## **Authors' reply**

Beverley Orser and colleagues correctly point out the limitations of our study,1 which were also highlighted in our discussion and the accompanying Comment.2 We agree that a more extensive follow-up of the children aged 5 years is essential, that indeed is our primary outcome. We also agree with Markus Weiss and colleagues that there are many other factors besides possible anaesthetic neurotoxic effects that might influence the short-term and long-term outcome of anaesthesia and surgery in infants. More evidence is required for many aspects of perioperative care in infants.

We applaud COMPare's efforts to improve clinical trial reporting; however, in this case. Eirion Slade and colleagues' conclusions are not correct. The trial was registered at ClinicalTrials.gov where we indicated that the primary outcome was the Wechsler Preschool and Primary Scale of Intelligence (WPPSI third edition) Full Scale IO score, and secondary outcomes were Bayley neurodevelopmental scale and postoperative apnoea. The apnoea data have been published and this is indicated in our paper.3 The protocol was also sent to The Lancet shortly after the study started and a summary of the protocol was published.4 The submitted protocol clearly indicated that the primary outcome was the WPPSI third edition Full Scale IQ score at 5 years of age. This protocol also indicated that postoperative apnoea was a secondary outcome, and that secondary outcomes at the 2 year assessment were cognitive motor abilities; language skills; social, emotional, and adaptive behaviour (these scales encompass the 21 scores reported); the MacArthur-Bates Communicative Development Inventory; and presence of cerebral palsy or reduced vision or hearing. Thus, all outcomes at 2 years prespecified in the submitted protocol were reported but were not included in the published protocol. There has been no selective reporting. The only outcome reported in the paper but not prespecified in the protocol was the presence or absence of autism.

The submitted protocol also indicated that the Bayley cognitive scale would be the secondary hypothesis, and thus in the paper, we noted and reported this scale as our main outcome of interest at 2 years of age. In our Article, we clearly indicated that the reported data are secondary outcomes and the implications for this effect were clear in both the discussion and the accompanying Comment.

COMPare's inaccurate conclusions do highlight the issue that trial registries often do not request or have space for sufficient detail about secondary outcomes, and that journals should perhaps publish the protocols in full rather than summaries.

We declare no competing interests.

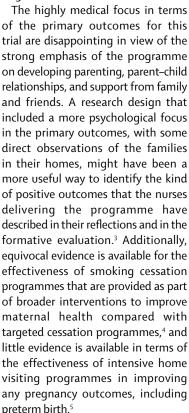
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## Questioning the outcome of the Building Blocks trial

Michael Robling and colleagues (Oct 13, p 146)1 are to be congratulated on conducting Building Blocks, a highly rigorous randomised controlled trial of the Family Nurse Partnership (FNP) programme in England, UK, and rightly highlighted the difficulty in showing changes similar to the US studies in a setting with comprehensive universal health services. The trial in the Netherlands,2 where FNP showed a positive effect on various primary outcomes, involved substantial adaptation of the programme to the local context, and was also more targeted in terms of risk.



Those of us who have been involved in studying the process of introducing the programme in the UK have witnessed a tremendous investment of highly valuable resource in terms of skills into the health visiting

