

DECIDING TO JOIN A PERINATAL RANDOMISED CONTROLLED TRIAL: EXPERIENCES AND VIEWS OF PREGNANT WOMEN ENROLLED IN THE MAGPIE TRIAL

Abstract

Objective

To provide insight into pregnant women's experiences of participating in a large multi-centre randomised trial.

Design

Qualitative semi-structured interviews.

Setting

Six UK maternity units.

Participants

Women recruited to the Magpie Trial. The Magpie Trial was a trial of prophylactic anticonvulsants for women with severe pre-eclampsia.

Measurements

Findings

A number of major but related themes emerged regarding influences on the women's decision-making: unpredictability of pre-eclampsia; quality of information received; role of others in the decision-making process; perceived personal benefit from trial participation; and perception of voluntariness of joining.

Key conclusions

The data presented give valuable insights into the women's views and experiences of decision-making. Research into many of the other elements of care given during

pregnancy and childbirth is still needed; and with this need comes the ethical responsibility of researchers to ensure trials are performed in the most scientifically robust ways, which are also acceptable to women. To examine the experiences of those involved in trial participation and their views about doing so is a crucial way of advancing this. The QUOTE Study increases understanding of the experiences of women participating in a randomised controlled trial.

Implications for practice

The general implication for practice is that procedures are needed that can improve the design and conduct of randomised trials and therefore ultimately enhance the experience for future women. Recommendations include informed consent should be tailored, recognising individual differences in the desire for information. For instance the time individuals need to make consent decisions varies, as do their desires to consult with family before agreeing.

Introduction

Randomised controlled trials (RCTs) are considered the most rigorous method for determining the efficacy of treatment. Issues regarding the randomisation of pregnant women have been identified as needing special consideration (Mohanna, 1997), (Mohanna and Tunna, 1999), (Lupton and Williams, 2004). Women undoubtedly feel responsible for the child they carry to the extent that they often modify their habits and lifestyle during pregnancy. Pregnancy may affect their ability to make free choices: they may feel bound to accept interventions that might benefit the unborn child which they would rather decline for themselves, or they may refuse treatment for themselves in case it should harm the baby. Given that increasing numbers of women are being approached to participate in trials, it is surprising that there is little research relating

specifically to pregnant women's experiences of participating in trials (Baker et al., 2005).

The broad aim of the QUOTE (Qualitative Understanding of Trial Experience) Study was to provide insight into pregnant women's experiences of participating in a large multi-centre randomised controlled trial – the Magpie Trial. This paper presents data from one aspect of participation explored in the QUOTE Study, namely, the process of decision-making around whether or not to join the trial.

The Magpie Trial

The Magpie Trial was a randomised trial of prophylactic anticonvulsants for women with severe pre-eclampsia. The trial recruited 10,141 women from 33 countries and demonstrated that magnesium sulphate more than halves the risk of eclampsia (Altman et al., 2002), without an increase in risk of death or neurosensory disability for the child by age 18 months (Magpie, 2007a), or in maternal death or serious morbidity potentially related to pre-eclampsia for the mother (Magpie, 2007b).

Women were eligible for the trial if they had pre-eclampsia (hypertension plus proteinuria), there was clinical uncertainty about whether to use magnesium sulphate, and they had either not yet given birth or were 24 hours or less postpartum. For many women, developing pre-eclampsia is an unexpected and very difficult experience. Due to its unpredictability and the speed at which pre-eclampsia can develop, many women

offered randomisation to the Magpie Trial would likely have had little understanding of the disease before it became evident. The nature of the trial meant that women were required to give informed consent in a relatively short space of time, as prolonged consideration could have meant delaying the start of treatment to the point it became futile, and therefore ethically problematic.

In the UK arm of the Magpie Trial, follow-up assessment for both women and children was by postal questionnaire (Magpie, 2004). Women were contacted when their children were approximately 2 years old to complete a questionnaire incorporating the Ages and Stages Questionnaires (ASQ) (Squires J, 1999). Children were considered 'screen positive' for neurosensory disability if they failed the ASQ, if the ASQ could not be scored, or if the child passed an ASQ for a younger age group. The families of these children were contacted by telephone and offered a home visit for further assessment. Children were considered 'screen negative' if they passed the ASQ for their own age group, or for an older child. A proportion of the screen negative children were also offered a home visit. Methods used for follow-up in the United Kingdom are described in more detail elsewhere (Smyth et al., 2009b).

Methods

The research methods utilised in the QUOTE study were in part determined by procedures already in place as part of the Magpie Trial follow up. The first part of the QUOTE Study involved analyses of data about trial experiences which were already

being collected as part of the postal questionnaire sent to women involved in the UK follow-up study. This questionnaire included questions exploring the women's experience of participating in the trial, findings from which have been reported elsewhere (Smyth et al., 2009a). In total, 619 women across the UK returned this questionnaire (81% response). The second part of the QUOTE study was designed to explore in greater depth the women's experiences of joining the Magpie Trial, by interviewing a subgroup who completed and returned the postal questionnaire.

The decision-making process around joining MAGPIE was a focal point of the interview schedule. Women were asked about several aspects of their decision to join the trial, such as how difficult or easy the decision was to make, what factors had to be taken into account, for example their circumstances at the time, who was with them and what involvement these people played, including the recruiting clinician. Women were asked about the timing of approach, how quickly their decision was made and about quality of the information received.

For practical reasons women were defined as eligible for interview if they lived within a 100 mile radius of the lead researcher in Liverpool (RMDS). Recruitment was therefore confined to six maternity units (three in the north west of England, two in Yorkshire and one in the Midlands). They included a mixture of district general and teaching hospitals. In total 219 women were recruited to the Magpie Trial from these hospitals, among whom an 83% (n = 181) response rate to the follow-up study postal questionnaire was achieved. Forty-five of these 181 women were offered a Magpie follow-up study home

visit, as their children screened positive on the ASQ. These women were therefore also eligible to be interviewed for QUOTE, of whom 30 were invited to take part and 24 agreed. Of the remaining families whose children screened negative and so were not eligible for a home visit (136 from the six units), 20 were selected at random and offered an interview, of whom 16 agreed to be interviewed for QUOTE (Figure 1).

Recruitment:

Methods of recruitment for the QUOTE Study interview depended on whether the women had had a home visit or not. Where a home visit was undertaken, eligible women (those from the six pre-selected units) were invited, at the end of the visit, to take part in a semi-structured interview at a later date. If they were willing, in principle, to consider doing so, they were given the QUOTE Study information leaflet, consent form and prepaid envelope. Women were not required to decide either to join or decline participation to the interview at the time of the follow-up study home visit. Rather, women were asked to consider being interviewed and, if agreeable, sign the form and return it in the prepaid envelope in their own time to the trial co-ordinating centre.

Where no home visit was undertaken (women not eligible for a home visit as child screened negative on ASQ), a random sample were sent a letter, after return of their completed questionnaires, informing them about the QUOTE Study and inviting them to take part in a semi-structured interview. The Magpie Trial co-ordinating centre identified

these women. The women were required to actively opt into the study by considering and signing the consent form and returning it in the prepaid envelope in their own time.

Analysis:

Thematic analysis of the data began with formal line-by-line analysis (Morse JM, 1996). The next stage was to develop an index for the content (Polit DF, 2006). This involved creating a coding scheme, with the support of a qualitative computer analysis package (WinMax pro) to facilitate the analysis. This stage of the analysis related to the major points of interest, for example the women's views and experiences of being recruited to Magpie and shared characteristics. After coding the data it was necessary to identify and select patterns and themes. The data were then grouped together within the defined themes. These steps were led by RMDS but to minimise possible interpreter bias and assess the plausibility and trustworthiness of the interpretation of the data, a sample of the interviews were themed independently by the other members of the study team (AJ and DE).

Ethics approval for the QUOTE study was obtained from the Northwest Multicentre Research Ethics Committee.

Findings

Fifty women were offered an interview and ten declined: six having had a home visit and four not. All those who declined had been recruited to the Magpie Trial while still

pregnant; three of their infants were admitted to the neonatal intensive care unit after birth, but the children of all those whose mothers declined an interview were developmentally normal at follow up.

The interviews were carried out at different time points after recruitment to the trial. Although the follow-up study aimed to assess children at two years of age, this was not always the case, as follow-up did not start until the Magpie Trial was complete. Hence the interval between randomisation and interview was greater for those women who were recruited early in the trial. Timing of the interviews also depended on completion of the follow-up study postal questionnaire, as women could only be contacted and offered an interview once they had completed their questionnaire and for the majority this was also after their follow-up study home visit (n=24). The children's ages therefore ranged from two years to four years and seven months (mean time three years and one month, $SD\pm 9.57$ months). For those women who had a home visit performed (n=24) the interview took place on average eight weeks later. The interviews took place from September 2002 to May 2004. In all but one, women were interviewed alone; for one woman (aged 16 at the time of recruitment) her mother was also present at the interview at her request and participated throughout. All interviews were performed in the women's homes. They lasted between 30 and 120 minutes (mean time 50 minutes, $SD\pm 20.91$ minutes), and all were tape-recorded with the permission of the women.

Sampling for the interviews was not aimed at trying to produce a statistically representative sample of the overall UK Magpie Trial population, but at ensuring that meaningful exploration could be made between different women's experiences of the Magpie Trial. It was acknowledged that the women's experiences, perceptions or recall of the Magpie Trial could be influenced by a number of factors. Those that were identified as important for consideration were: whether the resultant child had some degree of developmental delay or the woman herself was suffering long-term hypertensive problems (as it was thought possible that such women could attribute their problems to the trial and therefore view the study in a negative way); and pregnancy status at the time of recruitment (since approximately 78% of the women were recruited to the Magpie Trial while still pregnant this too could potentially influence their perceptions of the trial, given that the difficulty parents face when asked to consent to a research trial in which an unborn baby's needs are to be considered).

Twenty two of the women interviewed had been allocated to magnesium sulphate; and 18 to placebo. They were aged from 16 to 39 years (mean years 29). There were some differences between the women interviewed compared with UK trial participants overall, in terms of characteristics at trial entry and outcome after randomisation (Table 1). Although these differences were not statistically significant, a higher proportion of interviewed women were randomised to the trial postnatally (27% cf. 22%; Relative Risk (RR), 1.31 Confidence Interval (CI) 0.64 to 2.69); had had a caesarean section (76% cf. 60%; RR; 2.08 CI 0.87 to 4.97); had their labours induced (72% cf. 56%; RR; 1.45 CI 0.77 to 2.76); and were recruited before 34 weeks gestation (38% cf. 34%; RR;

1.07 CI 0.52 to 2.19). Due to purposive sampling, a statistically significantly higher proportion of women whose children screened positive on the ASQ were interviewed compared with women not interviewed (83% versus 29% (RR; 2.85 CI 2.29 to 3.56)).

Themes identified from the interviews relating to decision to join

A number of major but related themes emerged regarding influences on the women's decision-making:

- Unpredictability of pre-eclampsia
- Quality of information received
- Role of others in the decision-making process
- Personal benefit from trial participation
- Perception of voluntariness of joining

Unpredictability of pre-eclampsia

It became apparent in the interviews that the clinical circumstances around trial recruitment were an integral part of the women's decision-making experience. As with many emergency situations where treatment is needed urgently, women eligible for the Magpie Trial were required to make their decision to join in a very short space of time. Prolonged discussion could have meant delaying the start of treatment to the point

where it became futile. The women also expressed concerns associated with the seriousness of pre-eclampsia:

“I had so many people around my bed, I don't really remember. I had all sorts of people doing all sorts of things. It's not like being asked to join a trial when you are well is it? You are being asked to join a trial when you could die, basically.” [09]

“I recall him telling me what it was about but at the same time I had a paediatrician telling me what the odds of the baby surviving were.” [28]

However, for others their situations were different and they described a much more relaxed and calmer situation. It appeared from their accounts that the decision to participate in Magpie was relatively easy and uncomplicated:

“She came and talked briefly to us about it and gave us some leaflets and then walked away and came back later. I said 'Yes'. It was quite a casual decision in a way. We didn't really agonise over it.” [04]

“In my own mind it was a very quick decision to make. I had weighed up the pros and cons and decided yes, in probably minutes.” [13]

Many women had no prior knowledge of the trial; most said they would have preferred to know about it prior to the point at which they had to make a decision to join; and felt

that had they been asked earlier in their pregnancy they would have had a better appreciation of its purpose:

“It may be good to be told about it at the beginning of the pregnancy rather than you giving birth and you are really poorly or you are on drugs so your head is not quite there.” [23]

“I really don't think they should ask you when you are in the late stages of labour and about to give birth” [30]

Some women, however, did appreciate the justifiable limitations on the clinicians in being able to predict which women would become ill with pre-eclampsia and therefore eligible for the Magpie Trial. A substantial number of women interviewed acknowledged the difficulties associated with the provision of trial information in their particular circumstances and appreciated that giving information prior to the event was not necessarily a viable solution. There was awareness by some women that there can be no ‘best’ time to give this information, since earlier provision could have caused unnecessary worry:

“No one knew I was going to get sick, so I could not have been asked earlier.” [31]

“I don't know what is the way round it. They couldn't approach me when I was at home and nobody knew I had pre-eclampsia” [04]

“It can't be the midwife that you see for your antenatal things because they are not based in the hospital. It has to be a midwife based on the delivery suite and you don't really know because you only go in there when it's actually happening.” [01]

Quality of information received

Of the 40 women interviewed, 28 recalled being given the Magpie Trial information leaflet at the time of recruitment; eight reported they did not recall seeing the leaflet at any time; and four women were unsure. Nineteen women stated that they had read the information leaflet at the time of recruitment, although of those three felt that due to the difficult circumstances at the time, they could not comprehend its contents. Eight women reported they did not read the leaflet at the time of recruitment, though for two of these women their partners did. One woman did read the leaflet but only *after* agreeing to join the trial. None of the remaining women recalled seeing the leaflet. One woman recalled seeing a poster about the trial in the waiting area of the delivery suite prior to being admitted.

At the time of recruitment the majority of the women (n=30) were given information orally by a midwife about the trial; for six this was in conjunction with an obstetrician. An obstetrician discussed the trial with the other ten women. Most women (n=38) recalled hearing about the trial for the first time while they were being cared for in a high

dependency unit (situated on the delivery suite), either while in labour, or having their labours induced, or moments before having a caesarean section. The remaining two women were on an antenatal ward.

Women recruited to the Magpie Trial had noticeably differing requirements regarding the amount and content of trial information they sought. However, generally they felt that they did not receive adequate explanation and a sufficient level of detail about the trial prior to joining:

“I didn't know what it was for, whether it was to bring my blood pressure down. No one even mentioned fitting that was completely new to me. It is the details of actually what it is for more than what it does.” [40]

“I think they should have gone through it a little bit more to explain what would happen and a bit more information about the trial - no one really said it would stop convulsions or it would stop you from developing high blood pressure, they just did not explain it very well.” [30]

Women discussed several issues regarding information provision and gave suggestions of what they would have liked to receive. These included: what the aim of the trial was, what it was hoping to find out in relation to pre-eclampsia, how the trial treatment might

work, the possible risks of joining, and how the trial would be administered. Conversely, being overloaded with information and giving explicit descriptions of their situation was also seen as problematic for some women. Some appeared to prefer not being given a full and frank description of the trial or their condition, perceiving this additional information as either unnecessary or creating anxiety:

“It's like if I had known all that I would have been, I think my blood pressure would have been even higher! I think at the time the information I was given was as much as I could have taken in with everything else that is going on at the time.” [05]

“I think if someone would have said when I was two months pregnant this trial is going on I think it would have scared me. You know ‘oh my god those terrible things could go wrong with me!” [08]

For women who had difficulty comprehending the trial information, the language the midwives or obstetricians used to explain the trial appeared to be the cause of misunderstandings. Women stated that clinicians provided oral information that was too technical for them to grasp; and that the concepts used by the clinicians were often unfamiliar. Women wanted the information to be in clear, simple, lay language and presentation:

"I suppose if he (*the doctor*) had simplified it. The doctor who was telling us gave us this sales pitch in the words he had obviously come to use and when he hit a blank wall he did not know how to explain it in a more plain English way. What I had to do to make my decision was I had to ask him: 'the way you have explained this trial to me, I think it is x, y z am I right?' and I actually had to ask him 'is this what you are telling me?' I actually had to come up with my own way of interpreting what he said." [03]

"Not that I could really understand the doctor. It was the midwife really who explained it to me she explained it sort of in our words, you know, because doctors give you all these big words don't they that you don't understand?" [36]

Contrary to the assumption that clinicians would be familiar with the design and purpose of any trial they collaborated in and recruited patients to, a number of women in the QUOTE Study described instances where the recruiting clinicians appeared not to be familiar with some aspects of the Magpie Trial:

"I knew there was a minimum risk of things going wrong, but I don't think they knew that much about it themselves. If they'd of been trained more on it maybe that would have helped them. They were just a bit, I don't know, they just didn't give me that much information back." [16]

“She was nice, but she did not seem to know a great deal about it and there was not much information” [34]

Role of others in the decision-making process

Reassurance from attending clinicians

The influence of the clinicians emerged as key to the women’s decision-making process. Their accounts demonstrated that they had considerable faith and trust in their clinicians, and this appeared to be a motivator to joining:

“I just automatically trusted them I suppose.” [15]

“You trust that the doctor would not give you something that is going to give you a long-term problem. You have to take advice from the people who know more about it than you.” [09]

“I knew they would not give it to you if there was any serious risk to me or the baby. They would not do it if there was a serious risk, they were trying to get rid of it not produce more.” [30]

Role of family members

As previously described, women eligible to join the Magpie Trial were in an emergency situation, sometimes life-threatening. As with most hospital emergency situations, partners, family members or friends are able to be with the patient throughout the critical period. The women in the QUOTE Study were therefore asked who was with them at the time they were approached about the Magpie Trial and what influence, if any, this person(s) had on their decision to join. Most women (32) had a support person with them when they were asked to consider joining the Magpie Trial: this was usually their partner, but sometimes an additional family member. It was apparent however, that these partners and family members did not actively participate in the decision to join Magpie; in the main, the decision rested with the women themselves:

“My husband was there. I would think though that most women make the decision on their own, the way that my husband looked at it is it is not being administered to him it's my body so it's my decision.” [12]

“It was my decision. I think my partner knew at the end of the day it was my decision. Yes it was just very much my decision.” [13]

Some women, however, did acknowledge that their partner or support person played a part – even if relatively small - in their decision to join Magpie:

“I honestly believe he had input, because he does have an input, but it was my decision to take.” [39]

“I just wanted a second opinion from my friend. I just said what do you think? I remember her having a look at the leaflet.” [31]

For the eight women who were approached to join the trial while on their own, it was apparent from their responses that at the time of recruitment their partners had only recently left their side and being asked to join the trial while alone did not seem problematic:

“I just did it on my own. They asked me did I want to discuss it with my partner before I started the trial but to me it was my choice, it was me that was carrying the baby, it was me that was going through it.” [36]

“I was on my own, personally it didn't bother me. It might bother some people but personally it didn't bother me. Later on he fully agreed. He said whatever you decide is fine.” [26]

In summary, then, although partners and family members were often present they did not, in the majority of cases, play a significant role in the decision-making process. It was the women themselves who ultimately made the decision to join Magpie. The

reasons given for this were that it was the woman herself who would be receiving the trial treatment and it was therefore her right, ultimately, to choose.

Personal benefit from trial participation

Some women saw joining the Magpie Trial as a vehicle for obtaining the 'active' treatment - and for getting a drug that they would not otherwise receive, but which had been suggested to them by the recruiting clinicians as one that would prevent them from experiencing a seizure. As a result they believed participation to be beneficial to them:

“The way it was explained I got the impression that they had already got an idea that magnesium sulphate was of benefit. I probably hoped that I would have got the magnesium sulphate. I hope I do not get the dummy if you like. I hope I do get it. [03]

“They explained that the magnesium sulphate would bring my blood pressure down, and even though I was told one would be a dummy, I still did not click that I could have a dummy. I just thought yes I will have it” [24]

There was limited appreciation of any potential for harm to either the woman or her unborn baby; and a clear belief among the women that magnesium sulphate was beneficial. Women also appreciated that irrespective of which trial treatment they were randomised to, they would not be denied magnesium sulphate if this was clinically

indicated, i.e. when having an eclamptic convulsion. This made some women unconcerned regarding the implications of joining:

“I asked if I did get worse what would happen and she said we will take you off this and we would give you magnesium sulphate because it has been tested and that will help if you do get eclampsia.” [11]

“She said in America they gave magnesium sulphate routinely and yet it wasn't proven in this country and it would prevent if not a first fit then it would certainly prevent subsequent fits and that's how it was explained to me.” [37]

perceived voluntariness of joining

The responses from some women clearly showed that although in a clinically difficult situation, they did not feel pressurised by the clinician to take part in Magpie and understood the voluntary nature of joining:

“The midwife in the delivery room said it was my choice and there is no pressure. She explained there was no pressure and they would not come back to me and ask again”
[16]

“I did have a choice. I definitely had a choice I was not forced into it. It was completely my choice to take part.” [19]

Some women discussed the value of research *per se* and thought it was desirable to take part, even a person’s duty. Participating also improved their personal experience:

“I think if you are really kind and you think about other people then you should, then you’re thinking about the welfare of other people, no I think you should help other people out.” [22]

“I felt a bit honoured. I had gone through something that other people wanted to learn about and I am all for research. I mean if people can stop this happening then I am all for it.” [11]

“I think it’s good that research is done and I think if we didn't take part in research then we wouldn't have all these drugs so I do believe in research. I am glad I did take part in.” [25]

Willingness to participate also seemed to rest on the women’s awareness that they could withdraw from the trial at any time. For four women who volunteered this information it appeared this positively influenced their decision to join.

Discussion

Amount and timing of information

During the interviews most of the women described the time of recruitment as immensely frightening, stressful, and even very traumatic. Much of this was related to the unexpected and sudden occurrence of severe pre-eclampsia. For some women, however, it appeared the decision was made quickly because of its ease: the decision appeared casual even, a decision that was not particularly agonised over.

Due to the features of pre-eclampsia clinicians were unable to identify who would and would not be affected by the condition in advance, so the provision and timing of information about possible treatments and potential clinical trials relating to pre-eclampsia was challenging. Although the majority of women were reasonably satisfied with the level of detail of information received, it was evident the timing of information provision was problematic. Most indicated that had they been told earlier in their pregnancy they would have found the decision to join less stressful. However, some said they would not have wanted to know about the trial earlier and made comments to the effect that knowing about the trial before becoming eligible would have caused them unnecessary worry.

Our findings are similar to those of Mohanna (Mohanna and Tunna, 1999) in their study of pregnant women's decisions to withhold consent to a preterm labour trial. In that study, most of the women had not considered they were at risk of preterm labour and therefore could not see the relevance of being told early about the trial. Vernon et al

(Vernon et al., 2006) have outlined how informing women early in pregnancy can bring about tension between promoting pregnancy and labour as a normal physiological process and flagging up the possibility of experiencing an adverse event.

Self-interest is a key motive for participating

Research participants in randomised trials often believe that participation will result in better treatment. This 'trial effect', also known as the 'Hawthorn effect', has been explored in at least four systematic reviews (Stiller, 1994), (Braunholtz et al., 2001), (Peppercorn et al., 2004), (Vist Gunn et al., 2008). Although their conclusions differ regarding as to the extent to which trials actually have benefit, all these authors agree that it is more likely that trials have a positive than negative effect on the outcomes for those taking part. The findings from the QUOTE Study are consistent with this as the majority of women agreed to participate in Magpie primarily because they believed participation would result in benefit to either themselves or their baby. Major motivating factors for participation fell into three broad categories: self-benefit (trial might help treat pre-eclampsia), benefit to their child (treatment might minimise the associated risks of pre-eclampsia to the unborn baby) and altruism (participation might help future women or is for the good of medical science). In most cases, women identified more than one benefit; and just five of the 40 women interviewed identified altruism exclusively as their reason for taking part.

The majority of women expressed a preference for the active drug, magnesium sulphate, and very few voiced concerns about any possibility of risk to either themselves or their unborn baby. In a number of accounts it appeared the recruiting clinician had expressed the hope that the woman would be randomised to magnesium sulphate, because he/she was already convinced of its benefit. This is reflective of the fact that although at the time of the trial there was 'collective equipoise' (uncertainty within the medical community as a whole over which treatment is best) (Freedman, 1987) regarding the benefits of magnesium sulphate, some clinicians were not in 'personal equipoise'. This finding of lack of personal equipoise by recruiting clinicians supports the results of other studies (Canvin and Jacoby, 2006), and is perhaps not surprising given that a fundamental ethical perception of research is that the well-being of an individual must never be sacrificed for some perceived greater collective good.

Influences on participation

Trust in the midwife or obstetrician was another important element in the recruitment decision. Some women relied on the confidence they had in the recruiting clinician: trusting that s/he would not expose them or their babies to anything risky. However, health professionals involved in Magpie had dual roles both as clinician and as researcher. As clinicians, their objective was to apply existing knowledge in order to achieve the best possible outcome of each woman. As researchers, their objective was to gain further knowledge for the greater good and in the case of Magpie to leave some treatment decisions (administration of magnesium sulphate) to a chance process. In this

type of situation care and research are so closely interlinked that it is often impractical and impossible not to intermingle the two. Women may have expected their obstetrician or midwife to have acted first as clinicians whose primary concern was their physical well-being and care. The clinicians' dual role as researcher may have appeared irrelevant to the clinical decision to be made.

Although some women sought the opinion of family members and friends, it was apparent they had little involvement or influence on the woman's decision. Many women emphasised that their partner played a role in providing a second opinion, as someone to confer with. However, women dismissed the idea that their relatives or friends were in the position to influence their decision - either because they were distressed too, or because they were not able to interpret trial details any better than the women themselves. Most women said they made the decision to join independently; and the family being present was neither required nor a substantial influence.

The study findings demonstrate some of the difficulties women experience when considering joining a trial in the perinatal period. The general implication for practice is that procedures are needed that can improve the design and conduct of randomised trials and therefore ultimately enhance the experience for future women. We recommend that when explaining the trial clinicians should use simple language. The consent process should include particular attention to the distinctions between procedures performed as part of the trial and procedures performed as part of routine

clinical practice. Returning the results should be done in a careful and well-planned manner that provides comprehensive support; with an invitation to contact the researcher for a verbal discussion if the participant wishes. Researchers should budget for the costs of returning results including maintaining contact with research participants. Methods to disseminate the results should be included in research protocols. Offering unblinding of treatment arms on completion of the trial should be made available. Similar to the provision of results this needs to be well planned and done carefully. Procedures need to provide full support to participants, with available contact with the researchers for verbal discussion if they wish.

Conclusion

Despite widespread acceptance of the potential benefits of randomised controlled trials of clinical care in pregnancy (Hofmeyr JG, 2008), little attention has been paid to participants' reactions to and understanding of their trial experience. This study has attempted to shed some light on decisions about joining and taking part in the Magpie Trial, as experienced by the women who participated in it. The data presented give valuable insights into the women's experiences of decision-making about participation.

It is undisputed that clinical research is important for the continued development of healthcare and the wellbeing of society. The QUOTE Study increases understanding of the experiences of those participating in a randomised controlled trial. As more data of the type reported here accumulate, clinicians and researchers will have the option to modify research strategies to reflect participants' real concerns and needs.

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619 (81%) returned UK children & women's questionnaire

- 181 (29%) from the 6 selected maternity units

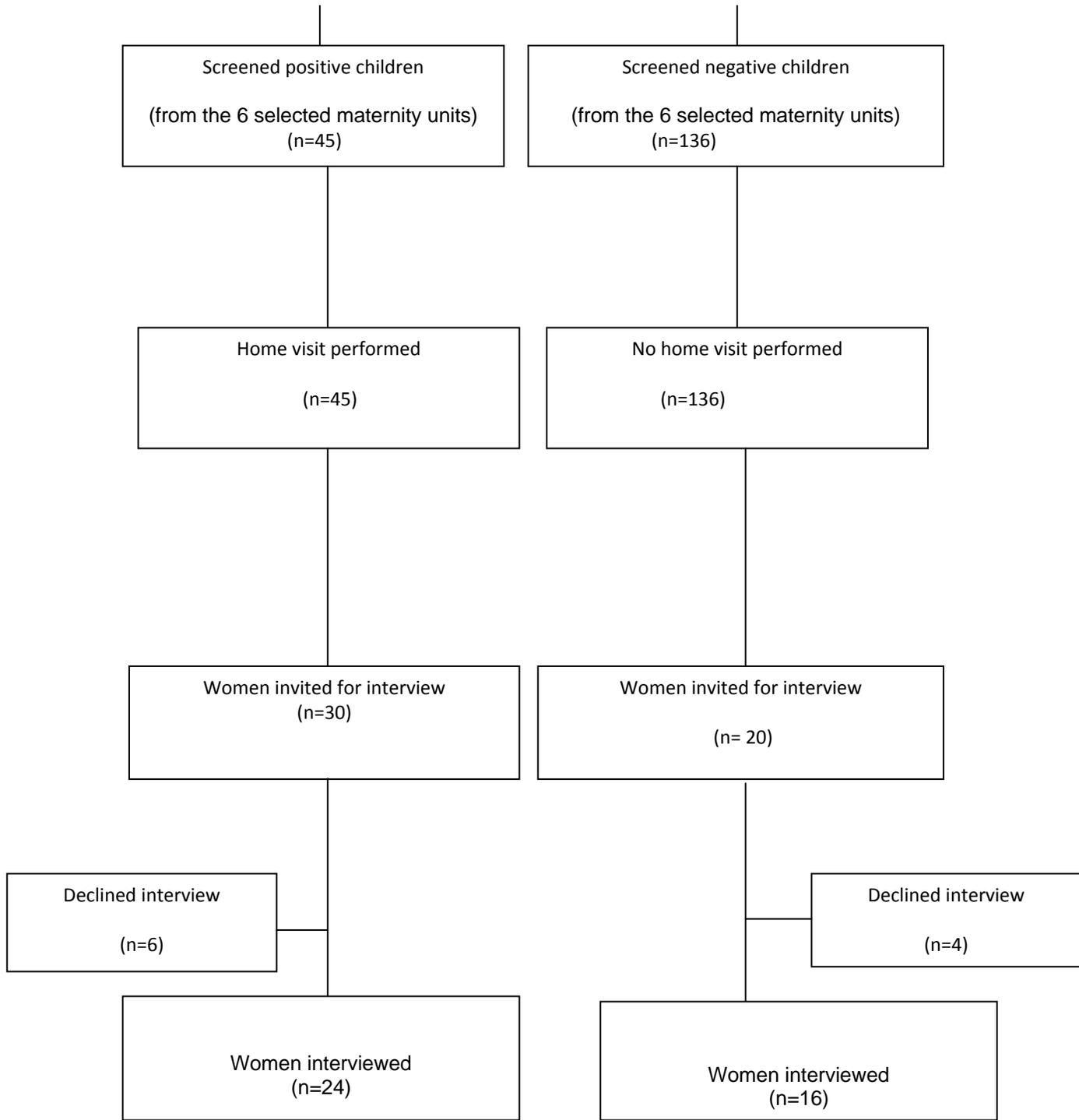


Figure 1 Women eligible for qualitative interview

	Interviewed		Not interviewed	
	n =40	(%)	n=579	(%)
Characteristics of women				
Primiparous	30	(75)	423	(73)
Multiple pregnancy	4	(10)	25	(4)
Age (less than 20 years)	2	(5)	46	(8)
Severe pre-eclampsia	23	(57)	261	(45)
Imminent eclampsia	9	(22)	157	(27)
Delivered before trial entry	11	(27)	127	(22)
Randomised magnesium sulphate	22	(55)	281	(49)
<i>Outcome after randomisation – maternal</i>				
Eclampsia	0	(0)	4	(<1)
Other severe morbidity				
Admission to high dependency care	36	(90)	485	(84)
On trial treatment more than 12 hours	31	(78)	486	(84)
Side effects	10	(25)	102	(18)
Randomised before delivery	29		448	
Caesarean section	22	(76)	269	(60)
Induction of labour	21	(72)	250	(56)
Outcome – Infant				
≤34 weeks at trial recruitment	11	(38)	152	(34)
Admitted to neonatal unit	17	(59)	308	(68)
ASQ Screen positive*	24	(83)	130	(29)

* Statistically significant when comparing those interviewed with those not

Table 1 Characteristics of women interviewed and not interviewed