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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Not Specified

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(s)
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.

Key secondary outcome(s)
Not provided at time of registration

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

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

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
United Kingdom

England

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

Sponsor information

Organisation
Department of Health

Funder(s)

Funder type
Government

Funder Name
Lewisham Research Unit (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration