

PARTICIPANT INFORMATION SHEET

Study title: Examining the quality of child stimulation in a sample of Ugandan children aged five years, and its impact on cognitive development.

Dr. Nampijja Margaret, Entebbe Mother and Baby Study, Uganda Virus Research Institute Entebbe.

PhD student Developmental Psychology, Lancaster University, LA1 4WY, Lancaster UK.

Invitation.

You are being invited to take part in this project. Before you decide, it is important that you read and understand this information. Part 1 tells you the purpose of this project and what will happen to you when you take part. Part 2 contains more information about the conduct of the project.

Part 1

What is the purpose of the study?

There are many factors that affect mental functioning and based on previous research findings it appears that how children are treated by their parents in the home environment is one of the factors that may influence their mental development. In the ongoing EMaBS study we have looked at various factors that possibly affect mental abilities, and we would also like to find out if the way different parents behave towards their children also affects these abilities at age 5 years.

From August 2009, children who will make 5 years will be included in this study. A total of 200 EMaBS participants living in Entebbe municipality and Katabi Division will be needed to participate in the study.

In the week that follows a successful mental assessment (playing) done at the 5 year visit, you and your child will be visited at home by a research staff to collect information regarding the way you relate with your child. The researcher will observe the way you and the child interact, and will record the information on a form. She will also video record the session. You will be asked questions relating to the home environment. The observation will be done in one session which will last about an hour.

Today, if you choose to participate, you will sign the consent form and we will fix the home visit on a day that is most convenient for you. Information collected will be put together and analysed and this will help us establish the cognitive impact of how children are treated in a home environment. A report will be written and submitted to the relevant authorities like Lancaster University, and results will also be communicated to you through your local council leaders.

Why have I (my child) been chosen?

The study is recruiting children in the EMaBS study aged 5 years. So you and other EMaBS parents whose children have made 5 years and have completed the tests of mental functioning have been approached and are going to be included in the study.

Do I (my child) have to take part?

No, participation is voluntary and whether you (your child) join is up to you. You are free to withdraw any time without giving a reason and declining in taking part will not affect your child's participation in the rest of EMaBS study.

What will happen if I take part?

You and your child will be required to stay at home on a day that will be most convenient for you. Two of the research team will come to your home to observe the way you relate with your child and record that information.

What do I have to do?

You (parent) will be required interact with your child the way you do normally at home, and as you interact, a member of the EMaBS research team will be observe you and record relevant information. You will also be required to answer a few questions related to your interaction with the child and home environment. A video recording will also be made as you interact with your child at home.

What are the possible disadvantages and risks of taking part?

None in particular; except for a little inconvenience of being observed as you interact with your child and having to answer some questions.

What are the possible benefits of taking part?

We cannot guarantee individual benefits but we hope that collective information will help us to understand the differences in family environment and identify factors in the home that improve mental functioning at age 5 years.

What will happen when the research stops?

When this part of the project is completed, your child will continue to be seen in the clinic normally.

What if there is a problem?

If you have any questions about your participation in this study, please feel free to ask one of the doctors, nurses or field workers at the clinic. If you prefer, you may speak to one of the principal investigators for this study: Dr Elliott (telephone: 0417 704000) or Dr Nampijja (0414 320448) or Dr Muwanga (telephone: 0414 320058). If you have any questions about your rights as a research subject, you may also speak with the Ethics Committee Chairman from Uganda Virus Research Institute, Dr. Tom Lutalo on 0414 320631. The programme staff will let you use a phone for the call.

Part 2

What will happen if I don't want to carry on with the study?

If you wish to withdraw from the study any time, you can do so and you don't have to give a reason. However, information collected will be kept and used in the analysis unless you object to this.

Will my taking part in the study be kept confidential?

Yes, your participation in the study and all information about you and your child will be kept confidential. The study forms will bear the child's identifications but data presented in the report will be anonymous. Access to study forms and data entered in our computers will all be restricted to only authorized staff who also have a duty to observe confidentiality.

What will happen to the results of the study?

We will write a report which, will be submitted it to the supervisors and funders of this project.

Who is organizing and funding this project?

This project is organized by Mother and Baby Study with supervision from the Department of Psychology Lancaster University. It is funded by the Wellcome Trust UK, and Medical Research Council/UVRI Uganda Research Unit on AIDS.

Who has reviewed the study?

This study has been reviewed and given ethical approval by the Ethics Committee Department of Psychology Lancaster University, and by the Uganda Virus Research Institute Science & Ethics Committee.

When you decide that your child takes part in this project, you (parent) will sign the consent form and a copy of the signed consent form together with the information sheet will be given to you to keep.

THANK YOU FOR TAKING TIME TO READ THIS SHEET.

CONSENT FORM

Examining the quality of child stimulation in a sample of Ugandan children aged five years, and its impact on cognitive development.

Dr Nampijja Margaret, Entebbe Mother and Baby Study, Uganda Virus Research Institute, P.O. Box 49 Entebbe.
PhD student Developmental Psychology, Lancaster University LA1 4WY, Lancaster UK.

Child's names..... Mother's/Guardian's names.....

BID No.....

I have read or had read to me the information sheet concerning this study and I understand what will be required of me and my child if my child and I take part in this study.

My questions concerning this study have been answered by.....

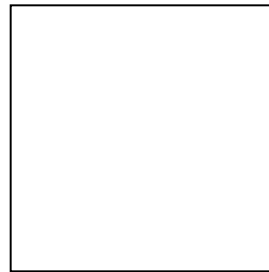
I understand that at any time my child may withdraw from the study without giving a reason and without affecting normal care or management.

I agree for my child to take part in this study.

Parent's signature.....

Parent/Guardian's thumb print.

Date.....



Witnessed by..... Signature.....
If the thumbprint is used, the witness must not be a member of the research staff.

Date.....

Investigator's name..... Signature.....

Date.....