Computerised interpretation of the fetal heart rate during labour: a randomised controlled trial (INFANT)

Peter Brocklehurst, 1* David Field, 2 Keith Greene, 3 Edmund Juszczak, 4 Sara Kenyon, 5 Louise Linsell, 4 Chris Mabey, 6 Mary Newburn, 7 Rachel Plachcinski, 8 Maria Quigley, 4 Philip Steer, 9 Liz Schroeder 10 and Oliver Rivero-Arias 4

Declared competing interests of authors: Keith Greene is the founder and shareholder of K2 Medical Systems (Plymouth, UK) and Clinical Director for the development of the INFANT system. Christopher Mabey is employed by, and is a shareholder of, K2 Medical Systems, the technology provider for the study. Edmund Juszczak reports grants from the National Institute for Health Research (NIHR) Health Technology Assessment (HTA) and Efficacy and Mechanism Evaluation programmes during the conduct of the study, and is a member of the NIHR HTA Commissioning Board. Peter Brocklehurst reports grants and personal fees from the Medical Research Council and grants from the National Institute for Health and Care Excellence, NIHR Health Services and Delivery Research, NIHR HTA and Wellcome Trust, outside the submitted work, and is chairperson of the NIHR HTA Women and Children's Health panel and is a member of the HTA Prioritisation Group. Sara Kenyon is a member of the NIHR HTA Women and Children's Health panel and received NIHR funding to undertake the HOLDS (High Or Low Dose Syntocinon® for delay in labour) trial, and was part funded by the NIHR Collaboration for Leadership in Applied Health Research and Care West Midlands.

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¹Birmingham Clinical Trials Unit, University of Birmingham, Birmingham, UK

²Department of Health Sciences, University of Leicester, Leicester, UK

³University College London, London, UK

⁴National Perinatal Epidemiology Unit Clinical Trials Unit (NPEU CTU), Nuffield Department of Population Health, University of Oxford, Oxford, UK

⁵Institute of Applied Health Research, University of Birmingham, Birmingham, UK

⁶K2 Medical Systems, Plymouth, UK

⁷Collaboration for Leadership in Applied Health Research and Care (CLAHRC) South London, King's College London, London, UK

⁸National Childbirth Trust, London, UK

⁹Imperial College London, London, UK

¹⁰Faculty of Medicine and Health Sciences, Macquarie University, Sydney, NSW, Australia

^{*}Corresponding author p.brocklehurst@Bham.ac.uk

Plain English summary

The INFANT RCT

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Plain English summary

The INFANT study aimed to find out if we can improve how we monitor babies during labour. In the UK, continuous monitoring is used if either the mother or the baby is considered likely to not cope well with contractions during labour. For these labours, a cardiotocograph is used to continuously record the baby's heart rate. The midwives/doctors look at a graph of the heart rate to find out how the baby is coping.

Interpreting the pattern made by the baby's heart rate is complicated. The INFANT study looked at whether or not a computer system that analyses the heart rate can help the midwives/doctors interpret the recording more accurately. The study asked questions about babies' health and well-being, medical procedures experienced by women and whether one approach provided better value for money than the other in terms of delivering high-quality care. Women who agreed to have continuous electronic fetal monitoring were divided at random into two groups. One group had the computer decision support software switched on and the other group had it switched off. This made it possible to assess the effect of the new software fairly, as the groups of women and babies were otherwise almost identical in terms of their health and chance of complications.

Between January 2010 and August 2013, 47,062 women took part in the study. After the different interventions in their care, we found no difference in the chance of babies being unwell between the two groups of women: 0.7% (n = 172) of babies were unwell in the decision support group, as were 0.7% (n = 171) of babies in the no decision support group. We found no differences in other outcomes, such as the risk of pregnant women requiring an emergency caesarean section.

In this study, decision support software did not improve the care for women in labour.

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