Patient Information and Consent Form

Behavioral change using a smart device application to promote healthy diet and physical activity for overweight/ obese adults with diabetes attending health care facilities in Muscat: A cluster randomized control trial

Dear Candidate:

You are being invited to take part in this project that aims to evaluate the effectiveness of behavioral change virtual based interventions in promoting physical activity and healthy diet in patients with diabetes. Before you make your decision to participate, please read the following information to understand why and how this project is conducted and sign the bottom of the form if you wish to join this clinical research. Take your time to decide whether you wish to take part or not.

If you have any inquiries please contact the study supervisors:

Dr. Riyadh Al Siyabi

Ms. Fathiya Al Jufaili

on 24782117

Part 1: Patient's information

What is the purpose of this study?

Diabetes is a common disease that affects around 16% of the population in Oman. The prevalence of diabetes is increasing and exceeding global rates. Healthy lifestyle including physical activity and healthy diet has been recognized as a “cornerstone” of diabetes management, however many patients fail to adhere to that despite receiving health education and counselling.

In this project, we aim to assess the effectiveness of using a smart device application that provides scheduled interactive counselling, pedometer features, and motivational messages on physical activity and healthy diet regimens. The participant is expected to use the app and follow the instruction for 12 months duration. Sociodemographic information will be collected at the beginning of the study. Weight, height, and blood glycated hemoglobin will be measured at the onset, at 3, 6, and 12 months. Blood cholesterol level, kidney function, eye retina check-up, and peripheral nerve assessment will also be performed at the start and the end of the study. The target patients are with type 2 diabetes, adults >18 years, overweight or obese with uncontrolled disease. Patients with contraindication to physical activity and on a special, restricted diet are excluded.

We believe that using smart device application based intervention help in promoting behavior change to adopt a healthy lifestyle among patients with diabetes which might help in improving diabetic patients outcome and prevent disease complications.

What are the risks or harms from this study?

We do not expect any serious risk from using a smart device application.

We do not experiment any drugs or invasive procedures.

Patients with kidney failure, bleeding in the retina, nerve problems, previous history of heart attack or stroke are not included in this study.

There might be a risk for heart attacks, joint pain, body aches with unguided exercises, but the risk is low. The health professionals in this study will use scientific-based regimens of diet and exercise, standardized internationally.

What are the benefits?

By participating in this study, you will have frequent follow-ups and check-ups. Your disease progress will be monitored closely. This project will provide an evidence about the effectiveness of virtual based interventions in managing diabetes and other chronic illnesses.

Are there any costs or rewards given to the participants?

No costs are given to the participants.

For you to take part in this project, you must:

1. have diabetes and known to be overweight or obese, and have uncontrolled diabetes. no restriction to

physical activity or standard healthy diet.

2. have to sign the informed consent form.

Part 2: Informed Consent

The research committee understands and respects the privacy of each and every individual. We guarantee that the information gathered through this research shall never be sold, shared, or disclosed to anyone without the consent of the patient. The participant has the right to his information including the right to share his or her information in journals. We may still continue to share the information as to our findings based on the participant's information but without disclosing the personal information of the said participant.

Please check below if necessary

- [ ] I declare that I have been informed of the nature of the study, its purpose, its duration, any risks and benefits and what is expected from me. I have taken note of the information document and the appendices to this document.
- [ ] I understand that my participation in this study is voluntary and that I am free to end my participation at any time without justification and without this affecting the quality of care provided to me nor my relationship with my GP.
- [ ] I understand that data about me will be collected throughout my participation in this study and that the investigators will guarantee confidentiality.
- [ ] I agree to my personal data being processed as described in the section dealing with confidentiality guarantees.
- [ ] I have had the opportunity to ask any questions that came to mind and have obtained a satisfactory response to my questions.
- [ ] By signing this form, I declare agreement to take part in this study, deciding this by myself, voluntarily and with full capacity
- [ ] I agree that any talks or discussion with the care provider on the electronic application will be used for study purposes with confidentiality guarantees.

Name

First Name Last Name

Date *

Month Day Year

NOTE: If the participant does not read or write, he can delegate a representative to sign this form, but after reading and understanding the given study information

Representative's Name:

First Name Last Name

For the Study Investigator use:

I affirm that informed consent has been explained to the participant clearly to the best of my knowledge. I have given the opportunity to the participant to ask questions he or she raised and by which I have answered them to the participant's satisfaction. I certify that the participant has already understood the information, including his or her rights, and agreed to participate in this research.

Investigator's name:

First Name Last Name

Date

Month Day Year