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# Optimising Baby to Breast Attachment (OBBA)

**Submission date**
28/03/2011

**Recruitment status**
No longer recruiting

**Registration date**
28/03/2011

**Overall study status**
Completed

**Last Edited**
28/01/2019

**Condition category**
Pregnancy and Childbirth

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] 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

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
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

## Secondary study design
Randomised controlled trial

## Study setting(s)
Hospital

## Study type(s)
Treatment

## Participant information sheet
Not available in web format, please use contact details below to request a patient information sheet

## 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 measure
Breastfeeding duration; Timepoint(s): 6 weeks

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

### Overall study start date
01/03/2011

### 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

### Age group
Adult

### Sex
Female

### Target number of participants
Planned Sample Size: 188; UK Sample Size: 188

### 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
England

United Kingdom

### Study participating centre
**Newcastle University**
Newcastle
United Kingdom
NE2 4HH

## Sponsor information

### Organisation
Newcastle upon Tyne Hospitals NHS Foundation Trust (UK)

### Sponsor details
Midwifery Research Dept, Leazes Wing,
Queen Victoria Road
Newcastle upon Tyne
England
United Kingdom
NE1 4LP

### Sponsor type
Hospital/treatment centre

### 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

### Publication and dissemination plan
04/04/2018: Results published in thesis 2014 https://theses.ncl.ac.uk/dspace/bitstream/10443/2828/1/Kelly%2C%20T.A.%202015.pdf

### Intention to publish date

### 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 |