Official Title: Rural Area Pharmacist Intervention for Diabetes - Management using eHealth: A Pilot Study
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RAPID-ME [RURAL AREA PHARMACIST INTERVENTION FOR DIABETES - MANAGEMENT USING EHEALTH]

INFORMATION SHEET TO PARTICIPATE IN RESEARCH

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SUMMARY

You are invited to participate in a research study titled RAPID-ME [Rural Area Pharmacist Intervention for Diabetes - Management using eHealth]. This research study is being conducted to find out if a clinical pharmacy program helps improve health outcomes of primary care patients with Type-2 diabetes in rural areas. As part of the study, you worked on identifying and addressing medication-related problems, optimizing medication regimens, and providing type 2 diabetes education and self-management support to patients. You are invited to be in this study because we are seeking responses from key stakeholders in the program. We are interested in soliciting your perspective on the usefulness, structure, and relevance of the program and your recommendations regarding how to improve the program structure. Your participation in this research will involve surveys that should take less than 15 minutes and a phone interview that takes 45 minutes to complete. The interview will be audio recorded and transcribed into text. After completion of the transcription process, the audio recording will be deleted. You may request to stop the recording at any time. You can also withdraw your consent to use the recording before it is used.

All research studies have some risks. A possible risk of participating is the risk of a loss of confidentiality. You may not directly benefit from participating in this study; however, the information you share will be integral to implementing this clinical pharmacy program to patients going forward. Your participation in this study is voluntary. You do not have to participate in this study if you do not want to. There may be other choices available to you. You will not lose any services, benefits, or rights you would normally have if you choose not to participate.

The remainder of this document contains a more complete description of this study. Please read this description carefully. You can ask any questions if you need help regarding deciding about joining the study. The person in charge of this study is Dr. Rohan Mahabaleshwarkar. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study, you can contact him by email [redacted] or telephone [redacted].

If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact the Institutional Review Board at [redacted] or the Research Subject Advocate at Wake Forest at [redacted].

How Many CLINICAL PHARMACISTS Will Take Part in the Study?

Up to 2 study clinical pharmacists are expected to take part in this study.

WHAT ARE THE RISKS OF THE STUDY?

The risk of harm or discomfort that may happen as a result of taking part in this research study is not expected to be more than in daily life or from clinical practice. You can discuss the risk of being in this study with the study staff.

There is a slight risk of a breach of confidentiality. We will do our best to protect your confidential information. Efforts, such as coding research records, keeping research records secure and allowing only authorized people to have access to research records, will be made to keep your information safe.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

You are not expected to receive any direct benefit from participation in this research study. We hope the information learned from this study will help us understand the utility of the clinical pharmacy program and if we need to make any changes for better outcomes.

WHAT ARE THE COSTS?

Any costs related directly to the study will be paid for by the study.

WILL YOUR RESEARCH RECORDS BE CONFIDENTIAL?

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. You will not be directly identified in any publication or presentation that may result from this study. Your identity and/or your personal health information will not be disclosed unless it is authorized by you, required by law, or necessary to protect the safety of yourself or others. Your information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

WILL YOU BE PAID FOR PARTICIPATING?

You will be provided with a $25 in the form of a ClinCard debit card if you complete the scheduled study interview.

WHAT ARE MY RIGHTS AS A RESEARCH STUDY PARTICIPANT?

You may choose to not participate or you may leave the study at any time. If you decide to stop participation in the study, we encourage you to talk to the investigators or study staff. The investigators also have the right to stop your participation at any time. This could be because you are comfortable with audio recording or do not wish to complete the surveys or interview. Information about you may be removed from the study data and could be used for future research or shared with other researchers without additional consent from you.

By continuing, I agree to take part in this study. I have had a chance to ask questions about being in this study and have had those questions answered satisfactorily. By taking part in the study, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents

from liability for negligence.