Feasibility of a RCT of techniques for managing an impacted fetal head during emergency caesarean section: the MIDAS scoping study

Kate F Walker,[1*] Eleanor J Mitchell,[2] Susan Ayers,[3] Nia W Jones,[1] Reuben Ogollah,[2] Natalie Wakefield,[2] Jon Dorling,[4] Phoebe Pallotti,[5] Arani Pillai,[6] Nicola Tempest,[7] Rachel Plachcinski,[8] Lucy Bradshaw,[2] Marian Knight[9] and Jim G Thornton[1]

[1]Lifespan and Population Health Academic Unit, University of Nottingham, Nottingham, UK
[2]Nottingham Clinical Trials Unit, University of Nottingham, Nottingham, UK
[3]Centre for Maternal and Child Health Research, School of Health Sciences, City, University of London, London
[4]Neonatal Unit, Southampton General Hospital, University Hospital Southampton NHS Trust, Southampton, UK
[5]Department of Midwifery, University of Nottingham, Nottingham, UK
[6]Department of Anaesthetics, Nottingham University Hospitals NHS Trust, Nottingham, UK
[7]Department of Women's and Children's Health, Liverpool Women's NHS Foundation Trust, Liverpool, UK
[8]National Childbirth Trust, Northampton, UK
[9]National Perinatal Epidemiology Unit, Nuffield Department of Population Health, University of Oxford, Oxford, UK

[*]Corresponding author kate.walker@nottingham.ac.uk

Disclosure of interests

Full disclosure of interests: Completed ICMJE forms for all authors, including all related interests, are available in the toolkit on the NIHR Journals Library report publication page at https://doi.org/10.3310/KUYP6832.

Primary conflicts of interest: Susan Ayers reports grants from the National Institute for Health and Care Research (NIHR) outside the submitted work. Nia W Jones reports grants from NIHR Health Technology Assessment (HTA) during the conduct of the study. Jon Dorling reports grants from NIHR during the conduct of the study, and grants from NIHR, Canadian Institute of Health Research, Izaak Walton Killam and Nova Scotia Research outside the submitted work. Jon Dorling also reports membership of the following committees: HTA Efficient Study Designs (2015–16), HTA Maternal, Neonatal and Child Health Panel (2013–18) and HTA General Committee (2016–18). Rachel Plachcinski reports personal fees from University of Nottingham, outside the submitted work. Marian Knight reports grants from NIHR during the conduct of the study and membership of the following committees: HTA Remit and Competitiveness Group (2021 to present), HTA Prioritisation Committee B Methods

Group (January 2021 to March 2022), HTA Funding Committee Policy Group (formerly Clinical Studies Group) (2021 to present), HTA Commissioning Committee (2021 to present) and HTA Programme Oversight Committee (2021 to present). Jim G Thornton reports membership of the NIHR HTA and Efficacy and Mechanism Evaluation (EME) Editorial Board (2016–21).

Published March 2023
DOI: 10.3310/KUYP6832

Plain language summary

Feasibility of a RCT of techniques for managing an impacted fetal

Health Technology Assessment 2023; Vol. 27: No. 6
DOI: 10.3310/KUYP6832

NIHR Journals Library www.journalslibrary.nihr.ac.uk

Plain language summary

One-quarter of United Kingdom pregnant women have a caesarean section. Most of these procedures are straightforward, but in a small number of cases unexpected complications can make the birth difficult.

One complication, an impacted fetal head, may happen when caesarean sections are done in the second 'pushing' stage of labour. If the baby's head is low and wedged in the woman's pelvis, lifting it can be difficult, which can result in damage to the mother's womb and vagina, and to her baby. Occasionally, babies die.

There are different techniques doctors and midwives can use to make these births easier, but there is uncertainty around which is best. To plan a trial to test these techniques, we needed to know how often impacted head happens, what techniques are used to manage it and whether or not research is acceptable to parents and health-care professionals.

We surveyed doctors and midwives to find out which techniques they use and what training they need. We surveyed parents and pregnant women and interviewed women who had experienced a second-stage caesarean. We collected information from UK hospitals to find out how common this is and the impact on women and babies.

We found out the following:

- Around 7% of caesareans take place in second stage, and impacted fetal head occurs in 16% of these births.
- One-third of women would consent to take part in a trial, if the complication happened to them.
- Nearly all midwives and doctors thought that this research was important and would be willing to take part.

Using all of the information we collected, we designed a clinical trial. We wanted to compare two techniques for managing an impacted fetal head. The first is the vaginal push technique, where the doctor or midwife puts their hand into the mother's vagina to push her baby's head up, and the second is the fetal pillow, a device inserted into the mother's vagina before the operation starts to dislodge the baby's head upwards.

Health Technology Assessment

ISSN 1366-5278 (Print)

ISSN 2046-4924 (Online)

Impact factor: 4.014

Launched in 1997, *Health Technology Assessment* (HTA) has an impact factor of 4.014 and is ranked 27th (out of 108 titles) in the 'Health Care Sciences & Services' category of the Clarivate 2021 Journal Citation Reports (Science Edition). It is also indexed by MEDLINE, CINAHL (EBSCO Information Services, Ipswich, MA, USA), Embase (Elsevier, Amsterdam, the Netherlands), NCBI Bookshelf, DOAJ, Europe PMC, the Cochrane Library (John Wiley & Sons, Inc., Hoboken, NJ, USA), INAHTA, the British Nursing Index (ProQuest LLC, Ann Arbor, MI, USA), Ulrichsweb™ (ProQuest LLC, Ann Arbor, MI, USA) and the Science Citation Index Expanded™ (Clarivate™, Philadelphia, PA, USA).

This journal is a member of and subscribes to the principles of the Committee on Publication Ethics (COPE) (www.publicationethics.org/).

Editorial contact: journals.library@nihr.ac.uk

The full HTA archive is freely available to view online at www.journalslibrary.nihr.ac.uk/hta.

Criteria for inclusion in the *Health Technology Assessment* journal

Reports are published in *Health Technology Assessment* (HTA) if (1) they have resulted from work for the HTA programme, and (2) they are of a sufficiently high scientific quality as assessed by the reviewers and editors.

Reviews in *Health Technology Assessment* are termed 'systematic' when the account of the search appraisal and synthesis methods (to minimise biases and random errors) would, in theory, permit the replication of the review by others.

HTA programme

Health Technology Assessment (HTA) research is undertaken where some evidence already exists to show that a technology can be effective and this needs to be compared to the current standard intervention to see which works best. Research can evaluate any intervention used in the treatment, prevention or diagnosis of disease, provided the study outcomes lead to findings that have the potential to be of direct benefit to NHS patients. Technologies in this context mean any method used to promote health; prevent and treat disease; and improve rehabilitation or long-term care. They are not confined to new drugs and include any intervention used in the treatment, prevention or diagnosis of disease.

The journal is indexed in NHS Evidence via its abstracts included in MEDLINE and its Technology Assessment Reports inform National Institute for Health and Care Excellence (NICE) guidance. HTA research is also an important source of evidence for National Screening Committee (NSC) policy decisions.

This report

The research reported in this issue of the journal was funded by the HTA programme as project number 17/75/09. The contractual start date was in February 2019. The draft report began editorial review in July 2021 and was accepted for publication in May 2022. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors' report and would like to thank the reviewers for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

This report presents independent research funded by the National Institute for Health and Care Research (NIHR). The views and opinions expressed by authors in this publication are those of the authors and do not necessarily reflect those of the NHS, the NIHR, the HTA programme or the Department of Health and Social Care. If there are verbatim quotations included in this publication the views and opinions expressed by the interviewees are those of the interviewees and do not necessarily reflect those of the authors, those of the NHS, the NIHR, the HTA programme or the Department of Health and Social Care.

Published by NIHR Journals Library (www.journalslibrary.nihr.ac.uk), produced by Prepress, final files produced by Newgen Digitalworks Pvt Ltd, Chennai, India (www.newgen.co).