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# Parents report positive experiences about enrolling babies in a cord-related clinical trial before birth

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**Short title:** Antenatal consent to enrol a preterm baby in a trial

**Abstract**

**Aim:** The aim of this study was to evaluate parents' perceptions when they were asked to enrol their unborn preterm infant in a randomised trial involving delayed cord clamping or cord milking.

**Methods:** The parents of 58 infants were asked to take part in a qualitative study using semi-structured interviews to provide feedback about how they felt about their infants being included in the research project. A total of 37 parents - 15 fathers and 22 mothers – agreed to take part.

**Results:** Parents were generally positive about their experiences of their baby taking part in the trial, but the findings raised some concerns about the validity of the consent obtained before delivery, as it was given in a hurry and some participants had difficulty remembering that they had agreed to take part. Four themes were identified from the interviews: implications of taking part, reasons for enrolling infants, experiences of recruitment and suggestions for improvement.

**Conclusion:** Overall, the parents were positive about their baby taking part in the trial, but the consent process could be improved, by providing information about relevant trials earlier in the pregnancy or implementing continuous consent at key points in the trial.

**Key words:** informed consent, interviews, preterm, randomised controlled trials

**Key notes**

- The aim of this study was to evaluate parents' perceptions when they were asked to enrol their unborn preterm infant in a randomised delayed cord clamping or milking trial.
- A total of 37 parents - 15 fathers and 22 mothers – agreed to provide feedback during semi-structured interviews.
- The parents were generally very positive about their experiences, but the findings raised some concerns about the validity of consent obtained before delivery.

High-quality, neonatal clinical research is essential to improve the treatment and outcome of sick newborn babies (1). Randomised controlled trials (RCTs) are considered the gold standard for comparing and evaluating different treatments. Valid informed consent is central to the conduct of RCTs and parents must give permission for their baby to participate in neonatal research (2). For this consent to be valid, parents must be deemed to be mentally competent, to have received appropriate information and to have given consent voluntarily (3). In trials involving infants receiving an intervention at, or near, the time of birth, families must be approached before the birth of their baby. Parental decisions are sometimes made when time is short and stress is high and this can make it challenging to adhere to the criteria for informed consent (4).

Two reviews of ten randomised trials suggested that a slight delay of 30 seconds in clamping the cord enabled placental blood to redistribute into the infant. This benefits preterm infants greatly by reducing intraventricular haemorrhages and the need for blood transfusions (5, 6). Milking the cord is an alternative method of enabling the redistribution of blood (7). A recent RCT compared the two methods for enhancing placental redistribution of blood into preterm neonates before 33 weeks of gestation (8). Consent for this trial was obtained before delivery from the parents who were facing the possibility of a very preterm birth. There is limited research on parents' experiences of enrolling their unborn babies into clinical trials and how they perceive providing antenatal consent when time is short and stress is high. Understanding parents' experiences is important, because it can help researchers to improve the design and conduct of future trials (9). Therefore, the aims of this study were two-fold. Firstly, we wanted to explore the parents' overall experiences of enrolling their unborn baby in an RCT involving a slight delay of cord clamping or milking the cord. Secondly, we were keen to explore the parents' experiences of providing antenatal consent for enrolling their child into the trial.

**Patients and Methods**

We carried out interviews with 15 fathers with a mean age of 33.12 years (range 21-46 years) and 22 mothers with a mean age of 29.9 years (range 19-41 years). Parents were eligible if they were fluent in English and their baby had participated in the cord clamping or milking RCT. Parents were asked for their consent to enrol their infants in the RCT by letter and this was followed by an informative discussion with a research staff member. Most of the parents consented to enrol their unborn baby on the day that it was born (range 0-24 days before birth). Parents were approached later to take part in the subsequent interview study, as advised by the ethics committee, a minimum of 14 days after the birth of their child.

This was a qualitative study using semi-structured interviews with the parents of preterm babies born at less than 33 weeks of gestation. The aim was to examine their experiences of enrolling their baby in an RCT where consent was provided antenatally. Ethical approval was obtained from the local National Health Service Research Ethics Committee. Eligible parents were sent individual letters of invitation which had a slip that they could return to indicate their interest in the research. Bereaved parents were also invited. The researcher then contacted them to provide further information and organise the interview. Participants were given the opportunity to ask questions and informed consent was obtained before the interview too place. Most interviews took place at the participant's home, but six were conducted in a quiet room in the hospital. Interviews were conducted by the same trained research nurse and lasted for approximately 60 minutes. When both parents were being interviewed, they always asked to be interviewed together. Interviews were recorded and then transcribed with identifying information removed. The time range between the infants participating in the RCT to the parents being interviewed was 16 days to 19.5 months. This wide range was due to parental choice, with some parents only agreeing to be interviewed after their baby was

discharged. The study results of the original RCT were not available at the time of interview. The interviews were conducted over a 12 months period.

*Materials*

An interview schedule was designed(see Appendix A), that consisted of open-ended questions covering six domains, including the parents' experiences of recruitment and the implications of enrolling the parent and baby. These questions were used as a guide to explore the research questions. However, the interviewer had the freedom to probe the interviewee in order to elaborate on the original response or to follow up a line of inquiry introduced by the interviewee. Cues and prompts were also used by the researcher to allow the interviewee to consider the topic further.

*Analysis*

The transcripts from the parental interviews were analysed using inductive thematic analysis, as outlined by Boyatzis (10). Firstly, transcripts were read and re-read to become familiar with the data. Secondly, a subsample of ten interviews were selected and used as the basis for creating a coding schedule. The transcripts were then coded for all possible themes, the codes and themes were examined by two authors (SA and CD) and a coding schedule was developed. All interview transcripts were then re-read, re-analysed and coded using this coding schedule. NVivo Version 8 software was used to organise the codes and themes

**Results**

The thematic analysis revealed four major themes: implications of taking part, reasons for enrolling infants, experiences of recruitment and suggestions for improvements.

Table 1 provides illustrative quotes and gives the number of participants who mentioned each theme. Participants were identified using their participant number and M or F to denote whether they were the mother or father.

**Implications of taking part**

This theme included any comments about the negative or positive effects of participating in the trial on either the parent or baby. It also included the parents' observations on the impact of taking part in the study on the health of the baby, together with any observations on other babies in the unit who did not take part in the study. The implications of taking part were categorised into positive impact on baby or self and the absence of negative effects.

The subtheme positive impact on baby or self, described the positive effects reported by parents on the recovery and general health of their baby as a result of taking part in the trial. Some parents compared the health of their baby to other babies not in the trial, suggesting that their baby had recovered more quickly or been less ill. A couple of parents were proud of themselves and their baby for taking part in this study and contributing to the research. There was a notable absence of negative effects, with none of the parents mentioning any negative impacts of taking part. There was a consensus that hospital staff did not differentiate between babies who were in the trial and babies who were not.

**Reasons for enrolling infants**

This theme comprised of any reasons, justifications or motivations behind the parents' decision to participate in the study. Most parents gave one or more reasons for deciding to take part in the study. The most common reasons were wanting to help, contributing to research and benefit to the baby. A few participants said trust in the medical team was also a reason.

The first sub-theme, helping behaviour describes parents' altruistic motives behind their decision to participate, which included aspirations to help future families going through the same experience. Some said they felt motivated to do the right thing. Many parents felt they were contributing to the research. Several parents expressed positive attitudes towards the research, as they felt they had benefited from previous similar trials. Many parents said they decided to take part because they believed it would benefit their baby. Furthermore, a couple of parents felt that the study had positive consequences for their baby, in that their baby had received special attention because they had taken part in the research. Interestingly, a few participants said it was their trust in the medical team that helped them make the decision to participate in the study.

**Experiences of recruitment**

This theme covered parents' experiences of being recruited into the trial. Four main sub-themes were identified: timing of recruitment, difficulty recalling recruitment, informed decision and initial hesitation.

The timing of recruitment was an issue for many parents. They felt that they would have liked more time to decide whether they wanted to participate. Their experience was often that, due to the critical situation, the decision had to be rushed, which left them little time to read the information provided about the study. More time would have enabled them to make a more informed decision. Some of the mothers, particularly the ones who had very traumatic deliveries, had difficulty recalling recruitment. Some of the parents also said that their main concern was the health of their baby and that, as a result, taking part in the study seemed unimportant and they did not pay much attention to it. Many parents emphasised the importance of receiving adequate information about the study and being able to ask questions, so that they felt comfortable about making an informed decision about whether to participate. Finally, a few parents expressed initial hesitation about

participating, mainly because they were worried that participating could have a negative impact on their baby.

### Suggestions for improvement

Parents provided useful feedback about how future research projects and recruitment procedures could be improved. The four main sub-themes were feedback on study results, information about previous studies, improvements in the recruitment procedure and improvements in antenatal classes.

The most common suggestion for improvement was that parents should be given more feedback on study results from the trial. Some parents also suggested that it would have been valuable to receive some information on previous studies, and the results of such research, before they made a decision about whether to take part. The two most common suggestions regarding improvements in the recruitment procedure were ensuring that both the mother and her birthing partner were approached at the same time, if possible, and approaching the parents about the study as early as possible during the pregnancy or labour. Several parents also suggested improvements for antenatal classes, such as creating more awareness about research projects so that people had a greater understanding about what was involved when they were approached.

## Discussion

The aim of this study was to explore parents' perceptions of enrolling their unborn preterm infant into an RCT that compared a slight delay in clamping the cord with milking the cord. This was one of the first studies to explore parents' experiences of providing antenatal consent for infants to receive an intervention at birth. Our study identified four main themes: implications of taking part, reasons for enrolling infants, experiences of recruitment and suggestions for improvement.

Overall, parents were very positive about their experiences of their baby taking part in the trial and many parents reported direct benefits on their baby's general health and recovery. Parents even felt that their baby's health was better than the babies who were not enrolled in the trial. The finding that parents perceived benefits for their child's health is consistent with previous studies (11, 12). Notably, none of the parents discussed any negative effects of taking part in the trial.

The main reasons parents gave for deciding to enrol their infant were helping to improve care for future babies and contributing to research. This altruistic principle is commonly reported in research studies (13). However, some studies report that although altruism is a contributing factor to study enrolment, it is rarely the primary reason for enrolment (14, 15). It is likely that the extent of altruistic motivation varies depending on the extent that the trial can benefit participants and the absence of major concerns. In one intra-partum trial with women who were presenting with preterm labour researchers found that altruism was conditioned by the understanding that participation would benefit their baby (16).

Another major reason that parents gave was that they thought that taking part in the trial would benefit the health of their baby. This finding is also consistent with previous research (3, 11, 12, 17). Some parents also thought that if they enrolled their baby in the trial they would receive special attention. However, the parents' responses indicated that hospital staff did not differentiate between the babies who had participated in the trial and those that did not. This is a promising finding, as parents in a previous study reported receiving additional or better care when their babies were enrolled in an RCT (11). Finally, some parents said that their trust in the doctors motivated them to take part in the study. Trust in the midwife or obstetrician was an important element in parents agreeing to take part in previous studies (18). In the Magpie trial some women relied on the confidence they had in the recruiting clinician, trusting that he or she would not expose them or their babies to anything risky (19). In another study, parents explained how they put themselves in the hands

of the medical staff (20). These findings confirm that parents felt vulnerable and were happy to rely on physicians (21).

Parents were approached about enrolling in the RCT study at a particularly stressful and anxious time. Therefore, it is not surprising that many parents raised concerns about the timing of their recruitment and the amount of information they received. They felt that they did not have time to read all the information and that their decision was rushed. However, because of the nature of the trial, it was often difficult to give parents extra time as delivery was imminent. This is similar to the findings from a labour trial which reported that 32% of women were not satisfied with information provision. Specifically, the timing of provision meant they could not consider it sufficiently (22).

Also, when they were interviewed, a number of parents could not recall being approached about the study. Other studies of parental consent in neonatal trials have reported similar findings. For example, Snowdon et al (23) interviewed the parents of 21 infants who were enrolled in the Extra Corporeal Membrane Oxygenation trial. They found that some were unsure whether their babies were in the trial or not.

These issues are a cause for concern, because they question whether consent given under such circumstances can be valid. To address such concerns, a number of modifications to the consent procedure have been recommended. Manning (4) suggests that, in the case of emergency neonatal trials, women should be informed antenatally and, unless they opt out, their baby should be included in the trial. However, research suggests that parents value the consent process and want to be involved in the decision to enrol their infant (1, 3, 21, 24). Another option is to mention the research study to parents in advance, either at their antenatal appointments or classes. Indeed, a number of parents in this study said that they would have liked information about the RCT earlier in their pregnancy, such as during antenatal classes. Parents in the Magpie trial (19), and in other studies

exploring parental consent (1, 12, 24), also said that they preferred to receive information about relevant research trials during pregnancy. This strategy is in accordance with the recommendations of the Association for Improvements in the Maternity Services (25) and the more recent Royal College of Obstetricians and Gynaecologists guidelines (26). However, there is concern that providing information during pregnancy could unnecessarily worry some parents (9). Researchers in The Total Body Hypothermia trial addressed concerns about the validity of consent using two methods. Firstly, clinicians were offered training and support in how to obtain consent. Secondly, the clinicians followed the principle of continuous consent, which is when parents are given information at more than one time point in the trial to help them understand it better (27). Specifically, parents were given initial information about the trial, then further information if they were interested. Finally, when the baby was receiving the trial treatment, a clinician explained the study again and ensured they were happy to continue. A recent qualitative study suggested that this method had positive effects when it came to obtaining valid informed consent (28). Therefore, researchers should implement some aspects of the continuous consent process in trials where fully informed consent may be difficult.

The most common suggestion for improvement was that the parents should be given more information about the study's results. There is growing ethical impetus to provide results to participants (29) and a recent narrative review of the literature concluded that participants wanted to see overall and clinically significant individual results (30). A qualitative study reported that feedback was important to parents, because it provided further information and clarity, helped them to remember an emotional time and re-explore their experiences and acknowledged their important contribution to medical research (31). However, it is important that a sensitive and supportive approach is taken when providing this information (31, 32).

Finally, parents emphasised that both the mother and her birthing partner should be approached together. This is similar to a previous study, which reported

that parents jointly made the decision about enrolling their infants in a clinical trial (33). Therefore, staff should focus on both parents and the emphasis should be on the parents making the final decision together.

One third of parents accepted the invitation to be interviewed, which is a good response for this type of study. Trustworthiness was also enhanced by careful construction of the interview questions, the use of a well-established and appropriate form of analysis, ensuring that participants were given adequate opportunity to refuse participation in the study, encouragement of a rapport between interviewer and interviewee, frequent debriefing sessions between the team members, and discussion of results with peers who were not part of the research team.

There are a number of limitations to this study. Firstly, the parents provided retrospective accounts of their experiences. It is important to gain an understanding of the perspectives of parents during their actual experience, as their accounts may be influenced by time and the health outcomes of their baby (34). The women were approached for informed consent of the original RCT shortly before giving birth to a preterm infant and sometimes when they were already in labour. For future studies we would recommend to use a process of continuous consent in which the parents would be reminded that their baby has been enrolled into a study during their hospital stay. Secondly, the experiences reported in this study may not be applicable to all parents who enrol their preterm baby into a clinical trial. Our results are based on a single trial and other factors may be more or less important in trials with different risk and benefit profiles. For example, the two interventions in the current trial were similar and not invasive or threatening. Also, the current trial did not include a placebo arm. One study found about parental attitudes towards enrolment in a Type 1 diabetes trial found that only a minority of parents were comfortable with the possibility of their child being randomised to a placebo arm

(35). We did not interview any parents whose baby had died after participation in the trial and it is likely that their perceptions of the trial would have been different (16).

Finally, parents who did not consent to take part in the RCT were not interviewed, which means that we were unable to explore the experiences of this group of parents. It is possible that these parents may have more negative perceptions of the recruitment process and/or of enrolling their baby in a trial.

This study provides valuable insight into parents' experiences of enrolling their newborn preterm baby into an RCT after providing consent antenatally. Overall, parents were positive about their baby's participation in the trial, which is a promising finding. However, the findings raise some concerns about the validity of consent taken before delivery. Parents were approached at a time of increased vulnerability and detailed discussions on the trial were not possible because of the urgency of the situation. Providing information earlier in the pregnancy is one option for improving the consent process. Although our initial findings suggest that parents would support this strategy, it has not been formally evaluated. Continuous consent is another option that could improve the validity of consent. It is essential that parents' perspectives are incorporated into discussions about the optimal method of obtaining consent in the antenatal period, to ensure that their concerns and needs are taken into account.

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**Abbreviations**

RCT  Randomised controlled trial

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Table 1. Themes, quotes, and the number of participants who mentioned each theme

| **Themes** | **Illustrative Quotes** | **Number who mentioned the theme (*N*=22)** |
|---|---|---|
| **Implications of taking part** | | 21 (96%) |
| Positive impact on baby or self | *"I said I think it does because [our baby] is the only baby that hasn't got ill in the ward. You know, all the other babies have been ill but [our baby] hasn't." (10F)* | 10 (46%) |
| | *"Yeah, I am quite proud that our daughter is in a study that can help other babies, so it's quite nice" (10M)* | |
| Absence of negative effects | *"Everyone just looked after him exactly the same. It made no difference to his care or anything like that, or to the way people have been with us. Not at all." (9M)* | 15 (68%) |
| **Reasons for enrolling infants** | | 21 (96%) |
| Helping behaviour | *"It makes you just feel like you are doing something good, you know, and your way of saying thank you for all the hard work that has been done to help get [our baby] to where she is now. You know, everybody has all had that input, all the staff have done all their bits to help her and all the research and that's why we just want to keep on doing anything that we can sort of do to help" ( 4M)* | 13 (59%) |
| Contributing to research | *"I kind of feel I owe something back to all the treatment that we had so I would do anything to help research" (51M)* | 10 (46%) |

| Themes | Illustrative Quotes | Number who mentioned the theme (*N*=22) |
|---|---|---|
| Benefit to the baby | *"If it was best for the baby, then we thought it was a good idea" (70M)*<br><br>*"…in a way because you feel that if you have volunteered to take part your baby will be given a special attention, maybe because of that, so that was the other reason probably why we agreed to take part" (75F)* | 10 (46%) |
| Trust in medical team | *"See at the time I was just thinking can we get hold of [the consultant] please and ask him what we should be doing because he had been with us all the way through, all the previous experiences, and we just had such trust in him that if he had said yes, dangle her out of the window and the baby will come out I would have said that's fine, [the consultant's] said it" (56F)* | 4 (18%) |
| **Experiences of recruitment** | | 22 (100%) |
| Timing of recruitment | *"I was taking on so much information because I had someone telling me that I was going to be rushed down for a caesarean, I had someone from [the neonatal intensive care unit] coming to see me and telling me what would happen with [the baby] and that he would be taken off when he was born, and then someone came to see me about the cord clamping study, so it all just seemed like quite a lot of information which I got. Hence why I said, I don't know just ask my mum. I was in such a state by then I couldn't believe I was having him" (47M)* | 12 (55%) |

| **Themes** | **Illustrative Quotes** | **Number who mentioned the theme (*N*=22)** |
|---|---|---|
| Difficulty recalling recruitment | *"So to be honest I am not convinced that I was approached about this study, at the time it probably seemed like it was sinking in but it wasn't a priority" (56F)* | 8 (36%) |
| Informed decision | *"It was a lady we spoke to and we asked questions and she frankly answered them so I was assured." (75F)* | 7 (32%) |
| Initial hesitation | *"Well the first thing I thought was, is it anything that is going to like (mother interjects 'harm the baby') yeah is it anything to worry about like that sort of thing but then when we found out it was not really anything that was going to be a worry then yeah we were up for anything like that weren't we?" (70F)* | 4 (18%) |
| **Suggestions for improvement** | | 14 (64%) |
| Feedback on study results | *"I would be interested in the results. I don't know whether or not you routinely give the results to the parents who have been involved, but personally I would be interested in the results." (14M)* | 9 (40%) |
| Information of previous studies | *"I also wanted to know whether or not there had been any results from any other studies. Just in terms of the cord clamping, where else it is done. I mean obviously verbally, but in terms of written information I wouldn't have had to have asked that if that was there. In terms of what studies have been done, have any previous studies been done here and what the results were and that sort of thing." (14M)* | 2 (9%) |

| **Themes** | **Illustrative Quotes** | **Number who mentioned the theme (*N*=22)** |
|---|---|---|
| Improvements in recruitment procedure | *"I mean if I could give you a tip for the future, maybe get both parents together and sit down and explain to them both together, but I mean that was the only thing I had that I didn't get the information (my partner) got so I was a little bit uncertain at first about what was involved in the process." (73F*<br>*"Well I think that getting to people slightly earlier – when I was admitted to the ward I was there for a couple of hours before I went to theatre. Someone should have approached me then because they know that you are premature when you come in though you try and put it off as long as possible, and then they make things happen. But we were there for probably two hours prior to being in the operating theatre so that may have been a little bit easier for me" (57M)* | 7 (32%) |
| Improvements for antenatal classes | *"Basically he suggests that at antenatal classes research projects could be discussed in general terms so that people are aware of them." (42F)* | 4 (18%) |

Appendix A: Interview Schedule

**Introduction e.g.**
"Thank you for agreeing to be interviewed as part of the research study you agreed to take part in. I realise this can be a very stressful time and appreciate your help. This interview takes approximately 15 minutes. However, if at any time you want to stop or do not want to answer a question just let me know and we can stop or move on to the next question.

One of the things we are interested in is your thoughts and feelings about taking part in this study, and if you think it has had any effect on you, your baby, or anything else."

**Questions**

**1. Experience of being recruited into the study e.g.**
"Could you start by telling me what you thought when you were asked to take part in the study?"
"How did you feel about taking part in the study?"
"What do you think generally about recruiting parents into this kind of study?"

**2. Implications and consequences for the baby e.g.**
"Do you think taking part in this study has had an effect on your baby / baby's care?"
If so, what?

**3. Implications and consequences for the parents e.g.**
"Do you think taking part in this study has had implications for you or your partner?"
If so, what?

**4. General implications and consequences**
"Do you think taking part in this study has general implications or consequences?"
If so, what?

**5. Overall evaluation**
"What are your overall thoughts and feeling about having taken part in this study?"

**6. Sum up and conclusion**
Give parents the opportunity to add anything, ask questions, and thank them for their help.