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

Submission date	<b>Recruitment status</b> No longer recruiting	<ul><li>Prospectively registered</li></ul>		
06/07/2006		☐ Protocol		
Registration date	Overall study status	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

Protocol serial number 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

#### Study type(s)

Quality of life

# 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(s)

- 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

# Key secondary outcome(s))

Maternal depression at 6 and 12 months postpartum

#### 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** 

# Healthy volunteers allowed

No

## Age group

Adult

#### Sex

Female

# 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

**United Kingdom** 

England

South Africa

# Study participating centre University of Reading

Reading United Kingdom RG6 6AL

# Sponsor information

# Organisation

The University of Reading (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**

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
Participant information sheet	Participant information sheet	11/11/2025 11/11/2025	No	Yes