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Testing the effectiveness of a parenting training program to improve the mental health of mothers and the well-being of their children in Rohingya refugee camps.

Submission date
24/04/2024

Recruitment status
No longer recruiting

Registration date
25/04/2024

Overall study status
Completed

Last Edited
25/04/2024

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Maternal depression is a global public health concern. It is not only a problem for affected mothers, it also affects the relationship and attachment between mothers and their infants. Poor maternal mental health and child stimulation are the most common causes of mental health and development problems in children and has also been linked with diarrhoea and respiratory / breathing infections in children in Bangladesh.
Since 2017 approximately 1 million Rohingya people, mainly women & children, have found refuge in Cox Bazar in Bangladesh, due to persecution in Myanmar. Many have experienced trauma, violence and loss or separation from family.
Traumatic experiences are known to increase mental health problems such as depression and anxiety. Mental health is not well recognised in Rohingya communities, but the long exposure to violence, stress and trauma suggests there is a high level of mental health problems.
There is little evidence about interventions or ways that can help Rohingya mothers and improve their mental health. However, there is a program called Learning Through Play Plus (LTP+) that's been changed to fit different cultures and tried in places like Pakistan and Kenya. We want to see if LTP+ could help Rohingya mothers and families.
Learning Through Play Plus (LTP+) is a way of helping mothers and is done in groups. It combines a parenting programme called Learning Through Play with parts of the Thinking Healthy approach from the World Health Organisation.
LTP+ works in two ways. One part helps parents to understand the importance of play and their child’s development. The second part helps mothers to think about their own mental health, by learning new ways of managing unhelpful and upsetting thoughts and learning new ways of solving daily problems.
Studies in Pakistan and Kenya have found that a programme of 10 group sessions can lead to important and lasting reductions in maternal depression and improvements in maternal knowledge and practice about child development.
This study wants to find out if the LTP+ program is helpful and works well in reducing depression and anxiety among mothers of young children (ages 0 to 12 months). It also aims to see if it can

improve their parenting skills and improve the development and health of their children, compared to mothers who don't receive the LTP+ program.
The study needs 420 women to participate, so 480 women will be asked to take part in the study from 6 refugee camps, because it is common for some people to leave studies before they finish.
The participants will be women who have had to leave Myanmar and are now living in the refugee camps in Cox's Bazar, and who have had a baby during the last 12 months.
No studies of this have been done in Rohingya communities or in Bangladesh, but we believe that the results will help to develop new and practical ways to support the mental health of mothers and improve the health and wellbeing of their children.

Who can participate?
The people participating will be Rohingya women who have had to leave Myanmar and now living in the refugee camps in Cox's Bazar, and who have had a baby during the 12 months before the start of the study.

What does the study involve?
The study will divide the participating women into two groups. One group will receive the LTP+ intervention as well as their usual care from health services. The other group will receive the usual care from health services only.
The group receiving LTP+ will attend 10 group sessions. The first 8 sessions will take place weekly, and the last 2 sessions will take place every two weeks. Each session is 60-90 minutes.
Women in both groups will be interviewed to ask them questions about their thoughts, feelings and child development knowledge and practice, before the intervention begins and then again after 3 months and 6 months. The infant children of mothers in both groups will also be weighed at the same times.
The study team will then compare the information provided by the women in both groups and the growth and number of illnesses their children experience. This will help them see if there are any changes and if there is any difference between the two groups that might be caused by the LTP+.

What are the possible benefits and risks of participating?
Studies in other countries have found that women have benefited from lower levels of depression, anxiety and stress, and increased knowledge of child development. In some studies, their children have also had improved levels of child development and fewer periods of illnesses such as diarrhoea and respiratory infections. However, LTP+ is being tested in Bangladesh and with mothers in refugee camps for the first time, so we do not know yet how helpful it will be.
By taking part, mothers will be helping us to find better ways of supporting mothers and their children.
The research involves answering questions about feelings or emotions that could be upsetting. If women taking part feel upset or are seen to be distressed, they can stop taking part at any time, and they will be offered support by a trained mental health professional.

Where is the study run from?
Save the Children International, Cox's Bazar Area Office, Cox's Bazar, Bangladesh

When is the study starting and how long is it expected to run for?
January 2023 to December 2024

Who is funding the study?
The study is funded by Save the Children International and Save the Children Italy.

Who is the main contact?
Ruma Khondaker, ruma.khondaker@savethechildren.org

Contact information

Type(s)
Public

Contact name
Mrs Ruma Khondaker

Contact details
Cox’s Bazar Area Office, Nuniarchhara, Airport Road
Cox's Bazar
Bangladesh
-
+880 1716644400
ruma.khondaker@savethechildren.org

Type(s)
Principal investigator

Contact name
Dr Golam Mothabbir

Contact details
Save the Children in Bangladesh, House No. CWN (A) 35, Road. No. 43, Gulshan-2
Dhaka
Bangladesh
12 12
+880 1714088400
golam.mothabbir@savethechildren.org

Type(s)
Scientific

Contact name
Mrs Jahanara Miah

ORCID ID
https://orcid.org/0000-0002-2122-7007

Contact details
Division of Psychology and Mental Health. The University of Manchester, Oxford Road
Manchester
United Kingdom
M13 9PL
+44 7813116618
jahanara.miah@mcglobal.org

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
49221062022

Study information

Scientific Title
A cluster randomised controlled trial to evaluate the effectiveness of a group-based parenting intervention to improve maternal mental health and child well-being outcomes in FDMN communities in the Cox Bazar camps.

Study objectives
What is the effectiveness of a group-based parenting intervention for reducing depression in Rohingya refugee mothers of young children (0 – 12 months) in Cox's Bazar?

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 29/08/2023, Bangladesh Medical Research Council (BMRC Bhaban, Mohakhali, Dhaka, 12 12, Bangladesh; +88 02222298396; info@bmrcbd.org), ref: 49221062022

Study design
Single centre two-arm cluster randomized controlled trial

Primary study design
Interventional

Study type(s)
Prevention, Quality of life, Efficacy

Health condition(s) or problem(s) studied
Prevention and reduction of depression and anxiety in post-natal women less than one year after delivery

Interventions
Learning Through Play Plus (LTP+) is a 10-session group-based intervention that integrates information about child development and Cognitive Behavioral Therapy. The elements of the intervention are derived from two evidence-based interventions: i) the LTP programme, helps stimulate early child development. It includes a pictorial calendar designed for parents, which is a key feature of this intervention. The pictorial calendar is made up of 8 successive stages of child development from birth to 3 years, with pictures of parent-child play and other activities

that promote parental involvement, learning, and attachment. ii) The CBT component is derived from the Thinking Healthy Programme (WHO THP) which has been adapted for a group setting. The THP adopts a 'here and now' problem-solving approach, uses CBT techniques of active listening and changing negative thinking. This integrated intervention, called LTP Plus (LTP+), provides information and strategies to promote child development and helps participants to identify and change their unhelpful thoughts related to their own health and wellbeing, their child's growth and development and their relationships.

The intervention is culturally adapted to the Rohingya context and translated and delivered in local language. Trained local Community Health Workers (CHWs) will deliver 10 sessions of LTP Plus intervention over a three-month period with co-facilitation from Mental Health Psychosocial Support Officers (MHPSS). The sessions will last from 60 to 90 minutes, delivered weekly over 8 weeks and then fortnightly during the final 4 weeks. Sessions will take place at a nearby health facility or agreed community space such as a school.

480 post-natal women participants (to ensure a minimum final sample of 420) will be recruited from six refugee camps with similar characteristics. Camps will be randomised into clusters using web-based randomization service www.randomizer.org. Randomisation lists will be generated in a 1:1 ratio, using block randomisation, stratified by camp size and risk of forced movement from camps. The randomisation list will be generated by a statistician at Pakistan Institute of Living and Learning (PILL). Half of the registered participant mothers will be randomly placed in the LTP+ intervention arm and half in the routine care arm, receiving regular health services and support.

Intervention Type
Behavioural

Primary outcome(s)
Maternal depression score, measured using the PHQ9 scale at baseline. 3 months, and 6 months.

Key secondary outcome(s))
1. Severity of maternal anxiety will be assessed using the Generalized Anxiety Disorder scale (GAD-7) at baseline, 3 months and 6 months.
2. Maternal health related quality of life will be assessed using the EuroQol Quality of Life Scale – 5 Dimensions (EQ-5D) at baseline, 3 months and 6 months.
3. Maternal social support will be assessed using the Multidimensional Scale of Perceived Social Support (MSPSS) at baseline, 3 months and 6 months.
4. Maternal knowledge and practice about child development will be assessed using a Knowledge, Attitude and Practices (KAP) Questionnaire at baseline, 3 months and 6 months.
5. The health, nutrition, and development of their infant child will be assessed using a questionnaire about recent illness and health seeking behaviour, weight-for-age measurement at baseline, 3 months and 6 months; and the Ages and Stages Questionnaire (ASQ) at baseline, 3 months and 6 months.
6. Cost-effectiveness will be assessed by the EuroQol Quality of Life Scale – 5 Dimensions (EQ-5D) at baseline, 3 months and 6 months.

Completion date
31/12/2024

Eligibility

Key inclusion criteria
1. Mothers that have given birth in the 12 months prior to the intervention
2. Residents of FDMN refugee camps
3. Willing to participate in the trial
4. Infants born to the same mothers above, in the 12 months prior to the intervention

Participant type(s)
Population

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
49 years

Sex
Female

Total final enrolment
470

Key exclusion criteria
1. Unlikely to be available for follow up assessments
2. Mothers with severe mental or physical health problem or communication disability that would prevent them from participating in the trial
3. Unable to provide informed consent

Date of first enrolment
11/12/2023

Date of final enrolment
11/03/2024

Locations

Countries of recruitment
Bangladesh

Study participating centre
Save the Children International (Bangladesh)
Cox's Bazar Area Field Office
Airport Road

Cox's Bazar
Bangladesh
N/A

Sponsor information

Organisation
Save the Children

ROR
https://ror.org/032e5zb24

Funder(s)

Funder type
Charity

Funder Name
Save the Children Italy

Funder Name
Save the Children International

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available on request from Ruma Khondaker
ruma.khondaker@savethechildren.org

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			25/04/2024	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes