COVER PAGE

Study Number: NCT04874415

Study Title: Behavioral Economics for Activity Motivation in Adolescents (BEAM)

PI: Mary Ellen Vajravelu, MD MSHP

Informed Consent

Date Approved: 3/31/2022

UPMC | CHILDREN'S HOSPITAL OF PITTSBURGH

Informed Consent to Participate in a Research Study,

HIPAA Authorization Form

Study Title: **Behavioral Economics for Activity Motivation in Adolescents and Young Adults with Prediabetes and Type 2 Diabetes Trial**

Version Date: July 2, 2021

Principal Investigator: Mary Ellen Vajravelu, MD MSHP Email: MaryEllen.Vajravelu@pitt.edu

Study Sponsor: National Institutes of Health

You, or your child, may be eligible to take part in a research study. This form gives you important information about the study. It describes the purpose of this research study, and the risks and possible benefits of participating.

In the sections that follow, the word "we" means the study doctor and other research staff. If you are a parent or legal guardian who is giving permission for a child, please note that the word "you" refers to your child.

Your physician may be involved as an investigator in this research study. Before agreeing to participate, or at any time during your study participation, you may discuss your care with another doctor who is not associated with this research study. You are not under any obligation to participate in any research study offered by your physician.

KEY INFORMATION

You are being asked to take part in this research study because you are between the ages of 13-22 years old and have prediabetes or type 2 diabetes.

The purpose of this research study is to find out if using text messages can help to motivate teens and young adults with prediabetes or type 2 diabetes to move and exercise more.

Study visits will be in person and over the phone. You will be asked to come to UPMC Children's Hospital of Pittsburgh (CHP) for 2 study visits. If you enroll, you will take part for up to 17 weeks. You will be asked to:

- Complete questionnaires,
- Complete interviews,
- Fast overnight for a minimum of 12 hours before in-person study visits
- Have research blood draws.
- Wear a Fitbit physical activity tracker when you are awake,

- Receive text messages on your smartphone,
- Complete dietary recalls by phone (where you answer questions about the foods you have eaten)

The main risks of this study are from the overnight fast prior to the blood draw, which may include an upset stomach, a headache, feeling light-headed, or low blood sugar if you take insulin.

You may benefit directly from being in this study by helping you to increase how much you move and exercise. There are many benefits to being more active and it is recommended for all people with prediabetes or type 2 diabetes. You also may benefit from the blood testing in the study by being aware of your results and needed actions.

If there is anything in this form you do not understand, please ask questions. Please take your time. You do not have to take part in this study if you do not want to. If you take part, you can leave the study at any time. If you do not choose to take part in this study, you can discuss treatment options with your doctor.

Please see below for additional details about the study.

What is the current standard of treatment for this disease?

Healthy lifestyle, including daily physical activity, is the main treatment for prediabetes. It is also a very important part of treatment for type 2 diabetes. Type 2 diabetes may also be treated with medications.

What is involved in the study?

We are testing a program to help young people with prediabetes or type 2 diabetes increase their daily physical activity. This program will include text messages, money given for achieving activity goals, and different strategies for setting activity goals. You will be assigned by chance to a combination of different text messages that vary in how often they are sent, money rewards, and goal setting strategies.

What are the study procedures?

Some of the procedures in this study will be repeated several times. Tests that are part of your regular, routine medical care will continue to be performed. The study involves the following tests and procedures:

Experimental Procedures:

Intervention: We will ask you to wear a Fitbit physical activity tracker on your wrist every day while awake for 14 weeks. The study goal is for you to meet step count goals, measured using the Fitbit. You can increase your steps in any way you want, including walking, jogging, running, or other exercise involving stepping or jumping. We will also ask you to respond to a text message once a week with a screenshot of your phone's activity tracker showing your weekly step count.

Routine Clinical Trial Procedures:

Interviews: A team member will take your complete medical history, family and social history, and a listing of any medications you are taking. Throughout the study, you will be asked to report if you think that anything bad has happened as a result of the study. At the end of the study, you will be asked for feedback on your experience.

Questionnaires: During the study visits, a member of the study team will guide you through filling out questionnaires. You may either read and answer the questionnaires yourself, or a staff person can read each survey out loud to you, and you will let that person know your answers.

Implementation Intention Statement: During the first study visit, a member of the study team will work with you to form an *Exercise Plan*. This is a specific plan to help you increase your physical activity in a way that works for you. The study team member will ask about your favorite physical activities, when you plan to do them, and things that may get in the way of your plans. This information will be used to make a "statement" (written plan) that you can refer to and change as needed during the study. Writing down what you want to do and having support from the study team can help you reach your goal.

Diet Assessment: A nutritionist will be in contact with you by phone/email to record the type/amount of food/drinks you ate during the last 24 hours 3 times during the study (2 times to report on weekdays and 1 time for a weekend day).

Review of Medical Records: With your permission, we will collect information from your medical record for the study. The purpose is to be sure that we collect all important and accurate information about your medical history including, any illness or medication use. We wil enter the blood test results from this study in your medical record.

Overnight Fast: You will not be able to eat or drink anything except plain unflavored water after 8:00 PM the night before the on-site study visits. You may eat after the blood draw is completed at each study. If you take insulin, we will ask you to check your blood sugar at home before coming to the study visit. If you blood sugar is low (less than 70 mg/dL), you will be asked to treat the low sugar as you would normally and reschedule the study visit.

Physical Examination: We will measure your weight, height, blood pressure, heart and breathing rate at the visits. The study doctor will also check how you are progressing in puberty by examining breast development (in girls/ women) or testicular size (in boys/men). You may refuse the exam you if you are uncomfortable.

Pregnancy Test: If you are pregnant, you will not be allowed to participate in this study. You will be asked to take a urine pregnancy test before starting this study.

The results will be shared with you and not with your parent(s). We strongly encourage you to share the results with your parents. If you are found to be pregnant, you will not be able to continue participation in the study.

Fasting blood sample: We will do a blood draw of about 2 teaspoons; the tests will include blood sugar, cholesterol and fat levels and hemoglobin A1c. Hemoglobin A1c is a measure of your average blood sugar over the past 2-3 months. The study team will inform you if any of the tests are in the abnormal range. With your permission we can send the results to your doctor. We will try not to stick you more than once.

Visit Schedule

The table below provides a brief description of the purpose and duration of each study visit.

Visit	Purpose	Main Procedures	Duration
Screening	Determine eligibility	Medical history review	15 minutes
Visit 1	Baseline measurements	Laboratory measurements, history, physical exam, questionnaires	1-1.5 hours
At home, 2 weeks	Measure baseline activity	Wear Fitbit and sync it daily for 14 days in a row while awake	2 weeks
Visit 2 (phone), Day 0	Assign step count goal; start 12-week intervention	Phone call with team member	10-15 minutes
At home, 12 weeks	Text messaging program	Wear Fitbit while awake and sync it daily	12 weeks
Visit 3, Intervention week 2	Safety check	Review any safety concerns by phone	5-10 minutes
Visit 4, Intervention week 6	Routine Visit and safety check	Troubleshoot Fitbit use, review step count goal; review any safety concerns by phone	10-15 minutes
Dietary recall, Intervention weeks 1-2	Assess nutrition	Dietary recall with study nutritionist by phone; 3 times during intervention	30 minutes each
Visit 5 , within 2 weeks of intervention end	End of Study	Laboratory measurements, history, physical exam, questionnaires, exit interview; return Fitbit	1-2 hours

What will be done with my data and specimens during this study?

During the study, we will collect blood samples from you. By agreeing to participate in the study, you agree to give these samples to Children's Hospital of Pittsburgh for research purposes.

Will I receive any results from the tests done as part of this study?

Results that could be important for your clinical care will be shared with you, as described above. We will not share other results with you.

What are the risks of this study?

Taking part in a research study involves inconveniences and risks. The main risks of taking part in this study are discussed below.

Risks associated with engaging in physical activity:

Risks could include physical discomfort or injury. If you take insulin, there is a very small risk of low blood sugar (hypoglycemia) during physical activity. To minimize risk of harm due to hypoglycemia, you should check your blood sugar (and treat if needed) as recommended by your endocrinologist or if you have symptoms that suggest hypoglycemia.

Risks of blood tests:

Taking blood may cause some pain, bleeding or bruising at the spot where the needle enters your body. Rarely, taking blood may cause fainting or infection.

Risks associated with overnight fast:

A 12 hour fast may cause you to have an upset stomach, a headache, or feel light-headed in the morning before the visit. These symptoms are uncomfortable but not serious. If you take insulin, you may also be at risk for having a low blood sugar, which can make you feel shaky, sweaty, overly hungry, irritable.

Risks associated with physical exam and blood pressure measurement:

There are no physical risks but you might experience momentary embarrassment or discomfort. The exam is similar to those that are performed as part of routine medical care. When blood pressure is taken during the physical exams, the blood pressure cuff may cause discomfort or bruising to the upper arm.

The exam of your pubertal status may make you uncomfortable. You may stop the exam at any time. To minimize this possibility, the exam is done in private by a health professional skilled in determining pubertal status. In addition, you will be asked in advance if you prefer to have your parent/guardian present when the puberty exam is done.

Risks associated with wearing a Fitbit:

You may experience discomfort related to wearing the Fitbit. It is uncommon but sometimes the band can irritate your skin.

Interview and questionnaires:

There are no physical risks but you might experience momentary embarrassment or discomfort. You do not have to answer any questions that make you too uncomfortable.
Breach of Privacy and Confidentiality:

As with any study involving collection of data, there is a possibility that someone could see your private information who does not have permission. This is called a breach of confidentiality. Every precaution will be taken to secure your personal information to

ensure confidentiality. When you sign this consent form, you will be assigned a study identification number. This number will be used on data collection forms, blood samples, and in the database instead of names and other private information. A separate list will be maintained that links each participant's name to the study identification number for future reference and communication.

Although every reasonable effort has been taken, confidentiality during Internet communication activities cannot be guaranteed. It is possible that additional information beyond that collected for research purposes may be captured and used by others not associated with this study.

You should also know that text messages are not encrypted or secure when they are sent, and they could be captured by someone who is not authorized.

Are there any benefits to taking part in this study?

There is a potential for the study to benefit you by increasing motivation and by doing more physical activity. This is recommended for all individuals, including those with prediabetes or type 2 diabetes. However, we cannot guarantee or promise that you will receive any direct benefit by participating in this study. You also may benefit from getting results from the blood tests.

The knowledge gained from this research may help doctors better understand how to use text message interventions to help youth with prediabetes or type 2 diabetes become more physically active. The results of this study may change how we care for teens and young adults who struggle with exercise and prediabetes or type 2 diabetes.

Do you need to give your consent in order to participate?

If you decide to participate in this study, you must sign this form. A copy will be given to you to keep as a record.

What are your responsibilities?

Please consider the study time commitments and responsibilities as a research subject when making your decision about participating in this study. You will need to follow the study doctor's instructions, keep all study appointments and participate in the study as directed.

What happens if you decide not to take part in this study?

Participation in this study is voluntary. You do not have to take part in order to receive care at Children's Hospital of Pittsburgh.

If you decide not to take part or if you change your mind later there will be no penalties or loss of any benefits to which you are otherwise entitled.

Can you stop your participation in the study early?

You can stop being in the study at any time. You do not have to give a reason.

Can the study doctor take you out of the study early?

The study doctor may take you off of the study if:

- You are no longer able to safely walk.
- The study is stopped.
- You cannot meet all the requirements of the study.
- New information suggests taking part in the study may not be in your best interests.

What choices do you have other than this study?

There are options for you other than this study, including not participating in this study. You may discuss other options available to you with your doctor.

What about privacy, authorization for use of Protected Health Information (PHI) and confidentiality?

As part of this research, we will collect information from your medical record at CHP, including prior tests, physical exams, medication use and past medical history. We will enter information from the study intoyour CHP medical record, include physical exams or tests done in the clinical lab. We will do our best to keep your personal information private and confidential. However, we cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law.

The results of this study may be shown at meetings and published in journals to inform other doctors and health professionals. We will keep your identity private in any publication or presentation.

Several people and organizations may review or receive your identifiable information. They will need this information to conduct the research, to assure the quality of the data, or to analyze the data or samples. These groups include:

- Members of the research team and other authorized staff at Children's Hospital of Pittsburgh and the University of Pittsburgh Office of Research Protections
- People from agencies and organizations that perform independent accreditation and/or oversight of research; such as the Department of Health and Human Services Office for Human Research Protections.
- Individuals monitoring the safety of this study;
- The National Institutes of Health who is sponsoring this research

By law, CHP is required to protect your health information. The research staff will only allow access to your health information to the groups listed above. By signing this document, you are authorizing CHP to use and/or release your health information for this research. Some of the organizations listed above may not be required to protect your information under Federal privacy laws. If permitted by law, they may be allowed to share it with others without your permission.

There is no set time for destroying the information that will be collected for this study. Your permission to use and share the information and data from this study will continue

until the research study ends and will not expire. Researchers continue to analyze data for many years and it is not possible to know when they will be completely done.

Certificate of Confidentiality (CoC)

A Certificate of Confidentiality (CoC) covers this research. A CoC helps protect your identifiable information and biological samples.

A CoC protects your private information from all legal proceedings. Unless you consent, information from this research study that identifies you will not be shared outside this research.

- No one can be forced to share your identifiable information or biological samples for a lawsuit.
- Your information can't be used as evidence even if there is a court subpoena.

If you consent, your data or biological samples could be shared for:

- other scientific research;

The CoC does not prevent some disclosures.

- The researchers can't refuse requests for information from those funding this research. The NIH may need information to assess this project.
- You can still share information about yourself. You can also freely discuss your involvement in this research.
- The researchers must disclose things required by law. This includes suspected child abuse and neglect, harm to self or others, or communicable diseases.

Can you change your mind about the use of personal information?

You may change your mind and withdraw your permission to use and disclose your health information at any time. You must inform the study team in writing. Please send your request to

Dr. Mary Ellen Vajravelu
Children's Hospital of Pittsburgh
Division of Pediatric Endcrinology, Diabetes, and Metabolism
One Children's Hospital Drive
4401 Penn Avenue Pittsburgh, PA 15224

MaryEllen.Vajravelu@pitt.edu

In the letter, state that you changed your mind and do not want any more of your health information collected. The personal information that has been collected already will be used if necessary for the research. No new information will be collected. If you withdraw your permission to use your personal health information, you will be withdrawn from the study.

Financial Information

While you are in this study, the cost of your usual medical care – procedures, medications and doctor visits – will continue to be billed to you or your insurance.

Will there be any additional costs?

There will be no additional costs to you by taking part in this study.

Will you be paid for taking part in this study?

- Participants will be paid up to $40 for travel or parking ($20 per study visit).
- Participants will be paid up to $125 for their time and effort, in addition to up to $98 in financial incentives for wearing the Fitbit daily or achieving step count goals. Time and effort compensation will be for attending study visits, completing dietary recalls, and returning the Fitbit when requested.

You will be paid on a reloadable debit card. Your name, address, and social security number will be released to the Accounting Office. All compensation is taxable income to the participant. If you receive $600 or more in a calendar year from one organization, that organization is required by law to file a Form 1099 – Miscellaneous with the IRS and provide a copy to the taxpayer. Individuals who do not provide a social security number may still participate in the research, but the IRS requires that 24% of the payment be sent by the institution to the IRS for 'backup withholding;' thus you would only receive 76% of the expected payment.

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What if you have questions about the study?

If you have questions about this study or how your samples/data are going to be used, email the study doctor, Dr. Mary Ellen Vajravelu at MaryEllen.Vajravelu@pitt.edu. You may also talk to your own doctor if you have questions or concerns.

The Institutional Review Board (IRB) at the University of Pittsburgh has reviewed and approved this study. The IRB looks at research studies like these and makes sure research subjects' rights and welfare are protected. If you have any questions about your rights as a research subject or wish to talk to someone other the research team, please call the University of Pittsburgh Human Subjects Protection Advocate toll-free at 866-212-2668.

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 will be done with my data and specimens when this study is over?

We will use and may share data and/or specimens for future research. They may be shared with researchers/institutions outside of CHP including federal repositories. This could include for profit companies. We will not ask for your consent before using or sharing them. We will remove identifiers from your data and/or specimens, which means that nobody who works with them for future research will know who you are. Therefore, you will not receive any results or financial benefit from future research done on your specimens or data.

None is planned for the current study but your samples may undergo genetic analysis in the future. This could include whole genome sequencing ("WGS"). WGS is identifying your unique genetic code from your biological parents.

There are risks to collecting genetic information. Genetics can tell us many things. It can confirm who your parents are by blood tests and if you are more likely to get certain diseases. This is confidential information. Whenever this information is stored, there is always a small chance someone can view it that is not supposed to. This is called a breach of confidentiality and is against the law. In some cases, it could be used to make it harder for you to get or keep a job, or insurance. Genetic information about diseases that some people have negative opinions about could be used in ways that could cause you or your family distress.

We protect you from this by taking your name or anything else that could identify you from the test results. The computer that holds the information has extra security with passwords. We limit how many people on the study team can know the password.

In addition, a federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get from this research.
- Health insurance companies and group health plans may not use your genetic information that we get from this research when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

Be aware that this new federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance, nor does it protect you against genetic discrimination by all employers. GINA does not protect you against discrimination from genetic diagnoses that were already known.

Consent to Inform Your Doctors of Your Study Participation (OPTIONAL)

Please indicate whether you would like us to inform your non-CHP doctor(s) of your participation in this study. Please note that this only applies to non-CHP doctors, as research results will be included in your medical record at CHP.

_____ (initials) I request that my non-CHP doctor(s) **not** be informed of my participation in this study.

_____ (initials) I request that my non-CHP doctor(s) be informed of my participation in this study.

VOLUNTARY CONSENT

By signing this form, you are indicating that you have had your questions answered, you agree to take part in this research study and you are legally authorized to consent to your/your child's participation. You are also authorizing the use of your/your child's medical record information as discussed above. If you don't agree to the collection, use and sharing of medical record information, you cannot participate in this study.

NOTE: *A foster parent is not legally authorized to consent for a foster child's participation.*

_____

Name of Subject

_____ _____

Signature of Subject (18 years or older) Date

_____ _____

Name of Authorized Representative (if different than subject)

Relation to subject:
☐ Self ☐ Parent ☐ Legal Guardian

_____ _____

Signature of Authorized Representative Date

Child Assent to Take Part in this Research Study

I have explained this study and the procedures involved to _____ in terms he/she could understand and that he/she freely assented to take part in this study.

_____

Person Obtaining Assent

_____ _____

Signature of Person Obtaining Assent Date

This study has been explained to me and I agree to take part.

_____ _____

Signature of Subject Date

INVESTIGATOR CERTIFICATION:

I certify that I have explained the nature and purpose of this research study to the abovenamed individual(s), and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions, concerns or complaints as they arise. I further certify that no research component of this protocol was begun until after this consent form was signed.

_____	_____
Printed Name of Person Obtaining Consent	Role in Research Study

_____	_____
Signature of Person Obtaining Consent	Date

CONSENT FOR CONTINUED RESEARCH PARTICIPATION

I understand that I am currently participating in a research study. I further understand that consent for my participation in this research study was initially obtained from my authorized representative since I was unable to provide direct consent at the time that this initial consent was requested. I have now turned age 18 and I am able to provide direct consent for continued participation in this research study.

The above information has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions, voice concerns or complaints about any part of this research study during the course of this study. Future questions, concerns or complaints will be answered by a qualified person or by an investigator listed on the first page of this consent document at the telephone number(s) given.

I understand that I may always request that my questions, concerns or complaints be addressed by a listed investigator. I understand that I may contact the Human Subjects Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668) to discuss problems, concerns, and questions; obtain information; offer input; or discuss situations in the event that the research team is unavailable. I agree to participate in this research study and provide my authorization for the use of my medical records.

By signing below, I agree to continue my participation in this research study. A copy of this consent form will be given to me.

Participant's Signature_____ Date_____