Author’s response to reviews

Title: A feasibility study of the Mini-AFTER telephone intervention for the management of fear of recurrence in breast cancer survivors: a mixed-methods study protocol

Authors:

Susanne Cruickshank (susanne.cruickshank@stir.ac.uk)
Emma Steel (emma.steel@stir.ac.uk)
Deborah Fenlon (d.r.fenlon@swansea.ac.uk)
Jo Armes (jo.armes@kcl.ac.uk)
Karen Scanlon (karen.scanlon@breastcancercare.org.uk)
Elspeth Banks (elspeth.banks@gmail.com)
Gerald Humphris (gmh4@st-andrews.ac.uk)

Version: 2 Date: 12 Jun 2017

Author’s response to reviews:

12/06/2017 Response to reviewer reports:

Dear Editor – Thank you for the opportunity to respond to the authors again. Any further changes made to the manuscript have been made in green to avoid confusion as the manuscript has so many track changes.

Reviewer #1: Thank you for the opportunity to see a further draft of this paper. The authors have strengthened the paper by their thorough responses to the comments received.

General: there are some instances where acronyms are not explained and additional text is not very well integrated into the existing sections.

Response: Additional link words/small changes made in response to all the authors comments have hopefully addressed these concerns.
Abstract: description of the design is difficult to follow. It would be clearer to explain that implementation, embedded and integration are stages of normalisation process theory. This amendment has not assisted clarity.

Response: Explaining the stages as you suggest has hopefully made the abstract clearer to a reader unaware of this theory.

BCN is not explained before use.
Response: BCN written in full

Additional text in Phase 2 method is long and difficult to follow - suggest additional punctuation.

p14 line 30: please explain how a sample of 20 has been chosen.
Response: Punctuation re-looked at. In addition, more detail is given about the sample size. At this stage we don't know how many will respond to an interview through the survey. However if we have sufficient numbers to develop the matrix, we expect a sample 20 participants would allow us to reach data saturation.

p15 line 35: please explain and justify why 25% of transcripts will be double reviewed.
Response: The authors believe this is good practice – no additions made

p18 lines 7-17: please explain which sections the lay members will be involved in and justify this approach. Do the researchers' mentioned on line 13 include the lay members. Further clarity is needed.
Response: We have added in an additional few words to indicate they will be involved in at least one step of the analysis approach as well. As mentioned on page 13, our co-applicant and collaborator are involved in all substantive study matters, including interpretation and data.

Reviewer #2: Thank you for your responses to my previous comments. I have a few additional comments below:
Abstract

Methods section: BCN needs to be defined.

Response: Added in a few extra words in background about these nurses to define their status/role

The final sentence of this section of the abstract is long and the last line does not make sense to me.

Response: A few words have been changes to address the long sentence and the last line.

Discussion section: suggest replacing "staff" with "nurses"

Response: Reviewed manuscript and where staff is written this has been changed to nurses

Background

Page 4: suggest not having first sentence as a standalone paragraph (i.e. merge with paragraph below)

Response: The paragraphs have been merged

"severe FoR" and "high levels of FoR" appear to be used interchangeably in parts of the manuscript; suggest sticking with one term to avoid confusion

Response: Used the term high throughout to improve consistency

Does the "brief 4 item" measure of FoR have a name? Also, what are the items that are included? I am not entirely clear what the percentiles refer to

Response: The section referring to this has been updated to include the following details, The ‘brief 4 item’ measure is called: Fears of Cancer Recurrence 4-item scale (FCR4). Three items refer to different aspects of anxiety and worry about the cancer returning and the fourth item invites a rating of frequency of ‘waves of strong feelings about the cancer coming back’.
We do not feel it is necessary to include an explanation of the 90th percentile. It is the score at which 10% of the sample will score at a higher level of FCR. If someone scores at the 90th percentile then that means simply that there are only 10 percent of patients who would score their FCR as higher. This is of course dependent on the generalisability of the 'normative' sample. so the percentile is based upon a 'rarity' principle. that is we can say with some precision that certain scores help us understand their rarity of the level of FCR that they express. In a way we don't need to get what is sometimes referred to as a clinical cut-off. If we think that a score at the 90th percentile is sufficiently rare then we can mobilise resource to assist patients in this rarity grouping.

P5, Line 48: are there specific cancer types for which the intervention has been found to be beneficial?
Response: The studies were in oral, head and neck cancers – added as an example

P5, Line 52: what is "symptom severity" referring to in this context? Is it FoR or some other forms of symptoms?
Response: Changed the wording slightly to improve clarity

Page 6 lines 22-33: I do not follow points 2, 3 or 4, that are trying to explain the reasons for the development of the intervention - please revise to aid clarity. The sentence starting with the word "Third" is particularly long and difficult to follow.
Response: Minor changes made in the sentence to improve its clarity

P6 Line32: please elaborate on the evidence base - what outcomes have been demonstrated?
Response: The outcome of the Mini-AFTER feasibility study was that 62% of participants changed their FCR level to be below the cut-off of high FCR following the intervention.

P6, Line 42: the term BCN be defined where it is first used; this is not the first part of the introduction to use the term
Response: Words removed and BCN abbreviation used
P7 Line 8: suggest including reference to back up this point.
Response: The ref is 12,23 and has been moved to reflect this.

P7, Line 49: suggest being more explicit that "acceptability and deliverability" is based on BCNs' views
Response: Added a few additional words

Methods section
P8, Line 43: suggest being more explicit that quantitative data is based on BCNs' views
Response: A few words added

P8, Line 51: I don't understand what the association being described is going to show or add to the value of the research - please clarify
Response: This is an important question in understanding how able and willing a BCN is to undertake the intervention. We would want to know if this is affected by some of their demographics; age, experience, education etc as this may be a factor in the level of training and support the BCN may require to implement this.

Is the survey anonymous? yes
P9 Line 24: should this sentence state that NPT "will be" as opposed to "has been"?
Response: Changed to “will be”

P9 Line 48: this sentence is very long; suggest breaking up
Response: Sentence slightly changed

Suggest including separate heading for Phase 1 and Phase 2 sampling and recruitment
Response: Heading added

Line 18: I am unclear as to how the authors would arrive at a decision about whether a larger trial could be developed based on the study findings; based on what is outlined in this manuscript I would have thought that a more appropriate decision to arrive at was how a larger study would be designed

Response: This is what we have said on page 15.

Limitations

P20, line 39: use of the word "staff" throughout this manuscript gives the impression that multiple stakeholders are involved and I think this is misleading; i would suggest referring to BCNs instead of staff

Response: Checked manuscript throughout and removed the use of the word staff – changed to BCN or nurse as appropriate.

Are there any plans to engage with other key stakeholders (other clinical staff within the sites where the BCNs work, patients) in progressing to a future evaluation of the intervention?

Response: This study focused only on the BCN who would deliver the intervention. Another study published separately focused on patients.

Reviewer #3: Thank you for the care you have taken in responding to the comments. The article seems to me to be much improved.

There are a few typos that need editing (e.g. BCN's/BCNs/BCNs', some extra full stops and commas), some of which may become obvious in a clean (rather than track changed) copy but I am sure the journal's editors will take care of those.

Response: We have amended those we have noticed.

Take care that all abbreviations are explained at first use (e.g. BCN and ICC) - this may have crept in as you have changed the order of some sections.

Response: Addressed and ICC written in full