

## Delivering a lifestyle and weight loss intervention to individuals in real-world mental health settings: lessons and opportunities

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### Abstract

Most weight loss interventions for obesity-related risks 11 exclude people with serious mental health conditions. Our goal was to adapt a successful lifestyle/weight loss intervention for this population, deliver it in mental health clinics, and concurrently measure implementation factors. Developmental and implementation-focused formative evaluations guided adaptations and identified barriers/facilitators to successful program deployment. Adaptations included content specific to the population's needs, consciousness-raising among clinicians and patients, additional case management, and greater program flexibility. Barriers included instability in both settings from different sources. Facilitators included familiarity with groups, manual integrity, and appreciation of the program. It was delivered consistently across settings with maximum exposure and fairly good fidelity to the protocol (mean rating=1.7, 2.0=complete fidelity). This mixed-method implementation evaluation demonstrated that lifestyle/weight loss interventions in mental health settings are complex, but feasible, and valued by participants. Main program outcomes will be reported at the trial's conclusion.

### Keywords

Obesity, Antipsychotic medications, Lifestyle change, Weight, Translational research, Mental health

Individuals with serious mental illness are at particularly high risk for developing obesity, impaired glucose tolerance, metabolic syndrome, and type II diabetes mellitus [1]. Although concerns about excess weight and diabetes in this population initially arose from recognition that use of antipsychotic agents and other mental health medications were associated with weight gain, metabolic syndrome, and increased risk of diabetes, findings now suggest that serious mental illnesses alone, irrespective of treatment, are associated with increased risk of obesity and diabetes [2, 3]. For example, the prevalence of type II diabetes among individuals with bipolar disorder or schizophrenia appears to be 2–4

### Implications

**Practice:** Overweight and obesity are among the leading causes of preventable deaths in the US, and individuals with serious mental illness, particularly those taking antipsychotic medications, represent a large underserved population at greatly increased risk of obesity, diabetes, metabolic syndrome, and subsequent early mortality.

**Policy:** Common misconceptions regarding the limitations of patients with serious mental illness present substantial barriers to these individuals receiving adequate health care and increasing awareness among clinicians, health services organizations, policy makers and the public is critical.

**Research:** This report demonstrates that an intensive and fairly complex, multicomponent lifestyle intervention can be delivered to high needs patients and implemented within the context of real-world health delivery systems—this is highly relevant to translational research.

times that of the general population [4]. Despite this, studies of lifestyle and weight loss interventions have typically excluded individuals with serious mental illness. In October 2005, the National Institute of Mental Health convened a special meeting to review the extant literature on obesity among those with mental illnesses [5]. The group concluded that obesity in this population had not received adequate research attention and empirically based adapted weight-control programs were needed.

Our group adapted a successful comprehensive and effective group lifestyle and weight loss intervention—PREMIER [6]—for use among overweight or obese individuals taking antipsychotic medications. We then implemented the modified program in a randomized clinical trial within two settings—an integrated health plan and two public mental health clinics—and simultaneously conducted an implementation-focused formative evaluation. Our implementation evaluation consisted of weekly participant satisfaction

ratings, qualitative interviews with intervention and control participants ( $N=32$ ), intervention session observations ( $N=16$ ), and planned weekly debriefing and supervision sessions with our clinical interventionists. We report our process and findings here.

#### DESCRIPTION OF THE CORE PROGRAM

The STRIDE program is based on the National Heart, Lung and Blood Institute-funded PREMIER lifestyle intervention, DASH diet arm [7]. PREMIER was a multicenter clinical trial testing the effects of two lifestyle interventions on blood pressure control, compared with advice only. Participants attended individual and group visits weekly for 3 months, bi-weekly for an additional 3 months, and then monthly for a year [8]. Both interventions implemented established national guidelines for blood pressure control [9–11] and the DASH diet arm tested the Dietary Approaches to Stop Hypertension diet. The DASH eating program was designed to promote weight loss and reduce blood pressure and obesity-related risks; it also reduces diabetes risk [12, 13]. Consistent with PREMIER, the STRIDE intervention promotes the following specific strategies for achieving changes in behavior, activity level, and weight loss: (1) self-monitoring of diet and physical activity, (2) developing personalized dietary and physical activity plans, (3) reducing calories moderately, (4) reducing portion sizes and substituting lower energy density foods for energy dense foods, (5) focusing on increasing intake of fruits, vegetables, fiber and low-fat dairy products, (6) increasing physical activity, (7) identifying problematic situations for undesired behavior and developing and rehearsing action plans to deal with those situations, and (8) graphing individual weight and behavioral progress. These eight strategies were considered “core” components of the original intervention and thus were retained in the modified program and measured as part of the fidelity metric in the implementation evaluation, along with two additional core components that were derived from the adaptations to the program.

The STRIDE intervention is built on prior research on motivation and behavior change theories to enhance self-efficacy and promote long-term behavior change [9]. Implementation strategies are consistent with NHLBI's clinical guidelines for treatment of overweight and obesity and include: frequent contacts, participant-centered group facilitation approaches, and individual contacts that tailor the intervention to the participant's preferences [14]. We also provide support for appropriate goal setting, facilitate the acquisition of new information and skills for behavior change, and encourage group interactions that foster social support and problem-solving. Consistent with adult-learning approaches recommending multiple learning modalities [15], we include interactive exercises that link prior

experience and knowledge to the material presented, use a variety of instructional techniques, provide handouts, and encourage additional follow-up with the group facilitators for participants who might need additional support. The program begins with a 6-month intensive counseling phase followed by a 6-month, less-intensive, maintenance phase. The program is designed to be delivered by two interventionists—one with a background in mental health and one with experience providing nutritional counseling services. We recognize that in many mental health delivery settings, experience and training of mental health staff varies, and nutritional counseling staffs are rarely a part of the treatment team. As such, we purposefully created an intervention manual that could accommodate a range of users. We also measured characteristics of our interventionists as part of the implementation evaluation to determine if implementation varied according to user characteristics.

#### ADAPTING PREMIER FOR INDIVIDUALS WITH MENTAL ILLNESS

After reviewing the relevant but limited literature on adapting lifestyle and weight loss programs for populations with mental illness, we consulted with national experts, local mental health clinicians and administrators, and consumer advocates. Based on these discussions, we adapted the PREMIER lifestyle and weight loss intervention to implement as a randomized trial in two settings—a private not-for-profit integrated health plan and a publicly funded community mental health clinic. Adaptations to the curriculum are described below.

##### Managing medications

We added a session addressing the effects of mental health medications on weight and weight gain. From our formative consultations, it became apparent that many patients do not know a great deal about the medications they take, their potential side effects, or about alternative options. We also learned that some clinicians were concerned we might inadvertently cause people to discontinue medications if we highlighted the associated weight gain usually seen with them. We were thus careful and deliberate in our approach to this session.

The *Medication Side Effects and Weight Gain* session has three goals: first, to educate participants about their mental illness and how the medications used to treat it could elevate their risk for weight gain; second, and perhaps more importantly, to validate their experiences of struggling to manage their weight while continuing their medications; and third, to empower and encourage participants to communicate with their prescribers when they felt their mental health medications were contributing to weight gain, particularly when they felt their

medications were not adequately treating their symptoms (that is, they felt they were experiencing unacceptable levels of symptoms or functional limitations). Toward this end, our session aims to give participants the information they need to engage in a collaborative conversation with their prescribing clinicians, with the overall goal of achieving the best possible treatment for optimal mental and physical health. Thematic analysis of our qualitative interviews suggests that this is an important adaptation from participants' points of view.

Interviewer: What was it about STRIDE that interests you?

Respondent: One thing I didn't understand at Weight Watchers is the medications and moods and emotions...really tie in...And, so when I would have to change dosage, or something, I might gain weight. I felt it was a lot of shame. And so I was really interested in being in a program that understood I was on those medications and was going to help me anyway. And then in a group with other people that are in the same situation as me.

In these groups and in study interviews, many participants expressed difficulty opening a dialogue with their clinicians and frustration with not remembering important information they need to share when they are in an appointment. As a solution, our session encourages advance preparation for appointments, offers tools similar to those used in the program to monitor caloric intake and weight (e.g., daily records, graphs), to monitor mood and side effects, and allows rehearsal of dialogue in group sessions in order to facilitate discussions outside of group. Also, the interventionists strongly urge participants to discuss any medication changes with their clinician prior to making such changes.

#### Anticipating episodes of mental illness

Because episodic changes in mental health status are expected among this population, we added a session specifically aimed at anticipating changes in mental health status and proactive planning for weight management during and following episodes of increased symptoms. This session begins with the acknowledgement that acute mental illness presents barriers to successful weight management and healthy living. The intent of the session is to provide participants the opportunity to recognize these barriers, problem solve and generate potential modifications and solutions to address them, and create a written plan to facilitate maintaining a healthy lifestyle when struggling with additional symptoms. Participants are encouraged to reflect on known triggers of their mental illness and to create a plan of action for maintaining healthy dietary and physical activity practices to the extent possible during episodes of symptom exacerbation.

This includes making a commitment to continuing certain strategies (such as attending the group unless symptoms are so severe it would be unproductive and continuing to keep food records) and modifying others (such as continuing to exercise, even if for less time than usual) as well as making an effort to get back on track as soon as possible. In order to minimize feelings of failure or guilt following episodes that result in weight gain, interventionists remind participants of their overall progress and encourage them to develop a plan for how they might handle the situation differently next time.

#### Stress management

As a lifestyle intervention, STRIDE aims to promote general wellness, particularly when specific wellness activities (e.g., stress management, adequate sleep) support weight management. The original PREMIER intervention devoted content to recognizing the potentially negative effect of stress on dietary behaviors and physical activity. That session promoted identifying, managing, and when possible, eliminating stressors; interventionists led participants through a guided progressive muscle relaxation exercise. We expanded the stress-management session to include an introduction to simple cognitive behavioral techniques for stress management, including recognizing negative cognitions and replacing them with more realistic evaluations, encouraging use of behavioral relaxation techniques, and promoting physical activity as a means for managing stress. We recognize that many participants will have had exposure to stress management through other resources (e.g., therapy) so this session is meant to highlight the importance of managing stress as part of a lifestyle change and to remind participants of resources that are available to them. An important goal of this session is to emphasize to participants the link between stress and poor dietary, exercise, and coping choices.

#### Sleep hygiene

Sleep problems are commonly comorbid with mental and physical health problems [16]. Insomnia greatly increases risk for mood disorder [17] and chronic sleep curtailment is associated with endocrine and metabolic consequences that may contribute to obesity [18]. Recognizing the importance of sleep, we added sleep promotion content to the original PREMIER curriculum. We promote better sleep hygiene by focusing on helping participants create a regular sleep-wake schedule and teaching them stimulus control techniques. Participants interested in improving the quantity or quality of their sleep are encouraged to set a sleep goal for the week and to record the number of hours they sleep each night in the space provided in their weekly records. In addition, we encourage participants to reflect on how their sleep affects their dietary and physical activity behaviors. We also provide

weekly individualized graphs that include hours slept, calories consumed, and minutes of physical activity in addition to weight. Our goal when reviewing these graphs is to assist participants in developing insight about how their sleep, diet, and physical activity levels are interrelated. Interventionists recommend participants share the data they've collected about their sleep patterns and other behaviors with their clinicians, particularly when adjustments to medications are being considered. This is another way the STRIDE program fosters collaboration with prescribing clinicians in working toward optimal mental and physical health.

Interestingly, in every group, our interventionists report that participants have asked for more time to discuss stress-management and sleep-hygiene techniques than we had originally planned, underscoring the importance of addressing mental health issues as a core component of the program. In addition, the interventionists report that groups routinely request these topics for review during the monthly maintenance sessions. Consequently, during the course of implementation, we have allocated more time to this topic and developed additional participant materials to meet this demand.

#### Eating healthfully on a budget

Finally, because many individuals with serious mental illness live on limited budgets, we added a session on how to eat healthfully with limited financial resources. This session was developed in concert with the Oregon Food Bank's educators and is delivered by its volunteer staff; it includes cooking demonstrations, tasting, and suggestions for healthy low-cost shopping and meal preparation. This session, titled *Eating Healthfully on a Budget*, is one of the most popular, according to weekly session evaluations and qualitative interviews. For example, one participant told us:

Interviewer: What do you like best or find most helpful about the group?

Respondent: The topics that they introduce, like... the Oregon Food Bank coming and showing us how to put [together] low-calorie/low-cost meals. Every week there's a topic and it's always an interesting topic to me, so far.

#### IMPLEMENTATION OF THE STRIDE PROGRAM

The STRIDE program is part of a 5-year NIH-funded randomized controlled trial. Implementation is ongoing; this report includes implementation results from our first five cohorts, spanning all settings. The STRIDE program was first implemented in a not-for-profit health plan (Kaiser Permanente Northwest) and later in two publicly funded community mental health clinics (Cascadia Behavioral Healthcare and LifeWorks Northwest).

Kaiser Permanente Northwest is a prepaid, group model, integrated health plan serving about 480,000 members in Oregon and Washington states. Kaiser Permanente Northwest provides outpatient and inpatient medical, mental health, and addiction treatment, and maintains an electronic medical record that contains comprehensive administrative and treatment data on all its members.

Cascadia Behavioral Healthcare provides comprehensive behavioral health care services to low-income individuals in the Portland metropolitan area. Cascadia Behavioral Healthcare has operations in three Oregon counties, provides mobile outreach and crisis services, 7-day per week urgent care services, and partners with community organizations to provide stable housing for clients in need. Clinical outpatient services include mental health, alcohol and drug treatment, intensive case management, and culturally specific services.

LifeWorks Northwest is also a community-based prevention, mental health and addiction service provider in the same metropolitan area. With a combined staff of nearly 600 employees, including Qualified Mental Health Professionals with graduate degrees in behavioral health, registered nurses, and physicians. LifeWorks Northwest operates 22 clinics serving more than 16,000 clients annually—the majority from impoverished, under-served populations. Programs are designed to meet the specific needs of the communities in which they are offered.

As we began delivering the STRIDE intervention in these settings, we simultaneously conducted an implementation-focused formative evaluation to measure the presence of the program, as it was intended, in each delivery setting. The implementation evaluation involved measuring dose of exposure; collecting participant satisfaction ratings at each session; conducting qualitative interviews with samples of intervention and control participants throughout the course of the program; weekly debriefing and supervision sessions with the interventionists; when possible conducting exit interviews with interventionists leaving the study; and rating fidelity to ten core dimensions of the intervention through session observations. Our implementation evaluation was essential to identifying additional modifications to the intervention that were made as necessary. These modifications addressed the real-world obstacles we encountered in order to ultimately produce a robust and sustainable intervention.

#### Individual tailoring

Our experience has shown that willingness and ability to make behavior changes shift frequently during long-term weight loss intervention programs. Accordingly, STRIDE allows interventionists to help participants tailor their weekly goals and action plans to their current stage of change and life

situation. Even before we began implementation, we recognized that flexibility for individual tailoring was an essential feature of the program and, as such, it was included as a “core” component of the program. Even so, our experience implementing STRIDE among participants with mental illnesses required more flexibility and responsiveness to individual needs than similar programs in general populations. For example, our interventionists report that compared with similar programs delivered in general populations, proportionately more STRIDE participants needed additional support and help with calorie counting and assessing portion size.

The interventionists also discovered that, for some participants, particularly those living in residential facilities where they had little control over what was prepared or served, the focus needed to shift away from calorie counting and toward portion control. For these participants, interventionists recommended increasing fruits and vegetables when possible, decreasing sweetened beverages, and working to promote good sleep and regular exercise. We have found that being flexible with our intervention targets keeps these participants engaged and helps them feel more in control of their choices within their specific environments.

#### Tailoring at the group level

Participants varied considerably in terms of their facility with keeping food records, monitoring calories, planning ahead, and implementing intervention targets. Relative emphasis and time spent on specific topics also varied widely across participant cohorts and, based on preliminary comparisons, did not appear to be driven by group size, illness severity, or setting. As a general strategy, interventionists use a strengths-based approach [19], keeping the participants focused on what is going well and attempting to build new skills from existing strengths. Recognizing that it is often most important to get participants back on track and closer to targets, we encourage participants to do what they can and support them with whatever suggestions

and tools (e.g., weight graphs, visual aides, etc.) seem most appropriate.

#### Case management

Preliminary analyses suggest that STRIDE participants required significantly more case management time than behavioral weight loss and lifestyle change interventions in general populations. While not unexpected, even our estimates for additional burden (30 min of participant-contact case management time each week for each cohort) have, to date, been substantially exceeded. Participants needed additional case management because of changes in mental health status, changes in physical health status (e.g., illness, self-reported chronic pain), instability in employment or living situation, changes in caregiving responsibilities, transportation difficulties, and unpredictable life challenges that could be particularly distressing for individuals with mental health problems (e.g., terminally ill family members, death of loved ones/pets). Interventionists report that early engagement through case management improves attendance and helps participants remain in the group. This is an important consideration in planning adequate staffing resources for a program of this nature.

#### Implementation evaluation preliminary results

Results from our first five cohorts show that the intervention group meetings have been conducted as scheduled 100% of the time, with 134 meetings conducted to date. Intervention fidelity was measured during randomly selected session observations and was rated by non-interventionist members of the clinical supervision team. Fidelity was rated on ten dimensions corresponding to the “core” components of the program. Each dimension was rated only if it was relevant to the session being observed and then according to level of implementation (0=not implemented at all, 1=partially implemented, 2=fully implemented). Dimension scores ranged from 1.5 to 2.0 with a mean of 1.7, indicating overall good fidelity to the program.

Core dimension (rating)	
Self-monitoring of dietary and physical activity (1.5)	Increasing physical activity (1.5)
Personalized diet and physical activity plans (1.7)	Planning for high-risk situations (1.8)
Reducing calories moderately (2.0)	Graphing progress (2.0)
Reducing portions and choosing alternatives (1.9)	Tailoring to the participant (1.5)
Increasing fruits, vegetables, fiber, and low-fat dairy (1.8)	Addressing mental health issues (1.5)

#### BARRIERS TO IMPLEMENTATION ACROSS SETTINGS AND SOLUTIONS

Perhaps of most practical importance to clinicians and researchers striving to implement a program like

STRIDE are the lessons we have learned during the process of rolling out the intervention across a private not-for-profit health plan and two large, but quite different, publicly funded community mental health clinics.

### Barriers to dissemination

All of the community partners we approached about the study ( $N=3$ ) were interested in collaborating with us. The leadership in these organizations expressed interest in bridging research and practice and reported they felt the STRIDE program was a worthwhile initiative. Despite this, in the publicly funded community settings in particular, we had difficulty securing the organization's commitment beyond the first or second cohort. Discussions with our partners revealed that ordinary demands of managing a community mental health clinic (e.g., coordinating existing programs, responding to budget cuts, managing high staff turnover) left little energy or time for participation in practice-based research. One agency partner articulately expressed his regret when his agency could no longer participate:

I am afraid that to try and have it be more successful than our last cohort would take more energy than we would be able to support... the juggling and coordination of existing services and programming will be daunting. I will probably need to simplify and reduce some things as opposed to add. I am so sad about this... I am a believer about the STRIDE benefit to the clients...

### Barriers to adoption

An unexpected barrier that we came to understand over time was the need for consciousness-raising among clinicians about the value of offering lifestyle interventions to individuals with mental illnesses and about such individuals' ability to make changes in response to such a program. This barrier was present in both the health plan and the community mental health clinics. We first experienced this need among a subset of clinicians who, during an informational session we held to orient them to the study, revealed concerns about participants being able to bear costs associated with increased fruit, vegetable, and low-fat dairy intake. We were able to counter these initial concerns by providing information about the sessions that address eating healthfully with a limited income and portion control. Later, throughout the project, similar concerns by other clinicians were spontaneously reported to our study staff. These clinicians were concerned that their clients would be unable to make changes in their lifestyles, particularly if they were living in institutional settings, while others were concerned that attention to medication side effects might make clients less willing to continue taking their medications. In cases where we were aware of clinicians experiencing these concerns, we were successful in convincing some that we had plans for working within constraints associated with living situations and worked very hard to clarify that we were encouraging people to discuss medications with their clinicians while strongly urging them not to

change their medication regimen without first discussing the changes with their clinicians. Incidentally, we have not been made aware of any participants that prematurely discontinued their medication without their clinician's knowledge as a result of being in the study and, among the first five cohorts, 90% of intervention participants who reported taking antipsychotic medications at baseline continued to report taking them at the 6-month follow-up assessment compared with 72% of control participants. That said, those clinicians we heard from probably represented even more clinicians who had these same reservations but never told study staff. Despite many varied efforts to educate clinicians about the study, a significant proportion of them did not sign/return recruitment letters, which substantially reduced the number of recruits that could have potentially been enrolled and benefitted from the intervention. Though we did not assess organizational capacity prior to our implementation, we think it would be useful to assess staff attitudes about weight loss/lifestyle interventions in the target population, existence of wellness-related programs, existing staff capacity to deliver the intervention (staff caseload/workload), facilities, and funding status of the agency.

We also encountered the need for consciousness-raising among patients. When recruiting from the integrated health plan, we found a great deal of interest in the project, even among those who did not end up enrolling in the program. We attribute this in part to Kaiser Permanente's focus on wellness and disease prevention: Members regularly receive lifestyle-related information from the health plan, and its clinicians and have a clear source of medical care in addition to mental health care. In contrast, one of the public clinics had not approached weight loss or lifestyle change in any kind of systematic way, while the other was implementing a new program to monitor weight and metabolic changes. In the former clinic, we found far less interest in the project among patients during recruitment than we did in the latter. We concluded that if clinics have not systematically addressed lifestyle, wellness, and weight with their clients, then the most useful first step in implementing a program like STRIDE may be wellness-related educational efforts with clinicians and clients, and perhaps implementing quality-monitoring procedures (like having clinicians measure their clients' weight and BMI regularly). Drawing attention to the importance of these factors appears to us to be an important component of project rollout.

### Barriers to identification of potential participants

In our efforts to identify potential participants, we encountered several logistical barriers that are likely to be common in both clinical and research implementation. At one community agency, we were able to use the electronic medical record

(EMR) to identify possible participants who might be eligible, but at this agency, no weight or BMI data were available. At the other community agency, weight and BMI data were collected as part of the EMR, but access to those data was constrained. Recruitment for cases thus relied on case managers and prescribing clinicians (participants could also self-refer by responding to posters in the clinic). While the case managers and clinicians were largely cooperative, we remained concerned about selection bias both in terms of clinicians referring only certain types of clients (e.g., those visibly overweight, those more compliant in treatment/groups, etc.) and were concerned that only a subset of clinicians was referring (e.g., highly motivated clinicians, clinicians with time to refer, etc.). We made additional efforts to encourage recruitment from all clinicians and to discourage any pre-screening by clinicians except for medical or psychiatric instability. Finally, we were able to use the health plan's EMR to identify potential participants, many of whom had a calculated BMI in their records, but found that we needed to connect with a large number of clinicians to obtain referrals because so many clinicians had only one or two persons on their panel that qualified for the study. The sheer volume of these clinicians was a problem, as was the effort required to obtain medical review—they were often busy primary care providers. Thus, despite what would appear to be minimal effort required to review and approve recruits for participation, a significant number of clinicians did not return recruitment letters, particularly without reminders. Across settings, clinicians were extraordinarily busy and, while many considered the project worthwhile, they simply did not have superfluous time to help with our recruitment efforts, particularly without prodding from study staff. These kinds of busy schedules may affect clinicians' willingness to discuss weight and make referrals to lifestyle change programs during already brief clinical encounters.

#### Barriers to recruitment

Once clinicians approved potential recruits to be contacted for the study, we ran into several barriers trying to reach the recruits. In particular, we had difficulty coordinating screening (and later follow-up) visits for people in residential facilities, many of whom were not responsible for their own appointments or transportation. It can be difficult to communicate by telephone under these circumstances and complex to make arrangements. From a clinical perspective, these individuals may be at greatest need for a program like STRIDE. From a practical standpoint, they are among the most difficult to reach, engage, and monitor. These barriers are further complicated by confidentiality issues if a case manager serves as a go-between.

Another research-specific barrier was that the consent document Kaiser Permanente's IRB required be sent to participants prior to their initial study orientation visit, was overwhelming. This adversely affected recruitment. In response, we requested IRB permission to send a brief, bulleted informational sheet with our study invitation letter and adapted our orientation visit to include group consenting followed by individualized consenting. This adaptation appeared to reduce this barrier in subsequent cohorts.

Despite these barriers, in the first five cohorts, we have enrolled and randomized a total of 143 overweight individuals taking antipsychotic medications. To date, our participants are 75% female and 86% white with a mean age of 48.6 years ( $SD=10.7$ ) and a mean BMI at baseline of 37 ( $SD=8.2$ ). Of those randomized, 74 are in the intervention condition. The majority of intervention participants (61%) have attended more than half of the intervention sessions (weekly and monthly). We have had only five study dropouts (two intervention participants, two controls, one deceased).

#### Barriers to clinical assessment

Another implementation barrier related to our clinical assessments, which included collecting a lab panel (fasting insulin, fasting plasma glucose, fasting triglycerides, and fasting cholesterol). Our clinical staff report that this sample has a much higher frequency of difficult blood draws, across settings, than encountered in other weight loss and lifestyle intervention studies carried out at the research center. Over the study's course, a larger proportion of participants had to be transported to Kaiser Permanente's oncology research lab to have their blood drawn by phlebotomists experienced in working with collapsed or difficult-to-locate veins. For community participants, this was additionally burdensome as it required an extra trip (by cab) to the oncology lab. This suggests that the regular monitoring of key metabolic indicators needed in this population will require phlebotomy staff with special skills, a factor that may be important to address in planning for an intervention of this type.

Similarly, on-site clinic and lab work at community agencies was challenging. For example, sinks were not necessarily available and space was limited—particularly space that would allow the privacy necessary to complete sensitive assessment screening visits and follow-up procedures (e.g., mental health assessments, waist measurements). The nature of these clinic assessments also required staffing levels that proved to be greater than what we had initially budgeted and planned. Typically, a nurse and phlebotomist needed to be available to collect physical measurements, and a mental health staff person needed to be available to respond to reports of suicide risk and other

mental health crises. We found that many participants needed assistance completing assessment paperwork. For example, some participants with limited literacy required a staff person to read questions and response options so they could complete paper-and-pencil questionnaires. Thus, we needed at least four or more staff at clinic assessment visits, regardless of the number of participants attending the visits. When group assessment visits were large, or when the participants attending had more complex needs (e.g., low cognitive functioning, low literacy, or interference from psychiatric symptoms), more staffs were needed. Predicting these needs was difficult. Some of these difficulties are unique to the research components of implementation, but also have implications for clinical roll-out, particularly low literacy and cognitive impairment resulting from symptoms or medications.

We had a higher rate of no shows to clinic assessment visits than is typical for clinical visits for weight loss/lifestyle intervention studies. In addition, clinical staffs report that participants had to be re-scheduled more frequently than is typical, sometimes multiple times. Rescheduling was needed to accommodate unexpected changes (e.g., hospitalizations, transportation changes) in addition to typical reasons for no shows (e.g., forgot appointment despite reminder). Also, some participants cancelled or did not attend appointments because their medications made them too drowsy to attend or they forgot to fast the night before. To accommodate these staffing issues, we assembled a team who could deploy with minimal notice to accommodate visits. We also attempted to consolidate roles. For example, the study nurse and a mental health staff assisted participants in completing forms and escorted participants through study visits. Our mental health staff also agreed to be available for cell phone consultations. We found that by having a highly efficient, cross-trained staff, we were able to streamline staffing and reduce costs.

#### Barriers to delivering the intervention

We encountered a fairly high rate of staff turnover both in the integrated health plan and in the community clinics. Turnover in public mental health clinics was typical for those settings, with individual clinicians and managers leaving or changing roles. This interfered with our goal of increasing capacity for delivering lifestyle interventions as it resulted in 100% turnover in community intervention staff we trained, prior to completing any individual cohort's intervention. In addition, organizational restructuring in the health plan resulted in a majority of psychiatrists resigning over a short period. This created a host of new clinician-patient relationships, required time for patients to be re-assigned and have appointments with new clinicians, and made it difficult for clinicians to refer patients

because they did not know them well or had not even had contact with people new to their panel. Moreover, an unknown but not insignificant proportion of patients were referred to mental health providers outside the health plan during this transitional period, making it even more difficult to accurately identify each patient's clinician.

These types of barriers are difficult to overcome. Staff turnover has the potential to threaten dose and quality of the intervention. In our project, we were able to conduct 100% of our group visits as planned, so dose was not diminished and preliminary results indicate that quality was not compromised. We attribute this to the co-leader model as in each case at least one of the co-leaders remained able to assist in the transition to a new co-leader. Each time we lost an interventionist mid-course, we were able to quickly identify a replacement, train them, and continue. While initially this was not the purpose of the co-leader model, we think it is a significant reason to staff this program with two interventionists. We also believe in cross-training staff, whenever possible, so that replacements are already familiar with the intervention. This minimizes the chance that the program might disappear if its only champion leaves the setting. Yet, despite our strong urging and willingness to provide broad staff trainings, none of the settings felt they could spare the resources required to cross-train staff. For the long-term viability of such programs, we believe that standard mental health clinical training programs need to include specific training for weight loss and lifestyle changes so that clinicians have the tools they need to address what have clearly become critical components of mental health care. With respect to organizational change and restructuring, our experience points to the disruption that rapid and significant changes can have in clinical relationships. Disruptions in continuity of care are often problematic but become particularly so in vulnerable populations like this [20].

#### Translational barriers to conducting research in community settings

Conducting research with our community mental health partners was a pleasure, but research in "real world" settings has its unique challenges. To begin, we collaborated with our original community partner to plan the grant application and study design. The goal of this effort was to make sure the research design matched the clinical setting and that the study goals were consistent with the agency's clinical goals. What we did not anticipate was that the agency would go through a major financial crisis, be defunded in large part, and be reduced significantly in size. This compromised our ability to recruit participants and thus it became clear early on that we would need to partner with at least one additional community agency. By that time, the study design was in place, with fewer opportunities for



modification. Thus, we had to begin developing relationships with another clinical partner, and try to meet that partner's needs in the context of the existing research design.

Other barriers to this community-based translational research project included budget development and maintenance. Among our community partners, we encountered differences in familiarity with developing budgets for this type of work (specifically, costs such as rent, inflation, materials, and technical support). We also found that it was difficult to get required compliance (e.g., HIPAA) documents in place for community staff. In particular, there was a significant disconnect between institutional requirements for research and those required for clinical work. This was a surprise given the overarching applicability of HIPAA across settings. To address both of these barriers, we made sure our project manager was very involved in carefully monitoring these aspects of the project.

#### **FACILITATORS OF IMPLEMENTING THE INTERVENTION AND OPPORTUNITIES**

Despite some of the challenges of implementing this type of program in clinical settings, we also identified some unexpected and interesting facilitators.

##### **Group “readiness”**

In weekly debriefing and supervision sessions, we repeatedly heard from our interventionists the perception that participants in public mental health settings were more “group ready” than those in the health plan. They attributed this to participants' familiarity with group counseling models compared to the individual sessions more common in the health plan. Group “readiness” resulted in less time spent early in the intervention orienting participants to group processes and facilitated quicker transition into the content presented in the groups.

##### **Integrity of the intervention manual across users**

For a number of reasons (e.g., low adoption of manualized treatments, high staff turnover in delivery settings, variability in experience of mental health staff, variability in experience with lifestyle and weight loss interventions), we sought to create an intervention manual that was accessible and usable by a variety of professionals. Our manual is structured with session outlines for quick reference by experienced users and has more thorough background, rationale, and recommended scripts for novice users. Individual sessions are organized according to core components that are most important to convey in a given session and supplemental material so that delivery can be flexible according to the unique needs of each group. Feedback from our interventionists suggests that the manual is easy to use and well-organized.

As part of the implementation evaluation, we were interested in measuring whether delivery of the intervention varied according to interventionist characteristics or setting. Our interventionists consisted of research staff interventionists and native clinicians in each setting. All were trained by the study to conduct the intervention. They were 60% female, had a mean of 18 years education ( $SD=1.41$ ), and the majority were Master's level counselors. They had a mean of 7.5 years experience conducting behavioral weight loss interventions ( $SD=7.6$ ) and a mean of 3.8 years conducting mental health interventions ( $SD=2.9$ ). Despite this variability, the mean fidelity rating across the intervention dyads was 1.8 (with a score of 2.0 meaning the core components of intervention were fully implemented), indicating that the intervention was delivered consistently across the cohorts and settings as planned.

##### **Appreciation**

Our interventionists also report that community mental health program participants appeared to appreciate STRIDE more than do the health plan members (who have more resources through the health plan that support lifestyle changes and wellness). For example, interventionists reported that participants from public clinics described the group as “a good opportunity” and sometimes as “a privilege,” whereas participants from the integrated health plan were less likely to see the program in this way. At the same time, participants across settings have been extraordinarily appreciative of both the research and clinical components of this project. Both through informal contact with study staff and through formal program evaluations and qualitative interviews, many participants reported that, before STRIDE, they felt they had been left out of mainstream efforts to address lifestyle effects on health outcomes. These participants saw the STRIDE program as an opportunity because it provides a test of an intervention designed to meet their specific needs and it gives them the chance to learn from similar others' experiences as they make lifestyle changes.

Interviewer: What made you decide to participate in this study?

Respondent: The reason why I wanted to do the study is because, for one, it would help me out with my weight and stuff, because my weight always fluctuates. And plus, when I heard it was for other people with kind of like my disability and... taking my medication...

#### **CONCLUSIONS**

A comprehensive and effective group lifestyle and weight loss intervention was adapted and delivered in an integrated health plan and two public mental

health clinics. Implementation results suggest that conducting this type of intervention among individuals taking antipsychotic medications is complex but feasible. Such an effort requires careful planning and budgeting, consistent monitoring of administrative details, buy-in from both the organizations and providers poised to deliver the intervention (and sometimes consciousness-raising), specific clinician training for weight loss and lifestyle changes, flexibility in expectations surrounding the intervention targets and pace of delivery, and significant case management time. Main outcomes will be published at the trial's conclusion, but preliminary analyses of mediator variables indicate intervention participants are making some healthy short-term behavior changes. For example, of those participants who attended groups in the first five cohorts, 63% of attendees kept food records more than 5 days a week. Preliminary results based on attendance and participant evaluations suggest this type of intervention is valuable to participants.

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