

Peer Navigators to Address Obesity-Related Concerns for African Americans With Serious
Mental Illness

NCT03382782

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Consent Document

Study Title: Addressing Weight Concern for African Americans with Serious Mental Illness by Using Peer Navigators and Behaviors for Healthy Lifestyle Program

You are being asked to participate in a study at the Illinois Institute of Technology. The goal of this study is to address an important health issue to African Americans with serious mental illness: being overweight and having health complications. In order to decide whether or not you want to be part of this research study, you should understand enough about the risks and benefits to make an informed decision. This consent form gives detailed information about this research study. Once you understand what is involved in the study you will be asked to sign this form if you decide to participate.

Purpose of Study

Many African Americans with serious mental illness also have challenges with being overweight, which worsens overall well-being. Sometimes people are unable to find and use resources to help them set and meet healthy living goals. Others may have difficulty talking with their health care provider or making full use of health services. Our study will test how useful trained community health workers (Peer Navigators) and an educational course (Behaviors for Healthy Lifestyles program) are to help people reach their healthy living goals. Our study will also look at gender differences and the impact of trauma on healthy living.

Groups of Study

Our study will last for 12 months. You will have an equal chance to participate in one of the three different **groups** described below:

- A)** If you are assigned to the **integrated health care group**, you will get services as you normally do and will not be scheduled to attend Behaviors for Healthy Lifestyles (BHL) program or partner with a peer navigator.
- B)** If you are assigned to participate the **BHL group**, you will be asked to participate in 26 weekly classes, followed by four review sessions. You will also meet with your BHL group leader twice a week for physical activity throughout the whole BHL program.
- C)** If you are assigned to **BHL plus peer navigator group**, we will arrange the first meeting between you and your peer navigator. Your peer navigator will help you with the resources and tools to meet your needs. For example, they can help you with exercising, choosing healthy foods, or planning your meals. You will also attend the weekly BHL classes and physical activity sessions.

If you are assigned to **group B or C**, you will be referred to Trilogy staff, who will guide you through the intake process. You will continue any other health services that you are receiving elsewhere.

You must meet the insurance requirements of Trilogy in order to enroll in services and remain in the study. Trilogy will bill your insurance for the BHL/Peer navigation services and for other services they may provide.

If you are assigned to **group A**, you will be provided with Trilogy intake information in case you are interested in enrolling services.

All three groups will complete surveys at the beginning of the project, 4 months, 8 months, and 12 months. Surveys questions will ask you about your mental health, physical health, exercise and eating patterns, and your experiences with trauma. We estimate each survey will take up to 2 hours. In addition to the surveys, we will measure your weight, height, waist circumference and blood pressure to monitor your progress with healthy eating and physical activities. In between surveys, we will call you once each month to ask about your recent activities related to healthy living. Phone calls will take about five minutes each.

During 8-month surveys, we will ask you about your experiences with program participation. You may be selected to answer more in-depth questions through a satisfaction survey. Your experiences will help us improve our program curriculum and delivery in the future. Your responses to the satisfaction survey will be audio-recorded, but will not be connected to your name. Your audio recording will be destroyed once transcribed and any potentially identifying information will be removed from the transcript.

Risks of Study

The risks are small for this study and we will work to reduce the risks. You might feel upset or stressed from the questions on the survey, or during your participation with the peer navigator or BHL program. You are free to stop participating in the study at any time you wish. A psychologist, Dr. Patrick Corrigan, is available for participants to talk to, free of charge, to discuss their situation or feelings related to participation in this study. Dr. Corrigan can be contacted at 312-567-6751.

Exercise carries a risk of injury. You need permission from your doctor for attending physical activities in BHL program. You should stop anytime if you feel pain or discomfort due to physical activity. If this happens, consult a doctor and let your BHL facilitators or peer navigator know.

There is a risk that your personal information could be released. To reduce this risk, you will be assigned a participant number so that your name or any other identifying information will not be connected with any of your responses to the survey. Your responses will be securely stored and will not be accessible to anyone other than your research team. BHL group facilitators will be trained to remind group members about confidentiality at every meeting. Peer navigators will also be trained to respect your privacy and confidential information.

Benefits of the Study

If you are assigned to attend BHL classes, you may benefit from taking this classes and completing physical activities with your facilitators. In the classes, you will be introduced to different strategies to lose weight and learn about behaviors that promote healthy lifestyles. If you are assigned to work with a peer navigator, you may benefit from peer navigation services, by having a support person who help you with your goals.

Participation Compensation

All compensation will be given through prepaid gift cards. You will receive \$15/hour for completing surveys plus \$5/appt for travel at baseline, 4, 8 and 12 months. You will be paid \$10 for each monthly phone call. Payment for the calls will be kept track of and paid at the time of next interview visit. If you are assigned to group B or C, you will have a chance to earn up to \$250 more by regularly attending weekly BHL, physical activity classes and/or meeting with your peer navigator.

For More Information

Any further questions about the research and my rights as a participant will be answered if I contact the project director, [REDACTED], Department of Psychology, at [REDACTED].

You will receive a copy of this consent form for later review.

I understand that the Illinois Institute of Technology (IIT) is not responsible for any injuries or medical conditions I may suffer during the time I am a research subject unless those injuries or medical conditions are due to IIT's negligence. I may address questions and complaints to Executive Office of IIT Institutional Review Board at [REDACTED].

I understand this study does not interfere with mental health or any other services such as primary care services or social services that I am currently involved in. I am free to begin, continue, or discontinue any treatment or service use independent of my participation in the study.

I have read the material above and any questions I asked have been responded to my satisfaction. I agree to participate in this activity, realizing that I may stop participating without penalty at any time.

Printed Name _____

Signature _____

Date _____