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Delivering a contextualized package of care for child development (0-12 months) and maternal mental health in the camps for forcibly displaced Myanmar nationals in Bangladesh

Submission date 25/01/2019	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 15/05/2019	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 05/05/2021	**Condition category** Other	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims

The study is going to target the Rohangian refugee population currently placed in more than 20 medium-sized camps in Bangladesh. As per current estimates, around three quarters of a million refugees have already reached; and with continued influx the refugee number will soon reach one million or more. In Myanmar, like most developing countries, early child development is considered to be a grossly neglected area of public health importance. Even before migration (i. e. in their own homeland), most of these refugees have been living in relatively poor circumstances. In refugee camps they are facing circumstances that increase the risk of delayed child development and occurrence of mental health conditions in women. About 1.75% of the 0.75 million refugees are estimated to be less than one year old (i.e. 13,125 infants). As per gross estimates, in the refugee population at least one-third of the less than one-year-old children are suffering from delayed development, and about the same number of mothers of infants are suffering from depression. The delayed development of child milestones relates mainly to: a) chronic child malnutrition due to poor child feeding practices and recurrent infections; and b) low childcare ability of mothers due to lack of child development care skills (<10%) and poor mental health condition of mothers. The refugee population currently lacks access to care for early child development and maternal mental health. The community-based intervention, implemented through modestly educated and enabled refugee women, will cover nutrition and hygiene, child brain development, and maternal mental health.

Who can participate?

Children aged 6 weeks or less and their mothers, living in the participating refugee camps

What does the study involve?

The participating refugee camps are randomly allocated into the intervention group or the control group. The intervention group receive the designed intervention for early child

development, nutrition and maternal depression. The intervention is delivered by mothers counseling through community-based care providers. The control group continue with the routine practice that is generally present in the camps.

What are the possible benefits and risks of participating?
The intervention is expected to reduce early child development delays and maternal depression. The control group will continue receiving routine care from the primary health outlets in the respective camps. There are no risks involved for the participants.

Where is the study run from?
Rohangian refugee camps (Bangladesh)

When is the study starting and how long is it expected to run for?
June 2018 to June 2020

Who is funding the study?
Grand Challenges Canada

Who is the main contact?
Dr Muhammad Amir Khan

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
SB-1810-19890

Study information

Scientific Title
Delivering a contextualized package of care for child development (0 - 12 months) and maternal mental health in the Rohingya refugee camps in Bangladesh

Study objectives
The main hypothesis to be tested is that the delivery of child development and maternal mental health care, by modestly educated community-based providers, is potentially effective and feasible in the refugee setting.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 24/10/2018, Bangladesh Medical Research Council (Bangladesh Medical Research Council, Mohakhali, Dhaka-1212, Bangladesh, Tel: 8819311, 8828396; Email: info@bmrcbd.org), ref: BMRC/NREC/2016-2019/843

Study design
Cluster randomized controlled trial with two arms

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. Please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Early child development, maternal health, child nutrition

Interventions
The population of 10000 people per cluster was needed to get the required sample size. The average population per block in each block is almost 5-6 thousand. Hence 2 blocks were combined together to make one cluster to get the required population i.e. 10000. After organizing 22 clusters with population more than 10,000, these were arranged with given numbers. These were further allocated into intervention and control arm by simple randomization of selected clusters by drawing clusters from a hat.

Intervention arm
1. Adapted set of intervention materials for the community-based providers to deliver home-based care i.e. pictorial counseling tool and leaflet
2. Trained community-based care providers to visit and counsel each mother, on a quarterly basis, about child development and depression management care (using the intervention materials)
3. The key care contents will include: a) breastfeeding and weaning food; b) infant nurturing and child brain development; c) infection control e.g. food hygiene and hand washing; d) behaviour activation for maternal depression; and e) identify and refer for clinical care

Control arm
Community-based care providers will visit each registered mother-child pair on a quarterly basis. On each quarter the care provider will offer general health guidance, and also facilitate the mother's access to a primary health care facility as needed.
Field Coordinator to monitor every month the performance of each community-based care provider in the trial.

The duration of intervention and follow-up is almost one year with three quarterly follow-ups.

Intervention Type
Behavioural

Primary outcome measure
Reduction in two or more than two child development delays, measured by ASQ-3 questionnaire by a trained external assessor at endline

Secondary outcome measures
Measured at endline by a trained external assessor:
1. Maternal depression measured by PHQ-9 questionnaire
2. Height-weight for stunting measured using infantometer and infant weight machine

Overall study start date
30/06/2018

Completion date
30/06/2020

Eligibility

Key inclusion criteria
1. Children aged 6 weeks or less
2. Children resident of respective refugee camp

Participant type(s)
Other

Age group
Mixed

Sex
Both

Target number of participants
This trial will have a total of 696 mother-child pairs in 22 clusters, randomly divided into equal number of intervention and control clusters.

Key exclusion criteria
1. Children of more than 6 weeks
2. Child known to have congenital abnormality, history of delayed cry or seizures, cretinism

Date of first enrolment
01/02/2019

Date of final enrolment
01/05/2019

Locations

Countries of recruitment
Bangladesh

Study participating centre
Ukhiya Refugee Camps (8)
Rohangian refugee camps Ukhiya

Kutupalong
Bangladesh
4700

Sponsor information

Organisation
Grand Challenges Canada

Sponsor details
MaRS Centre
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Sponsor type
Government

Website
http://www.grandchallenges.ca/who-we-are/

ROR
https://ror.org/02snbhr24

Funder(s)

Funder type
Government

Funder Name
Grand Challenges Canada

Alternative Name(s)
Grands Défis Canada, GCC

Funding Body Type
Government organisation

Funding Body Subtype

National government

Location
Canada

Results and Publications

Publication and dissemination plan
The trialists have planned to publish papers related to the main trial and process evaluation in peer reviewed journals.

2020 protocol in preprint https://doi.org/10.2196/preprints.25047 (added 04/01/2021)

Intention to publish date
30/06/2021

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		04/05/2021	05/05/2021	Yes	No