

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

Submission date 09/04/2018	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 09/05/2018	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 04/10/2022	Condition category 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)
dzabalan@gmail.com
2. Dr Mtisunge Kachingwe (Public)
mtkachingwe@gmail.com

Study website
<https://ywcamalawi.com/blog-posts/>

Contact information

Type(s)
Scientific

Contact name
Ms Nettie Dzabala

Contact details
P.O Box 2447
Blantyre
Malawi
N/A
+265 991 807 268
dzabalan@gmail.com

Type(s)
Public

Contact name
Dr Mtisunge Kachingwe

Contact details
P.O. Box 2447
Blantyre
Malawi
N/A
+265 995 542 832
mtkachingwe@gmail.com

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
South Tower
101 College street, suite 406
Toronto
Canada
M5G1L7
+1 416 673 6568
info@grandchallenges.ca

Sponsor type
Government

Website
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?
Results article		24/03/2021	09/08/2022	Yes	No
Results article		26/02/2021	04/10/2022	Yes	No