Comparison of Glycemic Control With Smartphone Application (Vivovitals) - Based Glucose Monitoring to Routine Home Glucose Monitoring in Poorly Controlled T2DM Patients Treated With Insulin
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STUDY INFORMATION:

Study Title: Comparison of Glycemic Control with Smartphone Application (Vivovitals) - Based Glucose Monitoring to Routine Home Glucose Monitoring in Poorly Controlled T2DM Patients Treated with Insulin

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SUMMARY OF THIS RESEARCH STUDY:

In medicine there are many unanswered questions. A research study is when scientists try to answer a question about something that we don't know enough about. Participation in a research study may or may not directly help you or others. Participation is entirely voluntary. It is completely up to you whether or not you take part. You can also change your mind at any time and it will not affect your ability to get medical care at NYC Health + Hospitals/ Queens.

The purpose of this research study is to know if a smartphone-based frequent glucose monitoring by a care provider can improve blood glucose control (as measured by hemoglobin A1c levels) in addition to standard care. It is observed that despite standard care and frequent follow up with care provider the blood glucose control of some patients does not improve as expected. There are many reasons for it but one of them is patients either do not regularly check their blood glucose levels at home or forget to bring their blood glucose diary at the time of the visit to their care provider. This can lead to the care provider not able to fully optimize the therapy. This research will attempt to solve this problem by integrating smartphone applications to their diabetic care. Subjects will be divided into two groups randomly. Intervention arm will use the smartphone application to document their glucose levels, Care providers will look into the glucose levels on his password protected computer, as the application is automatically connected to the computer and subjects phone application. Once the intervention arm document the glucose level on application, care provider will act upon on it by giving advice or by adjusting Insulin dose on a weekly basis by phone call visit. While the control arm will document their blood glucose level on daily diary, which will be provided from the research site and there will be no

intervention for the control group unless the subject has a specific question or query related to the diabetes and sugar levels. Both groups will get a weekly reminder call to document their glucose level.

If you choose to participate, you will be randomly assigned in any one of the groups. you will be asked to install a smartphone application on your phone called Vivovitals. The research team will educate you on using the application. You will be following with your care provider and do your home blood glucose monitoring as before, in addition, you will input your blood glucose levels into the smartphone application every time you check your blood glucose. control group will be provided the daily dairy and educate them how to use it. The study has two visits which are part of your standard care. The study duration is three months. There are no additional costs to you or your insurance provider as the blood tests and home glucose monitoring are part of your standard care you already receiving. There won't be any compensation for taking part in this study. The main risks to you if you choose to participate are bruising and slight pain and a possibility of infection at the venipuncture site from blood glucose testing but these risks are already part of your standard care. There is a minimal risk of loss of confidentiality of your health data particularly your blood glucose test results.

We believe that use of phone-based application will lead in better glycemic control by the 3 months.

If you are interested in learning more about this study, please continue to read below.

PARTICIPATION IN THIS RESEARCH STUDY:

This research study will be fully explained to you by a member of the study team. Feel free to ask all the questions you want before you make a decision about whether or not to participate. Any new information that develops during this research study that might make you change your mind about participating will be given to you promptly.

You may qualify to take part in this research study because you are a type 2 diabetic on insulin and with HbA1c levels more than 8% and are performing regular home glucose monitoring.

LENGTH OF TIME AND NUMBER OF PEOPLE EXPECTED TO PARTICIPATE:

Your participation in this research study is expected to last 3 months. The number of people expected to take part in this research study at our diabetic center in NYC Health + Hospitals/ Queens will be 100. 50 subjects in the intervention group (using smartphone application) and 50 subjects in the control group (using daily diary) Subjects. The intervention group checks their blood glucose level daily and will document data on smart phone application while the care provider will adjust the dose of insulin on a weekly basis according to their sugar levels. Control group will document their glucose level in their

daily diary but there will be NO intervention in the control group until their final visit after 3 months to clinic and unless the subject has specific questions regarding their glucose level or diabetes.
A weekly reminder call will be given to both groups to document their blood glucose level for 3 months.

DESCRIPTION OF WHAT'S INVOLVED:

If you agree to participate in this research study, the following information describes what may be involved.
As part of the study, you will be expected to make two visits to our diabetic center at NYC Health + Hospitals/ Queens, which are also part of your standard care.
On your first visit, you will be seen by the principal investigator. Your basic health information will be taken including your age, recent CBC, BMP, Fasting sugar level HbA1c value, weight, height, BMI and blood pressure, pulse, oxygen level in your blood will be check. You will be educated about the smartphone application and navigating it by one of our research coordinators. Once the application installed in your phone you will documents your sugar level reading in smart application till your next visit.

On your second visit,3 months later, you will be again seen by the primary investigator. This time again your basic health information will be taken, a blood test for CBC, Fasting blood glucose, BMP,HbA1c weight, height, BMI and blood pressure, pulse ,oxygen level in your blood will be check will be ordered. You will be asked to inform the research team of any deterioration in health, hospitalizations or death immediately and at the time of the second visit.

USE OF YOUR DATA AND/OR SPECIMENS:

The private information and/or samples collected as part of this research will never be used or shared for future research, even if the identifiable information is removed.

YOUR RESPONSIBILITIES IF YOU TAKE PART IN THIS RESEARCH:

If you decide to take part in this research study you will be responsible for the following things: You will be expected to follow all the recommendations suggested by your care provider regarding your diabetes control including lifestyle changes. You will be expected to regularly perform home blood glucose testing several times per day as per your care provider's recommendation. The test results should be immediately entered into your Vivovitals smartphone application. You should immediately report any deterioration of health or hospitalization to the research team.

COSTS OR PAYMENTS THAT MAY RESULT FROM PARTICIPATION:

You will not be paid for participating in this research study. Being in this research study will not lead to extra costs to you. You will not be reimbursed for your travel or time that may be required for study visits.

POSSIBLE BENEFITS:

It is important to know that you may not get any benefit from taking part in this research. Others may not benefit either. However, possible benefits may be: you will be getting additional attention in between your visits as your care provider will monitor your blood glucose values every two weeks and provide feedback or change in therapy when necessary.

REASONABLY FORESEEABLE RISKS AND DISCOMFORTS:

Risk of loss of private information; this risk always exists, but there are procedures in place to minimize the risk. The risks of a blood draw include pain, bruising, and the slight possibility of infection at the place where the needle goes in. Some people feel dizzy or may faint during or after a blood draw.

OTHER POSSIBLE OPTIONS TO CONSIDER:

You may decide not to take part in this research study without any penalty. The choice is totally up to you.

IN CASE OF INJURY DURING THIS RESEARCH STUDY:

If you believe that you have suffered an injury related to this research as a participant in this study, you should contact the Principal Investigator.

ENDING PARTICIPATION IN THE RESEARCH STUDY:

You may stop taking part in this research study at any time without any penalty. This will not affect your ability to receive medical care at NYC Health + Hospitals/ Queens or to receive any benefits to which you are otherwise entitled.

If you decide to stop being in the research study, please contact the Principal Investigator or the research staff

If you decide you don't want your data to be used for research anymore, you can contact the researcher and ask to have your data removed from future use. If any data have already been shared without your identity, it won't be possible to retrieve them because no one will know who you are. Samples and data that have already been used will not be affected by your decision. Any samples and/or data that are still linked to your identity by a code the researcher has will be withdrawn so that no future sharing of your samples and/or data will take place.

Withdrawal without your consent: The study doctor, the sponsor or the institution may stop your involvement in this research study at any time without your consent. This may be because the research study is being stopped, the instructions of the study team have not been followed, the investigator believes it is in your best interest, or for any other reason. If data have been stored as part of the research study, they too can be destroyed without your consent. More possible reasons for removal from the study include hospitalization, Death, loss of contact, develop malignancy.

CONTACT INFORMATION:

If you have any questions, concerns, or complaints at any time about this research, or you think the research has harmed you, please contact the office of the research team and/or the Principal Investigator at phone number 718-883-3337.
If you experience an emergency during your participation in this research, contact call 911 or go to the emergency room and inform the research team at the earliest possible time.

This research has been reviewed and approved by an Institutional Review Board. You may reach a representative of the Program for Protection of Human Subjects at the Icahn School of Medicine at Mount Sinai at telephone number (212) 824-8200 during standard work hours for any of the reasons listed below. This office will direct your call to the right person within the Mount Sinai:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You are not comfortable talking to the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

DISCLOSURE OF FINANCIAL INTERESTS:

Sometimes, physicians/researchers receive payments for consulting or similar work performed for industry. Effective September 2014 Mount Sinai reviews only payments to an individual totaling more

than $5,000 a year per entity when determining potential conflicts of interest. If you have questions regarding industry relationships, we encourage you to talk your physician/researcher or visit our website at http://icahn.mssm.edu/ where Mount Sinai publicly discloses the industry relationships of our faculty.

The research team has no financial interest in this study and are not affected by the outcome of the study.

MAINTAINING CONFIDENTIALITY – HIPAA AUTHORIZATION:

As you take part in this research project it will be necessary for the research team and others to use and share some of your private protected health information. Consistent with the federal Health Insurance Portability and Accountability Act (HIPAA), we are asking your permission to receive, use and share that information.

What protected health information is collected and used in this study, and might also be shared with others?
As part of this research project, the research team at the hospital(s) involved in the research will collect your name, address, telephone/fax numbers, medical records number. The researchers will also get information from your medical record include where these records will come from, for example, which hospital or clinic or your private doctor.

Why is your protected health information being used?
Your personal contact information is important to be able to contact you during the study. Your health information and the results of any tests and procedures being collected as part of this research study will be used for the purpose of this study as explained earlier in this consent form. The results of this study could be published or presented at scientific meetings, lectures, or other events, but would not include any information that would let others know who you are, unless you give separate permission to do so.

The research team and other authorized members of NYC Health + Hospitals/ Queens, New York City Health and Hospitals Corporation (also known as “NYC Health + Hospitals”), and Icahn School of Medicine at Mount Sinai (hereafter, “Mount Sinai”) workforce may use and share your information to ensure that the research meets legal, institutional or accreditation requirements. For example, the School’s Program for the Protection of Human Subjects is responsible for overseeing research on human subjects, and may need to see your information. If you receive any payments for taking part in this study, the NYC Health + Hospitals/ Queens Finance Department may need your name, address, social security number, payment amount, and related information for tax reporting purposes. I*f the research team uncovers abuse, neglect, or reportable diseases, this information may be disclosed to appropriate authorities.*

Who, outside Mount Sinai and NYC Health + Hospitals/ Queens, might receive your protected health information?
As part of the study, the Principal Investigator, study team and others in the NYC Health + Hospitals/ Queens and Mount Sinai workforce may disclose your protected health information, including the results of the research study tests and procedures, to the following people or organizations: (It is possible that there may be changes to the list during this research study; you may request an up-to-date list at any time by contacting the Principal Investigator.)

In all disclosures outside of NYC Health + Hospitals/ Queens and Mount Sinai, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier unless disclosure of the direct identifier is required by law. Some records and information disclosed may be identified with a unique code number. The Principal Investigator will ensure that the key to the code will be kept in a locked file, or will be securely stored electronically. The code will not be used to link the information back to you without your permission, unless the law requires it, or rarely if the Institutional Review Board allows it after determining that there would be minimal risk to your privacy. It is possible that a sponsor or their representatives, a data coordinating office, a contract research organization, may come to inspect your records. Even if those records are identifiable when inspected, the information leaving the institution will be stripped of direct identifiers. Additionally, when applicable, the monitors, auditors, the IRB, *the Office of Human Subjects Protection (OHRP) of the Department of Health and Human Services as well as the Food and Drug Administration (FDA) will be granted direct access to your medical records for verification of the research procedures and data. OHRP and FDA are authorized to remove information with identifiers if necessary to complete their task. By signing this document you are authorizing this access.* We may publish the results of this research. However, we will keep your name and other identifying information confidential.

For how long will Mount Sinai and NYC Health + Hospitals/ Queens be able to use or disclose your protected health information? Your authorization for use of your protected health information for this specific study does not expire.

Will you be able to access your records?
During your participation in this study, you will have access to your medical record and any study information that is part of that record. The investigator is not required to release to you research information that is not part of your medical record.

Do you need to give us permission to obtain, use or share your health information?
NO! If you decide not to let us obtain, use or share your health information you should not sign this form, and you will not be allowed to volunteer in the research study. If you do not sign, it will not affect your treatment, payment or enrollment in any health plans or affect your eligibility for benefits.

Can you change your mind?

You may withdraw your permission for the use and disclosure of any of your protected information for research, but you must do so in writing to the Principal Investigator at the address on the first page. Even if you withdraw your permission, the Principal Investigator for the research study may still use your protected information that was already collected if that information is necessary to complete the study. Your health information may still be used or shared after you withdraw your authorization if you should have an adverse event (a bad effect) from being in the study. If you withdraw your permission to use your protected health information for research that means you will also be withdrawn from the research study, but standard medical care and any other benefits to which you are entitled will not be affected. You can also tell us you want to withdraw from the research study at any time without canceling the Authorization to use your data.

If you have not already received it, you will also be given The Hospital's Notice of Privacy Practices that contains more information about how The Hospital uses and discloses your protected health information.

It is important for you to understand that once information is disclosed to others outside NYC Health + Hospitals/ Queens, the information may be re-disclosed and will no longer be covered by the federal privacy protection regulations. However, even if your information will no longer be protected by federal regulations, where possible, NYC Health + Hospitals/ Queens has entered into agreements with those who will receive your information to continue to protect your confidentiality.

If as part of this research project your medical records are being reviewed, or a medical history is being taken, it is possible that HIV-related information may be revealed to the researchers. If that is the case, the following information concerns you. If this research does not involve any review of medical records or questions about your medical history or conditions, then the following section may be ignored.

Notice Concerning HIV-Related Information

If you are authorizing the release of HIV-related information, you should be aware that the recipient(s) is (are) prohibited from re-disclosing any HIV-related information without your authorization unless permitted to do so under federal or state law. You also have a right to request a list of people who may receive or use your HIV-related information without authorization. If you experience discrimination because of the release or disclosure of HIV-related information, you may contact the New York State Division of Human Rights at (888) 392-3644 or the New York City Commission on Human Rights at (212) 306-5070. These agencies are responsible for protecting your rights.

ADULT PARTICIPANT:
Your signature below documents your permission to take part in this research and to the use and disclosure of your protected health information. A signed and dated copy will be given to you.

_____	_____	_____	_____
Signature of subject	Printed Name of Subject	Date	Time

PERSON EXPLAINING STUDY AND OBTAINING CONSENT:

_____	_____	_____	_____
Signature of consent delegate	Printed Name of consent delegate	Date	Time

WITNESS SECTION:
When a witness is required to observe the consent process, it should be documented below (for example, when subject is illiterate, visually impaired, or this document accompanies a short form consent).

My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject, and that consent was freely given by the subject.

_____	_____	_____	_____
Signature of Witness	Printed Name of Witness	Date	Time