Official Title:	Promoting Mental Health of Teachers and Caregiver Using a Personalized mHealth Toolkit in Uganda
NCT Number:	NCT06087159
Study Number:	23-00600
Document Type:	Informed Consent Form
Date of the Document:	• December 27, 2024

Research Subject
Parent and Teacher Informed Consent Form (for Pilot Study)

Title of Study:	PROMOTING MENTAL HEALTH OF TEACHERS AND CAREGIVERS USING A PERSONALIZED MHEALTH TOOLKIT IN UGANDA s23-00600
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1. **About volunteering for this research study**
   You are being invited to take part in a research study. Your participation is voluntary which means you can choose whether or not you want to take part in this study.
   People who agree to take part in research studies are called "subjects" or "research subjects". These words are used throughout this consent form. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. You may also decide to discuss this study and this form with your family, friends, or doctor. If you have any questions about the study or about this form, please ask us. If you decide to take part in this study, you must sign this form. We will give you a copy of this form signed by you for you to keep.

2. **What is the purpose of this study?**
   The purpose of this study is to test the appropriateness and usefulness of mWEL, a tool to screen and promote stress management strategies to promote mental health for parents and teachers. This research study is being done to collect your thoughts/reactions/opinions and experience interacting with mWEL. We will do this through Surveys/Questionnaires using tablets or questionnaires/Interview

3. **How long will I be in the study? How many other people will be in the study?**
   It is expected that 160 adults (80 teachers and 80 parents) will participate in this study over the course of 1 year. Participants will be asked to use and provide perspective or feedback over the course of the year.

4. **What will I be asked to do in the study?**
   If you agree to participate:
   - You will be asked to complete 2 survey assessments. The assessment will ask you questions about your stress, stress management, and wellbeing. Each assessment will take about 1-1.5 hours. The two assessments will be about 4-5 months apart.
   - You'll have the opportunity to sign up for a user account and interact with mWEL between January and July 2025. Schools will be assigned different schedules to sign up and access the mWEL tool, so your start

date will align with your school's assigned schedule. We'll notify you when it's time for parents and teachers at your school to start using mWEL. During this period, you'll receive support from a peer leader or school health partner as needed to ensure proper use of the application

- A subset of participants will be invited to join feedback focus groups after completing the two survey assessments and a session using the mWEL toolkit. If selected, the focus group will last approximately 1-1.5 hours. Meetings will occur about 2-3 months apart, each lasting around 60-90 minutes. Research staff will coordinate a time that works best for you. During these sessions, we will ask questions about your child and your experiences as a parent.

Identifiers will be removed from the identifiable private information. After such removal the private information may be used for future research studies or shared with other researchers and we will not request additional informed consent from you to use this information as we have noted here.

5. What are the possible risks or discomforts?

Risk of Study

There is minimal risk involved in participating in the study. The main risk of this study is a breach of confidentiality. This risk will be minimized by storing contact information and identifiers such as name separate from the research data collected and limiting access to this information to the research team.

Other Risks

You may become uncomfortable by some of the questions asked in the survey or in focus groups. You have the opportunity to not answer any questions that make you feel uncomfortable. Because the focus groups are in group format, there is the possibility of breach of confidentiality. Other participants may share discussed information with non-participant staff. To avoid a breach of confidentiality, we will remind participants to not share discussed information. We will reiterate to the group the purpose of these meetings is to learn from each other to support the Ugandan community. If you experience any discomfort or have concerns, please contact Dr. Nakigudde directly.

Unforeseeable Risks: The research may involve risks that are currently unforeseeable.

What if new information becomes available?

During the course of this study we may find more information that could be important to you. This includes information that might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available.

6. What are the possible benefits of the study?

There are many potential benefits to you and your community. You may develop knowledge and skills that are useful in stress management and mental health. The results of this study may also benefit communities in Uganda through knowledge sharing among participants, specifically in schools and the education system about mental health and well-being.

7. What other choices do I have if I do not participate?

Participation is voluntary and you can choose to not participate in the study.

8. Will I be paid for being in this study?

We recognize participation in the project will require your time commitment. If you agree to participate in the study, you will receive 30,000 UGX for completing the first assessment, and 30,000 UGX for completing the 2nd assessment. If you participate in both assessments/survey sessions, you will receive a total of 60,000 UGX. If you participate in the focus group you will receive 30,000 UGX for each focus group completed.

9. Will I have to pay for anything?

It will not cost you anything to participate in this study.

10. What happens if I am injured from being in the study?
It is not expected that your participation in this study will result in any injury, however, we will offer you the care needed to treat injuries directly resulting from taking part in this research. We may bill your insurance company or other third parties, if appropriate, for the costs of the care you get for the injury, but you may also be responsible for some of them. For medical emergencies contact 999 from your landline or 112 from your mobile phone. If you think you have been injured as a result of taking part in this research study, tell the principal investigator as soon as possible. The principal investigator's name and phone number are listed at the top of page 1 of this consent form. There are no plans for the NYU Grossman School of Medicine/NYU Langone Health or Makerere University to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this form.

11. When is the study over? Can I leave the Study before it ends?
This study is expected to end after all participants have completed all visits, and all information has been collected. If you decide to take part in the study, you may stop at any time without penalty. If you wish to stop participating, all you have to do is let the research staff know you wish to stop participating in the study. Leaving the study will not interfere with your future care, or any other benefits to which you are entitled.

12. How will you protect my confidentiality?
NYU Langone Health and Makerere University is committed to protecting the privacy and confidentiality of your information. This includes information about your participation in this study. In compliance with NYU Langone Health and Makerere University policies and procedures and with HIPAA, only members of the study team can access your survey responses and contact information. If you agree to participate in this study, we will not share your answers and personal information with anyone. Your contact or identifiable information we receive from you will be saved in a secure, password-protected database, and will be kept separate from any survey or focus group data we collect from you.We will never use your name or other personal information in any written reports or presentations.

What information may be used or shared with others in connection with this study?
All information in your research record for this study may be used and shared with those individuals listed in this section.

Who may use and share information in connection with this study?
The following individuals may use, share, or receive your information for this research study:

- The research team, including the Principal Investigator, study coordinators, and personnel responsible for the support or oversight of the study
- The study sponsor: NIMH
- Governmental agencies responsible for research oversight (e.g., the Food and Drug Administration or FDA).
- Makerere University College of Health Sciences
- National Database for Clinical Trials related to Mental Illness (NDCT)

Your information may be re-disclosed or used for other purposes if the person who receives your information is not required by law to protect the privacy of the information.

What if I do not want to give permission to use and share my information for this study?

Signing this form is voluntary. You do not have to give us permission to use and share your information, but if you do not, you will not be able to participate in this study.

Can I change my mind and withdraw permission to use or share my information?
Yes, you may withdraw or take back your permission to use and share your information at any time for this research study. If you withdraw your permission, we will not be able to take back information that has already been used or shared with others. To withdraw your permission, send a written notice to the principal investigator for the study noted at the top of page 1 of this form. If you withdraw your permission, you will not be able to stay in this study.

How long may my information be used or shared?
Your permission to use or share your personal information for this study will never expire unless you withdraw it.

Certificate of Confidentiality
To help us further protect your confidentiality, this research is covered by a Certificate of Confidentiality from the National Institutes of Health (NIH). The NIH has issued a Certificate of Confidentiality for this research. This adds special protection for the research information (data, documents, or biospecimens) that may identify you.

Research information protected by this Certificate of Confidentiality cannot be disclosed to anyone else who is not connected with the research, without your consent. With this Certificate of Confidentiality, the researchers may not disclose or use research information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, without your consent. However, disclosure, without your consent, is still necessary if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases). The Certificate of Confidentiality cannot be used to refuse a request for information from appropriate government agencies responsible for project oversight.

The Certificate of Confidentiality does not prevent you from releasing information about yourself and your involvement in this research, including for your medical treatment. Federal regulations may also allow for the use or sharing of information for other scientific research.

13. The Institutional Review Board (IRB) and how it protects you

The IRB reviews all human research studies – including this study. The IRB follows US and Uganda Federal Government rules and guidelines designed to protect the rights and welfare of the people taking part in the research studies. The IRB also reviews research to make sure the risks for all studies are as small as possible. The NYU Langone Health IRB Office number is 011-1-212-263-4110 and the Makerere University IRB number is 256-41-530022/3. Both IRB review boards are made up of:

- Researchers, doctors, nurses, non-scientists, and people from the Community

14. Who can I call with questions, or if I'm concerned about my rights as a research subject?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on top of the page 1 of this consent form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the NYU Langone Health or Makerere Institutional Review Board (IRB) at the number provided above.

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

When you sign this form, you are agreeing to take part in this research study as described to you. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer.

Name of Subject (Print)	Signature of Subject	Date

Name of Person Obtaining Consent (Print)	Signature of Person Obtaining Consent	Date