Author’s response to reviews

Title: The feasibility and acceptability of an early intervention in primary care to prevent Chronic Fatigue Syndrome (CFS) in adults: randomised controlled trial

Authors:

Hazel O. Dowd (hazel.o’dowd@nbt.nhs.uk)
Lucy Beasant (lucy.beasant@bristol.ac.uk)
Jenny Ingram (Jenny.Ingram@bristol.ac.uk)
Alan Montgomery (alan.montgomery@nottingham.ac.uk)
Will Hollingworth (william.hollingworth@bristol.ac.uk)
Daisy Gaunt (daisy.gaunt@bristol.ac.uk)
Simon collin (simon.collin@bristol.ac.uk)
Sarah Horne (sarah.horne@nbt.nhs.uk)
Beth Jones (beth.jones@nbt.nhs.uk)
Esther Crawley (esther.crawley@bristol.ac.uk)

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Response to editor comments:
We are pleased that both reviewers are now happy with our responses. Our response to your additional comments are below:

There are a few additional things to do before this paper can be accepted as follows:

1. In the abstract please take the subheadings out of the methods and make into full sentences. We have done this and changed the order slightly to improve readability.

2. The feasibility objectives are briefly listed at the end of the introduction. Please ensure all objectives are listed and the methods clearly address each objective, and similarly the results. In particular in the methods please add a Feasibility Outcomes section before the Patient Reported Outcomes section to describe the methods that address each feasibility objective. Also give an objective for collecting the patient reported outcomes eg. to determine completion, to determine the most appropriate main outcome for the trial etc.
We have added the following paragraph before Patient Reported outcome Measurement. We have changed “distribution” to “completion” in the introduction (with reference to Patient Reported Outcome Measurement.

Feasibility Assessment
We assessed the feasibility of recruitment by assessing the number recruited and the percentage of potentially eligible participants recruited. We assessed the acceptability of recruitment by interviewing participants over the recruitment methodology. We assessed the acceptability of the intervention by interviewing participants about the views of the intervention as well as exploring the numbers that completed the intervention. We assessed the completion of the patient-reported outcome measures as an assessment of the acceptability of the patient reported outcome measures.

3. Please give more detail in the Data analysis section. It is quite brief compared to the qualitative methods described - what methods are to be used eg mainly descriptive summary measures (such as mean (sd) for normally distributed continuous data, median (25%, 75% quartiles) for skewed data and count (%) for categorical data) presented with 95% CIs. No hypothesis tests were conducted because of the nature of the study as a feasibility study (this is mentioned but not under data analysis).

This has been added, and the paragraph now reads:

We estimated the number of eligible patients from routinely recorded data. We recorded the number of potentially eligible patients who consented to contact, the number who were eligible, and the number who consented to the study, were randomised and those who declined. We conducted a descriptive analyses of the baseline characteristics, (median and inter-quartile range), We described the group mean (95% confidence intervals) for the 6 month outcome in both groups. Analysis is presented of available cases following intention to treat (ITT) principles. No hypothesis tests were conducted because of the nature of the study as a feasibility study.

4. Page 19 line 8 'Sixteen in the usual care group and 28 in the EI group ...' please use full sentence.
Apologies but we were unable to find this sentence.

5. It would be helpful to put the sample size rationale (mentioned in two places) under its own subheading Sample Size before Data Analysis section. Please do so.

This has been added as below:
Sample Size
As the aim of this study was to assess the feasibility of a future definitive trial, we did not undertake a formal sample size calculation

6. In the results please either add the 3 month results or give a fuller reasoning as to why they have been omitted with some indication of what they were indicating.
We have added the following sentence but feel that this makes the results section difficult to read. You may wish to decide whether it improves the results or not:

“We have not presented the 3 month outcomes because we wanted to analyse the feasibility of collecting three month outcomes for future mediation analyses in a full trial. “

We are unable to say what the “results were indicating” as we have not looked.

7. The reviewers bring up some interesting points which could be further discussed in the Discussion. For example on screening/approaching/identifying patients; was the timing of the outcomes at 3 and 6 months appropriate. If 3 month data was not helpful then what are your thoughts on including this time point in a future trial?

The relatively low response rate is not the primary problem in this trial and 6 month outcome is the normal outcome for trials in this illness group. We do not feel we have anything further to say about outcomes but have added the following:

“Follow up rates were relatively low but there is insufficient data to comment on whether the timing of follow up was appropriate.”