

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

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

Study design

Randomised controlled trial

Primary study design

Interventional

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