Author’s response to reviews

Title: Study protocol for Enhancing Parenting in Cancer (EPIC): Development and evaluation of a brief psycho-educational intervention to support parents with cancer who have young children

Authors:
Lesley Stafford (lesley.stafford@thewomens.org.au; lesley@lesleystafford.com)
Michelle Sinclair (michelle.sinclair@thewomens.org.au)
Jane Turner (jane.turner@uq.edu.au)
Louise Newman (louise.newman@thewomens.org.au)
Claire Wakefield (c.wakefield@unsw.edu.au)
Mei Krishnasamy (meik@unimelb.edu.au)
G. Bruce Mann (bruce.mann@mh.org.au)
Leslie Gilham (gilhams@me.com)
Kylie Mason (kylie.mason@mh.org.au)
Paula Rauch (prauch@partners.org)
Julia Cannell (julia.cannell@icloud.com)
Penelope Schofield (pschofield@swin.edu.au)

Version: 1 Date: 15 Oct 2017

Author’s response to reviews:

Dear Madam/Sir

Re: Submission of revised version of PAFS-D-17-00126R1
Thank you for the opportunity to submit a revised version of this manuscript to BMC Pilot and Feasibility Studies. We have carefully considered each comment made by the reviewers and have made amendments in the manuscript using tracked changes. We thank the reviewers for their thoughtful input and believe that the manuscript has been strengthened by addressing these issues.

We hope that the revised version meets with your favourable consideration and look forward to hearing from you soon.

Sincerely

Dr Lesley Stafford, corresponding author

Reviewer #1:

1. Background. As the intervention is not only aimed for the parent with cancer but also the partner that is not sick it should be nice if you could add information about how cancer in one parent impacts the partner.

Thank you for this comment. Further information about the impact on the co-parent has been added on to the end of paragraph one of the Background section: “In families with two parents, co-parents may also experience substantial stress, reduced quality of life [8, 9] and decline in parenting efficacy [5]. In addition to providing emotional care and physical support for the parent with cancer, co-parents are often required to assume the ill parents’ role as well as their own. Co-parents may also struggle with meeting the often competing needs of their children and ill partner.”

2. Background l. 59: There is something wrong in the sentence: “In a randomized trial, mothers with breast cancer old child received...”

This typing error has been addressed.

3. Background: literature review: are there any studies of interventions aimed at children of parents with cancer?

There are indeed a small number of child-focused interventions in the empirical literature; however, these are beyond the scope of the current paper. We have included a sentence in the Background section to reflect the existence of these interventions: “A small number of interventions aimed at children, families or parents in the context of parental cancer have been developed and evaluated [25].”
4. DVD: are you sure that you want to produce an actual DVD and send to the participants? Why not just offer it as a web-based intervention? You can design it so that you can Watch it on a mobile phone if you are not sure that everyone has access to a computer.

As stated under Data Collection, a web-based intervention is an option: “DVDs and QPLs will be mailed to participants, or will be accessible via online platform (in password protected form).”

This has been stated again in the Background section: “The content of the intervention will be delivered via three components comprising a psycho-educational DVD (which may be mailed to participants or accessed via online platform), a question prompt list (QPL), and a telephone call supplemented by additional referrals/written resources, if needed”.

5: Consent form: Is there any way of obtaining digital consent and not sent by mail?

We have explored this idea with our institutional research and ethics committee. Digital consent is not yet standard in our health setting. Consequently, we will obtain consent in writing for this study.

6: Data Collection : There is something wrong in the sentence: "The questionnaire will be posted, or the emailed with a web-link..."

This typing error has been addressed.

7: SDQ: If you use the follow-up version you should include the impact questions

The follow-up SDQ with impact questions will indeed be used. Please see changes under the section ‘Parental perceptions of the behavioural functioning of children’: “The SDQ includes a follow-up questionnaire and additional impact questions which are ideal for use following an intervention such as the one proposed in this study”.

8: Analysis: Do you plan to use Wilcoxon Signed Rank Test because of the small sample (and therefore not normally distributed)?

We have reconsidered the analysis plan for this study. Given that this is a pilot study, we have amended the protocol in line with the policy of the U.S. Department of Health and Human Services National Institutes of Health regarding pilot studies*. In our amended protocol, only descriptive statistics and qualitative data will be analysed. No hypotheses will be tested and no inferential statistics are proposed. Instead, in line with the comments raised by Reviewer 2 (see below), this pilot study will function as an opportunity for the study team to enhance the rigour of the research and to answer feasibility/acceptability questions about recruitment, retention, fidelity, and so on. Please see our amendment in the Analysis section where we have deleted reference to inferential statistics and replaced with descriptive statistics.
Good luck conducting the study. I hope that you will find it feasible as there is a need for low cost interventions like this one.

Reviewer #2:

Major issues

Introduction

The description that starts at page 7, line 19 seems to be more appropriate for the Methods section.

Thank you for this comment. Most of this information has now been moved to the Methods/Design section (see tracked changes in Methods/Design section and Background).

Methods

The authors describe that the protocol comprises a literature review that has already been completed but do not show the results of this review. It is a bit confusing as the following steps depend on the results of this review. Wouldn't it be more appropriate to show the review's results and describe subsequent planning in line with those results?

The steps following the literature review describe the study protocol and procedure. This is the methodological framework within which the study will progress irrespective of the specific content of the literature reviewed. The specific content of the literature review will then be used to inform the content of consumer and health professional interviews which together then inform the content of the DVD and QPL. However, the findings of the literature review will not alter the overall methodological framework which is what we describe in this protocol paper. We hope that this explanation clarifies our decision to exclude the findings of the literature review from this paper.

Please justify the sample sizes chosen for the development and piloting phases. I understand that at this phase a proper power size calculation is not appropriate but there is probably a rationale behind the choice of sample sizes at this context.

We thank the reviewer for this comment. The proposed sample size is based on practical considerations including participant flow, budgetary constraints and the number of participants needed (based on our experience and other pilot studies) to reasonably evaluate the feasibility...
and acceptability of the intervention (e.g., recruitment rates, attrition rates, treatment fidelity, treatment adherence to protocol). The following sentence has been added to the Design section: “A sample size of 20 was chosen based on practical considerations including participant flow, budgetary constraints and the number of participants needed to reasonably evaluate the feasibility and acceptability of the intervention”.

No information on the effect of the intervention upon children will be collected at this phase, is that right? If so, please justify.

We agree that this is a limitation of this particular study and it outside the scope of this research. In the Limitations section we note: “the intervention is aimed at parents only and does not involve direct support or counseling of children or direct coaching of the parent-child interaction”. In this study, parents are the target of the intervention and information is collected only from parents. However, parental perceptions of child functioning will indeed be assessed (see section on Measures in which the Strengths and Difficulties Questionnaire is described).

The sample sizes aimed at this phase do not seem appropriate for the statistical analysis described by the authors. Isn't it more appropriate to work only with descriptive and qualitative analysis at this point?

Thank you for this comment. We have revised the protocol in line with the policy of the U.S. Department of Health and Human Services National Institutes of Health* regarding pilot studies. In our amended protocol, only descriptive statistics and qualitative data will be analysed. No hypotheses will be tested and no inferential statistics are proposed. Instead, this pilot study will function as an opportunity for the study team to enhance the rigour of the research and to answer feasibility/acceptability questions about recruitment, retention, fidelity, and so on. Please see our amendment in the Analysis section where we have deleted reference to inferential statistics and replaced with descriptive statistics.

Minor issues

Introduction

The following sentence in the introduction needs correction for better understanding: "In a randomized trial, mothers with breast cancer old child received…” (page 6, line 59)

This typing error has been addressed.

The Aims are described in a bit confusing manner. While the authors describe that only the feasibility study will be the aim of this manuscript and not the development phase, at the Methods section the protocol for the development of the intervention is also described. I also suggest that aims and rationale to be presented as different sections (the description of Aims is followed for a justification that is better suited as Rationale).
Thank you for this comment. The aims have been reworded to reflect that the study involves both the development of the novel intervention and its subsequent feasibility/acceptability evaluation. This section now reads “The aims of this study are two-fold: The first aim is to develop a novel psycho-educational intervention to support individuals with cancer who are parents to children aged 3-12 years. The second aim is to determine the feasibility and acceptability of our intervention.

Methods

It is not clear if the following information will be based on participants' report or on medical records: mental health treatment history; presence of major medical comorbidities; time since cancer treatment commenced; nature of cancer diagnosis (tumour stream, stage); and nature of cancer treatment. If it were to be based on medical records, how will the researchers be allowed access to those records? If it were to be based on subjects' report, how do the researchers plan to deal with missing and inconsistent information provided by participants?

We thank the reviewer for this comment. This has been clarified in the paragraph entitled “Relevant clinical and demographic data”. These data will be collected from the participants via self-report in the first instance. Missing data or inconsistent data can be followed up in the participants’ official medical records, a process for which participants provide consent. The following sentence has been added: “In the event of missing or inconsistent data, participants’ medical records will be checked. Participants will provide consent for access to their medical records”.

What is the estimated time participants might take to fill out the questionnaires? Please include this information in the Methods section.

A sentence has been added to the end of the second paragraph of the section ‘Data Collection’. “Questionnaires will take approximately 30 minutes to complete”.

Additional amendment

Please also note that we have amended the Protocol since our initial submission. The amendment is in the Methods/Design section in subsection f). Consumers and health professionals evaluating the DVD and QPL components of the intervention will now have the option of undertaking this evaluation in person or remotely (i.e., viewing the DVD via online platform and reviewing a PDF of the QPL. “The DVD and QPL will be evaluated for perceived usefulness and acceptability by a sample of consumers and oncology health professionals (approximately n=20). Invited consumers and health professionals will have the option of evaluating the DVD and QPL remotely via online platform, or by attending a screening event in person. Collaborating community-based organizations will circulate an invitation to the screening to their members and oncology health professionals will be invited by the research team through hospital- and professional networks. The DVD and QPL will be evaluated using a purpose-designed questionnaire and for those attending the viewing in person, also through
facilitated group discussion. The questionnaire will ask about demographic information, overall impressions of the DVD and QPL, their content and perceived usefulness.”