TITLE OF RESEARCH STUDY:

Title: TEEN HEED: An Adolescent Peer Education Intervention to Prevent Diabetes

PRINCIPAL INVESTIGATOR (HEAD RESEARCHER) NAME AND CONTACT INFORMATION:

Name: Dr. Nita Vangeepuram

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WHAT IS A RESEARCH STUDY?

A research study is when scientists try to answer a question about something that we don't know enough about. Participating may not help you or others.

People volunteer to be in a research study. The decision about whether or not to take part is totally up to you*. You can also agree to give permission for your child to take part now and later change your mind. Whatever you decide is okay. It will not affect your ability, or your child's ability, to get medical care within the Mount Sinai Health System.

Someone will explain this research study to you. Feel free to ask all the questions you want before you decide. Any new information that develops during this research study which might make you change your mind about your child's participating will be given to you promptly.

Basic information about this study will appear on the website http://www.ClinicalTrials.gov. There are a few reasons for this: the National Institutes of Health (NIH) encourages all researchers to post their research; some medical journals only accept articles if the research was posted on the website; and, for research studies the U.S. Food and Drug Administration (FDA) calls "applicable clinical trials" 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.

PURPOSE OF THIS RESEARCH STUDY:

The purpose of this study is to understand whether adolescents who are at high-risk for diabetes will be more likely to lose weight and keep from getting diabetes if they take part in peer education workshops. "Pre-diabetes" is when people have blood sugar levels that are higher than normal, but not high enough to be called diabetes. Most people with pre-diabetes will get diabetes, but if people with pre-diabetes who are overweight can lose weight, most can prevent or delay getting diabetes. Peer education workshops are sessions about healthy lifestyles and diabetes prevention led by trained adolescents supervised by experienced adults.

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*Throughout this document "child" refers to a minor under applicable state law and "you" refers to any individual who may legally act on the minor's behalf (e.g. parent or legal guardian)

Your child may qualify to take part in this research study because he/she is an adolescent at risk for diabetes.

Funds to do this research are provided by the National Institutes of Health.

LENGTH OF TIME AND NUMBER OF PEOPLE EXPECTED TO PARTICIPATE

Your child will be asked to attend 12 virtual workshop sessions through a web platform called Zoom. Your child may also receive text messages every week. Text messages will focus on setting weekly goals, tracking diet and physical activity behaviors, motivation, and providing support and guidance to help your child make healthy choices. At the end, your child will be asked to attend a feedback session to provide his/her feedback about the virtual workshop and text messaging program. Your child's participation in this research study is expected to last about 4 months.

The number of people expected to take part in this virtual research study is 50.

DESCRIPTION OF WHAT'S INVOLVED:

If you agree to permit your child's participation in this research study, the following information describes what may be involved.

Because your child answered some screening questions and because his/her weight is above the recommended range for his/her age, he/she is eligible to be in this study. If you and your child decide you would like to take part, we will read this form with you, answer any questions you have and make sure you understand this form and the research we are doing.

During the study visits, we will ask him/her to answer some questions about his/her health, the kinds of food he/she eats, and the types of exercises he/she does. We will check his/her blood pressure, measure the size of his/her waist, and get measurements of his/her body fat using a special scale. We will to do blood tests to measure things related to risk of diabetes including hemoglobin A1c and a lipid panel.

If you decide to allow your child to be part of this study after you read and sign this consent form, he/she will be asked to attend 12 virtual workshop sessions through a web platform called Zoom. Your child may also receive text messages every week. Text messages will focus on setting weekly goals, tracking diet and physical activity behaviors, motivation, and providing support and guidance to help your child make healthy choices. At the end, your child will be asked to attend a feedback session to provide his/her feedback about the virtual workshop and text messaging program. If you agree that your child may take part in this study, your child will complete these study related activities:

Your child will provide an email address where we are able to send a link to a web platform called Zoom. Each week, your child will receive a personal message about the workshop session that will take place via Zoom meeting. At each workshop your child will learn and discuss with our trained peer leaders and other participants through a curriculum targeted to adolescents at-risk for diabetes.

The peer-led workshops will be held via Zoom. Your child may join the virtual workshop from any location where he/she can follow social distancing guidelines and has internet access. The workshop will teach your child how to lose weight by eating healthy and exercising, so he/she can prevent or delay diabetes and other health problems. The workshop has 12 sessions that will each last about 1½ hours and will have about 10-15 adolescents in each session. The workshop will be led by a trained peer leader and an adult supervisor.

With your permission, we will send text messages to your child through our partnership with mPulse Mobile (a mobile technology company). Text messages will focus on setting weekly goals, tracking diet and physical activity behaviors, motivation, and providing support and guidance to help your child make healthy choices. Communication with the research team through mPulse mobile is secure. Standard text messaging (SMS) and data rates from your mobile provider will apply.

Do you consent for the researchers to collect and give your child's phone number to mPulse mobile for participation in the text messaging portion of this study, and future communication? Please initial below:

Yes________ No_________

After the program and follow ups are complete, we will ask your child to take part in a debriefing session so that he/she can give feedback about the program. The discussions will be audio taped with a digital recording device. The recording will be transcribed. The transcript will not include your child's name but will instead identify each participant speaking as "Boy #1" or "Girl #1" etc. You may give consent for your child to participate in the study even if you do not give consent for participation in the audiotaped debriefing session.

Will you allow your child to take part in the audiotaped debriefing session? Please initial below:

Yes________ No_________

RESPONSIBILITIES FOR PARTICIPATING IN THIS RESEARCH:

If you decide to permit your child to take part in this research study, your child would be responsible for the following things:

- Attending peer education workshops online via Zoom.
- With your consent your child may receive 12 weeks of text messaging from mPulse mobile.

COSTS OR PAYMENTS THAT MAY RESULT FROM PARTICIPATION:

There will be no financial costs to you or your child to participate in this study. However, standard text messaging (SMS) and data rates from your mobile and internet provider will apply.

Tax law may require the Mount Sinai Finance Department to report the amount of payment received from Mount Sinai to the Internal Revenue Service (IRS) or other agencies, as applicable. Generally this reporting would take place if payments received equal $600 or more from Mount Sinai in a calendar year. You would be responsible for the payment of any tax that may be due.

POSSIBLE BENEFITS:

It is important to know that your child may not get any benefit from taking part in this research. Others may not benefit either. However, the workshop may help your child prevent or delay diabetes by losing weight, and he/she may learn more about healthy eating and exercise. By taking part, your child may also help researchers design better ways to help people prevent diabetes or to lose weight. In this way, it may help others in the future.

REASONABLY FORESEEABLE RISKS AND DISCOMFORTS:

It is always possible to lose private information your child gives us. However, there are procedures in place to minimize this risk. Your child’s research records will be kept confidential (private) and will be stored under a special code (identification) number. It will not be stored under your child’s name. The list that has both your child’s name and the identification number will be kept in a locked cabinet in a locked room, or will be securely stored electronically. People who work on this study must sign a form saying that they will keep private the information of the people in the study. Any information we collect will be combined with all the other study participants’ answers for researchers to analyze. Names or other personal information will never be used. Zoom also has many security measures in place including using a unique password for each meeting and authentication measures to ensure that only those associated with TEEN HEED are in the virtual meeting. Study information may be printed in a scientific magazine or presented at a scientific meeting or used by other researchers, but no names of participants are included in these presentations or writing.

OTHER POSSIBLE OPTIONS TO CONSIDER:

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You may decide not to permit your child to take part in this research study without any penalty. The choice is totally up to you. If your child wishes to try and lose weight but doesn't want to participate in this study, we can provide you with educational materials and local resources and encourage you to speak with your child's regular doctor. If your child does not have a regular doctor, we can provide you with a list of local health care providers.

IN CASE OF INJURY DURING THIS RESEARCH STUDY:

If you believe that your child has suffered an injury related to this research as a participant in this study, you should contact the Principal Investigator, Dr.Nita Vangeepuram by phone at 917-478-2106.

ENDING PARTICIPATION IN THE RESEARCH STUDY:

You may decide to stop your child's participation in this research study at any time without any penalty. This will not affect your or your child's ability to receive medical care at any of the Mount Sinai Health System hospitals, or wherever he/she receives medical care, or to receive any benefits to which you, or your child, are otherwise entitled.

If you decide to stop your child's participation in the research study, please contact the Principal Investigator or the research staff.

You may also withdraw your permission for the use and disclosure of any of your child's 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 authorization, the Principal Investigator for the research study may still use the information that was already collected if that information is necessary to complete the research study. Your child's health information may still be used or shared after you withdraw your authorization if your child has an adverse event (a bad effect) from participating in the research study.

Withdrawal without your permission: The study doctor, the sponsor or the institution may stop your child's involvement in this research study at any time without your permission. 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 child's best interest, or for any other reason. If specimens or data have been stored as part of the research study, they too can be destroyed without your permission.

CONTACT PERSON(S):

If you have any questions, concerns, or complaints at any time about this research, or you think the research has hurt your child, please contact Dr.Vangeepuram at 917-478-2106.

This research has been reviewed and approved by an Institutional Review Board. You may reach a representative of the Program for the 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 Health System:

- 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 rights of research subjects.
- You want to get information or provide input about this research.

DISCLOSURE OF FINANCIAL INTERESTS:

The research team has no financial interests to disclose. 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.

MAINTAINING CONFIDENTIALITY – HIPAA AUTHORIZATION:

As your child takes part in this research project it will be necessary for the research team and others to use and share some of your child's 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.

<u>What protected health information is collected and used in this study, and might also be disclosed (shared) with others?</u>

As part of this research project, the research team at the hospital(s) involved in the research will collect your child's name, address, telephone number, email address, and date of birth.

During the study the researchers will gather information by:

- Discussions during the workshops via Zoom
- Answers to surveys and questions during the debriefing session
- Administering questionnaires on diet and exercise habits and other factors that may be related to diabetes risk
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Why is your child's protected health information being used?

Your personal contact information, and that of your child, is important to be able to contact you during the study. Your child's 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 your child is, unless you give separate permission to do so.

The research team and other authorized members of The Mount Sinai Health System ("Mount Sinai") workforce may use and share your child's 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 child's information. If any payments for taking part in this study, the Mount Sinai Finance Department may need names, addresses, social security numbers, payment amounts, and related information for tax reporting purposes. If the research team uncovers abuse, neglect, or reportable diseases, this information may be disclosed to appropriate authorities.

Who, outside Mount Sinai, might receive your child's protected health information?

As part of the study, the Principal Investigator, study team and others in the Mount Sinai workforce may disclose your child's 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.)

- The sponsoring government agency and/or their representative who need to confirm the accuracy of the results submitted to the government or the use of government funds: the National Institutes of Health
- The United States Department of Health and Human Services and the Office of Human Research Protection.

In all disclosures outside of Mount Sinai, you will not be identified by name, address, telephone number, date of birth, 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 your child 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 child's privacy. It is possible that a sponsor or their representatives may come to inspect your child's 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 for Human Research Protections (OHRP) and the Food and Drug Administration (FDA) will be granted direct access to your child's 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 tasks. By signing this document you are authorizing this access. We may publish the results of this research. However, we will keep your child's name and other identifying information confidential.

For how long will Mount Sinai be able to use or disclose your child's protected health information? Your authorization for use of your child's protected health information for this specific study does not expire.

Will you be able to access your child's records?

During participation in this study, you will have access to your child's medical record and any study information that is part of that record. The investigator is not required to release research information that is not part of your child's medical record to you.

Do you need to give us permission to obtain, use or share to you or your child health information?

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

Can you change your mind?

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

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

If as part of this research project your child's medical records are being reviewed, or your child's 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 child's 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 child's HIV-related information without authorization. If you or your child 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.

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Signature Block for Research Involving Children

Your signature documents your permission for the child named below to take part in this research and to the use and disclosure of this child's protected health information. A signed and dated copy will be given to you.

DO NOT SIGN THIS FORM AFTER THIS DATE →

Printed name of child	Date
Signature of parent or guardian	Time
Printed name of parent or guardian	☐ Parent ☐ Guardian (May provide permission only if legally authorized to consent to the child's general medical care.)

Person Explaining Study and Obtaining Consent

Signature of person obtaining consent	Date
Printed name of person obtaining consent	Time

If a witness is required to observe the consent process , document below:

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 parent(s)/guardian, and that permission was freely given.

Signature of witness to consent process	*Date*
Printed name of person witnessing consent process	*Time*

Assent
- ☐ Obtained
- ☐ Not obtained because the capability of the child is so limited that the child cannot reasonably be consulted

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This Section For IRB Official Use Only

This Consent Document is approved for use by an Institutional Review Board (IRB)

Form Approval Date: 5/31/2022 DO NOT SIGN AFTER THIS DATE → 5/30/2023