Informed Consent Form [App Use Group]

Informed Consent for Scientific Research-University of Baghdad - College of Pharmacy

Study Title: Evaluation of a Mobile Application Designed to Support Type 1 Diabetic Patients in Adjusting Their Insulin Doses.

Principal Investigator: Noor Kadhim Mohamed-Jawad, College of Pharmacy, University of Baghdad

Supervision: Assistant Professor Dr. Ehab Madhar Mikael and Assistant Professor Dr. Haider Al-Idrisi, Specialists in Diabetes, Endocrinology, and Metabolism.

Introduction: You are invited to participate in a research study. This form will explain the study's purpose, what you will be asked to do, and the potential risks and benefits. It is important to read this form carefully and ask any questions you may have before you decide to participate. Your participation is entirely voluntary. To ensure scientifically accurate results, participants in this study will be randomly assigned to one of two groups: one group will use the application in addition to usual care, and the other group will receive usual care only. You will be informed of the group to which you are assigned.

1. Purpose of the Study: The aim of this study is to evaluate a supportive mobile application designed to help Type 1 diabetic patients calculate their appropriate pre-meal insulin dose. We want to understand whether the application is easy to use and if it helps improve blood glucose control compared to usual care alone.
2. Procedures: If you agree to participate and are randomly assigned to the app-use group, we will ask you to: • Attend a training session on how to use the application. • Use the application to record your meals and calculate suggested insulin doses for 3 months, alongside your usual medical care. • Attend a follow-up visit at the center after 3 months. • Answer some questionnaires about your experience using the app and managing your diabetes.
3. Potential Risks and Inconveniences:

Medical Risks: There is a theoretical risk that the app might suggest an inaccurate insulin dose. Therefore, we will emphasize that you must always use your own judgment and consult your doctor before adjusting any doses, and that the app is only a supportive tool, not a substitute for a doctor's opinion.

Participation Inconveniences: It will require your time to train on using the app and to record data in it.

4. Potential Benefits:

This tool may help you regulate your blood sugar levels by adjusting doses according to your food type and blood sugar level.

The information we obtain from this study may help improve care for other patients in the future.

5. Voluntary Participation: Your participation in this study is entirely voluntary. You have the right to refuse to participate or to withdraw from the study at any time and for any reason without any negative consequences or impact on the medical care you receive. If you decide to withdraw, we can, at your request, delete all the data collected from you.
6. Confidentiality: All information you provide will be treated with strict confidentiality. Your identity will not be disclosed in any reports or publications resulting from this study.
7. Participation Costs and Compensation: The researcher can provide you with a home blood glucose meter, test strips, or any additional supplies as needed, in exchange for your time and continued participation in the study.
8. Contact for Questions: If you have any questions about the study, please contact the principal investigator: Name: Noor Kadhem Mohammed Jawad Phone: +9647801452504 Email: medicalapp24@gmail.com

If you have any inquiries or concerns about your rights as a research participant, you can contact: The Ethics Committee at the College of Pharmacy/University of Baghdad at

Email: COPHCLINICALPH@COPHARM.UOBAGHDAD.EDU.IQ

Participant's Consent

I confirm that I have read this form, or it has been read to me, and all my questions have been answered satisfactorily. I understand that my participation is voluntary and that the process of random assignment to the two groups has been clearly explained to me. I freely agree to participate in this study.

Participant's Signature: _____ Date: _____

Participant's Name: _____

Investigator's Statement

I confirm that I have explained the nature and purpose of this study to the participant named above, including the randomization process, and I have answered all of their questions.

Investigator's Signature: _____ Date: _____

Investigator's Name: Noor Kadhim Mohamed-Jawad

Informed Consent Form (Usual Care Group)

Informed Consent for Scientific Research University of Baghdad - College of Pharmacy

Study Title: Evaluation of a Mobile Application Designed to Support Type 1 Diabetic Patients in Adjusting Their Insulin Doses.

Principal Investigator: Noor Kadhim Mohamed-Jawad, College of Pharmacy, University of Baghdad

Supervision: Assistant Professor Dr. Ehab Madhar Mikael and Assistant Professor Dr. Haider Al-Idrisi, Specialists in Diabetes, Endocrinology, and Metabolism.

Introduction: You are invited to participate in a research study. This form will explain the study's purpose, what you will be asked to do, and the potential risks and benefits. It is important to read this form carefully and ask any questions you may have before you decide to participate. Your participation is entirely voluntary. To ensure scientifically accurate results, participants in this study will be randomly assigned to one of two groups: one group will use the new application in addition to usual care, and the other group will receive usual care only. You will be informed of the group to which you are assigned.

1. Purpose of the Study: The aim of this study is to evaluate a supportive mobile application designed to help Type 1 diabetic patients. We want to know if the application improves blood glucose control compared to usual care alone. Your participation as part of the comparison group (usual care) is essential to answering this scientific question.
2. Procedures: If you agree to participate and are randomly assigned to the usual care only group, we will ask you to:

Continue your usual medical care for diabetes as specified by your doctor, without any change.

Attend a follow-up visit at the center after 3 months to collect some information about your blood glucose control (such as an HbA1c test).

Answer some questionnaires about your experience in managing diabetes.

Important: During this study period (3 months), you will not receive the new application being tested. The purpose of your group is to help us compare the effectiveness of the app versus usual care alone.

3. Potential Risks and Inconveniences: There are no additional medical risks associated with participation in this group, as you will continue your usual care. The only risks are the inconveniences associated with the time required to attend the follow-up visit and answer the questionnaires.
4. Potential Benefits: You may not receive a direct medical benefit from participating in this group. However, your participation is essential and will significantly help in evaluating

this application, which may benefit other diabetic patients in the future. You will continue to receive your usual medical care throughout the study period.

5. Voluntary Participation: Your participation in this study is entirely voluntary. You have the right to refuse to participate or to withdraw from the study at any time and for any reason without any negative consequences or impact on the medical care you receive. If you decide to withdraw, we can, at your request, delete all the data collected from you.
6. Confidentiality: All information you provide will be treated with strict confidentiality. Your identity will not be disclosed in any reports or publications resulting from this study.
7. Participation Costs and Compensation: The researcher can provide you with a home blood glucose meter, test strips, or any additional supplies as needed, in exchange for your time and continued participation in the study.
8. Contact for Questions: If you have any questions about the study, please contact the principal investigator: Name: Noor Kadhem Mohammed Jawad Phone: 07801452504 Email: medicalapp24@gmail.com

If you have any inquiries or concerns about your rights as a research participant, you can contact: The Ethics Committee at the College of Pharmacy/University of Baghdad at Phone:

Email: COPHCLINICALPH@COPHARM.UOBAGHDAD.EDU.IQ

Participant's Consent

I confirm that I have read this form, or it has been read to me, and all my questions have been answered satisfactorily. I understand that my participation is voluntary, that I have been assigned to the usual care only group, and that I will not receive the new application during the study period. I freely agree to participate in this study.

Participant's Signature: _____ Date: _____

Participant's Name: _____

Investigator's Statement

I confirm that I have explained the nature and purpose of this study to the participant named above, including the randomization process and the fact that the group they are assigned to will not receive the new application, and I have answered all of their questions.

Investigator's Signature: _____ Date: _____

Investigator's Name: Noor Kadhim Mohamed-Jawad

Ministry of Higher Education and Scientific Research
University of Baghdad
College of Pharmacy

وزارة التعليم العالي والبحث العلمي
جامعة بغداد
كلية الصيدلة

Research Ethical Approval Form

Date: / /2022

The University of Baghdad-College of Pharmacy Research Ethics Committee has recently reviewed your responses to comply with the ethical principles of the International Ethical Guidelines for Health-related Research Involving Humans Prepared by the Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization (WHO), National Commission for the Protection of Human Subjects of Biomedical, and Behavioral Research entitled "Ethical Principles and Guidelines for the Protection of Human Subjects of Research" (Belmont Report) for the project involving human and human specimens and must follow the framework of the Office International des Epizooties' (OIE) principles on animal ethics guidelines for the project involving animals and animal specimens.

Your proposal is now deemed to meet the requirements and ethically approved.

Approval Number	REC062441BS
Proposal Title	**Development and assessment of mobile application designed to support type 1 diabetes patients in adjusting their bolus insulin doses**
Name of Applicant	**Noor Kadhim Mohamed-Jawad**
Department	**Clinical Pharmacy**
Approval Date	20-10-2024
Expiry date	20-10-2025
Research Ethics Committee Decision	Approved

In making this application, I certify that I have read and understand the University's Policy on Research Integrity according to the stated Guidelines, and I will comply with the ethical principles of these documents.

Name of Principal Investigator		
Ehab Mudher Mikhael	Signature	

Research Ethics Committee

This project has been approved by the **Research Ethics Committee**

Prof. Dr. Mowaffaq M. Ghareeb	Dr. Dheyaa J. Kadhim	Dr. Ali Saris Hassan	
Head of committee	Member	Member	Member