ISRCTN25664149 https://doi.org/10.1186/ISRCTN25664149

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

Contact name
Prof Peter Cooper

Contact details
School of Psychology and Clinical Language Sciences
University of Reading
Reading
United Kingdom
RG6 6AL
+44 (0)118 378 6617
p.j.cooper@rdg.ac.uk

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

Primary study design
Interventional

Study design
Randomised controlled trial

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