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

Submission date	Recruitment status No longer recruiting Overall study status	<ul><li>Prospectively registered</li></ul>		
06/07/2006		☐ Protocol		
Registration date		Statistical analysis plan		
10/07/2006	Completed	[X] Results		
Last Edited	Condition category	Individual participant data		
01/03/2017	Pregnancy and Childbirth			

### Plain English summary of protocol

Not provided at time of registration

### Contact information

### Type(s)

Scientific

#### Contact name

Prof Peter Cooper

#### Contact details

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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
United Kingdom
RG6 6AL
+44 (0)118 378 6617
p.j.cooper@rdg.ac.uk

### 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