Implementing a Mobile Health Application for HIV Infected and Uninfected Women with Co-morbidities in the Outpatient Setting

NCT04810260

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ALBERT EINSTEIN COLLEGE OF MEDICINE
MONTEFIORE MEDICAL CENTER
DOCUMENTATION OF INFORMED CONSENT (E-CONSENT) AND HIPAA AUTHORIZATION

Introduction

You are being asked to participate in a research study called Implementing, Evaluating, and Disseminating the Patient-facing Mobile Health Applications, ASTHMAXcel PRO and DiabetesXcel, in Patients with Asthma and Diabetes. Our research is investigating if the patient-centered mobile application, ASTHMAXcel PRO and DiabetesXcel, which can effectively address multiple co-existing chronic conditions among asthma and diabetes patients. Your participation is voluntary, and it is up to you whether you would like to participate. It is fine to say "no" now or at any time after you have started the study. If you say "no," your decision will not affect any of your rights or benefits or your access to care.

The researcher in charge of this project is called the "Principal Investigator." This project's Principal Investigator is: Sunit Jariwala, MD. You can reach Dr. Jariwala at:
Office Address: 3411 Wayne Avenue, 2nd floor, Bronx, NY 10467
Telephone #: 718-920-6089
For questions about the research study, or if you believe you have an injury, contact the Principal Investigator or the IRB.

The Institutional Review Board (IRB) of the Albert Einstein College of Medicine and Montefiore Medical Center has approved this research study. The IRB # is in the stamp in the upper right hand corner.
If you have questions regarding your rights as a research subject you may contact the IRB office at 718-430-2253, by e-mail at irb@einstein.yu.edu, or by mail:
Einstein IRB
Albert Einstein College of Medicine
1300 Morris Park Ave., Belfer Bldg #1002 Bronx, New York 10461

What is the study about and how long will it last?

Four in ten adults in the U.S. have two or more chronic conditions, and coexisting chronic diseases impose a huge burden for patients. This study seeks to demonstrate that a patient-centered mobile applications, ASTHMAXcel PRO and DiabetesXcel, can effectively improve the awareness of the chronic conditions like asthma and diabetes. This mobile intervention will deliver comprehensive health education while simultaneously collecting patient reported outcome (PRO) measures, which can improve clinical outcomes in the vulnerable population living with one or more co-morbidities. Individual participation will last for 6 months (baseline, 3 and 6 month sessions).

What are key reasons you might choose to volunteer for this study?
Possible benefits are improving your asthma, diabetes control and quality of life. In addition, the information learned from this study may, in the future, benefit other people with the same medical condition.

What are key reasons you might choose not to volunteer for this study?
You can refuse to participate in the study. If you decide not to participate, the medical care providers at this facility will still give you all of the standard care and treatment that is appropriate for you.

What will happen if I participate in the study?
If you decide to participate, during the 6 month study period, you will receive a comprehensive mobile health (mHealth) app, which includes: 1) guideline-based asthma and diabetes education delivered through interactive features such as animated videos and tailored push notifications; 2) the collection of PRO measures to enable patients symptom self-tracking.

During this study, we will evaluate the association between baseline digital health literacy and favorable results about the diseases related to the mobile health (mHealth) app. Assessments will be conducted at baseline followed by 3 and 6 months after baseline. Surveys will include questions about process outcomes (patient usage, acceptance and satisfaction with the app) as well as measures of disease morbidity (asthma and diabetes control, utilization measures in terms of asthma and/or diabetes-related ED visits and hospitalizations) and quality of life.

How many people will take part in the research study?
You will be one of approximately 60 people who will participate in this study. We will recruit 30 adult patients with persistent asthma and 30 adult patients with diabetes.

Will there be audio and/or video recording?
None.

Genetic Testing
This study will not involve genetic research or genetic testing.

Will I be paid for being in this research study?
If you participate, we will reimburse $20 for each study visit. You will receive a total of $60 for 3 (baseline, 3 and 6 month sessions) study visits. If you choose to withdraw from the study before all visits are completed, you will be paid only for the visits you completed. We will send you gift cards via mail.

Some researchers may develop tests, treatments or products that are worth money. You will

not receive payment of any kind for your specimens and information or for any tests, treatments, products or other things of value that may result from the research.

Will it cost me anything to participate in this study?
You will have to pay the transportation costs for coming to the visits. We will compensate you for each study-related visit that you complete, as described above.

Confidentiality
The researchers and study staff follow federal and state laws to protect your privacy. This part of the consent form tells you what information about you may be used and shared in the research described in this form. You do not have to sign this form but, if you do not, you may not participate in the research.

The health information that we may use or disclose for the research described in this form includes information from your entire medical record, such as your name, phone number, email, medical diagnoses, dates, test results, social security number, medical record numbers, etc.

Your information and research records will be kept confidential. Your study information will be kept as long as they are useful for the research described in this form.

The only people who can see your research records are:
Researchers and other individuals who work with the researchers
Organizations and institutions involved in this research, including those that fund the research, if applicable
Groups that review research such as central reviewers, Institutional Review Boards, the Office for Human Research Protections, the US Food and Drug Administration, data coordinating centers, and domestic and foreign agencies that regulate research.

The purposes of these uses and disclosures are to (1) conduct the study and (2) make sure the study is being done correctly. The information covered under this form may no longer be protected by federal privacy laws (such as HIPAA) once disclosed, and those persons who receive your health information may share your information with others without your additional permission. All of these groups have been asked to keep your information confidential.

Medical information collected during the research, such as test results, may be entered into your Montefiore electronic medical record and will be available to clinicians and other staff at Montefiore who provide care to you.

To maintain the integrity of this research study, you generally will not have access to your

research-related personal health information. If it is necessary for your care, your research-related health information will be provided to you or your physician.

Are there any risks to me?
You might have possible discomfort with answering questions related to the research, and potential loss of confidentiality or privacy. Loss of privacy means having your personal information shared with someone who is not on the study team and was not supposed to see or know about your information. The study team plans to protect your privacy - see the Confidentiality section above for details. You can choose not to answer questions that make you feel uncomfortable.

Are there possible benefits to me?
Possible benefits are improving your asthma and/or diabetes control and quality of life. In addition, the information learned from this study may, in the future, benefit other people with the same medical condition.

New Findings
If we learn any significant new findings during the study that might influence your decision to participate, we will contact you and explain them. If you decide to withdraw, the research study doctor and your personal doctor will make arrangements for your care to continue.

Are there any consequences to me if I decide to stop participating in this study?
To revoke (take back) your consent and authorization, you must contact the Principal Investigator in writing at the address on page 1 of this form. However, you may first call or speak to the Principal Investigator and he/she will stop collecting new information about you. If you take back your consent and authorization, you will not be allowed to continue to participate in this research study.

Can the study end my participation early?
Your participation will end if the investigator or study sponsor stops the study earlier than expected.

CONSENT TO PARTICIPATE

I have read the consent form and I understand that it is up to me whether or not I participate. I know enough about the purpose, methods, risks and benefits of the research study to decide that I want to take part in it. I understand that I am not waiving any of my legal rights by signing this informed consent document. I will be given a signed copy of this consent form.

I Agree/Accept _____

Name of Participant Date/Time

I Agree/Accept _____. _____

Name of Parent or Guardian (when applicable) Date/Time

_____. _____

Name of the person conducting the consent process Date/Time

Permission to be contacted for participation in future studies

We will store information about you, such as your name, medical record no. (MRN), and contact information in a "database", which is a library of participants from many of our ongoing digital health studies. This database will be kept in a secure manner and will be password protected, only the research staff will have access to it. In the future, with your permission this information can be used to contact you for participation in our future studies. Your information may be kept for a long time, perhaps longer than 50 years**.** You can choose not to participate in the database and still be part of the main study and this will not affect your treatment at this facility. You may remove your consent for future research at any time by contacting the Principal Investigator named on the first page of the consent or the IRB office at 718-430-2237.

INITIAL YOUR CHOICE BELOW

_____I consent to be contacted in the future to learn about:
_____New research protocols that I may wish to join.
_____General information about research findings.
_____I do not want to be contacted at all.