important. It was a way of including them and recognising them as having a stake in the research. Sending the results was an important way of showing that the contribution that their baby had made to the research was valued.

The communications from the trial could have a lot of personal meaning and significance for the parents. Trial results were particularly important as they could be a connection back to the time of the baby's care, a connection out to other families who might benefit from the research, and a connection forward as they had helped to improve medical knowledge for the future.

Trial paperwork such as consent forms, newsletters and the results were often carefully kept, with some parents placing them in their baby's memory box. Parents also felt that communications from a trial could be difficult, bringing painful memories to the surface. especially if they might arrive without warning. They felt that trial results, depending on what they show, could be challenging with complicated information for parents to process.

Parents often talked of their interest in having the results in relation to their lives as bereaved parents. They discussed how pain and sadness are everyday experiences. By the time of the interview most had found a way to live with these emotions and did not feel that having trial results would make things worse. Although the parents talked about the importance of sensitivity, they also said very clearly that bereaved parents should be treated normally. They felt that they should be given access to the same information as parents of babies who survived. Bereavement is a lifelong experience and reactions and views change over time. We found that responses to trial participation were also changeable with interest coming and going over time. It seemed that an interest in a trial, especially in what it shows, can fit into the longer-term experience of bereavement. This happens at a time when the clinicians and parents do not naturally come into contact with each other.

The BRACELET Study has shown that bereaved parents can be highly engaged in studies of their experiences, and are prepared to engage with the topic of bereavement and participation in trials. For the parents in this study, their involvement in BRACELET seemed to be a satisfying experience. The accounts that they gave were often seen as a way of honouring and commemorating their baby.

These results will be made available to people who design, run, and provide the funds for trials involving critically ill children. They will help them to make decisions about how their trials are run in the future.

Enquiries: claire.snowdon@lshtm.ac.uk and diana.elbourne@lshtm.ac.uk

For further details visit the BRACELET Study website (www.bracelet-study.org.uk) where the full study report , can be freely downloaded. The full report can also be found at: http://www.journalslibrary.nihr.ac.uk/hta/volume-18/issue-42

The BRACELET Study is funded by the NIHR Health Technology Assessment Programme and is part of the research portfolio of the Medicines for Children Research Network

The BRACELET Study

(The Bereavement and RAndomised ControlLEd Trials Study)

Summary of research findings

June 2014

Phase 1

To start to understand the topic of bereavement and trials, we looked at all paediatric and neonatal intensive care trials that were carried out in the UK in a five year period. We did this to find out how many of the babies and children enrolled into a trial go on to die. This would help us to know how often trial teams and clinicians would have to manage this situation.

We found that almost 17% of the babies enrolled in neonatal trials went on to die, (over 500 babies in the 5-year period). We also found that most of these babies had died in a small number of the larger hospitals which look after the sickest babies. This means that most doctors and nurses involved in trials in the UK would not come across this situation very often.

For paediatric trials which involve older babies and children, the situation was different. Fewer trials had been carried out in the 5-year period, and far fewer children had died, only 6%. This is partly because the children in paediatric intensive care are often (but not always) not as sick as the babies who need neonatal intensive care.

Phase 2

For the next part of the study we decided that our research questions should be explored in the neonatal setting. We decided to work with five of the trials that we had looked at in Phase 1. These were:

- The INIS Study
- The TOBY Trial
- The PROGRAMS Trial
- The Extreme Preterm Nutrition Study (EXPN)
- BOOST-II UK

We interviewed over 100 people: professionals who designed and ran these trials (the trial team members), the doctors and nurses (clinicians) who recruited to the trials in neonatal intensive care units, and bereaved parents of babies who took part in the trials.

Enrolling in a trial

The interviews with trial team members showed that when the trials were being designed, they were careful to take into account the situation of the babies who would take part in the trial. The trial team members and clinicians were aware of the demands that could be placed upon parents when they were asked about taking part in a trial, and by the way their trials were designed. They took this into account when they were planning their trials.

Parents described a range of different experiences in the run up to and the time around recruitment. Some babies were born very early, often in an emergency. Some were born at full term after very difficult labours and births.

The parents were usually asked to think about a trial when their baby or babies were in the neonatal unit. The subject of the trial could be brought up in relation to quite routine areas of intensive care, such as the ventilator (BOOST-II UK), feeding (EXPN), or because of a crisis such as an infection which was getting worse (INIS). In all of these situations there was a strong sense that parents and clinicians were pulling together. Although some parents pinned their hopes on a trial, for others it could be a small part of their experiences; however the parents saw the trial, they often said that they felt that it might help but would not harm their baby.

Summary of research findings

Bereavement

It was common for the trial to become less important for parents if they had not talked with their clinicians again about the research and if they did not see anything happening for the trial. Other events took over and once a baby had died the trial was largely forgotten in the middle of the parents' bereavement.

Providing for bereavement

The clinicians' interviews showed the care that they and their neonatal units take over bereavement support. They felt that they provided well for bereaved parents. They did not make any particular provision for situations where a baby had taken part in a trial, but felt that if parents had any interest or need relating to their babies' involvement in a trial they would be able to talk to their neonatal consultant about it.

The clinicians who were responsible for bereavement follow up made their own choices about whether or not to raise the topic of the trial with parents. Most did not as they felt that the family would not be involved in the trial any further and that other issues such as cause of death, implications for future pregnancy, or emotional support should be the focus of the bereavement follow-up meeting. They said that parents rarely bring up the subject of trial participation. The parents agreed. They said in their interviews that in the raw early stages of bereavement other things would be more important to them than the trial. Some of the parents did however feel that the neonatologists could mention the fact that their baby took part in a trial in case this started up a helpful discussion.

When we talked to the people who run trials, we found that different teams had different approaches to bereavement. In one trial (EXPN) there was no contact with bereaved parents. In another trial (TOBY) there was a well developed plan for contacting parents to give information about the research. It involved a condolence letter, newsletters, access to a web message board and sending trial results.

The work of the trial teams was complicated by rules about how people are contacted in relation to research (data protection and research governance). For instance the teams did not have a way to update contact details for bereaved parents, and this meant that they could not know whether they were sending things to the right address. As it was rare for them to hear back from bereaved parents, it was very difficult for the teams to know whether or not sending letters and newsletters was the right thing for parents.
In fact the parents saw having access to information about a trial as very important. Even if it had seemed like a very small part of what had happened to them, or it had faded into the background, they felt that giving parents access to information was