Official Title: PRACT to Investigate Controlling Alcohol Related Harms in a Low-Income Setting; Emergency Department BIs in Tanzania (PRACT)

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DUKE UNIVERSITY HEALTH SYSTEM

Emergency Department Brief Interventions in Tanzania" (All Phases V1.5)

)l-related Harms in a Low-Income

Kilimanjaro Christian Medical Centre

TUMAINI UNIVERSITY KILIMANJARO CHRISTIAN MEDICAL COLLEGE

CONCISE SUMMARY

The purpose of this research study is to determine the effectiveness of a health intervention among injury patients. Participants will answer questions about themselves, their behavior, and health. Most participants will be enrolled in an intervention, which consists of a discussion with a nurse counselor. Some participants will also receive text messages related to their health. Initial surveys and intervention, if assigned, will probably take about 45 minutes. Follow-up phone surveys will occur at 3 months, 6 months, 9 months, 12 months, and 24 months following enrollment, and will probably take about 30 minutes.

The greatest risk of this study is the loss of confidentiality.

If you are interested in learning more about this study and participating, please continue to read below.

INTRODUCTION

You are being asked to take part in this research study because you were treated at the Kilimanjaro Christian Medical Centre (KCMC) Emergency Department for an injury. Research studies are voluntary and include only people who choose to take part. Please read this consent form carefully and take your time making your decision. As your study staff member discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below. You are free to ask questions about this study at any time. If you agree to take part in this study, you will be asked to sign and date this consent form. You will get a copy to keep.

This study is being conducted by Dr. Blandina Mmbaga of Kilimanjaro Christian Medical Center and Dr. Catherine Staton of the Division of Emergency Medicine at Duke University. A grant from the US National Institutes of Health (NIH) will sponsor this study. Portions of the salaries of Drs. Mmbaga and Staton and their research team will be paid by this grant.

WHY IS THIS STUDY BEING DONE?

The purpose of this study to evaluate an intervention on health and wellness.

WHAT DO I HAVE TO DO IF I AM IN THIS STUDY?

If you agree to be in this study, you will be asked to sign and date this consent form. First, we will ask you some screening questions to see if you are able to participate in this study and we will administer an alcohol breath test. If you are not eligible to participate or do not sign this consent form, you will continue to receive standard care, but not as a part of this study. If you are able to be enrolled in the study, we will ask you to answer some questions about your lifestyle, behavior, and your injuries. Participants will be randomly chosen (like the flip of a coin) to take part in one of three interventions. These interventions could be just a discussion or a discussion plus a phone-based reminder system. Some participants will answer the questions, but not receive any additional

intervention. Our questionnaire will take about 45 minutes of your time. For all participants, we would like to contact you up to two years after the study enrollment by phone in order ask you about your health and your perspectives on these study interventions.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

As many as 1830 individuals will participate in this study at KCMC.

HOW LONG WILL I BE IN THIS STUDY?

Most likely, your initial survey and participation will last about 45 minutes, but we would like to contact you at 3 months, 6 months, 9 months, 12 months and 24 months after the study to follow up on your health. You can choose to stop participating at any time without penalty.

WHY WOULD THE DOCTOR TAKE ME OFF THIS STUDY EARLY?

There is a Data Safety Monitoring Board evaluating this trial. This board made up of researchers from Tanzania and abroad, and will evaluate the trial results. The study could be ended early by this Data Safety Monitoring Board, the Ministry of Health in Tanzania or by the Ethics Committee of KCMC. Ethics Committees and Institutional Review Boards watch over the safety and rights of research subjects. Also, the study could be ended early by the following groups in the United States, the Duke University Health System Institutional Review Board, the National Institutes of Health, and the Office of Human Research Protections.

WHAT ARE THE RISKS AND BENEFITS OF THE STUDY?

There may be no direct benefit to you for participating in this study. We hope that the information learned from this study will benefit other injured people. There are no physical risks associated with this study. There is, however, the potential risk of loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed. As some of the interventions will use a phone-based reminder system, we will be sending text messages to the phone number you give us, so we cannot ensure the confidentiality of your phone. If someone else is able to access your mobile phone, it is possible that they may read these messages, which may contain individually tailored information for your health, wellness, and alcohol use. Some of the questions we will ask you as part of this study may make you feel uncomfortable. You may refuse to answer any of the questions, and you may take a break at any time during the study. You may stop your participation in this study at any time. If your answers to questions show that you need further medical or social assistance, we are obligated to, and will, refer you to an appropriate medical professional for treatment. We will not pay for the costs of your medical treatment or transport costs associated with these additional treatments.

WILL MY INFORMATION BE KEPT CONFIDENTIAL?

Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total confidentiality. Your personal information may be viewed by individuals involved in this research and may be seen by people including those collaborating, funding, and regulating the study. We will share only the minimum necessary information in order to conduct the research. Your personal information may also be given out if required by law.

As part of the study, your records may be reviewed in order to meet federal or state regulations. Reviewers may include representatives and affiliates of US National Institutes of Health, the Duke University Health System Institutional Review Board, KCMC Ethics Committee, National Institute for Medical Research, and others as appropriate. If any of these groups review your research record, they may also need to review your entire medical record.

The US Department of Health and Human Services (HHS) has issued a Certificate of Confidentiality to further protect your privacy. With this Certificate, the investigators may not disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings, unless you have consented for this use. Research information protected by this Certificate cannot be disclosed to anyone else who is not connected with the research unless:

1) there is a law that requires disclosure (such as to report child abuse or communicable diseases but not for legal proceedings);

2) you have consented to the disclosure, including for your medical treatment; or

3) the research information is used for other scientific research, as allowed by federal regulations protecting research subjects.

Disclosure is required, however, for audit or program evaluation requested by the agency that is funding this project.

You should understand that a Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it. This means that you and your family must also actively protect your own privacy.

Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

Study records will be kept confidential as required by law. Your records will be assigned a unique study number. Information that links your name to the study number will be kept in a locked cabinet that can only be accessed by members of the research team. No personal identifiers will be sent to or used at Duke. If information from this study is presented at scientific meetings or in scientific journals, your identity will not be revealed. If you are enrolled in a study arm involving text messaging, and someone else is able to access your mobile phone, it is possible that they may read messages intended for you, which may contain individually tailored information for your health, wellness, and alcohol use.

Data from this study about your health and behavior will be submitted to the National Institute on Alcohol Abuse and Alcoholism Database ($NIAAA_{DA}$) at the US National Institutes of Health (NIH). $NIAAA_{DA}$ is a large database where deidentified study data is stored and managed to help researchers learn new and important things about alcohol problems. Deidentified study data means that all personal information about you (such as name, address, birthdate and phone number) is removed. Other researchers across the world can request your deidentified study data for other research. All researchers must promise to keep your data safe and promise not to try to learn your identity. Sharing your study data does have some risks, although these risks are rare. The study researchers will make every attempt to protect your identity. You will not be contacted directly about the study data you contributed to $NIAAA_{DA}$.

You may decide now or later that you do not want your study data to be added to the $NIAAA^{DA}$. You can still participate in this research study even if you decide that you do not want your data to be shared. If you know now that you do not want your data in the $NIAAA^{DA}$, please tell the study researcher today. If you decide any time after today that you do not want your data to be added to the archive, call the study staff who conducted this study, and they will tell $NIAAA_{DA}$ to stop sharing your study data. After your data is part of the $NIAAA_{DA}$, the study researchers cannot take back the study data that was shared before they were notified that of your withdrawal. If you would like more information about NIAAADA, this is available on-line at https://nda.nih.gov/niaaa.

Initial here to indicate consent for your study data to be added to the $NIAAA_{DA}$: *(choose only 1)*

____ **I consent** to the addition of my study data to the $NIAAA_{DA}$

____ **I do not consent** to the addition of my study data to the $NIAAA_{DA}$

WHAT ARE THE COSTS TO ME?

There is no additional cost to you for taking part in this research study. You or your insurance provider will be responsible for the cost of the care provided in at Kilimanjaro Christian Medical Centre.

WILL I RECEIVE ANY PAYMENTS?

If you consent and complete the study screening, you will be compensated 5,000 TSH (~$2 US). If enrolled, you will receive 5,000 TSH ($2 USD) for each follow-up appointment.

WHAT ABOUT RESEARCH RELATED INJURIES?

Immediate necessary care and support is available at KCMC if an individual is injured because of participation in this research project. However, there is no commitment by Duke University or KCMC for free medical care or for monetary compensation for such an injury. For questions about the study or research-related injury, contact Dr. Blandina Mmbaga (Tel 0768435116) or Dr. Francis Sakita (Tel. 0767865441).

VOLUNTARY PARTICIPATION/RIGHT TO WITHDRAW

You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you agree to participate, you may refuse to answer any question or stop the interview at any time. Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits, and will not affect your access to health care.

If you do decide to withdraw, we ask that you contact Dr. Blandina Mmbaga in writing and let her know that you are withdrawing from the study. Her mailing address is KCMC-Duke Collaboration, Box 3010, Sokoine Road, Moshi. We will tell you about new information from this or other studies that may affect your health, welfare or willingness to stay in this study. If you want the results of the study, let the study staff know.

WHAT DO I DO IF I HAVE QUESTIONS OR PROBLEMS?

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.

For questions about the study or a research-related injury, or if you have complaints, concerns or suggestions about contact Dr. Blandina Mmbaga (Tel 0768435116) or Dr. Francis Sakita (Tel. 0767865441).

For questions about your rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information about the research, contact the Kilimanjaro Christian Medical Centre (KCMC) Ethics Committee at telephone number (255) 27 27-53909, or mail Box 2240 or the Duke University Health System Institutional Review Board at +1-919-668-5111 or the National Medical Research Institute Tel. +255 222121400 or Box 9653 Dar Es Salaam.

STATEMENT OF CONSENT

"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

_____	_____	_____
Name of Participant (Print)	Signature	Date
_____	_____	_____
Name of Staff Obtaining Consent (Print)	Signature	Date