Participant Information Sheet – Trial Participation

Title of Project: Evaluation of the PDC/Baby Ubuntu programme

Introduction

We would like to invite you to take part in a research study. Joining the study is entirely up to you. Before you decide, you need to understand why the research is being done and what it would involve. I will read this information sheet to you now. Ask questions if anything is not clear or you would like more information. Please feel free to talk to others about the study if you wish. Take your time to decide whether or not to take part.

What is the purpose of the study?

The aim of this study is to help us to better understand the effect of a programme of early care and support for children at risk of developmental disabilities and their caregivers. We are interested in how the programme supports the knowledge, skills and well-being of caregivers and how it helps children to grow, develop and participate in family life.

The programme consists of a special follow-up clinic for children less than 5 years of age who are at risk of having delays in their early child development. This clinic is called the Pediatric Development clinic or 'PDC'. The programme also includes a community-based group programme called 'Baby Ubuntu' for young children with developmental disability.

Why have I been asked to take part?

You have been invited to take part because you are the caregiver of a child who has been identified as at risk for developmental delay or disability, and because you live in the catchment area of a health centre that is participating in this research. There are lots of reasons that a child may be at risk of developmental disability. These include complications around the time of birth such as a long or obstructed labour (birth asphyxia), or babies who were born too small or too early. Some children do not have any problems at birth but do not develop skills at the same speed as other children of the same age. We are asking you to take part because your child has been identified as having experienced factors, such as complications around the time of birth, that can increase the risk developmental delays or disability, though the majority of children will not have a developmental disability.

Do I have to take part?

No. It is up to you to decide to take part or not. If you don't want to take part, that's ok. Your healthcare provider will still care for you and your decision will not affect the quality of care you receive. We will discuss the study together and give you a copy of this information sheet. If you agree to take part, I will first ask you to sign/thumbprint a document confirming you've been told about the study and that you agree to participate.

What will happen to me if I take part?

If you agree to take part in the study, you will read and sign an informed consent form. This is to show that you have agreed for your child to take part in the study voluntarily. If you give written consent, your child will be examined, and their development will be assessed. Assessing your child's development includes an assessment of how they move, how they use their hands, and how they interact with others and communicate. This is done mostly through playing with your child and asking you some questions about what they can and cannot do. This assessment will take about 30 minutes.

We will then ask you some questions about you and your child. This will include questions on your child's health, well-being, access to services and participation in daily activities. You will also be asked questions about your own health, well-being, livelihood, and attitudes of others. You will also be asked about your knowledge on disability, supervising and disciplining your child, and your experiences of support. The discussion will last about 60 minutes.

We will also ask for your contact details (address and phone numbers) so that we can contact you in the future for these future visits. We will also take a GPS location of your home, so that we can more easily visit you next time.

The research study will run for a total of 3 years and we will contact you two more times during that time to repeat the developmental assessments and to ask similar questions about you and your child. Later in the study, we may also contact you to invite you to take part in some additional research that will explore family's experiences of taking part in the programme and what sorts of things might make it easier or more difficult to attend.

As part of the study, the PDC/Baby Ubuntu programme will be rolled out across 60 health centres in Rwanda but not all health centres will receive the programme at the same time. The roll out of the programme will occur in two phases, with half of the health centres starting to run the programme straight away (phase 1) and the second half in 9-12 months' time (phase 2). Whether your health centre falls into phase 1 or phase 2 is chosen by chance, like throwing a dice. By the end of the research however ALL health centres will be running the programme. If you agree to participate in the study, you and your child will ultimately receive the programme, but if your health centre is part of phase 2 you will have to wait 9-12 months before the programme becomes available to you. We will not know whether your health centre is allocated to phase 1 or 2 until after your first study visit. Once the programme has been started at your local health centre, you will be informed and asked to attend.

As part of the study, we would like to take photographs of you, your child and your family. Please refer to the separate consent form titled 'Participant Information Sheet – Photography and video recording'.

What happens at the PDC/Baby Ubuntu clinic?
As part of the PDC/Baby Ubuntu programme, you will be invited to attend regular visits at your local health centre. While you are there the health care worker running the clinic will assess your child's health, growth, nutrition, and development. You will receive individual counselling, support and advice depending on your child's needs. If your child has a disability, you will also be invited to take part in a Baby Ubuntu group. The Baby Ubuntu groups meet regularly over several weeks to teach caregivers knowledge and skills in caring for their child and to share experiences with other caregivers. These group sessions are run by a healthcare worker and an 'expert parent' who is themselves the caregiver of a child with disability. The content of the Baby Ubuntu group programme is divided into 11 modules, and the groups meet every 2-3 weeks. The content of Baby Ubuntu covers 'understanding disability', positioning and carrying, feeding, learning to move, communication, play, everyday activities, and experiences in the local community. Each group session lasts for 2-3 hours.

When taking part in the PDC/Baby Ubuntu programme, we will also ask you to report costs associated with caring for your child and attending programme sessions. This is to help us understand the costs incurred by families to attend the programme. This may include being asked about your income, your costs of buying equipment to support your child and the cost of transport when attending programme sessions.

What are the possible risks and disadvantages?
When answering questions, it is possible you may feel distressed at discussing your experiences. Your decision to take part, or what you tell us, will have no impact on the care you receive. Some people may experience some stigma as a result of participating in a programme for at risk children. The PDC/Baby Ubuntu programme includes sessions on stigma, discrimination and exclusion to support caregivers and their families. All of our study staff are trained in supporting families experiencing negative attitudes in the community due to child disability. You are welcome to contact members of the study team if you feel that you need any additional support. If you decide at anytime that you no longer want to be part of the programme or the research, then you can stop at any time and it will not affect care that you receive at the health centre.

What are the possible benefits?
We cannot promise the study will help you but the information we get from the study will help us gain a better understanding of how we might support children with or at risk of developmental delay and disability. We hope

that this will be of benefit to you and your child as each child will receive a comprehensive assessment of their development and be offered advice and support on caring for your child.

To compensate you for your time taking part in the study, we will provide you with 4,000 RWF after taking part in each survey.

Who can I contact for more information?
If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions: Erick Baganizi, 0788447693, ebaganizi@pih.org. If you remain unhappy and wish to complain formally, you can do this by contacting The Research Governance and Integrity Office at LSHTM at rgio@lshtm.ac.uk or +44 (0) 20 7927 2626 or the Rwanda National Ethics Committee (RNEC) at info@rnecrwanda.org, 0788592004.

The London School of Hygiene and Tropical Medicine holds insurance policies which apply to this study. If you experience harm or injury as a result of taking part in this study, you may be eligible to claim compensation.

Can I change my mind about taking part?
Yes. You can withdraw from the study at any time. You just need to tell us that you don't want to be in the study anymore. Neither the care your child receives, nor your child's treatment will be affected in the case of voluntary withdrawal or declining to participate. If you withdraw from the study, we will destroy all your identifiable information, but we will usually keep the data collected on you up to your withdrawal unless you ask us to destroy it.

What will happen to information collected about me?
Your data from the survey will be anonymised. This means that we will remove personal details, like your name, contact details and address, so that you cannot be recognised when looking at your data. Only the study staff and authorities who check that the study is being carried out properly will be allowed to look at your personal details, like your name and contact information. Your personal details will be kept in a different safe place to the other study data (e.g. recordings, write-up, notes), such as in a locked filing cabinet or a password protected computer. We will keep all information about you safe and secure. Your personal details will be destroyed within 2 years of the end of the study. An anonymized copy of your data will be sent to the research team at LSHTM in the United Kingdom.

At the end of the project, the study data will be kept in a safe place and we may include anonymised data in an online 'data repository'. By 'anonymised data' we mean data that has had all identifying information that could link the data back to you removed. A data repository is a website where other researchers outside this study team can look at information from different studies so that they can confirm our findings. They may also use the data for other research purposes. Similarly, we may also agree to share study data directly with other researchers or collaborating partners that are working on this topic, using a 'data sharing agreement' . However, again, your data will always be anonymised and your identifiable information will not be made available.

Where can you find out more about how your information is used?
You can find out more about how we use your information

- *At https://www.lshtm.ac.uk/files/research-participant-privacy-notice.pdf*
- *by asking one of the research team*
- *by sending an email to DPO@lshtm.ac.uk*

What will happen to the results of this study?
The study results will be published in a journal and a report so that policy-makers and practitioners can learn from them. We will also share the learning with policy-makers and practitioners directly. Your personal information will not be included in any study materials so that you can't be identified from it.

Who has reviewed this study?
All research involving human participants is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by The London School of Hygiene and Tropical Medicine Research Ethics Committee (<ref:>). The Rwanda National Ethics Committee (RNEC) has also reviewed the study and have agreed that it is okay for us to ask people to take part.

Further information and contact details

Thank you for taking time to read this information sheet. If you think you will take part in the study please read and sign the consent form. If you would like any further information, please contact Erick Baganizi or Francois Uwinkindi who can answer any questions you may have about the study.

Contact details:
Erick Baganizi
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You may also contact the Rwanda National Ethics Committee (RNEC) should you have any questions about your rights as a research participant: Dr. Jean Baptiste Mazarati (0788309807), RNEC Chairperson, or Dr. David K. Tumusiime (0788749398), RNEC Secretary.

PARTICIPANT CONSENT FORM

Statement	Please initial or thumbprint* each box
I confirm that I have read or been read, and that I understand, the Participant Information Sheet for the project: **Evaluation of the PDC/Baby Ubuntu programme**. I have had the opportunity to consider the information provided, ask questions about the study, and have had these answered satisfactorily.	
I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.	
I consent to the processing of my personal information for the purposes of this research study and understand that such information will be treated as strictly confidential.	
I understand that data about/from me/the participant may be shared via a public data repository or by sharing directly with other researchers and collaborating partners, and that I will not be identifiable from this information	
I consent to my child undergoing a developmental assessment and for this to be recorded if needed.	
I agree to be contacted again in 12 months and 24 months, to take part in the survey again	
I agree to take part in the above named study	

Printed name of participant	Signature of participant	Date

Printed name of impartial witness*	Signature of impartial witness	Date

I attest that I have explained the study information accurately to, and was understood to the best of my knowledge by, the participant and that he/she has freely given their consent to participate* in the presence of the above named impartial witness (where applicable).

Printed name of person obtaining consent	Signature of person obtaining consent	Date

[*Only required if the participant is unable to read or write.]