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OASI2: Evaluation of strategies for sustainable implementation of the OASI Care Bundle in maternity units

Submission date
25/01/2021

Recruitment status
No longer recruiting

Registration date
27/01/2021

Overall study status
Completed

Last Edited
17/02/2022

Condition category
Pregnancy and Childbirth

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims

Obstetric anal sphincter injury (OASI) refers to severe tearing of the perineum (the area between the vagina and anus) which may be sustained during childbirth. OASI may result in complications such as anal incontinence (difficulty or inability to control bowels and the passing of wind) with significant psychosocial consequences to women and long-term financial consequences for health systems. The OASI Care Bundle was developed in response to the tripling in rates of detected OASI identified in primiparous women (first-time mothers) in England between 2000-2012 by a group of national experts following the review of literature and pre-existing guidelines to standardise practice and address inconsistencies in training and skills.

In 2016-2018, the OASI Care Bundle was rolled out in 16 maternity units across England, Scotland and Wales in a study referred to as 'OASI1' (ISRCTN12143325). Implementation of the care bundle in these OASI1 units was led by clinical and implementation experts from the OASI1 project team. Findings from the OASI1 study demonstrated that the care bundle is associated with a 20% reduction in women's risk of OASI (after adjusting for case-mix factors) with no change in caesarean section or episiotomy rates. The study also confirmed the care bundle's acceptability to clinicians and women as well as the feasibility of its implementation in maternity units.

OASI2 is a follow-on study with two aims: to study the care bundle's sustainability in ten of the original OASI1 units, and to evaluate two methods of care bundle implementation that are more scalable and do not rely on continuous expert support. The two methods will be evaluated and compared to determine the minimum requirements for successful implementation and to inform the development of a final implementation blueprint that will operationalise study findings and guide wider scale-up of the OASI Care Bundle, nationally and beyond.

Who can participate?

Thirty NHS maternity units in England, Scotland, and Wales will participate in one of the three arms of OASI2. Within these participating units, there are two groups of study participants: clinicians (midwives and obstetricians) and women.

Two OASI Quality Improvement (QI) Leads (one midwife and one obstetrician) per participating

unit will be designated to lead the local implementation of the OASI Care Bundle, including training of midwifery and obstetric staff at their unit. All midwifery and obstetric staff at the participating units will be invited to participate in a survey at two points in the study period. This study will evaluate the level of compliance with the care bundle by staff across study units, which will be measured in terms of how many women of those eligible actually receive all four elements of the care bundle. Women receiving antenatal care and having a live, term, cephalic vaginal birth at a participating unit receive the care bundle if their birthing position allows the application of all care bundle elements and if they provide consent to the care bundle elements as they are communicated during and after birth, as per local routine practice. The estimated average number of care bundle-eligible births over a 12-month period is 2,374. Therefore, an estimated total of 71,220 women will be potentially eligible to receive the care bundle across all OASI2 participating units during the study period. All women who are eligible to receive the care bundle will also be invited to participate in a postnatal survey.

What does the study involve?
OASI2 involves testing different scale-up strategies of the OASI Care Bundle, a set of four evidence-based practices that when used together, have demonstrated effectiveness in reducing women's risk of severe perineal tearing during childbirth.

The four elements of the OASI Care Bundle are:
1. In the antenatal period, the midwife or doctor will discuss OASI with the woman and what can be done to reduce the risk of it occurring.
2. At the time of birth and with the woman's consent, the midwife or doctor will use their hands to support both the perineum and the baby's head (known as manual perineal protection, or MPP) while communicating with the woman to encourage a slow and guided birth.
3. If clinically indicated and with the woman's consent, an episiotomy (a cut made through the vaginal wall and perineum) should be performed at an angle of 60 degrees from the midline at crowning.
4. Following all vaginal births, a systematic examination of the perineum (including the vaginal and anus), should be systematically offered to all women even if the perineum appears intact. This is to ensure that any tears are identified immediately and that treatment options are discussed and implemented as necessary.
While the first three components of the care bundle contribute to the primary prevention of OASI, the fourth element aims to improve detection rates and therefore is a secondary prevention measure.

All 30 participating maternity units will designate two OASI QI Leads (one midwife and one obstetrician) who are responsible for care bundle implementation and will receive an implementation toolkit to guide and support their efforts.

There are three study arms with ten maternity units each: the 'sustainability' arm, the 'peer support' arm, and the 'lean implementation' arm.
Ten of the 16 maternity units that implemented the care bundle in OASI1 study are invited to take part in the sustainability arm of OASI2. Twenty other maternity units in England, Scotland and Wales that have expressed interest will be randomised into the peer support or lean implementation arms.
OASI QI Leads in all three arms will lead and support care bundle implementation over a 13-month period that includes a 1-month transition period (from study set up to interventions and data collection initiation). The three study arms are described in the Intervention section.

What are the possible benefits and risks of participating?
Midwives and obstetricians from participating units will have the opportunity to undergo additional training in the prevention of perineal trauma during childbirth.

Where is the study run from?
The study is managed by the Royal College of Obstetricians and Gynaecologists, in collaboration with the Royal College of Midwives, Croydon Health Services NHS Trust, and the London School of Hygiene and Tropical Medicine (UK)

When is the study starting and how long is it expected to run for?
July 2019 to December 2022

Who is funding the study?
The Health Foundation (UK)

Who is the main contact?
Miss Magdalena Jurczuk (OASI2 research fellow)
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Study website
https://www.rcog.org.uk/OASICareBundle

Contact information

Type(s)
Scientific

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Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
282750

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 47083, IRAS 282750

Study information

Scientific Title
OASI2: a hybrid effectiveness implementation RCT to inform scale up of care bundle to reduce obstetric anal sphincter injury (OASI) caused during childbirth

Acronym
OASI2

Study objectives
There are two hypotheses, one related to the primary clinical outcome and one to the primary implementation outcome:
1. The OASI rate will decrease in all study arms. There will be a significant difference in OASI rates between units in the peer support and lean implementation arms, such that the decrease in OASI rates will be higher in the peer support arm.
2. There will be a significant difference in care bundle adoption between units in the peer support and lean implementation arms, such that the levels of adoption will be higher in the peer support arm.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 01/12/2020, Social Care REC (Health Research Authority, Skipton House, Ground Floor, 80 London Road, London, SE1 6LH, UK; +44 (0)207 104 8127; Socialcare.rec@hra.NHS.uk), REC ref: 20/IEC08/0029

Study design

Randomized; Both; Design type: Diagnosis, Process of Care, Complex Intervention, Qualitative

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Obstetric anal sphincter injury (OASI) caused during childbirth

Interventions
The OASI Care Bundle has already demonstrated effectiveness in reducing women's risk of severe perineal tearing in childbirth - all 30 participating units will therefore apply the OASI Care Bundle. Each unit will designate two OASI QI Leads (one midwife and one obstetrician) to lead care bundle implementation. The OASI2 project team will provide all leads with an implementation toolkit that includes an updated OASI Care Bundle manual for clinicians, an accompanying e-Learning package, and implementation guidance for designated leads. The three study arms are distinguished by different facilitation models, which are the interventions that will be evaluated and compared in this study.

The three study arms will be evaluated and compared in terms of clinical and implementation outcomes.
1.Sustainability arm: The maternity units in this arm have already implemented the care bundle as part of the preceding OASI1 study and are paired with 'buddy' units from the peer support arm. The project team will organise and deliver a skills development module for these units and follow-up with OASI QI Leads on a monthly basis to track progress on agreed upon efforts to support the care bundle's long-term sustainability. This is the 'expert outreach' facilitation model. OASI QI Leads from this arm have a dual role: in their own units they will support the care bundle's sustainability, and in their buddy units, they will provide their buddy leads with continuous implementation guidance based on their own experience.
2. Peer support arm: OASI QI Leads of maternity units in this arm benefit from a 'peer support' facilitation model and will receive continuous external support from a nearby maternity unit that has previously implemented the care bundle (with 'peers' originating from the sustainability arm of the study, as described above).
3. Lean implementation arm: OASI QI Leads of maternity units in this arm will be testing the 'lean' facilitation model and will only receive the implementation toolkit– but no further external implementation support.

Intervention Type
Other

Primary outcome measure
1. OASI rates (primary clinical outcome) measured using Local Maternity Information Systems and the SMR02/SBR at baseline, months 3, 6, 9 and 12
2. Clinicians' adoption of the OASI Care bundle (primary implementation outcome) measured using the Normalization Measurement Development (NoMAD) tool at months 4 and 10

Secondary outcome measures
1. Women's perceptions of the acceptability of the care bundle, measured using postnatal questionnaire at months 5-8
2. Clinicians' perceptions of the acceptability, appropriateness and feasibility of the care bundle, measured using Intervention Acceptability Measure (IAM), Appropriateness of Intervention Measure (AIM), Feasibility of Intervention Measure (FIM) at months 4 and 10
3. Facilitators' perceptions of the acceptability, appropriateness and feasibility of the scale-up strategy, measured using Intervention Acceptability Measure (IAM), Appropriateness of Intervention Measure (AIM), Feasibility of Intervention Measure (FIM), and focus group discussions at months 4 and 10 (IAM, AIM, and FIM), and month 12 (focus groups)
4. Care bundle compliance recorded by clinician at months 3, 6, 9 and 12

Overall study start date
01/07/2019

Completion date
31/12/2022

Eligibility

Key inclusion criteria
There are two groups of participants in this study: midwifery and obstetric clinicians from participating units, who will be asked to incorporate the care bundle into their routine practice, and women giving birth in participating units who may receive the care bundle if eligible.

All midwives and obstetricians working at participating units are considered participants in the study. Two clinicians (one midwife and one obstetrician) will be selected by their unit leadership for the role of OASI QI Lead. All clinicians (including OASI QI Leads) will be invited to complete surveys at two points in the implementation period to share their experiences and thoughts about the care bundle and its implementation in their units.

Women who attend their antenatal care appointment at participating units are eligible to receive information about OASI and the OASI Care Bundle (discussing the care bundle with women during antenatal care is the first element of the care bundle). Women who subsequently have a singleton, live, term, cephalic, vaginal birth are eligible to receive the care bundle if they are in a birthing position that allows for it and if they provide verbal consent to the elements as they are communicated by the attending clinician, as per routine practice.

Eligible women will be recruited to participate in a postnatal survey about their birth experience as it relates to perineal protection/OASI prevention. To be eligible to participate in the survey, women must have had a singleton, live, term, cephalic, vaginal birth in any participating maternity unit.

Participant type(s)

Mixed

Age group
Adult

Sex
Both

Target number of participants
11107

Key exclusion criteria
1. Clinicians (OASI QI Leads and midwifery/obstetric staff) not employed by one of the 30 participating maternity units
2. Women will not be invited to participate in the postnatal survey if they had a caesarean section or multiple or preterm or breech or stillbirth

Date of first enrolment
27/11/2021

Date of final enrolment
31/10/2022

Locations

Countries of recruitment
England

Scotland

United Kingdom

Wales

Study participating centre
Milton Keynes University Hospital
Standing Way
Eaglestone
Milton Keynes
United Kingdom
MK6 5LD

Study participating centre
Birmingham Women’s Hospital
Birmingham Women's and Children's NHS Foundation Trust
Steelhouse Lane
Birmingham

United Kingdom
B4 6NH

Study participating centre
Saint Mary's Hospital
Manchester University
NHS Foundation Trust Cobbett House
Oxford Road
Manchester
United Kingdom
M13 9WL

Study participating centre
Chelsea & Westminster Hospital
NHS Foundation Trust Chelsea & Westminster Hospital
369 Fulham Road
London
United Kingdom
SW10 9NH

Study participating centre
Epsom Hospital
Epsom And St Helier University Hospitals NHS Trust
St Helier Hospital
Wrythe Lane
Carshalton
United Kingdom
SM5 1AA

Study participating centre
Calderdale Royal Hospital
Calderdale and Huddersfield NHS Foundation Trust
Trust Headquarters
Acre Street
Lindley
Huddersfield
United Kingdom
HD3 3EA

Study participating centre

University Hospital Of North Tees
North Tees and Hartlepool NHS Foundation Trust
University Hospital Of Hartlepool
Holdforth Road
Hartlepool
United Kingdom
TS24 9AH

Study participating centre
Queen Elizabeth Hospital Glasgow
NHS Greater Glasgow and Clyde
JB Russell House
Gartnavel Royal Hospital
1055 Great Western Road
Glasgow
United Kingdom
G12 0XH

Study participating centre
St John's Hospital
NHS Lothian
Waverley Gate
2-4 Waterloo Place
Edinburgh
United Kingdom
EH1 3EG

Study participating centre
Grange University Hospital (previously Royal Gwent Hospital)
Aneurin Bevan University LHB
Llanyravon
Cwmbran
United Kingdom
NP44 2XJ

Study participating centre
Southmead Hospital
North Bristol NHS Trust
Southmead Road
Westbury On Trym
Bristol
United Kingdom
BS10 5NB

Study participating centre
University Hospital Wales
Cardiff & Vale University LHB
Woodland House
Maes-Y-Coed Road
Cardiff
United Kingdom
CF14 4HH

Study participating centre
Ayrshire Maternity Unit
NHS Ayrshire And Arran
PO Box 13, Boswell House
10 Arthur Street
Ayr
United Kingdom
KA7 1QJ

Study participating centre
Forth Valley Royal Hospital
NHS Forth Valley
33 Spittal Street
Stirling
United Kingdom
FK8 1DX

Study participating centre
Aberdeen Maternity Hospital
NHS Grampian
Summerfield House
2 Eday Road
Aberdeen
United Kingdom
AB15 6RE

Study participating centre
Royal Victoria Infirmary
The Newcastle Upon Tyne Hospitals NHS Foundation Trust
Freeman Hospital
Freeman Road

High Haton
Newcastle Upon Tyne
United Kingdom
NE7 7DN

Study participating centre
Pinderfield's Hospital
Mid Yorkshire Hospitals NHS Trust
Pinderfields Hospital
Aberford Road
Wakefield
United Kingdom
WF1 4DG

Study participating centre
Harrogate District Hospital
Harrogate and District NHS Foundation Trust
Harrogate District Hospital
Lancaster Park Road
Harrogate
United Kingdom
HG2 7SX

Study participating centre
Royal Surrey County Hospital
Royal Surrey County Hospital NHS
Egerton Road
Guildford
United Kingdom
GU2 7XX

Study participating centre
St Peters Hospital
Ashford and St Peter's Hospitals NHS Foundation Trust
Guildford Road
Chertsey
United Kingdom
KT16 0PZ

Study participating centre

St Marys Hospital
Imperial College Healthcare NHS Trust
The Bays
South Wharf Road
London
United Kingdom
W2 1BL

Study participating centre
King's College Hospital
Kings College Hospital NHS Foundation Trust
Denmark Hill
London
United Kingdom
SE5 9RS

Study participating centre
Stepping Hill Hospital
Stockport NHS Foundation Trust
Poplar Grove
Stockport
United Kingdom
SK2 7JE

Study participating centre
Victoria Hospital
Blackpool Teaching Hospitals NHS Foundation Trust
Whinney Heys Road
Blackpool
United Kingdom
FY3 8NR

Study participating centre
Chesterfield Royal Hospital
Chesterfield Royal Hospital NHS Foundation Trust
Chesterfield Road
Valow
Chesterfield
United Kingdom
S44 5BL

Study participating centre
Manor Hospital
Walsall Healthcare NHS Trust
Manor Hospital
Moat Road
Walsall
United Kingdom
WS2 9PS

Study participating centre
Addenbrooke's Hospital (The Rosie Hospital)
Cambridge University Hospitals NHS Foundation Trust
Cambridge Biomedical Campus
Hills Road
Cambridge
United Kingdom
CB2 0QQ

Study participating centre
Broomfield Hospital
Mid Essex Hospital Services NHS Trust
Court Road
Chelmsford
United Kingdom
CM1 7ET

Study participating centre
Leeds General Infirmary
Leeds Teaching Hospitals NHS Trust
Great George Street
Leeds
United Kingdom
LS1 3EX

Sponsor information

Organisation
Croydon Health Services NHS Trust

Sponsor details

Croydon University Hospital
530 London Road
Thornton Heath
England
United Kingdom
CR7 7YE
+44 (0)20 8655 5520
ranee.thakar@nhs.net

Sponsor type
Hospital/treatment centre

Website
https://www.croydonhealthservices.nhs.uk/

ROR
https://ror.org/00sh7p618

Funder(s)

Funder type
Charity

Funder Name
The Health Foundation; Grant Codes: 1274142

Results and Publications

Publication and dissemination plan
The researchers' wide-reaching strategy includes dissemination of study design and results in peer-reviewed publications, conferences, and through the communications channels available to professional bodies which are able to reach clinicians and well-established women’s networks. The study protocol will be submitted for publication in a peer-reviewed journal. Study results will also be submitted for publication in high-impact peer-reviewed journals, made available on the study website, and shared with study participants in a Participatory Learning Day at the RCOG. One of the key products of the study is the development of an implementation blueprint, which will collate and operationalise key findings from the study to provide a generalisable guide to successful care bundle implementation in other maternity units. This implementation blueprint is intended to be made publically available in a web-based format.
Individual-woman level data extracted from the local Maternity Information System (MIS) for this study will be anonymised by staff at the participating unit prior to being shared with the study team. All study results will be reported at the study arm level and will not be identifiable to the participating unit.

Intention to publish date

31/03/2023

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available as they contain individual-level, sensitive health information.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Abstract results	study design presented at the 3rd UK Implementation Science Research Conference (16-17 July):	17/12/2020	27/01/2021	No	No
Protocol article		22/05/2021	24/05/2021	Yes	No
HRA research summary			28/06/2023	No	No