



# Incorporating parent, former patient and clinician perspectives in the design of a national UK double-cluster, randomised controlled trial addressing uncertainties in preterm nutrition

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## ABSTRACT

**Background** Comparative effectiveness randomised controlled trials are powerful tools to resolve uncertainties in existing treatments and care processes. We sought parent and patient perspectives on the design of a planned national, double-cluster randomised controlled trial (COLLABORATE) to resolve two longstanding uncertainties in preterm nutrition.

**Methods** We used qualitative focus groups and interviews with parents, former patients and clinicians. We followed the Consolidated Criteria for Reporting Qualitative Research checklist and conducted framework analysis, a specific methodology within thematic analysis.

**Results** We identified support for the trial's methodology and vision, and elicited themes illustrating parents' emotional needs in relation to clinical research. These were: relieving the pressure on mothers to breastfeed; opt-out consent as reducing parent stress; the desire for research to be a partnership between clinicians, parents and researchers; the value of presenting trial information in a collaborative tone; and in a format that allows assimilation by parents at their own pace. We identified anxiety and cognitive dissonance among some clinicians in which they recognised the uncertainties that justify the trial but felt unable to participate because of their strongly held views.

**Conclusions** The early involvement of parents and former patients identified the centrality of parents' emotional needs in the design of comparative effectiveness research. These insights have been incorporated into trial enrolment processes and information provided to participants. Specific outputs were a two-sided leaflet providing very brief as well as more detailed information, and use of language that parents perceive as inclusive and participatory. Further work is warranted to support clinicians to address personal biases that inhibit trial participation.

## INTRODUCTION

Many areas of neonatal practice lack an adequate evidence base; hence, treatments often vary, within and between centres. Comparative effectiveness research refers to

## What is known about the subject?

- Comparative effectiveness randomised controlled trials are powerful means of resolving uncertainties in existing treatments and care processes.
- Many areas of neonatal practice lack an adequate evidence base; hence, treatments often vary, within and between centres.
- The uncertainty around optimal practice creates risks for patients, anxiety for parents and confusion among staff.

## What this study adds?

- In addition to resolving practice uncertainties, comparative effectiveness research can help alleviate parent anxieties through metered study information, and partnership to improve newborn care.
- Early involvement of parents and former patients in trial development also enables researchers to support parents' emotional needs through appropriate recruitment materials and methods.
- Incorporating clinicians as stakeholders has potential to understand and address their personal biases that inhibit trial participation.

approaches to try and resolve uncertainties in established treatments.

COLLABORATE is a planned national, UK, double-cluster randomised controlled trial aiming to recruit at least 4700 babies to resolve two longstanding global uncertainties in preterm nutrition, the benefits of (1) pasteurised human donor milk in comparison with preterm formula to supplement a baby's own mother's milk when more milk is needed and (2) routine versus no routine protein-carbohydrate fortification of human milk.<sup>1 2</sup> The coprimary outcomes are survival to 36 weeks postmenstrual age without



surgery for necrotising enterocolitis (NEC) and survival to age 2 years without moderate–severe neurodevelopment impairment.

Currently in the UK less than 20% of very preterm babies receive any pasteurised donor milk and less than 40% receive any fortifier.<sup>3</sup> The uncertainty around optimal practice creates risks for patients, anxiety for parents, and confusion among staff. COLLABORATE offers a pragmatic response to these uncertainties. COLLABORATE will use data from the National Neonatal Research Database to minimise clinical burden,<sup>4–6</sup> and evaluate 2 year language and cognitive outcomes with a parent-completed questionnaire, the Parent Report of Children's Abilities-Revised.<sup>7</sup>

These clinical uncertainties, which affect the care provided to babies as well as the information provided to families, present an opportunity to understand how parents of very preterm babies can improve the recruitment materials for the COLLABORATE trial and clarify the acceptability of consent methods, as well as compare their views and reactions with those of clinicians. PPI consultations are enriching mechanisms to improve design, making studies more successful and relevant to their stakeholders.<sup>8–12</sup> In paediatric research, they have identified important guiding themes for future research, largely through centring the narratives and experiences of survivors and families.<sup>13 14</sup> Our aim at this preliminary stage was to involve parents, former patients and clinicians in trial development.

## METHODS

We recruited former neonatal intensive care patients and parents of patients from across the UK through a network of individuals with experience of preterm birth who had consented to be invited to participate in neonatal research activities.<sup>15</sup> We invited the participation of healthcare professionals through a national webinar. In total, 20 volunteers (10 clinicians, 7 parents, 2 former patients, and 1 parent/former patient) participated in virtual focus groups or semistructured interviews.<sup>16 17</sup> Sessions with single participants utilised the same topic guide. No clinicians attended the parent–patient groups to avoid inhibiting or influencing the discussions.<sup>16 17</sup> Participants gave verbal consent for participation and recording at the start of every discussion session.

We followed the Consolidated Criteria for Reporting Qualitative Research (COREQ) checklist for qualitative studies and created a topic guide to probe parent–patient and clinician experiences and understanding of the trial, based on a hybrid blend of deductive and inductive approaches to facilitate discussion and allow themes to emerge.<sup>18 19</sup> We provided a draft Parent Information Leaflet (online supplemental materials). Each session lasted approximately 90 min, and all were recorded with participant consent. WL and BM, non-clinical qualitative researchers led the discussions and conducted interviews. They transcribed recordings and conducted interviews.

WL and BM analysed all qualitative data using framework analysis, a specific methodology within thematic analysis.<sup>20</sup> Initial themes and concepts were identified through iterative review of the data, then used to construct a thematic index, or ‘framework’, and assign an index label to each phrase or passage of the transcripts.<sup>20</sup> The indexed and labelled raw data were then summarised and synthesised into thematic charts to preserve the data's context while facilitating systematic exploration. These thematic charts produced salient themes, which serve as descriptive and explanatory accounts of the data.<sup>20</sup> Data were organised and analysed using NVivo, V.1.0 (QSR International).<sup>21</sup> Participants were provided contact information for psychological support services in the event that discussions elicited strong emotions.

## Patient and public involvement (PPI)

At this preliminary stage of the development of COLLABORATE, we have used patient–public involvement to assist in developing the consent process and trial information leaflet. We have also involved clinicians to understand and address concerns related to their perspectives on opt-out consent, cluster randomisation and clinical uncertainties. This paper embodies the first phase of the study's public involvement strategy which includes parents, adults born preterm, and clinicians as research collaborators throughout the research cycle.<sup>22</sup>

## RESULTS

Nine volunteers, all women (seven parents, one former patient, and one parent who is also a former patient) participated in parent–patient focus groups (table 1). Eleven volunteers for clinician focus groups included eight neonatologists, a dietician and an infant feeding specialist midwife. One non-clinician adult born preterm also chose to attend a clinician focus group. Seven of the eleven participants were men. No participant required the psychological support services that were offered.

We identified three parent–patient themes; ‘pressure to breastfeed’, ‘consent process’, and ‘emotional trauma’; one clinician theme, ‘equipoise and personal beliefs’; and one theme combining parent–patient and clinician discussions, ‘collaboration and inclusivity.’

### Theme 1 pressure to breastfeed

Participants almost universally cited the refrain, ‘breast is best,’ but mothers' experiences of expressing milk and breast feeding provoked stress and feelings of inadequacy. One former patient articulated the challenges of breastfeeding with an anecdote from her own mother:

‘...my mum will share with me that she cried with her breasts bleeding, trying to express because she was told it was the best... And she had a woman sitting next to her in the expressing room who had, you know, 500 mls of milk sitting there...and this woman was saying, ‘Oh, it's not enough.’ My

**Table 1** Parent and patient participant characteristics 1

Participant	Gestational age of child or patient	Reason for interest in participating	Feeding method	Single/multiple birth	Incidence of necrotising enterocolitis (NEC)?	Survival of baby(ies)	Support for trial
Parent 1	33+3 weeks	Pharmacist w/RCT experience	Mum's milk	Single	N	Y	Y
Parent 2	n/a	NEC/preterm charity volunteer	Mum's milk and formula	Single	Y	Y	N
Parent 3	n/a	Breastfeeding peer supporter	Mum's milk and formula	Single	N	Y	Y
Parent 4	22 weeks	NEC/preterm charity volunteer	Mum's milk and donor milk	Twins	N/N	Y/N	Y
Parent 5	33 weeks	n/a	Mum's milk and fortifier	Single	Y	N	Unsure
Parent 6	29+5 weeks	n/a	Mum's milk and formula	Twins	Suspected NEC/N	Y/Y	Y
Parent 7	28 weeks	n/a	Mum's milk and formula	Single	Y	Y	Y
Patient/parent 12	29 weeks	NEC/preterm charity volunteer	Formula and donor milk/ formula and donor milk	Single/single	Y/Y	Y/Y	Y
Patient 1	28+4 weeks	Paediatric nurse	Mum's milk and Formula	Twin	N/suspected NEC	Y/N3	Y

mum was like, 'you're kidding me. I've got five ml from the last four hours. And I'm bleeding into it.' (NICU patient born at 28+4 weeks, now a paediatric nurse)

Parents showed understanding of the trial's aim of resolving feeding uncertainties. The discussion identified confusion around feeding options that were brought to the fore by the challenges of expressing sufficient milk.

'I remember when they talked about putting him onto formula, I said to the consultant, 'I'm really, really worried about him getting NEC [necrotising enterocolitis]. I'm really worried.' Cause I had it and...I know how bad it is...they assured me that the risk with formula was just as high as it was with donor milk. So I was like...if they need to gain weight and it's such a balancing act, isn't it?...I suppose it's the same for the doctors. They're just trying to balance the best options.' (Mother who had NEC as a preterm baby, whose baby was born at 29 weeks)

Participants emphasised sensitivity was needed to support mothers when discussing feeding.

'... And at the end of the day, it has to be what's best... for your circumstances and what's best for your baby because your mum's milk is best, but if mum's milk is not available... you shouldn't make mums feel as if they're kind of a failure.' (Mother of twins born at 29+5 weeks)

### Theme 2 consent process

Parent-patient participants and most clinicians supported opt-out as minimising the added stress of trial consent in an already stressful environment. One parent stated

'...I appreciate the opt-out allows a much larger number of people, and often families don't go there. Not because they don't necessarily want to do it, but for whatever reason they have...they're not thinking about it or they read [the consent form]...and forget to fill out...' (Mother of a preterm baby who had NEC)

Other participants echoed this sentiment noting that usual trial consent and information processes are often cumbersome and confusing. Some clinicians went further, suggesting that cluster randomisation meant that opt-out consent was required only from a neonatal unit rather than from parents themselves.

However, worries around transparency led some clinicians to feel uncomfortable with opt-out consent. For example, one told us they felt opt-out was only appropriate when a rapid decision was needed for a time-critical intervention.

### Theme 3 collaboration and inclusivity

Parent-patient participants emphasised the confusion and anxiety that results from lack of clarity or consistency in medical information communicated to them. They felt researchers can help alleviate these anxieties through the tone they adopt as well as the clarity of their communications.

'They need to be able to sometimes slightly dumb it down so we can understand it really well... I'm focusing on 'add extra protein and carbohydrate' [in the parent information leaflet.] I've never heard of that before...' (Mother of twin boys born at 22 weeks, one of whom did not survive)

They recommended we remove phrases in the draft parent information leaflet such as 'if a mother has insufficient milk' (online supplemental materials). They encouraged general use of words and phrases that expressed empathy for mothers' difficulties as opposed to ones that provoked feelings of guilt or inadequacy, supportive of an 'inclusive' tone.

'The document, as it reads, is looking to me like dumbed down 'science-y' stuff. Whereas I think it needs to come from a person to person, like where you have concerns and fears, and this is what we are trying to do together as a community of NICU [neonatal intensive care unit] survivors and clinicians...' (Mother of twin boys born at 22 weeks, one of whom did not survive)

This parent's reference to a 'community of survivors' illustrates their need for empathy.

Clinician participants recognised the importance of fostering a collaborative relationship with parents:

'I think this whole thing about us having to approach parents in a really collaborative way around the importance of...feeding...managing their expectations and their understanding of what is happening with that baby's gut, and that we're trying to help promote a healthy gut, not just for the time when they're in their unit, but beyond that time as a healthy gut for life—here is the one of the fundamental things that's going to influence their feeding for not just weeks, but months and years to come.' (Neonatal clinician)

They perceived a tension between ensuring information was shared transparently and managing parental anxiety. Offering clear and consistent explanations was seen as paramount, but this was sometimes difficult because of clinical uncertainties and professional differences of opinion.

#### Theme 4 trauma, powerlessness, and parental learning in the neonatal unit

Mothers experienced trauma and feelings of powerlessness, when their babies were 'taken away' for intensive care almost immediately following birth.

'...I had this baby ripped from me...I didn't see her after birth. It was horrific...her first nappy was changed by somebody else... All her cares were done by somebody else. The first person she saw was somebody else' (Mother of a preterm baby with NEC)

A lack of knowledge of neonatal care typically amplified these emotional experiences and participants described feelings of urgency to obtain more information.

... when you're in hospital and you've just had a new baby, especially if the baby's premature and you just have...so little time...' (Mother of a baby born at 33+3 weeks, pharmacist)

At the same time, often, you do have a lot of time to kill in the neonatal unit ... you will read every leaflet front to back' (Mother of a preterm baby)

Pursuing knowledge helped remedy feelings of powerlessness for some mothers, though a broader awareness of dangers facing babies often increased anxiety for others.

'I'm the sort of person that likes to know everything, so I would want to read every tiny little detail of everything...but I know from speaking to other parents in the neonatal unit that a lot of parents...don't want to be involved as much and they don't want to know things. (Mother of a preterm baby who had NEC)'

In summary, parents reported varying degrees of desire for knowledge, from those who wanted to know 'everything' and those who wanted a more general understanding.

#### Theme 5: equipoise and personal beliefs

Clinicians described the difficulty of managing their own anxieties about treatments in discussions with parents to minimise parent feelings of emotional distress and ensure equipoise across the unit.

'On a ward round, one negative sentence, a loose comment about something ... just spoils everything. We try to police that to some extent [and] share all our anxieties and disagreement beforehand ...we have our own personal agendas or personal biases but keep them to ourselves when we are ... in front of other people. That's where I see the issue about [a] unit that's sort of consenting to participate, but not then sticking to the protocol...and then bringing some of their own ideas into the consenting ... [and] recruitment process.' (Neonatal clinician)

Clinicians identified that the anxieties, disagreements, and biases that are common to care could amount to complications in trial procedures for some units. Despite broad acceptance of the need for a trial, many clinicians predicted neonatal units with a standardised feeding regimen would not agree to change them and would therefore decline to participate. Clinical focus group participants accepted the existence of clinical uncertainties and understood the need for a definitive trial. For example, one said:



'We've been asking these questions for so long and we still haven't got the answer' (Neonatal clinician)

## DISCUSSION

This PPI consultation with parent, former patient and clinician views about a planned national double-cluster randomised controlled trial involved participants with intimate knowledge of neonatal care, and the corresponding relevance and depth of their contributions provide novel insights. We identified support for the rationale and proposed methodology, and themes within and across groups. Particularly powerful themes related to the emotional needs of parents and the personal beliefs of clinicians. Parents experience stress and anxiety because of their baby's admission to intensive care. A novel insight provided by this consultation is that comparative effectiveness research might help alleviate parent anxieties in several ways. Clinician participants identified anxieties arising from the tension between their personal views and their acknowledgement of the need for evidence to guide practice. The methodology around PPI consultations continues to evolve.<sup>23</sup> Utilising PPI consultations in a study's early stages can assure relevance for patients and parents in the study's recruitment methods, ethics application, research protocol, and outcomes.<sup>8</sup> Our group illustrated an example of PPI consultations to identify a core outcome set for neonatology through consensus meetings around stakeholder viewpoints.<sup>4</sup> Others have called for 'integration' of parents in research by frequently inviting their feedback.<sup>14</sup>

Participants voiced support for the use of opt-out consent, noting it reduced the anxiety of decision-making. Some authors have criticised opt-out consent as not supporting informed consent.<sup>24</sup> However, the stress of neonatal intensive care complicates parent understanding of studies.<sup>25</sup> Our group has previously shown opt-out taps 'into parents' desire for normality in an abnormal situation'.<sup>26</sup> We have also shown that opt-out, as with opt-in consent, can be viewed as an ongoing consent process, leaving parents able to withdraw participation at any time, and that this approach is acceptable to the UK National Research Ethics Service.<sup>27</sup> Opt-out also allows parents to understand the trial and decline to participate without imposing a burden of additional information processing.<sup>26</sup>

The insights provided by consultation participants indicated the Parent Information Leaflet could be structured to provide emotional assistance by minimising the anxiety provoked by varying desires for information. This could be achieved by presenting information in a collaborative tone that situates the research as a partnership between clinicians, parents and researchers, and employing a format that allows parents to assimilate information at their own pace. The language used can also help avoid making mothers feel inadequate by recognising the challenges of providing milk for their babies and alleviating

the pressure to breastfeed. Our participants advised metering trial information to accommodate the needs of parents who want only a small amount of information as well as those who want to know more. The rationale for comparative effectiveness research is the relevance to patient safety of resolving uncertainties in care. However, 'uncertain' does not necessarily describe how parents experience the moment of selecting a nutritional option. What is 'uncertain' in terms of clinical practice is experienced as 'worry', guilt and even trauma by parents. This stems from a mixture of a shortfall in knowledge and the requirement to process substantial new information. The information provided through research participation enables parents to understand the issues facing their babies, providing direct benefit and a safe space to learn about neonatal treatments. As a consequence of these insights we undertook a redesign of the information leaflet to allow parents to adjust how much information they would receive by converting it into a two-sided format with a very brief explanation of the study on the front and a more detailed explanation on the back (online supplemental materials).

We identified anxiety among clinicians that manifest as a strong tendency to focus on the detail of the trial rather than the bigger picture even though the trial compares standard clinical practices. The main driver of anxiety was difficulty in managing uncertainty, both in terms of explaining this to parents and in accommodating it in their own practice. We found a cognitive dissonance at play, whereby the rationale for the trial is acceptable, yet involvement and being forced to confront their own personal views and biases led many to reject participation. In contrast, parents and patients felt that the proposed trial helped allay the anxieties invoked by the very uncertainties that justified the trial.

Our research has identified important areas for incorporation into the design of COLLABORATE and other comparative-effectiveness studies. Participating in research provides parents with a forum in which to learn about neonatal treatments, participate in knowledge production, and shape future care. Furthermore, in addition to the baby's medical care needs, this consultation, along with others, has identified that the provision of information to participants and enrolment to trials should consider the emotional needs of the parents as affected by study decision-making, information processing and language in study materials.<sup>28 29</sup> This consultation illustrates the need for further work to address the anxieties described and experienced by healthcare professionals. We hope this will help spearhead a truly collaborative research culture between parents, clinicians, and researchers.

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