Noom Health for Weight Management
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NCT04797169
Document Date: 9/26/2023

STUDY ID#: STUDY-20-01299M **Form Version Date: 02/10/2021**

STUDY INFORMATION:

Study Title: Noom Health for Weight Loss

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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 within the Mount Sinai Health System.

The purpose of this research study is to examine the effect of the Noom Health platform in comparison to the Noom Digital Health intervention for helping people to lose weight and increase their adherence to diet and exercise recommendations. By measuring how these programs work over time, we will be able to understand more about the elements needed in a smartphone app for the best long-term health outcomes. Our study will use the technology of the Noom Health platform to overcome obstacles to weight loss and the skills and advice to maintain weight loss over time.

If you choose to participate, you will be randomly assigned, like by flipping a coin, to one of two smartphone apps. The Noom Health intervention, which uses the Noom app and coaches, is the program that you would be able to download from the app store, and it will be compared to Noom Digital Health, a program developed for this study. Both apps will be provided in this study for research purposes only. Other study procedures include:

- This Zoom call, where we will also ask you some screening questions and weigh-in to see if you are eligible.
- two online surveys, the intervention, and 7 assessments (1, 4, 6, 12, 18, 24, and 30 months) where you will provide information about your weight and complete questionnaires.
- The intervention and assessments will all be done on a computer; standard care will not be affected.
- Both the Noom Health and Noom Digital Health will include 6 months of intervention followed by 6 months of maintenance (12 months total).
- The Noom Health app provides diet and exercise recommendations, feedback from a Noom Health Coach and includes content like logging meals, tracking physical activity, and reading articles.
- The Noom Digital Health app offers the same information about weight loss and same

tracking, but does not include feedback from a coach.
- You will be compensated for your time.

The main risks to you if you choose to participate are: (1) the potential for becoming upset or anxious when discussing personal issues, (2) loss of private information.

Participating in this research will not benefit you.

Instead of participating in this research, you may receive referrals for another type of weight loss treatment.

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 between the ages of 18 and 65, speak English, have access to a smartphone device, and are at a weight status where weight loss has the potential to improve your mental and physical health.

Funds for conducting this research are provided by Noom, Inc., the commercial company that developed the weight loss intervention being studied through this research.

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.

LENGTH OF TIME AND NUMBER OF PEOPLE EXPECTED TO PARTICIPATE:

Your participation in this research study is expected to last approximately 30 months but could last up to 32 months, depending on how long after the baseline assessment you start using the app and how quickly you complete the assessment at the 30-month time point. The number of people expected to take part in this research study at the Icahn School of Medicine at Mount Sinai is 600.

DESCRIPTION OF WHAT'S INVOLVED:

If you agree to participate in this research study, the following information describes what may be involved.

You will be assigned to one of two smartphone apps, either the Noom Health intervention, which uses the Noom app and coaches, or Noom Digital Health, which uses the Noom app with digitally-delivered

advice and tips on weight loss and exercise. The app you get will be chosen by chance, like flipping a coin. Neither you nor the study team will choose what experimental study treatment you get. You will have an equal chance of being given each experimental intervention. All participants will complete a screening visit, before being assigned to an intervention.

The study team will assess your weight loss progress and collect information on your physical, emotional, and social health at start of intervention, 1, 4, 6, 12, 18, 24, and 30 months.

Both the Noom Health and Noom Digital Health will include 6 months of intervention, 6 months of maintenance (12 months total), and you will complete the same assessments regardless of the app you receive. All visits will be completed remotely with a trained member of the study team at Mount Sinai. The details of each visit are described below.

Baseline Visit (Visit 1, 45 min):

This call is considered the baseline visit. We'll ask you some questions to see if you qualify and have you weigh yourself on your scale with us on the call. After this call, if you are eligible, we'll send you a couple of surveys including questions about your eating, mood, health, and demographic information and to weigh yourself on a scale with a member of the research team present on a video service (i.e., Zoom).

We'll also ask you your contact information so the study team may track your progress over time that includes contact information of individuals who may help us locate you if we are having trouble finding you and contact information for a primary care physician who may provide information about your weight status if we have trouble locating you.

Noom Health Intervention:

You will be using the Noom Health app on your phone to receive diet and exercise recommendations, and feedback from a Noom Health Coach. Through the app, your coach will introduce you to the various functions of the app and will be available for you to reach out to with any issues. Examples of ways you will use the app include logging meals, tracking physical activity, reading curriculum articles, and posting personal challenges and responding to others' challenges within groups. Additionally, you may track your mood, overall motivation, and sleep, and record your weight weekly. The app allows you to interact with other members in your group and your coach. You will receive the Noom Health app for 48 weeks. After these 48 weeks, the Noom app is available to use without a coaching for 18 months (1.5 years).

Noom Digital Health:

You will be using the Noom Digital Health app on your phone to receive diet and exercise recommendations. Examples of ways you will use the app include logging meals, tracking physical activity, reading curriculum articles. You will receive the Noom Health app for 48 weeks. After these 48 weeks, the Noom app is available to use for an additional (1.5 years).

Follow-up Assessments:

After this screening phase, we will reach back out to you at 1 month, 4 months, 6 months, 12 months,

18 months, 24 months and 30 months (1.5 years post intervention). During these times, we will ask you complete questionnaires that measure what you are eating, your physical activity, your quality of life and other mental health symptoms (problems with eating and mood), and an assessment of your weight by Zoom or a similar HIPAA compliant platform (e.g., VSee). We expect these assessments will take about an hour of your time. For Women: Because weight loss might not be safe for pregnant women, you are not eligible for the study if you are pregnant or planning to become pregnant during the course of the study.

For Women:
Since you are participating in a research study that involves an experimental treatment with unknown risks to a developing fetus, it is recommended, for your protection, that you not become pregnant for the duration of the study. Therefore, practicing effective birth control is important. No individual birth control is 100% effective.

Recommended methods of birth control are:

- The consistent use of an approved hormonal birth control (pill/patches, rings),
- An intrauterine device (IUD),
- Contraceptive injection (Depo-Provera),
- Double barrier methods (Diaphragm with spermicidal gel or condoms with contraceptive foam),
- Sexual abstinence (no sexual intercourse) or
- Sterilization.

Should you become pregnant, regardless of the outcome, the sponsor may ask for information on your pregnancy, even if you are withdrawn from the study. Your written consent will be obtained separately in the case that this happens.

USE OF YOUR DATA AND/OR SPECIMENS:

In the future, your identifiable information may be removed from the private information collected as part of this research. After this removal, the information could be used for future research studies or shared with other research teams for future research studies. You will not be informed of the details of specific research that is done with your medical information. That means that a research project might be done that you would not consent to if provided with the details of that research project.

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:

Make sure that you attend all scheduled study visits and inform the research team as soon as possible if cancelling or rescheduling an appointment, or withdrawing from the study.

In addition, you must inform the research team immediately if there are any changes to your neurological or mental health or if you become pregnant as these changes may impact eligibility to participate in the study.

COSTS OR PAYMENTS THAT MAY RESULT FROM PARTICIPATION:

If you agree to take part in this research study, we will pay you $175 for your time and effort. You will be given $35 for the first visit and $20 for each of the seven follow-up study assessments. Checks require some time to be prepared and will be sent to you as available.

Tax law may require the Mount Sinai Finance Department to report the amount of payment you receive from Mount Sinai to the Internal Revenue Service (IRS) or other agencies, as applicable. Generally, this reporting would take place if you receive payments that 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.

Because this study requires the use of a smartphone there is the possibility of over usage of your data plan. If this is the case, we will provide $10 reimbursement in the form of a Visa gift card for an overage of data usage caused by the app.

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 positive psychosocial and health outcomes and weight loss.

REASONABLY FORESEEABLE RISKS AND DISCOMFORTS:

We do not expect any risks with the study evaluation. However, because the evaluation involves discussing personal issues, you may become upset, tired, or anxious during these visits. If this happens, a member of the study team will ask you if you want to continue in the study. Your participation will end if you feel so upset that you do not wish to continue in the study.

During this study, you may be asked to make some significant lifestyle changes which can be challenging at times. You may end your participation in this study at any time without preventing you from accessing services at Mount Sinai in the future. If you experience emotional discomfort as a result of your participation in the study, the study coordinator will try to assist you, contact the Principal Investigator, and discuss with you the need for a referral for further mental health services.

As this study involves the potential for group therapy with the Noom Health app, if you are receiving this form of the app, there is a risk that other members of your group could violate your confidentiality. In an effort to reduce this risk, group leaders will caution group members to avoid discussing their sessions with others outside of the group.

Risk of loss of private information; this risk always exists, but there are procedures in place to minimize the risk. When you register for the Noom programs, you will input personal information including your name, email address, and demographic information (e.g., age, weight). Your name and other information that could directly identify you (such as address, date of birth or social security number) will never be placed into a scientific database. However, since the Noom app includes identifying information, a break in security may pose a potential risk to you. If your private information was misused

it is possible you would also experience other harms, such as stress, anxiety, stigmatization, or embarrassment from revealing information about your health conditions.

Noom continuously researches real-world attacks and trends and guards against them and follows the latest trends and established best practices when it comes to security. For the app you will use during

the study, like other apps you access through the app store, it might be possible for attackers to obtain access to Noom's network and attempt to access systems that are not otherwise public. There is always a possibility that someone could inappropriately access to your raw data from outside the organization and leak it through a targeted attack. However, significant effort and capacity would be needed to do this, like to either stumble onto an unlocked laptop set up with VPN access (Virtual Private Network that creates a secure connection to another network over the Internet) or other components that are quite difficult to access. Should an attacker bypass all of the security measures, they would be able to expose data from the database. It is not known how usable this data would be without the logic Noom uses to interpret it because it is very large and complex.

If you are or become pregnant, this research may hurt your baby or your pregnancy in ways that are unknown. The unknown risks might be minor or might be major (death) for the pregnancy. You should not become pregnant while part this research study. Please read the acceptable methods of birth control found under the Description of What's Involved section of this document.

Group Risks - Although we will not give researchers your name, we will give them basic information such as your race, ethnic group, and sex. This information helps researchers learn whether the factors that lead to health problems are the same in different groups of people. It is possible that such findings could one day help people of the same race, ethnic group, or sex as you. However, they could also be used to support harmful stereotypes or even promote discrimination.

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. Instead of being in this research study, your choices may include seeking referrals for behavioral weight loss groups, nutritionists, or clinicians, or to purchase the commercially available version of the Noom app.

IN CASE OF INJURY DURING THIS RESEARCH STUDY:

If you are injured or made sick from taking part in this research study, medical care will be provided. The sponsor will reimburse your reasonable and necessary medical expenses for diagnosis and treatment of a research-related injury or illness.

This does not prevent you from seeking payment for injury related to malpractice or negligence. Contact the investigator for more information.

The Centers for Medicare and Medicaid Services (CMS), the agency that administers the Medicare and Medicaid programs, has stated that payments by a clinical trial sponsor for injuries related to a trial are a form of liability insurance that must be reported to CMS. As a result, if the sponsor pays for any medical expenses to treat a trial-related injury, the sponsor may have an obligation to determine whether you are covered by CMS, and, if you are, the sponsor may be required to make a report to CMS. In order to perform these tasks, the sponsor (or its delegate) must have certain individually identifiable information about you, such as your name, date of birth, Social Security Number, CMS Claim Number, date of injury and description of injury. Because the sponsor would not normally receive such identifiable

information about you, the sponsor (or its delegate) has agreed to use this information only for the purposes described in this paragraph or as otherwise specified in the Authorization to Use and Disclose Protected Health Information section, which is included below.

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 any of the Mount Sinai Health System hospitals 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 to stop being in the research study, the following may occur: your weight could change or you might experience changes to your exercise and diet

You may also 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 the information that was already collected if that information is necessary to complete the research study. Your health information may still be used or shared after you withdraw your authorization if you have an adverse event (a bad effect) from participating in the research study

If you decide you don't want your samples and/or data to be used for research anymore, you can contact the researcher and ask to have your samples and/or data removed from future use. If any samples or 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. If your samples have already been deposited in an external repository, the study team will request that your samples be removed.

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 specimens or data have been stored as part of the research study, they too can be destroyed without your consent

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 212-659-8724.

STUDY ID#: STUDY-20-01299M **Form Version Date: 02/10/2021**

If you experience an emergency during your participation in this research, contact 911 or go to your nearest emergency room.

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 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 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.

1. The company sponsoring this research study manufactures the drug/device being tested and so has a financial interest that could be affected by the outcome of this research study.

2. One or more researchers has a financial interest that could be affected by the outcome of this research study. Principal Investigator's Department has a financial interest that could be affected by the outcome of this research study or receives significant support from the research study sponsor.

Dr. Thomas Hildebrandt (the Principal Investigator in this study) serves as an advisory board member for Noom (a non-publicly traded company, the study sponsor and manufacturer of the Noom weight management and health platform being evaluated in this study). Dr. Hildebrandt has been granted shares of Noom for his services.

If you have questions regarding paid relationships that your physician/researcher may have with industry, we encourage you to talk with him or her, or check for industry relationships posted on individual faculty pages on our website at http://icahn.mssm.edu/.

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 researchers will collect your name, address, telephone/fax numbers, e-mail addresses, date of birth, social security number. In addition, life history of information regarding emotional and psychological difficulties will also be collected; however, this information will be de-identified using individualized identifier codes. Coaching sessions occur in virtual (chat room) format; however, these videos are not recorded or stored.

The researchers will also get information about your weight from via a video observation using digital service (Zoom). These visits are not recorded.

During the study the researchers will gather information by:

- taking a medical history (includes current and past medications or therapies, illnesses, conditions or symptoms, weight status, family medical history, allergies, etc.)
- completing the tests, procedures, questionnaires and interviews explained in the description section of this consent.

You should also be aware of what information *will not be used*. There is no location tracking in the Noom programs. Any interaction beween the Noom app and external step trackers (e.g., Fitbit) only tracks the daily step count, not where the steps were made. You can decide to not automatically track steps using a device and instead manually input all exercise and/or steps. No other data from the Noom app is shared to partner apps except the user account name. You can choose a username that does include elements of your name. The Noom app does not have a voice recording system or any way to record audio from a phone.

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 The Mount Sinai Health System (“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 Mount Sinai Finance Department may need your name, address, social security number, payment amount, 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 protected health information?
As part of the study, the Principal Investigator, study team and others in the 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.)

- Contract Research Organization (whose job is to help organizations fulfill their responsibilities in the research and development process): Noom, Inc.
- A Data Safety Monitoring Board or other committee that will monitor the study on an ongoing basis for safety.
- 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, 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 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.

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 your information will no longer be protected by federal regulations, where possible, Mount Sinai 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.

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.

STUDY ID#: STUDY-20-01299M **Form Version Date: 02/10/2021**

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
_____	_____	_____	_____