

Optimising Baby to Breast Attachment (OBBA)

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

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

Primary study design

Interventional

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)

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