

Proactive telephone support for breastfeeding women in disadvantaged areas provided by a postnatal ward feeding support team

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Registration date 02/08/2010	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 19/09/2013	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Study website

<http://viis.abdn.ac.uk/hsru/Fest/>

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

2010PH001

Study information

Scientific Title

Proactive telephone support for breastfeeding women in disadvantaged areas provided by a postnatal ward feeding support team: A nested, pilot, randomised controlled trial

Acronym

FEST (FEeding Support Team Study)

Study objectives

1. Is additional pro-active (health service initiated) telephone breastfeeding support offered to women living in disadvantaged areas after hospital discharge feasible and likely to be more effective than reactive telephone support at increasing the proportion of women who are breastfeeding exclusively at 6-8 weeks?
2. Is it feasible to have a dedicated feeding team, with skill mix, based on a postnatal ward to deliver feeding support to women on the ward and a telephone support service for up to 2 weeks to breastfeeding women after hospital discharge?
3. What are the opportunities and barriers to implementing the above two interventions?

Ethics approval required

Old ethics approval format

Ethics approval(s)

North of Scotland Research Ethics Committee approved on the 23rd of April 2010 (ref: 10/S0801/22)

Study design

Single centre pilot randomised controlled trial embedded within a mixed methods action research study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Breast feeding

Interventions

A multi-skilled feeding team will be set up to provide breastfeeding support on the postnatal ward and deliver a pilot RCT of pro-active/reactive telephone support after hospital discharge.

All trial participants:

Specialised feeding support team care on the postnatal ward including watching a breast feed. Ability for patients to telephone the feeding support team for up to 2 weeks after hospital discharge.

Intervention arm:

In addition, pro-active (feeding team initiated) daily telephone calls following hospital discharge for 1 week, with the option to continue for an extra week unless she chooses to withdraw from the study or stops breastfeeding before then.

RCT embedded within a before (3 months) and during the feeding support team intervention (3 months) audit of any breastfeeding (initiation and at 6-8 weeks after birth)

1. Steering group to oversee the project

1.1. Steering group of lay and professional representatives to meet every 4 weeks (recorded). Reflective action cycles. PH to chair.

1.2. Identify pregnant women due to deliver during the feeding team intervention and send information leaflets when they are 32-36 weeks pregnant

1.3. Map existing care pathways and resources for breastfeeding in Grampian to optimise the fit between the new feeding team and existing care.

1.4. Develop a triage system to assess need and provide other non-telephone support when required

2. Feeding team member characteristics

2.1. Feeding team members should

2.1.1. have personally breastfed

2.1.2. be trained and up to date in breastfeeding management ideally to UNICEF level

2.2. The team composition to be decided through the action research process. It might include midwives, nursery nurses, maternity aids, peer supporters.

3. Feeding team roles

3.1. To identify women initiating breastfeeding and living in eligible postcodes (list drawn up by the research team) and gain informed consent to participate

3.2. To watch a complete breastfeed for all women prior to hospital discharge and provide breastfeeding support on the ward for all consenting women

3.3. Document feeding method at discharge. If breastfeeding and they consent to the RCT they will be randomised immediately after hospital discharge

3.4. Immediately after hospital discharge, the feeding support team will access a web based independent randomisation system set up by CHART, a registered clinical trials unit at the University of Aberdeen, and they will be informed whether the woman is in the intervention (proactive daily phone calls) or control (no further intervention women can phone the team) arm

3.5. All women randomised to the telephone support trial will be able to initiate phone calls to the feeding team for the first 2 weeks after hospital discharge

3.6. In the intervention arm, maximum support would be pro-active (feeding team initiated) daily

telephone calls following hospital discharge for 1 week, with the option to continue for an extra week unless she chooses to withdraw from the study or stops breastfeeding before then

3.7. Triage to other care pathways if indicated, including a face to face assessment at a mutually convenient time and place e.g. assessment of positioning and attachment

3.8. Complete a telephone and patient contact time log

3.9. Attend steering group meetings

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Any breastfeeding at 6-8 weeks after birth

Secondary outcome measures

1. Exclusive breastfeeding at 6-8 weeks after birth
2. Satisfaction with hospital care
3. Satisfaction with care after discharge home
4. Process evaluation - qualitative interview data
5. Health Economic evaluation

All outcomes to be assessed at 6-8 weeks after birth using modifications of the tools used in the BIG trial (ISRCTN44857041; see <http://www.controlled-trials.com/ISRCTN44857041>)

Overall study start date

26/07/2010

Completion date

20/12/2010

Eligibility

Key inclusion criteria

Women living in the three most disadvantaged postcode area quintiles of the Scottish Index of Multiple Deprivation, who initiate breastfeeding while on a postnatal ward and consent to participate.

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

60

Key exclusion criteria

1. Serious maternal medical or psychiatric problems
2. Serious infant health problems
3. Language problems that cannot be resolved through the use of language line

Date of first enrolment

26/07/2010

Date of final enrolment

20/12/2010

Locations**Countries of recruitment**

Scotland

United Kingdom

Study participating centre

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Sponsor information**Organisation**

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Sponsor type

University/education

ROR

<https://ror.org/016476m91>

Funder(s)

Funder type

Government

Funder Name

NHS Grampian (UK) - Chief Executive Letter (CEL) 36: Nutrition of women of childbearing age, pregnant women and children under five in disadvantaged areas (funding allocation 2008 - 2011) (ref: 2010PH001)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	24/04/2012		Yes	No
Results article	process evaluation results	25/04/2012		Yes	No