

PARTICIPANT INFORMATION SHEET (PIS)

Research title

“A 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”

Easy read title

Testing a new way of coming together in groups, to see if this is helpful for the mental health of mothers and the health of their children.

1: You are invited to take part in a research study.

This is a way of testing something to see if it is helpful or not. Before you decide, it is important to understand why the research is being done and what it will involve.

Please read this information carefully before deciding whether to take part and discuss it with others if you wish. You have at least 48 hours from when the study was explained to you to decide if you are interested or not. Please ask if there is anything that is not clear or if you would like more information.

2: What is the purpose of the research?

The research aims to see if a new activity called Learning through Play Plus (LTP Plus) is acceptable and helpful for mothers of young children (0 – 12 months) and their children. LTP Plus works in two ways. One part helps parents understand the importance of play for child 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.

3: Who will conduct the research?

Dr Golam Mothabbir is in charge of the team doing this research. He is a Senior Health Advisor at Save the Children, a Non-Governmental Organisation (NGO) that works in Cox Bazar. Save the Children is also working with the University of Manchester in the UK and the Pakistan Institute of Living and Learning (PILL) in Pakistan.

4: Why have you been chosen?

You are invited to participate because you belong to the Rohingya community, and you are a mother of a young child who is under 12 months of age.

5: Do you have to take part?

No. It is up to you to decide. If you do decide to take part, you will be given this information sheet to keep and you will be asked to sign a form giving your permission (consent).

6: What will you be asked to do if you take part?

Firstly, a health worker and a researcher will meet with you for about one and a half hours. You will be asked about your recent thoughts, feelings, experiences, and difficulties. After the interview, some women will be asked to participate in LTP Plus and some will not. Everyone will continue to receive the usual service from health workers.

7: What will happen if you join LTP Plus?

LTP Plus will involve you attending 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. You will join a parenting group, designed to help you play with your child in a way that stimulates the development and health of your child. A picture book will be used to show child development from birth to 3 years, with pictures of parents and-children playing together and other activities.

The other part is designed to help you with your mental health and well-being. It will help you learn different ways to deal with problems and to manage emotions or unhelpful thoughts.

8: What will happen if you do not join LTP Plus?

We call this 'treatment as usual'. It means that any care you would normally receive from community health workers and the health centre will continue.

9: What will happen after that?

Three months after the first meeting with the researcher, you will be invited to another meeting. This will be similar to the first meeting, and you will be asked about your mood, thoughts and any problems that you have experienced recently. They will also weigh and measure your baby and ask you questions about your baby's health and development.

10: How long does my participation in the research last?

Your participation in the study will last for about 3 months.

11: What are the benefits to taking part?

LTP Plus is being tested, so we do not know yet how helpful it will be. By taking part you would be helping us to find better ways of supporting mothers and their children.

12: What are the possible disadvantages of taking part?

The research will involve answering questions about feelings or emotions that could be upsetting. If you do feel upset, please tell the researcher and they will stop the session. You will also be asked if you want to talk to a health worker to discuss your problem and the researcher will tell you how to make contact with them.

13: What happens to the information and data collected?

Once we have collected the information from you and other women taking part, we will compare the information from mothers and children who took part in LTP Plus sessions and

mothers and children who did not., this will help us understand if LTP Plus made a difference to the mental health of mothers and the development of their children.

We will share the research results at conferences and publish them in scientific journals.

The data from the research will be stored for 10 years in a safe place. People from the University or regulatory authorities may need to see the information collected to make sure we have conducted the research properly.

14: How is confidentiality maintained?

All answers you give will be treated in the strictest confidence and will be handled carefully and safely throughout the study. No one else will see any personal information about you.

Data and information from interviews with you will be anonymised – this means it will not include any personal information through which someone can identify you.

Only authorised research people will be allowed to see your information. The only exception will be if we are concerned there is a serious and immediate risk for suicide or a risk of harm to you or another person. In this case we will share your information in order to get you or another person help, support and protection.

15: What happens if you agree to participate and then change your mind?

Even if you decide to take part, you are still free to change your mind and stop at any time. This will not affect any care that you usually receive from health workers.

16: Will you be paid for participating in the research?

No, you will not be paid for participating in the research.

17: Who has reviewed the research project?

A special committee called a Research Ethics Committee has checked the information about this study to protect your safety, rights, and dignity.

18: What if you have a complaint?

If you wish to complain or have concerns, please contact us on: **Dr. Md. Arafat Hossen** (+8801865505349 or email to arafat.hossen@savethechildren.org)

19: Contact Details:

If you have any more questions about the study, please contact with: **Ruma Khondaker** (call to +8801716644400 or email to ruma.khondaker@savethechildren.org)