PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form (see an example) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below. Some articles will have been accepted based in part or entirely on reviews undertaken for other BMJ Group journals. These will be reproduced where possible.

ARTICLE DETAILS

TITLE (PROVISIONAL)	The FEeding Support Team (FEST) randomised controlled feasibility trial of proactive and reactive telephone support for breastfeeding women living in disadvantaged areas
AUTHORS	Pat, Hoddinott Leone, Craig Graeme, Maclennan Dwayne, Boyers Luke, Vale

VERSION 1 - REVIEW

REVIEWER	Della Forster Professor of Midwifery La Trobe University Melbourne, Australia
REVIEW RETURNED	13-Dec-2011

THE STUDY	I think all the material included is well written and relevant, however the paper is really describing a group of studies, albeit nested withing each other, and as such is it quite complec to understand. E.g. the main outcome is not really clear - is it that this feasibility study shows the intervention looks promising and should be trialled? Is it that the cohort study found the rates were low? Is it that staff and women were happy? In its current form I think too much included the paper, making it hard to glean a key message. One aspect of the methods that is not clear to me is whether the feeding team saw ALL women on the postnatal wards (i.e. not just those in the RCT). Likewise did the women in the RCT form part of the cogort study? I think so but I am not 100% certain. The consort diagram still left me feeling unsure. There is one conclusion that the intervention may help increase breastfeeding. The study was not powered to make this conclusion, and the sentence does not end with a suggestion that an adequatley powered RCT should be conducted. Overall I think this is an excellent study and well written, but I would think it would be better as a series of papers.
RESULTS & CONCLUSIONS	See above comments - I think the methods and findings would be much clearer if this were different papers.
GENERAL COMMENTS	I don't think that in terms of the writing or methods etc this paper needs a major revision - there are only actually minor points of concern. Rather, i think that the paper would be better written and presented in its separate components, thus I have chosen the suggestion 'major revision'.

REVIEWER	Dr Kate Jolly Senior Lecturer in Public Health & Epidemiology Public health Building School of Health & Population Sciences University of Birmingham Edgbaston Birmingham B15 2TT
REVIEW RETURNED	08-Dec-2011

GENERAL COMMENTS	Table 1 – write SVD in full or add legend to table. The cost-effectiveness analysis was probably overly comprehensive for a feasibility study with very limited numbers of participants. The limitation of sample size and potential bias from differing follow-up rates between study arms needs firther discussion. I didn't understand how the authors moved from £87 per additional woman breastfeeding at 6-8 weeks (page 24) to £0.87 per 1% increase in breastfeeding – this needs more explanation. The supplementary data is very comprehensive – including the full results of a qualitative study (S5). These did add to that provided in the main text, but were like reading a whole additional paper.

REVIEWER	Maria Quigley Reader in Statistical Epidemiology National Perinatal Epidemiology Unit University of Oxford UK
REVIEW RETURNED	13-Dec-2011

GENERAL COMMENTS	The paper describes the results of a study with several components which aimed to increase breastfeeding in women in disadvantaged areas. The components were a 'before and after study', a pilot of an RCT, a mixed method process evaluation and a cost-effectiveness analysis. The authors should be congratulated on accomplishing such a complex research study. The results are extremely useful to the authors for the design of a full RCT, but will be of interest to other readers, particularly those interested in infant feeding or designing complex interventions. I have some specific comments: 1. Structure - I think it would make sense to re-order the methods and results so that the before and after study is described before the RCT, since the RCT was 'embedded' within the 'after' component. 2. Objectives of RCT - It says on page 8 that the aim was to pilot the effectiveness of proactive and reactive telephone support compared with reactive only telephone support. Did the authors have criteria for assessing 'effectiveness' or 'feasibility'? (e.g. see Thabane et al. A tutorial on pilot studies: the what, why and how. BMC Medical Research Methodology 2010, 10:1). For example, the intervention looks promising (e.g. OR=2.56 for any breastfeeding at 6-8 weeks) but the results are not statistically significant. In keeping with the recommended practice for pilot and feasibility studies, no sample

	size calculations were performed. But would the authors conclude that the intervention is effective and looks promising for an RCT? What if the odds ratios for the trial had been 1.5 rather than 2.5? It would be helpful to know how the results should be interpreted. Perhaps more focus should be given to feasibility criteria rather than effectiveness e.g. on the top of page 27, it mentions the feasibility of collecting trial data. 3. Table 3 - The effectiveness results are presented as odds ratios (for breastfeeding) and differences in mean/median (for satisfaction and number of occasions seen). Given that the odds ratios in Table 3 are unadjusted, it might be easier to present them as risk ratios since these would be easier to interpret and are more appropriate for a common outcome. 4. Missing follow-up data on breastfeeding at 6-8 weeks was a bit of a problem, especially in the more disadvantaged groups. For the design of the full trial, it would be worth exploring the possibility of obtaining routine data on breastfeeding at 6-8 weeks. 5. Costs and cost-effectiveness - The cost-effectiveness ratios for the RCT seem to be based on the telephone support arms only and do not take into account the cost of the team on the postnatal ward – while the latter would have the same cost for the two trial arms, there is presumably a relatively high cost of having the team on the postnatal ward? 6. Discussion - I think it would be helpful for there to be more coherent interpretation between the results of the RCT and the 'before and after' components. For example, the RCT of proactive support seems to be based on having a specialised feeding team on the postnatal ward in place. However, the specialised feeding team did not seem to have an impact on the breastfeeding outcomes, so it begs the question as to whether the specialised feeding team is needed. It would also be useful to have a bit more discussion as to why the specialised feeding team seemed to have no impact, particularly as the before and after results are not presented at all in the main paper (they are in supplementary tables S3 and S4). For example, was it because many women had a very short length of stay on the postnatal ward, or that some women may have already decided not to breastfeed. 7. First sentence of Conclusion on page 30 – I think this sentence should also include something about women for have been on a ward with a specialised feeding team e.g. "… for women living in more disadvantaged areas who were on a postnatal ward with a specialised feeding team …".

REVIEWER	Karen, McQueen
REVIEW RETURNED	19-Dec-2011

THE STUDY	The objectives listed in the abstract are just a small part of what is actually written in the manuscript. The introduction does not support the multiple objectives/aims of the study. The introduction is not even 2 pages of a 60 page manuscript.

	The methods are not clear. There were 4 components of the study. Considering the length of this manuscript it might be worthwhile to consider multiple manuscripts. The title suggests a randomised controlled trial yet there are sections on the rct component, a before and after component and qualitative interview data. However, I do not see a research question that calls for before and after study or qualitative interviews. The main outcomes are not clear. The qualitative interviews were not even identified as an outcome.
RESULTS & CONCLUSIONS	I did not review many of the findings or the discussion in light of the lack of clarity of the methods and intervention.
GENERAL COMMENTS	I am sorry that I cannot provide an extensive review of this manuscript. In all honesty I do not understand the methodology or what the intervention entailed. There are far too many objectives for one manuscript. I would recommend that the author's consider publishing components of this manuscript e.g RCT component separate from before and after or qualitative.

VERSION 1 – AUTHOR RESPONSE

Response to reviewers comments

Manuscript ID bmjopen-2011-000652: The FEeding Support Team (FEST) randomised controlled feasibility trial of proactive and reactive telephone support for breastfeeding women living in disadvantaged areas

From the managing editor:
There's a huge amount of information here, including the supplemental file too. As it contains core results this should really be reported in the main article.

Therefore we would like you to revise this into two separate papers.

paper 1 (000652.R1) should report the methods, results, and discussion of the before and after study, the RCT, and the economic analysis - in the order suggested by reviewer Quigley. This should include all the quantitative results that are currently in the supplemental file.

paper 2. A new paper reporting the process review/qualitative methods and results - including all the quotes etc that are currently in the supplemental file.

This would be far clearer than the current paper, which is really tough to take in.
We have revised the original paper as two papers as suggested.

Reviewer: Dr Kate Jolly
Senior Lecturer in Public Health & Epidemiology Public health Building School of Health & Population Sciences University of Birmingham

No competing interests

Table 1 – write SVD in full or add legend to table.
Changed

The cost-effectiveness analysis was probably overly comprehensive for a feasibility study with very

limited numbers of participants. The limitation of sample size and potential bias from differing follow-up rates between study arms needs firther discussion.
While we agree that the number of participants was small, we believe that we should be using the strongest methodology we can to make the best use of these data. We have added a sentence to the discussion addressing the limitations identified by the reviewer.

I didn't understand how the authors moved from £87 per additional woman breastfeeding at 6-8 weeks (page 24) to £0.87 per 1% increase in breastfeeding – this needs more explanation.
Both pieces of information can be useful to decision-makers. The incremental cost per additional woman breastfeeding is intuitively similar to presenting effectiveness data in terms of a number needed to treat. For a policy maker however it is also helpful to consider what the impact of increasing the proportion of women who breast feed. This latter information is provided by the incremental cost per 1% increase in breast feeding and is derived by simply dividing the incremental cost per woman breast feeding by 100. This is because the average additional woman is equivalent to saying that there is a 100% change. This has now been fully explained in the text.
The supplementary data is very comprehensive – including the full results of a qualitative study (S5). These did add to that provided in the main text, but were like reading a whole additional paper.
Now separated into two papers.

Reviewer: Della Forster
Professor of Midwifery
La Trobe University
Melbourne, Australia

I think all the material included is well written and relevant, however the paper is really describing a group of studies, albeit nested withing each other, and as such is it quite complec to understand. E.g. the main outcome is not really clear - is it that this feasibility study shows the intervention looks promising and should be trialled? Yes, the first sentence of the conclusion has been changed to reflect this. Is it that the cohort study found the rates were low? Breastfeeding rates in Scotland are routinely collected at 6-8 weeks for all women giving birth by hospital and by Health Board and we have added a new reference (28) to the "quantitative" paper and text to the discussion to highlight that our baseline rates before the FEST team intervention are consistent with this data. Is it that staff and women were happy? Yes, this acceptability data is now reported in the new process evaluation paper. In its current form I think too much included the paper, making it hard to glean a key message. We have now split the paper in two.

One aspect of the methods that is not clear to me is whether the feeding team saw ALL women on the postnatal wards (i.e. not just those in the RCT). We have added a bullet point in Box 1 to clarify this. The Team prioritised FEST trial participants; however the workload varied from day to day. Through discussion, it was decided that if the team had spare time, they would assist non-trial women with breastfeeding, particularly those living in disadvantaged areas. This helped with integration of the study into routine care and maintained good relationships between the ward staff and the FEST team. Likewise did the women in the RCT form part of the cogort study? Yes, we have changed the title of Table 1 to state "all women initiating breastfeeding" and clarified this in the results text for the before and after study. I think so but I am not 100% certain. The consort diagram still left me feeling unsure. The consort diagram has been modified to clarify that the RCT women formed part of the "after" cohort study.

There is one conclusion that the intervention may help increase breastfeeding. The study was not powered to make this conclusion, and the sentence does not end with a suggestion that an adequatley powered RCT should be conducted. This sentence has been revised.

Overall I think this is an excellent study and well written, but I would think it would be better as a series of papers.

I don't think that in terms of the writing or methods etc this paper needs a major revision - there are only actually minor points of concern. Rather, i think that the paper would be better written and presented in its separate components, thus I have chosen the suggestion 'major revision'.
This has now been done.

Reviewer: Maria Quigley
Reader in Statistical Epidemiology
National Perinatal Epidemiology Unit
University of Oxford
UK

I have no competing interests.

The paper describes the results of a study with several components which aimed to increase breastfeeding in women in disadvantaged areas. The components were a 'before and after study', a pilot of an RCT, a mixed method process evaluation and a cost-effectiveness analysis. The authors should be congratulated on accomplishing such a complex research study. The results are extremely useful to the authors for the design of a full RCT, but will be of interest to other readers, particularly those interested in infant feeding or designing complex interventions.

I have some specific comments:

1. Structure - I think it would make sense to re-order the methods and results so that the before and after study is described before the RCT, since the RCT was 'embedded' within the 'after' component.
The order has been changed as recommended.

2. Objectives of RCT - It says on page 8 that the aim was to pilot the effectiveness of proactive and reactive telephone support compared with reactive only telephone support. Did the authors have criteria for assessing 'effectiveness' or 'feasibility'? (e.g. see Thabane et al. A tutorial on pilot studies: the what, why and how. BMC Medical Research Methodology 2010, 10:1).
Thank you for drawing our attention to the Thabane et al. paper. We have reworded the objectives for the RCT (previously p8) to be consistent with the research questions stated in our original study protocol, which was written prior to publication of the Thabane paper. The sentence and the abstract now emphasise that we were assessing the potential effectiveness and the feasibility of implementing the RCT of proactive and reactive telephone support. For example, the intervention looks promising (e.g. OR=2.56 for any breastfeeding at 6-8 weeks) but the results are not statistically significant. In keeping with the recommended practice for pilot and feasibility studies, no sample size calculations were performed. But would the authors conclude that the intervention is effective and looks promising for an RCT? What if the odds ratios for the trial had been 1.5 rather than 2.5? It would be helpful to know how the results should be interpreted.
We have reworded the first sentence of our conclusion to emphasise that the results are sufficiently promising to warrant a full scale multi – centre trial. However robust conclusions about effectiveness cannot be made. Perhaps more focus should be given to feasibility criteria rather than effectiveness e.g. on the top of page 27, it mentions the feasibility of collecting trial data.
We have emphasised feasibility rather than effectiveness in the methods, discussion and conclusion sections.

3. Table 3 - The effectiveness results are presented as odds ratios (for breastfeeding) and differences in mean/median (for satisfaction and number of occasions seen). Given that the odds ratios in Table 3

are unadjusted, it might be easier to present them as risk ratios since these would be easier to interpret and are more appropriate for a common outcome.
We have no strong views about this and we have presented risk ratios in what are now tables 2 and 4 and in the text.

4. Missing follow-up data on breastfeeding at 6-8 weeks was a bit of a problem, especially in the more disadvantaged groups. For the design of the full trial, it would be worth exploring the possibility of obtaining routine data on breastfeeding at 6-8 weeks.
We agree and have added a sentence in the discussion and a new reference (28) to the "quantitative" paper. NHS Grampian started collecting routine 6-8 week infant feeding data in July 2010 and so it was not available when our study started.

5. Costs and cost-effectiveness - The cost-effectiveness ratios for the RCT seem to be based on the telephone support arms only and do not take into account the cost of the team on the postnatal ward – while the latter would have the same cost for the two trial arms, there is presumably a relatively high cost of having the team on the postnatal ward?
We would like to clarify that the feeding team costs on the postnatal ward were included and are reported in the supplementary tables. With respect to the estimation of incremental cost-effectiveness (which is calculated as the ratio of differences in cost between trial arms divided by the difference in the effectiveness between trial arms), we would like to confirm that feeding team costs on the ward did not differ between the intervention and control arms. As these feeding team costs are the same between trial arms they do not influence the incremental costs (i.e those costs that differ between trial arms) for the health economic analysis. Tables 5 and 6 of the "quantitative" paper report the costs and cost-effectiveness results. To aide reading of the text, we have reversed tables 5 and 6.

6. Discussion - I think it would be helpful for there to be more coherent interpretation between the results of the RCT and the 'before and after' components. For example, the RCT of proactive support seems to be based on having a specialised feeding team on the postnatal ward in place. However, the specialised feeding team did not seem to have an impact on the breastfeeding outcomes, so it begs the question as to whether the specialised feeding team is needed. It would also be useful to have a bit more discussion as to why the specialised feeding team seemed to have no impact, particularly as the before and after results are not presented at all in the main paper (they are in supplementary tables S3 and S4). For example, was it because many women had a very short length of stay on the postnatal ward, or that some women may have already decided not to breastfeed.
The before and after results are now presented in the "quantitative" paper and the discussion sections of both papers have been revised to expand on these points. Our data generate several alternative hypotheses about "why" the feeding team on the postnatal ward did not seem to impact on feeding outcomes, but we cannot state cause and effect at this stage. In the discussion of the process evaluation paper we outline as a series of research questions which warrant further investigation in an attempt to provide an explanation. However, we point out that this was a complex intervention intervening into a complex system, and identifying single components mediating or modifying effects may not be appropriate.

7. First sentence of Conclusion on page 30 – I think this sentence should also include something about women for have been on a ward with a specialised feeding team e.g. "… for women living in more disadvantaged areas who were on a postnatal ward with a specialised feeding team …".
This has been added.

Reviewer: Karen McQueen
Lakehead University

The objectives listed in the abstract are just a small part of what is actually written in the manuscript.
We have expanded the description of the objectives in the abstract for the new process evaluation paper.

The introduction does not support the multiple objectives/aims of the study. The introduction is not even 2 pages of a 60 page manuscript.
This has been expanded in the new process evaluation paper to address the multiple objectives.

The methods are not clear. There were 4 components of the study. Considering the length of this manuscript it might be worthwhile to consider multiple manuscripts.
The paper has been split into two, which we hope improves clarity.

The title suggests a randomised controlled trial yet there are sections on the rct component, a before and after component and qualitative interview data. However, I do not see a research question that calls for before and after study or qualitative interviews.
To address this, we have stated the research questions in full in the two papers.

The main outcomes are not clear. The qualitative interviews were not even identified as an outcome.
We hope this is clear now that the “quantitative” and process evaluation papers have been separated.

I did not review many of the findings or the discussion in light of the lack of clarity of the methods and intervention.

I am sorry that I cannot provide an extensive review of this manuscript. In all honesty I do not understand the methodology or what the intervention entailed. There are far too many objectives for one manuscript. I would recommend that the author's consider publishing components of this manuscript e.g RCT component separate from before and after or qualitative.

1. This manuscript is very confusing:
• The abstract method describes a rct design yet the methods in the manuscript is a RCT embedded in a before and after design
The abstract has been revised.
• The methods describes 4 components: the pilot RCT of proactive and reactive support, a before and after cohort study, a mixed quantitative and qualitative methods process evaluation and an economic evaluation.
• I do not understand the study? I do not understand what the intervention is as it is not described in sufficient detail to allow replication. Who was part of the FEST team, This has been added to Box 1, how often did they call participants? What was the structure of the intervention? The Box 1 describes some components of the intervention but it is not clear (e.g. the feeding team was continuously available during the intervention period). This has been revised to improve clarity. Who is on the feeding team, what is the intervention period? This is stated in the methods. What are they doing when when they were supporting women to breastfeed yet the women were not randomized until after discharge?
• What is “the intervention”? (e.g. qualitative interviews before and after “the intervention”.
What did the telephone call entail?
Detail is now provided in the process evaluation paper
2. I don’t understand the before and after cohort study. The authors state the aim is to compare the proportion of women breastfeeding (any and exclusively) at 6-8 weeks after birth for the 12 weeks before and 12 weeks after providing ...
We hope the revised text clarifies this.

3. There are too many components of this study to report in one manuscript. It is confusing because there are different methodologies and analyses.

4. I don't see anything in the review of the literature that justifies the qualitative analysis. There also isn't any research question or purpose identified with this part of the research. Additionally, there is no mention in the abstract.
This is now addressed in the new process evaluation paper.

5. The abstract and title focus on a RCT yet the RCT component was only a small cohort of a much larger group. The FEST flow chart I don't understand as I don't understand the before and after intervention.
We hope that we have addressed the aspects of our study that Karen found confusing in this complex intervention by splitting the paper into two and making changes in response to all reviewers' comments.

VERSION 2 – REVIEW

REVIEWER	Maria Quigley Reader in Statistical Epidemiology National Perinatal Epidemiology Unit University of Oxford
REVIEW RETURNED	15-Mar-2012

GENERAL COMMENTS	The new format for this paper (i.e. splitting into 2 manuscripts) is a good idea. The revised version of the first manuscript (i.e. the quantitative paper) is much clearer and I have no further comments.