Evaluation of Scaling Up Early Childhood Development In Zambia (SUpErCDZ)

Informed Consent Form

NCT03991182

Nancy A Scott, DrPH MPH
nscott@bu.edu

9-21-2021

RESEARCH CONSENT FORM
Caregiver of Child: CONSENT FORM
IMPACT EVALUATION OF SCALING UP EARLY CHILDHOOD DEVELOPMENT IN ZAMBIA

Background

Hello, my name is_____. I am working with Right to Care Zambia. We are working with the government and other organizations to improve early childhood development in rural Zambia through the creation of community-based parent groups. This study is funded by Grand Challenges Canada and USAID.

Purpose

Your household is being approached because we are following up on a survey that you or someone in this household participated in about two years ago when a child in the household was between 0-5 months of age. At the time, you or someone in this household enrolled in our research study to learn about knowledge and practices related to early childhood development within your community and understand if parenting groups are helpful. This is the follow-up visit we discussed then. We are asking you to voluntarily give us some more information on the child and household. As a reminder, what you tell us may help the Government as they try to make early childhood development services accessible to all children in Zambia and will help researchers and policy makers develop programs that meet your needs.

What Happens in this Research?

You are one of approximately 1170 households who enrolled in this study 2 years ago. This research is taking place in 10 health facility catchment areas in Zambia, 8 from Southern Province and 2 from Eastern Province.

If you agree to continue participating, we will again ask you to answer questions about the people who live in your household, your caregiver practices, knowledge and behaviors related to COVID-19, and the health of your child. We will ask you about your own characteristics, physical and psychosocial wellbeing. Some questions will ask about sensitive topics such as past and recent intimate partner violence you may have experienced.

For the children who were 0-5 months at baseline, we will conduct a developmental assessment of your child using activities and games that are appropriate for your child's age. For this child's older siblings who are now between the ages of 5 and 8 years (and are available) we will do a short developmental assessment that involves play activities and puzzles. We will then measure the weight and height of all children under 10 and the upper arm of children under 5. We will also ask for the birthweight of any children born since our last visit to your household 2 years ago.

If the data collector thinks you, your child, or anyone in your household might require additional support we will provide a list of helpful resources in your area, and we may inform the SMAG in your area to visit your household.

There is a possibility you will be selected for participation in a more in-depth discussion so we can get a better understanding of perspectives on the same topics. Our discussion during the interview (not the survey) will also be audio recorded.

Some of these activities will be conducted at the same time by our team of data collectors. The total process combined will take no more than 3 hours, including breaks.

Risk and Discomforts

The biggest risk is that other people may hear what you say. It is important that you not share anything that you are not comfortable sharing. If you or someone in your family had a bad experience, including experiences of violence, it may be difficult or uncomfortable to remember or to discuss. We will let you know before we begin questions that may cause emotional distress. You do not have to respond to any question unless you feel comfortable doing so. We can stop at any time if you need to. The only additional risk to taking part in this study is potential for COVID-19 transmission. However, that risk is very low as the entire process will take place outside. Data collectors will be masked at all times, will sit socially distanced, and will wash their hands before and periodically throughout the assessment. We will ask you to also wear a mask and wash your hands.

Potential Benefits

The benefits to taking part in this study are the same as before. You will receive no direct benefits from your participation in this study. However, your participation may help us better understand how to improve early childhood development services in your community.

Alternatives

You can choose not to continue your participation in the study. If you decide not to continue or withdraw from the study, you will not suffer any penalties or lose any benefits or services to which you are entitled.

Participant Costs and Payments

There are no costs to you for participating. You will not be paid to participate in this study. You will receive a small gift valued at no more than 70 kwacha ($3) to acknowledge the time it took you to participate in the study.

Confidentiality

As before, we will keep your name and answers private. Your survey has been assigned a number. Your information will be kept in a locked file, only study team can see this data. Other investigators will be able to see your data without identifying information. When the information is published, we will not link what you said to your name. Your answers will only be presented in aggregate form, not individually.

Participants Rights

By consenting to continue participation in this study, you do not waive any of your legal rights. Giving consent means you have heard or read the information about this study and that you agree to continue participating. You will be given a copy of this form to keep.

If at any time you withdraw from the study, you will not suffer any penalty or lose any benefits to which you are entitled. You may obtain further information about your rights as a research participate by contacting the University of Zambia Biomedical Research Ethics Committee at +260-1-256067 (unzarec@unza.zm; Ridgeway Campus, P.O. Box 50110, Lusaka, Zambia). The investigator or a member of the research team will try to answer all you question. If you have questions or concerns at any time, please contact Dr Ben Chirwa at +260 211 376 518 or, if he is not available, you can contact the Principal Investigator Miss Thandiwe Ngoma at +260 211 376 518 (thandiwe.ngoma@equiphealth.org; Mikwala House Plot 11059 Off Brentwood Lane, Longacres, Lusaka, Zambia).

Rights to Refuse or Withdraw

Continuing to take part in this study is voluntary. You have the right to refuse to continue participation. If you decide to continue participation in the study and then you change your mind, you can withdraw from the research. Your continued participation is completely up to you. If there are any new findings during the study that may affect whether you want to continue to take part, you will be told about them as soon as possible.

The investigator may decide to discontinue your participation without your permission because he/she may decide that staying in the study will be bad for you, or the sponsor may stop the study.

By signing below, you are agreeing to participate which indicate that you have read this consent form or have had it read to you, that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study. You may keep the copy of this for your records.

Names of participant: ……..…….. Date: ……

Thumb Print/ Signature of participant: …….

Name of the witness: ……

Thumb Print/Signature of the witness: ……...

BMC and BU Medical Campus IRB
IRB NUMBER: H-38950
IRB APPROVAL DATE: 09/21/2021