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A randomised controlled trial of the effectiveness of support from breastfeeding counsellors for women who want to breastfeed

Submission date
23/01/2004

Recruitment status
No longer recruiting

Registration date
23/01/2004

Overall study status
Completed

Last Edited
11/01/2010

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
RDC00941

Study information

Scientific Title

Study objectives
This proposal is for randomised controlled trial to test whether women who receive extra support from a breastfeeding counsellor breastfeed for longer than those who do not. Women having their first child or women who did not breastfeed their last child for more than six weeks will be randomly allocated to determine whether or not they receive additional support from a breastfeeding counsellor. The study will be performed in general practice and women will be recruited and followed up by members of their primary care team.
This project addresses the question of how we can help women who have difficulties with breastfeeding and improve breastfeeding rates nationally. It builds up on the applicants previous research and will be a value to many mothers. If this study shows that breastfeeding counsellors are effective, it would encourage more women to train as counsellors and suggest that the NHS should promote their work.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Other

Participant information sheet

Health condition(s) or problem(s) studied
Breastfeeding

Interventions
1. Support from a breastfeeding counsellor
2. Standard care

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Proportion of women breast-feeding to 4 months

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/12/1997

Completion date
01/12/1999

Eligibility

Key inclusion criteria
Women attending for antenatal care between 28 and 36 weeks of pregnancy are asked to complete the initial questionnaire, to determine if they are eligible for inclusion. Mothers were eligible for inclusion if they were considering breast feeding, not having breast-fed a previous child for more than 6 weeks

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
32 practices, 720 women (added 07/01/10)

Key exclusion criteria
1. No spoken English
2. Unsafe for a volunteer to visit the woman's home

Date of first enrolment
01/12/1997

Date of final enrolment
01/12/1999

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of General Practice and Primary Care
London
United Kingdom
E1 4NS

Sponsor information

Organisation
NHS R&D Regional Programme Register - Department of Health (UK)

Sponsor details
The Department of Health
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
NHS Executive London (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	03/01/2004		Yes	No