

# 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?

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<b>Registration date</b> 04/01/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 01/07/2013	<b>Condition category</b> Neonatal Diseases	<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

# 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

## Study type(s)

Other

## 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(s)**

1. HIV free infant survival at 12 weeks postpartum

2. Levels of exclusive and appropriate infant feeding at 12 weeks postpartum

### **Key secondary outcome(s)**

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

### **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

### **Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

Female

**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

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## Sponsor information

**Organisation**

Saving Newborn Lives (Save the Children) (USA)

**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

Government organisation

### Funding Body Subtype

International organizations

### Location

Switzerland

## Results and Publications

### Individual participant data (IPD) sharing plan

#### IPD sharing plan summary

#### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	06/02/2013		Yes	No
<a href="#">Protocol article</a>	study protocol	01/11/2011		Yes	No