Successful breastfeeding promotion: a motivational instructional model applied and tested

Submission date Recruitment status Prospectively registered 02/07/2007 No longer recruiting [] Protocol [] Statistical analysis plan Registration date Overall study status 16/07/2007 Completed [X] Results [] Individual participant data Last Edited Condition category 19/05/2017 Pregnancy and Childbirth

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Prof Marlene Sinclair

Contact details

Room 24L12, University of Ulster Jordanstown Belfast (Northern Ireland) United Kingdom BT37 OQB +44 (0)28 90 368118 m.sinclair1@ulster.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

EAT/1863/01 (The Research and Development Office Northern Ireland)

Study information

Scientific Title

Successful breastfeeding promotion: a motivational instructional model applied and tested

Study objectives

Breastfeeding initiation rates have increased over the last decade; however, breastfeeding duration rates have not (Infant Feeding Survey 2002). One fifth of women reportedly stop breastfeeding before leaving hospital. This study tested a motivational intervention delivered through routine midwife instruction with the intention of increasing women's motivation to sustain breastfeeding while receiving instruction from midwives.

The null hypothesis tested that there was no difference in the motivational outcomes of women who received the motivationally-enhanced version of midwife instruction and those who received current midwife instruction in accordance with best practice.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Received from University of Ulster Research Ethical Committee in October 2004, transferred to Office for Research Ethics Committees Northern Ireland (ORECNI) in May 2006 (ref: 03/97).

Study design

Intervention single-centred single-blind trial (women were blind to group, stickers indicated group to midwives). Prior to recruitment a randomised table was created

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Quality of life

Participant information sheet

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

Health condition(s) or problem(s) studied

Breastfeeding promotion

Interventions

Control group:

The control group received breastfeeding instruction in step with the Baby Friendly Initiative and according to National Institute for Clinical Excellence (NICE) guidelines.

Intervention group:

The intervention group received a motivationally-enhanced version of the same instruction which was called 'Designer Breastfeeding'. As a result both groups received a two-hour antenatal infant feeding class, a breastfeeding book and midwife support for the first three postnatal weeks.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Using seven point Likert scales women's motivational profile was measured in relation to three motivational factors:

- 1. Total value placed on breastfeeding
- 2. Total perceived midwife support
- 3. Total expectancy for successful breastfeeding

The Breastfeeding Instructional Motivation Measurement Tool was developed specifically for this study. Using factor analysis (n = 199) the reliability coefficients for the three motivational factors were satisfactory (Cronbach Alpha .8622, .8751, .8549). Data were collected on discharge from hospital by structured interview.

Primary outcomes were measured on discharge from hospital.

Secondary outcome measures

- 1. Breastfeeding behaviour was measured as a secondary outcome on discharge from hospital and at 3 weeks postnatal
- 2. Breastfeeding initiation was defined according to the Department of Health as giving one breastfeed or one episode of expressed breastmilk
- 3. Duration of breastfeeding was categorised in accordance with the Index of Breastfeeding Status (cited by Harmon-Jones, 2006), which classified breastfeeding on a scale in accordance with the amount of breastmilk the infant is receiving (1 = 100% breastmilk, 2 = more than 80% breastmilk and less than 20% other, 3 = 50 80% breastmilk, 4 = 50% breastmilk, 5 = 20 50% breastmilk, 6 = less than 20% breastmilk, 7 = 100% artificial milk).

Secondary outcomes were measured on discharge from hospital, and were repeated at 3 weeks postnatal (in the community and just prior to transfer of care to the health visiting services).

Overall study start date

01/12/2005

Completion date

01/10/2006

Eligibility

Key inclusion criteria

- 1. All consenting primgravida women (20 weeks gestation) who attended at the time of recruitment
- 2. Inclusion criteria included their intention to have their baby at the research hospital
- 3. No age limit was applied

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

Assessed for eligibility (n = 234), excluded (n = 34), declined (n = 9), consented (n = 182), completed (n = 144)

Key exclusion criteria

- 1. Incidents where a mother and baby were separated, for example when a baby was admitted to the neo-natal unit and did not receive routine instruction
- 2. Women who had already commenced the 'young mums' parentcraft program prior to 20 weeks gestation (19 years old or less)
- 3. Women who for ethical reasons were considered vulnerable, for example, women who neither spoke or understood English
- 4. Women who declined to participate

Date of first enrolment

01/12/2005

Date of final enrolment

01/10/2006

Locations

Countries of recruitment

United Kingdom

Study participating centre Room 24L12, University of Ulster

Belfast (Northern Ireland) United Kingdom BT37 OQB

Sponsor information

Organisation

University of Ulster (UK)

Sponsor details

Shore Road Jordanstown Belfast (Northern Ireland) Northern Ireland United Kingdom BT37 OQB +44 (0)8 700 400 700 online@ulster.ac.uk

Sponsor type

University/education

Website

http://www.ulster.ac.uk/

ROR

https://ror.org/01yp9g959

Funder(s)

Funder type

Government

Funder Name

The Research and Development Office of Northern Ireland (UK)

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	31/12/2013		Yes	No