**Reflections upon a randomised controlled trial and carrying out an intervention in partnership with an NHS hospital**

**Fiona Cust, Ruth Carter**

**Introduction**

The aim of this paper is to summarise the reflections of the research team during a randomised controlled study in partnership with a National Health Service (NHS) maternity provider. The aim of the pilot study was to explore the effect that peer support may have upon women in the antenatal period.

The paper will particularly consider the partnership working entailed in carrying out research with an NHS hospital trust. There will be a focus upon communication with the community midwives (CMWs), recruitment for the role of peer support worker (PSW), recruitment of participants, coordination of the intervention and finally, the collection and scrutinising of data.

**Background**

The National Institute for Health and Care Excellence (NICE) guidelines
(NICE 2014) recommend that support for mental health should, ideally, begin in the antenatal period. Depression and anxiety are the most common mental health problems during pregnancy, with around 12% of women experiencing depression and 13% experiencing anxiety at some point. Many women will experience both (NICE 2016).

Mental health problems in pregnancy, and the postnatal period, may require more urgent intervention than they would at other times because of their potential effect on the baby and on the woman’s physical health (Howard *et al* 2014). However, due to the complexities in diagnosis, problems are frequently unrecognised and untreated (Letourneau *et al* 2015). It has been well documented that services are minimal, and difficult to source for women suffering from antenatal depression within the United Kingdom (Darwin *et al* 2014, Cust 2016).

**Recruitment**

The research team had a number of meetings at the start of the project with the management team at the potential recruitment site. They were very positive about the study and were keen to offer support with recruitment of potential participants. The research team felt that it was also important to meet with the CMWs to ensure that they had an in-depth understanding of the study and recognised the potential benefits for the women and their families. Each meeting was well attended and many queries and concerns were addressed.

The main aim was for the midwives to feel involved, valued and motivated towards both the study and the recruitment of participants.

We were aware from a member of the research team, who had worked as a CMW, that workload was often very heavy and time spent with each pregnant woman very limited. A number of midwives reiterated this during discussions about the study. We were concerned that asking the midwives to recruit to the study may have been too time consuming.

Therefore, as per routine protocol and in agreement with the CMWs women were asked to complete the Whooley questionnaire (NICE 2016). Women who were identified as having low mood were then briefly informed about the study, and given an information leaflet that included contact details for the research team.

The CMWs sought permission from the women to share their details with a member of the research team so that we could initiate contact.

**Preconceived idea/belief**

The findings from a previous study (Cust 2016) about the positive effects of peer support, and the consensus from the community midwifery team, was that an intervention such as this would be a ‘welcome addition’ to their practice and subsequently recruitment would be both ‘easy’ and ‘speedy’.

The research team expected to recruit the 20 participants within a few weeks (ten participants for the intervention and ten for the control group). However, this was not the case and the research team now consider that this requires further exploration prior to the commencement of a large, national study which, it is hoped, will begin in the spring of 2018.

We sought feedback from the CMWs as to why recruitment was difficult:

‘*We simply do not have time to take on this additional role*.’ (CMW1)

‘*My workload is so heavy that I forget to ask the ladies about the study. I remember later and then think that it is too late to go back and ask then*.’ (CMW2)

‘*I worry that the lady will be placed into the group that will not receive the support and I would feel bad asking her to take part in a study, raise her hopes and then her not to be selected….so I guess I avoid it a little, which is wrong I know*.’ (CMW3)

‘*I don’t feel confident enough about what is involved to be able to really tell my clients about it*.’ (CMW4)

‘*I feel that it is just piling yet more work onto us by management – it makes me feel frustrated and fed up*.’ (CMW5)

Initially when the research team contacted women whose details had been provided by the CMWs, the women appeared to be a little confused regarding the nature of the intervention. A number of them reported that they had not received an information leaflet.

We decided to arrange a further meeting with the CMWs to reiterate the earlier information given and to attempt to provide a ‘question and answer’ session as to how we could assist in their recruitment. Again, this was well attended, and the issues raised (as cited earlier) were discussed. Positive reinforcement and encouragement were given, and a further in-depth explanation about the study was provided. We also provided each CMW with written information about the study for their own perusal/recollection.

This appeared to help, and recruitment of the 20 participants was finally achieved over the following few weeks. However, issues remained and, as mentioned earlier, it is important for us, as the research team, to reflect upon these in preparation for further studies.

**Potential participants**

The initial recruits declined to be involved in the study following telephone contact by the research team. Their reasons were varied but included still being in the workplace, and subsequently not having enough time to receive the support. The women also felt that they may be uncomfortable talking to a stranger, and that they were not sure if it would really offer any benefit to them.

The research team provided feedback to the CMWs to ensure that they were aware that the women had not given consent and were not recruited to be part of the study.

One of the CMWs seemed to particularly engage with the study and, indeed, recruited a high proportion of the participants. We decided that it would be beneficial to speak to the CMW to ascertain, again for future reference, what her approach was:

‘*I just feel that this may be really beneficial for women and because I believe in it then I think this may come across when I am discussing it with my clients. There are so many ladies out there who desperately need this extra support and for once, I have something that I can potentially offer to them*.’

‘*I understand that not everyone can receive the support – that some may be in the other group – but that is the way that research is and everyone may benefit eventually*.’

‘*I remember to ask about the study as I have a post-it note on the front of my diary reminding me!*’

This feedback is very useful and certainly provides guidance to the research team.

**Matching of a PSW to a participant**

The PSWs were recruited via an advertisement that was placed in two local health centres and within the information point at the university campus where the research team were based.

Four PSWs were recruited. The hospital where the midwives were based kindly organised, and funded, both their references and their disclosure and barring service reviews.

Because limited information was given to the research team about the potential participant, the PSW was primarily allocated via distance to travel.

**Characteristics of PSWs**

With reference to a previous study focusing upon peer support (Cust 2016), there had been an overwhelming number of applicants for the role of PSW. This was not the case with this particular study. Although four PSWs were recruited relatively quickly there were few applications and little enquiry. It will be useful to reflect as to why this may be so. Were the adverts placed appropriately? Was the wording too dictatorial/too vague? Do we need to widen our geographical area?

The four PSWs were from a variety of backgrounds. Two of the workers were first-year mental health students, one was a full-time mother and the fourth a teacher. All, as was a requirement, had previously suffered from either antenatal or postnatal depression.

The undergraduate mental health students, although ideal in many aspects, did pose a number of issues. The amount of university work and, of course, periods in practice, allowed minimal time to focus upon their peer support role. Although they did their best to achieve this, the pressure placed upon them was rather concerning at times.

The following reflections are taken from their log books:

‘*I am really enjoying the role of a PSW but finding it increasingly hard to juggle this alongside my degree; I wish that I had more time*.’ (PSW1)

‘*I am enjoying connecting with my lady and this has also increased my confidence about my own well-being. I just wish that I could focus completely upon this role rather than juggling everything else too*.’ (PSW2)

‘*I wonder if, as a mental health student, I am trying too hard. Am I using theories, without really acknowledging that I am using them? I really wanted to just do this as a fellow sufferer but wonder if, subconsciously, I am theorising it*.’ (PSW1)

‘*I am finding the role very consuming – but really enjoying it too. I can see the value and this means a lot to me personally. I just want to give something that I never, ever had – I wish I had*.’ (PSW3)

‘*It is such a responsibility and I worry about how effective I am. I can see there are so many issues with the ladies that I am supporting but if I am doing a little bit of good then it is more than worthwhile*.’ (PSW4)

These reflections, so far, are very encouraging but, indeed, require some thought as to how realistic volunteers need to be when considering the role. As the recruiters, we need to provide further specification as to how time consuming the role may potentially be. Again, this is a consideration for our larger, national study.

**Participants**

Although, as previously discussed, recruitment was rather slow to begin with, the midwives did recruit the required number of participants.

Clarification was sought from the midwives on a number of occasions and as discussed earlier, is an issue for further consideration. An exploration as to whether all of the midwives received the relevant information should be conducted and include the consideration of whether further meetings are required to clarify any issues arising.

A small number of the participants recruited did not respond to telephone calls from the PSWs. This proved to be frustrating for the workers and understandably, they were reluctant to carry on attempting fruitless communication.

The mothers allocated to the control group expressed their disappointment about not receiving the intervention and the midwives discussed their feelings of ‘guilt’ about this. This is a problem that many researchers must be faced with but seems particularly poignant when the lack of perinatal mental health services is so well documented (Rothera & Oates 2011, Darwin *et al* 2014, Cust 2016). The midwives shared with the research team that a number of their mothers were ‘desperate’ for some ‘form of intervention’.

One participant felt that she did not form a good relationship with her worker and asked if she could receive support from a different PSW. The participant stated that she felt ‘uncomfortable’ as the PSW had openly shared her own ‘dreadful’experiences with her. This is a further issue worthy of exploration as to how much information should the PSW share. One of the recognised values of peer support is the sharing of experiences (Jacobson *et al* 2012, MacLellan *et al* 2015) but is there a limit to how much should be shared? Was the PSW still ‘recovering’ and therefore not yet in a position to support other mothers? This is very difficult to measure but an important consideration.

Some of the data has now been collated in the form of log book reflections and interviews with both the PSWs and the participants. A number of the log book reflections were more detailed than others. The research team reflected that this was to be expected, and in order not to affect the spontaneity of the inserts did not want to impose guidelines on this process. Therefore, it was useful to carry out a number of face-to-face interviews with the participants to capture the essence of their experiences.

It was agreed within the research team, prior to the interviews, that although the approach would be primarily semi-structured, four standard questions would be asked at some point within the interview. However, the research team feel that because they had to include the questions at some point, potentially rich data may have been lost because the flow of conversation was interrupted. Unstructured interviews with very little guidance may be a consideration for the larger study.

**Recommendations**

Although this study has yet to reach conclusion, there are a number of recommendations that require further exploration prior to the evolvement of the larger study as follows:

* The midwives require support and encouragement to participate in the study, they are the crucial initial link and, indeed, their workloads are very consuming. The recruitment of the participants needs to be an efficient process and the steps to follow relatively straightforward. It would also be useful to select one key member of the research team to form links with the CMWs to ensure that clarity, support, and effective communication are key factors.
* The PSWs need to be realistically aware of how much time the role will take and if they feel able to undertake this. The research team need to ensure that this is communicated clearly to the volunteers.
* It would also be useful to speak directly to the referring midwife in an attempt to gain more insight into the woman being referred – this may assist in the ‘matching’ of the PSW to the participant. The referrals from the pilot study were received via email. This was initially agreed in an attempt to reduce the pressure upon the CMW but, in retrospect, may not be an ideal referral method.
* The PSWs need to be aware of certain limitations in respect to how much they divulge or share. This is a very difficult concept because, as discussed earlier, a key success of peer support is the sharing of experiences. This will have to be explored further and discussed with both participants and PSWs.
* The travel issues are a further consideration for the PSWs. A number of them were travelling long distances and this was placing further pressure upon their already restricted time allocation. For the larger scale study, it is recommended that one of the considerations will be geographical in the matching of PSWs to participants. This was attempted in this pilot study but due to the limited number of PSWs was not feasible.

The last point is also relevant with respect to the interview process conducted by the research team. Again, travel and interviewing time had a potentially negative impact upon the research team’s resources.

**Conclusion**

It is anticipated that by early 2018 this pilot study will reach conclusion. The pilot study has been invaluable in terms of enabling reflection upon the positives and negatives and the associated potential pitfalls. The study will assist in the shaping and developing of the large scale, national study into antenatal depression and the PSW intervention.

*Dr Fiona Cust is… a Senior Lecturer in Children’s Nursing at Staffordshire University.*

*Ruth Carter is…a Senior Lecturer in Midwifery at Staffordshire University.*

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