Does infant carrying in a soft carrier promote secure infant attachment and maternal care? A randomised controlled clinical trial

Submission date	Recruitment status	Prospectively registered
30/09/2005	Stopped	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
30/09/2005	Stopped	Results
Last Edited	Condition category	Individual participant data
12/04/2011	Neonatal Diseases	Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0125146731

Study information

Scientific Title

Study objectives

- 1. Does use of a soft baby carrier promote mother-infant sensitivity?
- 2. Does soft baby carrier use promote secure infant attachment in children from a variety of family backgrounds who would otherwise be at high risk of developing an insecure attachment?

As of June 2008: trial has not started.

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)

Not specified

Study type(s)

Not Specified

Participant information sheet

Health condition(s) or problem(s) studied

Neonatal Diseases

Interventions

- 1. Experimental: Provision of soft baby carrier(s) appropriate for infant carriage against the trunk for the first six months after birth, with ongoing encouragement to use for 2 hours daily.
- 2. Control: Provision of infant clothing vouchers.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

- 1. The means of measures of 3 axes of maternal care the Care Index (Crittenden, 1992) at 3 months.
- 2. The proportions of experimental and control groups with secure attachment Strange Situation Test at 13 months (Ainsworth, 1978).
- 3. Actual duration and intensity of soft baby carrier use at 1, 3, 5, 8 and 13 months.

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/01/2005

Completion date

30/09/2007

Reason abandoned (if study stopped)

Not started, awaiting approval/funding

Eligibility

Key inclusion criteria

Mothers of newborns that are eligible and give informed consent will be randomly assigned to the experimental or the control group, based on revealing the next in a series of random numbers.

Women who deliver a singleton live infant in the delivery suite of a large, inner-city hospital, aged 16+, accessible by telephone, able to speak conversational English, and not planning to move out of the area within 15 months will be eligible for participation in the study.

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

Not provided at time of registration

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/01/2005

Date of final enrolment

30/09/2007

Locations

Countries of recruitment

England

United Kingdom

Study participating centre Honor Oak Health Centre London United Kingdom SE4 1JN

Sponsor information

Organisation

Department of Health

Sponsor details

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.dh.gov.uk/Home/fs/en

Funder(s)

Funder type

Government

Funder Name

Lewisham Research Unit (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