

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

<b>Submission date</b> 23/01/2004	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 23/01/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 11/01/2010	<b>Condition category</b> 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

## Contact information

### Type(s)

Scientific

### Contact name

Dr Jonathan Graffy

### Contact details

Department of General Practice and Primary Care  
Queen Mary and Westfield College  
Mile End  
London  
United Kingdom  
E1 4NS  
+44 (0)20 7882 7702/7923 4122

## 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?
<a href="#">Results article</a>	results	03/01/2004		Yes	No