

1.1 INFORMED CONSENT FORMS

Annex 1.1.1 Informed Consent to Participate in the Entire Study

Consent to Participate in Research

Dept. of Psychology, University of Malawi/Human Resources for Health in 2030 (HRH2030), USA

Mobile-phone-based study of *online self-help for mental wellbeing*

Principal Investigator: Dr. Eckhard Kleinau, HRH2030/University Research Co. (URC)

Co-investigators: Tilinao Lamba (Country Lead), Edister Jamu, Demoubly Kokota, Limbika Maliwichi, Dept. of Psychology, University of Malawi; Alex Zumazuma, Queen Elizabeth Central Hospital

You are being asked to take part in a *Mobile-phone-based research study of online self-help for mental wellbeing*. Taking part in research is voluntary. Your decision whether or not to take part will have no effect on the quality of your medical care, academic standing, or your job status. **No information collected during the trial that could identify participants or their facilities of affiliation will be shared with the employers.** Please ask questions if there is anything about this study you do not understand. You can contact us at Tilinao Lamba, tilinao.otilera@gmail.com / tlamba@cc.ac.mw or Eckhard Kleinau, ekleinau@hrh2030program.org.

What is the purpose of this study?

The purpose of this study is to assess whether certain forms of *online self-help for mental wellbeing* are more effective than others. Challenges to mental wellbeing covers depression, anxiety, resilience, burnout, and loneliness due to work-related or personal pressures.

Are there any benefits from taking part in this study?

You might or might not personally benefit from being in this research study. Through this study we hope to gather information that may help health professionals like you in the future.

What does this study involve?

Your participation in this study may last up to **10 weeks**, beginning on or around October 4, 2021 and ending latest on December 18, 2021. At the beginning of the study you will be asked to provide some information about yourself, which will be used to determine eligibility for the study according to pre-established criteria. If you elect to participate, you will need a smartphone and access to the internet and study-related websites. Participants will be assigned to different websites at random; you do not have a choice in this matter. The research team will not know to which website you are assigned.

The study team will provide airtime with a mobile carrier contingent on your active participation in the study and, if necessary, a SIM card. During the study period the website will ask you to identify yourself and provide information about your work. You will also be asked to complete five short mental wellbeing tests at the beginning, middle and end of the study. We use the information collected in assessing your levels of mental wellbeing and will share this information with you in real

time. The website will prompt you periodically; depending on the website this may happen daily, every other day or weekly. You will receive specific instructions about how to interact with your website. The website will collect how often you access the study website and the duration of your interaction with different parts of the website. The website does NOT collect other information such as your location or web browsing history outside the study website. At the end of the study, we ask about your experience in using the website through an anonymous online survey and focus group discussions.

What are the options if you do not want to take part in this study?

Participation is voluntary. You are responsible for seeking approval for participating in this study from your supervisor, if so required; the study personnel will not be responsible for this. If you do not want to take part in the study do not complete this consent form (by clicking Submit below). Once enrolled in the study, you can withdraw from the study at any time by following the “leave the study” link on the study website. Your right to anonymity will be protected by ensuring that data related to you is kept anonymous and, in addition, any data that can identify you will be deleted at the conclusion of the trial.

What are the risks involved with being enrolled in this study?

No risks are expected. Should the information you provide indicate that you are feeling overwhelmed by depression, anxiety, burnout, or loneliness we will provide contacts in Malawi where you can get help. If the signs are acute and severe, you will not be able to continue with the study and will refer you for mental health counseling but only with your consent.

Other important items you should know:

- **Leaving the study:** You may choose to stop your participation in this study at any time; simply follow the “leave the study” link on the study website. Your decision to stop your participation will have no effect on your academic standing or job status.
- **Number of people in this study:** We expect over 1,000 health professionals to enroll in this study.
- **Funding:** This study is funded by the United States Agency for International Development (USAID) through the Human Resources for Health in 2030 (HRH2030) program.
- **Study Implementation:** The study is implemented jointly by the Dept. of Psychology, University of Malawi and the HRH2030 program, USA.
- **Product Development:** If the results of this research are used to develop a product sold for a profit, you will not share in the profit. You will not receive money from the profits.

How will your privacy be protected?

We value your privacy. For the duration of the study, we will collect your name, mobile number and email address. We will use this information to verify your identity, allocate airtime and any other compensation, and to contact you regularly during the study period with information. At the beginning of the study, you will be assigned a unique identification (ID) number. At the end of the study before data are analyzed we will securely encrypt this identification number and delete all personal identifying information so that the information collected during the study can never be related to you. The analysis will be performed with anonymized data only. We will never keep or share any identifiable information.

The information collected in this study includes your responses to the mental wellbeing test, and certain information about you and your work collected at the time of registration. We will store this information on a secure cloud server. The information will be used only for the purpose of this research study as stated earlier in this form and will be deleted when no longer needed. Your identifiable information will not be shared with any third party.

What about the costs of this study?

There is no cost to participate in this study.

Will you be paid to take part in this study?

You will receive a total of 10Gb airtime allowance valued at K15,500 (about \$20) with a specific mobile carrier for the time you participate in the study. This airtime allowance is provided contingent on your participation in the study. “Participation” means that you access the website on a regular basis as requested. The website automatically uploads the data to our secure server whenever a mobile signal or Wi-Fi is available, so to upload the data simply connect to the internet.

In addition, and following common practice in clinical trials, you will receive an appreciation allocation of about 5Gb airtime valued at K8,200 (about \$10) at the end of the trial, the final workshop, in recognition of your time sacrifice and as appreciation of your contribution to science. This incentive will hopefully encourage your continued use of internet resources to help your mental wellbeing.

Whom should you call with questions about this study?

If you have technical problems with our app, email us at ines@tnh.health.

If you have questions or concerns about this study, you can call the research directors for this study Tilinao Lamba, tilinao.otilera@gmail.com / tlamba@cc.ac.mw, 0885795906, or Eckhard Kleinau, ekleinau@hrh2030program.org.

If you have questions, concerns, complaints, or suggestions about human research, you may contact the Chairperson, UNIMAREC. P.O Box 280. Zomba at unimarec@cc.ac.mw.

CONSENT

I have read the above information about the *Mobile-phone-based study of online self-help for mental wellbeing*. I agree to participate in this study.

Full Name

My email address:

My phone #:

After you click submit, we will send you an email message with instructions on how to proceed to the study website and how to participate in the study.

Consent to Participate in Anonymous Online Survey

Dept. of Psychology, University of Malawi/Human Resources for Health in 2030 (HRH2030), USA

Mobile-phone-based study of *online self-help for mental wellbeing*

Principal Investigator: Dr. Eckhard Kleinau, HRH2030/University Research Co. (URC)

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You are being asked to complete this anonymous questionnaire in response to questions regarding your involvement in the above-named research project. The aim of this research project was to evaluate the effectiveness of mobile-phone-based resources in improving mental wellbeing in health workers.

For the past 10 weeks, as one of the participants of this study, you were presented with specific online resources to aid as self-help tools for improving your mental wellbeing. At this point, we would like to ask that you complete this survey with your honest evaluation of your experiences in this exercise.

Voluntary participation: Taking part in research is voluntary. You may refuse to take part in the research or exit the survey at any time without penalty. You are free to decline to answer any particular question you do not wish to answer for any reason. Your decision whether or not to take part will have no effect on the quality of your medical care, academic standing, or your job status.

Confidentiality: This survey is anonymous. No information collected during the trial that could identify participants or their facilities of affiliation will be shared with their employers.

Contact: If you have questions at any time about this survey, you can contact us at Tilinao Lamba, tilinao.otilera@gmail.com / tlamba@cc.ac.mw or Eckhard Kleinau, ekleinau@hrh2030program.org.

Electronic Consent: Please select your choice below. Clicking on the “Agree” button indicates that

- You have read and understood the above information
- You voluntarily agree to participate in this anonymous questionnaire to aid with the research of evaluating the effectiveness of mobile-phone-based resources in improving mental wellbeing.

☐ Agree

☐ Disagree

Consent to Participate in Feedback Focus Group Discussion

Dept. of Psychology, University of Malawi/Human Resources for Health in 2030 (HRH2030), USA

Mobile-phone-based study of *online self-help for mental wellbeing*

Principal Investigator: Dr. Eckhard Kleinau, HRH2030/University Research Co. (URC)

Co-investigators: Tilinao Lamba (Country Lead), Edister Jamu, Demoubly Kokota, Limbika Maliwichi, Dept. of Psychology, University of Malawi; Alex Zumazuma, Queen Elizabeth Central Hospital

You are being asked to participate in a Focus Group Discussion in response to questions regarding your involvement in the above-named research project. The aim of this research project was to evaluate the effectiveness of mobile-phone-based resources in improving mental wellbeing in health workers.

For the past 10 weeks, as one of the participants of this study, you were presented with specific online resources to aid as self-help tools for improving your mental wellbeing. At this point, we would like to ask that you take part in a Focus Group Discussion with other study participants and share your honest evaluation of your experiences in this exercise.

FGD format: You will be placed in a group with between 7 to 9 other health workers who have also been taking part in this study. You will then be engaged in a discussion according to an FGD guide, containing questions about your experiences in using mobile-phone-based self-help resources to improve mental wellbeing. We encourage you to be as honest as possible in your responses.

Voluntary participation: Taking part in research is voluntary. You may refuse to take part in the research or exit the survey at any time without penalty. You are free to decline to answer any particular question you do not wish to answer for any reason. Your decision whether or not to take part will have no effect on the quality of your medical care, academic standing, or your job status.

Confidentiality: Your responses during these FGDs will not be linked to your identity. All responses shall be made anonymous by the research team. No information collected during the FGDs that could identify you or your facilities of affiliation will be shared with your employers. FGD participants will be asked to respect the privacy of other participants by not disclosing any content discussed during the focus group discussion.

Contact: If you have questions at any time about this survey, you can contact us at Tilinao Lamba, tilinao.otilera@gmail.com / tlamba@cc.ac.mw or Eckhard Kleinau, ekleinau@hrh2030program.org.

Electronic Consent: Please select your choice below. Clicking on the “Agree” button indicates that

- You have read and understood the above information
- You voluntarily agree to participate in this FGD to aid with the research of evaluating the effectiveness of mobile-phone-based resources in improving mental wellbeing.

- ☐ Agree
☐ Disagree