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

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Study Protocol

CBPR Team Program Development

A CBPR team, comprised of key research staff from IIT (e.g., principal investigator, co-investigator, project manager, research assistant), one service provider, and six African Americans with serious mental illness, was convened at the beginning of the study. Team members worked together over the first 18 months to design a manualized diet and exercise program to address issues of weight management and physical activity among African Americans with serious mental illness. They conducted qualitative research to adapt an existing MOVE! Manual developed by the Department of Veterans Affairs National Center for Health Promotion and Disease Prevention (Goldberg et al., 2013; U.S. Department of Veterans Affairs, 2012). The resulting adaptation was called Behaviors for Healthy Lifestyles (BHL). The team also adapted an existing peer health navigation (PHN) manual utilized in prior research involving African Americans with mental illness who were homeless (Corrigan et al., 2017) and Latinx with serious mental illness (Corrigan et al., 2018) to address the healthy living goals of the current project. The CBPR team met when needed to provide additional guidance across the three study cohorts. This included assisting with recruitment, making decisions for participant compensation and incentives, and revising the curriculum into a virtual format during the COVID-19 pandemic.

Study Design

This study was a three-arm randomized controlled trial: (1) Integrated Care-Treatment as Usual (IC-TAU), (2) Behaviors for Healthy Lifestyles (BHL), or (3) Behaviors for Healthy Lifestyles plus Peer Health Navigation (BHL+PHN). Data were collected across three 12-month cohorts with survey assessments conducted at baseline, 4-month, 8-month, and 12-month timepoints along with monthly check in calls.

Recruitment

First, the research team at IIT partnered with three sites: (1) Heartland Alliance Health (HAH; formerly known as Heartland Health Outreach), an established non-profit organization primarily located in Chicago's Edgewater-Uptown neighborhood. HAH serves a large population of African Americans with serious mental illness; (2) ACCESS community health network serving underserved communities (30% African American) within thirty-five federally qualified health centers (FQHCs) located across Cook and DuPage counties; and (3) Trilogy, a not-for-profit behavioral health organization, primarily located in Chicago's Rogers Park neighborhood, with more than 45 years of experience of serving people with serious mental illness. HAH hosted the BHL and PHN programs during Cohort 1 of the study while Trilogy hosted them during Cohorts 2 and 3. Second, physical flyers were posted around the city of Chicago at other local clinics, non-profit organizations, churches, food pantries, and recreation centers. Third, members of the CBPR team approached individuals directly by providing details about the study and asking if they were interested in participating. Fourth, the project manager and other research staff conducted brief presentations to staff members at applicable community agencies to generate interest. Finally, study information was posted through social media accounts to recruit potential participants online. The target sample size for this study was 210 African Americans with serious mental illness and weight concerns (or 70 per condition).

Screening

Once potential participants expressed interest in the study, they were directed to complete a 5-to-10-minute screening questionnaire, conducted prior to obtaining consent for study participation. This began by either completing an abbreviated version of the screener online,

sending an email to the official research study account, or calling the screening phone line directly. If they chose one of the first two options, a member of the research staff would call them back to complete the remainder of the screening process. The screening questionnaire included questions to assess whether individuals met the inclusion criteria for the study:

- At least 18 years of age or older (no maximum cap)
- Identify as African-American
- Identify as either male or female
- BMI equal to 30 or greater for Cohort 1, or 28 or greater for Cohorts 2 and 3. Cutoffs were originally chosen based on the weight loss intervention study by Daumit et al. (2013) for people with serious mental illness, which indicates 30 is the minimum threshold for obesity (Daumit et al., 2013; Weir & Jan, 2021). This was later changed to 28 based on recommendations from the Institute of Translational Medicine's (ITM) Trial Recruitment Innovation Office (TRIO) (https://chicagoitm.org/itm-trio/).
- Must have a self-reported serious mental illness as indicated by disability (e.g., receiving SSI/SSDI, or the condition interferes with work, school, or independent living). Serious mental illness must be an existing diagnosis within the DSM-5 (APA, 2013).
- Interested in losing weight
- Willing to attend BHL sessions or work one-on-one with a peer for eight months

Individuals were excluded from participating in the study if they were currently receiving services from a peer support specialist or community health worker; weighed more than 400 pounds; had a lifetime diagnosis of an eating disorder; were pregnant or had plans to become pregnant; had lifetime bariatric surgery; or did not have qualifying health insurance (if participating in Cohorts 2 or 3 at Trilogy).

Medical Permission.

Successfully screened participants were told to obtain signed medical permission from their primary care provider, or another appropriate physical health care professional, for exercise before arriving for their scheduled baseline survey assessment. Providers indicated either "yes" or "no" for whether their patient could participate in "low-impact aerobic exercise, including walking and line dancing; strength training; stretching; and Tai Chi." Individuals who brought in a signed form indicating "yes" to their baseline survey assessment moved on to the informed consent process. Those whose form indicated "no," or those that did not have a signed form, were no longer eligible to participate.

Informed Consent.

IIT research staff guided all potential participants through an informed consent process prior to starting the baseline survey assessment. The informed consent included five key sections: (1) purpose of the study, (2) groups and requirements of the study, (3) risks, (4) benefits, and (5) compensation. Participants were also provided with the number for a psychologist to talk to, free of charge, to discuss any feelings related to participating in the study, or their rights as a participant.

Release of Information.

Individuals entering the study during Cohorts 2 and 3 with Trilogy were asked to sign a release of information form. The form was required so that the IIT research team could release relevant contact information to Trilogy for the purposes of informing them of the participant's assignment to one of the intervention conditions, confirming insurance eligibility, and scheduling

an intake meeting. Participants were not allowed to begin the intervention until Trilogy staff completed their intakes and registered them as existing clients within the organization.

Study Procedures

Once individuals were determined to be fully eligible and completed all necessary documentation, they were enrolled as research participants into a designated cohort and randomized to one of three study conditions for a period of 12 months. Cohort enrollment periods appear to be longer than twelve months because participants completed their baseline in sections: Cohort 1 sections were enrolled from December 2017 through March 2019. Cohort 2 sections were enrolled from January 2019 through August 2020; and Cohort 3 sections were enrolled from December 2019 through February 2021.

Randomization.

This study utilized stratified block randomization by gender. IIT research staff picked up an envelope labeled either "female" or "male" for the participant's identified gender, and blindly chose one of three cards at random which indicated the assigned research condition. Participants were randomized to either Integrated Care-Treatment as Usual (IC-TAU), Behaviors for Healthy Lifestyles (BHL), or Behaviors for Healthy Lifestyles plus Peer Health Navigation (BHL+PHN).

IC-TAU Condition. Integrated care is defined as care that involves both medical and behavioral health providers in collaboration to meeting the healthcare needs of patients (Agency for Healthcare Research and Quality, n.d.). Participants randomized to this condition received integrated care services "as usual" provided by either HAH for Cohort 1 or Trilogy for Cohorts 2 and 3. Those who were not already recruited as active patients at these sites were given information on how to enroll.

BHL Condition. Participants randomized to the BHL condition were asked to attend twenty-six weekly classes followed by four review classes over the course of the first eight months of their study enrollment. Each participant received a workbook to follow along with during class. The class curriculum covered topics related to diet and exercise such as portion control, alternative meal choices, getting active, and the impact of mental health and substance use. Classes were led by a BHL class facilitator at HAH for Cohort 1 and Trilogy for Cohorts 2 and 3. Facilitators received special manualized training from IIT research staff on how to deliver the BHL program to study participants. The Cohort 1 facilitator was a trained dietician who identified as White. The facilitator for the latter two Cohorts was an African American peer with lived experience of mental illness. Participants were also asked to attend between 1-2 weekly physical activity sessions. During these sessions, BHL facilitators led participants in different types of exercises such as yoga, Zumba, or brisk walks in the community. BHL facilitators also conducted weekly one-on-one sessions with group members outside of the class to review goals.

BHL+PHN Condition. Participants randomized to the BHL+PHN condition were asked to participate in the same BHL classes and physical activity sessions as those in the BHL condition. Additionally, they were assigned to work one-on-one with a peer health navigator (African American with lived experience of mental illness) for eight months. Three peer health navigators were employed by HAH for Cohort 1 and Trilogy for Cohorts 2 and 3. One of the Trilogy peer health navigators vacated her position before the start of Cohort 3, leaving two of them to deliver the intervention at the end of the project. They received special manualized training from IIT research staff on how to provide support to study participants such as accompanying them to healthcare appointments, mental and physical health crisis management, trauma-informed care, harm reduction, and relapse management. Peer health navigators were also trained to assist participants with their diet and exercise goals. Activities to facilitate these

goals included accompanying them to food pantries and grocery stores to purchase nutritious food, meal planning and cooking, and engaging in physical activity out in the community.

Survey Assessments. Participants in all three conditions completed survey assessments at baseline, 4-month, 8-month, and 12-month study timepoints. Both intervention conditions lasted for a total of 8 months with the last survey assessment being indicative of a 4-month follow up. Surveys were completed through a technique called computer-assisted personal interviewing (CAPI), where research staff and participants work together to complete questionnaires face-to-face (Sainsbury et al., 1993). Research staff were trained and demonstrated CAPI performance to a criterion inter-rater reliability of .90 before conducting these survey assessments with participants independently. Survey assessments included a demographic questionnaire (baseline only) and measures related to self-report of various physical and mental health outcomes.

Monthly Check-In. Participants in all three conditions were asked to complete monthly check-ins throughout the 12-month duration of their involvement in the study. Monthly check-ins during baseline, 4-month, 8-month, and 12-month timepoints were administered at the same time as the survey assessments. All other monthly check-ins were administered over the phone by a member of the research staff.

The monthly check-in was designed by the CBPR team as an assessment of diet and physical activity based on the healthy lifestyle behaviors included in the BHL curriculum and further promoted by peer health navigators. Participants were asked a total of 12 questions pertaining to diet, physical activity, and receiving support. Questions were answered on a 5-point scale (1=not at all [never], 5= most of the time [nearly every day]). For the purposes of this study, all twelve items were totaled to come up with a "Healthy Lifestyle Behaviors" score, with higher scores indicating greater frequency of behaviors. Next, the questions were divided into subscales with five items pertaining to physical activity and six items pertaining to diet. The five items pertaining to physical activity included: (Q1-3) How much did you participate in light /moderate /vigorous activities; (Q4) How much did you dance; and (Q5) How much did you walk up a flight of stairs? The six items pertaining to diet included: (Q7) How much did you eat a variety of foods from the 5 food groups; (Q8) How much did you eat only when you were hungry; (Q9) How much did you boil, steam, or bake your food instead of frying; (Q10) How much did you control your portion sizes; and (Q11-12) How much did you limit sugary drinks/fast food? The question regarding asking friends and family for support in health goals did not fall under the two subscales, but it was included in the total score.

Participant Compensation. All compensation was provided in the form of PNC Visa gift cards. Cohort 1 received $25 per hour for completing survey assessments, $10 for traveling to the assessment appointment, and $10 for each monthly check-in. Starting with Cohort 2, compensation was decreased slightly; they received $15 per hour for completing survey assessments, $5 for traveling to the assessment appointment, and $10 for each monthly check-in. For all three Cohorts, participants received an additional $25 for bringing in the signed medical permission form.

A raffle and punch card system was designed to provide incentives for participation in the intervention. Participants from BHL or BHL+PHN conditions received a punch card and earned one punch for each BHL class or physical activity session they attended. Participants earned $5 per punch for a chance to earn up to $250. Participants could cash in for a $50 gift card for every 10 punches.

COVID-19 Virtual Transition

Beginning in March 2020, all study activities were transitioned to a virtual format due to public health concerns and restrictions presented by the COVID-19 pandemic. This included the last portion of 8-month assessments and all 12-month assessments for Cohort 2 as well as all assessments following baseline for Cohort 3. IIT research staff conducted all survey assessments and monthly check-ins over the phone with participants. Participants were sent a copy of the answer choices to help them follow along. All gift card payments were mailed to their home addresses.

From March 2020 through October 2020, IIT and Trilogy staff met weekly to help BHL facilitators and peer health navigators transition to virtual services and monitor activities during the remainder of the 8-month intervention period for Cohort 3. Participants in BHL or BHL+PHN conditions were transitioned to individualized, telephonic services instead of group classes as follows:

- BHL Condition
  - 1-hour total
  - Cover class content and worksheets for the first 30-40 minutes
  - Offer short guided physical activity over the phone after content is complete
- BHL+PHN Condition
  - 1.5-hours total
  - Cover class content and worksheets for the first 30-40 minutes
  - Immediately before or after the individual course portion, engage in peer health navigation—this may include physical activity
  - As always, peer health navigation should apply lessons from the class and work toward the participants' weekly healthy living goals
  - Peer health navigation should be a distinct activity from the course content

Participants were able to use their workbooks to follow along with class content and guided physical activity sessions over the phone. Low-impact exercises were written out and transcribed for BHL facilitators so that they could be delivered verbally. Peer health navigation activities were also transitioned to a telephonic format and included extra guided physical activity sessions, identifying physical activity opportunities that could be conducted from home or safely in the community, meal planning, setting up grocery delivery at home, or applying for additional resources such as free ride cards and food stamps. By June 2020, peer health navigators were encouraged to meet with interested participants face-to-face under the appropriate COVID-19 safety protocols (i.e., everyone must wear face masks covering the nose and mouth, keep 6 feet of distance, and use hand sanitizer) to provide the intervention whenever possible. BHL and BHL+PHN participants continued to receive virtual punches on their cards and all gift card payments were mailed to their home addresses.

Statistical Analysis Plan

Due to missing data, data analysis plan was revised from 3x4 and 3x13 ANOVAs to 3x2 ANOVAs (treatment groups X timepoints [baseline & 8-month]) for all intent-to-treat analyses, minimizing missing data, retaining power, maintaining intended plans to observe interventions from pre-test to post-test. Post-hoc comparisons were conducted as needed. As-treated analyses were conducted through 2x2x2 ANOVAs (treatment groups [BHL & BHL+PHN] X timepoints [baseline & 8-month] X attendance [yes or no, attended at least once]). If significant findings were observed, secondary analyses incorporated 4-month (mid-test) and 12-month interviews (follow-up) to determine if any changes occurred during these timepoints.

Originally, it was also proposed that a few intervention-related variables may be included as potential covariates in the analyses. These variables included: Study site where interventions were hosted (i.e., HAH or Trilogy), method of participant compensation (i.e., raffle or punch card), and format of interventions (i.e., in-person or online). As the addition of these covariates would only allow for conservative analyses without meaningful interpretation, potential cohort effects were not examined. Still, demographics would have been included as covariates if any differences were observed across treatment groups at baseline.

A power analysis was carried out prior to the beginning of the study in MPLUS using the Saris and Satorra (1993) method. Based on past research, an effect size (standardized weight change) of -.07 in the BHL condition and -.20 in the BHL+PHN condition was expected. A sample size of 210 has 81% power to detect group differences. Prior to conducting any analyses, the data was assessed for missing values, normality, and skewness/kurtosis.

Missing Data. If participants were missing data for some items within in a scale, these were imputed using the "mean of nearby points" method in SPSS. This method of imputation takes the average of up to two nearby points in the scale to calculate a value for missing data.

Drop-Outs. Drop-outs were defined as those participants who informed IIT research staff that they no longer wanted to participate in the intervention before the end of the 8-month period. Participants who dropped out of the BHL or BHL+PHN interventions were not omitted from the dataset unless they did not complete any survey assessments after the initial interview. In other words, if at least one additional survey assessment was completed following baseline, missing data was imputed as described above.