

Building and Sustaining Interventions for Children: Task-sharing Mental Health
Care in Low-resource Settings (BASIC)

NCT03243396

Duke Health IRB: Pro00081913

Child Assent Form (English)
IRB Reference Date 6-May-2021



DUKE UNIVERSITY
HEALTH SYSTEM

Minor Child Assent to Participate in a Research Study:

Building and Sustaining Interventions for Children (BASIC):

Task-sharing mental health care in low-resource settings

Child Assent for Screening and Program, Version Date 20-November-2017

Administered at screening

****Revised 1/29/2018, 3/19/2020**

Concise Summary

The purpose of this study is to see if we can help children who have had one or both parents die by offering a program at schools and in the communities. In this study, we also want to learn how to best support teachers and community health volunteers to provide the program to children in their communities.

If you are a good match, we will invite you and your caregiver to participate in a Pamoja Tunaweza group. In Pamoja Tunaweza, there are 8 group meetings, and the meetings are once a week. There is a group for children and another group for caregivers. **If you are in the study we would ask you and your caregiver the study questions about your feelings and behaviors today, again after your group ends, and once a year until the study ends (1 to 3 more times depending on when your group ends). The questions take about 1 hour each time.**

There are no dangers, like injuries, that could happen as part of being in this study. You may worry about talking about private things. We make every effort to keep everything that you tell us private. Some of the questions we will ask you or some of the discussions in the groups may make you feel uncomfortable or sad.

If you are interested in learning more about this study, please continue reading below.

You and your caregiver are being asked to take part in a research study. This study is under the direction of ACE Africa and Drs. Kathryn Whetten and Shannon Dorsey of Duke University and the University of Washington in the United States. Research studies are voluntary and include only people who choose to take part. I am going to read you this form, and then you will have a chance to read it yourself, if you wish. I will tell you about how the study works and other important information about the study. Two things that are important to remember:

- Your participation is entirely voluntary—you can say yes or no to being in the study.
- If you decide to participate in the study, you can stop at any time.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to see if we can help children by offering a program at schools and in the communities. The program is called Pamoja Tunaweza and is for children who have had one or both parents die. Children and adults often have problems with feelings and behavior



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after the death of someone they love. Pamoja Tunaweza has been found to help children with grief, sadness, and worries. In this study, we also want to learn how to best support teachers and health workers to provide the Pamoja Tunaweza program to children in their communities.

HOW MANY PEOPLE WILL BE IN THIS STUDY?

We plan to talk to children and their caregivers until we identify approximately 1,536 caregivers and 1,536 children who are a match for the program here in Bungoma.

WHAT IS INVOLVED IN THE STUDY AND HOW LONG WILL I BE IN THIS STUDY?

If you and your caregiver both agree, we will ask each of you questions about your feelings and behavior. These questions take about 1 hour. The questions will help us decide if you are a good match for the program. If the answers tell us that you and your caregiver are not a match for the program, we will only ask questions of you and your caregiver this one time.

PROGRAM PROCEDURES

If you are a good match, we will invite you and your caregiver to participate in a Pamoja Tunaweza group. In Pamoja Tunaweza, there are 8 group meetings, and the meetings are once a week. There is a group for children and another group for caregivers. These groups meet at the same time. The groups are led by trained group leaders. In the groups, the leaders help the children and caregivers learn about grief, learn what people generally experience with the death of a loved one, and learn ways to cope with difficult feelings. Children will be able to share some memories of their parents with their caregiver and with the group. Some groups will be at school and others will be in the community. We will let you know later where your group will take place and when it will start. Sometimes an ACE supervisor may visit a group to make sure the group leaders are doing the best job possible. They are not listening for what you or your caregiver say, only what the leader says and does.

If you are in the study we would ask you and your caregiver the study questions about your feelings and behaviors today, again after your group ends, and once a year until the study ends (1 to 3 more times depending on when your group ends). The questions take about 1 hour each time.

WHAT ARE THE RISKS OF THE STUDY?

There are no dangers, like injuries, that could happen as part of being in this study. You may worry about talking about private things. We make every effort to keep everything that you tell us private. Some of the questions we will ask you or some of the discussions in the groups may make you feel uncomfortable or sad. You can decline to answer any of the questions, and you



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may take a break at any time during a group or any time during the study. You may stop being in this study at any time.

ARE THERE BENEFITS TO BEING IN THE STUDY?

If you agree to take part in this study, there may be no benefit to you. However, many of the Kenyan children who have taken part in Pamoja Tunaweza have said that the program helped them feel better after the death of a parent. If we find out the program works well at schools and in the communities, we plan to offer it to even more children.

COSTS AND PAYMENTS TO PARTICIPANTS

There is no cost to taking part in the study. Each time you and your caregiver complete the study questions, your caregiver will receive a gift worth about 100 KSH (about \$1.00 USD) as a thank you.

WILL MY INFORMATION BE KEPT PRIVATE?

All study papers and other records will be kept private. We are not allowed to tell anyone what you tell us, not even your family, teachers, or health workers. However, if you tell us something that makes us worried about your safety, we will talk with you and/or your caregiver about our worry and make sure everyone is safe. If we talk about this program to other people who may want to use it, we will never use your name.

CAN I DECIDE NOT TO BE IN THE STUDY OR TO LEAVE THE STUDY ONCE I START?

You may choose not to be in the study. If you agree to be in the study, you may stop being in the study at any time.

WHAT IF I HAVE QUESTIONS OR PROBLEMS?

If you have any questions, problems, concerns, or decide to withdraw from the study, please contact Augustine Wasonga (telephone number 0722 831834) or Cyrilla Amanyia (telephone number 0722 785039 or 0735 507761) at ACE Africa.

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



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STATEMENT OF ASSENT

“The purpose of this study and what will happen during the study have been explained to me. I have been allowed to ask questions, and my questions have been answered. I understand that I may stop the study at any time.”

**I AGREE TO TAKE PART IN ANSWERING 30 MINUTES TO 1 HOUR OF
QUESTIONS TO SEE IF WE ARE A GOOD MATCH FOR THIS PROGRAM.**

Name of Child in block letters

Signature of Child (Assent)

Date

Name of Interviewer in block letters

Signature of Interviewer

Date

**Name of Witness in block letters
(if participant cannot read)**

Signature of Witness

Date

**IF MY CAREGIVER AND I ARE A GOOD MATCH TO TAKE PART IN THE
RESEARCH STUDY, I AGREE TO BE IN MY ASSIGNED GROUP AND ANSWER
STUDY QUESTIONS.**

Signature of Child (Assent)

Date

Name of Interviewer in block letters

Signature of Interviewer

Date

**Name of Witness in block letters
(if participant cannot read)**

Signature of Witness

Date