

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

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Registration date 10/07/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 01/03/2017	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

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