clinical research. A case study and lessons learned.

Version: 3 Date: 21 May 2015

Reviewer: Angela Craigie

Reviewer’s report:

Major Compulsory Revisions

Minor Essential Revisions

Abstract
It would be useful to have a little more explanation as to the definitions of the two opt-out strategies, which aren’t necessary self-explanatory.

Recruitment methods:
P5 Para 1 – the numbers are quite confusing here. On one hand it is stated that ‘560 eligible patients... were recruited’, then that the target was 280 patients paired with a caregiver, however the experiences of only 370 of the patients were included. This reads as if more than twice as many as the target were recruited (why?), and that the experiences of only a proportion of these are being reported (why and on what basis were they selected?).

P5 line 1 of ‘Recruitment approaches’ – What was the ‘original recruitment strategy’, and have the results for it been included in the results?

P7 ‘Recruitment at a rehabilitation centre’ – this seems to have been considered an ‘opt in’ approach whereas, if I interpret the description correctly, you could argue that they may still have ‘opted out’ at this stage – it was just the staff member rather than the researcher that they gave their decision to. This could be picked up in the discussion.

Results
P9 Para 1 – While the figure is much clearer, the wording of this paragraph could be improved. For example, by ‘assessment for study participation’, do you really mean that they were ‘invited to take part and assessed for eligibility’? How was the ‘assessment’ done and what was the eligibility criteria? This would hopefully make the chain of events clearer.

P9 Para 2 and Table 1 tend to suggest that just 885 declined to participate whereas I’d suggest that it should be acknowledged that the 139 who accepted orally but did not return consent forms also ‘declined to participate’. It is quite possible that when contacting the researcher for more information, some may feel obliged to say yes, even though they didn’t really want to take part, or that
when reading more about the study they changed their minds.

P9/10 Bullet points. To verify the accuracy of the quotes, I’d recommend that the method for how they were ‘documented’ is described in the methods – did they complete a form or were the comments given verbally (and recorded / transcribed)?

Discussion

The discussion does address the impact of illness / treatment stage on the decision of patients to take part, but it would be helpful to know whether all participants were invited at the same stage or varying stages of treatment as this could add some complexity to the interpretation of the results.

Willingness of staff to introduce studies can be a challenge, particularly when recruiting patients at a sensitive time. If any feedback from the health care providers was collected it would be interesting to report this.

Discretionary Revisions

Abstract

A very minor wording issue, but participants were recruited as dyads so it isn’t clear without reading the paper whether the 1562 were half patients half caregivers, or all patients with another 1562 caregivers on top.

Recruitment method

P5 Para 3: Minor wording issue - the first sentence of ‘recruitment approaches’ (referring to low recruitment) initially seems contradictory to the last line of the previous paragraph (which states that the recruitment target was achieved).

In the numbered sections, I’d suggest adding ‘opt out’ or ‘opt in’ to the section headings.

Results

The reasons for non-participation in Table 1 are useful, but understandably only refer to those from the two recruitment methods you could collect this data from. Given that there will have been others from the other methods who, for example saw the adverts / flyers but decided not to respond, I wonder whether there is any way in which the number of patients who may have been eligible during this period of time could be estimated. This would give a better reflection of what proportion of the target population who actually volunteered to take part.

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.