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Is it possible to develop a home based package of interventions delivered by community based women that will improve levels of maternal, newborn, child and HIV care in a disadvantaged community in South Africa?

Submission date 03/11/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 04/01/2010	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 01/07/2013	**Condition category** Neonatal Diseases	[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Mark Tomlinson

Contact details
Department of Psychology
Stellenbosch University
Private Bag X1,
Matieland,
7602,
South Africa
Stellenbosch
South Africa
7602
markt@sun.ac.za

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
An effectiveness study of an integrated, community based package for maternal, newborn, child and HIV care in a disadvantaged community in South Africa

Study objectives
This study aims to test the hypothesis that infants in clusters receiving a home based package of interventions, will have significantly improved HIV free survival and higher levels of exclusive appropriate feeding at 12 weeks postnatally, relative to control clusters receiving improved health facility care and key information to the mother and family on available social grants and the processes for gaining access to these grants.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Medical Research Council (South Africa) Ethics Committee approved on the 5th of May 2008 (Protocol ID: EC08-002)

Study design
Cluster randomised unblinded active controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Other

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Mother to child transmission of HIV; neonatal health

Interventions

1. Antenatal visit 1 at home
Content in this visit will include:
1.1. Antenatal care action immunisations/micronutrient supplementation
1.2. Focus on the importance of VCT (linking this with the PMTCT programme and the benefits of testing to the mother)
1.3. Emphasise the importance of antenatal care
1.4. Key messages on appropriate infant feeding
1.5. Encourage exclusive breastfeeding in HIV negative women or women of unknown HIV status.
1.6. For HIV positive women, assist with thinking about infant feeding options
1.7. Input regarding infant communication and the mother-infant relationship

2. Antenatal visit 2 at home
Content in this visit will include:
2.1. Birth plans place of birth, support during labour, care plans if returning to work
2.3. Danger signs and emergency plans this will be done, if possible together with other family members in order to elicit their input regarding possible plans in the event of an emergency, including recognition of danger signs, emergency transport plan and emergency funds if needed
2.4. Homecoming arrangements
2.5. Follow up and re-emphasis on VCT, PMTCT, the key messages on appropriate infant feeding that were provided in antenatal visit 1; further discussion in terms of assisting with the implementation of chosen feeding option
2.6. Additional input on infant communication and the warning signs of postnatal depression

3. Postnatal visit 1 at home (24-48hrs)
Content in this visit will include:
3.1. Assessment of newborn breathing, thermal care, colour, bleeding, neonatal eye care, checklist of danger signs
3.2. Assessment of mother - bleeding, signs for infection, mastitis
3.3. Early recognition of illness (superficial or systemic) and help seeking
3.4. Exclusive breastfeeding or appropriate infant feeding support
3.5. Hygienic cord care and what to expect regarding when the cord will drop off
3.6. Thermal care, skin to skin care and Kangaroo care if needed for preterm babies
3.7. Ensure that babies of HIV positive women have received Nevirapine
3.8. Information about warning signs for mother or baby and what to do
3.9. Support for women who have the blues

4. Postnatal visit 2 at home (3-4 days)
Content in this visit will include:
4.1. Assessment of the mother and the newborn, Further input on the early recognition of illness (superficial or systemic) and help seeking
4.2. Monitoring and follow up of breastfeeding or appropriate feeding and possible feeding problems
4.3. Further support for hygiene, thermal care and cord care, with Kangaroo care input if needed for preterm babies
4.4. 1st week clinic visit reminder
4.5. Information about warning signs for mother or baby and what to do
4.6. Newborn Interactive Assessment - demonstration of the abilities of infants and infant communication and social responsiveness. Sleeping, crying, consolability and wider concerns

5. Postnatal visit 3 at home (10-14 days)
Content in this visit will include:
5.1. Early recognition of illness (superficial or systemic) and help seeking

5.2. Ongoing monitoring of breastfeeding or other appropriate feeding
5.3. Information about warning signs for mother or baby and what to do
5.4. Promote attendance at clinic for 6 week visit for mother to have access to family planning and baby to receive immunisations and the babies of HIV+ women been given bactrim and HIV testing
5.5. Mother infant interaction modelling and communication input
5.6. Assess for signs of postnatal depression

6. Postnatal visit 4 at home (3-4 weeks)
Content in this visit will include:
6.1. Early recognition of illness (superficial or systemic) and help seeking
6.2. Ongoing monitoring of breastfeeding or other appropriate feeding
6.3. Information about warning signs for mother or baby and what to do
6.4. Promote attendance at clinic for 6 week visit for mother to have access to family planning and baby to receive immunisations and the babies of HIV+ women been given bactrim and HIV testing
6.5. Mother infant interaction modelling and communication input
6.6. Assess for signs of postnatal depression

7. Postnatal visit 5 at home (7-8 weeks)
Content in this visit will include:
7.1. Further input on feeding including advice regarding weaning
7.2. Infant weight from clinic card (6 week visit)
7.3. Mother infant attachment
7.4. Checklist of signs of postnatal depression
7.5. Has the child been tested for HIV at six weeks and receiving cotrimoxazole
7.6. Formula sustainability for HIV positive women using formula milk
7.7. Family planning and counselling
7.8. Input on milestones and information and specific skills about the stimulation of infants

All intervention visits will be delivered by community health workers targeting pregnant women and postnatal women and their newborns to provide essential maternal and newborn care. All visits will take place in the home

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. HIV free infant survival at 12 weeks postpartum
2. Levels of exclusive and appropriate infant feeding at 12 weeks postpartum

Secondary outcome measures
1. Better uptake of a postnatal clinic visit within 7 days of life
2. Coverage of care and behavioural indicators (antenatal HIV testing, uptake of cotrimoxazole amongst HIV exposed infants at 6 weeks, family planning uptake at 6 weeks)
3. Levels of maternal depression at 12 weeks postpartum

4. To assess whether the intervention is cost-effective compared to improved health facility care alone. This will be evaluated in terms of cost per HIV infection averted and disability-adjusted life years (DALYs) saved

Overall study start date
17/06/2008

Completion date
31/10/2010

Eligibility

Key inclusion criteria
All pregnant women aged 16-49 years who give informed consent for study participation

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
A total of 3600 pregnant women will be recruited

Key exclusion criteria
Does not match inclusion criteria

Date of first enrolment
17/06/2008

Date of final enrolment
31/10/2010

Locations

Countries of recruitment
South Africa

Study participating centre
Department of Psychology
Stellenbosch
South Africa
7602

Sponsor information

Organisation
Saving Newborn Lives (Save the Children) (USA)

Sponsor details
2000 L Street NW, Suite 500
Washington, DC 20036
Washington
United States of America
20036
joylawn@yahoo.co.uk

Sponsor type
Charity

Website
http://www.savethechildren.org

ROR
https://ror.org/036jr6x18

Funder(s)

Funder type
Other

Funder Name
Center for Disease Control (CDC) (USA)

Funder Name
Saving Newborn Lives (Save the Children) (USA)

Funder Name
World Health Organization (WHO)

Alternative Name(s)
, , Всемирная организация здравоохранения, Organisation mondiale de la Santé, Organización Mundial de la Salud, WHO, , ВОЗ, OMS

Funding Body Type

Private sector organisation

Funding Body Subtype
International organizations

Location
Switzerland

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?
Protocol article	study protocol	01/11/2011		Yes	No
Results article	results	06/02/2013		Yes	No