

# A new system in the community for assisting well being in young mothers and their children

<b>Submission date</b> 09/04/2018	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 09/05/2018	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 04/10/2022	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Malawi has the fifth highest adolescent fertility rate in Africa at 145 births per 1000 girls aged 15 to 19 and is ranked 10th globally by the International Center for Research on Women. Teenage girls are not prepared for motherhood and as a result this can have harmful effects on the development of their children. These teenage mothers lack psychosocial support to better enable them to be mothers so as to improve outcome of children. The study provides critical evidence as to the importance of psychosocial support to teenage mothers and on what support mothers require to better cope with motherhood.

This study aims to improve early child development in children born to teenage mothers by identifying factors that can improve development and providing support to positively impact the development, growth and nutrition of children.

### Who can participate?

Mothers under 18 years old

### What does the study involve?

Participants are randomly allocated to one of two groups. Those in the first group receive a bi-weekly program of psychosocial support, in both individual and group sessions. Babies receive nutritional supplements and are engaged in activities to stimulate growth and bonding with the mothers, in safe baby corners. Participants may also receive counseling.

They are followed up with questionnaires and knowledge assessment before they start the program, and after 1 and 2 years.

### What are the possible benefits and risks of participating?

Participants may benefit from improved development of their children. There are no direct risks for those taking part in the study.

### Where is the study run from?

The following regions in Malawi:

1. Machinga
2. Mulanje
3. Blantyre

When is the study starting and how long is it expected to run for?  
July 2017 to June 2019

Who is funding the study?  
Grand Challenges Canada (Canada)

Who is the main contact?  
1. Ms Nettie Dzabala (Scientific)  
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2. Dr Mtisunge Kachingwe (Public)  
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**Study website**  
<https://ywcamalawi.com/blog-posts/>

## Contact information

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

P.05/17/2178

## **Study information**

### **Scientific Title**

Community model for fostering health and wellbeing for adolescent mothers & their children

### **Study objectives**

Our innovation takes a comprehensive, community led holistic approach with a focus on poor resourced areas in Malawi, where the prevalence of child marriages is high. The target group is marginalized married girls, pregnant girls, and adolescent mothers. The intervention focuses on creating an enabling and responsive environment for improved health outcomes for young mothers and their babies. This study aims to see improved early child development in babies and well-being of marginalized married adolescent pregnant girls and young mothers in Malawi.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

College of Medicine Ethics Committee University of Malawi, 27/09/2017, ref: P.05/17/2178

### **Study design**

Analytical quantitative and qualitative prospective case-control design

### **Primary study design**

Interventional

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

Community

### **Study type(s)**

Quality of life

### **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**

Child development

### **Interventions**

The study introduces an intervention to the teenage mothers to show the importance of psychosocial support and how this can improve development growth and children in the

children. This research project takes a holistic approach that includes local communities, the government, and local health services.

Almost 65 service providers are trained to provide strategic partnerships created with local communities, the Ministry of Health, Ministry of Gender, the College of Medicine and local health services, ECD centers and legal centers with a strong referral network to offer psychosocial support (PSS).

Participants are randomly allocated to an intervention or control group. Those in the intervention group receive an intervention that focuses on creating an enabling and responsive environment for improved health outcomes for young mothers and their babies for one year. Starting from the individual, relevant psychosocial support (with well tested tools and approaches) is offered to the young mothers and their babies on a weekly basis. This includes biweekly group sessions on learning about caring for oneself – physically, emotionally, spiritually, socially and mentally in a safe space <http://www.worldywca.org/wp-content/uploads/2014/02/Safe-Spaces-long-web.pdf>.

The babies are given nutritional supplements and are engaged in activities that stimulate growth, as well as bonding with the mothers. Safe baby corners are created where baby stimulation for improved health outcomes take place bi weekly.

With a focus on gender and intimate partner violence, monthly counseling is offered by a professional social worker.

Those in the control group start to receive the intervention after one year.

## **Intervention Type**

Supplement

## **Primary outcome measure**

Babies

1. Motor skills are measured using developmental milestones questionnaire at baseline, after 1 year and 2 years
2. Cognitive functions are measured using developmental milestone questionnaire at baseline, after 1 year and 2 years
3. Expressive language are measured using developmental milestone questionnaire at baseline, after 1 year and 2 years
4. Social emotional capacities are measured using developmental milestone questionnaire at baseline, after 1 year and 2 years

Adolescent mothers & pregnant girls

1. Knowledge about psycho social support, maternal and newborn health care practices, sexual reproductive health and rights, HIV and gender equality is assessed.
2. Confidence and psychosocial well-being are assessed using the following questionnaires; Brief resilience scale, Rosenberg self-esteem scale and Parental stress scale at baseline, after 1 year and 2 years

Health workers

Knowledge about psychosocial support and friendly maternal health care services at health centres is assessed using pre and post training questionnaires and follow up interviews at 1 year and 2 years.

## **Secondary outcome measures**

1. Babies development is monitored via the health passport at baseline, 1 year and 2 years.
2. The number of participants trained in parenting skills, nutrition, child care, sexual reproductive health and rights, HIV and gender equality is measured using attendance registers

at year 1 and year 2

3. Psychosocial wellbeing of the participants and babies is recorded using the hero book.

**Overall study start date**

30/07/2017

**Completion date**

30/06/2019

## **Eligibility**

**Key inclusion criteria**

1. Mothers below the age of 18 years old
2. In antenatal period or with children below the age of 5

**Participant type(s)**

Other

**Age group**

Other

**Sex**

Female

**Target number of participants**

290 young women

**Key exclusion criteria**

Aged 18 years and above

**Date of first enrolment**

17/10/2017

**Date of final enrolment**

27/10/2017

## **Locations**

**Countries of recruitment**

Malawi

**Study participating centre**

**Machinga**

Malawi

N/A

**Study participating centre**  
**Mulanje**  
Malawi  
N/A

**Study participating centre**  
**Blantyre**  
Malawi  
N/A

## **Sponsor information**

**Organisation**  
Grand Challenges Canada (Through Saving Brains)

**Sponsor details**  
MaRs Centre  
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**Sponsor type**  
Government

**Website**  
[www.grandchallenges.ca](http://www.grandchallenges.ca)

**ROR**  
<https://ror.org/02snbhr24>

## **Funder(s)**

**Funder type**  
Government

**Funder Name**  
Grand Challenges Canada

# Results and Publications

## Publication and dissemination plan

The project will comprise two publications, in the first year the project focuses on comparing outcomes in the control group versus the cases. In the second year the focus is on outcomes of the control group to see if there is a greater impact as compared to first year. It will work to follow outcomes of the cases from the first year.

Intended publication posted on open access website as well as the Malawi medical journal. Results will be shared with various audiences to engage them into the conversation on maternal and new-born health and to ensure long term impact of the project. Results will be presented to the ministry of health, clinics, health centers, pediatricians, communities and universities at various events and in various forms as well as COMREC. (College of Medicine Ethics Committee)

## Intention to publish date

31/12/2018

## Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date.

## IPD sharing plan summary

Data sharing statement to be made available at a later date

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		24/03/2021	09/08/2022	Yes	No
<a href="#">Results article</a>		26/02/2021	04/10/2022	Yes	No