



**University of Illinois at Chicago
Research Information and Consent for Participation in Biomedical Research
mHealth for Diabetes Adherence Support**

Principal Investigator/Researcher Name and Title: Ben S. Gerber MD, MPH and
Lisa K. Sharp, PhD

Department and Institution:

Division of Academic Internal Medicine and Geriatrics (Gerber)
Department of Pharmacy Systems, Outcomes, and Policy (Sharp)
University of Illinois at Chicago

Address and Contact Information:

1747 West Roosevelt Rd, Chicago, IL 60608 bgerber@uic.edu 312-996-8872 (Gerber)
833 South Wood Street Chicago, IL 60612 sharp1@uic.edu 312-355-3569 (Sharp)

Sponsor: This research is funded by the National Institute of Diabetes and Digestive and Kidney Diseases within NIH.

About this research study

You are being asked to participate in a research study. Research studies answer important questions that might help change or improve the way we do things in the future.

Taking part in this study is voluntary

Your participation in this research study is voluntary. You may choose to not take part in this study or may choose to leave the study at any time. Deciding not to participate, or deciding to leave the study later, will not result in any penalty or loss of benefits to which you are entitled and will not affect your relationship with the University of Illinois Hospital and Health Sciences System (UI Health) and/or University of Illinois at Chicago (UIC).

This consent form will give you information about the research study to help you decide whether you want to participate. Please read this form and ask any questions you have before agreeing to be in the study.

Important Information

This information gives you an overview of the research. More information about these topics may be found in the pages that follow.

<p>WHY IS THIS STUDY BEING DONE?</p>	<p>This study is being done to find out if a team consisting of a primary care doctor, pharmacist, and a Health Coach, supported by mobile health technology including text messaging and videoconferencing, improves diabetes care.</p>
<p>WHAT WILL HAPPEN TO ME DURING THE STUDY?</p>	<p>First, your medical record will be reviewed to see if you have the hemoglobin A1C level needed to qualify for the study. We will then ensure you are eligible for this study by asking a series of questions.</p> <p>An important part of this study involves regular home visits from your Health Coach, many of which will include video conferences with the pharmacist. To participate in this study, you must agree to allow the Health Coaches into your home for these monthly home visits.</p> <p>After signing this consent form and the HIPAA authorization, you will be enrolled in this study. As a participant in “mHealth for Diabetes Adherence Support,” we ask that you participate in three (3) parts of the study. This study will last approximately two years (24 months).</p> <p>1) The first part of the research will be a baseline data collection visit. We will schedule you for an appointment at the UIC Clinical Research Core (912 South Wood Street, Chicago IL 60612; 2nd floor, Room 200 S)</p> <p>You will be asked a series of questions about yourself, your medications, and use of health care services. Some of the surveys will ask questions that relate to taking care of your diabetes. This information is only being collected for research and will not be shared with others. This will take approximately 60 minutes.</p> <p>You will be asked a question regarding thoughts of suicide. For example, “Over the past two weeks, have you been bothered by thoughts that you would be better off dead or about hurting yourself in some way?” If the study interviewer believes you might be at risk of hurting yourself, a clinical psychologist will take necessary measures to help you.</p> <p>We will draw some blood from your arm to measure your Hemoglobin A1C and your cholesterol. You will be asked to fast (you may drink water but may not eat food for 12 hours prior to the test). The amount of blood drawn will be about 6 ml (approximately one teaspoon).</p> <p>Your height, weight, and blood pressure will be measured, similar to how this is done in your doctor’s office.</p> <p>You will be asked to return here after 6, 12, 18, and 24 months for similar testing (surveys, blood tests, height and weight, and blood pressure).</p>

2) **The second part** of the study will include 1 year of receiving your usual care. In addition:

You will be given contact information for a diabetes educator who can help you learn about lifestyle changes you can make to more easily manage your diabetes and blood sugar.

You will also be given contact information for a clinical pharmacist who will help you with your medications.

Finally, you will receive a one-page contact sheet with the names and phone numbers of your local healthcare team, as well as diabetes education information.

3) **The third part** of the study will last for 1 year. It includes working with a Health Coach: a representative of your community who specializes in helping our patients bridge the gap between their homes and their health care system. The Health Coach will work with you and your pharmacist in helping you manage your diabetes. This may occur at clinic visits, home visits, or by phone calls or text messages. The Health Coach will talk to you and your pharmacist about the food you are eating, physical activity, medications, and other lifestyle issues relating to diabetes. The overall role of the Health Coach is to work with you to set goals and to help you meet your goals.

Home Visits

You will receive a home visit from your Health Coach once a month, as well as on-going telephone support. Home visits are meant to allow the Health Coach to understand your living environment and to help you make adjustments necessary to better support your diabetes care. We also hope to provide you with education during these visits on topics related to diabetes management.

You can set the terms for who joins in during your home visits. Family members, friends, or others that help you with your diabetes can be included with your permission. Home visits can also be kept private between yourself and the Health Coach if you prefer.

Video Conferences

Every other month, the home visit will include a video conference (a live video call, like Skype or FaceTime) with a UI Health clinical pharmacist. Video conferences will be conducted using an iPad tablet with wireless internet that the Health Coach will bring to the home visit.

The pharmacist will discuss medications, blood sugar, blood pressure, and cholesterol goals. They will ask questions about your

	<p>diabetes, including the medications you take.</p> <p>The pharmacist will discuss your medications with you, help you set new goals, review your home blood sugar levels, ask you about any medication side effects you may be having, and will try to make managing your medications easier for you.</p> <p>The pharmacist will work with your doctor to adjust your medications. If you experience any side effects, your doctor will be informed.</p> <p>Home visits without the videoconference will last 30-45 minutes. Home visits that include the videoconference will last 60-90 minutes in total.</p> <p>Text Messaging</p> <p>As part of this research study, Health Coaches will be in contact with you via text messaging on a regular basis. We will need your telephone number for the cell phone upon which you want to receive text messages. A text messaging computer program will use this number to send you text messages. A welcome text message will be sent to that phone, so you can see the phone number from which your Health Coach will be contacting you.</p> <p>We ask that you respond back immediately by sending a text message. This process is done as a test to make sure that you can receive and respond to future text messages.</p> <p>Your Health Coach will work with you to determine what types of messages you will receive and when they will be sent. This will depend on what your health goals are, your medication regimen, and other needs you may have.</p> <p>For example, your Health Coach may send a text message that reads: “Hello Mr. Marquez, have you had time to check your sugar today?”</p> <p>We hope that these types of text messages will allow Health Coaches to provide better support for you. Your Health Coach will be able to receive text messages that you send as well. No more than seven (7) messages will be delivered weekly, except for optional medication reminders. If you wish to stop receiving text messages all together, you can text in any of the following words: STOP, QUIT, or END at any time.</p>
<p>HOW MUCH TIME WILL I SPEND ON THE STUDY?</p>	<p>Participation in this study will last 24 months. The amount of time involved will vary depending on how many visits you have with the health coach and how many video conferences you have with the pharmacists. The number of visits and length of these visits is up to you to decide with input from your health coach if you chose to</p>

	<p>consider her input. The home visits without the videoconference will last approximately 30-45 minutes. Home visits that include the videoconference will last approximately 60-90 minutes in total.</p> <p>You will be asked to return here after 6, 12, 18, and 24 months to complete surveys, blood tests, height and weight, and blood pressure. Each of these visits will take approximately 60 minutes.</p>
ARE THERE ANY BENEFITS TO TAKING PART IN THE STUDY?	<p>You may not directly benefit from participation in the research. However, the expectations are that you may benefit from the support provided by pharmacists and Health Coaches. The benefits may include improved blood sugar, blood pressure, and cholesterol levels.</p> <p>This study may provide additional, generalizable knowledge regarding the impact of using Health Coaches and mobile health technology to improve pharmacist services for people with diabetes. If this improves blood sugar, blood pressure, and cholesterol levels, then other health organizations that treat similar patients may consider using this approach.</p>
WHAT ARE THE MAIN RISKS OF THE STUDY?	<p>The risks of this study are small. The main risks include:</p> <p>A small risk that your blood sugar levels will run too low or too high when changing your diabetes medication. This is similar to the same risk that occurs when your doctor changes your diabetes medication.</p> <p>A small risk of loss of confidentiality. Your Health Coach will receive training and supervision to help protect your health information. All members of the research team are certified in protecting research participants and have many protective measures in place to keep your information secure.</p> <p>A small risk that you will experience pain or bruising at the site where blood is drawn (less common risks include fainting, the formation of a small blood clot or swelling of the vein and surrounding tissue, bleeding from the site, and infection). The Clinical Interface Core (CIC) employs health professionals who can assist in any unanticipated event.</p> <p>A small risk that you feel annoyed by receiving study text messages. You may always ask to reduce the frequency of text messages sent or stop the messages all together.</p> <p>While unlikely, if a member of the research staff becomes aware that you may be at risk for suicide or serious self-harm, they will need to notify the researchers leading the study. If necessary, they can refer you to an appropriate doctor or the nearest emergency room to ensure your personal safety and wellbeing.</p>

	It is unlikely that any of these risks would result in serious consequences.						
DO I HAVE OTHER OPTIONS BESIDES TAKING PART IN THE STUDY?	You have the option to not participate in this study. Instead, you can receive a brochure about how to take care of your diabetes and continue to be managed by your doctor. As a reminder, you can see a pharmacist to help you with your diabetes without participating in the study.						
QUESTIONS ABOUT THE STUDY?	<p>For questions, concerns, or complaints about the study, please contact the researchers:</p> <table><tr><td>Dr. Ben Gerber</td><td>312-996-8872</td><td>bgerber@uic.edu</td></tr><tr><td>Dr. Lisa Sharp</td><td>312-355-3569</td><td>sharp1@uic.edu</td></tr></table> <p>If you have questions about your rights as a study subject; including questions, concerns, complaints, or if you feel you have not been treated according to the description in this form; or to offer input you may call the UIC Office for the Protection of Research Subjects (OPRS) at 312-996-1711 or 1-866-789-6215 (toll-free) or e-mail OPRS at uicirb@uic.edu.</p>	Dr. Ben Gerber	312-996-8872	bgerber@uic.edu	Dr. Lisa Sharp	312-355-3569	sharp1@uic.edu
Dr. Ben Gerber	312-996-8872	bgerber@uic.edu					
Dr. Lisa Sharp	312-355-3569	sharp1@uic.edu					

Please review the rest of this document for details about these topics and additional things you should know before making a decision about whether to participate in this research. Please also feel free to ask the study team questions at any time.

Who may participate in the study?

You are being asked to participate in the research study because you receive healthcare within the University of Illinois Hospital and Health Sciences System (UI Health) and have diabetes with high blood sugar levels.

Your participation in this research is voluntary. Your decision whether or not to participate will not affect your current or future dealings with the University of Illinois at Chicago (UIC) or UI Health. Approximately 300 subjects may be involved in this research at UIC.

What procedures are involved?

This research will largely take place in your home. We will schedule you for appointments at the UIC Clinical Research Core (912 South Wood Street, Chicago IL 60612; 2nd floor, Room 200 S) to collect information from you at five times over the next 24 months. Today will be the first appointment.

If you agree to be in the study, you will be asked to do the following procedures: First, your medical record will be reviewed to see if you have the hemoglobin A1C level needed to qualify for the study. We will then ensure you are eligible for this study by asking a series of questions.

An important part of this study involves regular home visits from your Health Coach, many of which will include video conferences with the pharmacist. To participate in this study, you must agree to allow the Health Coaches into your home for these monthly home visits.

After signing this consent form and the HIPAA authorization, you will be enrolled in this study. As a participant in “mHealth for Diabetes Adherence Support,” we ask that you participate in three (3) parts of the study. This study will last approximately two years (24 months).

You will be asked a series of questions about yourself, your medications, and use of health care services. Some of the surveys will ask questions that relate to taking care of your diabetes. This information is only being collected for research and will not be shared with others. This will take approximately 60 minutes.

You will be asked a question regarding thoughts of suicide. For example, “Over the past two weeks, have you been bothered by thoughts that you would be better off dead or about hurting yourself in some way?” If the study interviewer believes you might be at risk of hurting yourself, a clinical psychologist will take necessary measures to help you.

We will draw some blood from your arm to measure your Hemoglobin A1C and your cholesterol. You will be asked to fast (you may drink water but may not eat food for 12 hours prior to the test). The amount of blood drawn will be about 6 ml (approximately one teaspoon). Your height, weight, and blood pressure will be measured, similar to how this is done in your doctor’s office.

You will be asked to return here after 6, 12, 18, and 24 months for similar testing (surveys, blood tests, height and weight, and blood pressure).

The second part of the study will include 1 year of receiving your usual care. In addition:

You will be given contact information for a diabetes educator who can help you learn about lifestyle changes you can make to more easily manage your diabetes and blood sugar.

You will also be given contact information for a clinical pharmacist who will help you with your medications.

Finally, you will receive a one-page contact sheet with the names and phone numbers of your local healthcare team, as well as diabetes education information.

The third part of the study will last for 1 year. It includes working with a Health Coach: a representative of your community who specializes in helping our patients bridge the gap between their homes and their health care system. The Health Coach will work with you and your pharmacist in helping you manage your diabetes. This may occur at clinic visits, home visits, or by phone calls or text messages. The Health Coach will talk to you and your pharmacist about the food you are eating, physical activity, medications, and other lifestyle issues relating to diabetes. The overall role of the Health Coach is to work with you to set goals and to help you meet your goals.

Home Visits

You will receive a home visit from your Health Coach once a month, as well as on-going telephone support. Home visits are meant to allow the Health Coach to understand your living environment and to help you make adjustments necessary to better support your diabetes care. We also hope to provide you with education during these visits on topics related to diabetes management.

You can set the terms for who joins in during your home visits. Family members, friends, or others that help you with your diabetes can be included with your permission. Home visits can also be kept private between yourself and the Health Coach if you prefer.

Video Conferences

Every other month, the home visit will include a video conference (a live video call, like Skype or FaceTime) with a UI Health clinical pharmacist. Video conferences will be conducted using an iPad tablet with wireless internet that the Health Coach will bring to the home visit.

The pharmacist will discuss medications, blood sugar, blood pressure, and cholesterol goals. They will ask questions about your diabetes, including the medications you take.

The pharmacist will discuss your medications with you, help you set new goals, review your home blood sugar levels, ask you about any medication side effects you may be having, and will try to make managing your medications easier for you.

The pharmacist will work with your doctor to adjust your medications. If you experience any side effects, your doctor will be informed.

Home visits without the videoconference will last 30-45 minutes. Home visits that include the videoconference will last 60-90 minutes in total.

Text Messaging

As part of this research study, Health Coaches will be in contact with you via text messaging on a regular basis. We will need your telephone number for the cell phone upon which you want to receive text messages. A text messaging computer program will use this number to send you text messages. A welcome text message will be sent to that phone, so you can see the phone number from which your Health Coach will be contacting you.

We ask that you respond back immediately by sending a text message. This process is done as a test to make sure that you can receive and respond to future text messages.

Your Health Coach will work with you to determine what types of messages you will receive and when they will be sent. This will depend on what your health goals are, your medication regimen, and other needs you may have.

For example, your Health Coach may send a text message that reads:

“Hello Mr. Marquez, have you had time to check your sugar today?”

We hope that these types of text messages will allow Health Coaches to provide better support for you. Your Health Coach will be able to receive text messages that you send as well. No more than seven (7) messages will be delivered weekly, except for optional medication reminders. If you wish to stop receiving text messages all together, you can text in any of the following words: STOP, QUIT, or END at any time.

Importantly, you must NOT send health information over text message. Also, the text messaging application is an automated system, so any text messages that you send may not be read immediately. Text messaging should NOT be considered an Emergency Response System. Urgent health questions should be shared with your physician and not sent in a text message.

For the 2 years in this study, 1 year will be spent with assistance from your Health Coach, and 1 year will be spent receiving your usual care with the paper materials we will provide you, as described above. Which year comes first will be decided by chance (like the flip of a coin). At the end of your year with the health coach, you will be given a survey to provide feedback on your experience with the health coach, pharmacist, and video conferences.

What are the potential risks and discomforts?

The risks of this study are small. The main risks include:

A small risk that your blood sugar levels will run too low or too high when changing your diabetes medication. This is similar to the same risk that occurs when your doctor changes your diabetes medication.

A small risk of loss of confidentiality. Your Health Coach will receive training and supervision to help protect your health information. All members of the research team are certified in protecting research participants and have many protective measures in place to keep your information secure.

A small risk that you will experience pain or bruising at the site where blood is drawn (less common risks include fainting, the formation of a small blood clot or swelling of the vein and surrounding tissue, bleeding from the site, and infection). The Clinical Interface Core (CIC) employs health professionals who can assist in any unanticipated event.

A small risk that you feel annoyed by receiving study text messages. You may always ask to reduce the frequency of text messages sent or stop the messages all together.

While unlikely, if a member of the research staff becomes aware that you may be at risk for suicide or serious self-harm, they will need to notify the researchers leading the study. If necessary, they can refer you to an appropriate doctor or the nearest emergency room to ensure your personal safety and wellbeing.

It is unlikely that any of these risks would result in serious consequences.

Will I be told about new information that may affect my decision to participate?

During the course of the study, you will be informed of any significant new research findings (either good or bad), such as changes in the risks or benefits resulting from participation in the research or new alternatives to participation, that might cause you to change your mind about continuing in the study. If new information is provided to you, your consent to continue participating in this study may be re-obtained.

Are there benefits to taking part in the research?

You may not directly benefit from participation in the research. However, the expectations are that you may benefit from the support provided by pharmacists and Health Coaches. The benefits may include improved blood sugar, blood pressure, and cholesterol levels.

This study may provide additional, generalizable knowledge regarding the impact of using Health Coaches and mobile health technology to improve pharmacist services for people with diabetes. If this improves blood sugar, blood pressure, and cholesterol levels, then other health organizations that treat similar patients may consider using this approach.

What other options are there?

You have the option to not participate in this study. Instead, you can receive a brochure about how to take care of your diabetes and continue to be managed by your doctor. As a reminder, you can see a pharmacist to help you with your diabetes without participating in the study.

What about privacy and confidentiality?

The people who will know that you are a research subject are members of the research team, and if appropriate, your physicians and nurses. No information about you, or provided by you, during the research, will be disclosed to others without your written permission, except if necessary to protect your rights or welfare (for example, if you are injured and need emergency care or when the UIC Office for the Protection of Research Subjects monitors the research or consent process) or if required by law. If the researchers become aware of possible child abuse or elder abuse, or that you may cause serious harm to yourself, the researchers may report this to the appropriate authorities.

Study information which identifies you and the consent form signed by you will be looked at and/or copied for examining the research by:

National Institute of Diabetes and Digestive and Kidney Diseases
UIC Office for the Protection of Research Subjects, State of Illinois Auditors, or
The UIC data safety officer for this research.

A possible risk of the research is that your participation in the research or information about you and your health might become known to individuals outside the research. However, many measures have been put in place to prevent this from happening. Information that may be collected about you will be stored in a locked, secure location. Any information stored electronically will be password protected and only those people who need to access your information for this study will have access to it. Messages sent to you may have personal information such as reminders of your health goals. Be aware of who is around you when you read the texts. This will decrease the chance of others reading your messages.

When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity.

During this study, Dr. Gerber and Dr. Sharp and their research team will collect information about you for the purposes of this research. Information collected as part of this research

includes the following:

Collected before you sign consent: Questions about your diabetes and your future plans for leaving Chicago are asked to make sure you qualify for the study.

Blood: We will draw 6 ml (approximately 1 tablespoon) of blood today and each time you come back for data collection at 6, 12, 18, and 24 months. This will be used to measure your hemoglobin A1c and cholesterol.

Blood pressure: We will measure your blood pressure today and each time you come back for data collection. This is to measure if your blood pressure has changed over the course of the study.

Height and weight: We will measure your height and weight today and each time you return to complete the surveys. This is to measure if your weight has changed over the course of the study.

Surveys: We will ask you a series of questions about yourself, your medications, and use of health care services. Some of the surveys will ask questions that relate to taking care of your diabetes. You will be asked a question regarding thoughts of suicide. For example, “Over the past two weeks, have you been bothered by thoughts that you would be better off dead or about hurting yourself in some way?” If the study interviewer believes you might be at risk of hurting yourself, a clinical psychologist will take necessary measures to help you.

Health information from your medical records: If you agree and sign the HIPAA form that will be presented after you sign this form, we will look at your medical information to understand more about your healthcare. That form explains in detail what we will look for. You do not have to sign that form to participate in this study.

Will I receive my results from the study?

We may learn things about you from this study which could be important to your health or treatment. If this happens, this information will be shared with you. We will be measuring your hemoglobin A1c, blood pressure, and cholesterol today and again at 6, 12, 18, and 24 months if you are willing. You can receive the results of those tests by asking the research assistant when they draw take the measures or you can also ask your health coach. We will not routinely share those results unless you ask for them.

What are the potential risks and discomforts of the study?

Side effects, risks, and/or discomforts from participation in this study include:

- A small risk that your blood sugar levels will run too low or too high when changing your diabetes medication. This is similar to the same risk that occurs when your doctor changes your diabetes medication.
- A small risk of loss of confidentiality. Your Health Coach will receive training and supervision to help protect your health information. All members of the research team are certified in protecting research participants and have many protective measures in place to keep your information secure.

- A small risk that you will experience pain or bruising at the site where blood is drawn (less common risks include fainting, the formation of a small blood clot or swelling of the vein and surrounding tissue, bleeding from the site, and infection). The Clinical Interface Core (CIC) employs health professionals who can assist in any unanticipated event.
- *A small risk that you feel annoyed by receiving study text messages. You may always ask to reduce the frequency of text messages sent or stop the messages all together.*
- While unlikely, if a member of the research staff becomes aware that you may be at risk for suicide or serious self-harm, they will need to notify the researchers leading the study. If necessary, they can refer you to an appropriate doctor or the nearest emergency room to ensure your personal safety and wellbeing.
- It is unlikely that any of these risks would result in serious consequences.

There may be risks from the study that are not known at this time.

A risk of this research is a loss of privacy (revealing to others that you are taking part in this study) or confidentiality (revealing information about you to others to whom you have not given permission to see this information).

What about privacy and confidentiality?

Efforts will be made to keep your personal information confidential; however, we cannot guarantee absolute confidentiality. In general, information about you, or provided by you, during the research study, will not be disclosed to others without your written permission. However, laws and university rules might require us to tell certain people about you. For example, study information which identifies you and the consent form signed by you may be looked at and/or copied for quality assurance and data analysis include:

- Representatives of the university committee and office that reviews and approves research studies, the Institutional Review Board (IRB) and Office for the Protection of Research Subjects.
- Other representatives of the State and University responsible for ethical, regulatory, or financial oversight of research.
- Government Regulatory Agencies, such as the Office for Human Research Protections (OHRP).
- The sponsor of the research study, National Institute of Diabetes and Digestive and Kidney Diseases.
- The National Institutes of Health

A possible risk of the study is that your participation in the study or information about you and your health might become known to individuals outside the study. Your personal information and research data will be coded and stored on a password protected computer without any identifying information to prevent access by unauthorized personnel. Text messages sent to you may have personal information such as reminders of your health goals. Be aware of who is around you when you read the texts. This will decrease the chance of others reading your messages.

Your individual data will be stripped of indirect identifiers at the end of the research after results are published.

When the results of the study are published or discussed in conferences, no one will know that you were in the study.

What if I am injured as a result of my participation?

If you get ill or injured from being in the study, UIC will help you get medical treatment. You should let the study doctor know right away that you are ill or injured. If you believe you have become ill or injured from this study, you should contact Dr. Ben Gerber at 312-996-8872.

You should let any health care provider who treats you know that you are in a research study. If you do seek medical treatment, please take a copy of this document with you because it may help the doctors where you seek treatment to treat you. It will also provide the doctors where you seek treatment with information they may need if they want to contact the research doctors.

You or your health insurance plan will be billed. No money has been set aside to pay the costs of this treatment. Health insurance plans may or may not cover costs of research-related injury or illness. You should check with your insurance company before deciding to participate in this research study. [*Include if applicable* – The study staff will assist you in obtaining pre-authorization from your insurance company.] Costs not covered by insurance could be substantial.

UIC has not set aside any money to pay you or to pay for your treatment if you get ill or injured from being in the study. There are no plans for the University to provide other forms of compensation (such as lost wages or pain and suffering) to you for research related illnesses or injuries. The only exception to this policy is if it is proven that your injury or illness is directly caused by the negligence of UIC.

By signing this form, you are not giving up any legal rights to seek compensation of injury.

What are the costs for participating in this research study?

There are no costs to you for participating in this research study. Standard co-pays and fees for usual medical care still apply. However, the pharmacist and Health Coach services will be provided free of charge, as will the blood draws.

Will I be reimbursed for any of my expenses or paid for my participation in this research study?

You will receive \$30 for each completed study visit at the Clinical Interface Core (CIC). This is for the time taken for blood testing and answering surveys.

If you are assigned a health coach in the first year of the study:

- At 6 months, you will receive an extra \$50 if you complete at least one videoconference with the pharmacist between baseline and 6 months.

- At 12 months, you will receive an extra \$50 if you complete at least one videoconference with the pharmacist between 6 and 12 months.

If you are assigned a health coach in the second year of the study:

- At 18 months you will receive an extra \$50 if you complete at least one videoconference with the pharmacist between 12 and 18 months.
- At 24 months you will receive an extra \$50 if you complete at least one videoconference with the pharmacist between 18 and 24 months.

Everyone will spend one year receiving only their usual care without a health coach.

Blood draw and Survey Visits					
	Baseline	6 month	12 month	18 month	24 month
Health coach in Year 1	\$30	\$30	\$30	\$30	\$30
		(+ \$50 for 1 videoconference)	(+ \$50 for 1 videoconference)		
Health coach in Year 2	\$30	\$30	\$30	\$30	\$30
				(+ \$50 for 1 videoconference)	(+ \$50 for 1 videoconference)

If you do not finish the study, you will only be compensated for the visits you have completed. You will only receive reimbursements at the CIC. If you complete the study, attending all five visits at the CIC and have completed videoconferences with the pharmacist as described above, you will receive a total of \$250.

Will I be told about new information that may affect my decision to participate?

During the course of the study, you will be informed of any significant new research findings (either good or bad), such as changes in the risks or benefits resulting from participation in the research or new alternatives to participation, that might cause you to change your mind about continuing in the study. If new information is provided to you, your consent to continue participating in this study may be re-obtained.

Can I withdraw or be removed from the study?

If you decide to participate, you have the right to withdraw your consent and leave the study at any time without penalty.

The researchers and sponsor also have the right to stop your participation in this study without your consent if:

- They believe it is in your best interests;
- You were to object to any future changes that may be made in the study plan.

If you choose to no longer be in the study and you do not want any of your future health information to be used, you must inform Dr. Ben Gerber in writing at the address on the first page. Dr. Gerber may still use your information that was collected prior to your written notice.

What if I am a UIC student?

You may choose not to participate or to stop your participation in this research at any time. This will not affect your class standing or grades at UIC. The investigator may also end your participation in the research. If this happens, your class standing or grades will not be affected. You will not be offered or receive any special consideration if you participate in this research.

What if I am a UIC or UI Health employee?

Your participation in this research is in no way a part of your university duties, and your refusal to participate will not in any way affect your employment with the university, or the benefits, privileges, or opportunities associated with your employment at UIC. You will not be offered or receive any special consideration if you participate in this research

Remember:

Your participation in this research study is voluntary. Your decision whether or not to participate will not affect your current or future relations with the University. If you decide to participate, you are free to withdraw at any time without affecting that relationship.

Signature of Subject

I have read (or someone has read to me) the above information. I have been given an opportunity to ask questions and my questions have been answered to my satisfaction. I agree to participate in this research study. I will be given a copy of the signed and dated form.

Signature

Date

Printed Name

[Required]

Signature of Person Obtaining Consent

Date (must be same as subject's)

Printed Name of Person Obtaining Consent