Permission to Take Part in a Human Research Study

University at Buffalo Institutional Review Board (UBIRB)
Office of Research Compliance | Clinical and Translational Research Center Room 5018
875 Ellicott St. | Buffalo, NY 14203
UB Federalwide Assurance ID#: FWA00008824

Adult Consent to Participate in Research Study

Title of research study: ***Weight Management Program for Patients with First Episode Psychosis***

Version Date: ***November 15, 2021***

Investigator: ***Daniel Antonius, PH.D.***

Key Information: The following is a short summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form.

Why am I being invited to take part in a research study?

You are being invited to take part in a research study because you plan to start or are taking antipsychotic medication.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?

The purpose of this research is to see if a behavioral weight control program prevents patients, who are taking antipsychotic medication(s), from gaining weight. Weight gain is a common side effect of antipsychotic medications.

A parent or household family member will be asked to join this research study with you. We want to see if having a parent or family member participate with you in the behavioral weight control program will help prevent weight gain.

How long will the research last and what will I need to do?

We expect that you will be in this research study for up to nine months.

If you are eligible and agree to participate to continue, we will collect health information, information about your behavior, and you will have your height and weight measured. You may also complete tasks to measure your reading skills. You will be asked to weigh yourself daily for approximately 9 months with a Bluetooth scale that we will provide. You'll be asked to attend weekly sessions with your family member and a case manager for 12 weeks. These sessions will last up to 60 minutes. You will also attend 2 educational sessions that will last up to 60 minutes each. These sessions may be in person or through telemedicine.

After you have completed the 12 weekly sessions, you will have another in-person meeting in which we will measure your weight. You may also information about your usual behavior. We will ask you to complete these measurements on final time, two months after treatment.

More detailed information about the study procedures can be found under ***"What happens if I say yes, I want to be in this research?"***

Is there any way being in this study could be bad for me?

You may feel uncomfortable answering some of the sensitive questions in this study about your health and decisions. You may experience hunger from changes in eating patterns and possible discomfort related to changes in physical activity.

More detailed information about the risks of this study can be found under ***"Is there any way being in this study could be bad for me? (Detailed Risks)"***

Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include the prevention of weight gain and changes in your eating and physical activity behaviors. You may also learn about the experimental research process and your health.

What happens if I do not want to be in this research?

Participation in research is completely voluntary. You may choose not to enroll in this study.

Detailed Information: The following is more detailed information about this study in addition to the information listed above.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at 716-858-2792. You may also contact the research participant advocate at 716-888-4845 or researchadvocate@buffalo.edu.

This research has been reviewed and approved by an Institutional Review Board ("IRB"). An IRB is a committee that provides ethical and regulatory oversight of research that involves human subjects. You may talk to them at (716) 888-4888 or email ub-irb@buffalo.edu if:

- You have questions about your rights as a participant in this research
- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You want to get information or provide input about this research.

How many people will be studied?

We expect about 30 patients and their household family members will be in this research study.

What happens if I say yes, I want to be in this research?

Screening/Baseline visit (in clinic)
After signing this consent form, we will ask you to sign a release of medical records to be sent to your psychiatrist. We may ask them to send us information confirming your start of an antipsychotic medication any information pertaining to your eligibility for this study or other medical conditions (like high blood pressure or high cholesterol).

You will complete assessments where we will collect demographic and health information and you will have your height and weight measured. We will calculate your BMI. You will also complete questionnaires about your eating habits and how you think about time.

Baseline Phase (2 months)
You will be asked to weigh yourself daily on a Bluetooth scale provided to you.

Treatment visits (3 months/12 weeks)
All participants in this study will receive access to a behavioral program designed to control weight gain.

Treatment visits may occur in the clinic or remotely via Zoom once a week for 12 weeks. During these sessions, you will be asked to weigh yourself via a home scale and show that measure to a staff member either by showing the result directly during the video call or by sharing a picture of the result to our study email address. These sessions will last about 60 minutes.

You will also have about a 60-minute educational session with a case manager two times. The educational sessions review information about weight loss and maintenance and engage in- problem solving for participants who are struggling with behavior change. Quizzes to assess mastery of educational materials will be given. You will receive feedback and your interventionist will assist with your progress and problem solving and communicate with you to structure solutions.

Intervention sessions may be audio or video recorded to ensure treatment is provided as planned.

At the end of treatment, you will be asked to complete the same assessments completed at the Baseline visit including measuring your weight. We will calculate your BMI. You will also complete questionnaires about your eating habits and how you think about time.

Follow-up visit (in clinic)

Two months after the end of your 12-week Treatment Period, you will be asked to complete the same assessments completed at the Baseline visit including measuring your weight. We will calculate your BMI. You will also complete questionnaires about your eating habits and how you think about time.

What are my responsibilities if I take part in this research?
If you take part in this research, you will be responsible for adhering to study procedures and attending study sessions. Specifically, you will be responsible to:

- Take your medication as prescribed.
- Weigh yourself daily on the provided Bluetooth scale.
- Answer questions about your preferences and how you think about time.
- Participate in 12 weekly meetings with a trained case manager

- Participate in 2 educational sessions
- Complete assigned readings and quizzes from our Weight Control on Medications manual.
- Follow-up with your behavioral health care provider as directed.

What happens if I say yes, but I change my mind later?

You can leave the research at any time and it will not be held against you. Your participation does not affect the participation of the parent or support participant. If you decide to leave the research, no further data will be collected and the Bluetooth scale will be collected but any information that had been provided may be retained by the researcher and analyzed.

Is there any way being in this study could be bad for me? (Detailed Risks)

You may feel uncomfortable answering some of the sensitive questions in this study about your health and decisions. You may refuse to answer any questions you feel discomfort answering and may choose to withdraw from the study for any reason, at any time. You may experience hunger from changes in eating patterns and possible discomfort related to changes in physical activity.

Due to the public nature of the internet, any data collection completed online does create potential breach of confidentiality issues. This occurs when your private information is accessed without yours and the research team's permission and then disclosed to a third party. However, all data collected during your sessions will be coded and your responses will be linked to a unique participant ID. Additionally, there are security features in place that makes a breach of confidentiality very unlikely to occur.

You and your insurance company will be charged for the health care services that you would ordinarily be responsible to pay. In some cases, insurance will not pay for services ordinarily covered because these services were performed in a research study. You should check with your insurance to see what services will be covered by your insurance and what you will be responsible to pay.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical or education records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this organization. In order to monitor this research study, representatives from federal agencies such as NIH (National Institutes of Health) and OHRP (Office of Human Research Protection) may inspect research records which may reveal your identity.
All questionnaires will be coded with a numeric code. The numeric code will be linked to your identity through a master list retained by delegated team members. The only written connection between your participation in this study and the study itself will be this signed consent form but your identity will not be made a part of any published findings resulting from this study.

The audio recordings of treatment sessions (one on one sessions with your case manager) will contain your voice and may have reference to your first name, however, no other identifying information will be available from this recording. These recordings will be stored as an electronic audio file (e.g. mp3) on a secure and encrypted server that is password protected, which only research staff will have access to. Audio recordings will be used to ensure treatment is being provided as planned and will be listened to by a supervisor to give feedback to your case manager. After the audio is reviewed and feedback is provided to your case manager, the recording will be deleted. In most cases the audio recording will be deleted within two weeks, but may be retained for the duration of the study. Once the study is complete

all audio recording will be deleted.

Your information that is collected as part of this research will not be used or distributed for future research studies, even if all of your identifiers are removed.

Federal law provides additional protections of your medical records and related health information. These are described in the HIPAA section of this document.

Can I be removed from the research without my OK?

If you leave the NAVIGATE program or become hospitalized for longer than one week, you will be removed from the study. If this occurs, you will be debriefed about the nature of the study and be compensated for the amount of time spent in the study. We will also arrange to collect the Bluetooth scale. If your family member withdraws from the study, you may continue to participate.

What else do I need to know?

Who is paying for this research?

This research is being funded by the UB Department of Psychiatry.

What medical costs am I responsible for paying?

Tests or procedures required by the research study that would not otherwise be part of your standard care will be covered by the sponsor of this study. The tests or procedures that would be provided to any patient with your condition, regardless of whether he/she was participating in the research study, are considered standard care and will be billed to you or your private or public health insurance company. You will still be responsible for the cost of your usual ongoing medical care, including deductibles and co-payments. If you have any questions about what expenses are covered by the sponsor and what expenses are the responsibility of you or your health insurance provider, please contact a member of the study staff and/or your health insurance provider.

Will I get paid for my participation in this research?

You will earn $1 per completed daily weighing using a Bluetooth scale for a maximum of $210. There will be three payments by check, one at the end of the 2 month baseline, one at the end of the treatment sessions, and one at the end of the follow-up.

If you agree to take part in this research study, you will be paid $25 each for the Baseline visit, End of Treatment Visit and Follow-up Visit for a total of $75 if all three visits are completed.

Payments will be made by check after each completed assessment session.

Payments that you receive for your participation in this research are considered taxable income. If the amount of payment that you receive reaches or exceeds $600.00 in a calendar year, you will be issued a form 1099.

What are my alternatives to participating in this research study?

Instead of being in this research study, your choices may include consultation with your physician for any health concerns. The important risks and possible benefits of these alternatives include: meeting with a professional familiar with your health history, which may have a monetary cost associated.

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What will happen to my information and samples?

Your information and samples (both identifiable and de-identified) may be used to create products or to deliver services, including some that may be sold and/or make money for others. If this happens, there are no plans to tell you, or to pay you, or to give any compensation to you or your family.

HIPAA: Authorization for the Use and Disclosure of Identifiable Health Information for Research Purposes

This section describes information about you and about your health that will be obtained by the researchers when you participate in the research study. By signing this form you are agreeing to permit the researchers and/or other parties (described in detail below) to have access to this information and to use or disclose it for the purposes of the research described in this document. If there are any parts of this form that you do not understand, please be sure to ask us for further clarification.

A. What individually identifiable health information will be collected about you as part of this research study?

- Information from your full medical records: We may collect information confirming your start of antipsychotic medications, diagnosis, and comorbid conditions and medications.
- New Health Information created from study related tests, procedures, visits, and/or questionnaires as described in this consent form.

B. Who is authorized to create or provide this information for research use?

- ECMC Healthcare Network, Buffalo NY
- UBMD Clinical Practice Plan(s): Psychiatry
- Principal Investigator or designee
- Other(s): primary care physician, your pharmacy, your behavioral health provider

C. Who is authorized to receive the information from the information providers identified in (B)?

- Principal Investigator or designee
- Other(s): Your primary care physician, your behavioral health provider

D. With whom may your protected health information be shared?

Your health information may be shared with others outside of the research group for purposes directly related to the conduct of this research study or as required by law, including but not limited to:

- Clinical staff not involved in this research study who may become involved in your care if it is potentially relevant to your treatment
- The organization(s) responsible for administering this research such as Research Foundation.

Your information may also be shared with individuals or entities responsible for general administration, oversight and compliance of research activities. Examples of this include the institution's Privacy and Security Officers or other internal oversight staff, Safety Monitoring Boards, an Institutional Review Board, The Research Foundation of the State University of New York, University at Buffalo Foundation Services, and accrediting bodies, or with certain government oversight agencies that have authority over the research including the Department of Health and Human Services (HHS), the Food and Drug Administration (FDA), the National Institutes of Health (NIH), and the Office of Human Research Protections (OHRP). Your information may also be shared with other entities as permitted or required by law. All reasonable efforts will be used to protect the confidentiality of your individually identifiable health information that may be shared with others as described above.

Although safeguards are in place to prevent accidental disclosure of your information beyond the purposes described above, the information disclosed through this authorization is no longer protected by HIPAA. There is the potential for this information to be re-disclosed by the recipient(s). After such a disclosure, the information may no longer be protected by the terms of this authorization against further re-disclosure.

E. How long are the information providers listed in (B) authorized to provide your information for this research project?

This authorization has no expiration date. The researchers may continue to rely on this authorization to obtain and use protected health information about you unless you revoke this authorization in writing.

F. What are your rights after signing this authorization?

You have the right to revoke this authorization at any time. If you withdraw your authorization, no additional efforts to collect individually identifiable health information about you will be made. You should know, however, that protected health information acquired using this authorization prior to its withdrawal may continue to be used to the extent that the investigator(s) have already relied on your permission to conduct the research. If you chose to withdraw this authorization, you must do so in writing to the following individual(s): *Daniel Antonius, Ph.D., UB Department of Psychiatry, 462 Grider Street, Buffalo, NY 14215, Phone: 716-898-5290.*

If you send us a request to withdraw your authorization, we will forward that request to the institutions we have shared it with in order to collect your individually identifiable health information.

G. What will happen if you decide not to sign this authorization?

Refusing to sign this authorization will not affect the present or future care you receive at this institution and will not cause any penalty or loss of benefits to which you are otherwise entitled. If you decide not to sign this authorization, you will not be able to participate in the research study.

Should you agree to participate in this research, this consent document will be placed in

your medical record.

Signature Block for Capable Adult

Your signature documents your permission to take part in this research. By signing this form you are not waiving any of your legal rights, including the right to seek compensation for injury related to negligence or misconduct of those involved in the research.

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