Informed Consent Form

Title: Pragmatic Research in Healthcare Settings to Improve Diabetes and Obesity Prevention and Care for our program MAINTAIN PRIME (Promoting Real (World) IMplEmentation through care teams).

NCT04420936
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CONSENT FORM for a FOCUS GROUP PATIENT

Study Name: MAINTAIN PRIME (Promoting Real (World) IMplEmentation through care teams): *Focus group, Provider*

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STUDY SPONSOR

National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)

University of Utah
Institutional Review Board
Approved 8/8/2024
Expires 8/7/2025
IRB_00132802

DESCRIPTION OF RESEARCH STUDY

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. This study uses a series of focus groups to evaluate the patient, provider, MA, and nurse coach experiences during the weight maintenance intervention. Each focus group will consist of 6-8 patients who participated in the 2 year intervention.

TO POTENTIAL PARTICIPANTS

Federal regulations require written informed consent before participation in a research study. This is to be certain that research subjects know the nature and risks of the study, as they make a decision to participate or not to participate. You are asked to read the following information and discuss it with the investigator, so that you will be fully informed about this research study and how it may affect you. Your signature on this form means that you have been fully informed and that you freely give your consent to participate.

VOLUNTARY PARTICIPATION IN THE VISIT SCREENING & WITHDRAW FROM THE STUDY

Participating in the post-intervention focus groups for our study is voluntary. You don't have to take part if you don't want to. Choosing not to take part won't affect your medical care in any way and will have no effect on your current or future relationship with the University of Utah. Even if you decide to join, you can change your mind later and leave the study. Also, most focus group participants in will find the discussion interesting however, if you feel uncomfortable in any way during the focus group session, you have the right to decline to answer any question or to end your participation.

BACKGROUND

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. The objective of research study is to test the use of routine clinical staff to deliver a tested, effective weight maintenance intervention that is delivered through primary care. To accomplish this goal, we will compare an Electronic Health Record–based coaching weight maintenance to a tracking only intervention. The implementation will be refined through a) workflow assessments, b) focus groups c) intervention mapping; d) Health Information Technology build and testing; and e) initial implementation at 2 clinics and modification of the intervention as needed. What we learn from your participation will help us design, modify and implement this intervention.

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STUDY PROCEDURES

We expect to conduct 3 focus groups of patients. Your name was given to us by a site liaison who has contacted you to participate. The focus group will be held at a time that is convenient for you and will be expected to last 1.5 hours. The focus group will be led by Dr. Charlene Weir and an assistant. Participants will first be read a description of the problem in general and then 1-2 vignettes will be discussed in a staged manner. All comments are important and we will try to create a positive and supportive environment. The focus groups will take about 1.5 hours and will be tape recorded. The tapes will be later transcribed and all identifying information stored in a separate location.

DATA MANAGEMENT

All data will be stored in a secure University of Utah internet site where access is tightly controlled and data analysis will be conducted without identifiers.

RISKS

The risks of this study are minimal. These risks are similar to those you experience when discussing personal information with others. If you feel upset from this experience, you can tell the researcher, and he/she will tell you about resources available to help. Every effort will be made to ensure that no comments can be referenced to any single person and all descriptive data will be distilled to major themes and issues. Because being observed may increase anxiety and evaluation apprehension, we will assess you regularly.

BENEFITS

The participant will have the satisfaction and the opportunity to help design future systems to improve care.

COMPENSATION

Participation will earn each person $100 per 1.5 hour session.

ALTERNATIVE PROCEDURES

There are no reasonable alternative procedures, however there is no coercion by the study investigators or local supervisors to participate.

CONFIDENTIALITY

After the sessions are transcribed, no reference to you personally will be made in the data collection. No patient data will be recorded after data analysis. Only aggregate data will be reported.

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CONTACT INFORMATION

The study is being conducted by investigators at the University of Utah and is sponsored by the National Institute of Diabetes and Digestive and Kidney Diseases. If you have any questions or concerns about any part of this study or believe you have been injured, please contact the Principal Investigators at the following numbers: Dr. Conroy: 801-581-7818, Dr. Kawamoto: 801-587-8076.

Contact the Institutional Review Board (IRB) if you have questions regarding your rights as a research participant. Also, contact the IRB if you have questions, complaints or concerns which you do not feel you can discuss with the investigator. The University of Utah IRB may be reached by phone at (801) 581-3655 or by e-mail at irb@hsc.utah.edu.
You may also contact the Research Participant Advocate (RPA) by phone at (801) 581-3803 or by email at participant.advocate@hsc.utah.edu.

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Participant Participation Statement and Signature

I understand the information printed on this consent form. My questions so far have been answered. By signing this form, I agree to participate in this research study. A copy of this consent form will be given to me.

_____
Printed Name of Participant

_____ _____
Participant's Signature Date

_____
Printed Name Person Obtaining Consent

_____ _____
Signature of Person Obtaining Consent Date

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