PARTICIPANT (ADOLESCENT) INFORMATION SHEET – CONTROL GROUP

Testing the Impact of Family-based Intervention to Improve Developmental and Health Outcomes for Female Adolescents (ANZANSI Family Program)

Research Collaborators: University of Ghana
New York University
BasicNeeds Ghana
BIBIR Ghana

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INTRODUCTION

We are a group of researchers based at New York University, in the United States of America, and the University of Ghana, working with BasicNeeds Ghana and BIBIR Ghana to find out what kinds of programs can be helpful to support girls in staying in school and avoiding migration for work, as well as strengthen the psychosocial wellbeing of girls and their families.

This study is funded by the U.S. National Institute of Child Health and Human Development (NICHD). This means that the University of Ghana, BasicNeeds and BIBIR Ghana are receiving payments from NICHD to support the activities that are required to conduct the study. No one on the research team will receive a direct payment or increase in salary from NICHD for conducting this study.

We are asking you to participate in this study because you are an adolescent girl between the ages of 11-14 years enrolled in school in the Greater Tamale Metropolitan area and living with your family. The purpose of this form is to give you the information you will need to help decide whether to participate in the study or not. You may ask any questions about this study, including possible risks and benefits, your rights as a potential participant, and anything else about the research or this form that is not clear to you. This process is called 'informed consent.' You will be provided with a copy of this form for your records. Most importantly, know that you are allowed to say "no" to participation today or at any point in the future without suffering any negative consequences.

PURPOSE

The study we are inviting you to participate in aims to test whether the ANZANSI Family Program will successfully help adolescent girls stay in school and not migrate for work while also strengthening family relationships and communication. This research project is a collaboration between New York University (USA), University of Ghana, BasicNeeds Ghana, and BIBIR Ghana.

EXTENT OF PARTICIPATION

If you agree to participate in this study, you will be provided with some school materials. We will ask you to participate in four confidential (private) surveys with a member of our research staff, such as myself and/or through audio computer-assisted devices. Each survey will last approximately 60 minutes and the information we collect during these interviews– which will be at baseline (i.e. at the start of the program) and at 12, 24, and 36 months after the program (intervention) start date– are for research purposes only. During these interviews, we will assess your attitudes towards school, future educational plans, psychosocial wellbeing and family support. We will also ask you about your attitudes/thoughts towards women, child employment, savings and migration. Over the course of 3 years, we will ask for a total of 4 hours of your time.

Withdrawal: Your participation in this study is entirely voluntary. You are allowed to withdraw from the study at any time, for any reason. There will be no consequences to your withdrawal. You won't be penalized or lose benefits you're otherwise entitled to. You can also refuse to answer any questions at any time. None of your choices will affect the services you or your caregiver receives at school. You both have the right to review any materials and request that we erase any of your responses. In addition, we will inform you if we know of any new findings during the course of the study that might influence your decision to continue participation.

ALTERNATIVES TO PARTICIPATING IN THE STUDY

You may choose not to participate in this research study, in which case you will continue to receive the services you normally receive at your school.

POSSIBLE RISKS

During the interviews, you may feel embarrassed or uncomfortable when answering sensitive and personal questions. If you are uncomfortable with a particular topic, you can tell us that you prefer not to discuss it, and we will move on.

One risk of participating in this study is that confidential information about you may be accidentally disclosed. We will use our best efforts to keep the information about you secure. Please see the section in this consent form titled “Confidentiality of your information” for more information about procedures we put in place to protect your confidentiality.

There could be other unforeseeable risks to participation in the study. If we become aware of new risks, we will inform you.

COMPENSATION

If you choose to participate in this study, you will be compensated 80 Ghana Cedis upon completion of each survey, totaling 320 Ghana Cedis. The compensation is for the time and the valuable information you may provide during the interviews.

BENEFITS

You will receive school supplies if you participate in the study. Your participation will help in the successful completion of this study, which will allow us to better understand the impact of this program and make it available to other adolescent girls and their families.

CONFIDENTIALITY OF YOUR INFORMATION

We will keep your participation in this research study confidential to the extent permitted by law. The information you give will be used by New York University and University of Ghana only for research purposes. We will not share any information or answers with any of your family members, friends, neighbors, teachers or community leaders. However, it is possible that other people such as those indicated below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you.

- Government representatives in the United States, (including the Office for Human Research Protections) to complete federal or state responsibilities
- National Institute of Child Health and Human Development
- The Ghana Health Service Ethics Review Committee for auditing purposes. The Ethics Review Committee reviewed and approved this study
- New York University's Institutional Review Board (a committee that oversees the conduct of research involving human participants) and Human Research Protection Office. The Institutional Review Board has reviewed and approved this study.

To protect your confidentiality, hard copies of documents will be maintained in locked cabinets at BasicNeeds Ghana. All data will be coded with ID numbers and stored on computerized, password-protected computers. Participant consent forms and ID logs will be kept in a separate location in a locked cabinet at the BasicNeeds offices. Information about participants will also be kept in password protected computer files. The master list of study participants will only be used to coordinate data collection. All the research staff will receive training on confidentiality issues. In addition, research staff will be trained how to collect human subjects data in a way that protects your privacy. All research staff will also sign a confidentiality pledge in which they will pledge not to share anything you shared in your questionnaires. If we write a report or article about this study or share the study data set with others, we will do so in such a way that you cannot be directly identified.

Important Exception:

The only circumstance in which confidentiality may be breached is in cases of risk of immediate harm. For example, if you tell us that you intend to harm yourself or someone else, we will be required to report this information to the appropriate local authorities.

___Please initial here to acknowledge your understanding of this.

DATA SHARING

Data from this study will be submitted to NICHD's Data Sharing for Demographic Research (DSDR). DSDR is a centralized resource that allows researchers to share and access de-identified

data from studies funded by NICHD. A data repository is a large database where information from many studies is stored and managed. Deidentified information means that all personal information about research participants such as name, address, and phone number is removed and replaced with a code number.

Your data will be stored in DSDR without your name or any other kind of link that would enable us to identify what data is yours. During and after the study, the researchers will send deidentified data to DSDR. Other researchers nationwide can then file an application with the NICHD to obtain access to your deidentified study data for research purposes. Experts at the NICHD who know how to protect health and science information will look at every request carefully to minimize risks to your privacy.

You may not benefit directly from allowing your information to be shared with DSDR. The information provided to DSDR may help researchers around the world find solutions for adolescent girls so that they have better outcomes. NICHD will also report to Congress in the United States and on its website about the different studies that researchers are conducting using DSDR data. However, you will not be contacted directly about the data you contributed to DSDR.

You may choose at any time, now or in the future, to withdraw your consent for sharing your information through DSDR. If you decide to do so, please contact the researchers who conducted this study, and they will inform DSDR to stop sharing your research data. However, DSDR cannot take back information that was shared before you changed your mind. If you would like more information about DSDR, please contact the study team.

A description of this clinical trial will be available at http://www.ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of results. You can search the website at any time.

CONTACT INFORMATION

If you have any questions about this study, you are encouraged to contact:

Dr. Adolphina Ado-Lartey, Senior Lecturer at the School of Public Health, University of Ghana, Legon Boundary in Accra at 0261458709, or by email at: aaddo-lartey@ug.edu.gh, Dr. Alice Boateng, Senior Lecturer at the Department of Social Work, University of Ghana at 050-607-4933or by email at: aboateng@ug.edu.gh, or Dr. Abdallah Ibrahim, Senior Lecturer at the School of Public Health, University of Ghana, Legon Boundary in Accra at 026-645-0012 or 020-445-0012, or by email at: aibrahim@ug.edu.gh, or Dr. Ozge Sensoy Bahar, Research Associate Professor at New York University on 001-617-610-6814 or by email at: osb208@nyu.edu.

If you have any questions regarding your rights as a research participant, or if at any time you have comments regarding the conduct of this research, you may contact the Ethical Review Board of the Ghana Health Service (GHS-ERC) office between the hours of 8:30am-5pm, or by telephone: 0503539896 or 0559886678 or by email at: ethics.research@ghs.gov.gh. Additionally, you may contact the Institutional Review Board Office at New York University by telephone at (001) 212-998-4808 or via e-mail at ask.humansubjects@nyu.edu. The Institutional Review Board is a committee organized to protect the rights and welfare of human subjects involved in research.

ADOLESCENT ASSENT FORM – CONTROL GROUP

ANZANSI Family Program: A family-based intervention for female youth at risk of migration for Kaya work and their families in Northern Ghana

STATEMENT OF PARTICIPANT CONSENT
Testing the Impact of Family-based Intervention to Improve Developmental and Health Outcomes for Female Adolescents (ANZANSI Family Program)

PARTICIPANTS' STATEMENT

I have read the information above, or it has been read to me. I have had the opportunity to ask questions, and all of my questions have been answered to my satisfaction. I voluntarily consent to

participate in this study. I understand that I have the right to withdraw from the study at any time, and that doing so will not affect any services to which I am otherwise entitled.

Name: ……..

Parental Permission on File: ☐ **Yes** ☐ **No** (If "No", do not proceed with assent or research procedures)

Signature/Thumb Print…… Date:……..

DATA SHARING CONSENT STATEMENT

I understand that the data collected in this study, including survey responses, interview transcripts, and other study-related information, may be shared with other researchers for future research purposes. This data will be de-identified to remove any personally identifiable information, ensuring privacy and confidentiality. The data may be stored in a secure research repository, such as NICHD's Data Sharing for Demographic Research (DSDR), and shared with other researchers who request access. I acknowledge that choosing not to share my de-identified data will not affect my participation in the study.

☐ **Yes**, I agree to the sharing of my de-identified data for future research purposes.
☐ **No**, I do not agree to the sharing of my de-identified data.

Name: ……..
Signature/Thumb Print: …… Date: ……..

INTERPRETERS' STATEMENT (where applicable)
I interpreted the purpose and contents of the Participants' Information Sheet to the afore named participant to the best of my ability in the (*Dagbani*) language to his proper understanding.

All questions, appropriate clarifications sort by the participant and answers were also duly interpreted to his/her satisfaction.

Name of Interpreter……
Signature of Interpreter……..
Date:…… Contact Details: …….

STATEMENT OF WITNESS (where the adolescent cannot read the form themselves)
I was present when the purpose and contents of the Participant Information Sheet was read and explained satisfactorily to the participant in the language he/she understood (*Dagbani*).

Name of Witness:…… Signature/Thumb Print: …….....
Date:……

INVESTIGATOR STATEMENT AND SIGNATURE

I certify that I have taken time to read the purpose and other relevant aspects of the participant informed consent issues and have all questions and clarifications raised by the participant thoroughly explained and addressed.

Researcher's Name…… Signature …… Date:……