

Cover page

Official title: A mobile phone-based triage tool to identify discharged trauma patients in need of further care in Cameroon

NCT number: NCT03805646

University of Buea Faculty of Health Sciences
IRB Approval Document date: February 16, 2019

MINISTRY OF PUBLIC HEALTH, CAMEROON
UNIVERSITY OF BUEA, CAMEROON
UNIVERSITY OF CALIFORNIA, LOS ANGELES

ADULT ORAL CONSENT SCRIPT

Study Title: A mobile phone-based triage tool to identify discharged trauma patients in need of further care in Cameroon

Principal Investigators:

Alain Chichom Mefire, MD, University of Buea, Cameroon

Catherine Juillard, MD, MPH, University of California, Los Angeles

What you should know about this study

You are invited to take part in a research study. This study is being done by the Ministry of Public Health, the University of Buea, and the University of California, Los Angeles. We will explain the research study and your part in the study. Please listen carefully and ask any questions that you may have.

You are a volunteer. You can choose not to take part and if you join, you may quit at any time. There will be no penalty if you decide to quit the study.

Purpose of research project

Broadly, this study aims to understand more about injuries in Cameroon. By “injuries,” I mean damage to your body that may be caused by cuts, bruises, broken bones, burns, or unconsciousness. These injuries also cause people to lose money or stop working. We hope to understand how injuries affect individuals and their families and overall, what we can do to reduce the number of injuries in Cameroon. Specifically, in this project, we want to find out if we can use phone calls to identify people who need extra help after being discharged from the hospital. We are asking everyone who came to the hospital with an injury to be in this study.

Why you are being asked to participate

We are asking you to participate in this research study because you are either:

- A patient who received emergency or trauma care at this hospital.
- The surrogate of a patient who received emergency or trauma care at this hospital.

Procedures

If you agree to take part in this study, I will ask you questions about how you or the injured person in your family is doing now. This will take no more than 5-10 minutes of your time. Additionally, based on the time point at which we are contacting you, we will request you or your family member to attend an in-person physical examination by a health care provider to make sure you or your family member is healing well.

Please note that this phone survey does not constitute medical advice. You should seek medical attention promptly for any health concerns.

Risks/Discomforts

There are minimal risks from being in this study. The risk of unintentionally disclosing identifying information is unlikely as is the risk of physical or psychological distress. While we anticipate participants needing to spend some time completing the survey and traveling to and from the hospital for the physician exam, we expect the risk of losing time due to participation to be minimal. Also, we anticipate the financial risk involved with participation to be minimal.

While the risk for physical and psychological discomfort are low, you are free to skip any questions that make you feel uncomfortable. If you must appear for physician examination, you should know that you are free to excuse yourself at any point should you experience any level of discomfort. All your responses will be copied on physical papers, which will be stored in secure lock boxes and then entered into a password-protected, encrypted online database. Data will only be accessible to research personnel.

Benefits

Research participation may directly benefit you as you will receive additional follow-up care including a physical exam and subsequent medical advice free-of-charge. Moreover, you will be paid to cover the cost of this phone call and any travel that you will need to do for the physician examination.

Protecting data confidentiality

Your identity will remain confidential. All information that you tell us will be stored under lock and key and/or digitally encrypted. Only members of the research team will have access to this information. All identifiers will be removed from records and will be stored for up to five years at the hospital.

Voluntary participation

You do not have to agree to be in this study, and you can change your mind at any time.

- Call the project coordinator at +237 72 67 55 55 if you have questions or complaints about being in this study.
- If you have any questions about your rights as a research participant, or if you think you have not been treated fairly, you may contact the Secretary of the Faculty of Health Sciences Institutional Review Board at the University of Buea via their website: <http://www.irb.fhs.ubuea.cm/index.php/contact-us>. You may also contact the Office of the Human Research Protection Program at the University of California, Los Angeles at +001 (310) 825-5344.

Information available on ClinicalTrials.gov

This study is considered what is called a “clinical trial.” Therefore, information related to this study is available on ClinicalTrials.gov.

Permission to proceed

Have you understood me? Do you have any further questions? Is it okay to proceed with the telephone interview?

Yes: Mark it on the form and proceed with telephone interview.

No: Thank the respondent for their time.

MINISTRY OF PUBLIC HEALTH, CAMEROON
UNIVERSITY OF BUEA, CAMEROON
UNIVERSITY OF CALIFORNIA, LOS ANGELES

MINOR ORAL ASSENT SCRIPT
AGES 13-20 YEARS

Study Title: A mobile phone-based triage tool to identify discharged trauma patients in need of further care in Cameroon

Principal Investigators:

Alain Chichom Mefire, MD, University of Buea, Cameroon

Catherine Juillard, MD, MPH, University of California, Los Angeles

What you should know about this study

We are asking you to be in a research study. A research study is when scientists collect information to learn more about something. The Ministry of Public Health in Cameroon, the University of Buea, and the University of California, Los Angeles in the USA are doing this research study. We are going to explain the study and your part in it. Please listen carefully and ask any questions that you may have.

You are a volunteer. You can choose not to be in the study and if you join, you may quit at any time. There will be no penalty if you decide to quit the study.

Purpose of research project

Broadly, this study aims to understand more about injuries in Cameroon. By “injuries,” I mean damage to your body that may be caused by cuts, bruises, broken bones, burns, or unconsciousness. These injuries also cause people to lose money or stop working. We hope to understand how injuries affect individuals and their families and overall, what we can do to reduce the number of injuries in Cameroon. Specifically, in this project, we want to find out if we can use phone calls to identify people who need extra help after being discharged from the hospital. We are asking everyone who came to the hospital with an injury to be in this study.

Why you are being asked to participate

We are asking you to help us in this research study because you are a patient who has received emergency or trauma care at this hospital.

Procedures

If you agree to be in this study, I will ask you and/or your family members questions about you are doing now. This will take no more than 5-10 minutes.

This phone survey is not the same thing as going to a doctor. Please go to the doctor as soon as you can for any health concerns.

Risks/Discomforts

There are minimal risks from being in this study. The risk of unintentionally disclosing identifying information is unlikely as is the risk of physical or psychological distress. While we anticipate

participants needing to spend some time completing the survey and traveling to and from the hospital for the physician exam, we expect the risk of losing time due to participation to be minimal. Also, we anticipate the financial risk involved with participation to be minimal.

While the risk for physical and psychological discomfort are low, you are free to skip any questions that make you feel uncomfortable. If you must appear for physician examination, you should know that you are free to excuse yourself at any point should you experience any level of discomfort. All your responses will be copied on physical papers, which will be stored in secure lock boxes and then entered into a password-protected, encrypted online database. Data will only be accessible to research personnel.

Benefits

You will be getting a free check-up by the doctor. We will also be giving you money to cover the cost of this phone call and if we tell you that you need to travel to the doctor.

Protecting data confidentiality

Your identity will remain private. All information that you tell us will be locked up. Only members of the research team will have access to this information. The information will be kept for up to five years at the hospital.

Voluntary participation

You do not have to be in this study, and you can change your mind at any time.

- Call the project coordinator, at +237 72 67 55 55 if you have questions or complaints about being in this study.
- If you have any questions about your rights as a research participant, or if you think you have not been treated fairly, you may contact the Secretary of the Faculty of Health Sciences Institutional Review Board at the University of Buea via their website: <http://www.irb.fhs.ubuea.cm/index.php/contact-us>. You may also contact the Office of the Human Research Protection Program at the University of California, Los Angeles at +001 (310) 825-5344.

Information available on ClinicalTrials.gov

This study is considered what is called a “clinical trial.” Therefore, information related to this study is available on ClinicalTrials.gov.

Permission to proceed

Have you understood me? Do you have any further questions? Is it okay to proceed with the telephone interview?

Yes: Mark it on the form and proceed with telephone interview.

No: Thank the respondent for their time.

MINISTRY OF PUBLIC HEALTH, CAMEROON
UNIVERSITY OF BUEA, CAMEROON
UNIVERSITY OF CALIFORNIA, LOS ANGELES

SIMPLIFIED ORAL ASSENT SCRIPT
AGES 7-12 YEARS

Study Title: A mobile phone-based triage tool to identify discharged trauma patients in need of further care in Cameroon

Principal Investigators:

Alain Chichom Mefire, MD, University of Buea, Cameroon

Catherine Juillard, MD, MPH, University of California, Los Angeles

What you should know about this study

We are asking you to be in a research study. A research study is when scientists collect information to learn more about something. The scientists in this hospital are doing a study to learn more about injuries in Cameroon. We will tell you about it and ask you if you want to be in it or not. You can ask any questions that you want.

You are a volunteer. You can choose to be in the study or choose not to be in the study. Nothing will happen if you don't want to be in the study.

Purpose of research project

We want to understand more about injuries in Cameroon. When I say "injuries," I mean what happens when you hurt yourself, like when you get cuts and bruises or break your bones. For this research study we want to find out if we can use phone calls to identify people who need extra help after they left the hospital. We are asking everyone, including boys and girls like you, who come to the hospital with an injury to be in this study.

Why you are being asked to participate

We are asking you be in this research study because you are someone who has received emergency or trauma care at the hospital.

Procedures

If you want to be in this study, I will ask you or a family member of yours questions for me to understand how you are doing now. This will take no more than 5-10 minutes.

This phone survey is not the same thing as going to a doctor. Please go to the doctor as soon as you can for any health concerns.

Risks/Discomforts

There are very little risks from being in this study. Only people on the study team will be able to see to the personal information you tell me. We also do not think this research study will take too much of your time and money up.

You are free to skip any questions or parts of the study that make you feel badly.

Benefits

You will be getting a free check-up by the doctor. We will also be giving you money to cover the cost of this phone call and if we tell you that you need to travel to the doctor.

Protecting data confidentiality

Your identity will remain private. All information that you tell us will be locked up. Only members of the research team will have access to this information. The information will be kept for up to five years at the hospital.

Voluntary participation

You do not have to be in this study, and you can say yes now and change your mind later. If you don't want to be in this study, just tell us. If you want to be in this study, just tell us.

- Call the project coordinator, at +237 72 67 55 55 if you have questions or complaints about being in this study.
- If you have any questions about your rights as a research participant, or if you think you have not been treated fairly, you may contact the Secretary of the Faculty of Health Sciences Institutional Review Board at the University of Buea via their website: <http://www.irb.fhs.ubuea.cm/index.php/contact-us>. You may also contact the Office of the Human Research Protection Program at the University of California, Los Angeles at +001 (310) 825-5344.

Information available on ClinicalTrials.gov

This study is considered what is called a "clinical trial." Therefore, information related to this study is available on ClinicalTrials.gov.

Permission to proceed

Have you understood me? Do you have any further questions? Is it okay to proceed with the telephone interview?

Yes: Mark it on the form and proceed with telephone interview.

No: Thank the respondent for their time.