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# A controlled trial of a community based mother-infant intervention in a South African peri-urban settlement

**Submission date**
06/07/2006

**Recruitment status**
No longer recruiting

**Registration date**
10/07/2006

**Overall study status**
Completed

**Last Edited**
01/03/2017

**Condition category**
Pregnancy and Childbirth

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

**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**
057243; B574100

# Study information

### Scientific Title
A controlled trial of a community based mother-infant intervention in a South African peri-urban settlement

### Study objectives
Compared to a no treatment control group, a mother-infant intervention which provides emotional support and sensitises mothers to infant communicative capacities will lead to more sensitive maternal interactions with more expressions of positive affect and less intrusive behaviour. This will also lead to a higher rate of securely attached infants and, secondarily, will reduce maternal depression.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
1. University of Reading ethics and research committee, 21/10/1999, ref: 99/20
2. University of Cape Town Medical School research ethics committee, 02/02/1998, ref: 180/97

### Study design
Randomised controlled trial

### Primary study design
Interventional

### Secondary study design
Randomised controlled trial

### Study setting(s)
Home

### Study type(s)
Quality of life

### Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

### Health condition(s) or problem(s) studied
Pregnancy

### Interventions
An index intervention is compared with no intervention. All pregnant women within a defined area of Khayelitsha will be randomised to a no treatment control group or the index intervention. The intervention, which runs from late pregnancy until six months postpartum, involves two antenatal and 13 postnatal home visits by community workers trained to provide emotional support and to sensitise mothers to infant communicative capacities. Assessments are made at six, 12 and 18 months postpartum.

### Intervention Type
Other

### Phase
Not Specified

### Primary outcome measure
1. The quality of the mother-infant relationship at 6 and 12 months (sensitivity, positive effect, intrusiveness)
2. Security of infant attachment at 18 months

### Secondary outcome measures
Maternal depression at 6 and 12 months postpartum

### Overall study start date
01/01/2000

### Completion date
31/12/2006

## Eligibility

### Key inclusion criteria
Pregnant women within a defined area of Khayelitsha, a peri-urban settlement on the outskirts of Cape Town

### Participant type(s)
Patient

### Age group
Adult

### Sex
Female

### Target number of participants
300

### Key exclusion criteria
Does not meet inclusion criteria

### Date of first enrolment
01/01/2000

### Date of final enrolment
31/12/2006

## Locations

### Countries of recruitment
England

South Africa

United Kingdom

### Study participating centre
**University of Reading**
Reading
United Kingdom
RG6 6AL

## Sponsor information

### Organisation
The University of Reading (UK)

### Sponsor details
Whiteknights
Reading
England
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### Sponsor type
University/education

### Website
http://www.reading.ac.uk

### ROR
https://ror.org/05v62cm79

## Funder(s)

### Funder type
Charity

### Funder Name

Wellcome Trust (grant ref: 057243)

### Alternative Name(s)

### Funding Body Type
Private sector organisation

### Funding Body Subtype
International organizations

### Location
United Kingdom

## 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 | 14/04/2009 | | Yes | No |
| Results article | results | 28/02/2017 | | Yes | No |