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Investigation of the effect of swaddling upon psychomotor and mental development in children at 13 and 36 months of age in Mongolia

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Registration date 20/11/2009	**Overall study status** Completed	
Last Edited 20/03/2013	**Condition category** Respiratory	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.lshtm.ac.uk/ideu/research/ideu_research_detail.php?id=226

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
063468

Study information

Scientific Title
Investigation of the effect of swaddling upon psychomotor and mental development in children at 13 and 36 months of age in Mongolia: a randomised controlled trial

Study objectives
Null Hypothesis: Swaddled children do not have worst developmental scores at 13 months compared to non-swaddled infants.

Primary outcome study question:
1. What is the effect of tightly swaddled Mongolian infants upon their Bayley Scales of Infant Development (BSID-II) scores at around 13 months compared to those not swaddled?
2. What is the effect of tightly swaddled Mongolian infants upon their BSID-II scores at around 3.5 years compared to those not swaddled?

Secondary outcome study questions:
1. What are the BSID-II scores for our trial population as a sample of Mongolian infants?
2. What is the effect of swaddling upon the weight, height, head circumference of infants in Ulaanbaatar at 13 months?
3. What are the BSID-II scores for our trial population as a sample of Mongolian infants at 3.5 years of age?

Please note that this is the phase II and III study of the Swaddling and Health Research Project, phase I trial details can be found at: http://www.controlled-trials.com/ISRCTN01992617

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. London School of Hygiene and Tropical Medicine (LSHTM) Ethics Committee approved on the 5th April 2001 (ref: ETH2003-04/107). Additional approval received on the 5th February 2003.
2. Ministry of Health (MOH) of Mongolia approved on the 15th January 2004 (ref: 3/124)

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)

Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Infant motor/psychosocial development

Interventions
All infants were recruited at birth and randomised to swaddling versus non-swaddling groups. Babies were then followed up intensely for 7 months (see phase I for more details) and then not seen again until 12 months of age; they had another follow-up contact at 13 months of age (or as soon after this time when they came for testing). There was also another visit at 3.5 years of each to each child and family when background, morbidity and mother related data were collected, and children tested for development achievements..

Swaddling group:
The babies randomised into the swaddling group were to be swaddled in the common traditional Mongolian method as much as they felt comfortable at least until 7 months follow-up. Traditional swaddling in Mongolia was as follows:
Swaddling was a tightly wrapping (2 adult fingers pass under the cloth) of a baby in several layers of cloth, covered by one warmer blanket from head to toe in a straight position after birth for about six months. Two or three ropes were used across a baby's body for binding to avoid unwrapping. For the first three months baby was swaddled most of the day and night with changes of the soiled cloth made every three or eight hours. After this age, practice varies with reducing hours of swaddling, but most infants were swaddled during sleep at least until 7 - 12 months. Duration and tightness of wrapping decreased with age. Furthermore as the baby grew, swaddling clothes for indoor may not have covered the head and would enclose the legs, trunk and arms up to the infant's necks, while after 6 months, in some occasions it only enclosed up to the waist. In the swaddling group, there was expected to be some variation in the swaddling period after 2 to 3 months, but it was usually expected to be more than 17 in 24 hours for those living in colder dwellings. Since the non-swaddling clothes had to be provided with alternatives to the readily available swaddling clothes and blankets, the swaddled group were given a blanket and 3 cotton sheets at the time of recruitment.

Swaddling, a cultural norm, was not a difficult infant care practice to achieve in this study. Swaddled babies would often be placed horizontal on a bed or carried, and not positioned vertically as with some cultures.

Non-swaddling group:
The non-swaddling group were instructed not to swaddle at all. The Mongolian stores did not sell the required size and warmth of clothing required to keep a newborn infant warmly clothed during the Siberian winters of Mongolia. Our recruitment pilot, in September 2000, indicated that in order to enable this alternative childcare method to be possible for the families randomised to the non-swaddling group, the project needed to provide some alternatives. Therefore, at the time of recruitment, the project gave each family a sheepskin sleeping bag and hat, a cotton sleeping bag, 8 cotton 0 - 3 months outfits. At 4 and then 12 weeks, the non-swaddling group was given another sheepskin hat and 10 outfits of a bigger size, which would fit the babies until 6 months of age. Half the outfits were made in Mongolia and half were body-suits made in the UK and transported to Mongolia. The sleeping bags were designed in

consultation with 'Grobags' company in England, who have worked closely with Professor Fleming (a collaborator with the study at Bristol University, and an international expert in infant temperature regulation and SIDS). The sleeping bags were made in Mongolia but the manufacturers applied specific requirements developed in the UK. The families were encouraged to make or buy their own additional outfits for their infants, but if they could not, the project ones given to them were supplied in a large enough number in order to allow for washing dirty outfits at the same time as wearing up to 3 layers of outfits for the cold winter.

The sleeping bags were to be used at the parent's discretion, but the sheepskin sleeping bag especially was thought to be particularly useful for the cold evenings and when going outside. A leaflet was prepared for each family to explain what outfits they should expect to receive and how to use these to clothe their baby.

Monitoring
In the non-swaddling group, it was expected that some families would not adhere to their instructions of not swaddling because of cultural pressures. To monitor compliance and obtain a measure of exposure, multiple sources of information were used:
1. A retrospective 24-hour history of swaddling/clothing: recorded by the field-workers during each 3-weekly home visit through recording the carer's descriptions of the style of dress /clothing/ swaddling and length of each during the past 24-hour within the 24-hour retrospective diaries (a kind of behaviour diary adapted to record swaddling/clothing pattern)
2. Direct observation of fieldworker during 3-weekly visits: of the dressing/clothing/ swaddling of each child and discreetly recording observations of the type of baby clothing items that each family washed and hung to dry on the day of visit (available for observation during the majority of visits)
3. Analysis of the 4-days prospective mother's diaries used for sleeping and crying/fussing outcome measure: as mother's own reported behaviour during 2 time periods
4. Unscheduled visits from a monitoring fieldworker: in order to estimate unreported non-compliance conducted for all families 1 to 3 times
5. End-study fieldworker impressions' questionnaire: of their impression about compliance in each family and the consistency and extent of accuracy of the reports from each family during each 3 months of child's life

For analysis, the first and third methods of exposure recordings above were quantifiable and were combined to reveal exposure to swaddling per child for use in per-protocol analysis. The other three methods detailed above were triangulated with the data from the diaries and concluded that over 95% of families' compliance was revealed through the 3-weekly 24-hour retrospective diaries and the 4-day prospective diaries.

Data was collected retrospectively at 13 months on the last dates of swaddling during day time and sleep. For the swaddling group most were after the 7 months follow-up. These were triangulated with the data from the phase I (mentioned in the hypothesis above).

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure

BSID-II, an internationally acclaimed test of mental and psychomotor development in early childhood, measured at 12 - 15 months of age and again at 3.5 years:
1. BSID-II mental scale: evaluates childrens sensory/perceptual acuities, discriminations, and response; acquisition of object constancy; memory learning and problem solving; vocalization and beginning of verbal communication; basis of abstract thinking; habituation; mental mapping; complex language; and mathematical concept formation
2. BSID-II psychomotor scale: evaluates the degree of body control; large muscle coordination; fine manipulatory skills of the hands and fingers; dynamic movement; postural imitation; and stereognosis (ability to recognize objects by sense of touch)

Test scores are reported as scaled scores based on the infants age, with a normed mean of 100 (SD = 15 points). Both scales have high correlation coefficients (0/83 and 0/77 respectively) for test-retest reliability.

Secondary outcome measures
Length or height, head circumference, or Mid Upper Arm Circumference (MUAC) in cm (to the nearest 0.5cm); and weight in grams. Measured at 12 - 15 months of age.

Overall study start date
10/09/2002

Completion date
01/07/2006

Eligibility

Key inclusion criteria
1. All babies born in the only four maternity hospitals of Ulaanbaatar (greater than 95% births were in these facilities)
2. Within 48 hours of birth if resident of Ulaanbaatar
3. Mother was well enough to discuss consent

Participant type(s)
Patient

Age group
Child

Sex
Both

Target number of participants
1250

Key exclusion criteria
1. Refusal to consent
2. Birth weight less than 2500 g
3. Less than 36 weeks gestation
4. Obvious congenital abnormalities (with clear medical consequences)
5. Need for infant intensive care treatment

6. Residence in very warm apartments (defined by the mother) since a pilot study indicated such families considered the home to be too hot for the baby to be wrapped

Date of first enrolment
10/09/2002

Date of final enrolment
01/07/2006

Locations

Countries of recruitment
England

Mongolia

United Kingdom

Study participating centre
Public Health, Epidemiology & Biostatistics
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Sponsor information

Organisation
Individual Sponsor (UK)

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Sponsor type
Other

Funder(s)

Funder type

Charity

Funder Name
The Wellcome Trust (UK) (grant ref: 063468)

Funder Name
United Nations Children's Fund (UNICEF) Mongolia office and Canada Fund (Mongolia) (ref: MON2003/2004.02)

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?
Results article	results	01/02/2007		Yes	No