Brief Title: Coach to Fit Weight Loss Intervention for Individuals With Serious Mental Illness

NCT Number: NCT04560335

Unique Protocol Id: IIR 19-153

Date of last IRB approval: 2/11/2026

1.0

* **Study Name:** CoachToFit: Adapted Weight Loss Intervention for Individuals with Serious Mental Illness

2.0

* **Brief Description (using layman's terms) - 500 words or less:**

Background: Between 40% to 60% of individuals with serious mental illness (SMI) are obese. Obesity and physical inactivity result in increased rates of chronic diseases, increased risk of death, and substantial health care costs. Treatment guidelines recommend that individuals with SMI who are overweight should be offered evidence-based weight loss interventions, including psychosocial interventions. The VA's weight management program, MOVE!, is attended by less than 5% of the overweight population and is not adapted to the cognitive needs and patient preferences for the population with SMI. Effective adapted weight management programs are not offered in VA because they are time-intensive and require the skills of trained providers who are often in short-supply. CoachToFit can address this gap in care. CoachToFit is a weight management program, adapted for the population with SMI, that includes a smartphone app delivering evidence-based weight management services with weekly telephonic support from a VA peer specialist who acts as a wellness coach. Peer specialists are individuals who draw upon lived experiences with SMI to provide services to others with SMI in clinical settings. CoachToFit was shown to have high rates of acceptability and usability and was efficacious for weight loss in a small sample. VA has an opportunity to address obesity in the population with serious mental illness, currently a substantial gap in care.

Significance/Impact: This project addresses obesity in the population with SMI by evaluating a weight management program that is not only evidence-based, it is sustainable, transportable, appealing to patients, easy to use, and minimally burdensome to the healthcare system. This effort addresses two HSR&D priority areas: 1) Mental Health: Testing new models of care to improve access, cost, and/or outcomes, and 2) Health Care Informatics: Building the evidence base for ehealth/mhealth tools.

Innovation: CoachToFit's use of mobile technology is an important innovation in VA service delivery and its user-centered design involving individuals with SMI was the first of its kind. CoachToFit is enhanced by data visualization in real-time via a web-based dashboard used by VA peer specialists and their supervisor. We are aware of no other evidence-based mobile platforms to help people with SMI reduce their weight.

Specific Aims: The project aims to 1) Test the efficacy of CoachToFit, compared to usual care, in decreasing weight among Veterans with SMI who are obese; 2) Assess the hypothesized mechanisms of action for CoachToFit, including self-efficacy, motivation, and readiness to change; and 3) Characterize factors that will inform future implementation and maintenance of CoachToFit using a multi-stakeholder qualitative post-intervention evaluation guided by the RE-AIM framework.

Methodology: The study design includes a randomized controlled trial to test the efficacy of CoachToFit and assess the hypothesized mechanisms of action. This will include enrollment of obese Veterans with SMI from the mental health clinics at one VA medical center (n=256). Individuals will be randomized to CoachToFit or usual care. Those in CoachToFit will have access to the app and coaching for 6 months. Outcomes are assessed at 6- and 12-months. Efficacy outcomes utilize objective measures. The design also includes a multi-stakeholder qualitative post-intervention evaluation guided by the RE-AIM framework to characterize factors that will inform future implementation and maintenance of CoachToFit. This will include interviews with Veterans randomized to CoachToFit (n=30); interviews with staff stakeholders (n=18); a discussion with Veterans in local Veteran groups (n=2 groups; n=11 Veterans), and interviews with national leadership (n=3).

Next Steps/Implementation: If CoachToFit is found to be efficacious, the VA National Center for Health Promotion and Disease Prevention, along with input from national leadership in Peer Support Services and Mental Health Informatics, will assist in integration into the VA context.

3.0

* **Is this research study a Greater than Minimal Risk Clinical Trial?** ○ Yes ◉ **No**

4.0

* **Is this study a Greater than Minimal Risk Comparative Effectiveness research?** ○ Yes ◉ **No**

5.0
* **Principal Investigator:**
Matthew Chinman
5.1
* **VA hours per week the PI is devoted to project:**
10
5.2
* **Is the PI working with ionizing radiation?** ○ Yes ◉ **No**
5.3
* **Is the PI working with biological hazards?** ○ Yes ◉ **No**
5.4
* **Is the PI shipping biological hazards?** ○ Yes ◉ **No**

5.5
Upload Financial Conflict of Interest Statement:
Form 450_Coach to Fit_MC.pdf(0.01)
6.0

Study Identification Information (Continued)
1.0
* **Do you certify that all research staff administering informed consent are knowledgeable about the study?**
yes
2.0
* **To the best of your knowledge do you, or any member of your research staff, have any potential, actual or perceived conflict of interest of a professional or personal nature that may affect any aspect of the research, including, but not limited to, the review and/or conduct of this study?**
○ Yes ◉ **No**
If yes, provide a description, including name of study team member with conflict:

3.0
* **Qualifications of the Investigators:**
Dr. Chinman is a clinical/community psychologist and Research Scientist at the VISN4 Mental Illness Research, Education and Clinical Center at the VA Pittsburgh Healthcare System (VAPHS) and a Senior Behavioral Scientist at the RAND Corporation. He is also the Director of the Implementation and Evaluation Core in the VA HSR&D Center for Health Equity Research and Promotion (CHERP) at VAPHS. A major focus of his research centers on the deployment of Peer Specialists, individuals with SMI who receive training to provide support to others with SMI, in traditional clinical settings. As the VA has deployed more than 1,100 Peer Specialists nationwide over the last decade, Dr. Chinman's research has investigated the implementation factors critical to their successful deployment, conducted randomized and quasi-experimental trials assessing their impact, and prospectively tested implementation strategies to support their deployment. In his role as lead of the Peer Support subgroup of the Mental Health QUERI, he provided guidance to several VA stakeholders (e.g., National Director of Peer Support; VISNs 4, 5, 16; Mental Health QUERI researchers) in how to hire and deploy Peer Specialists. For example, Dr. Chinman developed an implementation toolkit titled Peer Specialist toolkit: Implementing Peer Support Services in VHA that was distributed to all VAMCs. This is just one example of his research directly supporting practice. Dr. Chinman is well-qualified for leading this weight loss intervention for Veterans with serious mental illness.

Sharon McCarthy, PhD, Co-PI and Project Manager is a licensed social worker and organizational psychologist, and investigator in the VISN4 MIRECC and CHERP at VAPHS. Dr. McCarthy has worked with Dr. Chinman on various peer specialist projects for nearly 10 years. She has extensive qualitative skills and expertise, most recently publishing a qualitative study of the experience of Veterans receiving peer specialist

services in a VA homeless program. Dr. McCarthy will coordinate and manage the implementation and conduct of the study and serve as the qualitative methodologist. She will coordinate the efforts of the investigative team, develop the project manual of operations, oversee the development of the data tracking and management systems, assure the integrity of the data and protection of human subjects by directly working with the IRB, and help to manage the project budget. She will also contribute to the preparation of reports, presentations, and manuscripts related to the project.

Raymond Panas, PhD, MPH serves as Co-PI and Project Manager in the VISN4 CHERP and MIRECC at VAPHS. Dr. Panas is a certified clinical research professional having spent over 25 years in pharmaceutical drug development and medical affairs education efforts. He has also served for over 10 years as adjunct faculty supporting masters and doctoral students on their dissertations as well as teaching various courses in public health, health education, health communication campaigns, and clinical research. He has extensive quantitative and qualitative skills having published a number of articles and presented at several conferences. Dr. Panas recently joined Dr. Chinman on various peer specialist projects within the VA. Dr. Panas will coordinate and manage the implementation and conduct of the study and serve as the qualitative methodologist. He will coordinate the efforts of the investigative team, oversee the development of the data tracking and management systems, assure the integrity of the data and protection of human subjects by working with the IRB, and help manage the project budget. He will also contribute to the preparation of reports, presentations, and manuscripts related to the study project.

ID:
Pro00003522

View: 1.2 VA Involvement

VA Involvement

1.0
Does the proposed research involve any of the following?:

Name
☑

VA Funding
☑

VA Personnel Funded Effort
☑

VA Patients or their Private Health Information
☐

Other VA Resources: Central IRB
☑

Other VA Resources: VA Equipment
☑

Other VA Resources: VA Property (Including space leased to, or used by VA)
☑

Other VA Resources: VA Databases
☐

None of the Above apply to this research

ID:
Pro00003522

View: 1.3 Study Funding Information

Study Funding Information

1.0
* **Funding Sources:**

Funding Source
(Other)
Code
View
Merit Review (CC 103)

9003

2.0
Upload Grant Application, if applicable (If NIH, VA, voluntary agency, must upload):
Name
Modified Date
09_VA_DMAP_Coach2Fit- MC.pdf
8/20/2020 2:33 PM
Chinman ITP.pdf
8/14/2020 2:03 PM
CoachToFit_Grant.pdf
6/1/2020 1:31 PM

ID:
Pro00003522

View: 1.4 Resources

1.0

* **Do you currently have adequate resources (e.g., staff, physical space, information technology, etc.) to protect the safety of participants, staff, and the confidentiality of subjects' data during the conduct of this study?**

(•) **Yes** ( ) No

If yes, include a listing of the VAPHS resources that will be used for this study and are necessary to protect participants.

Dr. Chinman will have access to the extensive infrastructure and facilities of the Center for Health Equity Research and Promotion (CHERP, which just received a renewal to 2023) and the VA Pittsburgh Healthcare System (VAPHS). CHERP focuses on improving the quality and equity of health and health care for vulnerable Veterans, including racial and ethnic minorities, women, the homeless and others. CHERP is co-located at the VISN 4 hub VA Medical Centers in Pittsburgh and Philadelphia. This strong collaboration between VA Pittsburgh Healthcare System (VAPHS) and the Corporal Michael J. Crescenz VA Medical Center in Philadelphia (CMCVAMC) provides an excellent research infrastructure with a strong track record of high impact health services research and evaluation, partnership with operations and policy leaders, and implementation of research findings into practice and policy.

CHERP currently has 41 core investigators with broad expertise in quantitative and qualitative research methodology, including clinical trial development, quality improvement, community-based participatory research, clinical epidemiology, large database analysis, pharmacoeconomics, psychometrics, econometrics, decision and cost-effectiveness analysis, meta-analysis, technology assessment, and implementation science.

Annual core funding from HSR&D, VISN 4, VAPHS, and CMCVAMC enable CHERP to support 6 infrastructure cores and a highly successful Pilot Research Program that, together, maximize investigator capacity to conduct high impact health services research.

• The Research Development & Stakeholder Engagement Core supports development of research proposals by CHERP faculty, including preparatory data acquisition, proposal development, pre- submission internal scientific review, administrative review of all research applications, and administration of the CHERP Pilot Research Program. The Core assists investigators in ensuring that their research is aligned with and responsive to Veteran, provider, and other stakeholder priorities. The Core also provides post-award support to investigators completing Just-In-Time requirements and Institutional Review Board submissions for new awards.

• The Biostatistics and Informatics Core (BIC) provides technical assistance and expert consultation to CHERP investigators in areas related to study design, data management, and statistical analysis; manages an integrated database architecture to support CHERP research; implements a data management framework that ensures data integrity, security, and confidentiality; and maintains expertise in the collection, integration, and use of electronic data from VA and non-VA sources. Through the BIC, with proper approvals, CHERP investigators have access to local, regional, and national VA administrative and clinical databases, including the unique VISN 4 warehouse of detailed clinical information for all VISN 4 patients. CHERP has multiple secure data servers at each site that are maintained and backed up daily by each facility's OI&T Service. The servers reside behind the VA firewall and are compliant with Federal Information Security Management Act standards. CHERP investigators and staff at both sites have access to statistical and other software packages, including SAS, STATA, SPSS, CART, ArcGIS, AtlasTi, StatTransfer, SQL, and others. CHERP investigators also have access to non-VA databases to facilitate their research, including the American Hospital Association Annual Survey and the Medispan Master Drug Data Base, an essential tool for drug research.

• The Qualitative Methods Core provides scientific consultation and technical assistance to CHERP and other investigators in areas related to qualitative and mixed methods research. The core maintains efficient systems for qualitative data collection, data management, and analysis; develops tools, templates, and other resources for shared use across projects and staff; and meets investigator and staff needs for qualitative research support, including hardware, software, and training. Additional services provided by the core include: (1) assistance with development of research applications and quality improvement initiatives that employ qualitative or mixed methods; (2) training and oversight of qualitative research staff; (3) instrument design and pilot testing of interview guides; (4) qualitative data collection, coding, and analysis; (5) written documentation of methods and findings for use in manuscripts, grants, and reports; and (6) transcription and verification.

• The Dissemination & Implementation Core (lead by Dr. Chinman) guides CHERP investigators in developing and executing effective strategies across the research continuum to support the translation of evidence-based research into practice and policy. This Core also provides CHERP investigators access to expertise in implementation science and creates a culture in which investigators routinely engage operations and policy partners in developing research projects.

• The Communication Core helps CHERP investigators develop effective dissemination strategies to relevant audiences and stakeholders. The Core supports all CHERP investigators in disseminating research results to a wide range of target audiences, including health equity researchers and stakeholders, the media, Veterans and the general public. Dissemination strategies are tailored to the needs of each study and the stakeholders involved.

• The Health Equity Capacity Building Core is CHERP's newest core and serves as a resource to support the conduct and effective dissemination of high-impact health equity research by CHERP and other HSR&D investigators.

VAPHS and CMCVAMC host Comprehensive Women's Health Centers and are members of the HSR&D Women's Health Practice-Based Research Network. VAPHS and CMCVAMC are both urban VAMCs that serve large proportions of underrepresented minorities (e.g., 10.4% African American at VAPHS and 40.9% African American at CMCVAMC).

If no, please describe the resources that will be needed and explain how the resources will be obtained before the study is initiated:

2.0

* **VAPHS requires that either the PI or co-PI have a *physical presence* at VAPHS. Please describe the role the PI and/or co-PI have at VAPHS with respect to clinical responsibilities or in relation to other research activities.**

Dr. Chinman is a Research Health Scientist at VA Pittsburgh. Physically located at the Research Office Building, Dr. Chinman is part of two different research centers: the VISN-4 Mental Illness Research Education, and Clinical Center (MIRECC) and the Center for Health Equity Research and Promotion (CHERP), where he is the Director of the Implementation Core. Dr. Chinman is a licensed clinician and currently has clinical privileges, but does not have any direct clinical responsibilities outside of his studies. Dr. Chinman is 5/8ths at the Pittsburgh VA and spends all of that time conducting research.

3.0

* **Will off-site ancillary service facilities (e.g., radiology services, central labs, non VA space, etc) be used for this study?**

○ Yes ◉ **No**

If yes, please provide the location and a brief description of the project activities to be conducted at the off-site ancillary facilities:

4.0

* **Will a firm be contracted to obtain consent from subjects, collect private individually identifiable information from human subjects, or be involved in activities that would institutionally engage the firm in human subjects' research?**

○ Yes ◉ **No**

If yes, please provide a description of the contracted service(s):

* Please specify the IRB that has oversight of the firm's activity(ies):

Name of Site / Institution
IRB Approval Document
FWA Number
There are no items to display

5.0
Collaborations

Please list any non-VAPHS institutions or individuals (i.e. co-authors, mentors, etc.) that you will collaborate with and describe their specific role in the research:
Dr. Amy Cohen authored the original grant, which has been transferred to Dr. Chinman, and will be consulted in the implementation of the study. She will not access or see any Veteran Data.
The UCLA Mobilize Labs team will be contracted to assist in developing and fine tuning the Coach to Fit app, and purchasing the fitness trackers and scales.

The UCLA Mobilize Labs team has software development, design, and wireframing software, with a 10 Gigabit connection to the internet. The group utilizes private GITHUB repositories for software development versioning purposes. Mobilize Labs has a variety of software testing platforms and a wide selection of mobile devices for testing purposes including Android phones (with several of the Android versions installed) and iPhones. This team will not access or see any Veteran data.

5.1

If this is not Multi-Site Research, please upload the appropriate written agreement(s) here:
Name
There are no items to display

ID:
Pro00003522

View: 1.5 Project Information

1.0
Does the project involve any of the following (check all that apply):

Type
☐

Biological Hazards (including human biological specimens)
☐

Chemicals
☐

Ionizing radiation or use of radioactive materials
☐

Drug, Biological, or Nutritional (e.g. herbal or dietary) Supplement

2.0
Project Focus (check if applicable):

Type
☐

Traumatic Brain Injury (TBI)
☐

Post Traumatic/Post Deployment Stress Disorder (PTSD/PDSD)
☐

Operation Iraqi Freedom/Operation Enduring Freedom (OIF/OEF)

3.0
KEYWORDS
Please provide a minimum of 3, maximum of 6 keywords. Please use MeSH terms.
* Adapted Weight Loss Intervention
* Serious Mental Illness
* Web-based application

4.0
* **Please describe the type of study:**
The study design includes a randomized controlled trial to test the efficacy of CoachToFit and assess the hypothesized mechanisms of action. The design also includes a multi-stakeholder qualitative post- intervention evaluation guided by the RE-AIM framework to characterize factors that will inform future implementation and maintenance of CoachToFit.

5.0

* **Will any of the research being conducted as a part of this study be used to fulfill academic requirements (e.g., master's thesis, dissertation, or other academic program requirements necessary to obtain a degree/certification, etc.)?** ○ Yes ◉ **No**

ID:
Pro00003522

View: 1.6 (CR) Study Locations

Study Locations
1.0
* **Please add the local sites where this study will be conducted:**

Location
View
VAPHS University Drive Division

If Other, Please Specify:

ID:
Pro00003522

View: 1.6.1 (CR) Multi-Site Study

1.6.1 Multi-Site Study
1.0
* **Is this a multi-site study:**
○ Yes ◉ **No**

ID:
Pro00003522

View: 1.7 Section Chief and Service Line VP approvals

Please upload the approval of the Section Chief, if applicable and the Service Line VP.

1.0
* **Institutional Approval Document:**
Part-I-Request-to-Conduct-Research - 11.13.2018_CHINMAN-rev.pdf(0.01)

ID:
Pro00003522

View: 2 Study Objectives & Design

Study Summary

1.0
Funding End Date:
8/1/2024
2.0
* **Abstract. Please provide a brief description of the study**.

Between 40% to 60% of individuals with serious mental illness (SMI) are obese. Obesity and physical inactivity result in increased rates of chronic diseases, increased risk of death, and substantial health care costs. Treatment guidelines recommend that individuals with SMI who are overweight should be offered evidence-based weight loss interventions, including psychosocial interventions. The VA's weight management program, MOVE!, is attended by less than 5% of the overweight population and is not adapted to the cognitive needs and patient preferences for the population with SMI. Effective adapted weight management programs are not offered in VA because they are time-intensive and require the skills of trained providers who are often in short-supply. CoachToFit can address this gap in care. CoachToFit is a weight management program, adapted for the population with SMI, that includes a smartphone app delivering evidence-based weight management services with weekly telephonic support from a VA peer specialist who acts as a wellness coach. Peer specialists are individuals who draw upon lived experiences with SMI to provide services to others with SMI in clinical settings. CoachToFit was shown to have high rates of acceptability and usability and was efficacious for weight loss in a small sample. VA has an opportunity to address obesity in the population with serious mental illness, currently a substantial gap in care.
Significance/Impact: This project addresses obesity in the population with SMI by evaluating a weight management program that is not only evidence-based, it is sustainable, transportable, appealing to patients, easy to use, and minimally burdensome to the healthcare system. This effort addresses two HSR&D priority areas: 1) Mental Health: Testing new models of care to improve access, cost, and/or outcomes, and 2) Health Care Informatics: Building the evidence base for *e*health/*m*health tools.
Innovation: CoachToFit's use of mobile technology is an important innovation in VA service delivery and its user-centered design involving individuals with SMI was the first of its kind. CoachToFit is enhanced by data visualization in real-time via a web-based dashboard used by VA peer specialists and their supervisor. We are aware of no other evidence-based mobile platforms to help people with SMI reduce their weight.

3.0
* **Describe the study objectives. Please include primary aim and hypothesis, if applicable any secondary aims and hypotheses.**

Specific Aims: The project aims to 1) Test the efficacy of CoachToFit, compared to usual care, in decreasing weight among Veterans with SMI who are obese; 2) Assess the hypothesized mechanisms of action for CoachToFit, including self-efficacy, motivation, and readiness to change; and 3) Characterize factors that will inform future implementation and maintenance of CoachToFit using a multi-stakeholder qualitative post- intervention evaluation guided by the RE-AIM framework.
Methodology: The study design includes a randomized controlled trial to test the efficacy of CoachToFit and assess the hypothesized mechanisms of action. This will include enrollment of obese Veterans with SMI from the mental health clinics at one VA medical center (n=256). Individuals will be randomized to CoachToFit or usual care. Those in CoachToFit will have access to the app and coaching for 6 months.

Outcomes are assessed at 6- and 12-months. Efficacy outcomes utilize objective measures. The design also includes a multi- stakeholder qualitative post-intervention evaluation guided by the RE-AIM framework to characterize factors that will inform future implementation and maintenance of CoachToFit. This will include interviews with Veterans randomized to CoachToFit (n=30); interviews with staff stakeholders (n=18); a discussion with Veterans in local Veteran groups (n=2 groups; n=11 Veterans), and interviews with national leadership (n=3).

4.0

* **Provide a summary of the background of the study, and explain how this research will contribute to existing knowledge. Describe previous studies that provides a basis to show that the proposed research can be carried out without undue risk to human subjects.**

The VA's weight management program, MOVE!, is attended by less than 5% of the overweight population and is not adapted to the cognitive needs and patient preferences for the population with SMI. Effective adapted weight management programs are not offered in VA because they are time-intensive and require the skills of trained providers who are often in short-supply. CoachToFit can address this gap in care.

BACKGROUND. Between 40% to 60% of individuals with serious mental illness (SMI) are obese, compared to about 30% of the general population.1, 2 Obesity has many detrimental health consequences, including increased cardiovascular morbidity and reduced life expectancy.3 Fortunately, the harmful effects of obesity are reversible with even modest weight loss. Therefore, weight loss interventions for individuals with SMI are a high priority.4 Treatment guidelines recommend that individuals with SMI who are overweight should be offered evidence-based weight loss interventions, including psychosocial interventions.5, 6 In May 2014, a call to action was published by leading international experts and patient stakeholders asking for policies to mandate appropriate Treatments to address obesity and other critical problems in this population.7 Less than 5% of overweight Veterans participate in MOVE!, the Veterans Administration's weight management program.8 This rate is similar in those with SMI.9, 10 Patients with SMI have cognitive deficits that make many aspects of MOVE!, including numerous handouts, calorie counting, and meal diaries, especially challenging for this population. In-person interventions for weight management that are adapted for these cognitive deficits have been developed by our group and others and found in multiple trials to result in lower weight.11-15,21 Unfortunately, similar to MOVE!, the impact of these interventions is limited by low rates of engagement and retention. Veterans with SMI report that they do not attend due to a reluctance to engage in group treatments and issues with transportation.9

Barriers could be eliminated if an adapted weight intervention were made available via a smartphone application ("app"). While evidence-based interventions are being delivered online for the general population (e.g., CBT for insomnia), there has been almost no effort to do the same for the population with SMI.16, 17 Smartphones have become increasingly affordable with comparable growth trends and ownership rates in the SMI population as that of the general population.18 This provides a timely opportunity to enhance disease prevention and management by extending a health intervention beyond the reach of traditional care settings, closing an alarming gap in care. Studies have shown that people with SMI can successfully use technology as part of care.19, 20 Furthermore, requiring clinic visits to address weight is not necessary and has not been successful in this population.

PRELIMINARY STUDIES. This study builds upon a previous pilot effort to develop and test an evidence-based weight program adapted for the needs of the population with SMI that is delivered via a smartphone app (HSR&D IIR 03-213). The app is coupled with telephonic support from peer specialists who serve as wellness coaches. Peer specialists are individuals with SMI who draw upon lived experiences to provide services to others with SMI. The intervention package, called CoachToFit, was the first of its kind to be developed using a user-centered iterative process involving individuals with SMI through focus groups, in-lab usability testing, and experiential usability testing. Mobile capabilities of the app allow users to access education and support when needed, track goals as they are addressed, view their activity and weight progress, and receive reminders. A coaching dashboard allows real-time access to user progress. CoachToFit was tested with 37 overweight and obese Veterans with SMI who carried the app and received coaching for up to 8 weeks. Results indicated high rates of acceptability and usability and statistically and clinically significant weight loss.

REFERENCES

1. Dickerson, FB, Brown, CH, Kreyenbuhl, JA, et al., Obesity among individuals with serious mental illness. Acta Psychiatr Scand. 2006;113(4):306-13.
2. Centers for Disease Control and Prevention. Obesity and overweight [online]. 2016; https://www.cdc.gov/nchs/fastats/obesity-overweight.htm. Accessed June 1, 2017.
3. Marder, SR, Essock, SM, Miller, AL, et al., Physical health monitoring of patients with schizophrenia. Am J Psychiatry. 2004;161(8):1334-49.
4. Alvarez-Jimenez, M, Hetrick, SE, Gonzalez-Blanch, C, et al., Non-pharmacological management of antipsychotic-induced weight gain: Systematic review and meta-analysis of randomised controlled trials. Br J Psychiatry. 2008;193(2):101-7.
5. Dixon, LB, Dickerson, F, Bellack, AS, et al., The 2009 schizophrenia port psychosocial treatment recommendations and summary statements. Schizophr Bull. 2010;36(1):48-70.
6. World Health Organization. Guidelines for the management of physical health conditions in adults with severe mental disorder. World Health Organization, 2018.
7. Fleischhacker, WW, Arango, C, Arteel, P, et al., Schizophrenia--time to commit to policy change. Schizophr Bull. 2014;40 Suppl 3:S165-S194.
8. Littman, AJ, Boyko, EJ, McDonell, MB, et al., Evaluation of a weight management program for veterans. Prev Chronic Dis. 2012;9:E99.
9. Niv, N, Cohen, AN, Hamilton, A, et al., Effectiveness of a psychosocial weight management program for individuals with schizophrenia. J Behav Health Serv Res. 2014;41(3):370-80.
10. Goldberg, RW, Reeves, G, Tapscott, S, et al., "MOVE!" Outcomes of a weight loss program modified for veterans with serious mental illness. Psychiatr Serv. 2013;64(8):737-44.
11. Kwon, JS, Choi, JS, Bahk, WM, et al., Weight management program for treatment-emergent weight gain in olanzapine-treated patients with schizophrenia or schizoaffective disorder: A 12-week randomized controlled clinical trial. J Clin Psychiatry. 2006;67(4):547-53.
12. Weber, M and Wyne, K, A cognitive/behavioral group intervention for weight loss in patients treated with atypical antipsychotics. Schizophr Res. 2006;83(1):95-101.
13. Wu, MK, Wang, CK, Bai, YM, et al., Outcomes of obese, clozapine-treated inpatients with schizophrenia placed on a six-month diet and physical activity program. Psychiatr Serv. 2007;58(4):544-50.
14. Daumit, GL, Dickerson, FB, Wang, NY, et al., A behavioral weight-loss intervention in persons with serious mental illness. N Engl J Med. 2013;368(17):1594-602.
15. Young, AS, Cohen, AN, Hamilton, AB, et al., Implementing patient-reported outcomes to improve the quality of care for weight of patients with schizophrenia. J Behav Health Serv Res. 2019;46(1):129-139.
16. Luxton, D, McCann, R, Bush, N, et al., mHealth for mental health: Integrating smartphone technology in behavioral healthcare. Prof Psychol Res Pr. 2011;42(6):505-512.
17. Alvarez-Jimenez, M, Alcazar-Corcoles, MA, Gonzalez-Blanch, C, et al., Online, social media and mobile technologies for psychosis treatment: A systematic review on novel user-led interventions. Schizophr Res. 2014;156(1):96-106.
18. Pew Research Center. Mobile fact sheet 2018 (online). 2018; https://www.pewinternet.org/factsheet/mobile/. Accessed April 8, 2019.
19. Wenze, SJ, Armey, MF, and Miller, IW, Feasibility and acceptability of a mobile intervention to improve treatment adherence in bipolar disorder: A pilot study. Behav Modif. 2014;38(4):497-515.
20. Ben-Zeev, D, Mobile technologies in the study, assessment, and treatment of schizophrenia. Schizophr Bull. 2012;38(3):384-5.
21. Johns, DJ, Hartmann-Boyce, J, Jebb, SA, et al., Weight change among people randomized to minimal intervention control groups in weight loss trials. Obesity 2016;24(4):772-280.

5.0

* **Describe the overall significance of the research in terms of the problem to be studied and potential findings, as well as its relevance to the care of veterans, the VAPHS, and the VHA:**

RESPONSE: Between 40% to 60% of individuals with serious mental illness (SMI) are obese. Obesity and physical inactivity result in increased rates of chronic diseases, increased risk of death, and substantial health care costs. Treatment guidelines recommend that individuals with SMI who are overweight should be offered evidence-based weight loss interventions, including psychosocial interventions. The VA's weight management program, MOVE!, is attended by less than 5% of the overweight population and is not adapted to the cognitive needs and patient preferences for the population with SMI. Effective adapted weight management programs are not

offered in VA because they are time-intensive and require the skills of trained providers who are often in short-supply. CoachToFit can address this gap in care. CoachToFit is a weight management program, adapted for the population with SMI, that includes a smartphone app delivering evidence-based weight management services with weekly telephonic support from a VA peer specialist who acts as a wellness coach. Peer specialists are individuals who draw upon lived experiences with SMI to provide services to others with SMI in clinical settings. CoachToFit was shown to have high rates of acceptability and usability and was efficacious for weight loss in a small sample. VA has an opportunity to address obesity in the population with serious mental illness, currently a substantial gap in care.

This project addresses obesity in the population with SMI by evaluating a weight management program that is not only evidence-based, it is sustainable, transportable, appealing to patients, easy to use, and minimally burdensome to the healthcare system. This effort addresses two HSR&D priority areas: 1) Mental Health: Testing new models of care to improve access, cost, and/or outcomes, and 2) Health Care Informatics: Building the evidence base for ehealth/mhealth tools.

CoachToFit's use of mobile technology is an important innovation in VA service delivery and its user-centered design involving individuals with SMI was the first of its kind. CoachToFit is enhanced by data visualization in real-time via a web-based dashboard used by VA peer specialists and their supervisor. We are aware of no other evidence-based mobile platforms to help people with SMI reduce their weight.

6.0
Please upload any additional documents:
Name
Version
There are no items to display

ID:
Pro00003522

View: 2.1 Required Reviews

Required Reviews

1.0
Type of Submission:
New study
If this is a 'New Paper Conversion' please include the MIRB Number:

Please upload a letter certifying that you have made no modifications or amendments in converting this research study from paper to electronic:

2.0
* **Requested Review Type:**

Name

Exempt

◉

Expedited

○

Full IRB Review

○

Not Human Subject Research

3.0

Please check which of the following Service Lines/Departments/Entities will be impacted or used in the conduct of this study
Upload Letter of Support

☐ Clinical Support

☐ Medical Specialty

☐ Investigational Drug Service

☐ Imaging

☐ Community Based Care

☐ Patient Care Services

☐ Behavioral Health

☐ Primary Care

☐ Surgical Specialty

☐ Critical Care

☐ Clinical Trials Center

☐ Regulatory Coordinator Support Core

☐ Clinical Coordinator
Support Core

☐ Ancillary Support Core

☐ Data Support Core

☐
Research Registry
Registry Number:

☐
Other

If Other, please specify:

ID:
Pro00003522

View: 2.1.1 Expedited Qualification

REQUEST FOR EXPEDITED REVIEW

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

AND

Identification of the subjects and/or their responses would not reasonably place them at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, insurability, reputation, or be stigmatizing, or reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are minimal.

1.0
* **Please certify that ALL of the following are true:**
Case
Research presents no more than MINIMAL RISK to subjects (considering physical, psychological, social, legal and economic risk)
Identification of the subjects and/or their responses WOULD NOT reasonably place them at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, insurability, reputation, or be stigmatizing, OR reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are minimal.
The research is not classified.
The research involves only procedures listed in one or more of the categories listed in Section 2.

2.0
If you check any of the items below, the study is qualified for EXPEDITED review status under federal guidelines.
* **Select all that apply:**

Description

1. Clinical studies of drugs and medical devices only when condition **(a)** or **(b)** is met:

(a) Research on drugs for which an investigational new drug application **(21 CFR Part 312)** is not required.

(b) Research on medical devices for which an investigational device application **(21 CFR 812)** is not required OR the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

(a) From healthy, non-pregnant adults who weigh at least 110 pounds. [not to exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or

(b) From other adults and children, considering the age, weight and health of the subjects, the collection procedure, the amount of blood to be collected: The amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

3. Prospective collection of biological specimens for research purposes by non-invasive means. Examples:

(a) hair and nail clippings in a nondisfiguring manner;

(b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;

(c) permanent teeth if routine patient care indicates a need for extraction;

(d) excreta and external secretions (including sweat);

(e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue;

(f) placenta removed at delivery;

(g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;

(h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques;

(i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;

(j) sputum collected after saline mist nebulization.

☑

4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are used, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical devices are not generally eligible for expedited review, including studies of cleared medical devices for new indications)
☑

5. This research involves materials (data, documents, records, or specimens) that have been collected for any purpose including previous research or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).
☑

6. This research involves the collection of data from voice, video, digital, or image recordings made for research purposes.
☑

7. This research will be performed on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or will employ a survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

ID:
Pro00003522

View: 3 Research Design

Methods & Procedures
1.0

* **Does this research study involve any of the following:**

Name
☐

Deception
☑

Interview/Focus Groups
☐

Use of Drug, biological, or nutritional (e.g., herbal or dietary) supplement (investigational or FDA approved)?
☐

Use of medical devices
☐

Prospective Analysis of Specimens
☐

Banking of Specimens-Data
☐

Retrospective use of specimens
☑

Audio/Video Recordings or Photographs
☐

Honest Broker or other similar service
☐

None of the Above

ID:
Pro00003522

View: 3.2 Interview-Focus Groups

Interview-Focus Groups

1.0
* **Attach copies of any scripts and/or questions that will be used to guide the interviews/groups:**
Name
Version
CoachToFit Interview Questions-v1.docx
0.01

2.0

* **Please describe the Study Team qualifications (for example, special training):**
Dr. McCarthy has professional training and experience as an investigator in mixed methods and qualitative research, and has successfully managed qualitative projects and research teams, and brings practical experience as a trainer,mentor, and manager of qualitative interviewers to this project. In addition, she has extensive research and practical experience working with VA Peer Specialists and a comprehensive understanding of their roles. These complementary proficiencies prepare her well for the responsibility of providing expertise for conducting these focus groups.

Dr. Panas serves as Co-PI and Project Manager in the VISN4 CHERP and MIRECC at VAPHS. Dr. Panas is a certified clinical research professional having spent over 25 years in pharmaceutical drug development and medical affairs education efforts. He has also served for over 10 years as adjunct faculty supporting masters and doctoral students on their dissertations as well as teaching various courses in public health, health education, health communication campaigns, and clinical research. He has extensive quantitative and qualitative skills having published a number of articles and presented at several conferences. Dr. Panas recently joined Dr. Chinman on various peer specialist projects within the VA. Dr. Panas will coordinate and manage the implementation and conduct of the study and serve as the qualitative methodologist. He will coordinate the efforts of the investigative team, oversee the development of the data tracking and management systems, assure the integrity of the data and protection of human subjects by working with the IRB, and help manage the project budget. He will also contribute to the preparation of reports, presentations, and manuscripts related to the study project.

ID:
Pro00003522

View: 3.8 Audio/Video Recordings or Photographs

3.8 Audio/Video Recordings or Photographs
1.0
* **Please provide a description of the audio and/or visual recordings or photographs and who will have access to them:**
Leaders will be asked to reflect on provision of evidence-based practices via apps, reflections on our findings, encouraging provider referrals, and implementation and sustainability needs. These 30-minute interviews will be digitally recorded and transcribed by approved CHERP staff members.
2.0
* **Please describe why this study could not be done without collecting this information in this manner:**
Audio recordings are necessary to ensure accurate collection of qualitative feedback which will be used to help design a weight loss program tailored to Veterans with Serious Mental Illness.
3.0
* **Please specify your plans for deidentifying or anonymizing the material and when it will be destroyed:**
The audio recordings to be transcribed by CHERP staff will be labeled by the subject's unique alphanumeric code and saved behind the VA firewall in the study's secure shared project folder on the research server. The transcription staff will be given access to a sub-folder within the study's secure project folder. Approved study staff will place a copy of the audio files in this folder for an approved transcriptionist to access for the purposes of transcription. The transcriptionist will transcribe each interview verbatim and save the completed transcript in the sub-folder using the same alphanumeric code. No data (audio files, in process transcripts, or completed transcripts) will leave the secure research server. The CHERP transcriptionist will be part of the study staff.

ID:
Pro00003522

View: 4 Research study methods

Research Study Methods

Describe all study related procedures following enrollment of a subject in this study.

Please see Section 6 for where the study team defines when a subject will be considered enrolled in the study.
1.0
* **Research Procedures/Interventions:**

After completing consent, participants will participate in a baseline assessment, which will consist of: Measuring body weight and height using a hospital quality scale; Assessing Cardiorespiratory Fitness (collection of blood pressure, heart rate/pulse, and oxygen saturation) ; Assessing self-efficacy regarding health-related eating and exercise behaviors; Assessing motivation to lose weight; Assessing food intake and patterns of eating, physical activity patterns, familial weight history, major medical conditions and other complicating factors, including readiness to change behavior, motivation, and self-efficacy.

The assessment will take approximately 25 minutes, and participants will receive $25 reimbursement for their time. During this assessment, Google Fit will be downloaded to the phones of Android users and we will confirm that Apple Health Kit is on the phone of iPhone users. We will teach each participant how to read the step data collected by these programs and will encourage them to keep their phone with them. Following the baseline assessment, in the same meeting, all participants will meet with a peer coach (peer specialists) who will discuss with them the importance of losing weight (using a structured conversation that follows a handout which is provided to the participant). The handout was developed with input from a VA dietitian as well as Veterans and is graphically appealing, with a simple layout, and provides information on diet and activity as well as the local MOVE! schedule. The Research Assistants will then use the DACIMA database) randomization module to assign participants to a study arm, and the peer coach will inform the Veterans of their assignment.

Study Arms
CoachToFit: Those randomized to CoachToFit will have the CoachToFit app downloaded to their phone by the peer coach and will work with the coach to initialize the app. [Individuals are assigned in order of study enrollment to each coach in turn, building the coaches' cohorts evenly.] Individuals will receive an activity tracker compatible with Android OS and iOS (Amazfit Bit) and a Bluetooth scale (Smart Body scale). As we did in the CoachToFit development merit, [participants will be instructed by the peer to complete at least two CoachToFit modules per week.] 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. They will also set up a time for the first 20-minute coaching call, which will then continue weekly. Weekly coaching calls reinforce and emphasize what is learned in the modules. The coaches use motivational strategies to help participants develop the self-efficacy to make dietary and physical activity behavioral changes. Coaches identify barriers associated with attainment of stated goals and engage Veterans in active problem solving. Coaches receive individual weekly supervision by the study PI. Access to the app and coaching continues for 6 months. There is no reimbursement for use of the app or coaching.

6- and 12-months Post-Baseline Assessment: In-person assessments, lasting approximately 25 minutes are completed at 6- and 12-months post-baseline. Participants will receive $25 for each assessment. 6-month Qualitative Interview: For those randomized to the CoachToFit arm, after the 6-month assessment, 30% (n=30) will be invited by the Project Director to complete a qualitative interview. If an individual declines, the next participant assessment completed will be offered the opportunity. Participants will be reimbursed $15 for these 15-minute qualitative interviews.

Peer Specialists interviews: At the conclusion of the study, Peer Specialists who have been involved as Peer Coaches will be interviewed to determine their perspective on the intervention. The interview will be one time for approximately an hour and will be voluntary. An informed consent will be conducted prior to the interview. Peer Specialists are VA employees and will not be compensated for this interview, should they choose to participate.

Please upload a table of procedures if applicable.
The study procedures table must be completed for:
- All Greater than Minimal Risk (GTM) studies; and
- All Minimal Risk studies that use Standard of Care or Usual Care/Interventions.

Name
Modified Date
data collection C2F.docx
9/28/2020 4:03 PM

2.0
* **Will Usual Care Procedures/Interventions be used?"**
(●) **Yes** ( ) No

If yes, please specify and include a description of what the usual care or expected level of care is at VAPHS (e.g., medications, testing, timing, etc.) for patients, similar to those individuals that meet the inclusion/exclusion criteria for this research study:

Those randomized to usual care will continue with usual VA care around diet and activity, which consists of access to MOVE!. Individuals in MOVE! receive pedometers and are weighed in class weekly.

2.1
If Usual Care Procedures/Interventions will be used, who is the individual or entity responsible for relevant aspects of the usual care (i.e., which of the above usual care activities will the research study team be responsible for)?:
MOVE! program

2.2
Does the usual care at VAPHS for the condition of interest in this research study differ from national guidelines/recommendations (i.e. standard of care)?
( ) Yes (●) **No**

If yes, please describe the differences:

2.3
Are any procedures that are considered standard for this patient population performed more frequently than usual care?
( ) Yes (●) **No**

If yes, please indicate which time points are considered usual care and which are considered research.

2.4
If there is more than one standard, does VAPHS limit which one is followed (e.g. warfarin use for atrial fibrillation vs. one of the newer anticoagulants).
( ) Yes (●) **No**

If yes, please explain:

3.0

* **Does clinical expertise need to be enlisted?**

○ Yes ◉ **No**

If yes, please provide the provisions for enlisting the services of a clinician with appropriate expertise and privileges to perform duties, if the investigator is not a clinician [i.e. reviewing the data, adverse events, and new study findings; also making required decisions to protect the health of the subject (e.g., stopping the participant's involvement in the study or determining when to notify the subject or the subject's health care provider of information that may affect the health of the subject)]:

4.0

Please upload any surveys, questionnaires, and data collection forms.

Document
Description
Version Number
View
15_VA_Appendix_5_UsabilityandAcceptablity.pdf(0.01)

0.01
View
16_VA-Appendix_6_InterviewGuide.docx(0.01)

0.01
View
4 item stages of control short form.pdf(0.01)

0.01
View
MOVE11_NoSSN.pdf(0.01)

0.01
View
Selfefficacy_coverandexercise.pdf(0.01)

0.01

ID:
Pro00003522

View: 4.1 Research study methods: analysis Plan

1.0

* **Please describe the analysis plan for the study** *(it is acceptable to refer to the sponsor/multi-site protocol for section if applicable):*

Aim 1: Test the efficacy of CoachToFit, compared to usual care, in decreasing weight among Veterans with SMI who are obese. We will analyze the differences between the groups in change over time using a generalized linear mixed model (GLMM). The GLMM accounts for differences at baseline and the within- subject autocorrelation of the repeated measures in the same person, and additionally

provides unbiased parameter estimates when missing data are present, as long as the missing data are missing at random. [The GLMM uses a full information estimation approach that ensures that all available data is used, including the data of participants that only provide partial information, making these analyses intention-to-treat (ITT). We will determine if there are systematic differences between participants with complete data and those with missing data by comparing their baseline data. Additionally, we will conduct sensitivity analyses by replicating the ITT analyses in the sample with only participants with complete data and evaluating if the results and parameter estimates differ. The GLMM also allows us to include person-level and time-varying covariates in secondary analyses to explore additional determinants of the change in our outcome variables. The main person-level covariates of interest for these secondary analyses will be race, ethnicity, and income. If there is evidence that suggest moderating effects of these subgroups on the efficacy of CoachToFit, we will characterize the results for each subgroup separately based in post hoc analyses. For subgroups that are below n=15 no post hoc analyses will be conducted but we will describe the effects using descriptive statistics and effect sizes as the subgroup only GLMMs would be underpowered.] The [26-item survey] will be used to characterize usability and acceptability of the app, reflecting on their 6-month usage period. We will determine if the ratings are associated with user characteristics ([race, ethnicity, income,] cognitive measures, age, diagnosis category, highest education, previous MOVE! attendance [yes/no], length of time of phone ownership [months], number of healthy lifestyle apps on phone, number of apps total on phone). If there are strong associations present we will use this to identify the characteristics of the subgroups of participants that are not served well and to determine what features would improve the usability of CoachToFit for this population.

Aim 2: Assess the hypothesized mechanisms of action for CoachToFit, including self-efficacy, motivation, and readiness to change. We will analyze the pattern of change within the CoachToFit group over time using a GLMM. GLMM accounts for differences at baseline and the within-subject autocorrelation of the repeated measures in the same person, and additionally provides unbiased parameter estimates when missing data are present, as long as the missing data are missing at random. We will also use the GLMM to include the antecedents of change of interest as time-varying covariates in models of change of the outcome variables to establish that the pattern of change in the intermediate targets is associated with corresponding change in the main outcome variables. [We will evaluate the effects of missing data using the same approach as in Aim 1.]

Aim 3: Characterize factors that will inform future implementation and maintenance of CoachToFit using a multi-stakeholder qualitative post-intervention evaluation guided by the RE-AIM framework. Analysis of the Veteran, staff, and leader interviews and Veteran group meetings will initially focus on data consolidation to use findings rapidly and iteratively to inform interpretation of study findings as well as next steps for CoachToFit. Specifically, using a rapid analysis approach developed by Co-I Hamilton,94, 95 interview transcripts will be summarized in a template organized by key interview domains (see Appendix 6). Summaries will be organized into matrices to compare and contrast findings across types of stakeholders and to explore the RE-AIM dimensions. In our extensive experience, this data consolidation approach is sufficient for generating study-related products such as executive summaries and presentations to leaders and other stakeholders. The approach will help generate a preliminary codebook, to be used for more in-depth analysis of the interviews using ATLAS.ti, a qualitative data analysis software program that allows for fluid interaction of data across types and sources. Initially, a top-level codebook will be developed by the team based on the semi- structured interview guide and the summaries.96 Using a constant comparison analytic approach, this codebook will be elaborated upon by the analysts based on emergent themes and iteratively adjusted.97 These approaches and groupings are easily facilitated within ATLAS.ti, which has the capacity to group data in multiple ways (e.g., by site, role) and allows for maximum efficiency in navigating a narrative dataset. Should ambiguous trial results arise, the post-intervention evaluation data will be explored to illuminate possible explanations for unexpected findings, particularly according to RE-AIM dimensions. For example, per Holtrop and colleagues, qualitative inquiry related to the effectiveness dimension includes examining “whether various stakeholders find the effectiveness findings meaningful, why interventions produce different pattern of results across different RE-AIM dimensions, reasons for differences in results across subgroups, and why unanticipated negative results are observed.”68 [To compliment these qualitative data, Toggl data will allow for reports of effort required to deliver and support CoachToFit by role (coaches, supervisors, software developers) and time (experience of coach; maturity of the app) and cohort size.]

ID:
Pro00003522

View: 5 Sub-Studies

1.0
* **Is there a sub-study or are there sub-studies associated with this study?**
There is no sub-study associated with this study.

ID:
Pro00003522

View: 6 Study Population Summary

Study Population Summary
1.0
* **What is the maximum number of subjects you plan to enroll at VAPHS?**
256
2.0
* **Do you plan on enrolling patients into different categories:**
(●) **Yes** ( ) No

If yes, please explain:

CoachToFit: Those randomized to CoachToFit will have the app downloaded to their phone by the peer coach and will work with the peer coach to initialize the app. They will receive an activity tracker compatible with Android OS and iOS (Amazfit Bit) and a Bluetooth scale (Smart Body scale). Participants will be instructed by the peer to complete at least two CoachToFit modules per week. 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. They will also set up a time for the first 20-minute coaching call, which will then continue weekly. Weekly calls from the coach reinforce and emphasize what is learned in the modules and help to support ongoing behavior change efforts. Access to the app and coaching continues for 6 months. There is no reimbursement for use of the app or coaching.

Usual Care: Those randomized to usual care will continue with usual VA care around diet and activity, which consists of access to MOVE!. Individuals in MOVE! receive pedometers and are weighed in class weekly.

6- and 12-months Post-Baseline Assessment
In-person assessments will be conducted, lasting approximately 25 minutes, at 6- and 12-months post-baseline, and participants will receive $25 for each as a reimbursement for their time.

6-month Qualitative Interview
For those randomized to the CoachToFit arm, after the 6-month assessment, 30% (n=30) will be invited by the Project Director to complete a qualitative interview. If an individual declines, the next participant assessment completed will be offered the opportunity. Participants will be reimbursed $15 for these 15-minute qualitative

interviews.

3.0
If this is a multi-site study, indicate the projected total subject accrual:

4.0
* **Please provide a justification for the sample size:**
Disparities and subgroup differences were considered by exploring and presenting the demographics from the CoachToFit development merit (described above and in the revised proposal) and also in the revised power and data analysis plan. Our enhanced power analysis section now indicates that if the effect size within a subgroup is comparable to the f=.41 that was observed in the pilot data, this design provides sufficient power (>.8) to detect within subject effects for subgroups as small as 15. This suggests that this study will provide sufficient power for at least the subgroups where these effects are the largest. The generalized linear mixed model (GLMM) planned allows us to include person-level and time-varying covariates in secondary analyses to explore additional determinants of the change in our outcome variables. The main person-level covariates of interest for these secondary analyses will be race, ethnicity, and income. If there is evidence of subgroup moderating effects on the efficacy of CoachToFit, we will characterize the results for each subgroup separately based in post hoc analyses. For subgroups that are below n=15 no post hoc analyses will be conducted but we will describe the effects using descriptive statistics and effect sizes as the subgroup only GLMMs would be underpowered.

ID:
Pro00003522

View: 6.1 Study Population

Study Population

1.0
* **Check all that apply to describe your study population:**

Study Population
☐

Non-Veterans
☑

Special Populations
☑

Veterans
☐

Vulnerable populations

☐

Other

2.0
* **Indicate the inclusion criteria for enrollment:**
1) chart diagnosis of schizophrenia, schizoaffective disorder, bipolar disorder, or recurrent major depressive disorder; 2) age 18 and over; 3) BMI ≥ 30.0 (obese); and 4) ownership of a phone running Android OS or iOS (iPhone).

Peer Specialists who have worked with the study will be interviewed following the study completion. Only Peer Specialists who have been directly involved as Peer Coaches for this study will be interviewed. They will complete an informed consent process prior to being interviewed, and the decision to be interviewed is voluntary. Peer Specialists are VA employees.
3.0
* **Indicate exclusion criteria for enrollment:**
1) chart diagnosis of dementia; 2) history of bariatric surgery; 3) pregnant and nursing mothers; 4) patient has a conservator/legally authorized representative who makes their medical decisions; 5) psychiatric hospitalization during the month prior to enrollment.

4.0
If there are any age, ethnic, language, or gender-based exclusion criteria, including the exclusion of any pregnant or lactating women, or those of child-bearing potential, please provide justification:
It is not be prudent for individuals who are pregnant and or nursing to engage in a weight loss program.
5.0
Please specify why vulnerable subjects and/or special populations will not be enrolled:

6.0
With some exceptions as listed in VHA Handbook 1200.05, incompetent subjects cannot be enrolled in VAPHS approved research. Specify that you will not enroll incompetent subjects and the general rules to be used in making that determination:
Potential subjects who are not able to understand informed consent will not be enrolled. We will not enroll incompetent subjects, including those with dementia.

ID:
Pro00003522

View: 6.3 Study Population- Special Populations

Study Population

1.0
* **Check all that apply to describe your study population:**

Name
☑

Employee and Student Subjects

Investigators Clinical Population

2.0
* **Provide a justification for including these subjects:**
The staff participants, as VA employees, may be considered a vulnerable population since they have the potential to be coerced by supervisors; however, their involvement is critical to the successful development and evaluation of the intervention given their unique position as stakeholders with valuable information about the context where the intervention would be implemented and the Veteran population who would be users.

ID:
Pro00003522

View: 6.3.1 Employee and Student Subjects

Employee and Student Subjects

1.0
* **Target Number of Participants:**
3
2.0
* **Please indicate how you will minimize the potential for them to feel coerced to participate. Discuss how the potential confusion in roles will be addressed:**
Research staff will reiterate that study participation is completely voluntary and that their decision to participate (or not) in this research project will not have an impact on their employment.

ID:
Pro00003522

View: 7 Risk/Benefit Assessment-Risks

Risk/Benefit Assessment-Risks

1.0
* **Risk classification for this study (select one).**

Name

Minimal Risk

Greater than Minimal Risk

2.0

* **Basis for making the above recommendation:**

This adapted weight loss intervention is one of the first systems to conveniently address the needs of adults with SMI by making weight loss resources available when and where it is convenient to access them. It will also minimize time and resource burdens for clinicians. To accomplish this, it is critical to have the involvement of individuals who are representative of the population so that the intervention can be evaluated and future implementation can be informed. The minimal risks to subjects of participating are reasonable in relation to the importance of the knowledge that reasonably may be expected to result.

3.0

* **Describe the safety precautions that will be taken to minimize risks/harms:**

Breach of Confidentiality.
Discomfort with procedures or disclosure.
Financial burden.
Physical activity.
Nutrient intake.
Hypoglycemia related to diet and exercise interventions.
Symptomatic hypotension related to diet and exercise interventions.

4.0

* **Provide details regarding the nature of each risk using the area provided below:**

Risk Name
View
Nutrient intake.
View
Physical activity
View
Financial burden.
View
Hypoglycemia related to diet and exercise interventions.
View
Discomfort with procedures or disclosure.
View
Symptomatic hypotension related to diet and exercise interventions
View
Breach of Confidentiality

5.0

* **Do you plan on using the research answering service:** Yes **No**

If yes, please Upload the research answering service form:

6.0

If your study involves a treatment or intervention, please upload the Patient ID Card:

ID:

Pro00003522

View: 7.1 Risk/Benefit Analysis-Potential Benefits and Alternatives

Risk/Benefit Analysis-Potential Benefits and Alternatives

Describe any potential for benefits to participants in this study:
1.0
* **Direct and Indirect Benefits to Subjects:**
There are some potential benefits to human subjects for participating in the proposed research. It is theorized that participants will benefit from the trial of the program by improving their diet, increasing their exercise, and losing weight, as suggested by the pilot trial. Also, they may be able to impact the development of an adapted weight loss intervention in a way that most closely meets their needs. This may affect their treatment in the future, especially if the intervention is found to be effective. The minimal risks to subjects of participating are reasonable in relation to these anticipated benefits.

Even participants in the control group may indirectly benefit from this research. The assessments that all participants will complete (control group included) will provide information about their health that could be motivating to improve their health and could provide concrete information about what their health goals should be. Thus, participants will have significantly more information about their health at their disposal when communicating with clinicians about their dietary, exercise, and other personal habits, which could improve the weight loss care they receive from these clinicians. Also, participants may gain satisfaction from participating in a research study for themselves and their self-motivation. Research suggests that individuals who participate in weight monitoring (what the control group is) can experience a weight loss benefit.

2.0
* **Describe alternatives (research or non-research) that are available to subjects if they choose not to participate in this study:**
The only alternative is not to participate in this study. There may be other ways of weight management if Veterans do not wish to participate in this research they may participate in usual care for weight management at the VA like the MOVE! program. Veterans may discuss these options with their doctor.

ID:
Pro00003522

View: 8 Methods of Recruitment and Retention

Recruitment Methods and Materials used for Retention
1.0
* **Select recruitment methods used on this study:**

Name
☑

Mail Campaign

☐

Referral by independent source
☐

Advertising such as fliers, letters, or ads (newspaper, TV, radio)
☐

Web Site
☐

Research registry
☑

Selected from pre-existing records
☐

Pre-existing relationship with participants
☐

Other

If Other Methods Specify:

2.0
* **Specify how subjects will be identified and how study eligibility will be determined:**
A list of potentially eligible participants will be identified. We will obtain mental health diagnoses, age, most recent weight and height, name, last 4 of social security number, and telephone number. These data are available through VA Informatics and Computing Infrastructure (VINCI) accessing the Corporate Data Warehouse (CDW), or medical center data systems. We will use an opt-in letter to invite individuals to find out more about the study. If eligible participants are interested, they will be directed to contact study staff for further information. The RAs will field calls in response to the letter and will also make follow-up phone calls to potentially eligible participants who receive this opt-in letter, to determine their interest. We have used this method successfully in multiple studies to recruit large samples of VA patients with SMI and believe this additional recruitment method is warranted because of the benefit they could receive from participating in the study, regardless of group assignment (e.g. learning more about their health, improving their diet, increasing their exercise, and losing weight).

For those interested in participating, additional eligibility criteria will be confirmed by self-report via a phone call from a RA. We will ask the prospective participants if they own a smartphone and help them to determine if it is running Android OS or iOS. If the eligible participant has an eligible phone, he/she will be scheduled to complete the informed consent.
3.0
* **Provide the location (or locations) of the sites where participants will be recruited:**
Pittsburgh Healthcare System University Drive

4.0
Please include information regarding any advertisements (print, TV, radio, etc) that will be used to recruit subjects including a general description of where this information will be posted:

5.0
Please UPLOAD the documents that will be used for recruitment and an introductory statement or letter to accompany consent for those studies obtaining written informed consent using methods such as fax, email or mail (if applicable). Please also upload any screening/recruitment questions that will be verbally asked of potential research subjects. Also, if you will be providing any retention materials, please upload them here.

Name
Reviewer
Modified Date
Version Number
veteran outreach letter-with signature_Chinman PI_signed.pdf
Chinman, Matthew
9/29/2020 3:16 PM
0.01

ID:
Pro00003522

View: 8.1 Mail Campaign

Mail Campaign
1.0
* **Please specify whether an "opt-in" or "opt-out" recruitment approach will be used. If an "opt-out" approach is planned, please provide a rationale for why the IRB should approve this approach including an assessment of the level of risk of this study and a description of the direct benefit of this study to all participants:**
An Opt-in approach will be taken for this study.

ID:
Pro00003522

View: 9 Informed Consent

Informed Consent

1.0

* **Indicate the types of consent that will be involved in this study (check any or all that apply):**
Informed Consent Category
Written/signed consent by subject
Waivers are being requested.

2.0
* **Waivers: If you are applying for any waivers of consent (check any or all that apply):**

Name
☐

Waiver of Informed Consent
☑

Waiver of HIPAA Authorization
☑

Waiver of Documentation of Informed Consent (telephone consent, verbal script)
☐

No Waiver at all

3.0
* **Will this study include non-English speaking participants?**
○ Yes ◉ **No**

ID:
Pro00003522

View: 9.1 Waiver of HIPAA

You have indicated you are requesting a waiver of HIPAA.

1.0
* **Is the request only for Screening/Recruitment purposes?**
◉ **Yes** ○ No
If yes, please describe your screening/recruitment method:
A list of potentially eligible participants will be identified. We will obtain mental health diagnoses, age, most recent weight and height, name, last 4 of social security number, and telephone number. These data are available through VA Informatics and Computing Infrastructure (VINCI) accessing the Corporate Data Warehouse (CDW), or medical center data systems. We will use an opt-out letter to invite individuals to find out

more about the study. If eligible participants do not opt out, they will be contacted by a Research Assistant (RA) to inquire about study interest. The RAs will field calls in response to the letter (both those who want to opt out and those who self-initiate a call for more study information). Follow-up phone calls to the letter will be made by the RAs to determine potential interest and the study or to opt out of further contact. We will also post flyers at VAPHS clinics inviting participation and field calls in response to these. Potential referrals from other VAPHS clinics will receive follow-up calls in response to a potential interest. We have used these methods successfully in multiple studies to recruit large samples of VA patients with SMI.

We believe follow-up phone calls is warranted because of the benefit Veterans could receive from participating in the study, regardless of group assignment (e.g. learning more about their health, improving their diet, increasing their exercise, and losing weight). For those interested in participating, additional eligibility criteria will be confirmed by self-report via a phone call from a RA. We will ask the prospective participants if they own a smartphone and help them to determine if it is running Android OS or iOS. If the eligible participant has an eligible phone, he/she will be scheduled for an in-person meeting to complete the written informed consent process.

If no, the request is for the full study (e.g. retrospective chart reviews and certain observational studies) Please describe the types of records and/or databases to be accessed:

THE IDENTIFIABLE INFORMATION BEING REQUESTED:
Note: If participants will be receiving payment and HIPAA Authorization is not being obtained, you must select Names, Addresses and Social Security Numbers as that information will be disclosed for payment purposes.
2.0
* **Identifiable Information per HIPAA Definition**

Name
☐

None
☐

Account numbers
☐

Biometric identifiers, including finger and voice prints
☐

Certificate/license numbers
☐

Device identifiers and serial numbers
☑

Elements of dates (except year, for example, date of birth, admission date, discharge date, date of death, date of procedures; and all ages over 89)
☐

Email Address

☐

Fax Numbers
☐

Full-face photographic images or any comparable images
☑

Geographical subdivisions smaller than a State (street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code)
☐

Health plan beneficiary numbers
☐

Internet Protocol (IP) address numbers
☐

Medical Record Numbers
☐

Name or any derivative of name such as initials
☑

Social Security Numbers
☑

Telephone Numbers
☐

URLs (Web Universal Resource Locators)
☐

Vehicle identifiers and serial numbers, including license plate numbers
☐

Any other unique identifying number, characteristic, or code (Note: The study ID number, code or other means of record identification is not considered one of the identifiers that must be excluded for de-identification)

3.0
* **Patient Protected Health Information:**

Name
☑

Demographic Information (e.g., Name, Address, Phone Number, Social Security Number
☐

Billing and Payment Information
☐

Hospital or Medical Records
☐

History and Physical Exam Notes
☑

Mental Health Records
☐

Data Previously Collected for Research Purposes
☐

Progress Notes
☐

Consultation Reports
☐

Laboratory Test Results
☐

Operative Reports
☑

Other

Please indicate the 'Other' Patient Protected Health Information:
Most recent height and weight
4.0
Other Health Information:
Name

There are no items to display

ID:
Pro00003522

View: 9.1.1 Waiver of HIPAA - More Information

Waiver of HIPAA- More Information
1.0
* **Describe how the identifiable information is to be used and/or disclosed only by members of the research team and the following persons *(identify with specificity and justify the need to disclose the information to anyone outside the VHA.)* Note: If participants will be receiving payment and HIPAA Authorization is not being obtained, you must also describe this disclosure to representatives of the VA for administrative purposes here.**

Also describe how this activity meets the "minimum necessary standard" described in the HIPAA Privacy Rule:
The screening procedures propose a minimal risk to privacy because the data that we are requesting (mental health diagnosis, age, most recent weight and height, name, last 4 SSN, address, and telephone number) is the minimum necessary to assess eligibility.

The proposed study poses minimal risk to the privacy of the subjects because...
2.0
* **Describe how the identifiable information will be protected from improper use or disclosure by (detail how this will be accomplished including the limitations of physical or electronic access to the information and other protections):**
All information gathered will be housed in a password-protected database on a shared drive that is behind the VA firewall.
3.0
* **Describe how the identifiers will be destroyed at the earliest opportunity consistent with the research (discuss the timeframe or the reasons the identifiers must be retained, including health or research justifications or any legal requirement to retain them) (Note: At this time, identifiers used for research screening and all other screening records must be retained indefinitely and this must be documented by checking "Other" below):**
Screening is only to identify potential subjects. All research records will be maintained in accordance with the Veterans Health Administration (VHA) Records Control Schedule. Paper records will be disposed of using methods deemed appropriate by the VAPHS Privacy Officer, and all electronic data will be sanitized using methods rendered appropriate by the VAPHS ISO.
* **When will screening data be de-identified or destroyed:**
Name
Other

If Other, please describe:
All research records will be maintained in accordance with the Veterans Health Administration (VHA)

Records Control Schedule. Paper records will be disposed of using methods deemed appropriate by the VAPHS Privacy Officer, and all electronic data will be sanitized using methods rendered appropriate by the VAPHS ISO.

4.0

* **Describe how the identifiable information will not be reused or disclosed to any other person or entity outside the VHA other than the manner described in the protocol, except as a required by law, for authorized oversight of this research study, or as specifically approved for used in another study by an IRB:**

Records will be kept locked and in the possession of appointed research staff who will oversee the privacy of the collected PHI and it will not be used in any other manner by any other entity that has not been approved by the VAPHS IRB.

5.0

* **Describe why the proposed study cannot be practicably conducted without a waiver of authorization: (discuss reasons why it would not be possible to obtain authorization from individual subjects. Time constraints themselves are generally not considered adequate for this justification:**

The proposed study cannot be practicably conducted without a waiver of authorization because of the need to identify eligible Veterans based on multiple criteria. By being able to screen the charts in CPRS this will allow for the maximum patient enrollment with the minimalist amount of patient burden.

6.0

* **Describe why the proposed study cannot be done without the specified identifiable information: Discuss reasons why it would not be possible to conduct the research without the identifiable information being collected.**

There are multiple eligibility criteria in the study that may be missed if records cannot be reviewed. Without patient records, eligibility cannot be assured.

ID:
Pro00003522

View: 9.3 Waiver of Documentation of Informed Consent

Waiver of Documentation of Informed Consent

You have selected a waiver of Documentation of Informed Consent

1.0

This is a request for Waiver of Documentation of Informed Consent because this research study conforms to either A and/or B (Check if 'yes' and provide the verifying information requested):

* A: The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern.

Yes ◉ **No**

AND/OR

* B: The proposed study poses minimal risk to the subjects. ◉ **Yes** ○ No

If yes, please explain why the proposed study poses minimal risks to the subjects. (Outline the subject's involvement in the project and why the study poses minimal risk):

Risks are minimal as they are only interviews with peer specialists

2.0

* **The research involves no procedures for which written consent is normally required outside of the research context. Research procedures include:**
Interviewing Peer Specialists to see how weight loss strategies are working

3.0
* **Explain how whenever appropriate, the subjects will be provided with additional pertinent information (e.g. an information sheet):**
An information sheet is provided for Peer Specialists who will be invited to be interviewed at the conclusion of the study.
4.0
Please upload SCRIPT here:

Document
Description
Version Number
View
C2F Info Sheet_Peer Specialist_090220.docx(0.01)

0.01

ID:
Pro00003522

View: 9.4 Consent Forms & Process of Consent

Consent Forms & Process of Consent

1.0
Upload the completed forms into the correct lists below.
1.1
Informed Consent Form (clean copy):

Document
Modified Date
Version Number
View
C2F ICF and HIPAA_22Sept 2020-clean.doc(0.01)
9/22/2020 12:00 AM
0.01

1.2
Provider Behavior Informed Consent Form (clean copy):

Document
Modified Date
Version Number

There are no items to display

1.3
Screening Informed Consent Form (clean copy):

Document
Modified Date
Version Number

There are no items to display

2.0
Consent Forms (modified copy):

Document
Modified Date
Version Number
View
C2F ICF and HIPAA_26JUNE20 -tracked.doc(0.01)
9/24/2020 2:45 PM
0.01

3.0
* **Describe how, where, when, and by whom the consent process will be initiated:**
The consent process will be initiated once eligibility is determined and research staff receive permission to contact potential subjects or when potential subjects contact research staff to express interest in study participation.
4.0
* **Will you be maintaining a Master List of Subjects?**
Yes
5.0
* **Describe when the subject's name will be added to the master list and how the list will be maintained in a secure fashion.**
Subjects information will be entered in an Excel spreadsheet with password protected behind the VA firewall.

ID:
Pro00003522

View: 10.0.0 Data Security and Privacy: Data Types Storing

10.0 Data Types Collecting and Storing
1.0
Click the add button (below) to open an entry form to indicate the types and/or sources of the data that will be collected/stored as part of the project.

Instructions: **For each type/source of data that will be collected as part of the project, this includes screening data, click the add button to open an entry form that lists the types and/or sources of data. Select a source/type of the data that will be collected/stored. Then indicate what, if any, identifiers or sensitive information will be collected/stored from the source/type (None is an option). To add another source/type click "OK Add Another" button to open up a new entry form to repeat the process.**

Example 1: You are collecting data from VA Medical records including names, last 4 of SSN, and addresses. Therefore, you would select "VA medical record data" as the source, and then select in the identifiers: "Name or any derivative of name, such as initials," "Social Security Numbers," and "Geographical subdivisions smaller than a State (street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code)" as the identifiers being collected.

Example 2: You are screening VA Medical Records and recording the information you use to screen (i.e.: names, last 4 of SSN, and addresses, etc.) Note: This information must be treated as a Source document, please select "Screening" as the source and then select the identifiers "Name or any derivative of name, such as initials," "Social Security Numbers,", as applicable.

*

Data Type/Source
Collection Details
Identifiers
View
VA medical record data (i.e., diagnoses, procedures, visits) via **data warehouse/VINCI extraction**
Mental Health Diagnoses will also be pulled. Research staff will complete a request to pull the data and any relevant information will be entered into DACIMA, the electronic database that is housed behind the VA Firewall.

- Any other unique identifying number, characteristic, or code (Note: The study ID number, code or other means of record identification is not considered one of the identifiers that must be excluded for de-identification)
- Telephone Numbers
- Social Security Numbers
- Geographical subdivisions smaller than a State (street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code)
    - Name or any derivative of name such as initials

View
Questionnaires/Surveys, electronic
Study staff will collect questionnaire data by telephone and record it directly into the study data base on DACIMA.

- Elements of dates (except year, for example, date of birth, admission date, discharge date, date of death, date of procedures; and all ages over 89)

View
VA medical record data (i.e., diagnoses, procedures, visits) via **chart review**
Research staff will collect this data and will record it in DACIMA, the electronic database that is housed behind the VA Firewall.

- Telephone Numbers
- Social Security Numbers
- Geographical subdivisions smaller than a State (street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code)
    - Name or any derivative of name such as initials

ID:
Pro00003522

View: 10.0.1 Data Security and Privacy: Social Security Numbers

10.0.1 Data Security and Privacy: Social Security Numbers
1.0
You indicated that you will be using all or some part of the research subjects' SSNs as part of this study. Which of the following will you be using:
Real Social Security numbers
* (•) **Yes** ( ) No
Scrambled Social Security numbers
* ( ) Yes (•) **No**
Last 4 digits of Social Security Number
* (•) **Yes** ( ) No
Other (some derivation of the SSN)
* ( ) Yes (•) **No**
If other, please explain:

2.0
* **Please describe how subjects' Social Security numbers will be used in this study:**
The last 4 SSN will be used for subject identification purposes and the full SSN will be used to process study payments.

3.0
* **Please describe the security measures that will be taken to protect SSNs.**
SSNs stored electronically be will be maintained in DACIMA, the electronic database, that is housed behind the VA Firewall. Only research staff who need this information to complete their jobs will have access to this information. Any paper copies will be stored in a locked file cabinet in a locked office.

ID:
Pro00003522

View: 10.1.0 Data Security and Privacy: Incoming Data

10.1.0 Incoming Data
1.0
* **Will data be transferred into VAPHS?**
Yes. Data is being obtained from another VA source (not VAPHS) and will be transferred to VAPHS

ID:
Pro00003522

View: 10.1.1 Data Security and Privacy: Incoming Data - Identifiable Data

10.1.1 Incoming Data - Identifiable Data
1.0

* **Is any of the data being transferred *into* VAPHS identifiable?** (•) **Yes** ( ) No

If yes, please describe what the identifiable data is and where it is coming from:
VINCI will provide identifiable data based on recruitment criteria.

ID:
Pro00003522

View: 10.2.0 Data Security and Privacy: Outgoing Data

10.2.0 Outgoing Data
1.0
* **Will any of the data being collected/stored be transferred outside of VAPHS?**
No. The data is not being transferred outside of this facility.

ID:
Pro00003522

View: 10.3.0 Data Security and Privacy: Local Data Storage Types

10.3.0 Local Data Storage Types
1.0
* **How will data be stored on this project? (Select all that apply)**
On Paper
Electronically

ID:
Pro00003522

View: 10.3.1 Data Security and Privacy: Local Data Storage Types - Paper

10.3.1 Local Data Storage Types - Paper

1.0
* **All VA research data collected in paper must be stored in a locked room at VAPHS.**
List the room number(s) and the campus(es) where data will be stored in the text box below.
Hard copies will be stored in the Research Office Building at the University Drive Campus in a locked file cabinet in Cube 1-2.

ID:
Pro00003522

View: 10.3.2 Data Security and Privacy: Local Data Storage Types - Electronic

10.3.2 Local Data Storage Types - Electronic
1.0
* **Where is the electronic data being stored? Select all that apply.**
VAPHS Network (shared drive)

If "Other" please describe OR if you would like to provide additional information for clarification, please elaborate in the text box below.

If you selected VAPHS or VA Network (Shared Drive), please provide the name of the drive (i.e. "MySharedDriveName (\\vapthshsare) (X:)"):
\\oitpthhsmsvm200.v04.med.va.gov\Research\Chinman_Pro00003522

ID:
Pro00003522

View: 10.4.0 Data Security and Privacy: Reusing Data

10.4.0 Data Security and Privacy: Reusing Data
1.0
* **Will the data collected in this study be reused in other studies?** ○ Yes ◉ **No**
If yes, please describe where the data to be reused will be stored and how access to that data will be provided and monitored:

2.0
If this research is part of a grant, please upload the Data Management Access Plan (DMAP) or Resource Sharing Plan for this study.
Name
Modified Date
There are no items to display

The DMAP is uploaded into Section 1.3, Question 2.0.

ID:

Pro00003522

View: 10.6.0 Data Security and Privacy: HIPAA

10.6.0 Data Security and Privacy: HIPAA
The Healthcare Insurance Portability and Accountability Act (HIPAA) prohibits the use of a person's Protected Health Information without a valid authorization.
1.0
* **Select the option which fits this study:**

Name
Not applicable: No PHI is being used or disclosed by VAPHS
Not applicable: Waiver has been requested
HIPAA Authorization (Combined Consent and HIPAA Authorization)
HIPAA Authorization (Standalone)

Upload HIPAA authorization (Standalone) here:

Document
Modified Date
Version Number
View
Combined Consent and HIPAA is being used. No standalone HIPAA Authorization.docx(0.01)
8/27/2020 6:34 AM
0.01

2.0
At screening will clinical personnel be asked to share potential participants PHI:
Yes **No**
If yes, please upload the 10-5345:

ID:
Pro00003522

View: 10.7.0 Data Security and Privacy: Additional Information

10.7.0 Data Security and Privacy: Additional Information
1.0
Does this research involve...

* **...specially obtained software?** (•) **Yes** ( ) No

If yes, please describe the software and what it is being used for:

Members of our team developed and tested an evidence-based weight program adapted for the needs of the population with SMI that is delivered via a smartphone app (HSR&D IIR 03-213). The app is coupled with telephonic support from peer specialists who serve as wellness coaches. Peer specialists are individuals with SMI who draw upon lived experiences to provide services to others with SMI. The intervention package, called CoachToFit, was the first of its kind to be developed using a user-centered iterative process involving individuals with SMI through focus groups, in-lab usability testing, and experiential usability testing. Mobile capabilities of the app allow users to access education and support when needed, track goals as they are addressed, view their activity and weight progress, and receive reminders. A coaching dashboard allows real-time access to user progress.

DACIMA will be used to develop a data base of information and data collected from this study. DACIMA is a data base tool which resides behind the VA firewall. SPSS software will be used to analyze data from this study.

* **...one or more Web-based applications?** (•) **Yes** ( ) No

If yes, please describe the application and what it is being used for:

The CoachToFit app allows tracking of personalized nutrition and exercise goals, tracking and visualization of weight and step counts over time, and review of completed modules. Specific data visualization is also available in real time via the CoachToFit Dashboard, allowing a peer wellness coach and his/her supervisor to monitor user progress in real time and deliver weekly coaching personalized to the user's progress. The dashboard leads a coach through a structured call survey so that topics covered are consistent across calls and coaches. Previous call surveys can be accessed by the coach and the supervisor to check on coaching content.

The dashboard also allows for panel management, identifying upcoming calls, patient learning progress, and last activity by the user.

* **...mobile devices?** (•) **Yes** ( ) No

If yes, please describe:

Subjects will be provided with a Bluetooth activity tracker compatible with Android OS and iOS (Letsfit EW1) and a Bluetooth scale (True Integral Intelligent Body Scale). In addition, a Philips – DPM8000 recorder will be used to record interviews.

2.0

* **Will a Certificate of Confidentiality be obtained for this study?** ( ) Yes (•) **No**

If yes, please attach the Certificate of Confidentiality:

3.0

* **Will VA sensitive information be transported and utilized outside protected environments?** ( )

Yes (•) **No**

ID:
Pro00003522

View: 10.8.0 Data Security and Privacy: Certifications

10.8.0 Certifications

1.0

* **I certify that all study staff are up-to-date and will remain up-to-date with Information Security Awareness Training, Rules of Behavior, and VHA Privacy Training.** (•) **Yes** ( ) No

2.0

*** I also certify that when an individual is no longer part of the study team, access will be removed to research study data.** (•) **Yes** ( ) No

3.0
*** I certify that all research records will be maintained in accordance with the Veterans Health Administration (VHA)Records Control Schedule. Paper records will be disposed of using methods deemed appropriate by the VAPHS Privacy Officer, and all electronic data will be sanitized using methods rendered appropriate by the VAPHS ISO.** (•) **Yes** ( ) No

4.0
*** I certify that any loss or compromise of any VA sensitive information (including research data), VA equipment or device, or any non-VA equipment or device that is used to transport, access, or store VA information will be reported in accordance with the reporting requirements outlined in VA Handbook 6500.** (•) **Yes** ( ) No

5.0
*** I certify that, in accordance with VA Handbook 6500, no personal laptops will be used for official VA business in conjunction with this study.** (•) **Yes** ( ) No

ID:
Pro00003522

View: 11 Local Data Safety Monitoring Plan

Local Data Safety Monitoring Plan

For local studies, a data and safety monitoring plan (DSMP) must be established.

1.0
*** Please describe how the study procedures and data being collected will be continuously monitored so that changes in the risk/benefit ratio can be determined in a timely fashion during the course of the study:**

Data Safety and Monitoring Plan

Data Security
Computers: Research staff use VA computers. These are either desktop computers, or laptop computers provided and managed by the local Office of Information Technology (OI&T). All laptops are encrypted with VA-approved encryption software to ensure that if laptops are ever lost or stolen, no data could ever be removed. In addition, no study data will be stored on laptops. Electronic data will be stored on a study drive behind the VA firewall.

Servers: Research staff have access to a secure VA research server managed by the CHERP. CHERP staff will manage folder access by means of controlling membership in the security groups. Only staff that are listed on IRB approved project staffing lists, are credentialed by Research, have completed all required data security training, and are approved by the CHERP will be given access to the project folder on the server. Staff may only access this folder by using their VA login behind the VA firewall. Staff members have varying levels of access to data, with access to identifying information limited by the server manager. Server backup is managed by the VA OI&T Storage team. Data are backed up every day and Commvault backups of the data are stored at a distant VA location for 45 days.

The study will also utilize a secure Amazon Web Server under a UCLA agreement for the CoachtoFit app system and data, which will not include any PHI, PII, or sensitive data. This server is in compliance with VA Handbook 6500 standards and FISMA requirements and there will be a protocol for secure transfer of data back to the VA. This set-up was approved by VA Risk Vision for the CoachToFit development merit and we will present it again to Risk Vision for continued approval and input on data security.

Assessments: Assessment data will contain no PHI and will be captured and managed using DACIMA electronic data capture tools hosted on a VA Pitttsburgh server VA. DACIMA is an online database hosted behind the VA firewall and is available through the VA Intranet only.

Audio files and transcripts from qualitative interviews will not include any individually identifiable information other than the voice. Approved staff from the CHERP will transcribe the audio files. No data (audio files, in process transcripts, or completed transcripts) will leave the secure research server. As completed transcripts become available, approved study staff will move these files from the transcription sub- folder into another sub-folder that is only accessible to study staff, where they will be stored and accessed for qualitative analyses.

Data collected in paper form will be minimal consisting of notes or any data collected on a paper version of the assessments, if DACIMA is offline. This data will not contain any identifiers. Any data collected on paper will be stored in locked filing cabinets in the locked offices of project staff at the CHERP.

Ohmage software platform: CoachToFit leverages ohmage for data storage, as it is an open-source data collection backend for Android and iPhone smartphone apps. The ohmage platform collects raw data from both the app and the dashboard (coaching call survey data). All data captured are automatically uploaded for analysis and visualization. The data collected by ohmage will not include any PHI, PII, or sensitive data and will be hosted on a secure Amazon Web Server under a UCLA agreement.

2.0

* **Describe how frequently Investigators, study personnel, and the clinical coordinators involved in the study will meet and/or review study data.**

The research team will meet weekly to review current study data. This will be facilitated by the Coach to Fit Dashboard, which has real-time information about weight and exercise. Research assessments will also be reviewed once they are available.

3.0

* **Will this study use a Data Safety Monitoring Board or Data Monitoring committee?**

○ Yes ◉ **No**

4.0

* **Will this study use a Medical Monitor?**

○ Yes ◉ **No**

ID:
Pro00003522

View: 12 Costs and Payments

Costs and Payments

1.0

* **Does this study have a budget?:**

(●) **Yes** ( ) No

If yes, please upload the current budget:

Budget(0.01)

2.0

* **Will patients receive payments for this study?**

(●) **Yes** ( ) No

If yes, please upload the financial letter of support (either from the Business Service line or the Veterans Health Foundation) or documentation waiving the requirement of a letter of support:

VA Financial LOS Memo_C2F Chinman-signed.pdf

0.01

3.0

* **Are you paying patients using the WePay system?**

no

ID:
Pro00003522

View: 12.1 Costs

Costs

1.0

* **Will subjects be required to pay for any services outside of the VHA that may be required as part of participating in this research study?**

No

ID:
Pro00003522

View: 12.2 Participant Payments

Participant Payments

1.0

* **Please explain how the proposed payments are reasonable and commensurate with the expected contributions of the subject:**

This payment is similar to other payments we have made for a similar population of Veterans. We expect the interview will take 2-3 hours, and this works out to a rate slightly higher than minimum wage.

2.0

* **Please provide information on how the subject payments are fair and appropriate, and that they do not constitute (or appear to constitute) undue pressure or influence on the prospective research subjects to volunteer for, or to continue to participate in, the research study. In additional the payments do not constitute (or appear to constitute) coercion to participate in, or continue to**

participate in, the research study:
While payment and scale are an incentive to participate, they are not in excess to coerce individuals to participate. Although Veterans receive a scale to keep, they will be asked to use it on a regular basis during the study period. The scale represents a small compensation for this effort.
3.0
* **Specify the amount, form of payment and the specific disbursement schedule of payments:**
Participants will be offered a $25 payment for their participation in the baseline interview, $25 for participation in the 6-month follow-up interview, and $25 for participation in the 12-month follow-up interview. A subset of participants randomized to CoachToFit will be offered a $15 payment for participation in a qualitative interview at the 6-month timepoint.
4.0
* **Are the subjects being paid employees?**
yes
If yes, please describe how it will be in accordance with the SOP:
Peer specialists involved in the intervention will be invited to be interviewed at the conclusion of the study, they are paid employees and will be consented if they chose to participate, and will not be compensated.

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References:
1.0
* **Please provide a list of references** *(Multi-site protocols: You may reference the page numbers in the original protocol):*
REFERENCES

1. Dickerson, FB, Brown, CH, Kreyenbuhl, JA, et al., Obesity among individuals with serious mental illness. Acta Psychiatr Scand. 2006;113(4):306-13.
2. Centers for Disease Control and Prevention. Obesity and overweight [online]. 2016; https://www.cdc.gov/nchs/fastats/obesity-overweight.htm. Accessed June 1, 2017.
3. Marder, SR, Essock, SM, Miller, AL, et al., Physical health monitoring of patients with schizophrenia. Am J Psychiatry. 2004;161(8):1334-49.
4. Alvarez-Jimenez, M, Hetrick, SE, Gonzalez-Blanch, C, et al., Non-pharmacological management of antipsychotic-induced weight gain: Systematic review and meta-analysis of randomised controlled trials. Br J Psychiatry. 2008;193(2):101-7.
5. Dixon, LB, Dickerson, F, Bellack, AS, et al., The 2009 schizophrenia port psychosocial treatment recommendations and summary statements. Schizophr Bull. 2010;36(1):48-70.
6. World Health Organization. Guidelines for the management of physical health conditions in adults with severe mental disorder. World Health Organization, 2018.
7. Fleischhacker, WW, Arango, C, Arteel, P, et al., Schizophrenia--time to commit to policy change. Schizophr Bull. 2014;40 Suppl 3:S165-S194.
8. Littman, AJ, Boyko, EJ, McDonell, MB, et al., Evaluation of a weight management program for veterans. Prev Chronic Dis. 2012;9:E99.
9. Niv, N, Cohen, AN, Hamilton, A, et al., Effectiveness of a psychosocial weight management program for individuals with schizophrenia. J Behav Health Serv Res. 2014;41(3):370-80.
10. Goldberg, RW, Reeves, G, Tapscott, S, et al., "MOVE!" Outcomes of a weight loss program modified for veterans with serious mental illness. Psychiatr Serv. 2013;64(8):737-44.
11. Kwon, JS, Choi, JS, Bahk, WM, et al., Weight management program for treatment-emergent weight gain in olanzapine-treated patients with schizophrenia or schizoaffective disorder: A 12-week randomized controlled clinical trial. J Clin Psychiatry. 2006;67(4):547-53.

12. Weber, M and Wyne, K, A cognitive/behavioral group intervention for weight loss in patients treated with atypical antipsychotics. Schizophr Res. 2006;83(1):95-101.
13. Wu, MK, Wang, CK, Bai, YM, et al., Outcomes of obese, clozapine-treated inpatients with schizophrenia placed on a six-month diet and physical activity program. Psychiatr Serv. 2007;58(4):544-50.
14. Daumit, GL, Dickerson, FB, Wang, NY, et al., A behavioral weight-loss intervention in persons with serious mental illness. N Engl J Med. 2013;368(17):1594-602.
15. Young, AS, Cohen, AN, Hamilton, AB, et al., Implementing patient-reported outcomes to improve the quality of care for weight of patients with schizophrenia. J Behav Health Serv Res. 2019;46(1):129-139.
16. Luxton, D, McCann, R, Bush, N, et al., mHealth for mental health: Integrating smartphone technology in behavioral healthcare. Prof Psychol Res Pr. 2011;42(6):505-512.
17. Alvarez-Jimenez, M, Alcazar-Corcoles, MA, Gonzalez-Blanch, C, et al., Online, social media and mobile technologies for psychosis treatment: A systematic review on novel user-led interventions. Schizophr Res. 2014;156(1):96-106.
18. Pew Research Center. Mobile fact sheet 2018 (online). 2018; https://www.pewinternet.org/fact-sheet/mobile/. Accessed April 8, 2019.
19. Wenze, SJ, Armey, MF, and Miller, IW, Feasibility and acceptability of a mobile intervention to improve treatment adherence in bipolar disorder: A pilot study. Behav Modif. 2014;38(4):497-515.
20. Ben-Zeev, D, Mobile technologies in the study, assessment, and treatment of schizophrenia. Schizophr Bull. 2012;38(3):384-5.
21. Wu, EQ, Birnbaum, HG, Shi, L, et al., The economic burden of schizophrenia in the United States in 2002. J Clin Psychiatry. 2005;66(9):1122-9.
22. Bowersox, N, Visnic, S, and McCarthy, J. Care for veterans with psychosis in the Veterans Health Administration: Fy15. Seventeenth Annual Report on Veterans with Psychoses in the Veterans Health Administration. Serious Mental Illness Treatment Resource and Evaluation Center, June, 2017.
23. Mitchell, AJ, Vancampfort, D, De Herdt, A, et al., Is the prevalence of metabolic syndrome and metabolic abnormalities increased in early schizophrenia? A comparative meta-analysis of first episode, untreated and treated patients. Schizophr Bull. 2013;39(2):295-305.
24. Newcomer, JW, Metabolic considerations in the use of antipsychotic medications: A review of recent evidence. J Clin Psychiatry. 2007;68 Suppl 1:20-7.
25. Colton, C and Manderscheid, R, Congruencies in increased mortality rates, years of potential life lost, and causes of death among public mental health clients in eight states. Prev Chronic Dis 2006;3(2):A42.
26. Saha, S, Chant, D, and McGrath, J, A systematic review of mortality in schizophrenia: Is the differential mortality gap worsening over time? Arch Gen Psychiatry. 2007;64(10):1123-31.
27. Dixon, L, Postrado, L, Delahanty, J, et al., The association of medical comorbidity in schizophrenia with poor physical and mental health. J Nerv Ment Dis. 1999;187(8):496-502.
28. Weiden, PJ, Mackell, JA, and McDonnell, DD, Obesity as a risk factor for antipsychotic noncompliance. Schizophr Res. 2004;66(1):51-7.
29. Romanova, M, Liang, LJ, Deng, ML, et al., Effectiveness of the MOVE! Multidisciplinary weight loss program for veterans in Los Angeles. Prev Chronic Dis. 2013;10:E112.
30. Littman, AJ, Damschroder, LJ, Verchinina, L, et al., National evaluation of obesity screening and treatment among veterans with and without mental health disorders. Gen Hosp Psychiatry. 2015;37(1):7-13.
31. Garvin, JT, Hardy, D, and Xu, H, Initial response to program, program participation, and weight reduction among 375 MOVE! Participants, augusta, georgia, 2008-2010. Prev Chronic Dis. 2016;13:E55.
32. Chan, SH and Raffa, SD, Examining the dose-response relationship in the veterans health administration's MOVE!(r) weight management program: A nationwide observational study. J Gen Intern Med. 2017;32(Suppl 1):18-23.
33. Mohamed, S, Paulsen, JS, O'Leary, D, et al., Generalized cognitive deficits in schizophrenia: A study of first-episode patients. Arch Gen Psychiatry. 1999;56(8):749-54.
34. Brar, JS, Ganguli, R, Pandina, G, et al., Effects of behavioral therapy on weight loss in overweight and obese patients with schizophrenia or schizoaffective disorder. J Clin Psychiatry. 2005;66(2):205-12.
35. Jean-Baptiste, M, Tek, C, Liskov, E, et al., A pilot study of a weight management program with food provision in schizophrenia. Schizophr Res. 2007;96(1-3):198-205.
36. Knowler, WC, Barrett-Connor, E, Fowler, SE, et al., Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. N Engl J Med. 2002;346(6):393-403.
37. Elmer, PJ, Grimm, R, Jr., Laing, B, et al., Lifestyle intervention: Results of the treatment of mild hypertension study (TOMHS). Prev Med. 1995;24(4):378-88.

38. Cutler, J, Effects of weight loss and sodium reduction intervention on blood pressure and hypertension incidence in overweight people with high-normal blood pressure: The trials of hypertension prevention, phase II. Arch Intern Med. 1997;157:657-667.
39. Eliahou, HE, Iaina, A, Gaon, T, et al., Body weight reduction necessary to attain normotension in the overweight hypertensive patient. Int J Obes. 1981;5 suppl 1:157-63.
40. Lean, ME, Powrie, JK, Anderson, AS, et al., Obesity, weight loss and prognosis in type 2 diabetes. Diabet Med. 1990;7(3):228-33.
41. Sonne-Holm, S, Sorensen, T, Jensen, G, et al., Independent effects of weight change and attained body weight on prevalence of aterial htn in obese and non-obese men. BMJ. 1989;299:767-770.
42. Drake, RE, Bond, GR, and Essock, SM, Implementing evidence-based practices for people with schizophrenia. Schizophr Bull. 2009;35(4):704-13.
43. Berry, K and Haddock, G, The implementation of the NICE guidelines for schizophrenia: Barriers to the implementation of psychological interventions and recommendations for the future. Psychol Psychother. 2008;81(Pt 4):419-36.
44. Miller, KH, Ziegler, C, Greenberg, R, et al., Why physicians should share pda/smartphone findings with their patients: A brief report. J Health Commun. 2012;17 Suppl 1:54-61.
45. Aronson, I, Marsch, L, and Acosta, M, Using findings in multimedia learning to inform technology- based behavioral health interventions. Translational Beh Med. 2012:1-10.
46. Schrank, B, Sibitz, I, Unger, A, et al., How patients with schizophrenia use the internet: Qualitative study. J Med Internet Res. 2010;12(5):e70.
47. Rotondi, AJ, Eack, SM, Hanusa, BH, et al., Critical design elements of e-health applications for users with severe mental illness: Singular focus, simple architecture, prominent contents, explicit navigation, and inclusive hyperlinks. Schizophr Bull. 2015;41(2):440-8.
48. van der Krieke, L, Emerencia, AC, Aiello, M, et al., Usability evaluation of a web-based support system for people with a schizophrenia diagnosis. J Med Internet Res. 2012;14(1):e24.

49. Rotondi, AJ, Sinkule, J, Haas, GL, et al., Designing websites for persons with cognitive deficits: Design and usability of a psychoeducational intervention for persons with severe mental illness. Psychol Serv. 2007;4(3):202-224.
50. Valimaki, M, Anttila, M, Hatonen, H, et al., Design and development process of patient-centered computer-based support system for patients with schizophrenia spectrum psychosis. Inform Health Soc Care. 2008;33(2):113-23.
51. Aschbrenner, KA, Naslund, JA, Gill, LE, et al., A qualitative study of client-clinician text exchanges in a mobile health intervention for individuals with psychotic disorders and substance use. J Dual Diagn. 2016;12(1):63-71.
52. Ben-Zeev, D, Kaiser, SM, Brenner, CJ, et al., Development and usability testing of FOCUS: A smartphone system for self-management of schizophrenia. Psychiatr Rehabil J. 2013;36(4):289-96.
53. Schlosser, D, Campellone, T, Kim, D, et al., Feasibility of prime: A cognitive neuroscience-informed mobile app intervention to enhance motivated behavior and improve quality of life in recent onset schizophrenia. JMIR Res Protoc. 2016;5(2):e77.
54. Mohr, DC, Cuijpers, P, and Lehman, K, Supportive accountability: A model for providing human support to enhance adherence to eHealth interventions. J Med Internet Res. 2011;13(1):e30.
55. Christakis, DA, Saint, S, Saha, S, et al., Do physicians judge a study by its cover? An investigation of journal attribution bias. J Clin Epidemiol. 2000;53(8):773-8.
56. Dennison, L, Morrison, L, Lloyd, S, et al., Does brief telephone support improve engagement with a web-based weight management intervention? Randomized controlled trial. J Med Internet Res. 2014;16(3):e95.
57. President's New Freedom Commission on Mental Health. Achieving the promise: Transforming mental health care in America. Rockville, MD: President's New Freedom Commission on Mental Health; 2003.
58. Chinman, M, Lucksted, A, Gresen, R, et al., Early experiences of employing consumer-providers in the VA. Psychiatr Serv. 2008;59(11):1315-21.
59. Hamilton, AB, Chinman, M, Cohen, AN, et al., Implementation of consumer providers into mental health intensive case management teams. J Behav Health Serv Res. 2013;42(1):100-8.
60. Bennett, LL, Cohen, AN, and Young, AS, Factors associated with weight intervention participation among people with serious mental illness. J Nerv Ment Dis. 2018;206(11):896-899.
61. Young, AS, Cohen, AN, Goldberg, R, et al., Improving weight in people with serious mental illness: The

effectiveness of computerized services with peer coaches. J Gen Intern Med. 2017;32(Suppl 1):48-55.
62. Cohen, AN, Golden, JF, and Young, AS, Peer wellness coaches for adults with mental illness. Psychiatr Serv. 2014;65(1):129-30.
63. Locke, EA and Latham, GP, Building a practically useful theory of goal setting and task motivation. A 35-year odyssey. Am Psychol. 2002;57(9):705-17.
64. Bandura, A, Self-efficacy: Toward a unifying theory of behavioral change. Psychol Rev. 1977;84(2):191-215.
65. Miller, NH, Motivational interviewing as a prelude to coaching in healthcare settings. J Cardiovasc Nurs. 2010;25(3):247-51.
66. Prochaska, JO, DiClemente, CC, and Norcross, JC, In search of how people change: Applications to addictive behaviors. Am Psychologist. 1992;47(9):1102-1114.
67. Glasgow, RE, Vogt, TM, and Boles, SM, Evaluating the public health impact of health promotion interventions: The RE-AIM framework. Am J Public Health. 1999;89(9):1322-7.
68. Holtrop, JS, Rabin, BA, and Glasgow, RE, Qualitative approaches to use of the RE-AIM framework: Rationale and methods. BMC Health Serv Res. 2018;18(1):177.
69. Brown, AH, Cohen, AN, Chinman, MJ, et al., EQUIP: Implementing chronic care principles and applying formative evaluation methods to improve care for schizophrenia: QUERI series. Implement Sci. 2008;3(1):9.
70. Young, AS, The client, the clinician, and the computer. Psychiatr Serv. 2010;61(7):643.
71. Cohen, AN, Chinman, MJ, Hamilton, AB, et al., Using patient-facing kiosks to support quality improvement at mental health clinics. Med Car. 2013;51(3 Suppl 1):S13-S20.
72. Chinman, M, Shoai, R, and Cohen, A, Using organizational change strategies to guide peer support technician implementation in the Veterans Administration. Psychiatr Rehabil J. 2010;33(4):269-77.
73. Muralidharan A, Niv N, Brown CH, et al., Impact of an online-delivered weight management intervention with peer coaching on physical activity levels for veterans with serious mental illness. Psychiatr Serv. 2018:ePub ahead of print.
74. VA Office of Inspector General. Healthcare inspection: Atypical antipsychotic medications and diabetes screening and management. Washington, DC: U.S. Department of Veterans Affairs; 2007.
75. Office of the Surgeon General (US). The surgeon general's call to action to prevent and decrease overweight and obesity [electronic resource], ed. United States. Public Health Service. Office of the Surgeon, et al., Rockville, MD: U.S. Dept. of Health and Human Services, Public Health Service, Office of the Surgeon General; 2001.
76. American College of Sports Medicine. ACSM‘s guidelines for exercise testing and prescriptions. 6 ed., Philadelphia, PA: Lippincott Williams & Wilkins; 2000.
77. Thomas, S, Reading, J, and Shephard, RJ, Revision of the physical activity readiness questionnaire (PAR-Q). Can J Sport Sci. 1992;17(4):338-45.
78. Cohen, J, A power primer. Psychol Bull. 1992;112(1):155-9.
79. Folstein, MF, Folstein, SE, and McHugh, PR, Mini-mental state: A practical method for grading the cognitive state of patients for the clinician. J. Psychiatr. 1975;12:189-198.
80. Balke, B, A simple field test for the assessment of physical fitness. Rep 63-6. Rep Civ Aeromed Res Inst US. 1963:1-8.
81. Larsson, UE and Reynisdottir, S, The six-minute walk test in outpatients with obesity: Reproducibility and known group validity. Physiother Res Int. 2008;13(2):84-93.
82. Rasekaba, T, Lee, AL, Naughton, MT, et al., The six-minute walk test: A useful metric for the cardiopulmonary patient. Intern Med J. 2009;39(8):495-501.
83. Wise, RA and Brown, CD, Minimal clinically important differences in the six-minute walk test and the incremental shuttle walking test. COPD. 2005;2(1):125-9.
84. Ng, MM, Firth, J, Minen, M, et al., User engagement in mental health apps: A review of measurement, reporting, and validity. Psychiatr Serv. 2019;Advance Online Publication.
85. Brooke, J, SUS-a quick and dirty usability scale. Usability evaluation in industry. 1996;189(194):4-7.
86. Zhou, L, Bao, J, Setiawan, IMA, et al., The mHealth app usability questionnaire (MAUQ): Development and validation study. JMIR Mhealth Uhealth. 2019;7(4):e11500.
87. Davidson, L, Haglund, KE, Stayner, DA, et al., "It was just realizing ... That life isn't one big horror": A qualitative study of supported socialization. Psychiatr Rehabil J. 2001;24(3):275-92.
88. Fruhling, A and Lee, S, Assessing the reliability, validity, and adaptability of PSSUQ, in AMCIS 2005 Proceedings. 2005: Omaha, NE.
89. Sallis, JF, Pinski, RB, Grossman, RM, et al., The development of self-efficacy scales for health related diet

and exercise behaviors. Health Educ Res. 1988;3(3):283-292.
90. Cancer Prevention Research Center. Weight: Stages of change – short form [online]. 2008; http://web.uri.edu/cprc/weight-control-stages-of-change-short-form/. Accessed June 1, 2017.
91. Brandt, J and Benedict, R, Hopkins verbal learning test—revised. Professional manual. 2001, Psychological Assessment Resources: Lutz, FL.
92. Wechsler, D, Adult intelligence scale (WAIS-III). San Antonio, TX: The Psychological Corporation. 1997.
93. Hagedorn, HJ, Stetler, CB, Bangerter, A, et al., An implementation-focused process evaluation of an incentive intervention effectiveness trial in substance use disorders clinics at two Veterans Health Administration medical centers. Addict Sci Clin Pract. 2014;9:12.
94. Hamilton, AB, Spotlight on women's health. Qualitative methods in rapid turn-around health services research. 2013. VA HSR&D Cyberseminar.
95. Taylor, B, Henshall, C, Kenyon, S, et al., Can rapid approaches to qualitative analysis deliver timely, valid findings to clinical leaders? A mixed methods study comparing rapid and thematic analysis. BMJ Open. 2018;8(10):e019993.
96. Fereday, J and Muir-Cochrane, E, Demonstrating rigor using thematic analysis: A hybrid approach of inductive and deductive coding and theme development. Int J Qual Methods. 2006;5(1):80-92.
97. Bradley, EH, Curry, LA, and Devers, KJ, Qualitative data analysis for health services research: Developing taxonomy, themes, and theory. Health Serv Res. 2007;42(4):1758-72.

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View: 15 Miscellaneous Documents

Miscellaneous Documents
If you have any documents that need to be included in this submission, but do not fit in any of the previous sections please upload them here.

Document
Description
Version Number
View
Investigator COVID Risk Assessment and ACOS decision v8_final-smc.pdf(0.01)

0.01

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View: SF - Final Page

Final Page

You have completed your application!

Please hit "Finish" to save and exit the application. Doing so will NOT submit the application for review.

Please note that a submission may only be forwarded to the IRB by the Principal Investigator. To do this, the Principal Investigator must press the "SUBMIT STUDY" button in My Activities for this Study ID:Pro00003522.

You can track the ongoing status of your submission by logging into the study workspace.

Please feel free to contact the IRB with any questions or concerns.

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View: Create/Edit

Study Funding Source

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* **Funding Source Name:**
Merit Review (CC 103)
If you can't find the Funding Source above, choose "Other" and enter it here:

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View: Risk Detail Entry

Address for each screening procedure, research intervention/interatction, and follow-up/monitoring procedure:
* Research Activity:
Nutrient intake.
Common Risks:

Infrequent Risks:
Calorie restriction could theoretically lead to inadequate nutrition or excessive, rapid weight loss. With the proper precautions, this is unlikely (see “Protection Against Risk” section below). The alternative would be treatment as usual.
Other Risks:

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View: Risk Detail Entry

Address for each screening procedure, research intervention/interatction, and follow-up/monitoring procedure:
* Research Activity:
Physical activity
Common Risks:

Infrequent Risks:
Increased physical activity may result in greater risk for injury or the need for treatment. With the proper precautions, this is unlikely (see “Protection Against Risk” section below). The alternative would be treatment as usual.
Other Risks:

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View: Risk Detail Entry

Address for each screening procedure, research intervention/interaction, and follow-up/monitoring procedure:
* Research Activity:
Financial burden.
Common Risks:

Infrequent Risks:
It is possible that participants randomized to CoachToFit 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 CoachToFit development merit. The CoachToFit 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. This will be discussed with each participant when the app is downloaded to the phone and the peer coach, who originally downloads the app, can also address any issues with data usage during weekly coaching calls. The possibility of financial burden will be made clear in the consent form, discussed after randomization, and can be adjusted by turning off cellular data at any time. The alternative would be treatment as usual.
Other Risks:

ID:
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View: Risk Detail Entry

Address for each screening procedure, research intervention/interaction, and follow-up/monitoring procedure:
* Research Activity:
Hypoglycemia related to diet and exercise interventions.
Common Risks:

Infrequent Risks:
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. With the proper precautions, this is unlikely (see “Protection Against Risk” section below). The alternative would be treatment as usual.
Other Risks:

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View: Risk Detail Entry

Address for each screening procedure, research intervention/interaction, and follow-up/monitoring procedure:
* Research Activity:
Discomfort with procedures or disclosure.
Common Risks:

Infrequent Risks:
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. Participation in the research assessments, the use of the app, peer coaching phone calls, and the qualitative interviews is voluntary, and the alternative would be to not choose to participate.
Other Risks:

ID:
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View: Risk Detail Entry

Address for each screening procedure, research intervention/interaction, and follow-up/monitoring procedure:
* Research Activity:
Symptomatic hypotension related to diet and exercise interventions
Common Risks:

Infrequent Risks:
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. With the proper precautions, this is unlikely (see “Protection Against Risk” section below). The alternative would be treatment as usual.
Other Risks:

ID:
Pro00003522

View: Risk Detail Entry

Address for each screening procedure, research intervention/interaction, and follow-up/monitoring procedure:
* Research Activity:
Breach of Confidentiality
Common Risks:

Infrequent Risks:
Given that the study will include asking sensitive questions and gathering information from individuals with SMI, 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. The alternative would be treatment as usual.
Other Risks: