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A virtual learning collaborative to implement health promotion in routine mental health settings: Protocol for a cluster randomized trial

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ABSTRACT

Background: Despite widespread use of learning collaboratives in health care, few randomized trials have evaluated their effectiveness. The primary aim of this cluster randomized implementation trial is to evaluate the effectiveness of a virtual learning collaborative (VLC) in the implementation of a lifestyle intervention for persons with serious mental illness (SMI) in routine mental health settings, compared to standard individual technical assistance.

Methods: Forty-eight mental health provider organizations from across the United States will be recruited to participate in the trial. The evidence-based practice to be implemented is the InSHAPE health promotion intervention for persons with SMI. Sites will be stratified by size and randomized to receive an 18-month intensive group-based VLC with monthly learning sessions or individual technical assistance with four scheduled conference calls over 18 months. Sites will be enrolled in three blocks of 16 sites each. The primary outcomes are InSHAPE program participation and fidelity, and participant weight loss; secondary outcomes are program operation, program uptake, participant health behaviors of physical activity and nutrition, organizational change, and program sustainment. Implementation outcomes are measured at 3, 6, 12, 18, and 24 months after the program start-up. Participant-level outcomes are measured at fixed intervals every 3 months after each participant enrolls in the study.

Discussion: This study will determine whether VLCs are an effective implementation strategy among resource-limited providers when the new practice necessitates a shift in mission, scope of practice, type of services delivered, and new financing.

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Registered 25 March 2019, retrospectively registered.
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Abbreviations: DOSS, Dartmouth Organizational Structure Scale; GOI, General Organizational Index; GOI-IS, General Organizational Index for InSHAPE; PDSA, Plan-Do-Study-Act; PRISM, Practical, Robust, Implementation, and Sustainability Model; SMI, Serious mental illness; TA, Technical assistance; VLC, Virtual learning collaborative

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1. Introduction

Behavioral health services for people with serious mental illness (SMI) are at a crossroads. People with SMI, about 6% of the US population [1,2], have one of the greatest health disparities of any group, with a life expectancy up to 25 years less than the general population. Preventable, obesity-related conditions (heart disease, hypertension, diabetes) due to sedentary lifestyle, poor nutrition, and medications are major causes of this disparity. Mental health organizations have conventionally viewed health promotion and health care as outside of their mission and scope of practice. Despite this dramatic health disparity and a variety of evidence-based health promotion practices for persons with SMI, it is not known how to effectively implement these programs in routine mental health settings.

Given the potential benefits of collective problem solving and applying quality improvement methods in the process of implementation, it is logical to assume that "learning collaboratives" present a distinct advantage when new evidence-based practices are introduced that require significant organizational changes. Learning collaboratives typically use a structured framework where teams work together to learn about best practices, apply quality-improvement methods, and exchange their experiences in making improvements [3,4]. Despite widespread use of learning collaboratives in health care, few randomized trials have evaluated their effectiveness using quantitative outcomes [5]. In addition, virtual learning collaboratives delivered remotely via telephone and web-based platforms, have the potential to maximize access and scalability by reducing costs and time associated with in-person learning collaboratives [6], but research on their effectiveness is lacking.

The overarching goal of the current study is to evaluate the effectiveness of a VLC in the implementation of the evidence-based InSHAPE health promotion program for persons with SMI [7–10] in routine mental health settings, compared to typical implementation consisting of training and individual site follow-up TA. We will use a clustered randomized trial to compare VLC to TA with respect to service outcomes, implementation outcomes, and participant outcomes.

1.1. Primary study aims

The primary service aim of this study is to compare the effectiveness of VLC to TA with respect to *Program Participation* as measured by the proportion of enrolled individuals who received an adequate exposure to the evidence-based practice, as defined by attending at least 50% of the InSHAPE sessions over 6 months. The primary implementation aim is to compare VLC to TA with respect to *Program Fidelity*. The primary participant aim is to compare VLC to TA with respect to the proportion of InSHAPE participants achieving clinically significant weight loss ($\geq$5% weight loss).

1.2. Secondary aims

We will also examine the following exploratory hypotheses: VLC compared to TA will result in (E1) more rapid Full Program Operation; (E2) greater Program Uptake; (E3) significantly improved participant health behaviors of physical activity and nutrition; and (E4) greater likelihood of Program Sustainment at 24 months. We will also explore (E5) the effect of Organizational Change on Program Participation, and (E6) agency participation and adherence to the core elements of a Learning Collaborative as a predictor of InSHAPE participation, InSHAPE fidelity, and participant weight outcomes.

2. Materials and methods

2.1. Study setting

This cluster randomized implementation trial (see Fig. 1) involves mental health organizations from across the United States providing behavioral health services to people with SMI who are at risk for cardiovascular disease due to overweight or obesity. Forty-eight mental health provider organizations will be recruited to participate in collaboration with the National Council for Behavioral Health. Since the evidence-based practice to be implemented (InSHAPE) has been shown to be effective in improving outcomes across different settings (e.g., rural and urban areas, large and small agencies) and populations (e.g., ethnic and racial diversity), a diverse array of sites will be included to maximize study generalizability and inform future widespread scale-up. The primary units of analysis in this trial are study sites.

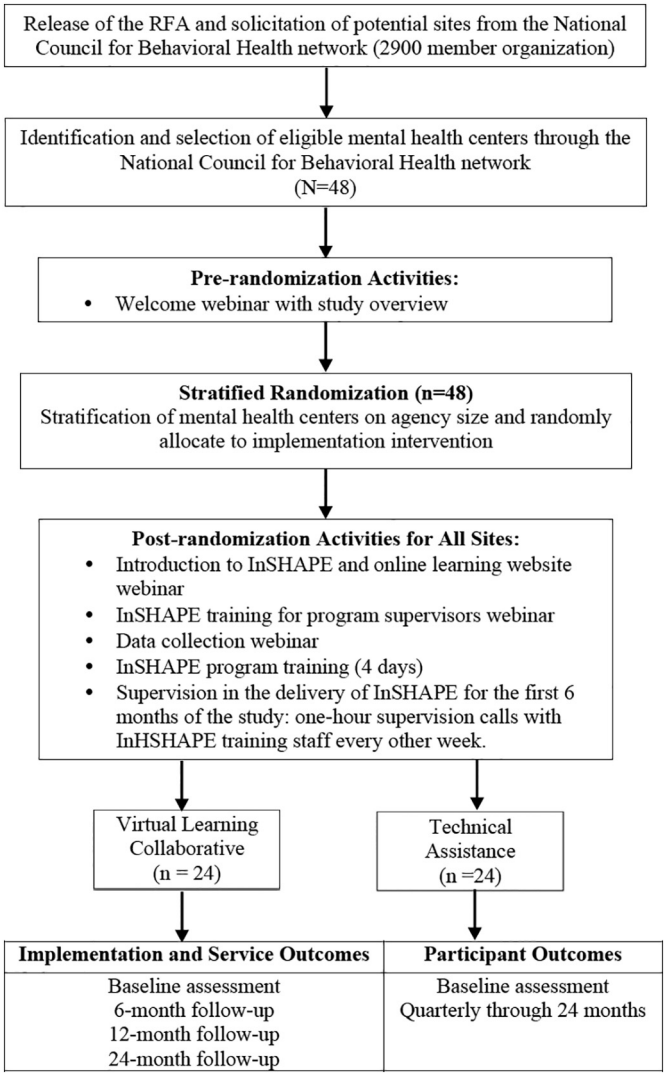

Fig. 1. Implementation trial design.

2.2. Site inclusion criteria

To be included in the study, mental health provider organizations will: (1) provide outpatient behavioral health services to people with SMI as defined by primary DSM-V Axis I diagnosis of schizophrenia, schizoaffective disorder, bipolar disorder, major depressive disorder or any other state-certified serious mental illness diagnosis (e.g., post-traumatic stress disorder), and (2) agree to study procedures including a commitment by CEO or designee to: (a) participate over the full program, including randomization to VLC or TA; (b) engage (if randomized to VLC) in monthly web-based meetings with other VLC members, including sharing implementation outcome data and

performance evaluations; (c) collect and submit aggregate participant-level data, including demographics, weight/BMI, physical fitness as measured by a 6-minute walk test, waist circumference, frequency of physical activity, and self-reported changes in nutrition; and (d) participate in phone-based organizational change and implementation assessments, including organization leadership, middle management, and InSHAPE staff.

2.3. Participant inclusion criteria

Participant eligibility criteria for the evidence-based practice (InSHAPE) implemented at the agencies includes the following: (1) age 18 or older; (2) SMI as defined by primary DSM-V Axis I diagnosis of schizophrenia, schizoaffective disorder, bipolar disorder, major depressive disorder or any other state-certified SMI diagnosis (e.g., post-traumatic stress disorder); (3) verbal permission from participant to share de-identified data with the research team; (4) overweight or obesity as indicated by BMI of 25 kg/m^2 or greater; and (5) medical clearance for participation in an exercise and dietary medication program by a physician, physician assistant, or nurse practitioner.

2.4. Site recruitment

Eligible mental health provider organizations will be identified within the National Council for Behavioral Health member network. The National Council is a 501(c) (3) association that advocates for policies that ensure people who have mental health and substance use disorders have access to comprehensive, evidence-based health care services. The National Council has 2900 member organizations serving over 10 million adults, children and families living with mental illnesses and addictions across the U.S. The National Council has extensive experience in the process of identifying member organizations for targeted program initiatives, evaluating organizational readiness for program participation, and selecting participants for specific training and program implementation initiatives, including learning collaboratives.

Our study team will partner with the National Council to select and finalize the 48 participating mental health provider organizations. The study PI (SB) and founder of InSHAPE (Ken Jue) will announce the request for applications for each study cohort during informational webinars that will be advertised to the National Council's members. Agency applications will be scored by research team dyads according to scoring criteria that considers funding mechanism, organizational readiness and support, and organizational characteristics. Agencies with top scores will be selected to complete phone interviews that include the intended site implementation team and the research team, after which a final selection will be made. Final candidate organizations will be selected taking into account geographic distribution, and ethnic and racial diversity. We will oversample sites with greater representation of ethnic and racial minorities.

2.5. Evidenced-based practice to be implemented

InSHAPE is an evidence-based lifestyle intervention for persons with SMI consisting of a free or low cost gym membership and weekly individual meetings with a certified fitness trainer (i.e., health mentor) who provides instruction on both exercise and healthy eating, and who organizes and leads group celebrations. InSHAPE was shown to result in clinically significant cardiovascular risk reduction (defined as $\geq$5% weight loss or improved fitness) among persons with SMI in two randomized controlled trials (RCTs) and a statewide implementation study [8–10]. In the first RCT of the program (N = 133) delivered at a community mental health center, 49% of program participants achieved clinically significant cardiovascular risk reduction [8]. These findings were replicated in a second RCT (N = 210) conducted in two community mental health centers in a large urban area serving an ethnically diverse population [9]. Findings from a subsequent statewide implementation of InSHAPE in four community mental health centers resulted in reductions in cardiovascular disease risk similar to the previous RCTs of the InSHAPE intervention [10]. The statewide implementation study demonstrated that a practical implementation of InSHAPE in the community could achieve effect sizes that were similar to the controlled clinical trials, and supports implementation of InSHAPE as a potentially effective approach for reducing cardiovascular risk and early mortality among individuals with SMI served by state funded mental health centers nationwide.

Mental health centers that adopt InSHAPE are expected to develop community-based partnerships with providers of fitness programming and with other community resources, such as recreation departments, university sponsored cooperative extension services, and grocery stores. InSHAPE health mentors develop and tailor person-centered wellness and exercise plans to the individual needs and circumstances of participants. Medical clearance from a primary care provider is a prerequisite to individual enrollment in the program. InSHAPE individual sessions follow a basic structure that includes discussion of weekly exercise and healthy eating objectives, as well as instruction and engagement in exercise and/or a healthy eating activity (e.g., cooking lesson). Health mentors meet with participants individually each week for 45–60 min in a community setting, such as a local community gym (e.g., YMCA). The nutrition education component emphasizes a balanced diet, portion control, and healthy eating on a budget. InSHAPE health mentors hold quarterly group “celebrations” in community locations (e.g., park, library, senior center) to acknowledge and reward participant progress and showcase the program to key stakeholders (e.g., community partners, mental health center staff, friends and family of participants).

2.6. Site randomization

Because agency size may affect capacity for implementation, we will randomize sites stratified by size. Agency size will be calculated based on the average number of clients served annually who are age 18 and over and eligible for SMI services. To facilitate appropriate resource allocation and to accommodate preferences in the implementation timeframe, sites will be enrolled in three blocks of 16 sites each. The first block will be randomized in Month 8, the second in Month 19, and the third in Month 31. By staggering enrollment using this schedule, it will also allow sufficient time for training each successive cohort on implementing InSHAPE (described below). A random number generator will be used to randomize the interval's 16 organizations into the two implementation conditions (24 VLC; 24 TA). This strategy will control for potential biases related to historical events (e.g., policy or funding changes). Given their geographic spread, the likelihood of contamination from an employee leaving one organization for another will be very small.

2.7. Implementation strategies

The VLC and TA will receive the same instruction on implementing InSHAPE within mental health settings and ongoing supervision by the InSHAPE training team. Both will have access to the same training and certification resources for health mentors to ensure that the hypothesized differences in outcomes are isolated to the effect of the VLC. Both interventions will be delivered over an 18-month period.

2.8. InSHAPE training

InSHAPE teams from each agency, including program supervisors and health mentors, will receive a four-day in person training with instruction on core components of the model: (1) developing community partnerships, including securing free or low cost gym memberships for participants; (2) weekly individual meetings with a certified fitness

trainer (i.e., health mentor) who provides instruction on both exercise and healthy eating; and (3) group celebrations. In addition, agencies will receive instruction in motivational interviewing to support persons with SMI in adopting lifestyle changes; setting personally meaningful life goals and healthy lifestyle objectives; healthy eating; tracking eating and physical activity behaviors; instruction on principles of healthy eating and nutrition; and training in serious mental illness pathology and tailoring individual wellness plans to the needs of persons with SMI with overweight or obesity. Interactive didactic assessments and role-play sessions will be used to evaluate program supervisors' and health mentors' knowledge of the core components of InSHAPE to ensure that each team understands fidelity to the model before implementing it at their agencies. Ken Jue and Associates representing Monadnock Family Services will lead the four-day InSHAPE training in this study which will involve instruction from a health psychologist, a dietician, and a senior level InSHAPE program manager and trainer. Each InSHAPE team will be asked to bring a copy of the treatment manual to the training.

2.9. InSHAPE supervision

All sites will receive supervision in the delivery of InSHAPE for the first 6 months of the study. Specifically, health mentors will participate in one-hour supervision calls led by the InSHAPE training team every other week. During supervision calls, the team will review and reinforce core components of the InSHAPE model and assess the delivery of the intervention at each site to monitor intervention fidelity, ensure adherence to the intervention, and discuss challenging cases.

2.10. Technical assistance

The TA condition will include four scheduled conference calls and the option for sites to request additional calls as needed through 18-months post-InSHAPE training. Scheduled calls will occur at 1 month, 2 months, 8 months, and 14 months following their participation in initial InSHAPE training following randomization. The TA provider will contact each site randomized to the TA intervention to schedule 30–45 min conference calls that will include the agency's InSHAPE health mentor, program supervisor, and one or more members of agency leadership (e.g., Director of Outpatient Services, Medical Director, COO or CEO). A structured protocol will be used to facilitate the scheduled TA conference calls, including a checklist of topics specific to implementation of the InSHAPE program, including: recruitment; participant engagement; health mentor role; establishing community partnerships; integration of the program within the agency; program promotion; data collection; celebrations; fundraising; and sustainability. The TA provider will begin the call by asking how implementation is going at the site and whether they have experienced any challenges during the implementation process. Before reviewing the checklist of implementation topics, the TA provider will first respond to any issues raised by the site. At the end of each scheduled TA conference call, the TA provider will schedule the next call with the site.

2.11. Virtual learning collaborative

The VLC is an 18-month intensive training, skill building, and structured implementation process focused on reinforcing fidelity to the InSHAPE model. Table 1 provides a summary of specific VLC implementation strategies and activities. InSHAPE teams consisting of health mentors, supervisors, and senior leaders (e.g., CEO, medical director) from each mental health agency randomized to the VLC will be invited to attend an in-person initial kick-off meeting followed by once per month 90-min VLC sessions.

Building on the Institute for Healthcare Improvement Breakthrough Series model [3], the VLC is organized into three stages: Prework, Action, and Continuous Improvement. Each stage consists of phases with corresponding activities and tasks for both the VLC faculty and participants (i.e., InSHAPE teams): Getting Started (Phase 1), Virtual Learning Sessions (Phase 2), Between Virtual Learning Sessions (Phase 3), and Post-Learning Session (Phase 4). VLC faculty, including interventionists with expertise in implementation science, quality improvement, and subject matter (i.e., InSHAPE) experts, will facilitate VLC sessions following a structured protocol to standardize the planning and execution of the VLC across three cohorts enrolled in the study.

Virtual learning sessions

Each 90-minute monthly virtual learning session will cover the following areas: (1) review of ongoing InSHAPE programmatic issues, didactic training on the InSHAPE program, training on quality improvement techniques (e.g., setting aims, conducting small tests of change using Plan-Do-Study-Act (PDSA) cycles; (2) review of monthly and agency-specific process and outcome data over time collected by the InSHAPE health mentor during visits with participants (e.g., number of clients enrolled in InSHAPE, number of clients who met with the health mentor one or more times per month, or percentage of clients who stayed within, gained, or lost four or more pounds from their baseline weight); (3) foster cross-site sharing on implementation progress, successes, and challenges; and (4) review of action items for the next session.

During each learning session, team attendance by role is tracked for each agency, including the Health Mentor, InSHAPE Supervisor, InSHAPE Director, Senior Leader, and other personnel (e.g., peer support). At the completion of each session, VLC faculty will evaluate agency adherence to the VLC model.

Between the monthly virtual learning sessions, InSHAPE teams will be tasked with the following activities: (1) complete an online post-session evaluation; (2) conduct implementation activities, including collecting and submitting de-identified participant-level data; (3) pilot a change method taught in the VLC (e.g., conduct a PDSA using new knowledge gained during the learning session); (4) complete and submit VLC homework, including a progress report and application of a quality improvement approach or technique learned on the previous learning session; and (5) communicate with other InSHAPE teams in the learning collaborative to learn from each other.

VLC faculty will offer coaching outreach between learning sessions. Faculty will contact teams if there is evidence of an ongoing issue identified on the previous learning session, no VLC attendance or homework submitted, or a general lack of progress. Outreach will start as email, but may lead to a request for a phone call with the health mentor and the InSHAPE supervisor to discuss the concern and develop a plan to address the challenge identified. Faculty will also review archived notes and chat box discussion to create supportive implementation resources such as “Tip Sheets” designed to help address issues raised on the calls. Lastly, faculty will track attendance, homework submissions (submitted or not submitted), review homework and submitted data, provide written feedback to teams within one week of the learning session that just occurred, and encourage communication between teams on successes and challenges using the web-based platform. For example, if a team is struggling with establishing community partners, faculty will share about the success of another team and suggest contacting that team to promote an “all teach, all learn” community.

During the last learning session, each team will present a summative report on implementation successes, challenges, and future plans. At the end of the Action Phase, teams will complete: (1) a final progress report documenting the total number of referred and eligible consumers identified, the total number of participants currently enrolled in the InSHAPE program, the total cumulative enrollment since InSHAPE program inception, the total number enrolled but discharged from the InSHAPE program, and the total number of participants who have completed the InSHAPE program; (2) a Transition Plan Survey to

Table 1
Summary of key virtual learning collaborative components and tasks.

Components	Tasks
VLC Learning Sessions	Monthly 90-minute web-based VLC sessions led by expert faculty who are implementation experts and subject matter (i.e., InSHAPE) experts who help agency teams organize, select, test, and implement changes on the front lines of care.
o Training in quality improvement methods	Provide foundational knowledge on quality improvement methods (e.g., Plan-Do-Study-Act (PDSA) cycles) to aid in the implementation process.
o Application of quality improvement methods	Facilitate the application of PDSAs at each stage of the implementation process and assign "homework" between monthly meetings with required posting of results for review and discussion at subsequent sessions to promote transparent sharing of results and problem-solving solutions in a "all teach – all learn" community.
o Group discussion and peer-to-peer interactions	Identify additional topics of interest for discussion (e.g., referral process, training health mentors, establishing community partnerships) and facilitate small group discussions and presentations to compare and contrast implementation process and common themes identified in homework.
Action Periods	Agency teams test planned changes at their respective agencies between learning sessions and collect data to measure the impact of these changes. Teams submit monthly progress reports for the VLC faculty to review, and are supported by web-based discussions and conference calls that enable them to share information and learn from InSHAPE experts and other mental health agencies. The aim is to build collaboration and support the agency as they implement the InSHAPE program.
o Between-session collaboration and interactions	Encourage between-session exchanges/communication between teams to promote sharing, collaboration, and group problem solving.
o "As Needed" coaching outreach	Contact teams if there is evidence of an ongoing issue identified on the previous learning session, no VLC attendance or homework submitted, or a general lack of progress.
o Email or web support	Facilitate and manage a platform for team-to-team communication and communication with faculty.
Measurement and Evaluation	VLC involves regular measurement and assessment.
o Data reporting, feedback, and review	Distribute data & data displays for review between learning sessions. Present and discuss monthly participant-level data, data over time, and data displays to drive improvement activities.

identify the plan to sustain the InSHAPE program; (3) an End of Program Survey to rate the overall experience and faculty; and (4) a follow-up Team Characteristics Questionnaire.

2.12. Primary outcomes and measures

See Table 2 for a summary of study measures. Implementation outcomes are measured at 3, 6, 12, 18, and 24 months after the program start-up. Participant-level outcomes are measured at fixed intervals every 3 months after each participant enrolls in the study. Primary study outcomes include: (1) Program Participation, (2) Program Fidelity, and (3) Participant Outcomes. InSHAPE health mentors and/or supervisors from each agency will collect and submit de-identified patient-level data on program participation and participant weight outcomes. Program Participation will be measured as the proportion of individuals who have been enrolled and have received adequate exposure to the intervention, defined by attending at least 50% of Health Mentor sessions over 6 months. Participant Weight Outcomes will be defined as clinically significant weight loss of ≥5% body weight since baseline, and weight will be measured to the tenth of a pound on a digital bathroom scale. The data will be submitted through a combination of: (1) de-identified paperwork emailed or faxed to study staff members, and (2) survey data entered remotely on a web-based data collection program equipped with service activity log and participant outcome measures installed on a secure, password protected tablet.

InSHAPE Fidelity Scale. The 22-item InSHAPE Fidelity Scale assesses structural elements of program implementation in the domains of staffing, organization, and services. There are seven sections to the scale: (1) Staffing and Organization; (2) Initial Health and Fitness Assessments; (3) Creation of InSHAPE Plan; (4) Health Mentor Meetings with Participants; (5) Ongoing Health and Fitness Assessments; (6) Group Celebrations; and (7) Community Integration. Items are rated on a 5-point behaviorally-anchored scale ranging from 1 (not implemented) to 5 (fully implemented) (e.g., weekly review of exercise objectives is scored 5 if 90–100% of required exercise logs are completed, a score of 1 represents 0–24%). The 22 items give a total score ranging from 22 to 110.

Table 2
Primary and secondary outcomes, measures, and time points.

Outcome	Instrument	Time Points
Primary Outcomes and Measures		
(1) Program Participation	Service Use: individuals enrolled who have received adequate exposure to the intervention (≥50% of Health Mentor sessions over 6 months)	Baseline, 6, 12, 18, 24 months
(2) Program Fidelity	22-item InSHAPE Fidelity Scale rated on a 5-point scale from 1 (not implemented) to 5 (fully implemented) with total scores ranging from 22 to 110	Baseline, 6, 12, 24 months
(3) Participant Outcomes	Body weight defined as clinically significant weight loss of ≥5% body weight since baseline	Baseline, 6, 12, 24 months
Secondary Outcomes and Measures		
(1) Full program operation	Time to having 1 full time Health Mentor with a caseload of 20 participants	12 and 24 month
(2) Program uptake	Number of full-time Health Mentors and participants served	12 and 24 months
(3) Participant health behaviors	Cardiorespiratory fitness assessed with the 6-Minute Walk Test (6-MWT)	Baseline, 6, 12, 24 months
	Readiness to change eating behaviors assessed using a scale adapted from the Stages of Change Modified Motivational Interviewing instrument	Baseline, quarterly through 24 months
	Physical activity measured using the short-form International Physical Activity Questionnaire (IPAQ)	Baseline, quarterly through 24 months
(4) Program sustainment	Number of sites still implementing InSHAPE, as defined by having a Health Mentor who has a personal trainer certification and who meets with at least one InSHAPE participant.	12 and 24 months
(5) Organizational change	Dartmouth Organizational Structure Scale (DOSS) 11-item scale where each item is scored on a 5-point scale with values ranging from 11 to 55	3, 12, and 24 months
(6) VLC adherence	11-item VLC Adherence Tool to capture the extent to which teams adhered to the critical components during the 18-month VLC. Total score ranges from 0 (poor VLC adherence) to 41 (strong VLC adherence)	18 months

2.13. Secondary outcomes and measures

Secondary study outcomes include: (1) Full program operation; (2) Program uptake; (3) Participant health behaviors; (4) Program sustainment; (5) Organizational change; and (6) VLC adherence. InSHAPE health mentors and/or supervisors at each agency will collect and submit de-identified patient-level data using the web-based system described above at fixed intervals every 3 months after starting the study: (1) Full program operation measured by time to having 1 FTE Health Mentor with a caseload of at least 20 participants; (2) Program uptake will be measured by the number of full-time Health Mentors and participants served at 12 and 24 months; and (3) Participant health behaviors, including cardiorespiratory fitness, dietary behavior, and physical activity described in detail below.

Cardiorespiratory Fitness. Cardiorespiratory fitness will be assessed with the 6-Minute Walk Test (6-MWT) [11], which measures the distance an individual can walk in six minutes. In adults with obesity, the 6-MWT is a reliable and valid measure of cardiovascular fitness with favorable test-retest and discriminant validity [12,13], and has been used in adults with a variety of chronic health conditions [14–23], including individuals with SMI and overweight or obesity in prior RCTs of InSHAPE [8,9]. An increase in distance of > 50 m on the 6-MWT is associated with clinically significant reduction in risk for cardiovascular disease [24,25].

Dietary Behavior. Readiness to change eating behaviors will be assessed using a scale adapted from the Stages of Change Modified Motivational Interviewing instrument [26] focused on dietary behaviors and physical activity. Higher scores indicate greater readiness to change dietary behaviors. We will calculate an overall dietary behavior score consisting of the mean for the items related to three domains: portion control, consumption of dietary fat, and intake of fruits and vegetables.

Physical Activity. Physical activity will be measured using the short-form International Physical Activity Questionnaire (IPAQ) [27]. Summary scores will be calculated for vigorous activities obtaining an estimate of weekly metabolic equivalent expenditure (MET) minutes of vigorous physical activity. The reliability and validity of the IPAQ for use among persons with serious mental illness is comparable to that in the general population [27].

InSHAPE Program Sustainment at 24-month follow-up will be measured by the number of sites still implementing InSHAPE, as defined by currently employing a health mentor who has a personal trainer certification and who meets with at least one InSHAPE participant.

Organizational Assessment. Organizational change will be measured using the Dartmouth Organizational Structure Scale (DOSS). The DOSS is an 11-item interviewer-rated scale developed by the investigators for this study. It measures a set of practices and procedures aimed at supporting the organization's capacity to implement and sustain the InSHAPE program. The content dimensions of the DOSS include *leadership, financing, policies, agency commitment to the evidence-based practice, process and outcome monitoring for quality improvement,* and other organizational factors found in prior implementation studies to be associated with successful implementation of evidence-based practices [28,29]. The DOSS is an adaptation of the General Organizational Index for InSHAPE (GOI-IS) used in an earlier statewide implementation study of InSHAPE [30]. The GOI-IS was based on the General Organizational Index (GOI), a scale measuring general operating characteristics of an organization related to the organization's capacity to implement and sustain an evidence-based practice [28].

Using a semi-structured interview guide, an independent assessor from the research team will conduct a series of five telephone interviews (each 30–60 min in length) with key leaders and staff responsible for implementing, providing operational supports, and delivering InSHAPE services at each site. Those interviewed will be: (1) the health mentor; (2) the health mentor supervisor; (3) representatives from senior leadership (such as the chief executive officer or clinical program director), and representatives from: (4) the financial and (5) quality improvement departments. The interviews will be conducted individually (or in some cases, with two or three staff depending on their availability to participate in the scheduled interviews). Interviewees will be asked to provide factual information about their practices and policies as they pertain to InSHAPE and health promotion. Interviewing different members of the organization will provide an opportunity to determine the agreement of responses from multiple perspectives and provide a check of the completeness and accuracy of the item rating (for example, if one source identifies a community partnership that another has overlooked).

Each DOSS item is scored on a 5-point behavioral-anchored continuum. The interviewer assesses five objective criteria for each item, giving one point for each criterion met for a maximum score of 5. The 11 items are summed, yielding a total DOSS score with possible values ranging from 11 to 55. The DOSS will be rated three times during the study period; three months after the initial InSHAPE training, and again at 12-month and 24-month follow-up for each site. The results of the interviews will not be shared with the site during the 24-month implementation study period.

VLC adherence will be measured using an 11-item VLC Adherence Tool to capture the extent to which teams adhered to the critical components during the 18-month VLC. The tool was developed based on a review of the literature, feedback from experts and the research team, and feasibility testing. Key domains include the extent to which a team engages in verbal participation, chat box participation, implementation progress, use of quality improvement tools or approaches, use of data collection to drive improvement, collaborative learning and sharing, and planning for program sustainment. VLC faculty score each team on every domain by consensus at the conclusion of each learning session based on a review of submitted homework, participation, and group interaction. Total score ranges from 0 (poor VLC adherence) to 41 (strong VLC adherence).

2.14. Analyses

Data analysis will begin with careful examination of the distributions and summary statistics for each outcome and predictor variable. In addition, plots of the outcome and predictors over time will inform the specification of the longitudinal statistical models. Prior to data analysis, all variables will be examined descriptively and identified outliers will be inspected. When necessary due to high skewness, transformations will be used to normalize continuous data, or continuous variables will be recoded to ordinal or dichotomous scales.

Analysis for Aim 1 (Services Outcomes). A multi-level mixed-effects logistic regression model will compare the VLC and TA groups on Program Participation over time. For each participant an adequate dose of the InSHAPE program will be defined as attending at least 50% of health mentor sessions over a 6-month period of participation. Data are submitted weekly and will be aggregated in 6-month intervals for analysis. Thus, each participant will have a binary indicator (met criterion or not) as the repeated outcome. Group (i.e., VLC vs. TA), time (i.e., 6, 12, 18, and 24 months) and group*time interaction will be included as fixed effects. The intervention effect will be evaluated by a significance test of time-average group difference over 24 months (shows group average difference) and group*time interaction (shows group difference in change). Site-level and participant-level variables that are associated with program participation (theoretically or empirically) and outcomes may be added to the model as covariates. A random intercept and slope of time at individual level will be included as random effects to account for correlated nature of the data due to repeated measures, and sites will be treated as a random effect to adjust for the clustering of participants within sites.

Analysis for Aim 2 (Implementation Outcomes). Program fidelity will be assessed at 6, 12, and 24 months. The unit of analysis for this aim is

the agency; hence, the *n* for each of the implementation strategy conditions is 24. We will use a covariance pattern model, analogous to repeated measures analysis of variance/covariance with unspecified covariance structure to test this hypothesis. Group (VLC vs. TA), time (6, 12, and 24 months) and group*time interaction will be included in the model. Comparative advantages of VLC (relative to TA) will be evaluated by significance test of group (shows time-average group difference) and group*time interaction (shows group difference in change). Based on their association with the fidelity outcome variables, provider-level variables may be added as covariates.

Analysis for Aim 3 (Participant Outcomes). The participant weight outcomes for Aim 3 are also dichotomous (≥5% weight loss or not). Thus, the same multilevel mixed-effects logistic regression model for Aim 1 will be used to analyze this aim with baseline weight included in the model. A longitudinal mixed-effects logistic regression model will be used.

2.15. Analysis of secondary aims

Independent-groups *t*-tests will test hypotheses E1, E2, and E4 related to implementation outcomes as they are cross-sectional and the outcome is continuous (two t-tests for E2 at 12 and 24 months, respectively). E3 compares participant health behaviors of physical activity and nutrition. For E3, we will describe for each implementation strategy the proportion of participants in the InSHAPE program. Differences between the VLC and TA groups will be tested using same longitudinal mixed-effects logistic regression models.

E5 compares the effect of Organizational Change and VLC Adherence on Program Participation. We will explore the effect of organizational change on the primary study outcome of program participation. To assess causality, we will use a lagged model; that is, using organizational change at 3 months and 12 months to predict 12-month and 24-month program participation. As program participation is a binary outcome, we will specify a mixed-effect (random intercept) logistic regression model with group, time, and organizational change, and group by organizational change interaction effects as fixed effects in the model. The effect of organizational change on Program Participation will be evaluated by the group*organization change interaction. In addition, we will explore the effect of lagged time-varying covariate, adherence to the VLC (baseline, 6, 12, and 18 months), on Program Participation (6, 12, 18, and 24 months) for the VLC group only. A mixed-effect logistic regression model with time, adherence, and their interaction will be specified. We will examine the effect of adherence on program participation by evaluating both the main effect of adherence and adherence*time interaction. The same analytic strategy for E5 will be used to assess E6, agency participation and adherence to the core elements of a Learning Collaborative as a predictor of program participation, program fidelity, and participant weight outcomes. Specifically, we will use agency participation and adherence as the core elements of a Learning Collaborative at 6 months and 12 months to predict 12-month and 18-month program participation, InSHAPE program fidelity, and participant weight outcomes in a generalized linear mixed-effect model framework with appropriate link functions.

2.16. Sample size and power

Power analysis for Aims 1 and 3. Because data analysis for Aim 1 is based on participant-level data, there will be ample statistical power to detect a small effect. For power analysis, first, we will adjust clustering effect at site level using an approach and intraclass correlation (ICC = 0.02) as recommended in the literature [31,32]. We expect to enroll 24 sites per group with a conservative estimate of 30 participants per site, thus we estimate that there will be approximately 720 participants per group overall. After adjustment, the effective sample size is reduced to 456 participants per group. Next, we will use a method [33] implemented in PASS 16 software [34] to estimate the power for time-averaged group difference over 24 months. Assuming alpha = 0.05, two-tailed, and cross-time correlation of 0.50 due to repeated measures, we can detect a small effect size of 1.38 in odds ratio metric with 82% power (odds ratio effect size of 1.5 = small, 2.5 = medium, and 4.3 = large).

Power analysis for Aim 2. Participation in the 18-month VLC will require a considerable commitment of organization time and related expenses, compared to participation in TA. Hence, we will consider a larger effect size as a necessary threshold to justify adopting a more complex and labor-intensive implementation strategy compared to brief participation in TA. With this significant threshold in mind, we estimate power for average group difference over 6 to 24 months. We set alpha = 0.05, two-tailed, 24 sites per group, and assume an over-time correlation of 0.50. We will have 80% power to detect an effect size of 0.66, which is between medium (0.50) and large (0.80) effects.

2.17. Ethics approval

Ethical approval to conduct this study has been obtained from the Dartmouth Committee for the Protection of Human Subjects (approval no. 00028067).

2.18. Trial status

The trial is currently underway with the third and final cohort of study sites. Data analysis will commence in the summer of 2019.

3. Discussion

The overarching aim of this study is to assess the effectiveness of a VLC compared to typical implementation consisting of site training and one-on-one individual technical assistance with respect to quality and outcomes of the initial implementation of a new evidence-based practice by community providers. We plan to conduct a cluster randomization design to evaluate the effectiveness of a VLC in implementing an evidence-based practice (InSHAPE health promotion intervention for people with SMI) that is outside of the usual set of services provided. This study addresses a major gap in implementation research on the effectiveness of learning collaboratives compared to standard one-on-one technical assistance as an implementation strategy. Furthermore, this study evaluates the use of virtual meetings as a practical and scalable implementation strategy. We will use a multi-level, multi-domain measurement approach to obtain comprehensive ascertainment of key implementation outcome variables, including organizational change, program fidelity, program sustainability, and participant-level outcomes.

From an implementation research perspective, there are two major study limitations. The first limitation is our focus on the initial implementation of a new evidence-based practice including full program operation, as defined by the program operating with a health mentor serving a caseload of 20 participants. Our outcome measure of Program Participation (the proportion of individuals who received an adequate exposure or “dose” of the intervention among enrolled participants) focuses on the quality (but not overall quantity) of the implementation. Although we will document differences in program uptake and expansion, studying program reach (proportion of eligible individuals in an identified population receiving the intervention) is beyond the scope, time frame, and feasibility of this study. Our primary goal is to evaluate the comparative effectiveness of VLC vs. one-on-one individual technical assistance in achieving uptake and full implementation of a new evidence based-practice. However, studying program reach could be an appropriate aim for a future long-term follow-up study evaluating outcomes of a population-based approach [35]. The second limitation is a consequence of our selected approach, which uses a randomized controlled trial study design (emphasizing internal validity) as opposed

to a less constrained alternative design (emphasizing external validity). In selecting a study design that emphasizes controlling as many variables as possible to isolate the effect of the primary independent variable (assignment to VLC vs. TA), we have imposed artificial constraints and assumptions of the generalizability of results. However, despite its inherent limitations, our selection of an RCT design addresses limitations experienced in using alternative methods. For example, in our statewide implementation study [10], we were unable to disentangle the effect of recent Medicaid demonstration funding to integrate health promotion programming into community mental health centers from the effect of the implementation process without a randomized or quasi-experimental comparison condition. Furthermore, our literature review found widespread use of learning collaboratives, despite few (if any) randomized trials evaluating their effectiveness using quantitative outcomes—a notable gap in the literature that this study is designed to address [5].

In summary, findings from this study will inform implementation strategies demanding organizational transformation among resource-limited providers when the new practice necessitates a shift in mission, scope of practice, type of services delivered, and new financing. This study will also address the need to identify effective and scalable implementation strategies for health promotion addressing obesity as a risk factor for early mortality in health disparity populations, including high-risk persons with SMI. Finally, this study focuses on implementing interventions for obesity with broad public health significance, while also targeting the dramatic health disparity of early mortality in individuals with SMI with overweight or obesity, with potential generalizability to other disadvantaged, low-income disparity populations.

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Availability of data and materials

Not applicable.

Authors' contributions

SJB is the principal investigator who led the conceptualization of the study and obtained grant funding. All authors helped to prepare the grant proposal and made a substantial contribution to the study design. KA drafted the manuscript. SIP, GRB, LZ, KJ, MC, GW, and SB drafted sections of the manuscript and provided critical feedback on early drafts. JAN critically reviewed subsequent drafts. All authors read and approved the final manuscript.

Ethics approval and consent to participate

Ethics approval was granted by the Dartmouth Committee for the Protection of Human Subjects, approval number 00028067.

Consent for publication

Not applicable.

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