Midwifery 31 (2015) 779–786

Contents lists available at ScienceDirect

Midwifery

journal homepage: www.elsevier.com/midw

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

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ARTICLE INFO

Article history:
Received 18 November 2014
Received in revised form
24 March 2015
Accepted 22 April 2015

Keywords:
Pregnancy
Recruitment
RCTs
Qualitative methods

ABSTRACT

Objective: to explore barriers to the involvement of community midwives in identifying women in early pregnancy as potential participants in the first steps study, 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-recorded 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.

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 first steps RCT trial of Group Family Nurse Partnership (gFNP). The multisite randomised controlled trial aimed to examine if provision of gFNP, compared to routine antenatal and postnatal services, could reduce risk factors for child maltreatment (Barnes et al., 2013). 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

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http://dx.doi.org/10.1016/j.midw.2015.04.011
0266-6138/

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 8–10 women have similar expected delivery dates (Barnes and Henderson, 2012). 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. On the basis of 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 (Barnes et al., 2013).

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 27–80 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. On the basis of 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 (Barnes et al., 2013).

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 ($N=16$, eight intervention and eight 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 as 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