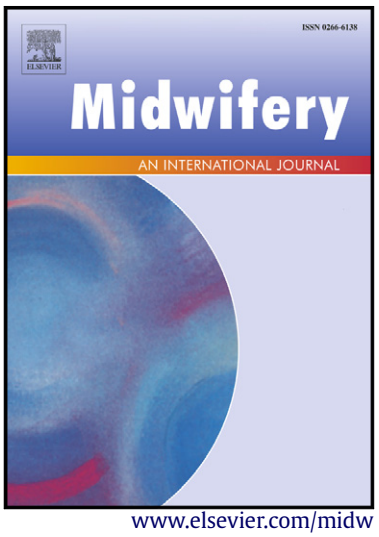

Understanding barriers to involving community midwives in identifying research participants; experience of the first Steps randomised controlled trial

Jane Stuart BA, MSc, PhD, Jacqueline Barnes BSc, MSc, PhD, Helen Spiby Rm, RGN, MPhil, Diana Elbourne BSc, MSc, PhD

PII: S0266-6138(15)00126-6
DOI: http://dx.doi.org/10.1016/j.midw.2015.04.011
Reference: YMIDW1673

To appear in: *Midwifery*

Received date: 18 November 2014
Revised date: 24 March 2015
Accepted date: 22 April 2015

Cite this article as: Jane Stuart BA, MSc, PhD, Jacqueline Barnes BSc, MSc, PhD, Helen Spiby Rm, RGN, MPhil, Diana Elbourne BSc, MSc, PhD, Understanding barriers to involving community midwives in identifying research participants; experience of the first Steps randomised controlled trial, *Midwifery,* http://dx.doi.org/10.1016/j.midw.2015.04.011

Understanding barriers to involving community midwives in identifying research participants; experience of the First Steps Randomised Controlled Trial

Jane Stuart[a]

Jacqueline Barnes[a]

Helen Spiby[b]

Diana Elbourne[c]

[a] Institute for the Study of Children, Families and Social Issues, Department of Psychological Sciences, Birkbeck, University of London, Malet Street, London WC1E 7HX, UK

j.stuart@bbk.ac.uk;

Corresponding author jacqueline.barnes@bbk.ac.uk (+44) 207 079 0837

[b] School of Health Sciences, 12th Floor, Tower Building, University of Nottingham, Nottingham, NG7 2RD, UK

helen.spiby@nottingham.ac.uk

[c] Department of Medical Statistics, London School of Hygiene and Tropical Medicine, University of London, Keppel Street , London, WC1E 7HT, UK

Diana.elbourne@lshtm.ac.uk

Abstract

Objective: to explore barriers to the involvement of community midwives in identifying women in early pregnancy as potential participants in the XX, a randomised controlled trial of a new intervention to provide health and parenting support to potentially vulnerable women.

Design: descriptive qualitative investigation using semi-structured audio-recoded interviews.

Setting: community midwifery offices.

Participants: volunteer sample of 13 community midwives.

Measurement: themes derived from content analysis.

Findings: understanding of their role in the research process was unclear to many midwives. Confusion arose about the difference between potential participant identification and trial recruitment. There were concerns about the eligibility criteria and it was suggested that there was insufficient time during booking appointments, and sometimes insufficient information, to determine potential eligibility. Midwives had concerns about some aspects of the intervention, which incorporated routine midwifery care, and had expectations that women may not like a group programme. This may have led some not to mention the trial. They were, however positive about the programme's potential for beneficial impacts on mothers and infants.

Key conclusions: Dedicated research midwives may be the best option if research studies need to identify potential participants early in pregnancy, so that they can communicate with all their colleagues.

Implications for practice: If community midwives are asked to be involved in time-critical research they are likely to need additional local resources and support.

Keywords

Pregnancy, recruitment, RCTs, qualitative methods

INTRODUCTION

The aim of the present qualitative study was to investigate the perceptions of community midwives about their role in identifying potential participants in early pregnancy for the XX RCT trial of Group Family Nurse Partnership (gFNP). The multi-site randomised controlled trial aimed to examine if provision of gFNP, compared to routine antenatal and postnatal services, could reduce risk factors for child maltreatment (author citation 1). The research team conducting the evaluation, including the interviews with midwives, was completely independent of the delivery of the programme.

The gFNP programme

The newly developed programme designed to support young and potentially vulnerable mothers has the same theoretical basis as the home-based parent support programme Nurse Family Partnership (NFP; Olds et al., 1997), known in the UK as Family Nurse Partnership (FNP) which also starts at about 16 weeks pregnancy. The aims are to improve birth outcomes, develop a warm and authoritative parenting style, good attachment, knowledge of babies' developmental needs, promote effective local support networks, increase take-up of local services, and enhance parental self-efficacy (Olds, 2006). Both FNP and gFNP are delivered by specially trained Family Nurses (FNs), FNP during one-to-one home visits and gFNP by two FNs, one of whom must also be a practising midwife; the group of 8 to 10 women have similar expected delivery dates (author citation 2). The gFNP curriculum is based on FNP materials, adapted for delivery in a group, and the FNs provide routine midwifery care in pregnancy and routine infant health checks. Reflecting 'Centering Pregnancy' (Robertson et al., 2009) mothers are encouraged to conduct some of the necessary pregnancy and child development checks themselves. Based on pilot work and to distinguish recipients of gFNP from those eligible for FNP, eligibility for gFNP and for the trial was: expectant mothers aged <20 with one or more previous live births or aged 20-24 with low/no

educational qualifications and no previous live births. Exclusions were: under the age of 20 and has received home-based FNP and, for both age groups, psychotic mental illness or not able to communicate in English (author citation 1).

The trial recruitment pathway

In the UK midwifery care is provided through the NHS maternity system, free to all women at the point of service. Community midwives are employed by local NHS organisations and provide antenatal, postnatal and some intrapartum care in community locations, including women's homes. In many areas, after a woman visits her General Practitioner (GP) to confirm her pregnancy, her details are sent to maternity services and the community midwifery team so they can begin midwifery care by arranging the 'booking appointment', ideally at about 10 weeks pregnancy. This makes them the ideal professionals to identify women for research starting early in pregnancy. The trial design included a staged recruitment strategy. The first stage was community midwives identifying potentially eligible participants based on three characteristics: age, parity and expected delivery date. At booking appointments they were asked to give all *potentially* eligible women a trial leaflet and, after answering any questions, ask them to sign an '*agreement to contact'* form so their name and contact details could be passed to the research team. The second stage was telephone contact by a researcher to establish eligibility by asking, among other things, about educational qualifications. The third stage was a home visit by the researcher to gain informed consent to participate. The trial leaflet, at the request of the ethics committee, detailed all the eligibility criteria: age, parity and educational qualifications, but it was explained at meetings to introduce the trial to midwives that they were not required to ask potential participants about their educational qualifications, that the researcher would do this during the screening phone call. Initial discussion with local midwifery teams had established

that they did not routinely ask about education or keep details in their records of qualifications.

Identifying sites and involving midwives

All FNP teams in England with a midwife as part of their team were invited to take part in the trial and an introductory meeting was held with those coming forward. While funding to support FN training was provided by the FNP National Unit, local commissioners were required to agree funding to support the delivery of the programme, which limited the number of teams coming forward. Interested teams were asked to respond to a formal Invitation To Tender, to include information about the likely number of potentially eligible women giving birth in their area per year, and also assurance that collaboration with local midwifery had been established. Further visits were made to each potentially eligible site to explain the trial to midwifery managers in more detail and to gather further details about birth rates in previous years. After confirmation of trial involvement researchers again met with midwifery managers and meetings were arranged, more than one per site if necessary, so that all the local community midwives could learn about the trial. In addition to discussion a purpose-made DVD was shown explaining both the programme and the recruitment process, as well as explaining how routine maternity care was delivered within gFNP. Managers were provided with copies of the DVD to share with team members who could not be present at meetings.

After establishing how many community midwives worked in each location (range 27 to 80 per site), each was provided with a laminated card detailing the age and parity requirements, the time frame for seeking trial participants with the associated EDD range, and a suggested script that they could use to introduce the trial. Each was also provided with a bundle of trial information leaflets, 'agreement for contact' forms, and prepaid envelopes so that any signed

forms could be posted directly to the research team, with the option of collection from the midwifery office by the local researcher.

Recruitment challenges

The sample size was calculated on the basis of scores on the Adult Adolescent Parenting Inventory (AAPI-2) (Bavolek, 1999) one of the key measures to be used to measure outcomes. The trial proposed to recruit sufficient mothers and babies (families) to allow the trial to detect a difference between groups of 0.5 standard deviations, with 90% power at a significance level of 0.05 (2-tailed), considered to represent a moderate size of effect (Cohen, 1988). Allowing for an expected 30% drop out rate (based on pilot applications of the programme in England) it would be necessary to recruit a minimum of 84 families per arm of the trial. Given the vulnerable nature of the participants a conservative proposal was to recruit 100 families per arm. Based on the assumption that recruitment to the trial would be in the region of one in three identified, and experience from two pilot sites, 600 eligible women would therefore need to be identified (author citation 1).

Each FNP team was to deliver two groups with starting dates separated by at least three months so recruitment was planned in two phases. It became apparent partway through phase 1 of the trial, seeking to recruit the first 100 participants (out of 200), that the number of names of potential participants coming from community midwives was not sufficient to enable 100 to be recruited within the planned time frame. Follow up visits were made to midwifery departments at all sites by the research team timed to coincide with local midwives' weekly meetings and further presentations about the trial were made. In the absence of additional resources directly into the community midwifery services to acknowledge the midwifery contribution, the Head of Midwifery in each site was offered funding for a midwife to attend a key midwifery conference during the following year if

sufficient potential participant names were provided to enable recruitment of a viable sample for that site (N=16, 8 intervention and 8 control).

At the same time alternative strategies for identifying potential participants were developed and implemented following approval by the Research Ethics Committee. It was agreed that they could also be identified by other professionals with approved access to maternity records, specifically FNP midwives planning to deliver gFNP for the trial and, where available, Comprehensive Local Research Network (CLRN) research midwives and nurses. It was also agreed by the REC that that 'agreement for contact' could be gained by telephone rather than face to face since these professionals were not seeing pregnant women for routine pregnancy booking visits. The implementation of these alternative strategies improved the identification rate of potential participant names, enabling continuation of the trial.

A record was kept by the trial manager of the number of potential participant names received during recruitment for phase 1 and the professional identity of the individual providing the name. Despite additional strategies the total number fell short of the expected 300 (N=207, see Table 1). Community midwives identified a small proportion of the potential participants (37/207, 18%) with the majority (72%) identified by FNP midwives. Of the potential participants, 122 (59%) were found by researches to be definitely eligible and of those 65 (53%; 31% of all names received) consented to be in the trial, matching the expected agreement rate of 1:3 upon which power calculations were based. In subsequent phases of trial recruitment potential participant identification did not involve community midwives.

Qualitative interviews with community midwives were integral to the trial in order to gain their views on the process of identifying potential participants. The trial, including the current qualitative study, was approved by the National Research Ethics Service (NRES) Committee South West – Frenchay on 28th May 2013.

METHODS

Participants

The research team, as external researchers, had no right of access to contact details for the community midwives (N=304 at the start of the trial, range 27 to 80 per site) so requests for potential interviewees were made via managers. Community midwifery managers were contacted in six of the seven participating sites, excluding one that was experiencing major re-organisation. They were requested to forward our invitation to volunteer to take part in a research interview about the trial. The only requirement was that the midwives had been working in the department at the time the trial was launched. With a target of at least 2 per site (N=12), 17 names and contact e-mails were forwarded to the research team by midwifery managers. They were then contacted by e-mail, by the local regional fieldworker, and 13 were interviewed. Reasons for not being interviewed were that they now did not have time (2) or that there was no response to e-mail contact (2). All participating midwives gave full written informed consent. Midwives' participation was not fed back to their managers.

Procedure

After gaining informed consent, qualitative, face-to-face semi-structured audio-recorded interviews were conducted by the regional fieldworkers in private offices in the community midwives' workplaces. All fieldworkers received training in the administration of this style of interviewing. Interview topic guides with prompts were designed by XX and XX and based on those used in previous FNP evaluation research (author citation 3). They covered knowledge of FNP and gFNP, knowledge of the trial and the process of involving community midwives in participant identification, their personal experience (if any) of identifying participants for the trial, thoughts about the potential future incorporation of gFNP into mainstream services, its possible impact on mothers and children and on maternity services.

Interviews were transcribed for analysis with anonymisation. Thematic content analysis (Robson, 2011; Silverman, 2006) was used to identify major themes and sub-themes (see Table 2). Interviews were read by XX and XX and emerging themes were discussed until consensus was achieved that the themes covered all the issues raised in the interviews. Respondents were randomly numbered from 1 to 13 to maintain individual and site anonymity; the number in brackets following each quote indicates which respondent made the comment.

FINDINGS

Five major themes were identified and 13 subthemes (see Table 2).

Theme 1. Issues with the midwifery role in the trial process

(a) Insufficient information about their role

A key point was that many of the midwives were unaware of what they were expected to do for the trial. The research team made presentations to community midwifery teams at all sites, about the gFNP intervention and about the trial, with information on PowerPoint slides and a DVD, but in a number of cases there were some practitioners who could not be present. Whilst this can be understood due to clinical priorities, it makes efficient cascading to disseminate the research information essential. Some interviewees had attended a research team presentation at their site but only one reported that she had seen the DVD. While interviewees recalled being provided with the trial materials (agreement to contact forms, trial information leaflets, laminated card with local EDD range and suggested script), these were not always studied in detail nor was additional information about the trial, which would have been covered in the DVD, given by managers or by colleagues who had been present at

the explanatory meetings. The distribution of trial materials was also held up in some sites, due to staff changes or sickness.

"A lot of the community midwives had been to that meeting, but there was slow take-up and you know all the stuff was in the office, just sitting there." [1]

"It was given to me, a folder with a little leaflet and the contact sheet permission to be shared with FNP… those that did attend meetings did disseminate it down but it is like Chinese whispers… … I wish I had been at the meeting rather than getting it second hand, we were getting a bit confused by it all." [8]

"…our team leader didn't go through it, she just said there's a pack in everybody's drawer to refer people, I spoke to some of the other midwives… they said exactly the same thing, it was just in the drawer… under a pile of notes. Which is awful, because I think probably we missed a lot of people not knowing." [12]

(b) Recruiting versus identifying trial participants

Many of those interviewed appeared to think that their role was to recruit women straight into the trial rather than this being the first stage in the process. While some talked about referring others specified taking consent or recruiting to the trial.

"I did try and get the girls in and we did recruit a few of them; it's just getting the consent after and some of them were suitable but they, for whatever reason, didn't want to take part". [2]

"*I really wanted to randomise someone because I knew the midwife who was going to be working with these girls and I wanted to try and get girls onto the trial but I had no one that fitted the (criteria)…., I was trying to recruit women into the trial."* [6]

"*There were a couple of girls who had just booked that met the criteria so I rang them up, discussed it with them and asked for their consent."* [7]

(c) Insufficient time for research activities

Some respondents explained that research was not a priority for the community midwives because they were too busy most of the time to take on anything else, and were experiencing staffing difficulties.

"It's just time constraints, you're so busy, having to go through your caseload so often, more of us have got more than one caseload… we did flick through to pick out women that met the criteria…it's just added work, added pressure." [5]

"… in our team we're very short staffed, we are trying their best to recruit people, but it's quite hard…if the staffing situation was better, and there wasn't as much stress there might be more referrals." [13]

"Some people will just think 'Oh no, another research study, more work for me.'" [12]

In addition several explained that during the booking visit there would not be time to explain the trial. In the time that they get with newly pregnant women there were other, more important things they had to address.

"We have about one hour and there is so much information we have to cover and you get so bogged down with it all. We have targets, loads of things we have to address and it is just huge to remember it all." [8]

"*I think, and this is a really poor excuse, but I think it's the reality of it, we have so much information that we have to give them at booking and I think they* [community midwives] *might have seen this as just another that we have to do."* [1]

Theme 2. Issues with the criteria for trial participants

(a) Difference between identifying for FNP and gFNP

Most of those interviewed had some experience of identifying first time pregnant women under the age of 20 for FNP and passing their names directly to the FNP teams with good referral systems in place. However, the different criteria for the trial and different way to communicate names could lead to confusion.

"Yes I've referred quite a few ladies [to FNP]. *Normally if I've got ladies that want to become part of it* [FNP] *I just give them* [the FNP team] *a ring and do it that way."* [9]

"I had referred girls to the Family Nurse Partnership but not to the group one." [2]

"I do mention it [FNP] *to them … what we do is pass that on the teenage pregnancy midwife so that lady is open to being recruited by FNP."* [3]

"I had referred girls to the Family Nurse Partnership but not to the group one." [2]

"I find it a bit confusing with FNP, with the criteria for the normal FNP and then the group FNP and now the research FNP. We get confused as we don't get much time on it." [13]

(b) Criteria too detailed

Many respondents remarked that the criteria to identify potential participants for the trial were too stringent or that they did not have the necessary information at the booking visit to be able to identify women, which would mean that they could not determine eligibility ahead of the booking visit.

"I think it was quite difficult because the criteria were so strict, and, so they fit one part of the criteria, but then failed to fit on another, so it was quite time consuming for use to actually trawl through everybody's to see if anybody would fit the criteria." [4]

"I think that they found it difficult to actually, for the women to actually fit the criteria because it was a strict criteria, and if they did fit it, then most of them didn't want to do it." [9]

Some midwives reported that they found it challenging to apply the educational criteria set out in the trial information leaflet (included at the request of the Ethics Committee), although they were not expected to enquire about this aspect of eligibility. Having all the eligibility criteria on the leaflet that the midwives distributed to potential participants is likely to have brought this to their minds and may have elicited queries as they were telling women about the trial.

"I think the thing about the eligibility was the GCSEs and the education, I think we struggled a bit with that." [1]

"…the difficulty was if we did have suitable candidates, how you put it the wording of the GCSEs, how to put it in a sensitive way without being derogatory." [8]

I found it a bit mind-blowing, in age this and educational level that, and you have to keep checking, have I got this right? Is this woman the right criteria? And I didn't really understand why it was so specific on the educational level." [3]

(c) Not a fit with their population

Some midwives explained the low number of potential participants identified by their colleagues by expressing the view that the criteria excluded the women they most commonly saw in their local area.

"The majority of my caseload is women in their thirties." [4]

"Twenty to twenty four, a lot of our women in that age group are going on to have their third baby; it should be more for under twenty and their first baby." [12]

"*I had a lot of twenty year olds that already had two or three children, so they weren't meeting the criteria."* [7]

"… because the diversity of the population that we see here, I've got 80% are not necessarily English speaking… Yes I think I struggled on the recruitment side with that." [3]

Theme 3. Reasons for potential participant refusal

Many of the respondents mentioned reasons why they expected that pregnant women would not want to be considered for the trial, with the chance to receive the gFNP programme. These were partly based on responses from women who were approached, but also based on midwives' views about their likely negative responses.

(a) Pregnant women dislike groups

Almost all the respondents describe their own experiences of providing antenatal classes in a group setting (e.g. bumps and babies; parentcraft) and mentioned that pregnant women were not keen about attending groups and this was a reason why they did not raise the possibility of being part of the trial.

"There were two ladies that just fitted the criteria. We didn't pass the details on as we know the women wouldn't come to group." [4]

"I think a lot of time these days women don't particularly want to come along to a group setting, and a lot of the time they would just kind of sit there in silence, because they don't want to speak up in front of everybody else. A lot of them have got fears of their own that need addressing on a one-to-one basis… [11]

Knowing my ladies they find groups really difficult because a lot of my ladies aren't very articulate, a lot can't read." [9]

(b) Will not be able to travel to groups

Another frequent reason why refusal was expected was because midwives predicted that the pregnant women would have concerns about travelling to group. It was the act of travelling that was expected to be a barrier rather than cost as the respondents may have been aware that reasonable transport costs for group participants would be covered from research funds.

"We struggle to get them to clinic, never mind getting them to go to a different area [for gFNP]*."* [4]

"I think a lot of it with our girls is getting to wherever they needed to go, transport things like that. A lot of them were reluctant to take part in anything else and obviously we were given limited information that we could give to the girls." [2]

(c) Targeting vulnerable group who do not want more support

Although research (author citation 3) has indicated that the offer of the home-based FNP has been generally received with enthusiasm by young parents-to-be, some respondents believed that it was not the best option to offer the identified population any additional intervention or that targeting itself was not the best use of resources.

"If they have got pregnant at a young age, it's a bit of turning a leaf for them and they think they are mature and responsible enough to do it themselves."[10]

"We seem to be researching the same issues about giving women more support then they'll do better, but it seems it's always targeted at specific groups that don't tend to want to take part anyway. I think it would be better to spend the resources in a general population."[4]

Theme 4. Reservations about midwifery care as part of gFNP

(a) Concern about the midwifery care and system breakdown

Respondents expressed anxieties about what would happen to pregnant women regarding antenatal care. They feared that, for those receiving gFNP, the FN midwives would not know the hospital systems and guidelines and consequently women could be lost or missed so that they would not receive the appropriate care. All respondents also raised concerns about what might happen if there were problems, either with the pregnancy or more generally with the family, wondering who would have responsibility and how they could ensure that the women for whom they were ultimately responsible did not 'fall through the cracks' if they were allocated to receive gFNP.

"I think they were just worried about are they [FNP midwife] *acting as a midwife? Would they action it the same way we would if there was anything wrong and needed actioning? Are the FNP midwives trained beforehand? It is all about what happens if something was going wrong clinically."*[3]

"I think people have been a little bit dubious… they're a bit worried that things might go wrong…. I would like to know what is going on with my women, we don't know if things have been missed." [7]

" Things like child protection, who would refer them, who would check…when we book, we check the GP records in case the ladies haven't told us things that we need to know… who is going to do that?" [9]

(b) Concerns about self-care

Reflecting comments made to the research team during presentations about the trial, concern was expressed about the focus in gFNP on women being encouraged to check their own health status during the sessions.

"There was a lot of talk about group antenatal sessions and that it would be mums would be feeling each other's bumps, checking each other's blood pressures… So there was a lot of apprehension. I think there were a lot of midwives thinking 'well this is a bit strange'." [6]

It could be dangerous, it can promote more unnecessary work, we get calls all the time from women who have taken their own blood pressure and looked on the internet… they don't know what they are looking for ….." [13]

Theme 5. Views about the gFNP programme in the future

a) Potential for positive impact

While many reservations had been expressed about the trial process and about gFNP, when asked their opinion about the potential for programmes such as gFNP the responses were almost all positive:

"I think the impact will be a positive impact. Better health for mums, better health for babies, post- natally as well, reaching developmental goals." [10]

"I just think it would allow a wider access to more services rather than just being stuck with a midwife. We have good knowledge but no great knowledge of everything going on around us." [12]

"Having that section of the population removed from your care, for the mums, maybe that would be the best kind of care for them." [11]

b) Possible identification in future mainstreaming

Interviewees were asked what the best strategy would be for identifying women to refer to gFNP if it were to become a mainstream service and, their previous concerns notwithstanding, they generally believed that the route would need to be from community midwifery.

"Other than going through the [confidential form kept by midwives at the GP surgery] I couldn't think of another way that you could possibly get the information [to identify women for gFNP." [5]

It still has to come from us otherwise you'd have to have the other [gFNP] *midwife coming in right at the start, midwives would have to identify women for a roll-out."* [6]

I think at booking… that's a good opportunity to get the women because that's when we spend most time with them and get background information." [2]

DISCUSSION

It has been well documented that randomised controlled trials (RCTs) generally need more time to recruit participants than originally planned (Kenyon et al., 2005; author citation 4; Fletcher at al., 2012). Barriers to participant recruitment by clinicians can include time constraints, concern for patients, worry about equipoise and lack or reward or recognition for their involvement in research studies (Eborall et al., 2014; Treweek et al., 2103). Thompson and colleagues (2006) proposed that a culture of 'busyness' can lead to lack of involvement by nurses. Even nurses whose predominant role is research could lose motivation with hostility from colleagues about research (Spilsbury et al., 2007). A review concluded that clinicians may be suspicious of, or resistant to, research, may be selective in who they approach, or simply have no interest in research as it applies to their own professional activities (Fletcher at al., 2012). Dyson and Dyson (2014) also refer to the notion of 'hired

hand research' to suggest workers who perceive themselves as having little power in an organisation will not cooperate willingly or effectively in research endeavours. Giving more attention to the views of the clinicians (Fletcher et al., 2014) and their understanding of research (Ziebland et al., 2007; Paramasivan et al., 2011; Donovan et al., 2014) may help to resolve this issue.

There has been little research specifically about strategies for involving midwives in research. Compensating National Health Service (NHS) organisations for midwifery time was suggested by one review (Raftery et al., 2008) and has been successful (Kenyon et al., 2005). It has been found that midwives' involvement in research can be influenced by their overall attitudes towards research (Plumb, 2002; Poat, McElligott & Fleming, 2003) and whether they could see the value of the research for their own practice (Hicks, 1995). More recently Thomas (2013) suggested that opportunities for midwives to take part in research are infrequent and that organisational barriers such as high workloads or lack of funding prevent research activity.

This trial appeared to be a low priority for most community midwives for a number of reasons. For most of the sites, although several visits had been made by the research team, it was never possible for all the relevant community midwives to be present so information and research materials had to be passed on from others, which did not always take place. This meant that the relatively limited role required of midwives, to gain permission from women so that researchers could explain the trial, was not always fully understood. Many thought, perhaps based on experiences with other trials, that they were being asked to recruit, which would require a detailed conversation and more time for the women to think about taking part, getting back to them possibly at a later date. They also found that they did not have detailed knowledge of this (relatively new) intervention - another reason why they may have not wanted to raise the trial with women at booking appointments. We have reported the

experience of this RCT as it may have implications for similar future research projects in this field. Researchers may wish to consider alternative ways of providing information to clinical staff that do not rely on cascade between colleagues, all of whom have similar workloads.

The senior midwifery managers contacted for this trial had been involved in signing the submissions to tender to be part of the trial; they had been positive about the planned strategy in a number of meetings with the research team and assured them that they were keen to present their department as research active and research interested. But decisions about research involvement made by department heads and team leaders do not necessarily translate down to positive engagement from individual workers. Several of the trial sites, where maternity services had been in a position to support the trial at the time of the research team's first contact, subsequently experienced significant reconfiguration or other pressures. These changes restricted support for the trial and identification of potential participants. We also became aware of changes in senior midwifery teams during the course of the research that disrupted organisational knowledge and support for the trial.

The eligibility requirements for the trial were complex and specifically designed so that women offered the gFNP programme were those who were not eligible for home-based FNP, which caused confusion in that the midwives were routinely referring women to FNP. The leaflets designed to introduce the trial contained complete details of all eligibility criteria including educational qualifications. Some midwives thought that the mention of qualifications in the leaflet meant that they needed to ask about them. This was not the case; nevertheless anxiety about broaching the topic of qualifications may have led some to avoid mentioning the research.

One important aspect of the new gFNP programme was that routine (but not all) midwifery care would be provided by one of the Family Nurses delivering the programme. There was

concern about both the potential quality of that care and also how liaison with other mainstream midwifery services would take place. This represented for some an intrusion into their domain which could be perceived as a threat to their own way of working. Many comments suggested that they believed this could pose a risk to women assigned to receive gFNP, who might miss important checks or have crises that were not managed effectively. In addition some midwives expressed doubts about encouraging women to check their own health status in pregnancy. These concerns may have reduced the likelihood that the midwives actively sought out potential participants for the research trial of gFNP. It is therefore interesting that most of those interviewed expressed many positive expectations about the impacts that the gFNP programme might have, and they also indicated that, if it were to be offered as a mainstream service, they and their colleagues would be the most suitable people to look out for women to refer. Of course in clinical practice midwives can exercise their judgement about which of the potentially eligible women to refer to gFNP whereas for the trial they were being asked to pass on all relevant names, which is an important difference.

It has been made clear by Department of Health (2013) that all NHS patients should have the opportunity to decide whether they take part in research. This study was focussed on the potential for community midwifery to be involved in research and to be part of a staged process to identify young women who were potentially eligible to be part of a trial evaluating a new kind of support. The community midwifery role has expanded considerably over the past few years (Vision and Strategy: an approach in midwifery care http://www.england.nhs.uk/wp-content/uploads/2012/12/6c-midwifery.pdf). Time pressures in combination with inadequate 'cascading' of all the trial's requirements were of concern for many of those interviewed. If community midwives are to be involved in identifying participants for research trials, or in recruiting them, it might be an advantage to have a

dedicated local lead midwife to work with other midwives (Kenyon et al., 2005). However, for studies that fulfil the criterial for being in the NIHR CRN portfolio, a database of research studies eligible for CLRN support, this strategy may now be less necessary (http://www.crn.nihr.ac.uk/). With the surge in early intervention activity in the UK (Allen, 2011) there were other studies being carried out in community midwifery departments 'competing' for participants and for attention from midwifery. For these reasons CLRN research midwives, a role introduced specifically to increase recruitment into trials, may be best placed to carry out research related duties leaving community midwives free to carry out their normal duties unencumbered by research related demands on their time. Unfortunately the availability of CLRN research midwives is not consistent across regions and trusts.

A challenge for CLRN or community midwives was the lack of standardised record keeping during pregnancy across the NHS (author citation 5). Due to data confidentiality requirements within organisations, it was a time-consuming challenge to access and examine records and different databases for seemingly basic information (e.g. age and parity) relating to the same pregnant woman to find out if they might fit the initial criteria for the trial. The development of a national dataset may ameliorate this particular issue.

While some interesting points were raised during the interviews to inform future research, the limitations of the study should be noted. This small number of respondents may not represent all experiences, which would have been possible with a larger sample if the study had been funded to explore midwives' experiences in more depth.

Early intervention is high on the policy agenda in the UK and elsewhere (Allen, 2011) which often means identifying potentially vulnerable populations during pregnancy, with community midwives prime professionals for research involvement. However 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. It is also essential that midwives have sufficient understanding of the various approaches to participant recruitment and this requires continuing attention in midwifery education.

Role of the funding source: Funding was provided by a grant from the National Institute for Health Research, Project 11/3002/02. The funder had no involvement in the study design, the collection, analysis and interpretation of the data or the decision to submit the article for publication

References

Allen, G.A., 2011. Early Intervention: the next steps. HM Government Cabinet Office, London.

Author citation 1 (2013)

Author citation 2 (2012)

Author citation 3 (2008)

Author citation 5 (2012)

Bavolek, S. J., 1999. Research and Validation report. Adult-Adolescent Parenting Inventory. Park City, Utah: Family development resources.

Cohen, J., 1988. Statistical Power Analysis for the Behavioral Sciences, Second edition. Hillsdale, N.J.: Erlbaum.

Department of Health, 2013. 2013/14 Choice Framework. Accessed at http://www.nhs.uk/choiceintheNHS/Rightsandpledges/NHSConstitution/Documents/2013/choice-framework-2013-14.pdf.

Donovan, J.L., Paramasivan, S., de Salis, I., Toerien, M., 2014. Clear obstacles and hidden challenges: understanding recruiter perspectives in six pragmatic randomised controlled trials. Trials 15, 5.

Dyson, S.M., Dyson S.E., 2014. The politics of health services research: health professionals as hired hands in a commissioned research project in England. Sociological Research Online 19, 14.

Eborall, H. C., Dallosso, H. M., Daly, H., Martin-Stacey, L., Heller, S. R., 2014. The face of equipoise - delivering a structured education programme within a randomized controlled trial: qualitative study. Trials 15, 15

Fletcher, B., Gheorghe, A., Moore, D., Wilson, S., Damery, S., 2012. Improving the recruitment activity of clinicians in randomised controlled trials: a systematic review. BMJ Open, 2, e000496.

Hicks. C., 1995. A factor analytic study of midwives' attitudes to research. Midwifery 11, 11-17.

Kenyon, S., Rhodes, A., Taylor, D. J., 2005. A recipe for successful recruitment to a randomised controlled trial. MIDIRS Midwifery Digest 15, 16-19.

Author citation 4

Olds, D., 2006. The Nurse-Family Partnership: an evidence-based preventive intervention. Infant Mental Health Journal 27, 5-25.

Olds. D., Kitzman, H., Cole, R., Robinson, J**.,** 1997. Theoretical foundations of a program of home visitation for pregnant women and parents of young children**.** Journal of Community Psychology 25, 9-25.

Paramasivan, S., Huddart, R., Hall, E., Lewis, R., Birtle, A., Donovan, J.L., 2011. Key issues in recruitment to randomised controlled trials with very different interventions: a qualitative investigation of recruitment to the SPARE trial (CRUK/07/011). Trials 12, 78.

Plumb, R., 2002. Midwives' attitudes to research-based practice. Part 2. MIDIRS Midwifery Digest 12, 308-312.

Poat,A., McElligott, M., Fleming, V., 2003. How midwives' attitudes can affect the research process. British Journal of Midwifery 11, 396-400.

Raftery, J., Bryant, J., Powell, J., Kerr, C., Hawker, S., 2008. Payment to healthcare professionals for patient recruitment to trials: systematic review and qualitative study. Health Technology Assessment 12, No. 10.

Robertson, B., Aycock, D.M., Darnell, L.A., 2009. Comparison of Centering Pregnancy to traditional care in Hispanic mothers. Maternal and Child Health Journal 13, 407-414.

Robson, C. 2011. Real world research. Third Edition. John Wiley & Sons, Chichester.

Silverman, D., 2006. Interpreting qualitative data: methods for analysing talk, text and interaction. Third edition. Sage, London.

Spilsbury, K., Petherick, E., Cullum, N., Nelson, A., Nixon, J., Mason, S., 2007. The role and potential contribution of clinical research nurses to clinical trials. Journal of Clinical Nursing 17, 549-557.

Thomas, S., 2013. Research within the field of midwifery: the monster under the bed or just an old sock? British Journal of Midwifery 21, 435-438.

Thompson, D.S., O'Leary, K., Jensen, E., Scott-Findlay, S., O'Brien-Pallas, L., Estabrooks, C.A., 2006. The relationship between busyness and research utilization: it is about time. Journal of Clinical Nursing 17, 539-548.

Treweek, S., Mitchell, E., Pitkethly, M., Cook, J., Kjeldstrøm, M., Johansen, M., Taskila, T.K., Sullivan, F., Wilson, S., Jackson, C., Jones, R., Lockhart, P., 2013. Methods to improve recruitment to randomised controlled trials: Cochrane systematic review and meta-analysis. BMJ Open 3, e002360.

Ziebland, S., Featherstone, K., Snowdon, C., Barker, K., Frost, H., Fairbank, J., 2007. Does it matter if clinicians recruiting for a trial don't understand what the trial is really about? Qualitative study of surgeons' experiences of participation in a pragmatic multi-centre RCT. Trials 8, 4.

Table 1. Source of potential participant names and recruitment in phase 1 of the study

Participant identified by:	Site							Totals
	A	B	C	D	E	F	G	
Community midwives	2	5	1	18	2	3	6	37(17.9%)
FNP midwives	14	30	27	10	25	22	21	149 (72.0%)
CLRN midwives/nurses	8	-	-	7	-		6	21 (10.1%)
Outcome after research contact								
Eligible and recruited	7	10	9	7	7	10	15	65 (31.4%)
Eligible and declined	12	11	2	9	13	5	5	57 (27.5%)
Not eligible	4	7	17	9	4	5	13	59 (28.5%)
Not able to contact	1	7	0	10	3	5	0	26 (12.6%)
Total names received	**24**	**35**	**28**	**35**	**27**	**25**	**33**	**207**

Table 2. Qualitative themes and subthemes emerging from community midwife interviews

Main themes	**Sub-themes**
1. Issues with midwifery role in the trial process	(a) Insufficient information about their role
	(b) Recruiting versus identifying study participants
	(c) Insufficient time for research activity
2. Issues with criteria for trial participants	(a) Identification for ongoing service (FNP) versus intervention for trial (gFNP)
	(b) Criteria too detailed
	(c) Not a fit with local population
3. Reasons for potential participant refusal	(a) Pregnant women don't like groups
	(b) Women will not travel to groups
	(c) Vulnerable population do not want to be identified for more support
4. Reservations about midwifery care as part of gFNP	(a) Concern about quality of midwifery care and system breakdown
	(b) Concern about self-care in gFNP
5. Expectations about gFNP in the future	(a) Potential for positive impact
	(b) Possible role of midwifery in identification

Acknowledgements: We would like to thank all the community midwives who took the time to talk to the research team and all those who identified participants for the study. We would also like to than the fieldworkers who conducted and transcribed the interviews: Laura Dean, Julie Henderson, Claire Taylor, Hannah Want and Melissa Watson.