Washington University in St. Louis

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Title: Sibling-Support for Adolescent Girls (SSAGE): A study protocol for a pilot randomized-controlled trial of a whole-family, gender transformative approach to preventing mental illness among forcibly displaced adolescent girls

NCT number: NCT06078124

Date: July 15, 2024

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INFORMED CONSENT DOCUMENT

Project Title: Sibling-Support for Adolescent Girls (SSAGE):A whole-family, gender transformative approach to preventing mental illness among forcibly displaced adolescent girls
Principal Investigator: Lindsay Stark
Research Team Contact: Arturo Harker Roa, +57 310 7551902
If you are the parent/guardian providing parental permission the word "you" refers to your child.
This consent form describes the research study and helps you decide if you want to participate. It provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights and responsibilities as a research participant.

KEY INFORMATION

The first section of this document contains some key points that the research team thought you would find important. The research study is described in more detail after this section.

This is a research study conducted by Drs. Lindsay Stark and Ilana Seff having to do with the health and well-being impacts of the Sibling Support for Adolescent Girls (SSAGE) program, a gender-transformative intervention to support family functioning. You should carefully consider the information in this consent document and discuss it with the research team. You should understand why you might want to participate, or why you might not want to participate. You may choose to participate or not. Before you decide whether to be in this study, you may wish to consider other options that are available to you.

If you agree and sign this consent, you will be volunteering to participate in the research study. As a voluntary participant, your child will be asked to spend approximately one hour filling out two survey questionnaires, three months apart. You will need to come to the private facility to do so. During that time, your child will be asked to fill out a survey questionnaire. The main risks if your child participates are possible feelings of unease when answering questions based on personal experience.

We don't expect this study to benefit you directly, but it will help us understand how to improve health and wellbeing for communities in humanitarian contexts including Colombia. By volunteering you may help someone else in the future. There is no cost to you and you will not be paid for being a volunteer participant. All of this information will be explained and is listed in more detail in this consent document. The research team must give you a copy of this signed consent document.

The rest of this document provides more details about the study.

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We invite you to participate in this research study because your child is an adolescent girl who has recently migrated to Colombia.
The purpose of this research study is to understand if and how the SSAGE program helps promote wellbeing among adolescent girls, a population that receives little attention in humanitarian work.

WHAT WILL HAPPEN DURING THIS STUDY?

As a participant in this study, your child will fill out two questionnaires, three months apart. The

questionnaires will take place in person at the private facility in a private area with female facilitators. Your child is free to skip any question they would prefer not to answer or withdraw from the study at any time. After the initial survey, your child (along with three other members of your family) may also be randomly selected to participate in the SSAGE program or to be part of a control group. If you are selected to be part of the SSAGE program, you, along with a male and female caregiver and an adolescent male relative will each take part in a twelve week program with a group of your peers (that is, you will only meet with other adolescent girls). You and the three members of your family participating in the intervention will meet with your group for a couple hours each week to share discussions and take part in activities.

If you tell us that you are thinking about hurting yourself or others, the research staff may give you referrals for treatment. We may need to work with you on a plan that might include getting you to a medical facility for safety. We also want to provide you with contact information for available resources, should you decide you need assistance at any time. You can call the national mental health hotline at 106, or the hotline for Bolivar, at 125.

Will you save my research data to use in future research studies?

The data we are obtaining in this study may be made available for studies going on right now as well as studies that are conducted in the future. These studies may be done by researchers at Washington University, the University of Los Andes, other research centers and institutions, or private companies involved in research. However, your data will not be sold or used for commercial purposes.

We may also share your research data with large data repositories (a repository is a database of information) for use by others, such as the research community, institutions, private companies and other researchers. If your individual research data is placed in one of these repositories, your name and other identifying information will be removed. All reasonable precautions will be taken to protect your privacy and confidentiality. Necessary approvals will be obtained to use the data. Certain summary information may be available to the general public.

These studies may provide additional information that will be helpful in understanding health and wellbeing for adolescent girls in humanitarian contexts. It is unlikely that what we learn from these studies will have a direct benefit to you. By allowing us to use your data you give up any property rights you may have in the data. We will protect the confidentiality of your information to the extent possible. If you change your mind and do not want us to store and use your data for future research you should contact the research team member identified at the top of this document. The data will no longer be used for research purposes. However, if some research with your data has already been completed, the information from that research may still be used. Also, if the data has been shared with other researchers it might not be possible to withdraw the data to the extent it has been shared.

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 180 adolescent girls will take part in this study conducted by investigators at Washington University and the University of Los Andes.

HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, your involvement will last for approximately five months. Each survey will take about one hour to complete. This study will require two visits, not including the SSAGE programming. There will be approximately four months between visits.

WHAT ARE THE RISKS OF THIS STUDY?

You may experience one or more of the risks indicated below from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study.
There is the possibility for negative or uncomfortable feelings to arise while completing the survey depending on the participants' experiences of violence, conflict, displacement, and prior mental health challenges. If these issues arise, the facilitators can refer your child to follow-up support through Mercy Corps, as well as other local services, as needed.
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 *"How will you keep my information confidential?"* for more information.

WHAT ARE THE BENEFITS OF THIS STUDY?

You may or may not benefit from being in this study.
However, we hope that, in the future, other people might benefit from this study because the information participants provide will be used to improve health and wellbeing for communities in humanitarian contexts including Colombia and expand knowledge within global health and child health fields.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

You will not have any costs for being in this research study.

WILL I BE PAID FOR PARTICIPATING?

You will not be paid, but you will be reimbursed for your travel associated with being in this research study. You will receive a small transportation stipend to cover the costs associated with traveling to and from each of the two data collection sessions in the form of cash.

WHO IS FUNDING THIS STUDY?

The National Institute of Mental Health (NIMH) is funding this research study. This means that the Washington University is receiving payments from NIMH 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 NIMH for conducting this study.

HOW WILL YOU KEEP MY INFORMATION CONFIDENTIAL?

Other people such as those listed 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 (including the Office for Human Research Protections) to complete

federal or state responsibilities
- National Institute of Mental Health
- University representatives to complete University responsibilities
- Washington University's Institutional Review Board (a committee that oversees the conduct of research involving human participants) and the Human Research Protection Office. The Institutional Review Board has reviewed and approved this study.

Any report or article that we write will not include information that can directly identify you. The journals that publish these reports or articles require that we share your information that was collected for this study with others to make sure the results of this study are correct and help develop new ideas for research. Your information will be shared in a way that cannot directly identify you.
To help protect your confidentiality, we will not share any information regarding you and your child and this research. All research team members have been trained appropriately on confidentiality. All identifiers will be removed and data with code numbers will be placed in a separate locked file cabinet while waiting for entry. Once data is entered into computer files and password protected, only the research team will have access to these files. Any data files given to other individuals will be stripped of identifiers and contain only code numbers.
To further protect your privacy, this research is covered by a Certificate of Confidentiality from the United States federal government. This means that the researchers can refuse to disclose information that may identify you in any legal or court proceeding or to anyone who is not connected with the research except if:
- there is a law that requires disclosure, such as to report child abuse and neglect, or harm to self or others*;*
- you give permission to disclose your information, including as described in this consent form; or
- it is used for other scientific research allowed by United States federal law.

This Certificate may not be effective for information held in foreign countries.

You have the right to share your information or involvement in this study with anyone at any time. You may also give the research team permission to disclose your information to a third party or any other person not connected with the research.

IS BEING IN THIS STUDY VOLUNTARY?

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. Any data that was collected as part of your participation in the study will remain as part of the study records and cannot be removed. If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

What if I decide to withdraw from the study?

You may withdraw by telling the study team you are no longer interested in participating in the study. If you decide to leave the study early, we will ask you to contact the research team member identified at the top of this document to indicate your wish to withdraw from the study. There will be no consequence to you should you choose to withdraw

Will I receive new information about the study while participating?

If we obtain any new information during this study that might affect your willingness to continue participating in the study, we'll promptly provide you with that information.

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Can someone else end my participation in this study?

Under certain circumstances, the investigator might decide to end your participation in this research study earlier than planned. This might happen for no reason or because the funding for the research study has ended, etc.

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact: Arturo Harker Roa, +57 310 7551902. If you feel that you have been harmed in any way by your participation in this study, please contact Lindsay Stark, +1 646 629 1773.

If you have questions, concerns, or complaints about your rights as a research participant please contact the Human Research Protection Office at 1-(800)-438-0445, or email hrpo@wustl.edu. General information about being a research participant can be found on the Human Research Protection Office web site, hrpo.wustl.edu. To offer input about your experiences as a research participant or to speak to someone other than the research staff, call the Human Research Protection Office at the number above.

This consent form is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by agreeing to participate in this study. Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a signed copy of this form.

Do not sign this form if today's date is after $STAMP_EXP_DT.

_____ _____

(Signature of Participant) (Date)

_____

(Participant's name – printed)

Parent/Guardian Name and Relationship to Participant:

Do not sign this form if today's date is after $STAMP_EXP_DT.

_____

(Child's name – printed)

_____ _____

(Signature of Parent/Guardian) (Date)

_____ _____

(Name of Parent/Guardian- printed) (Relationship to participant – printed)

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Statement of Person Who Obtained Consent

The information in this document has been discussed with the participant or, where appropriate, with the participant's legally authorized representative. The participant has indicated that they understand the risks, benefits, and procedures involved with participation in this research study.

_____ _____

(Signature of Person who Obtained Consent) (Date)

_____

(Name of Person who Obtained Consent - printed)