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

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

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
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
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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