Informed Consent Cover page

Title: Adaptation of an Evidence-based Interactive Obesity Treatment Approach (iOTA) for Obesity Prevention in Early Serious Mental Illness: iOTA-eSMI.

NCT Number: NCT03980743

Date: January 14, 2022

Washington University in St. Louis

FOR IRB USE ONLY
IRB ID #: 201911123
APPROVAL DATE: 01/14/22
RELEASED DATE: 01/14/22
EXPIRATION DATE: N/A

INFORMED CONSENT DOCUMENT

Project Title: Adaptation of an Evidence-based Interactive Obesity treatment Approach (iOTA) for Obesity Prevention in Early Serious Mental Illness: iOTA-eSMI

Principle Investigator: Ginger Nicol, MD

Research Team Contact: Demetrius Perry, (314) 747-5514

If you are the legally authorized representative providing consent the word "you" in this document refers to the person you represent.

This consent form describes the research study and helps you decide if you want to participate. It provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights and responsibilities as a research participant.

KEY INFORMATION

The first section of this document contains some key points that the research team thought you would find important. The research study is described in more detail after this section.

This is a research study having to do with a mobile weight loss intervention. You should carefully consider the information in this consent document and discuss it with the research team. You should understand why you might want to participate, or why you might not want to participate. You may choose to participate or not.

If you agree and sign this consent, you will be volunteering to participate in the research study. As a voluntary participant, you will be asked to participate in the health intervention for 36 weeks – 24 weeks meeting with a health coach and receiving text messages, and then 12 weeks receiving text messages only.

If you take part in this study, your involvement will last for a total of 36 weeks or 9 months. During the first 24 weeks, you will have a monthly meeting with a health coach to learn about healthy eating, activity, and psychological principles to help you with your health goals. You will have up to 9 study visits, and each study visit will last approximately 1-3 hours. You will also receive weekly text messages during the study to help keep you motivated. After approximately 24 weeks, you will just receive text messaging for another 12 weeks without coming in for in-person visits. After this 12-week period, you will come in for a final in-person visit. Your study visits can be conducted by phone or video conference if you are unable to attend in-person.

We don't expect this study to benefit you directly, but we hope that other people may benefit in the future because the information that we collect form this text-based intervention can be translated to other clinical or community-based settings to reduce obesity and diabetes risk among patients with a psychiatric condition. There is no cost to you, and you will be paid for being a volunteer participant. You will receive $25 for every visit you complete. You may choose to be paid via Visa Gift Card or mailed check. Please allow 2-6 weeks for mailed check to arrive if you choose this option. All of this information will be explained and is listed in more detail in this consent document. The research team

will give you a copy of this signed consent document.

The rest of this document provides more details about the study.

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We invite you to participate in this research study because you have been diagnosed with a psychiatric condition and are interested in learning how to live a healthier lifestyle.

The purpose of this study is to test the feasibility of a weight loss coaching program using a text messaging system and personal health coaching to reduce obesity and improve lifestyle habits in individuals with chronic, severe mental illness.

WHAT WILL HAPPEN DURING THIS STUDY?

If you agree to participate in this study, you will be randomized to one of two different study treatment groups, the Interactive Obesity Treatment Approach Program for obesity prevention in serious mental illness (iOTA) or the health education group.

If you are randomized to the iOTA intervention group, you will have several in-person study visits. You will have an initial start-up visit 1-2 weeks before your first study visit. The start-up visit will consist of a familiarization with the study and completion of questionnaires related to demographics, eating and physical activity habits, and other health topics. You may receive an activity monitor to wear for two weeks. At the end of two weeks, you will be asked to return the activity monitor if you received one, either in person or by mail with a stamped and addressed mailing envelope provided by the study team. You will then have up to 8 study visits over 24 weeks. Each study visit may be conducted in person in the Healthy Mind Lab at Washington University School of Medicine, by phone or virtually and will last approximately 1-3 hours During each study visit, you will meet with a health coach to discuss your current health habits and opportunities to make improvements in your eating and physical activity habits. Your health coach is a member of the Washington University research team and he/she will meet with you in person, or conduct a phone or virtual session with you in a private location at the research team's office. You will also be asked to complete questionnaires at each visit. These questionnaires are about your overall health in the past month, your eating and physical activity habits, and to how you feel about participating in the program. These questionnaires can be completed either on paper or with digital survey on a tablet computer at in-person study visits, or via an emailed or texted survey link. You are free to skip any questions that you would prefer not to answer. At each study visit, your health coach will discuss health behavior goals related to your eating and physical activity behaviors. You will also have your height and weight checked at every visit. For phone or virtual visits, your health coach will walk you through how to weigh yourself at home during your phone or virtual visit. In addition to the study visits, you are asked to participate in the weekly text messaging program. This program will send you text messages every day. Some of these messages will be health tips related to your health goals and a response is not required. Other messages will be questions about your progress on your selected health behavior goals and a weekly weight check-in. After approximately 24 weeks, you will receive text messages only for another 12 weeks without any health coaching visits. After these 12 weeks, you will have a final study visit. Two to three weeks before the end of the study, you may receive an activity monitor to wear for another two weeks. At the end of two weeks, you will be asked to return the activity monitor, if you received one, either in person or by mail with a stamped and addressed mailing envelope

provided by the study team, and will have a final visit conducted in person, by phone or virtually.

If you are randomized to the health education control group, you will be asked to complete several in-person study visits. You will have an initial start-up visit 1-2 weeks before your first study visit. The start-up visit will consist of a familiarization with the study and completion of questionnaires related to demographics, eating and physical activity habits, and other health topics. You may also receive an activity monitor to wear for two weeks. At the end of two weeks, you will be asked to return the activity monitor, if you received one, either in person or by mail with a stamped and addressed mailing envelope provided by the study team. You will then have up to 8 study visits over 24 weeks. Each study visit may be conducted in person in the Healthy Mind Lab at Washington University School of Medicine, by phone or virtually and will last approximately 1-3 hours. At each study visit, you will meet with a health coach to learn about nutrition, physical activity, and energy balance, and will discuss lifestyle changes you can make, such as, and eating a well-balanced diet. Your health coach is a member of the Washington University research team and he/she will meet with you in person, or conduct a phone or virtual session with you in a private location at the research team's office. You will also be asked to complete questionnaires at each visit. These questionnaires are your eating and exercise habits, how you have felt over the past month, and your experience of taking part in the study. These questionnaires can be completed either on paper or with digital survey on a tablet computer at in-person study visits, or via an emailed or texted survey link. You are free to skip any questions that you would prefer not to answer. Your height and weight will also be checked at every visit. For phone or virtual visits, your health coach will walk you through how to weigh yourself at home during your phone or virtual visit. After approximately 24 weeks, you will receive text messages only for another 12 weeks without any health coaching visits. After these 12 weeks, you will have a final study visit. Two to three weeks before the end of the study, you may receive an activity monitor to wear for another two weeks. At the end of two weeks, you will be asked to return the activity monitor,if you received one, either in person or by mail with a stamped and addressed mailing envelope provided by the study team, and will have a final visit conducted in person, by phone or virtually.

Support from a case manager

In order to take part in this study, you will need to have a case manager or community social worker. We will ask your case manager/community social worker to complete questionnaires regarding your experiences with the study as well as feedback on the program. We will ask your case manager/community social worker to sign a separate consent form. This will say that they agree to provide helpful information to study personnel regarding your study participation.

Will you save my samples or research data to use in future research studies?

As part of this study, we are obtaining health data about you from you. We would like to use this health data for studies going on right now as well as studies that are conducted in the future. These studies may provide additional information that will be helpful in understanding obesity prevention and treatment in persons with a mental illness, or other diseases or conditions, including research to develop investigational tests, treatments, drugs or devices that are not yet approved by the U.S. Food and Drug Administration. It is unlikely that what we learn from these studies will have a direct benefit to you. There are no plans to provide financial compensation to you should this occur. By allowing us to use your data you give up any property rights you may have in the health information data you have shared with us.

We will share your data with other researchers. They may be doing research in areas similar to this research or in other unrelated areas. These researchers may be at Washington University, at other research centers and institutions, or industry sponsors of research. We may also share your research data with large data repositories (a repository is a database of information) for broad sharing with the research community. If your individual research data is placed in one of these repositories only qualified researchers, who have received prior approval from individuals that monitor the use of the data, will be able to look at your information.

If you change your mind and do not want us to store and use your data for future research you should contact the research team member identified at the top of this document. The data will no longer be used for research purposes. However, if some research with your data has already been completed, the information from that research may still be used. Also, if the data has been shared with other researchers it might not be possible to withdraw the data to the extent it has been shared.

Please place your initials in the blank next to Yes or No for each of the questions below:

My health data may be stored and used for future research as described above.

_____Yes _____No
Initials Initials

My data may be shared with other researchers and used by these researchers for the future research as described above.

_____ Yes _____ No
Initials Initials

Identifiers may be removed from your private information (including data) and used for future research or shared with others. If this occurs, we will not ask you for additional consent.

Audio recording/video recording/photographs

One aspect of this study involves making audio & video recordings of you. If you are randomized to the iOTA intervention group, your monthly in person health coaching sessions with your health coach will be audio & video recorded for treatment monitoring. This is so the research team may review the audio & video recordings to confirm that the same important information is given to all participants in this study. The audio recordings are important for data collection to help the research team evaluate the effectiveness of the iOTA program. . These recordings may also be used to train other researchers/coaches on how to conduct iOTA sessions. Only the research team will have access to your audio & video recordings. All recordings will be labeled with your subject ID number, and not your name. The recordings will be saved on the University's secure server on password protected computers. You may still participate in this study if you do not want to have your meetings with your health coach audio & video recorded.

I give you permission to make audio & video recordings of me during this study.

____Yes ____No
Initials Initials

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 80 people will take part in this study conducted by investigators at Washington University.

HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, your involvement will last for 36 weeks. During this time, you will have a total of 9 study visits conducted either in-person, by phone, or virtually. Each study visit will last approximately 1-3 hours. You will have a start-up visit and then a study visit every 4 weeks (up to 8 study visits), followed by a wrap-up visit.

WHAT ARE THE RISKS OF THIS STUDY?

You may experience one or more of the risks indicated below from being in this study. In addition, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study.

- You may find that some of the study questions are uncomfortable to answer. You may choose to not answer any questions that you do not want to answer.

One risk of participating in this study is that confidential information about you may be accidentally disclosed. We will use our best efforts to keep the information about you secure. Please see the section in this consent form titled *"How will you keep my information confidential?"* for more information.

WHAT ARE THE BENEFITS OF THIS STUDY?

You may or may not benefit from being in this study. However, we hope that, in the future, other people may benefit from this study because the information that we collect form this text-based intervention can be translated to other clinical or community-based settings to reduce obesity and diabetes risk among patients with a psychiatric condition.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

You will not have any additional costs for being in this research study.

WILL I BE PAID FOR PARTICIPATING?

You will be paid for being in this research study. You will receive $25 for every study visit you complete. You will need to provide your social security number (SSN) in order for us to pay you. You may choose to participate without being paid if you do not wish to provide your social security number (SSN) for this purpose. You may choose to be paid via Visa Gift Card or mailed check. You may also need to provide your address if a check will be mailed to you. Please allow 4-6 weeks to receive payment by check in the mail. If your social security number is obtained for payment purposes only, it will not be retained for research purposes.

WHO IS FUNDING THIS STUDY?

The National Institute of Mental Health (NIMH) and Washington University School of Medicine

Institute for Public Health are funding this research study. This means that Washington University is receiving payments from NIMH to support the activities that are required to conduct the study. No one on the research team will receive a direct payment or increase in salary from NIMH for conducting this study.

WHAT IF I AM INJURED AS A RESULT OF THIS STUDY?

Washington University investigators and staff will try to reduce, control, and treat any complications from this research. If you feel you are injured because of the study, please contact the investigator at 314-362-2461 and/or Human Research Protection Office at 1-(800)-438-0445.

Decisions about whether payment for medical treatment for injuries relating to your participation in research will be made by Washington University. If you need to seek medical care for a research-related injury, please notify the investigator as soon as possible.

HOW WILL YOU KEEP MY INFORMATION CONFIDENTIAL?

Other people such as those indicated below may become aware of the participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you. We will keep your participation in this research study confidential to the extent permitted by law.

- Government representatives (including the Office for Human Research Protections) to complete federal or state responsibilities
- The U.S. Food and Drug Administration
- The National Institutes of Health
- Hospital or University representatives to complete Hospital or University responsibilities
- Information about your participation in this study may be documented in your health care records and will be available to anyone with access to your health care record, including your health insurance company. This information may also be released as part of a release of information request.
- Washington University's Institutional Review Board (a committee that oversees the conduct of research involving human participants) and the Human Research Protection Office. The Institutional Review Board has reviewed and approved this study.

To help protect your confidentiality, we will have all data collected as part of the study coded with a unique study identification number. A master list linking the identification number ad your name will be kept separately from where data are stored. Your identifiable information will not be shared with anyone outside of the research team.

Although the text messages you receive in this study may be specific to your health goals, none of the text messages will contain health information that identifies you. Only the research team and the technology vendor that is assisting the research study will have access to your text messages. The technology vendor will only have your phone number, and they will not know your name or any other information that you provide outside of the text messages. We will use a secure internet connection to send and receive text messages.

If you agree to participate in study visits virtually by video link, we will use a secure internet connection to conduct the virtual session, and will only use approved video conferencing programs like Skype or Zoom. These services have been approved by Washington University as safe for conducting medical care. The privacy of any sensitive health information discussed during virtual sessions is protected with data encryption, and video is transmitted from point-to-point such that the provider of the video link (e.g. Skype or Zoom) does not have access to any identifiable health information communicated during the session.

Any report or article that we write about this study will not include information that can directly identify you. The journals that publish these reports or articles require that we share your information that was collected for this study with others. Sharing this information will allow others to make sure the results of this study are correct and help develop new ideas for research. Your information will be shared in a way that cannot directly identify you.

A description of this clinical trial will be available on http://www.CliniaclTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

To further protect your privacy, this research is covered by a Certificate of Confidentiality from the federal government. This means that the researchers can refuse to disclose information that may identify you in any legal or court proceeding or to anyone who is not connected with the research except if:

- there is a law that requires disclosure, such as to report child abuse and neglect, or harm to self or others*;*
- you give permission to disclose your information, including as described in this consent form; or
- it is used for other scientific research allowed by federal law.

You have the right to share your information or involvement in this study with anyone at any time. You may also give the research team permission to disclose your information to a third party or any other person not connected with the research.

If information about you or your involvement in this research is placed in your medical record the information may no longer be protected under the Certificate. However, information in your medical records is protected in other ways.

Are there additional protections for my health information?

Protected Health Information (PHI) is health information that identifies you. PHI is protected by federal law under HIPAA (the Health Insurance Portability and Accountability Act). To take part in this research, you must give the research team permission to use and disclose (share) your PHI for the study as explained in this consent form. The research team will follow state and federal law and may share your health information with the agencies and people listed under the previous sections titled, *"How will you keep my information confidential?"*

Once your health information is shared with someone outside of the research team, it may no longer be protected by HIPAA.

The research team will only use and share your information as talked about in this form or as permitted or required by law. When possible, the research team will make sure the information cannot be linked to

you (de-identified). Once information is de-identified, it may be used and shared for other purposes not discussed in this consent form. If you have questions or concerns about your privacy and the use of your PHI, please contact the University's Privacy Officer at 866-747-4975.

Although you will not be allowed to see the study information, you may be given access to your health care records by contacting your health care provider.

If you decide not to sign this form, it will not affect:

- your treatment or the care given by your health provider.
- your insurance payment or enrollment in any health plans.
- any benefits to which you are entitled.

However, it will not be possible for you to take part in the study.

If you sign this form:

- You authorize the use of your PHI for this research
- This authorization does not expire.
- You may later change your mind and not let the research team use or share your information (you may revoke your authorization).
  - To revoke your authorization, complete the withdrawal letter, found in the Participant section of the Human Research Protection Office website at https://hrpo.wustl.edu/participants/withdrawing-from-a-study/ or you may request that the investigator send you a copy of the letter.
    - **If you revoke your authorization:**
      - The research team may only use and share information already collected for the study.
      - Your information may still be used and shared as necessary to maintain the integrity of the research, for example, to account for a participant's withdrawal from the research study or for safety reasons.
      - You will not be allowed to continue to participate in the study.

Can we contact you by email?

We would like to contact you by email for the purposes listed below. Some of these emails may contain health information that identifies you.

- To schedule appointments and send you reminders about your appointments
- To provide you with resources that are related to your mental health and healthy lifestyle changes
- To send you a secure link to study questionnaires

Only the research team will have access to your email communications. We will only communicate by email to send you the information listed above. If you have any questions or need to contact us for an urgent or emergent situation, please contact the research team member identified at the top of this document.

You should be aware that there are risks associated with sending your health information via email.

- There is always a risk that the message could be intercepted or sent to the wrong email address. To avoid sending messages to the wrong email address, the first email we send you will be a test message to ensure we have the correct email address.
- When using any computer you should be careful to protect your username and password. Make sure you log-out before getting up from the computer.
- If you share a home computer with other family members, and do not want them to know you are participating in this study make sure you provide an email address that only you can access.
- Your employer will have access to any email communications sent or received on any electronic devices used for work or through a work server.

Do you agree to allow us to send your health information via email?

_____ **Yes** _____ **No**
Initials **Initials**

IS BEING IN THIS STUDY VOLUNTARY?

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. Any data that was collected as part of your participation in the study will remain as part of the study records and cannot be removed.

If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

What if I decide to withdraw from the study?

You may withdraw by telling the study team you are no longer interested in participating in the study or you may send in a withdrawal letter. A sample withdrawal letter can be found at https://hrpo.wustl.edu/participants/withdrawing-from-a-study/ under Withdrawing from a Research Study.

Can someone else end my participation in this study?

Under certain circumstances, the investigator might decide to end your participation in this research study earlier than planned. This might happen for no reason or because in our judgment it would not be safe for you to continue, because you are or became pregnant, or because funding for the research study has ended.

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact Demetrius Perry 314-747-5514. If you experience a research-related injury, please contact

Demetrius Perry or the Human Research Protections Office at 1-(800)-438-0445.

If you have questions, concerns, or complaints about your rights as a research participant, please contact the Human Research Protection Office at 1-(800)-438-0445, or email hrpo@wustl.edu. General information about being a research participant can be found on the Human Research Protection office website, http://hrpo.wustl.edu. To offer input about your experiences as a research participant or speak to someone other than the research staff, call the Human Research Protection Office at the number above.

This consent form is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by agreeing to participate in this study. As a participant you have rights and responsibilities as described in this document and including:

- To be given enough time before signing below to weigh the risks and potential benefits and decide if you want to participate without any pressure from the research team or others.
- To understand all of the information included in the document, have your questions answered, and receive an explanation of anything you do not understand.
- To follow the procedures described in this document and the instructions of the research team to the best of your ability unless you choose to stop your participation in the research study.
- To give the research team accurate and complete information.
- To tell the research team promptly about any problems you have related to your participation, or if you are unable to continue and wish to stop participating in the research study.

Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a signed and dated copy of this form.

Do not sign this form if today's date is after EXPIRATION DATE: N/A.

_____ _____

(Signature of Participant) (Date)

_____

(Participant's name – printed)

Legally Authorized Representative's Name and Relationship to Participant:

Do not sign this form if today's date is after EXPIRATION DATE: N/A.

_____
(Participant's name – printed)

_____ _____
(Signature of Legally Authorized Representative) (Date)

_____ _____
(Name of Legally Authorized Representative - printed) (Relationship to Participant – printed)

Who should sign as the Legally Authorized Representative (LAR)?
If the participant has a legal guardian or attorney-in-fact this individual must sign as the LAR.

If there is no legal guardian or attorney-in-fact the individuals listed below may sign in order of priority.

(1) Spouse unless the participant has no spouse, or is separated, or the spouse is physically or mentally incapable of giving consent, or the spouse's whereabouts is unknown or the spouse is overseas;
(2) Adult child;
(3) Parent;
(4) Brother or sister;
(5) Relative by blood or marriage.

Statement of Person Who Obtained Consent

The information in this document has been discussed with the participant or, where appropriate, with the participant's legally authorized representative. The participant has indicated that they understand the risks, benefits, and procedures involved with participation in this research study.

_____ _____
(Signature of Person who Obtained Consent) (Date)

_____
(Name of Person who Obtained Consent - printed)