Study Title: Implementing HEARTS in Guatemala

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Institutional ID: HUM00234613

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Study of the Integrated Diabetes and Hypertension Primary Care Model in Guatemala

Form: Informed consent among participants interviewed

Version 1.0, 11-Aug-2023

Study title: Implementing integrated diabetes and hypertension management in Guatemala using the HEARTS model: Protocol for a pilot study in the national primary care system

Principal Investigators: David Flood, MD MSc; Manuel Ramirez-Zea, MD PhD; Michele Heisler, MD, MPA

Study Coordinators: Irmgardt Alicia María Wellmann Castellanos, MD MSc; Jose Javier Rodriguez Szaszdi, MD

Institutions: Institute of Nutrition of Central America and Panama (INCAP); Ministry of Public Health and Social Assistance; University of Michigan

Sponsored by: U.S National Institutes of Health and the University of Michigan

GENERAL INFORMATION

Good afternoon days. How are you? My name is _____. I am a researcher at the Institute of Nutrition of Central America and Panama (INCAP). INCAP has worked with the Ministry of Health to improve the management of diabetes and hypertension in primary care facilities. This is sometimes also known as the “HEARTS” pilot project.

We are doing a study to learn more about the implementation of the HEATS project. To get information, we are conducting interviews with patients, doctors, nurses, and health authorities about the project. We expect the interview to take about 45 minutes.

Participating in the interview is voluntary. You do not have to answer it if would rather not. You can skip any questions that you do not want to answer, whatever the reason, and you do not have to tell us why. If you are a patient, choosing not to participate in the interview will not affect the medical care you receive at health centers or health posts. If you are a Ministry of Health employee, please know that your answers will not be shared, and the Ministry will not know if you participated or did not participate in the interview.

It is possible that some of the questions may make you feel uncomfortable. If a question makes you uncomfortable, you can just skip it and go to the next question. There are no right or wrong answers. We are interested in understanding what is working and what is not, so that we can improve things in the future.

To keep your information confidential, we will label your answers with a code, rather than your name or any other details that someone could use to identify you. Although we’ll keep a list of all the people who answered our questions, no one outside our study team will be able to figure out who gave answers, or which people gave which answers. We also will record portions of the interview so that we can best remember what you told us. We plan to publish what we learn from this study, but we will not include any of your personal information.

Participating in this interview will not benefit you directly, apart from feeling good that you are helping to improve care for patients with diabetes and hypertension in the future.

We do not plan on sharing any of the information you share with any person outside this project.

A description of this clinical trial will be available on www.ClinicalTrials.gov. 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.

Do you have any questions?

CONTACT INFORMATION

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You may also express a concern about a study by contacting the Institutional Review Boards:

University of Michigan Medical School
Institutional Review Board (IRBMED)
2800 Plymouth Road
Building 520, Room 3214
Ann Arbor, MI 48109-2800
734-763-4768
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Institutional Ethics Committee, Institute of Nutrition for Central America and Panama
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VERBAL INFORMED CONSENT

Statement of person giving informed consent

- I have read this consent form or had it read aloud to me.
- This research study has been explained to me, including risks and possible benefits, procedures, and other important things about the study.
- I have had the opportunity to ask questions.
- I understand the information given to me.

Statement of study researcher obtaining consent

- I have explained the research to the person being interviewed.
- I have answered all questions about this research study to the best of my ability.
- I am fluent in the preferred language of the person being interviewed or have conducted the interview with the help of an intepreter.

Name and surnames of study researcher	**Date**
Signature of study researcher	**Date**