Reviewer’s report

Title: Testing a pain self-management intervention by exploring reduction of analgesics' side effects in cancer outpatients and the involvement of family caregivers: a study protocol (PEINCA-FAM)

Version: 2 Date: 03 Sep 2018

Reviewer: Susan Latter

Reviewer’s report:

The authors have produced a comprehensive response to the queries raised and all the additions and amendments provide greater clarity, detail and consistency.

There just remains an issue with the consistency of the sub-study aims and objectives however:

P7 Aims of the sub-study are stated as improving analgesic side-effects, carer knowledge and exploring carer involvement in pain self-management; P9 Aims are stated which include carer self-efficacy, but self-efficacy is not included in the objectives (nor on p7); learning processes are included in the objectives, but not in the Aim or on page 7. P15, self-efficacy is referred to as a primary FC outcome, so it should be reflected consistently in the Aims for the sub-study.

P19 Aim 2 - still refers to PPQ, when this should be FPQ presumably.

Two other observations that might warrant consideration:

P10 Sample size determination:

The authors have added detail which explains how the number of FCs will be recruited but the justification that 'This number of FCs is expected to be sufficient for the sub-study analyses' is rather weak. It would be stronger to state that a power calculation had been included for the primary outcome measure.

P17 the authors state that the self-efficacy questionnaire has established reliability and validity - the reader might need to be aware that this is only for patients and not carers, according to the reference provided.

Are the methods appropriate and well described? If not, please specify what is required in your comments to the authors.

Yes

Does the work include the necessary controls?
If not, please specify which controls are required in your comments to the authors.

Yes

**Are the conclusions drawn adequately supported by the data shown?**
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