**Manuscript Number: YMIDW-D-14-00319**

**Title: Understanding barriers to involving community midwives in identifying research participants, experience of the First steps randomised controlled trial.**

**Reviewer #1:**

1. This article is written in a clear and simple style, although there are issues with structure. The introduction is confusing and should firstly set out what the paper will discuss, and needs to explain the background to this study more clearly. It is unclear whether the authors are involved in the FPN programme or are independent.

*The introduction has been re-written so that it presents what the paper will discuss first, then the background in terms of the trial in question. Other literature, pertaining to recruitment to trials in general and the involvement of midwives in research, has been moved to the discussion.*

1. The authors have drawn on a range of literature to inform the discussion however some papers are a little old and could be updated to more recent sources.

*The literature has been revised removing dated literature and adding some more recent literature.*

1. I have some concerns about ethical approval for this study and the process of recruitment.

*The reviewer has not spelt out what his/her concerns are, and whether with the trial itself or this specific qualitative study. But there was full ethical approval for all aspects of the trial and this sub study. No midwife took part in the qualitative study without reading the Information Sheet, being given full opportunity to ask questions and discuss responses, and giving signed consent.*

1. Managers nominating their employees is fraught with issues of coercion and there is no discussion about these midwives' confidentiality and anonymity which would be particularly important in these circumstances. So there would need to be more discussion around this in my view.

*We apologise that the wording was unclear in the original submission, it has been revised. Managers were not asked to nominate specific participants but were asked – as the manager was the only person in midwifery for whom the study had contact details – to ask if any of their local community midwives would volunteer to be interviewed, with the proviso that they had to have been working in the relevant areas at the time of the trial. If they volunteered then their name and e-mail were passed to the research team who then contacted them by e-mail. The names of midwives who actually participated were not fed back to their managers. This has been made clear in the revision*

1. The findings are interesting and the inclusion of the data extracts adds to their authenticity. The findings reflect some problems with the recruitment process to the original trial in terms of information giving to the community midwives and in recognising that the timing was not ideal.

*We agree that the timing of the trial was not ideal, but this only became apparent after the trial had commenced.*

1. There seem to have been significant failings in the way information about the FPN study was imparted and there is some analysis and recommendations for how the process could be improved in the future.

 *We do not agree that there were failings to impart information about the trial; a substantial amount of effort was made over many months to communicate with community midwives about the trial. However, given the structure of their management and their work patterns, even when there was enthusiastic attendance at meetings to hear about the research, inevitably some midwives could not be present. As a team we were surprised, given the interest expressed at the meetings, that there was then such a low response to identifying potential participants for the trial. This paper is offered to present the context to these challenges and to inform future similar trials.*

1. Overall this paper reflects the difficulty in relying on busy workers to support the recruitment of research participants. The findings give some useful data which could inform strategies for avoiding problems such as these in the future

*We hope that the paper will provide some useful information for future research, this was our aim in writing it.*

**Reviewer #2:**

1. The description of the study that the midwives were required to refer to appears to be missing some basic details.

*More detail has been added about the process of setting up the trial and it has been clarified that the role of the midwives was to identify potential participants based on some, but not all, of the eligibility criteria and, where possible, gain their agreement for the research team to contact them, to explain the trial in more detail and establish full eligibility. If fully eligible then it was the researcher’s role to recruit to the trial.*

1. Participating sites appear to have been selected on the basis of the enthusiasm of FNP teams, and this may fundamentally not have been where, despite good links the community, midwives were equally keen.

*It was essential that the trial be carried out in areas where FNP work was well-established. To become a site the FNP team and local midwifery both had to agree that it would be viable, and subsequent meetings focussed on midwifery to ensure, as much as could be possible based on births for previous years, that there would be sufficient potential participants in the local area.*

1. In the background the authors state that the "hired hand" approach works against research activity, and yet there is no description as to how this was ameliorated in this study. Indeed the authors appear to have spoken to the managers and involved them far more in the induction and site initiation process than discussing it with all available community midwives.

*Literature on the hired hand approach was read after conducting the study, so has been moved more appropriately to the discussion. Efforts were made to explain and discuss the trial with all midwives in each of the seven sites. However, as researchers external to an organisation, there are no rights of access to any professional groups, and attendance at meetings is by negotiation.*

1. There is no described power calculation or explanation as to why 300 women would be required for a sample size of 100. When under recruitment was recognised, it appears from the manuscript that alternative strategies were sought, but no attempt was made to increase referral rates form the community midwives.

*Power calculation details for the trial have been included (and were in the publicly available trial protocol, which is one of the author citations). We also have made it clear that in addition to implementing additional participant identification strategies for the trial, ongoing communication was attempted with all community midwifery teams and the offer of a paid conference place was made if the research team was able to recruit a minimum number of participants (N=16) in that site [note it was identification methods for potential participants that were amended- the actual recruitment remained the responsibility of the research team]. This has been clarified in the text.*

1. There are no details re ongoing support. Indeed respondent 2 acknowledges she had "limited information that we could give the girls" suggesting that knowledge levels were low.

*The research team attempted to provide information about the intervention and the trial process, both with the specially prepared DVDs, shown during meetings with additional copies made and distributed to local midwifery team leaders, and by answers during Q&A at the presentations. The researchers also provided contact details to manager, e-mail and telephone so that enquiries could be addressed. However it is clear that the information did not reach all the relevant midwifery personnel. .*

1. The selection of the 13 midwives involved in the qualitative interviews was also achieved via managers and therefore could be a biased selection. How many midwives could have been approached, i.e. what was the total number of midwives expected to refer to the study?

 *See response #4 to reviewer #1. It has been made clearer that there were potentially 304 community midwives working in the relevant sites. The university research team, as external to the Trusts, did not have names, telephone numbers or e-mails for all these midwives so instead asked the managers, with whom we had communicated, if they would convey our request for volunteers. The original wording, using the term ‘nominate’ has been removed as this was potentially confusing. Since only two interviews per site were planned for, this also reduced the likelihood that a large number might contact us, but then could not be interviewed.*

1. Why weren't the midwives contacted directly and asked to consider participation? The interview topic guide was very specific about FNP knowledge but if training was inadequate how could the midwives know about this, respondent 2 obviously felt this?

*See above, as external researchers, we have no right of access for direct contact with midwives, it has to take place through the Head of Midwifery. If midwives names were provided as those who had volunteered to be potential interviewees, their managers were not notified as to whether they took part or not*.

1. Comments from respondent 9 appear to confirm that referral to the trial was not aligned to standard referral pathways, the rationale for this could explain some of the lack of referral, but is not commented on. At the bottom of p10 it states the midwives were not expected to enquire re educational attainment, and yet if they did not know, how could they refer eligible multiparous women 20-14 years of age?

*It has been explained more clearly that gFNP was not offered in any location in the country as a possible service so standard referral pathways were not relevant. Midwives were not being asked to refer women aged 20 to 24 - it was made clear in the information provided that they only had to identify 20 to 24 years olds as primiparous, and with an EDD that would fit with group delivery; the researcher would then contact anyone identified in this way and agreeing to be contacted, to enquire about educational qualifications.*

1. The comments of respondents 4, 12 and 7 identify the rarity of women in this eligibility category. Was referral low, or where there simply few eligible women?

 *Based on birth data from previous years [noted in the revised manuscript that this was checked] there should have been sufficient numbers.*

1. What strategies were in place for women for whom English was not a first language, or those with literacy issues- which could be high given the eligibility criteria?

*This particular intervention is not suitable for women who cannot communicate in English so it can be seen from the Trial protocol that they were not eligible for the study. Literacy was not relevant, all research contacts are interviews and not questionnaires to be read, and in the intervention the FNs would deal appropriately with clients who have literacy problems, which was established in the pilot implementation evaluation.*

1. In the discussion would it be worth identifying and discussing the use of other means of support - if women truly don't like groups, especially in this young age group that are digitally savvy?

*This is an important topic but beyond the scope of this paper [and word limitations]. The paper is focussing on the role of midwives in research, not whether group care is suitable for a young age group. However we expect to write about that topic once the trial is completed.*

1. Were transport costs available for participants as respondent 4 and 2 mention this as an issue?

*Transport costs were provided for group participants. This has been noted. It was explained at group presentations that this would be the case.*

1. Theme 4 would also appear to point to lack of education and information about the trial and the planned intervention as being problematic to referral.

*Again midwives were not asked to refer, but were given some specific but limited criteria (age parity, EDD) and asked if any women on their lists for booking met those criteria*

1. In the discussion- it is unsurprising that the trial had low priority for midwives, they did not know much about it, and had their clinical responsibilities to consider. If it was never possible for all community midwives to be present at training, could there not have been some strategy regarding other forms of information giving and more local dissemination (not relying on managers, who also have other priorities)? Then failure of the team to ensure the midwives understood their limited role again, points to poor planning and study set up, and a lack of a central information point for midwives to go to, as does the "poor knowledge of the {relatively) new intervention". The timing of the study at a time of reconfiguration and senior staff change, again is unfortunate. Were these changes planned or foreseen at study set up? Changing location could have brought about a different result. The eligibility criteria do not appear complex when reading this, so the fact the midwives thought they were needs explanation. Midwives concerned discussed on p17 should have been addressed, again comes back to the education of local staff.

 *It has been explained that all possible effort was made to reach as many of the community midwives as possible in each area to give full details of the trial and of the intervention. As a research team we feel that we made extensive efforts, and we provided several e-mail addresses and telephone numbers so that the study PI and the trial manager could be contacted, but people with busy working lives may express interest at a meeting and then forget the information provided as they continue with clinical duties that must take priority. Several meetings were held in some locations at the request of midwifery managers Posters were put up in all midwifery departments and many additional leaflets about the study were distributed. . The extent of change within organisations that occurred during the trial was not expected by participating Trusts or the research team at the start of the trial. Such information would certainly have influenced site selection, although there was only a limited pool of potentially suitable sites; they had to be experienced in delivering FNP and also have a qualified midwife as part of their Family Nurse team.*

1. A study like the original one which ran across several sites and was based in the community would rely on local support even with the introduction of CRN research midwives.

*This was well understood by the research team which is why almost a year was spent talking to relevant individuals in all sites, and why the response to the Invitation to Tender had to include the signature of local midwifery managers, data on births in the area, and the assurance that there was good communication between midwifery and the FNP teams. This has been specified in the revised manuscript.*

1. Improved standardised notes would make life easier and there is no reference in the discussion to the proposed national dataset. The basic information such as age and parity generally is not too difficult to ascertain, educational attainment may well be harder!

*Researchers do not have access to NHS standardised datasets. The research team was aware that midwifery datasets across the country would contain varying information and indeed found that only age was reliably present in all systems. No midwife was required to ask about or know about educational qualifications - this was ascertained by the local researcher only after potentially eligible women, based on age, parity and EDD, had agreed to be contacted.*

1. The authors state that "in a climate when clinical workloads are high, with a workforce that is depleted the added burden of identifying potential participants for research studies is for many not feasible". This is not compliant with the DoH policies of all patients in the NHS having the opportunity to take part in research. This needs discussing.

*We are particularly grateful to the reviewer for highlighting this important point. We have added a note about this in the discussion. We agree that all potentially eligible women should have a right to take part in research, but are struggling to work out how this can be achieved when they need to be identified in early pregnancy. When participant identification was slow within the present study posters inviting participation were placed in hospital maternity departments/waiting rooms, local GP surgeries and local Children’s Centres. Leaflets were also positioned near the posters where possible. This strategy resulted in only one potential participant identifying herself which would suggest that encouragement needs to come from relevant professionals.*

1. There are 8 author citations which mean they constitute more than 25% of the references (8/31)

*Three author citations have been removed, but so have some of the more dated references, with some new ones added. There are now only 5 author citations, out of 29 references (17%).*