Subject Name: _____Last 4 SSN:_____ Date: _____

Title of Study: CoachToFit: Adapted Weight Loss Intervention For Individuals With Serious Mental Illness

Principal Investigator: Matthew J. Chinman, PhD VAMC: Pittsburgh (646)

LAY TITLE: *Using Peer Support to Help Veterans with Serious Mental Illness Lose Weight*

KEY ELEMENTS:

This is a research study to find out if using a smartphone application or "app" for weight loss combined with peer coaching will better help Veterans lose weight compared to usual care for weight management in the VA. Your participation in this study is voluntary. This study is designed specifically for Veterans with serious mental illness who are overweight and also have an iPhone or Android smartphone. Participants in the study will be randomly chosen to use the app + peer coaching or to continue with the usual care for weight management in the VA.

If you agree to take part in this study, you will be in this study for about 12 months and will need to have 3 research assessments to answer survey questions, either in-person, over the phone, or via video call. Veterans who are randomized to the group that uses the app will have access to the app and peer coaching for 6 months.

There are risks to this study that are described in this document. Some risks include: You may feel discomfort in answering questions as part of the survey and you may feel frustrated when using the app or peer coaching. You may choose to skip the questions that cause discomfort or tell the interviewer you would like to stop.

If you do not participate in this study, alternate treatments for weight management include the usual care for weight management in the VA

If you are interested in learning more about this study, please continue reading below.

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STUDY CONTACT INFORMATION:

If you have a general question about this research study, or if you have any concerns or complaints related to this research study, you may call one of the research assistants at 412-360-2286 or any of the investigators listed below.

If you experience any illness, injury or other medical problem that you feel may be related to this study, please call Dr. Matthew Chinman at 412-360-2438.

**Principal Investigator**
Matthew Chinman, PhD
VA Pittsburgh Healthcare System University Drive C [151]
Pittsburgh, PA 15240
412-360-2438

**Co- Investigator**
Raymond Panas, PhD, MPH
VA Pittsburgh Healthcare System University Drive C [151]
Pittsburgh, PA 15240
412-360-2847

**Co-Investigator**
Jessica Dodge, PhD, MPH, LLMSW
VA Pittsburgh Healthcare System University Drive C [151]
Pittsburgh, PA 15240
734-845-3609

STUDY SPONSOR:

This study is sponsored by the VA Office of Research and Development. Additional information regarding the study sponsor can be provided upon request.

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PURPOSE OF THE RESEARCH STUDY:

The purpose of this research study is to learn if the smartphone app we have designed is more effective than usual care for weight management in the VA, for participants with serious mental illness. Usual care for weight management in the VA may not meet the needs of participants who have a serious mental illness.

You are being asked to participate in this research study because you are a Veteran who has been diagnosed with a serious mental illness, are overweight, and have either an iPhone or Android smartphone. We expect that about 260 Veterans at the VA Pittsburgh Healthcare System will join and participate in this research study.

DESCRIPTION OF THE RESEARCH STUDY:

If you choose to participate, this is what will happen.:

**1. Complete a Survey and Prepare for Participation**

a. In a private office, by phone, or video call, you will be asked to complete a survey with research staff about your basic information (gender, race, ethnicity, education, current living situation, current employment, phone ownership, phone service package, app usage, and internet usage). You will also be asked questions about diet and exercise, your weight, and your symptoms and functioning.

b. You will also complete a test (6-minute Walk Test) where research staff ask you to walk on a flat surface for 6 minutes. This includes measuring your oxygen saturation, blood pressure, and heart rate/pulse.

c. If you have an iPhone, research staff will confirm that Apple Health Kit is on your phone. If you have an Android phone, research staff will download Google Fit to your phone. They will teach you how to read the step data collected by these programs.

d. This will take up to approximately 90 minutes and you will be paid $50 for your participation.

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**2. Talk with Research Staff and Receive Random Study Assignment**

a. The research staff will randomly assign you to either use the app + peer coaching or continue with usual care at the VA. Being randomly chosen is like drawing straws. If you are assigned to receive the app + peer coaching, the research staff will also inform you of your Peer Coach assignment.

**If you are assigned to receive the app + peer coaching**

Research staff will help you download the app to your phone and work with you to start up the app and show you how to use it. You will receive and activity tracker and a Bluetooth scale. They will also put you in touch with your Peer Coach to set up a time for the first 20-minute coaching call, which will you then have once a week.

**If you are assigned to continue with usual care**

You may continue with usual VA care around diet and activity, which consists of access to the VA's MOVE! Program.

**3. Participate in the Study**

**If you are assigned to receive the app + peer coaching:**
The app delivers lessons on nutrition and physical activity, and helps you set goals for each. The app also tracks your steps through an activity tracker and your weight through the Bluetooth scale.

- You will use the app on your own for 6 months. You may use the app on your own schedule, anywhere or anytime that is best for you.
- You will be instructed by the peer coach to complete at least 2 app modules per week. The modules take about 15 minutes to complete and have embedded knowledge quizzes and end with a choice of three goals to practice over the next week.

- You will receive weekly coaching calls from your peer coach (20 minutes each call) You will be asked by your peer coach to regularly check your steps on your activity tracker and check your weight on your Bluetooth scale.

**If you are assigned to continue with usual care:**

You may continue with usual VA care around diet and activity, which consists of access to the VA's MOVE! program.

**4. Complete a 6-month and 12-month Survey**

**All Veterans**

- At 6 months and 12 months after you enroll in the study, you will be asked to complete follow-up surveys.
- Letters will be sent at 7-months and 9-months to remind you of the 12-month post assessment and of the contact details for any issues during the interim period.
- The follow-up surveys will be very similar to the initial survey, which also includes the 6-minute Walk Test, and will take place in person.
- These interviews will take about 60 minutes each and you will be paid $50 for your participation.

**If you are assigned to receive the app + peer coaching**

You will be asked some additional questions about the app.

At the end of the 12-month follow-up survey, the research staff will stop tracking your weight and steps.

**5. Complete an additional interview**

**If you are assigned to receive the app + peer coaching**

- You may be invited to participate in an additional interview at the 6-month follow-up time point. About one-third of participants assigned to receive the app will be randomly selected to participate in

this additional interview in person, over the phone, or by video call. **The interview will be audio recorded, and we will transcribe it so we can remember what you've said. The recording and transcription will be kept at the VA, and only study team members will see it.**

- This interview will include questions about how easy it was to use the app, ways the app may be hard to use, and questions about diet and exercise. This will take about 15 minutes to complete and you will be paid $25 for your participation.

**6. Study extension**

**All Veterans**

- Your participation in the study may be extended if you are unable to participate for two weeks or more due to an event that made it impossible to exert physical activity (i.e., virus, accident, unrelated hospitalization), track physical activities (i.e., misplaced/lost equipment, loss of internet/Bluetooth connectivity), or due to broken study equipment (i.e., activity tracker, Bluetooth scale, no access to phone for coaching calls).
- The timing of the 6-month and 12-month surveys may be adjusted based on when the event occurred after enrollment.
- We will verify with you if you want to extend your participate in the study. Your participation in the study will only be extended for the time that was missed.

SHARING OF INDIVIDUAL AND OVERALL RESEARCH RESULTS

We may learn information about your health as part of this research. Generally, tests done for research purposes are not meant to provide clinical information and therefore no results from this study will be shared with you. There is a slight possibility that during the research we could learn things about you that could affect your health. If it is necessary to contact you about research results, which might affect your health, we will work with your VA health providers to inform you about these results, if necessary.

We will share aggregate data with you from this research project. Aggregate data combine all data from the participants into a report, which describes the findings of the study. Results from this study will be published

in research journals when the study is completed. If you would like to be contacted when results are published, you may contact the research team at 412-360-2286.

RISKS AND BENEFITS:

The risks associated with participation in this study are minimal and include:

*Breach of Confidentiality.* Given that the study will include asking sensitive questions and gathering information from individuals with serious mental illness, there is risk for embarrassment and negative effects on subjects if sensitive information was improperly disclosed and used in a discriminatory fashion against the individual. This is very unlikely as there will be precautions in place to prevent this.
*Discomfort with procedures or disclosure.* During the course of participation, a subject could feel uncomfortable participating in screening, research assessments, using the app, peer coaching phone calls, or qualitative interviews. This will be very unlikely since a research staff member is always available to address questions that the subject may have, and all subjects are informed that they may choose to skip any questions or procedures that they find uncomfortable or withdraw from the project at any time.

*Financial burden.* **For participants randomized to use the app,** it is possible that they could risk financial burden from data use associated with the app. Most recent commercial plans have unlimited data. However, there is a risk that the user could incur additional costs by going over plan data usage limits. This is not expected and was not a problem in the previous development grant which used this same app. The apps on both iOS and Android can be configured to "turn off" the use of cellular data. This will restrict the app from downloading or uploading unless it is on WiFi. The peer coach can address any issues with data usage during weekly coaching calls.

*Physical activity.* **For participants randomized to use the app,** increased physical activity may result in greater risk for injury or the need for treatment. This is very unlikely as there will be precautions in place to prevent this, including referring high-risk participants for their physician's clearance before beginning an exercise program and teaching Veterans proper exercise techniques, and the importance of warm-up and cool-down exercises.

*Nutrient intake.* **For participants randomized to use the app,** calorie restriction could theoretically lead to inadequate nutrition or excessive, rapid weight loss. This is very unlikely as there will be precautions in place to prevent this including regular discussions about any weight loss and importance of maintaining adequate calorie intake.

*Hypoglycemia related to diet and exercise interventions.* Hypoglycemia, also known as low blood sugar, is a fall in blood sugar levels to below normal. **For participants randomized to use the app,** for those who may be susceptible to hypoglycemia due to use of anti-diabetic medications, weight loss interventions have the potential to increase the risk of hypoglycemia, especially during the time when diet or physical activity interventions are implemented. This is very unlikely as there will be precautions in place to prevent this including encouraging you to contact your physician as soon as you begin to experience any symptoms.

*Symptomatic hypotension related to diet and exercise interventions.* Hypotension, also known as low blood pressure, is any blood pressure that is below the normal expected for an individual in any given environment. **For participants randomized to use the app,** for those who may be susceptible to hypotension because they are using medications that lower blood pressure, weight loss interventions have the potential to increase the risk of hypotension. This is very unlikely as there will be precautions in place to prevent this including having your regular physician manage any changes in blood pressure.

Risks of the usual care you receive are not risks of research. Those risks are not included in this consent form. You should talk with your health care providers if you have any questions about the risks of usual care.

Potential Benefits

We cannot promise any benefits to you or others if you decide to join this research. You may however, receive indirect benefit given that you are contributing to medical science or helping to advance future understanding of how to design a program that is effective in helping you and other people with serious mental illness to manage their weight.

There is some change that participants may benefit from the trial of the program by improving their diet, increasing their exercise, and losing weight.

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ALTERNATIVES TO PARTICIPATION:

You have the alternative not to participate in this study. There may be other ways of treating your condition if you do not wish to be in this research. These include participating in usual care for weight management at the VA, like the MOVE! Program. You may discuss these options with your doctor.

NEW FINDINGS: You will be informed of any significant new findings during the course of the study, which may affect your willingness to continue to participate. You will not receive individual research results from this study.

INVESTIGATOR INITIATED WITHDRAWAL: The investigator(s) may stop your participation in this study without your consent for reasons such as: it will be in your best interest, you do not follow the study plan, you experience a study-related injury, the investigator decides that continuing your participation could be harmful to you, you are pregnant, you need treatment not allowed in the study, you enroll in another conflicting study, or in the event of unanticipated circumstances.

VOLUNTARY PARTICIPATION/RIGHT TO WITHDRAW: Your participation in this study is voluntary. You do not have to take part in this study, and your refusal to participate will involve no penalty or loss of rights to which you are entitled. Also, if you first agree to participate and then you change your mind, you are **free to withdraw** your consent and stop your participation at any time. If you decide to withdraw from the study, you will not lose any benefits to which you would otherwise be entitled, and your decision will not affect your ability to receive medical care for your condition.

If you want to stop being in the study, you should tell the investigators or study staff. You can do this by phone by calling the project researchers at 412-360-2286. You should ask for a HIPAA revocation form, which you can sign in order to revoke any data collection, which does not require your participation. The project director can provide this to you, upon request.

If you withdraw from the study, and you were randomized to use the app:

- Research staff will stop tracking your weight and steps
- Research staff will request that you return the activity tracker and Bluetooth scale

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If you withdraw your consent and HIPAA authorization for such use, you may not be able to continue to participate in the research study.

MEDICAL TREATMENT: In the event that you sustain injury or illness as a result of your participation in this VA approved research study, conducted under the supervision of one or more VA employees, all medical treatment (emergent as well as medical treatment beyond necessary emergent care) will be provided by the VA. Except in limited circumstances, the necessary medical care must be provided in VA facilities.
However, if such injury or illness occurred as a result of your failure to follow the instructions for this study, you may not be eligible for free care unless you have independent eligibility for such care under Federal Law.

FINANCIAL COMPENSATION: If you sustain an injury or illness as a result of participating in this research study, you may be eligible to receive monetary compensation for your damages pursuant to applicable Federal law. If you believe that you are injured as a result of participation in this study, please contact the Principal Investigator. If compensation is available the Principal Investigator will provide you with an explanation as to what that compensation consists of, or where you can obtain further information regarding it.

COST AND PAYMENTS: You or your insurance will not be charged for any costs related to the research. However, if you are receiving medical care and services from the VA that are not part of this study, and you are a veteran described in Federal regulations as a "category 7" veteran, you may be required to make co-payments for the care and services that are not required as part of this research study. *included*: If you are a Veteran eligible for Beneficiary Travel, please speak with the research team to understand how research visits may impact your ability to receive Beneficiary Travel.

Veterans will be compensated for their time and effort. You will receive $50 for each visit that you complete for this study. The surveys will be completed at the beginning of the study, 6-months after the study begins, and at the 12-month mark. A certain number of Veterans who are randomized to the app + peer coaching will be invited to complete an additional interview, for which they will receive $25.

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You may receive transportation from a taxi service on an as needed basis if you are having difficulty traveling to the VAPHS University Drive Research Office Building for research appointments. The research assistant will determine if transportation is available when scheduling the appointments. If appropriate, transportation may be provided at the baseline , 6-month, and 12-month appointments.

Except in limited circumstances, payments issued through the VA are generated by Electronic Funds Transfer (EFT). Therefore, in order to receive payment associated with your participation in this study, you must be willing to receive EFT and to provide banking information to VA, if that information has not already been provided. If you are not able to receive payment through EFT, the Direct Express Debit MasterCard may be issued. The Direct Express Debit MasterCard is a prepaid debit card. Please refer to the flyer that study personnel have provided about which services may require a fee if using your Direct Express Debit MasterCard. In addition, due to limitations in the Financial Management System, payments made to you will generate Internal Revenue Services (IRS) Form 1099 regardless of amount. Payments will be reported to the IRS as income and your social security number will be used for this purpose.

RECORD RETENTION: Your research records will be retained in accordance with the Veterans Health Administration (VHA) Records Control Schedule, or longer, if required by other Federal regulations.

CONFIDENTIALITY AND USE AND DISCLOSURE OF DATA: There are rules to protect your private health information. Federal and State laws and the Federal medical law, known as the HIPAA Privacy Rule, also protect your privacy. By signing this form, you provide your permission called your 'authorization', for the use and disclosure of information protected by the HIPAA Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. They may also collect other information including:

- Information from your Health Records such as diagnoses, progress notes, medications, lab or radiology findings
- Demographic Information such as name, age, race, date of birth

- Photographs, Digital Images, Video, or Audio Recordings
- Questionnaire, Survey, and/or Subject Diary

The research team may also need to disclose your health information and the information it collects to others as part of the study progress. Others may include the: VA Office of Research and Development

A progress note stating you are participating in this study will be placed within your medical record.

In addition, Institutional Review Board, Food and Drug Administration, Office (FDA), Office of Human Research Protections (OHRP), the VA Office of Research Oversight (ORO), and the Government Accountability (GAO) may have access to your research records. Your health information disclosed pursuant to this authorization may no longer be protected by Federal laws or regulations and may be subject to re-disclosure by the recipient. Additionally, any medical information may be shared with your healthcare provider(s) with your consent, and possibly without your consent if permissible under Federal laws and regulations.

Finally, you consent to the publication of the study results or release of the data when published, so long as the information about you is anonymous and/or disguised so that your identity will not be disclosed.

**Confidentiality risks and precautions to decrease risk:**
Every effort will be made to make sure that the information about you obtained from this study will be kept strictly confidential. As private information is collected about you as part of this study, there is a risk to your privacy and confidentiality. The research staff will take every precaution to protect your identity and the confidentiality of the information collected about you.

We will protect the confidentiality of your research records by keeping all sensitive or personally identifiable information at the VA. Your name and any other information that can directly identify you will be stored separately from the data collected as part of the project.

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We will keep your name and all the information about you used in this study as confidential as possible. We may publish the results of this study for others to read about, but you will not be identified in any articles about the study by name, social security number, address, telephone number, or any other direct personal identifier. Also, other federal agencies as required, such as the VA Office of Research Oversight and the VA Office of the Inspector General may have access to your information.

Also per VA directives, if a participant in the study becomes pregnant while enrolled in the study, they will need to be withdrawn from the study, followed to assess outcomes, and we may need to report this information to the VAPHS Institutional Review Board (IRB).

A description of this clinical trial will be available on http://www.ClinicalTrials.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.

**Future Use**

We will not keep your research data to use for future research or other purposes and we will not share your research data with other investigators.

**Revocation:**
You can revoke this authorization, in writing, at any time. To revoke your authorization, you must write to the Principal Investigator at the address below. Your request will be valid when the Release of Information Office receives it. If you revoke this authorization, you will not be able to continue to participate in the study. This will not affect your rights as a VHA patient to treatment or benefit outside of the study.

Matthew Chinman, PhD
VA Pittsburgh Healthcare System
University Drive C [151]
Pittsburgh, PA 15240

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Treatment, payment or enrollment/eligibility for benefits cannot be conditioned on you signing this authorization. This authorization will expire at the end of the research study unless revoked prior to that time.

RESEARCH SUBJECTS' RIGHTS: You have read or have had read to you all of the above. Dr. Matthew Chinman or his/her authorized representative has explained the to you and answered all of your questions. The risks, discomforts, and possible benefits of this research study, as well as alternative treatment choices, have been explained to you.

A description of the study has been provided to you, including an explanation of what this study is about, why it is being done, and the procedures involved. You have the right to ask questions related to this study or your participation in this study at any time. You should be giving your consent only under conditions in which you (or the person representing you) have sufficient opportunity to carefully consider whether or not to participate in this study. Your consent should not be given under conditions that pressure you or try to influence your decision in any way.

Your rights as a research subject have been explained to you, and you voluntarily consent to participate in this research study. You will receive a copy of this signed consent form.

If you have any questions about your rights as a participant in this study or wish to speak more about the study with someone not associated with the research study, you can call the Associate Chief of Staff for Research and Development at (412) 360-2394.

As long as the study is renewed as required by the IRB, your signature on this document is valid for the duration of the entire research study. Should any changes occur during the course of the study that may affect your willingness to participate, you will be notified.

***By signing this form, you agree to participate in this research study.***

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| _____ | _____ | _____ |
|---|---|---|
| Subject's Signature | Date | Time |
| _____ | _____ | _____ |
| Investigator/Person Obtaining Consent* | Researcher (Print) | Date |

**If person other than the Investigator is obtaining consent, he/she must be approved by the IRB to administer informed consent.*

**Version date: January 23, 2024**