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Optimising Baby to Breast Attachment (OBBA)

Submission date 28/03/2011	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 28/03/2011	**Overall study status** Completed	
Last Edited 28/01/2019	**Condition category** Pregnancy and Childbirth	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
9863

Study information

Scientific Title
Optimising Baby to Breast Attachment (OBBA): a mixed method study

Acronym
OBBA

Study objectives

Phase 1: Refinement of a complex intervention to teach mothers how to Optimise Baby to Breast Attachment (OBBA).

Phase 2: RCT - final design determined by findings from phase 1.
Women will receive: a. Standard breastfeeding support or b. Standard breastfeeding support plus the intervention

Phase 3. Process evaluation
a. In-depth interviews with a selection of women from both groups.
b. One-to-one interviews with women who decline participation in RCT.
c. Focus groups with health professionals.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Newcastle & North Tyneside 1 Research Ethics Committee. Original approval given 20/01/2011. Amendment No 1 (08/02/2011) approval given 21/02/2011

Study design
Both; Interventional and Observational; Design type: a) Quantitative (RCT) and b) Qualitative (one to one structured interviews, one to one in-depth interviews, and focus groups)

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Topic: Reproductive Health and Childbirth; Subtopic: Reproductive Health and Childbirth (all Subtopics); Disease: Reproductive Health & Childbirth

Interventions
OBBA, Education session with mothers to teach how to optimising baby to breast attachment; Study Entry : Registration and One or More Randomisations

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Breastfeeding duration; Timepoint(s): 6 weeks

Key secondary outcome(s))
1. Breastfeeding self efficacy
2. Number and type of breastfeeding problems
3. Satisfaction with breastfeeding experience
4. Acceptability of intervention (intervention group only)

Completion date
01/04/2013

Eligibility

Key inclusion criteria
1. Mothers whom have delivered a singleton full-term healthy baby more than or equal to 37wks gestation, and more than or equal to 2500g
2. Mothers who initiate breastfeeding prior to discharge from hospital
3. Mothers who have a good command of the English language
Target Gender: Female; Upper Age Limit 50 years ; Lower Age Limit 16 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
1. Women with babies with major congenital anomalies
2. Women whose babies are admitted to the special care baby unit
3. Women unable to converse in the English language will be excluded due to the developmental nature of the study and the large qualitative element and limited resources to translate the intervention, education material and questionnaires

Date of first enrolment
01/03/2011

Date of final enrolment
01/04/2013

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Newcastle University
Newcastle

United Kingdom
NE2 4HH

Sponsor information

Organisation
Newcastle upon Tyne Hospitals NHS Foundation Trust (UK)

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK) - Doctor Research Fellowship

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		21/01/2019	24/01/2019	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes