







# Mphatlalatsane: Early Morning Star

<b>Submission date</b> 25/06/2015	<b>Recruitment status</b> No longer recruiting	 Retrospectively registered
		 Protocol added
<b>Registration date</b> 03/07/2015	<b>Overall study status</b> Completed	 SAP not yet added
		 Results added
<b>Last Edited</b> 27/12/2023	<b>Condition category</b> Infections and Infestations	 Raw data not yet added
		 Study completed

## Plain English Summary

### Background and study aims

The Mphatlalatsane (Early Morning Star) project is an intervention (or programme) that integrates Early Childhood Care and Development (ECCD), HIV testing and treatment services, and nutrition support for families with young children in Lesotho. The intervention was developed to increase early childhood stimulation, HIV testing and treatment and child nutrition for children aged 1-5 years. The program will be implemented in 34 villages in the Mokhotlong district of Lesotho, making use of a community-based participatory approach to intervention development. The project aims to make use of the existing pre-school centers that are based in the villages to deliver the intervention to families in the Mokhotlong district. In addition to the intervention sessions delivered at the preschools, local organizations will be mobilized to coordinate community outreach days that aim to increase HIV testing among families through promoting an overall focus on child health.

### Who can participate?

The intervention is designed for primary caregivers and their children between the ages of 1 and 5 years. Caregivers will be invited to attend the intervention program with their children.

### What does the study involve?

The intervention consists of 2-3 hour sessions weekly for 8 consecutive weeks, delivered to groups of 5/6 carers and their children at a time. The sessions include group and individual activities and make use of group presentations, video materials and practical exercises. The intervention teams (comprised of two facilitators) give sessions to caregivers and their children to address critical factors for early child development, health and growth. For growth and health, the intervention focuses on key messages and identifying available resources/services in the primary caregiver's environment to motivate positive practices. For ECCD, the caregiver receives training in building sensitive "book-sharing" skills – a strategy that stimulates the child cognitively and encourages caregiver-child engagement. As part of the book-sharing component, carers also receive a picture book and take-home card at the end of each session that include a summary of the important messages from the session. Carers are encouraged to apply what they learned during the session with their children at home by using the picture book. They will receive a different picture book to take home each week.

What are the possible benefits and risks of participating?

Discussing parenting experiences and HIV and other content in the intervention sessions and assessments may cause emotional discomfort to participants. In the event that participants showing signs of extreme distress, facilitators will facilitate referral to local counseling and health services.

On the other hand, participants will be very likely to benefit in terms of improvements in child health and development outcomes if the intervention is successful through their involvement in the intervention groups. They will also receive a number of children's books over the course of the project that they will be free to keep at the end of the project. The potential benefit to society is substantial: should this study achieve its aims, it will produce a scientifically cost-effective, and scalable community-based intervention, which is deliverable in a low-resource context, for the improvement of child health and development outcomes for children affected by HIV.

Where is the study run from?

The research team has an office in Mokhotlong where the study is based. The study is run by researchers at Stellenbosch University, University College London and Oxford University, in partnership with the University of Reading. The research team works in partnership with a range of other project partners, including the funder USAID, Management Sciences for Health and Grow, a local NGO.

When is the study starting and how long is it expected to run for?

July 2014 to December 2017

Who is funding the study?

USAID through a management contract with Management Sciences for Health.

Who is the main contact?

Professor Mark Tomlinson

### **Study website**

N/A

## **Contact information**

### **Type(s)**

Scientific

### **Contact name**

Dr Mark Tomlinson

### **ORCID ID**

<http://orcid.org/0000-0001-5846-3444>

### **Contact details**

Department of Psychology,  
Stellenbosch University  
Stellenbosch  
South Africa  
7600

# Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Protocol/serial number

Internal ethics review board reference number: N14/09/127

## Study information

### Scientific Title

Integrating early childhood care and development, HIV testing and treatment support, and nutrition information into rural informal nursery care in Mokhotlong, Lesotho, to improve HIV testing rates, treatment adherence and early childhood development : a cluster randomized control trial.

### Study hypothesis

1. Participation in an integrated HIV testing, treatment and early childhood care and development (ECCD) intervention increases the rate of HIV testing for children aged 12 – 60 months in rural Lesotho
2. Participation in the intervention results in better child cognitive and language outcomes
3. Participation in the intervention increases uptake of ART for children aged 12-60 months after testing
4. Participating in the intervention results in a higher rate of adherence to ART for children aged 12-60 months
5. Participation in the intervention results in better child growth

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

1. Health Research Ethics Committee at Stellenbosch University, 02/03/2015, ref: N14/09/127
2. Lesotho Ministry of Health Ethics Committee, 19/05/2015, ref: 138-2014

### Study design

Cluster randomised controlled trial design with wait-list control group

### Primary study design

Interventional

### Secondary study design

Cluster randomised trial

### Study setting(s)

Community

### Study type(s)

## Prevention

### **Participant information sheet**

Not available in web format

### **Condition**

HIV testing and treatment, early childhood care and development, and nutrition

### **Interventions**

The intervention is an integrated early childhood care and development (ECCD), HIV and nutrition intervention. It is targeted at caregivers with children between the ages of 1 and 5 years. Primary caregivers attend group sessions over 8 weeks with their children, followed by monthly consolidation sessions over 1 year. Children will be divided into groups based on their age so that younger children (12-30 months) and older children (31-60 months) receive the intervention in different groups. The intervention differs slightly by the two age groups, and the two variations are called the Infant and Toddler Intervention and the Child Intervention.

The intervention will be hosted in local village preschool centres. An intervention facilitator (IF) and community-based mentor (CBM) will work together to deliver the sessions, each focusing on a different component of the intervention. The IF will deliver the ECCD component of the intervention while the CBM will deliver the HIV and nutrition component. The early childhood development component consists of caregiver training in sensitive “book-sharing” skills – a strategy that stimulates the child cognitively and encourages caregiver-child engagement. The HIV and nutrition component consists of key messages and facilitating the identification of available resources/services in the primary caregiver’s environment to motivate positive practices.

The intervention consists of group sessions with 5-6 caregivers and their children which last for 2-3 hours, and are held weekly for 8 consecutive weeks. This initial period is followed by one monthly group/visits by members of the intervention team over the course of a 12 month period. Each intervention session consists of a session involving group activities and a short individual session. The sessions include group and individual activities and makes use of presentations and practical exercises.

The control group will not receive the intervention during the intervention period. However during the project duration, local organisations will be capacitated and trained to roll out the intervention to the other villages upon completion of the trial, and will be supported in doing so by project partners.

### **Intervention Type**

Behavioural

### **Primary outcome measure**

All measures will be implemented at baseline, 3 months and 12 months.

1. HIV testing rate (no. of children who have tested for HIV in past 3 months)
2. Child language (MacArthur Communication Development Inventory, Peabody Picture Vocabulary Test, Mullen Receptive Language Scale)
3. Child attention (Early Childhood Vigilance Task)

### **Secondary outcome measures**

All measures will be implemented at baseline, 3 months and 12 months.

1. Child cognitive development (Mullen Visual Reception Scale)
2. Child growth: Z scores, based on WHO standards
3. HIV treatment uptake: Number of children initiating ART therapy after testing
4. HIV treatment adherence: ART adherence rates in children, defined as % adhering to ART within defined periods (3 days, 1 week, 1 month)
5. Child emotional and behavioural functioning: Child Behaviour Checklist (selected subscales), Strengths and Difficulties Questionnaire
6. Child executive function: Inhibitory control task, Attention shifting task, Working memory task
7. Parental discipline: Discipline and Violence Questionnaire of Lansford and Deater-Deckard, developed from the Parent-Child conflict tactics scale and the World-SAFE survey, 4. Directly observed prohibition task rated with adapted version of the Murray Global Rating Scales
8. Parenting stress: Parenting Stress Index
9. Parental sensitivity: Directly observed book sharing task rated with adapted version of the Murray Global Rating Scales
10. Caregiver mental health: Patient Health Questionnaire – 9, Self-Reporting Questionnaire – 20, Shona Symptom Questionnaire

**Overall study start date**

01/07/2014

**Overall study end date**

31/12/2017

## **Eligibility**

**Participant inclusion criteria**

In total, 1160 children and their primary carers living in 32 villages near Mokhotlong and their caregivers will be enrolled in the study.

Villages have been selected based on them falling within two community councils, having an informal preschool, and being within the geographical area receiving services from the community-based partner of the study.

Inclusion criteria for children include:

1. Ages 12-60 months at baseline
2. Has an adult primary caregiver who lives in the household who consents to participate in the study

Inclusion criteria for adults include:

1. Age 18 or older
2. Serves as the primary caregiver of the child participant
3. Lives in the house at least 4 nights per week

**Participant type(s)**

Mixed

**Age group**

Mixed

**Lower age limit**

12 Months

**Upper age limit**

60 Months

**Sex**

Both

**Target number of participants**

In total, 1160 children and their primary carers living in 34 (amended from 32 on 14/06/2016) villages near Mokhotlong and their caregivers will be enrolled in the study.

**Total final enrolment**

1040

**Participant exclusion criteria**

N/A

**Recruitment start date**

29/06/2015

**Recruitment end date**

31/08/2016

**Locations****Countries of recruitment**

Lesotho

**Study participating centre**

**Mokhotlong District**

Mokhotlong

Lesotho

-

**Sponsor information****Organisation**

Stellenbosch University

**Sponsor details**

Private Bag X1

Matieland, 7602

South Africa

Stellenbosch

South Africa

7602

**Sponsor type**

University/education

**ROR**

<https://ror.org/05bk57929>

## **Funder(s)**

**Funder type**

Government

**Funder Name**

United States Agency for International Development

**Alternative Name(s)**

U.S. Agency for International Development, Agency for International Development, USAID

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

United States of America

## **Results and Publications**

**Publication and dissemination plan**

We intend to publish at least 8 peer reviewed publications from the trial. We will also publish a policy brief. Findings will be presented at local and international conferences. This USAID funded study is part of a broader special initiative with two other countries involved – Zimbabwe and Swaziland. We will be endeavouring to also publish a number of cross country papers from the trial as well as use the platform of this special initiative to disseminate findings and lessons learnt.

**Intention to publish date****Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

**Study outputs**

<b>Output type</b>	<b>Details</b>	<b>Date created</b>	<b>Date added</b>	<b>Peer reviewed?</b>	<b>Patient-facing?</b>
<a href="#">Protocol article</a>	protocol	09/11/2016		Yes	No
<a href="#">Results article</a>		21/12/2023	27/12/2023	Yes	No