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STUDY APPROVAL NOTIFICATION

A PILOT OPEN LABEL CLINICAL TRIAL TO EVALUATE THE COMBINED IMPACT OF TWO MOBILE HEALTH PRODUCTS ON HEALTH OUTCOMES IN OVERWEIGHT ADULTS WITH TYPE 2 DIABETES

Sponsor: **Medidata Solutions Inc.**

Protocol Number: **MOVE-2014**
August 8, 2014

The new study listed above was reviewed and approved through expedited review **August 15, 2014** by **Susan M. Abramson, MD (S) ***, Aspire IRB Board Member. This study was approved at that time with no additional restrictions added to the conduct of the study.

Diane R. Krieger, MD was approved to conduct this study at the following locations:

Miami Research Associates
6141 Sunset Drive, Suite 301
South Miami, FL 33143

MRA Clinical Research, LLC
6280 Sunset Drive, Suite 200, 400, 600 & 603
South Miami, FL 33143

You must use the enclosed approved consent documentation stamped with "Aspire IRB Approved" located at the bottom of each page.

- Informed Consent dated August 15, 2014

Additional Materials:

- Informed Consent Understanding Questionnaire - Reviewed August 15, 2014
- Database Screening Script - Approved August 15, 2014
- Phone Screen Script - Approved August 19, 2014
- Flexsheet - Approved August 15, 2014
- Pregnancy Prevention - Reviewed August 15, 2014
- Patient Cloud – Approved August 15, 2014
- Print Ad - Approved August 15, 2014
- Radio Ad – Approved August 15, 2014
- Instruction Sheet – Reviewed August 15, 2014

The IRB has determined that your study is **Minimal** risk, and assigned an approval period of **Annual** review. Your approval period ends on **August 14, 2015**; as a reminder, you will receive a Research Status Report Form approximately sixty days prior to this date.

The Principal Investigator is responsible for providing the IRB with the necessary materials for re-approval by the due date provided on the application. **This form must be received by the due date to allow ample time for adequate review prior to the study's expiration date.** Missed submissions are the responsibility of the Principal Investigator regardless of whether or not the IRB notifies you.

The continuation of research after expiration of IRB approval is a violation of the regulations governing research.

It is required that *Aspire IRB* be notified of:

- All amendments or changes to the protocol
- Changes to the protocol that are implemented without prior IRB approval to eliminate an apparent immediate hazard to subjects (must be reported within 24 hours of implementation)
- Unanticipated problems involving risks to subjects or others (within 10 calendar days of discovery). This includes protocol deviations that fit the criteria for an unanticipated problem.
- All material used to recruit study subjects (prior IRB approval is required before use)
- Any other changes in the research activity

The Principal Investigator may not make any changes in the research, without prior approval of *Aspire IRB,* except when necessary to eliminate immediate risk to study subjects. In addition, it is the responsibility of the Principal Investigator to uphold the following three ethical principles outlined in the Belmont Report during the conduct of this study:

- Respect for persons: individuals should be treated as autonomous agents and persons with diminished autonomy are entitled to protection.
- Beneficence: maximize possible benefits and minimize possible harms.
- Justice: benefits and burdens of research should be distributed equally.

Aspire IRB is duly constituted and has written procedures in compliance with requirements defined in 21 CFR Parts 50 and 56, 312, 812, 45 CFR 46 and ICH Guidelines relating to Good Clinical Practice. Aspire IRB's mission is to ensure that research is conducted ethically according to the principles of the Belmont Report and in compliance with federal regulations, international regulations, ICH Guidelines for Good Clinical Practice, applicable state and local laws, Aspire IRB Standard Operating Procedures, and that the rights and welfare of human subjects are protected.

Taylor Lazar, LVN, Project Lead

8/15/14
Date

INFORMED CONSENT TO PARTICIPATE IN CLINICAL RESEARCH STUDY

A PILOT OPEN LABEL CLINICAL TRIAL TO EVALUATE THE COMBINED IMPACT OF TWO MOBILE HEALTH PRODUCTS ON HEALTH OUTCOMES IN OVERWEIGHT ADULTS WITH TYPE 2 DIABETES

Sponsor: Medidata Solutions Inc.

Protocol Number: MOVE-2014
August 8, 2014

Principal Investigator: Diane R. Krieger, MD
Miami Research Associates
6141 Sunset Drive, Suite 301
Miami, FL 33143

24-Hour Telephone Number: (305) 598-3125

This consent may be hard to understand in places. Please ask questions if there are parts you do not understand.

This is a clinical trial (a type of research study). Clinical trials include only individuals who choose to take part. Please take your time to make your decision. Feel free to discuss the study with your friends and family. Be sure to ask questions about anything you don't understand.

You are being asked to take part in this study because you are a healthy adult, 18 to 60 years old, who is overweight and has Type 2 Diabetes.

To participate in this study you must have the following:

- A compatible Apple mobile device with the iOS 7 operating system installed:
  - iPhone 4 or newer
  - iPad 2 or newer
  - iPad Mini
  - iPod touch 5th gen (2012 model) or newer
- 500MB of free space on the iPhone, iPad, or iPod touch
- A valid mobile phone number to receive daily messages via SMS text messaging
- An active iTunes account/password to install study-related software ("apps")
- Access to Wi-Fi or a mobile data plan to send study data

PURPOSE & DESCRIPTION OF THE STUDY

The purpose of this study is to explore the effects of using the Medidata Patient Cloud mobile application in combination with the Fitbit Flex activity tracker on health outcomes, including glucose control and body weight in overweight adults with Type 2 Diabetes.

The Medidata Patient Cloud captures data through the iPhone, iPad (including iPad Mini) and iPod touch. If you participate in the study, you will complete questionnaires and diaries for the study using your iPhone, iPad or iPod touch. Medidata will also send you daily messages about nutrition and exercise to your cellular phone through SMS text messages.

The Fitbit Flex activity tracker is a rubber wristband that can track your daily physical activity. The Fitbit Flex does this by counting the number of steps you take each day. The Fitbit Flex synchronizes wirelessly to your iPhone, iPad or iPod touch and you can see your steps accumulate in real-time.

If you participate in this study you will use the Patient Cloud and the Fitbit Flex for 8 weeks. The goal of the study is to see if the combination of the Patient Cloud that sends daily messages about nutrition and exercise and the activity tracker that shows you your steps have an effect on the way you exercise and eat.

The study will last approximately 8 weeks and includes a screening visit and three follow-up visits (on Days 0, 28 and 56). Study visit procedures include monitoring weight, blood pressure and heart rate, completing questionnaires in the Patient Cloud and collecting blood samples for markers of glucose control. At the second and third visits (on Days 0 and 28), you will also participate in a lifestyle modification instructional/motivational session which includes development of a personal care plan.

The personal care plan will include a nutrition component and an exercise/activity component. The nutrition component includes three specific nutrition goals to work on between visits 2 and 3 and three specific nutrition goals to work on between visits 3 and 4. Nutrition information to assist you in following the nutrition goals will be provided. The exercise/activity component will include activity/exercise goals based on the number of steps you take per day. The activity/exercise goal involves increasing your steps per day each week of the study. The daily text messages you receive will reinforce the nutrition and exercise goals.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

WHAT MAKES THIS DIFFERENT FROM THE USUAL TREATMENT?

This study does not involve testing a treatment (medication) for a medical condition. There may be no improvement in your health as the result of participating in this study. The study is looking for overweight adults with Type 2 Diabetes to study the effects of using the Medidata Patient Cloud in combination with a Fitbit Flex activity tracker on health outcomes such as glucose control and body weight.

INFORMATION ABOUT THE STUDY PRODUCTS

Product 1 – Medidata Patient Cloud

The Medidata Patient Cloud is a mobile application for capturing data directly from subjects, enabling entry of diary and quality of life data into internet-enabled iOS devices (iPhone, iPad, and iPod touch). The data captured by this application automatically synchronizes with the Medidata Clinical Cloud, a technology platform that uses cloud technology to plan, set up and run clinical trials. The Medidata Clinical Cloud is not designed to diagnose, prevent, or treat disease or other conditions.

Product 2 – Fitbit Flex

The Fitbit Flex is an activity tracker worn on the wrist that tracks several biometric parameters, including steps walked, activity minutes, sleep duration, and sleep efficiency. The Fitbit Flex uses a three-dimensional accelerometer to sense user movement. It measures steps taken, and combines it with user data to calculate distance walked, calories burned, activity duration and intensity. It also measures sleep quality by tracking periods of restlessness, how long it takes the wearer to fall asleep, and how long the wearer is asleep.

If you decide to enroll in the trial, you will be asked to enable the Medidata Clinical Cloud to access your Fitbit Flex data as part of the onboarding process. This will allow your data to be analyzed by statisticians at the end of the trial, and your data will be secure and protected.

Your Fitbit Flex data will also be subject to Fitbit Flex privacy policies. Fitbit Flex will only use your personal information to:

- Provide you with the Service;
- Analyze Site usage and improve the Service;
- Deliver to you any administrative notices and communications relevant to your use of the Fitbit Flex Products and Service;
- Provide you with updates regarding Fitbit Flex Products and Services;
- Perform internal market research, project planning, troubleshooting problems, and to detect and protect against error, fraud or other criminal activity;
- Enforce the Fitbit Flex Terms of Use.

Fitbit Flex may disclose non-personally identifiable aggregated user data, such as aggregated gender, age, height, weight, and usage data gathered from Fitbit Flex devices (without the inclusion of a user's name or other identifying information) to:

- Organizations approved by Fitbit Flex that conduct consumer research into health and wellness;
- Users of the Service for purposes of comparison of their personal health and wellness situation relative to the broader community; and
- Advertisers and other third parties for their marketing and promotional purposes.

Product use instructions:

You will be provided access to the Medidata Patient Cloud and a Fitbit Flex at visit 2. The coordinator will instruct you on how to use both mobile devices. You will leave the study site after visit 2 using the Medidata Patient Cloud and Fitbit Flex.

You will be instructed to wear the activity tracker daily throughout the 8-week study period, including during sleep. If for some reason you can't use your activity tracker (it gets lost, stolen or broken), please let the coordinator know as soon as possible. Your activity tracker may be replaced one time during the study period. You can shower and perform all your normal daily activities with the activity tracker on.

You will be responsible for keeping your Fitbit Flex charged (the device will require charging approximately every four days), and for putting the Fitbit Flex in sleep mode each evening (this requires a few light taps on your device). Detailed instructions for charging the device and putting it in sleep mode will be provided.

You will also be instructed to use the Medidata Patient Cloud weekly (to complete the weekly questionnaire) and to check your phone daily (to receive the daily texts). You must keep the app on your iOS 7 device for the duration of the study. Each week you will receive a reminder that it is time to open the Medidata Patient Cloud and complete your questionnaire, which will ask you a series of questions on your quality of life. The coordinator will help you set up the weekly reminders during visit 2.

You will stop using the Medidata Patient Cloud for study purposes the day of visit 4.

You will be instructed to wear your activity tracker and bring the iPhone, iPad, iPad Mini or iPod touch with the Patient Cloud installed to all visits.

HOW LONG WILL I BE IN THIS STUDY?

If you participate, you will be one of approximately 20 adults taking part in this study. The study will last approximately 8 weeks. You can stop participating at any time. However, if you decide to stop participating in the study, we encourage you to talk to the study doctor and your regular doctor first.

If you decide to leave the study, you and the study doctor will discuss the best way to do this. All data and samples collected during your study participation will still be used for the study.

With your permission provided in this consent form, you may be contacted between visits to learn about your well-being. This may be done via phone calls, emails, or text messages. You may be asked for the name and contact information of a family member or friend. We may contact him or her if we are unable to contact you during the study.

WHAT IS INVOLVED IN THE STUDY?

If you qualify for the study, which will be determined at the screening visit, you will attend three visits which will last approximately two hours each.

Study requirements:

Study product requirements:

You will be instructed to wear the Fitbit Flex daily throughout the 8-week study period. If the Fitbit Flex breaks or gets lost or stolen, let the coordinator know as soon as possible.

You will also be instructed to use the Medidata Patient Cloud weekly to complete the weekly questionnaires.

You will also be instructed to keep your cellular phone on you daily to receive the daily texts. The daily texts will be sent at noon and it is requested that you read them at your earliest convenience.

Pre-visit requirement:

You will be required to fast (no food or beverage other than water, no caffeine) after midnight the nights prior to the study visits.

Diet and exercise requirements:

You will be required to follow the nutrition plan provided to you for the duration of the study. You will be given three nutrition goals to work on between visits 2 and 3, and three nutrition goals to work on between visits 3 and 4 for a total of six nutrition goals for the study.

You will be required to follow the exercise/activity plan provided to you for the duration of the study. At visit 2, you will be instructed to do your usual activity and exercise for your first week in the study. Using your average number of steps per day from the first week, weekly step per day goals for the remaining 7 weeks of the study will be developed. The exercise goal for the study will be to increase steps per day by 10% each week. In other words, if your baseline average number of steps per day is 2500, your goal for week 2 would be 2750 steps per day (2500 x .10 = 250 + 2500 = 2750) and your goal for week 3 would be 3025 steps per day (2750 x .10 = 275 + 2750 = 3025) and so on.

You will receive daily text messages throughout the study that will help you follow the nutrition and exercise goals.

Vitamin, mineral and supplement requirements:

You may continue taking vitamins and minerals that you were taking prior to starting the study (same frequency as prior to study start). If you were not previously taking any vitamins and/or minerals, you will be asked to not start taking any during the study. In other words, please do not start any new vitamins and/or minerals while participating in the study.

You will not be allowed to take any dietary or herbal supplements during the study. Please do not take any product that has "Supplement Facts" on the product label while participating in the study.

Medication requirement:

If at any time during the study you are prescribed a medication or have a change to one of your current medications, please notify either the study coordinator or study doctor as soon as possible.

Birth Control Methods:

If you are a female of childbearing potential, you are required to use a reliable method of birth control throughout your study participation.

Acceptable birth control methods include:

- Double-barrier method (condoms with spermicide, diaphragm with spermicide)
- Hormonal contraceptives (vaginal rings, patches, oral birth control pills)
- Hormone implants
- Long-term injectable contraceptives
- Intrauterine devices

- Vasectomized partner with vasectomy performed greater than six months prior to the screening visit
- Same sex partner
- Abstinence

If you take part in this study, you will have the following tests and procedures:

The screening visit includes the following procedures:

- Informed consent will be obtained (your permission to participate in the study); this includes describing to you exactly what the study involves and providing you the opportunity to ask any questions you might have.
- Your medical history and the medications you are taking will be reviewed.
- If you are a female of childbearing potential, you will have a urine pregnancy test.
- Your height, weight, blood pressure and heart rate will be checked.
- An electrocardiogram (ECG) will be performed to look at your heart.
- You will have a physical examination.
- Your blood will be collected to assess your eligibility for study participation (approximately 1 ounce).
- You will be provided handouts explaining the study requirements which will be reviewed with you by the coordinator.

If you qualify for the study, the follow-up visits (visits 2, 3 and 4) will include the following procedures:

- The coordinator will monitor for changes in your health and medication usage.
- If you are a female of childbearing potential, you will have a urine pregnancy test.
- Your weight, blood pressure and heart rate will be checked.
- At visit 2, you will be provided the activity tracker and the Medidata Patient Cloud and the study coordinator will explain to you how to use them. You will complete a questionnaire to assess your quality of life using the Medidata Patient Cloud as part of the instruction.
- At visits 2 and 3, you will be provided nutrition and exercise information and goals to work on by the coordinator.
- At visits 2 and 4, your blood will be collected and assessed for markers of glucose control (approximately 1 ounce).
- At visits 3 and 4, you will be asked about your progress with the nutrition and exercise goals.

The study coordinator will call you on Day 8 to help you with your exercise goals.

In addition to this scheduled call, the study coordinator may call, email or text you between visits to assess your progress.

Risks

There are no known risks to participating and using the Medidata Patient Cloud and the Fitbit Flex wristband. There may be risks that are not known.

Your confidentiality and privacy will be protected. You will be in control of your own apple device and do not have to reveal your apple ID password in order to participate.

Blood Collection: We will draw your blood one time at the screening visit, visit 2 and visit 4 for a total of three times during this study. The total amount of blood collected for the study will be approximately 2 ounces. Blood will be drawn via individual needle sticks.

The most common risks or side effects seen with blood draws are:

- Feeling faint
- Redness of the vein
- Pain, bruising or bleeding at the site of the needle puncture

Less common risks or side effects seen with blood draws are:

- Infection

Medication Interactions

Per the sponsor, there are no known medication, supplement or food interactions with the study product. Please inform the study doctor if you change any medication, supplement or vitamins during this study.

The study doctor will review the medications you take prior to the study and throughout your participation in the study.

Contraindicated Medical Conditions

There are no known contraindicated medical conditions with the use of this product and the Fitbit Flex per the sponsor.

The study doctor will monitor you throughout your participation in the study.

Possible Side Effects

There are no known adverse effects reported by the sponsor or known about the Medidata Patient Cloud and Fitbit Flex.

OTHER ALTERNATIVES

Since this study is for research only, the alternative would be to not participate.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this study, there may or may not be direct medical benefit to you.

CONFIDENTIALITY

Efforts will be made to keep your personal information confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law.

Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as:

- The sponsor of this study and or its agents [e.g., monitor(s) and auditor(s)]
- The Food and Drug Administration (FDA)
- Aspire IRB (protects the rights and welfare of research subjects)

The study doctor may publish the results of this study but you will not be identified.

In the rare event that your information is required to be disclosed by law to another entity, neither the sponsor nor Aspire IRB can guarantee that confidentiality of your personal information will be maintained.

WHAT ARE THE COSTS?

There are no costs to you for participating in this study.

INVESTIGATOR PAYMENT

The sponsor, Medidata Solutions Inc., is paying the study site for conducting this study.

WHAT HAPPENS IF YOU HAVE COMPLICATIONS OR ARE INJURED?

The sponsor will be responsible for any research related injuries or complications.

WILL YOU BE COMPENSATED DURING THE STUDY?

You will be compensated $25 for attending the screening visit. You will receive $250 for attending visit 2, $200 for attending visit 3, and $200 for attending visit 4. You will also be paid $50 for completing the phone call. This results in a total of $725 if you complete the study. If you decide to stop early, you will be paid for the study visits you completed.

You will also receive a Fitbit Flex device at no cost. The device will be yours to keep once the study has completed.

Compensation will be paid via a ClinCard, a re-loadable payment card.

YOUR RIGHTS AS A RESEARCH SUBJECT

Taking part in this study is voluntary. You may choose not to take part or may leave the study at any time. Leaving the study will not result in any penalty or loss of benefits to which you are entitled.

We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

The study doctor may stop your participation at any time, for example, for your health. You will be told of any tests or follow up recommended for your health if you leave the study early.

WHO TO CALL IF YOU HAVE QUESTIONS

For questions, concerns or complaints about the study or a research-related injury, contact the study coordinator/doctor at 305-279-0015 extension _____ during daytime hours. If you have questions or medical concerns after business hours, call 305-598-3125.

This study was reviewed by Aspire Independent Review Board (IRB). An IRB reviews research to protect the rights and welfare of study participants. If you have problems, concerns, suggestions, questions or information about the study, and for information regarding research subject's rights, please call Aspire's Quality Assurance and Reguiatory Compliance Department at 1-877-366-5414 (toil free).

Although Aspire IRB has approved the information provided in this informed consent form and has granted approval for the investigator to conduct the study this does not mean Aspire has approved your participation in the study. You must evaluate the information in this informed consent form for yourself and decide whether or not you wish to participate.

If you have any questions or issues with the Medidata Patient Cloud during the study, contact Medidata at 1-866-MEDIDATA (633-4328).

If you have questions or issues with your Fitbit Flex device, visit the Fitbit website at https://help.fitbit.com/.

SIGNATURE AND CONSENT TO BE IN THE STUDY

Your signature below means you have read the above information pertaining to the MOVE-2014 study, an opportunity was given to you to ask questions, and all questions were answered to your satisfaction. Also you are aware that your participation in this study is voluntary, and at any time you can withdraw your consent. By signing this form you are not giving up any of your legal rights, and you will be given a signed and dated copy of this informed consent.

_____ _____/_____

SIGNATURE OF SUBJECT DATE

_____

PRINTED NAME OF SUBJECT

The contents of this informed consent describing the MOVE-2014 study have been discussed with the subject. All questions were answered. I witnessed the subject sign this form, and I confirm that a copy of this informed consent will be given to the subject.

_____ _____/_____

SIGNATURE OF PERSON OBTAINING CONSENT DATE

_____

PRINTED NAME OF PERSON OBTAINING CONSENT