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: 1 Date: 14 Aug 2017

Reviewer: Susan Latter

Reviewer’s report:

The paper reports a protocol for a study underway on an RCT testing a self-management intervention for pain in cancer patients and their family carers. In general, most sections of a study design and operation that the reader would expect to be included are included. The main issue is that the sub-study reported here is not sufficiently clearly distinguished from the main study. The sub-study aims are clear, but the sampling of family carers (FCs) less so, and the outcome section is really focused on the patient (umbrella study) as opposed to the FCs that this sub-study focuses on. As a result, it is difficult to understand the coherence and detail of the sub-study sufficiently clearly.

I could not see evidence that the protocol for the main study had been published? It would seem logical to have published this before publishing a protocol for the sub-study, but if the main study protocol is not yet published, it would be helpful to perhaps outline the aims of the umbrella study. If there is room for this sub-study to be published as a separate protocol from the main study (??), the authors need to separate it out more clearly and in more detail.

More specific comments are as follows:

There are hyphens and inverted commas in the Abstract that are unnecessary; there are occasional grammatical errors throughout.

Where patients and FCs are recruited from is not clear - e.g. is this as they attend for an outpatient appointment?

I assume the researchers had ethical approval to approach patients and FCs directly - this would not be acceptable in the UK.

Some patients will be recruited without a FC - what are the implications of this for the sample size of FCs required?

The authors state that additional data on for the aims of the sub-study were collected via audio-recording of intervention sections. More detail on this is required - for example, how were these sampled? How were they judged to reflect the core foci? How did the recording happen (by whom)? How were these audio-recordings analysed?
Why was it not possible for the outcomes to be assessed blind?

A little more detail on the specialist nurses who conducted the interviews would be helpful. Were they from a different area of the hospital? Had they had skills in interviewing for research purposes? I wonder why the researchers did not conduct the interviews with patients?

P12 brief details of the training provided to IN nurses are needed.

How many nurses are providing the intervention?

P12 how is adherence measured?

P13 can the authors be more specific about when and how often audio-recordings are reviewed and discussion held with nurses?

P13 what are the family carer outcome measures that this paper is focused on - knowledge, self-efficacy? The FPQ is mentioned under the PPQ outcome section, and the family outcomes deserve greater prominence throughout this section.

Generally the outcomes section focuses on patient outcomes, and I assume this is relevant for the main study. For the sub-study reported here, the FC outcomes need to be driving this section.

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

No

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?
If not, please explain in your comments to the authors.

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