Author’s response to reviews

Title: A controlled pilot trial of a nurse-led intervention (Mini-AFTERc) to manage fear of cancer recurrence in patients affected by breast cancer

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Author’s response to reviews:

REVIEWER 1

Comment 1:
Thank you for these questions about misconceptions about cancer recurrence.

Some patients express opinion that they will definitely get a recurrence and it is simply a matter of time. This belief is easily identifiable by the nurse and can be discussed specifically to confirm that the patient should not necessarily expect a recurrence.

Nurses may know the patients they speak to and will have an overview of the patient diagnosis and treatment record during the phone discussion. We have included an new “Intervention delivery” section in the Methods which includes this information.

A correct conception of cancer recurrence is that there is a risk which has already been discussed in many cases at the end phase of treatment. The nurse’s discussion in the intervention is to assess the patients current perspective. See examples below.
Two common examples that are included in training scenarios and manual are as follows:

1. Patients present with symptoms or sensations such as ‘tingling’, ‘numbness’; ‘sharp intermittent pains’, from various locations such as shoulder or lower back that they say is a possible recurrence. Nurses respond by assessing the frequency, intensity and duration of these changes in sensations to talk through with the patient the likelihood of these experiences indicative of a recurrence. This is similar to their conversations that would be conducted in ordinary contact, however in this telephone call there is specific focus on the possibility of recurrence and a discussion of anxiety associated with these sensations. Patients are never encouraged to ignore possible warning signs of recurrence, rather nurses attempt to normalise new symptoms that are common after invasive cancer treatments.

2. When patients discuss how they are managing in response to their concerns about recurrence nurses ask about planning for the future. Patients with moderate to high FCR are known not to plan ahead. Therefore patients who indicate that they cannot plan more than a couple of weeks ahead are counselled to consider opening their view of the future to many months ahead and start considering weekend breaks or family holidays, as a way to relieve the burden of worries about imminent recurrence.

For brevity we have included the following example in the Introduction of the manuscript:

“A common example of misconception is that patients will interpret new symptoms or sensation, such acute pain, numbness or tingling, as cancer recurrence. Before the cancer diagnosis, patients may have interpreted these new experiences as harmless, but post-diagnosis patients may assume that they have sinister connotations.”

Comment 2:
Thank you for these comments. We have clarified these points by added the following text to the Methods section of the manuscript:

“Nurses will have frequent interaction with the research team during the trial and will be encouraged to feedback any challenges or difficulties they encounter during the trial. The research team will work with the nurses to find a suitable solution.”

“Thirty minutes is considered the optimal time required to fully address two of the discussion topics. Nurses will be advised to complete the discussion within 30 minutes however this is not categorical. Nurses will be encouraged to use their discretion to extend the discussion beyond 30 minutes. The duration of discussions will be recorded as part of the study.”

Comment 3:
We have added the following text to eligibility section on the Methods:

“Any patient who score &gt;14 (i.e. high) on the FCR4 will be offered a referral onto psychological support services, in line with standard practice at each cancer centre.”
Comment 4:
The paper to the FCR4 is referenced and we have now included the reliability coefficient with the following text:

“The FCR4 has been previously shown to be reliable ($\alpha$ 0.93, 95% CI 0.91-0.94).”

The measure has shown ability to detect change in our previous studies with versions of this measure in the process of assessing trajectories of FCR during the radiotherapy treatment phase.

Comment 5:
The EQ-5D was chosen as part of the trial process evaluation to determine a health economic approach, which would be applied in the development and implementation of a full RCT.

Comment 6:
Thank you for pointing this out. We have now updated the reference list. Reference no. 35 is currently under review at BMC Implementation Science Communications.

REVIEWER 2

Comment 1:
Yes, all referrals onto specialist support serviced during the study will be recorded and included on the pilot trial evaluation. We have added the following sentence to the Methods (Phase 3: Evaluation section) to clarify this:

“This will also include numbers referred onto further specialist services during the study.”

Comment 2:
For this pilot trial, cancer centres were selected pragmatically, through our contacts within NHS Scotland we focused on the north and east of the country. The benefit was also shown in less travel time for our research team to attend clinics. We did not randomise as one of the smaller Units had been involved in the original feasibility study and could not ‘unlearn’ the intervention. We have now addressed this in the Methods (Trial design section):

“The selection of cancer centres was dependant on the proximity of the research institutions and local knowledge of service provision.”

Comment 3:
Yes, we ask patients at control sites (i.e. receiving standard post-treatment care only) to complete the FCR4 at 3 follow-up time points. This will allow us to determine what impact standard care alone has on patients’ FCR level in the weeks following treatment.

Comment 4:
We have included the demographic profile to check that the recruits from the centres and the intervention/ control groups are similar. In addition, we are keen to know which categories of patients tend to gain advantage (or not) from the intervention.
Comment 5:  
Members of the team especially the PI (Humphris) who will seek advice from our Divisional Statistician (as stated in IRAS protocol). As this is not a formal RCT powered of effectiveness of the intervention – we have not blinded this analysis by group assignment. We have made this explicit by adding the following sentence to the Methods (Phase 3: Evaluation section):

“Analysis will not be blinded and will be conducted by the local research teams (St Andrews and Stirling Universities) who will seek advice from a divisional statistician (St Andrews).”