Southern California CSU DNP Consortium

California State University, Fullerton California State University, Long Beach California State University, Los Angeles

FIGHTING ANTIPSYCHOTIC-INDUCED OBESITY USING A COMMON-SENSE APPROACH

A DOCTORAL PROJECT

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DOCTOR OF NURSING PRACTICE

By

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ABSTRACT

The metabolic consequences of long-term antipsychotic use may lead to a lower quality of life and an increased risk for premature mortality, either through the direct impact of these medications on cardiovascular health or by its significant effects on weight. This DNP project was designed to develop, implement, and evaluate a *tailored* intervention at a community clinic to promote healthy lifestyle behaviors, with a longterm goal of decreasing the weight of overweight or obese mentally ill individuals taking antipsychotic medications. An interview prompt based on Leventhal's Common-Sense Model of Self-Regulation (CSM) was created and incorporated in three monthly appointments with 14 participants. A food/activity journal and a healthy lifestyle resource packet were also provided. At the end of three months, 11 of 14 participants lost weight even though BMIs changed only slightly. Thirteen participants acknowledged that the intervention was helpful. This DNP project focused on modifying lifestyle behaviors that may eventually lead to weight loss rather than achieving rapid weight loss in a short time span. As demonstrated through this project, the weight management tool kit grounded by Leventhal's CSM model can be helpful in fighting antipsychotic-induced obesity. It also showed that implementing a behavioral intervention is feasible in a fast-paced community health clinic and is acceptable to stable patients suffering from mental illness.

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BACKGROUND

Obesity has a higher prevalence in people suffering from severe mental illness, compared with the general population (Green, Janoff, Yarborough, & Yarborough, 2014). Consequently, because of obesity, cardiovascular risk is doubled, and endocrine issues are substantially higher for the mentally ill. Antipsychotic use, which is the necessary pharmacological intervention to treat schizophrenia and a broad spectrum of mood disorders, leads to increased weight and decreased metabolic health (Bak, Fransen, Janssen, Van Os, & Drukker, 2014). The metabolic consequences of long-term antipsychotic use may lead to a lower quality of life and an increased risk for premature mortality, either through the direct impact of these medications on cardiovascular health or by its significant effects on weight. If left unaddressed, the physical, emotional, social and economic burdens of obesity for those who are mentally ill have very negative consequences for individuals and society (Goldstein et al., 2011; Withrow & Alter, 2011).

In the United States (U.S.), more than one-third of the American adult population now suffers from obesity (Centers for Disease Control, 2015). The economic burden alone broadens the magnitude of this public health concern – U.S. health care costs related to obesity amounted to \$190 billion dollars in 2012, exceeding health care costs related to smoking (Ungar, 2012). Obesity is also one of those physical health issues that takes a heavy emotional toll on its sufferers. Negative emotions associated with obesity include feelings of shame, rejection, and low self-esteem, further adding to the emotional turmoil for the patient with mental illness.

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Local Context and Problem Statement

The project setting is a fast-paced community clinic that serves low-income clients. Mental health services are offered at the clinic; patients receive monthly counseling and medication management to treat psychotic, mood, and anxiety disorders. Approximately 50 patients are taking antipsychotic medication. Most of these patients are either overweight or obese. This problem calls for an increased effort in addressing antipsychotic-induced weight gain. It is usual practice that educational handouts are given to patients after a clinic visit. These handouts describe healthy lifestyle habits with the hope that the patient will follow through. However, it is already known that a healthy lifestyle is not achieved solely through health education, since an increase in knowledge does not automatically lead to a change in behavior, let alone its sustenance. Researchers have found that people engage more in changing health behaviors to meet a short or a long-term goal rather than the prevention of disease itself (Worawong, Borden, Cooper, Perez, & Lauver, 2018). Therefore, a tailored intervention, customized on individual motives, preferences, values, goals, beliefs, and needs may be more useful for the patient. A person-centered approach, respecting the individual's autonomy to make decisions and that consider his or her personal aspirations may be more efficacious and motivational for the patient.

Project Purpose

The purpose of this project is to develop, implement, and evaluate a patientcentered intervention at a community clinic to promote healthy lifestyle behaviors, with a long-term goal of decreasing the weight of overweight or obese mentally ill individuals taking antipsychotic medications.

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Supporting Framework

Professional nursing has a strong tradition of using theoretical frameworks for the purposes of guiding clinical projects. A model or a framework establishes boundaries, provides organization and structure, defines concepts and relationships, eliminates confusion and inconsistencies, and increases the efficiency of a project (Bonnel & Smith, 2014). Therefore, it is imperative that interventions materialize from the scaffolding of an existing framework that is deemed to be a good fit with the desired objectives of a clinical project.

The Common-Sense Model of Self-Regulation (CSM) explicates the cognitivebehavioral processes underlying an individual's overall representation of a health threat (Leventhal, Phillips, & Burns, 2016). These processes are influenced by a person's experience about an illness, and inputs may come from somatic sensations, cultural beliefs, interpersonal discussions, and environmental cues. They are further enriched by observation and communication, with family, friends, and information derived from various forms of media. The person's memory structure, or *prototype*, generates an individualized mental representation of an illness threat that CSM classifies into five domains: the *identity* of the threat; the *cause* of the threat; the *consequences* of the threat; the *controllability* of the threat (the belief of whether the illness can be cured/managed); and the projected *timeline* (the perceived illness duration). These variables do not necessarily come in an ordinal fashion or have a hierarchy in importance. The perceived illness threats do not occur in a single, defined moment; rather, they complement and compete with each other in creating a behavioral response to an illness and influencing health decisions. Basically, the CSM concretely formalizes an individual's "commonsense" collective understanding of a health threat.

It is essential to give an identity to a problem before it can be addressed. In the field of mental health, cognitive-behavioral interventions rely heavily on the cognizance and the correct labeling of automatic negative thinking to counter and replace these thoughts. The CSM in a way, is similar as it helps identify a health problem in a more concrete fashion. It breaks down the abstract perception of how "bad" an illness is to concrete constructs. The understanding of the five domains is important for the development of an action plan that would match these representations and ultimately affect behavior change. In other words, the illness must be viewed from the lens of the patient to create a deeper insight on how to attack the underlying problem.

Leventhal's model also claims that these illness representations must be activated; the individual must perceive that there is a deviance from the normal self, based on an individual's framing of his or her past experiences with the illness. Both representations and prototypes interact and complement each other in the patient's formation of an illness identity. The CSM suggests that prototypes and their representations are antecedents to action. Illness representations are associated with health behaviors (Hagger & Orbell, 2003), and the recognition of even some of its five domains may prove to be invaluable predictors of decision making. A meta-analysis conducted by French, Cooper, and Weinman (2006) found that cardiac patients who possess strong beliefs in illness identity, consequence, and controllability were more likely to attend cardiac rehabilitation post myocardial infarction. A systematic review by Law, Tolgyesi, and Howard (2014) associated controllability beliefs in predicting self-management behaviors for children with chronic illness.

The individualized representation of an illness must relate to proposed action plans to provide a compelling case for behavioral change (Breland, Fox, Horowitz, & Leventhal, 2012). It is also important to note that health threat representations and action plans are interdependent variables; neither leads to behavioral change when presented by themselves. Therefore, the interplay of illness perception and intervention must make "sense" to the patient to promote action.

Based on this premise, interventions should be effective if they are congruent with the patient's illness and treatment representations. Additionally, Leventhal's model suggests that the five constructs are continuously fed back in a loop which allows for modifications based on changing experiences and inputs. The patient's cognitive and emotional representations consistently evolve as he or she observes or experiences a health threat and more information is acquired (Jones, Smith, & Llewellyn, 2016).

Some studies have demonstrated an improvement in adherence behaviors when the CSM was incorporated into the design of the intervention. A systematic review by Jones, Smith, and Llewellyn (2016) identified six studies which reported significantly improved adherence behaviors and three studies demonstrating large effects in improvement, one of which was adherence to exercise and dietary advice (Keogh et al., 2011). Keogh and colleagues' (2011) intervention was individually tailored and *challenged* inaccurate and negative perceptions. How illness perceptions influenced health behaviors were also examined and adapted to each patient's personalized action plans. The CSM ultimately guides this DNP project by the objectification of illness perceptions and the individualization of treatment planning, so that interventions and action plans make sense to the patient. For example, for obese and overweight patients, determining the perceived identity of the health threat (e.g., "obesity" or "I have a muffin-top"); the perceived cause (e.g., "I eat a lot of sugar" or "I work a lot and I don't have time to exercise"); its consequences (e.g., cardiovascular issues, "I don't feel good", or stigma); its controllability (e.g. "If I stop drinking soda, I will not gain a lot of weight"); and timeline (e.g. "This will probably take just a few months") will yield information that will allow their health care provider to attack misconceptions and challenge inaccurate and negative perceptions about the illness, or stimulate a change if there is a lack of perceived deviance from their normative view of self. After utilizing these constructs for assessment, and subsequent modifications or reattributions of illness representations were instituted, a tailored action plan with concrete, attainable goals based on each of the domains will be designed in partnership with the patient.

In a larger sense, especially with regards to the problem of obesity and weight management, the progression from behavioral initiation to adherence and maintenance behaviors is the primary concern of this project. According to Leventhal, Phillips, and Burns (2016), routinized adherence develops from the accurate recognition of a threat, but one must eventually put that aside. When dealing with chronicity, illness perceptions generally dissolve into daily living, and assume a normative identity. The focus therefore, must eventually shift from health threat recognition to the tailored action plan which is integrated with the individual's daily routine. The action plan must also assume a habitual identity and become second nature to the patient (e.g., walking the dog every morning, routine personal hygiene). This means that identifying interests, patterns, time slots, and environmental factors play a part in the development of an action plan to promote automatic self-management.

In clinical practice, CSM is a conceptual model that calls for a more comprehensive approach to patient assessment. This project focuses on obese and overweight patients who are stable on their antipsychotic medications. Hence, the practitioner avoids sacrificing face-to-face time intended for the more pressing issues of mental health such as the acute treatment of psychosis.

REVIEW OF LITERATURE

Overview

A literature search was conducted using these databases: PubMED, CINAHL Plus, Google Scholar, and PsycINFO. A gray literature search was also performed using the New York Academy of Medicine Grey Literature Gateway (www.greylit.org) and general search engines such as Google and Bing. Databases were searched for articles, statements, and guidelines published in the English language between 2003 to 2018. The timeframe was extended from the standard five-year period to cast a wider net on articles which have used interventions framed after the Common-Sense Model of Self-Regulation (CSM), a model developed by Howard Leventhal in 2003. Search terms included were as follows: obesity, overweight, weight gain, antipsychotic medications, severe mental illness, behavioral weight-loss interventions, common-sense model of self-regulation, self-regulation, and chronic illness management. Studies that were excluded from the search are those which employed pharmacological strategies to address weight gain due to antipsychotic medications, those which were conducted in an inpatient setting, and those which have non-adult subjects.

Literature Review

Obesity is a chronic illness caused by an excess in energy intake relative to energy expenditure (McElroy, 2009). Individuals with obesity have shorter life spans and have a higher risk of developing cardiovascular illness and endocrine diseases such as diabetes mellitus type 2 (CDC, 2015). Obesity is also associated with the metabolic syndrome, an umbrella term used to describe factors contributing to cardiovascular risk, which includes glucose and insulin intolerance, elevated cholesterol and triglycerides, visceral adiposity,

and hypertension. Both obesity and the metabolic syndrome lead to elevated mortality risk for all causes of death (Bak, Fransen, Janssen, Van Os, & Drukker, 2014).

Measurements

A characteristic sign of obesity is excessive abdominal fat (or visceral/central adiposity) which is determined by a waist circumference of more than 88 cm. in women and more than 102 cm. in men (National Institutes of Health, National Heart, Lung and Blood Institute, 1998). Enlarged or increased amount of intra-abdominal fat cells is associated with the cardiovascular and metabolic sequelae of obesity; this excess of intra-abdominal adipose tissue is commonly referred to as abdominal obesity (McElroy, 2009). The body mass index (BMI) is commonly used in the U.S. to classify overweight and different degrees of obesity. A BMI of 25 to 29.9, expressed as weight in kilograms divided by metric height squared, would be considered overweight, and a measurement of anything equal or above 30 would classify an individual as obese (National Institutes of Health, National Heart, Lung and Blood Institute, 1998).

Treatment Options

Treatment options for obesity include behavioral and pharmacological interventions. For people with obesity, nutritional counseling and increased participation in physical activities are the usual behavioral interventions, which may also be supported by obesity medications and in more severe cases, invasive procedures such as bariatric surgery (Erickson et al. 2016). However, there are no gold standard treatments for obesity, given the complex nature of the disease. Pharmacological treatments for weight loss, while shown to be effective in the short term, have effects that are not sustained in the long term (Das, Mendez, Jagasia, & Labbate, 2012).

In contrast, behavioral interventions for achieving weight loss are the least medically invasive and least likely to have side effects associated with obesity medications (Erickson et al. 2016). This review of literature aims to present existing evidence on the efficacy of behavioral weight-loss interventions, its collateral effects particularly on the cardiometabolic indicators of health and its feasibility and acceptability in mental health settings despite variations in delivery and duration.

Behavioral interventions, sometimes used interchangeably with the term *lifestyle* interventions, are any non-pharmacological strategies aimed at self-monitoring, diet modifications, exercise, and nutrition education (Naslund et al., 2017). Primarily, the outcome of interest for studies employing behavioral weight-loss interventions is weight change; however, some studies have not limited their outcomes to anthropometric measurements. Other cardiometabolic indicators, such as lipids, glucose, insulin levels, and blood pressure have also been measured in conjunction with weight. This makes sense, considering the long-term ramifications of obesity. Even though body weight is the primary measure used in the determination of obesity (height usually being a constant in the calculation of the BMI), it is not simply and singly a problem of weight (Walker, McGee, & Druss, 2015).

Lifestyle interventions are utilized as first-line treatment options for obesity (Ratliff, Palmese, Tonizzo, Chwastiak, & Tek, 2012). The Diabetes Prevention Program (DPP) is currently the gold standard in behavioral weight management for the general population and is widely replicated in weight loss studies (Jefferson, 2018; Aschbrenner, Naslund, Shevenell, Mueser, & Bartels, 2015). The DPP focuses on goal setting, problem solving, and maintenance of weight loss. A large clinical trial reported that half of its DPP participants lost over 7% of body weight after receiving this lifestyle intervention (Olson, Bond, & Wing, 2017).

One component of lifestyle approaches for weight loss includes diet interventions through caloric restriction – the intake of less calories relative to caloric expenditure (McElroy, 2009; Olson, Bond, & Wing, 2017). While there are existing data supporting caloric restriction rather than the modification of the dietary macronutrient composition (such as low-fat or low-carbohydrate diets), these programs still recommend reducing fat and carbohydrate intake to meet calorie goals.

Another component of lifestyle intervention is the institution of gradual increases in physical activity. Obese individuals are encouraged to participate in moderate intensity workouts and decrease sedentary activity. To help enhance motivation, a variety of selfregulation skills are employed to aid in behavior change and maintenance. When physical activity is combined with diet modification in behavioral weight loss programs, they typically produce a mean weight loss of 7 kilograms in 6-12 months (Olson, Bond, & Wing, 2017).

Obesity in Mental Illness

As obesity is a a growing public health concern, it is an even more pressing issue for certain clinical populations, particularly for individuals with severe mental illnesses (SMI) such as schizophrenia and bipolar disorder. Compared to the general population, obesity is nearly twice as prevalent in patients with SMI, regardless of antipsychotic use (Scott & Happell, 2011; Thakore, Mann, Vlahos, Martin, & Reznek, 2002). Dickerson, Brown, and Kreyenbuhl (2006) compared the obesity rates of the general population with 169 randomly selected patients with SMI; when compared with an age, gender and race matched group from the National Health and Nutrition Examination Survey (NHANES), 41% of the male psychiatric sample were obese compared with 20% of the male NHANES sample, and 50% of the female psychiatric sample were obese compared with 27% of the female NHANES sample. Some studies have reported higher proportions – in a U.S. study, for example, 79% of almost 10,000 people diagnosed with schizophrenia, bipolar disorder, or depression were overweight or obese (Correll et al. 2010).

Compared to the general population, there is also a twofold increase in cardiovascular risk for schizophrenia patients, and the risk for developing an endocrine illness such as diabetes mellitus type 2 is more than five times higher for people with SMI (Bak, Fransen, Janssen, Van Os, & Drukker, 2014). When long-term antipsychotic use is factored in, it adds to the increased mortality risk of people with SMI either through metabolic dysregulation or its direct cardio-toxic effects. Antipsychotic use is also associated with an increase in body weight for people with SMI, due to its interactions with certain neurotransmitter systems that induces changes in appetite and food intake. McEvoy, Meyer, and Goff (2005) compared NHANES data with patients diagnosed with schizophrenia who participated in the Clinical Antipsychotic Trials of Intervention Effectiveness (CATIE) and found that male schizophrenia patients were 138% more likely to have metabolic syndrome, while female schizophrenia patients were 251% more likely to develop it. While psychiatric medications are frequently cited as the primary cause of weight gain for individuals with SMI (Manu et al. 2015; Bak, Fransen, Janssen, Van Os, & Drukker, 2014), lifestyle behaviors (such as sedentariness) are a major contributing factor for obesity in this clinical population (Aschbrenner, Naslund, Shevenell, Mueser, & Bartels, 2015).

Behavioral Weight-loss Interventions

According to a review by Bartels (2015), there is sufficient material to conclude that behavioral weight-loss interventions for the mentally ill should be considered standard evidence-based practice. A behavioral intervention's safety, efficacy, and acceptability makes it an attractive approach in addressing obesity and antipsychoticinduced weight gain. A series of randomized control trials evaluating behavioral interventions supports this claim (Attux et al. 2013; Usher, Park, Foster, & Buettner, 2012; Daumit et al., 2013; Green, Janoff, Yarborough, & Yarborough, 2014).

Lifestyle education. Lifestyle education defined as a behavioral intervention aimed to promote healthy lifestyle habits (Wang, Cai, Padhye, Orlander, & Zare, 2018) is often used to encourage people with SMI to lose weight. Patients are educated about techniques for monitoring food intake, recognizing errant food habits, and increasing exercise. In a study by Goldberg et al. (2013), group sessions incorporated educational brochures and handouts about the importance of diet and exercise. Iglesias-Garcia, Toimil-Iglesias, and Alonso-Villa (2010) included counseling on increasing motivation and self-esteem led by a psychiatric nurse in one of their study's twelve healthy lifestyle sessions.

In a randomized controlled trial (RCT), Weber and Wyne (2005) investigated the effectiveness of a cognitive-behavioral lifestyle intervention for obese patients with schizophrenia taking antipsychotics. A weekly, 1-hour group session involving role playing, goal setting, problem solving, and healthy diet and lifestyle education was led by a researcher-trained psychiatric nurse practitioner. After 16 weeks, the intervention group had a mean loss of 5.4 lbs., compared to 1.3 lbs. for the control group. Attux et al. (2013) evaluated the outcomes of one-hour lifestyle education sessions to reduce weight gain for

individuals taking antipsychotics. Findings showed that intervention participants continued to lose weight beyond 6 months.

Green et al. (2015) studied the efficacy of weekly group meetings covering healthy lifestyle topics in decreasing the weight of obese individuals who were taking antipsychotic medications. At 24 months, the intervention group lost an average of 3.7% of baseline weight compared to 2.1% for the control participants. The researchers found that while intervention participants did not have a statistically significant difference in weight loss, other cardiometabolic indicators such as fasting insulin levels significantly improved at the end of the study, and there were reduced hospitalizations, suggesting the long-term benefits of their lifestyle intervention.

Lovell and colleagues (2014) conducted an RCT where intervention participants were in the INTERvention to encourage ACTivity, improve diet, and reduce weight gain (INTERACT) program. The INTERACT program was tailored towards individuals with SMI who take clozapine or olanzapine, two antipsychotics which cause weight gain (Bak, Fransen, Janssen, Van Os, & Drukker, 2014). Existing illness beliefs were explored by interviews based on the Common-Sense Model, followed by the development of patientcentered goals and patient-led action plans. Both behavioral and motivational components were integrated in the INTERACT program and were administered in seven individual face-to-face sessions over 6 months. A "booster" session was done in the ninth or tenth month. This 12-month study garnered modest results; at the end of the study, there was a 0.31 mean decrease (p = .44) in BMI for the INTERACT group, while there was no weight change in the control group. **Fitness training.** Fitness training has been utilized by some studies in promoting lifestyle-based weight loss. Centorrino et al. (2006) utilized the combination of 45-minute individualized fitness training and counseling sessions in a span of 24 weeks, which produced promising results for individuals maintained on antipsychotic agents. Participants lost an average of 6.3 kilograms of body weight and decreased their baseline blood pressure at the conclusion of their lifestyle change program. A 12-week, nurse-led weight management and exercise intervention designed for individuals with SMI taking antipsychotics produced a modest 0.74 kg decrease in the weight of intervention participants at 12 weeks (Usher, Park, Foster, & Buettner, 2012).

Nutritional counseling and food diaries. Some studies focused on nutritional counseling and the use of food intake diaries to help monitor food intake. Erickson et al. (2016) had their intervention group keep food and activity journals after a comprehensive nutrition assessment as part of the Lifestyle Balance (LB) intervention. At 12 months, LB participants reported a 92% adherence rate with their food journals and were able to decrease their average daily calorie intake from 2055 to 1650 calories (p < .001). While both intervention and control groups lost weight after 12 months, the intervention group had a greater decrease in waist circumference and body fat percentage. Green, Janoff, Yarborough and Yarborough (2014) integrated the Dietary Approaches to Stop Hypertension (DASH) diet into their 2-hour group sessions with SMI participants. The DASH diet is rich in fruits, vegetables, whole grains, and includes various protein sources except red meat. It is also limited in sugar-sweetened foods and beverages. They found that after 12 weeks, the intervention group lost significantly more weight (213.3 to 206.6 lbs) compared to the control group's weight which did not change. Daumit and

colleagues (2013) reported a 7 lb. mean weight loss for persons with SMI following a longer (18 months) behavioral intervention designed to promote weight loss through a reduction in caloric intake.

Use of technology. Technological devices have been used in some studies to aid behavioral weight-loss interventions for individuals with SMI (Aschbrenner, Naslund, Shevenell, Kinney, & Bartels, 2016; Aschbrenner, Naslund, Shevenell, Mueser, & Bartels, 2015; Methapatara & Srisurapanont, 2011). Aschbrenner, Naslund, Shevenell, Kinney, and Bartels (2016) explored the feasibility of incorporating wearable Fitbit trackers and smartphone mobile applications intended to facilitate self-monitoring of daily physical activity and motivate participants to stay active. Social media such as Facebook was utilized to promote weight-loss content and provided a way for participants to interact with each other and provide peer support. Based on quantitative data from feedback questionnaires, 89% reported satisfaction with the program, and considered Facebook a useful platform for giving and obtaining peer support outside group sessions. In another RCT conducted in Thailand, wearable devices such as pedometers were used in conjunction with motivational interviewing to encourage more physical activity through self-monitoring of step goals (Methapatara & Srisurapanont, 2011).

Contingency management. Contingency management is a behavioral intervention that is often used in reducing substance use in mental health populations. It is based on a principle that rewarding a targeted behavior will correspond to an increase in its frequency (Ratliff, Palmese, Tonizzo, Chwastiak, & Tek, 2012). In Ratliff and colleagues' (2012) study, financial rewards of up to 20 dollars per week were used as

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behavior reinforcement. Participants who purchased food items from a healthy food list were rewarded by weekly financial reimbursements. At eight weeks, the intervention group lost significantly more weight (-2.54 kg; p = .02) compared to the control group.

In a quasi-experimental study, Ball, Coons, and Buchanan (2001) investigated a behavioral intervention to treat olanzapine-related weight gain. Aside from weekly group therapy and exercise sessions, tokens were given to participants to reinforce weight-loss behavior, which they could use to buy gift items at an auction held after the final group session. Tokens were earned based on weight loss, attendance, participation in exercise sessions, and documentation of diet adherence. After 10 weeks, the 11 participants who completed the sessions lost an average of 5 pounds.

Variations in Intervention Duration

A meta-analysis of 17 RCTs by Naslund et al. (2017) concluded that both shortterm (≤ 6 months) and long-term (≥ 12 months) lifestyle interventions are effective for treating overweight and obesity among people with serious mental illness. The researchers were not able to isolate whether group or individually focused interventions were more contributory to weight loss due to overlapping components within some studies. However, there are intervention components which were consistently similar in most studies: the use of manuals or clearly defined procedures in intervention delivery, the use of principles of psychiatric rehabilitation in justifying nutritional counseling and exercise, and the implementation of interventions in an outpatient or community health setting (15 out of 17 studies showed interventions conducted in these settings).

Feasibility and Acceptability

Another striking observation from all the studies included in this review is the feasibility and acceptability of behavioral interventions for the mentally ill. While cognitive limitations may be expected for some individuals with schizophrenia, there are minimal difficulties encountered in the delivery of the interventions other than the chance relapse of psychotic symptoms (Weber & Wyne, 2015) and the occasional need for adapting the intervention content to aid comprehension (Green, Janoff, Yarborough, & Yarborough, 2014).

Summary

Obesity is prevalent in the general population but is even more common in people with SMI. The use of antipsychotic medications and poor lifestyle behaviors contribute to obesity. Lifestyle interventions are often used as a first-line treatment due to overall safety, efficacy, and acceptability in the SMI population. Lifestyle education, fitness training, nutritional counseling, contingency management, and the use of technology and food diaries are some of the ways to implement lifestyle changes.

METHODS

This DNP project was designed to help psychiatric nurse practitioners promote healthy lifestyle behaviors and improve weight outcomes for overweight and obese individuals taking antipsychotic medications. As presented in the review of literature, the use of behavioral interventions to address antipsychotic-induced weight gain has been evaluated in prior studies (Attux et al. 2013; Usher, Park, Foster, & Buettner, 2012; Daumit et al., 2013; Green, Janoff, Yarborough, & Yarborough, 2014) and has led to some success in effecting healthy lifestyle changes. The project utilized Leventhal's Common-Sense Model of Self-Regulation as its framework. The model helped shape the strategies used for the behavior change intervention. Prior studies also support the use of food diaries, technology, and health education manuals as behavioral intervention components (Erickson et al., 2016; Aschbrenner, Naslund, Shevenell, Kinney, & Bartels, 2016; Methapatara & Srisurapanont, 2011). In a busy and fast-paced outpatient setting, providers need an efficient way to deliver a behavioral intervention in a limited timeframe. A weight management tool kit, consisting of a food and activity journal, a healthy lifestyle resource packet, and interview prompts based on the Common-Sense Model (CSM) were used in this project to address that need.

Setting and Participants

The project was conducted in a Southern California community health clinic which serves a low-income population. The health clinic consists of five patient examination rooms, three mental health offices, and an area for dental services. The clinic has a multidisciplinary team that provides primary care, mental health services, dental cleanings, and acupuncture. The behavioral health team is comprised of two psychiatric nurse practitioners supervised by an off-site psychiatrist, and two mental health counselors (a Licensed Marriage and Family Therapist and a Clinical Social Worker) who provide weekly psychotherapy services. Each psychiatric nurse practitioner sees patients with psychotic, mood, and anxiety disorders. The main responsibilities of the clinic's psychiatric providers are to diagnose and treat mental health disorders through psychotherapy, medication management, or both. New patients receive an initial 45minute mental health evaluation with a psychiatric nurse practitioner followed by monthly 20-minute sessions. While the initial appointment entails a comprehensive psychiatric assessment and an extensive discussion of medication options, follow-up sessions focus more on assessment of medication response/side-effects and brief healthy lifestyle education.

The weight management tool kit was administered to adults between the ages of 18 and 65 years who have a BMI \geq 25, have been diagnosed with schizophrenia, schizoaffective disorder, or bipolar disorder, and have been taking at least one antipsychotic medication. Pregnant women, individuals experiencing a relapse of psychotic symptoms, and individuals with comorbid substance abuse disorders were excluded from participating in this project. *Purposive* sampling was used to select participants. Per Polit and Beck (2017), purposive sampling involves the use of the researcher's knowledge about characteristics of a population in the selection of a sample. Participants for this project were selected from the clinic's pool of behavioral health patients. During their clinic visits, clients who met inclusion criteria were asked by the psychiatric nurse practitioner if they would be interested in participating in a weight management project. A brief description of the weight management project was given,

along with a recruitment flyer (Appendix A) which contains contact information for more details. No compensations were offered to this project's participants.

After patients expressed their interest to take part in the project, an informed consent form (Appendix B) was given to them. They were informed that if they did not wish to be part of the project, their care would not be affected. They were also assured that they could withdraw at any time and that the information that they provided would be kept confidential. An Institutional Review Board (IRB) approval for the project was granted by the California State University, Fullerton IRB, and a letter of approval from the community health clinic's Chief Executive Officer was obtained prior to the performance of this DNP Project.

Procedure

The tool kit consisted of a food and activity journal, a healthy lifestyle resource packet, and a CSM interview form containing prompts intended for provider use (Appendix C). The project was implemented during the 20-minute monthly medication follow-up visit with a psychiatric nurse practitioner. During these visits, an assessment of medication response and side-effects was done along with recommendations for medication changes, dose adjustments, and routine lab orders if necessary. A 5-minute problem assessment focused on lifestyle followed by a 5-minute development of a tailored action plan were done in collaboration with the patient on each visit. This assessment was guided by a series of interviewing prompts encompassing the five domains of CSM (Identity, Cause, Consequences, Controllability, and Timeline). To assess if the patient readily identified his/her weight as a health threat – questions establishing illness identity, such as "would you say that you are underweight, normal weight, or overweight at this point in your life?" were asked. If the patient did not view the current weight as a health threat, the psychiatric nurse practitioner then educated the patient about obesity, its causes, its potential *consequences* (e.g. cardiovascular risk, metabolic risk, threats to quality of life), *timelines* (e.g. at what age is loss of mobility most likely, diabetes onset), and risks to gaining additional weight due to their current medications, lifestyle, and eating habits.

Interview questions included an assessment of the participant's own representations of health and obesity and actions related to each of the five domains. For example, asking the patient if s/he thought s/he is overweight and if so, why, established illness causality. By asking the patient what s/he thought s/he could do to lose weight shed light on the patient's representation of controllability. The psychiatric nurse practitioner also enriched the patient's representation of obesity by bringing into awareness the patient's experienced consequences of obesity, such as abnormal lab results, difficulty in mobility, or decreased self-esteem.

After conducting the problem assessment, the psychiatric nurse practitioner -- in collaboration with the patient -- created an action plan with a focus on encouraging weight loss behaviors that *fit* with the patient's model of obesity. For example, if the patient thought that a high-calorie diet causes obesity, the action plan was tailored more on replacing foods consumed with low-calorie options rather than focusing on ways to increase activity levels. To help the patient identify the early benefits of healthy lifestyle behaviors, personal benchmarks (e.g., better fit of clothes, less strain when getting up, feeling more energetic) were discussed and then utilized to reinforce the patient's action plan. After the first follow-up visit, the patient was instructed in how to use a food and

activity journal to track daily diet and exercise. Patient progress was reviewed with the psychiatric provider on the succeeding follow-up visits. A resource packet was also provided to the client. The resource packet contained lists of free mobile weight-loss applications, local parks, healthy food substitutes, and easy recipes. At the end of three monthly follow-ups, a survey was filled out by participants to assess whether the proposed tool kit had been effective in instituting health lifestyle changes.

Measures

During the first visit, participant demographic details were obtained through the clinic's password-protected electronic health record (EHR). Demographic details included age, race, and gender. The participants' weight in pounds and height in feet/inches collected at the first visit were used to calculate baseline BMI. Weight was measured using the same calibrated scale for every patient on each visit and height was measured using a wall-mounted stadiometer at baseline. The client's BMI was calculated on each follow-up visit. Anthropometric measurements collected in the clinic were recorded by nursing staff in the client's EHR. Diet and exercise progress were reviewed via the patient's daily food and activity log.

Evaluation

The final survey contained questions assessing the helpfulness of the weight management tool kit (healthy lifestyle counseling + food/activity journal + resource packet) and if the client perceived that his/her lifestyle behaviors had changed at the end of three months. Difference scores in participant weight and BMI were recorded. A Likert-type scale was incorporated in the survey to assess the degree of weight management tool helpfulness. At every follow-up visit, client feedback regarding barriers encountered while participating in this weight management project (including barriers from the performance of healthy lifestyle behaviors such as keeping up with the daily food/activity log) was collected and documented in the client's EHR. Client feedback was reviewed at every follow-up visit to provide insight on how this weight management project could be improved and how actual barriers could be addressed or avoided.

RESULTS

There were 8 male and 6 female clients who took part in this project. Participants' ages ranged from 26 to 64 years, with a mean age of 44 (SD = 10.6). Fifty percent of the participants were Hispanic, 36% were White, and 14% were other races. Forty-three percent were diagnosed with Bipolar Disorder, 36% with Schizophrenia, and 21% with Schizoaffective Disorder. All participants were taking at least one antipsychotic medication with one participant taking two different antipsychotic medications.

Participants' heights ranged from 64 to 71 inches with a mean of 67.8 inches (*SD* = 1.8). Their baseline weights ranged from 176 to 312 pounds with an average of 234 pounds (SD = 44.4). The calculated baseline BMIs ranged from 26.0 to 53.5 with a mean of 35.9 (SD = 7.7). Using the National Heart, Lung, and Blood Institute (NHLBI) categories for overweightness, at baseline, 21% of the 14 clients were overweight, 50% were either Obese I or II, and 29% were extremely obese.

Table 1

	N	Minimum	Maximum	М	SD
Height ^a	14	64.00	71.00	67.8571	1.83375
Weight ^b	14	176.00	311.60	233.7714	44.35353
BMI	14	26.00	53.50	35.8571	7.73819
N	14				

Baseline Participant Information

Note. BMI = body mass index.

^aHeight values are in inches. ^bWeight values are in pounds.

Table 2

Participant	Baseline	Time 1	Time 2	Time 3
1	201.2	193.8	197.0	196.6
2	239.0	233.2	230.2	232.8
3	185.0	186.2	185.4	178.6
4	265.6	257.0	258.0	238.0
5	222.6	213.2	213.4	216.6
6	268.4	271.2	272.0	276.0
7	200.2	205.6	206.2	208.4
8	311.6	314.8	308.0	309.2
9	303.6	_	_	292.2
10	247.6	254.2	249.0	250.8
11	176.0	178.0	172.8	170.4
12	196.8	192.8	_	_
13	264.6	261.0	_	258.0
14	190.6	-188.4	188.2	190.2

Participant Weights at Baseline and Monthly Follow-ups

Note. All participant weight values are in pounds.

Given the slow nature of changing BMIs and the short time frame for this project, a repeated measures analysis of variance was done to determine changes in weight over time. The overall *F* was not significant, F(3) = 8.00, p = .336, although weight decreases are seen in Table 3 by the changing estimates of mean weights over time.

Table 3

			95% CI		
Weight	M	SE	LB	UB	
Baseline	227.982	12.796	199.470	256.494	
Time 1	226.873	13.020	197.863	255.883	
Time 2	225.473	12.687	197.203	253.742	
Time 3	224.327	12.820	195.762	252.892	

Estimates of Mean Weights over Time

Note. CI = confidence interval; LB = lower bound; UB = upper bound.

With time 3 data available for 13 participants, which consists of participant weight and BMI at the third monthly follow-up, this changed only slightly (one less person was extremely obese). A cross tabulation with the 13 participants shows that only one person changed BMI categories over time: following the intervention, one client went from extremely obese to Obese II.

Table 4

		BMI Category (Time 3)				
		Overweight	Obese I	Obese II	Obese III	Total
	Overweight	3				3
BMI Category (Baseline)	Obese I		4			4
	Obese II			2		2
	Obese III			1	3	4
Total		3	4	3	3	13

Crosstabulation between Baseline BMI and BMI at Time 3

Note. Obese Class III is considered extreme obesity according to the NHLBI categories for overweightness. BMI = body mass index.

At the end of three monthly follow-ups, the weight loss tool helpfulness survey was administered to participants. Using a Likert scale, with "1" representing "not helpful" and "5" representing "very helpful", the degree of helpfulness was assessed for each of the three components of the weight management tool kit (food/activity log + resource packet + healthy lifestyle counseling). The survey also included a multiplechoice question inquiring which of the five CSM domains were the most motivating for participants to lose weight. Thirteen of the 14 participants completed the survey, as the psychiatric nurse practitioner failed to provide the weight loss tool helpfulness survey to one participant during his final follow-up appointment and this participant was unable to be contacted by phone. All 13 of the survey respondents acknowledged that the intervention was helpful.

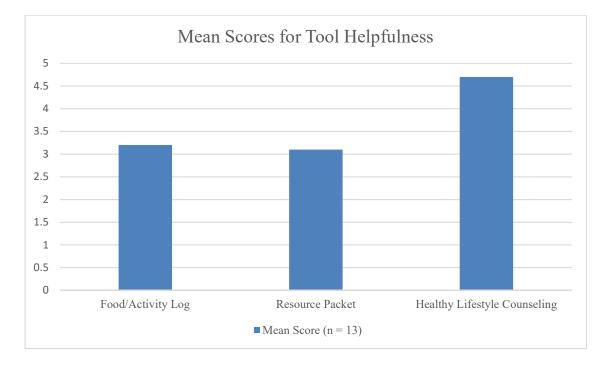


Figure 1. Mean scores for weight loss tool helpfulness.

Participant responses indicated that the use of a food/activity log and the provision of a healthy lifestyle resource packet were only moderately helpful in weight loss, while the monthly healthy lifestyle counseling by the psychiatric nurse practitioner was very helpful. The mean scores for the helpfulness of the food/activity log, resource packet, and healthy lifestyle counseling were 3.2 (SD = 1.3), 3.1 (SD = 1.8), and 4.7 (SD = 0.6), respectively.

In a debriefing session discussing the project, one client stated that the food/activity log was not very helpful, although she acknowledged that its presence was a constant reminder for her to eat healthily. Another stated that he did not use the log at all since a smartphone application was easier to use and writing on the log after every meal was too burdensome. A third client reported that she appreciated having a healthy lifestyle packet, stating that she exercised in one of the parks listed in the resource. She stated: "I didn't even know that there's a park close to us." A fourth client said he found the packet uninteresting and unhelpful. He concluded: "It's one of those you read once, then you leave it on the desk and forget about it."

Ten of the 13 participants who filled out the final survey agreed that they found the monthly healthy lifestyle counseling to be very helpful. Clients had varying responses to the interview prompts during the counseling, but they seemed to be more actively engaged in discussion when interview prompts under the *consequence* domain were asked.

Of 13 participants, 10 said that knowledge of the consequences of obesity and overweightness was the most motivating factor. The three other clients chose the CSM

29

domains of *identity*, *causes*, and *timeline* respectively. No survey respondent picked the domain of *controllability* as the most motivating factor.

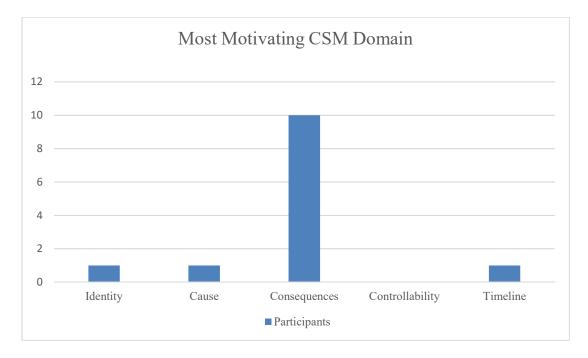


Figure 2. Most motivating CSM domain for project participants.

DISCUSSION

This DNP project was designed to develop, implement, and evaluate an intervention to promote healthy behaviors and decrease weight of overweight mentally ill patients taking antipsychotic medications who were seen at a clinic in the southwestern U.S. The project findings demonstrated that a CSM-based tool can be well-received and helpful in weight loss efforts. Eleven of 14 participants lost some weight and all 13 survey respondents acknowledged that the intervention was helpful. The question of what motivates a person to change current behaviors is the question at the very heart of this project. The CSM suggests that interventions should be effective if they are congruent with the patient's illness and treatment representations (Leventhal, Phillips, & Burns, 2016). Tapping into client common-sense understanding of a health problem, in this case, overweightness and obesity, is a promising way of motivating clients to adopt healthier lifestyles.

It is worth noting the season when this project was implemented. After recruitment was finalized by late September 2018, monthly follow-ups were scheduled in the succeeding months of October, November, and December, with some clients rescheduling as late as mid-January 2019 for their third follow-up due to the expected scheduling conflicts brought about by the winter holiday season. It is likely that these clients found it difficult to lose weight since weight gain is the norm during the holidays (Helander, Wansink, & Chieh, 2016; Schoeller, 2014; Cunningham, 2013). Factoring in with it the side effect of weight gain from antipsychotic medication use, odds are against losing weight during this season. Additionally, there is a higher chance to see a significant decrease in weight and BMI if the lifestyle intervention is applied for a longer duration (Naslund et al., 2017).

The dynamics of client education administered to mental health patients suffering from psychotic symptoms are slightly different from those with patients who have other health concerns. Fifty-seven percent of project participants were diagnosed with schizophrenia or schizoaffective disorder, both under the umbrella of psychotic disorders. Psychosis, a collective term used to describe the symptom of detachment from reality, may still be residually apparent for some clients even though all project participants were considered stable or *functional* on their medications (Chien & Chan, 2013). This means that routine assessment of current mental states is necessary during any similar weight loss program to ensure that symptoms of psychosis are not present at the time when the CSM-based interview is being done and action plans are discussed. Furthermore, client rapport must have already been established prior to the implementation of such an intervention to decrease the risk of exacerbating paranoid ideations. Ultimately, this project has demonstrated that a CSM-based tool within existing practitioner-client interactions can be utilized and is acceptable for stable mental health clients. Other than a chance relapse of psychotic symptoms, the difficulties encountered in this project's implementation are minimal.

The tangible components of the weight management tool kit (food/activity log + resource packet) were only moderately helpful in eliciting a short-term behavioral change. While prior studies support the use of food diaries and external devices to support weight loss (Erickson et al., 2016; Aschbrenner, Naslund, Shevenell, Mueser, & Bartels, 2015), the pedestrian response of participants towards these tangible components

may be attributed to individual preference or the archaic manner of tracking food intake via a written log in an age when reliance on digital devices is the norm. Additionally, the resource packet was found by most patients to be generally dull, impersonal, and unindividualized; it was informational at best.

On the other hand, the monthly healthy lifestyle counseling using the CSM-based interview prompts garnered positive feedback, with almost all survey respondents considering it "very helpful." Thus, the individualized nature of a face-to-face interview along with a provider-patient collaboration in developing a healthy lifestyle plan seems to be key to eliciting a potential behavioral change. Monthly follow-ups also promote accountability, foster increased communication between the patient and the psychiatric NP, and provide more avenues for discussion of client barriers, motives, preferences, values, goals, beliefs, and needs. It is also patient-centered, and allows for *tailoring* an intervention that the client is more likely to adopt (a tenet that is a foundation for the CSM model), and subscribes to the notion that individualized representation of an illness should be linked with proposed action plans to provide a compelling case for behavioral change (Breland, Fox, Horowitz, & Leventhal, 2012).

Rather than taking a pedagogical approach to client education offered by a practitioner, a patient-centered approach may be more efficacious and motivational for the client. It challenges the client to provide personalized solutions to his or her own health problems, under the guidance and facilitation of the provider. It respects the individual's autonomy to make decisions and utilize common-sense, and considers the client's culture and past experiences, allowing the individualization of action plans. In a sense, this is wholistic care; the recognition that the client is a human being with

interdependent needs rather than a fragmented sum of mechanical parts. Achieving wholistic care also requires developing rapport with the client, which calls for a degree of savviness on part of the nurse provider, ultimately defining nursing not only as a science but equally, an art.

In this project, the CSM domain involving knowledge of consequences was found to be the most motivating factor in starting a healthy lifestyle among participants responding to the weight loss tool helpfulness survey. Most participants were in their forties (mean participant age was 44) and at that age, adults are usually concerned about medical illness chronicity and projected quality of life as they grow older. When the pervasive and insidious effects of overweightness and obesity were presented, they were able to relate more to the discussion and even connected their own personal struggles with the problem of obesity. Even though CSM domains are not hierarchical in importance (Leventhal, Phillips, & Burns, 2016), there seemed to be, at least in this project, a quintessential light bulb moment whenever consequences were discussed. In many cases, this provoked further questioning and exploration of the other CSM domains of identity, causes, controllability, and timeline.

While the CSM-based interview prompt serves as a starter guide for opening discussions regarding the client's common-sense collective of overweightness and obesity, it also permits flexibility in the format of questioning and allows additional questions the provider may have regarding a client's representation of each CSM domain. It is not supposed to be treated as a structured questionnaire because, as such, the flow of conversation may be interrupted or may become too segmental. Again, the goal in CSMbased interviewing is to assist clients to reflect and discuss so that the provider may effectively assess the overall representation of a health threat to individual clients. The CSM interview prompt provides recommended questions to help the provider explore CSM domains and develop a tailored action plan.

The project was well-accepted by the administrators and the medical director of the community clinic where it was implemented. They expressed support and have stated that as the clinic transitions to follow an integrated model of care, all providers will be encouraged to approach client wellness in a wholistic fashion, operating not only within the bounds of their respective fields but reaching out to other aspects of client care. While overweightness is typically not addressed in mental health visits, it is nonetheless integral to address this potentially life-threatening side effect of antipsychotic treatment. In fact, the U.S. Preventive Services Task Force (2018) published recommendations for providers to guide all obese clients (BMI > 30) to seek weight loss help with a multimodal behavioral health intervention. Accordingly, the marriage between behavioral health and physical health cannot be entirely fragmented (McDermott, 2015). It is inevitable that the psychiatric NP collaborates with other members of the health team to effectively tackle this health issue. An intended effect of this project in the clinic is that the weight management tool kit would, over time, lead clients to significantly lose weight, adopt a healthier lifestyle, and encourage them to visit their Primary Care Physician (PCP) regularly to discuss how they could improve other aspects of their health.

Limitations

There are some limitations that warrant consideration. While one of the outcomes of interest for this project is weight and BMI change, assessing for other anthropometric measurements such as waist circumference may have been helpful to gauge effectiveness

of the behavioral intervention. Considering the long-term ramifications of obesity, clinical indicators such as lipids, glucose, and insulin levels would have provided a better picture of metabolic health and could have been measured in conjunction with weight. However, ordering multiple fasting labs in a span of three months would have imposed undue hardships to participants, as it is not included as standard care delivered at most psychiatric clinics. In addition to capturing anthropometric measurements and cardiometabolic indicators, gauging physical fitness would have been an important target for this project. Recent studies suggest that people with serious mental illness may view improved physical functioning as a greater motivator for adopting a healthy lifestyle as opposed to weight loss (Naslund et al., 2017; Firth, Cotter, Elliott, French, & Yung, 2015). Unfortunately, fitness assessments are not standard practice for mental health visits and would have taken substantial time from the 20-minute follow up session. It might not be feasible to implement these assessments in a busy and fast-paced mental health setting, unless perhaps, the assessments are done by a different team at a different time. In this case, additional resources such as costs and manpower should be considered.

Timing and length of the intervention may also have been issues that affected our findings. After recruitment was finalized by late September 2018, monthly follow-ups occurred during October through December, with some clients rescheduling as late as mid-January 2019 for their third follow-up. These clients could have found it difficult to lose weight since weight gain is likely during the holidays (Helander, Wansink, & Chieh, 2016). Seasonal variations may also affect physical activity, with the lowest physical activity levels observed during winter in a predominantly overweight population (Ma et

al., 2006). Additionally, it is more likely to see significant weight decreases if lifestyle interventions are applied for a longer duration (Naslund et al., 2017).

Conclusions

The weight management tool kit aimed to help promote healthy lifestyle behaviors and improve weight outcomes for overweight and obese individuals taking antipsychotic medications. The tool kit consisted of a food and activity journal, a healthy lifestyle resource packet, and a CSM-based interview prompt. It was designed for providers to be able to efficiently deliver a behavioral intervention in a very limited timeframe.

As demonstrated through this project, the weight management tool kit grounded from Leventhal's CSM model can be helpful in fighting antipsychotic-induced obesity. Rather than achieving rapid weight loss in a short time span, changes in lifestyle behaviors that may eventually lead to weight loss is at the heart of this project. This project also showed that implementing a behavioral intervention is feasible in a fastpaced community clinic and is acceptable to patients suffering from mental illness.

Sustainability is an important aspect of this weight management project that should extend beyond the confines of this project's three-month timeline. Even though instituting healthy lifestyle behaviors is one of the objectives of this project, it is hoped that weight loss would eventually occur to normalize client BMI and lessen associated metabolic risks. With clinic support, it is hoped that the weight management tool kit could be incorporated in patient's clinic visits with other health providers as part of a quality improvement initiative.

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APPENDIX A

RECRUITMENT FLYER

7212 Orangethorpe Ave Suite 9A **Korean Community Services Health Center** Buena Park, CA 90621 FREE YOURSELF FROM WEIGHT GAIN Are you at least 18 years old, overweight, and taking an antipsychotic medication? You may want to participate in a weight management project. Contact Gabriel Fernandez, PMHNP-BC for questions about the project at 714-503-6550

APPENDIX B

INFORMED CONSENT

California State University Fullerton Doctor of Nursing Practice Project Consent Form

Project Title: Fighting Antipsychotic-Induced Obesity using a Common-Sense Approach

Protocol Number: (HSR-18-19-29)

Researchers: Gabriel Fernandez, PMHNP-BC, under advisement of Jill Berg, PhD, RN from California State University Fullerton School of Nursing

This is a weight management project by Gabriel Fernandez, a doctor of nursing practice student at California State University, Fullerton. Since you are at least 18 years old, with a BMI of at least 25, and are taking at least one antipsychotic medication, you have been invited to participate in this project. Please read this form carefully, taking as much time as you need. Ask if there is anything you do not understand. You can decide not to participate in this project. If you decide to participate, you can change your mind later and withdraw at any time. There will be no penalty or loss of services or benefits if you decide to not take part in the project.

The main goal of this project is to change lifestyle behaviors that may lead to weight gain. To help achieve this goal, you will be provided with a weight management toolkit, containing a healthy lifestyle resource packet and a food/activity tracker. The resource packet will include information to help you achieve a healthy lifestyle – details on free exercise classes around your area, lists of parks and recreational facilities, healthy food substitutes, easy recipes, and a list of mobile health apps can all be found inside the packet. The food/activity tracker is a great tool you can use to track your food choices and daily calorie intake, and you may also use it to log how many minutes you have exercised in a day. During your monthly follow-up visits with your psychiatric nurse practitioner, he will guide you towards creating a personalized action plan on how to manage your weight. He will also review your food/activity tracker and offer some recommendations. At the 2nd and 4th month from the start of the project, he will ask you to fill out a survey about your experience with the toolkit.

Taking part in this project will take about four months. You cannot take part in this study if you are pregnant, are experiencing a relapse of psychotic symptoms, or have a comorbid substance abuse disorder.

There are potential risks to anticipate upon electing to participate in this project. Even with careful attempts to minimize the risk for loss of confidentiality, it cannot be entirely eliminated. A revision in food choices may potentially incur a higher cost in your food budget. Since this project may encourage physical activity, you may get injured or experience dizziness or shortness of breath when exercising. It will be best to consult your primary care provider first before engaging in any exercise program. In the event of any emergency, do not hesitate to call 911.

The data for this study will be kept confidential to the extent allowed by law. No published results will identify you, and your name will not be associated with the

findings. Under certain circumstances, information that identifies you may be released for internal and external reviews of this project

All consent forms will be kept inside a locked file cabinet for three years following the completion of the project, and will only be accessed if needed for this project's purposes. Afterwards, the consent forms will be destroyed.

There will be no costs to you for taking part in this project. You will not receive money or any other form of compensation for taking part in this project.

If you have any more questions, please call Gabriel Fernandez, PMHNP-BC at (714) 503-6550 or e-mail him at <u>gabrielrn@csu.fullerton.edu</u>. If you have questions about your rights as a research participant, or would like to report a concern or complaint about this project, please contact the Institutional Review Board at (657) 278-7719, or e-mail irb@fullerton.edu.

By signing this consent form, you certify that you have read its contents and voluntarily agree to participate in this project. If you choose not to participate, your care will not be affected. You may choose not to answer specific questions and are also free to withdraw from the project at any time.

What does my signature on this consent form mean?

Your signature on this form means that:

- You understand the information given to you in this form
- You have been able to ask the researcher questions and state any concerns
- The researcher has responded to your questions and concerns
- You believe you understand the project and the potential benefits and risks that are involved.

Statement of Consent

I have carefully read and/or I have had the terms used in this consent form and their significance explained to me. By signing below, I agree that I am at least 18 years of age and agree to participate in this project. You will be given a copy of this signed and dated consent form to keep.

Name of Participant (please print)	
Signature of Participant	Date
Signature of Investigator	Date

APPENDIX C

WEIGHT LOSS TOOL HELPFULNESS SURVEY

KCS Health Center

Please answer the following questions regarding the weight management project that you have participated in.

Please rate the helpfulness of the food/activity journal in meeting your weight loss goals.

□ 1	□ 2	□ 3	□ 4	□ 5
Not helpful		Very helpful		
Ploase rate the	bolofulor	or of the k	o althy life	

Please rate the helpfulness of the healthy lifestyle resource packet in meeting your weight loss goals.

	01	□ 2	□ 3	□ 4	
Not he	elpful				Very helpful

Please rate the helpfulness of the healthy lifestyle counseling in meeting your weight goals.

	□ 1	□2	□ 3	□ 4	□ 5
Not he	lpful				Very helpful

If you did try to lose weight, what motivated you most in trying to lose weight? (Please choose one)

□ Knowing that you are overweight

□ Knowing why you are overweight

Chowing the consequences of being overweight and/or knowing the benefits of losing weight

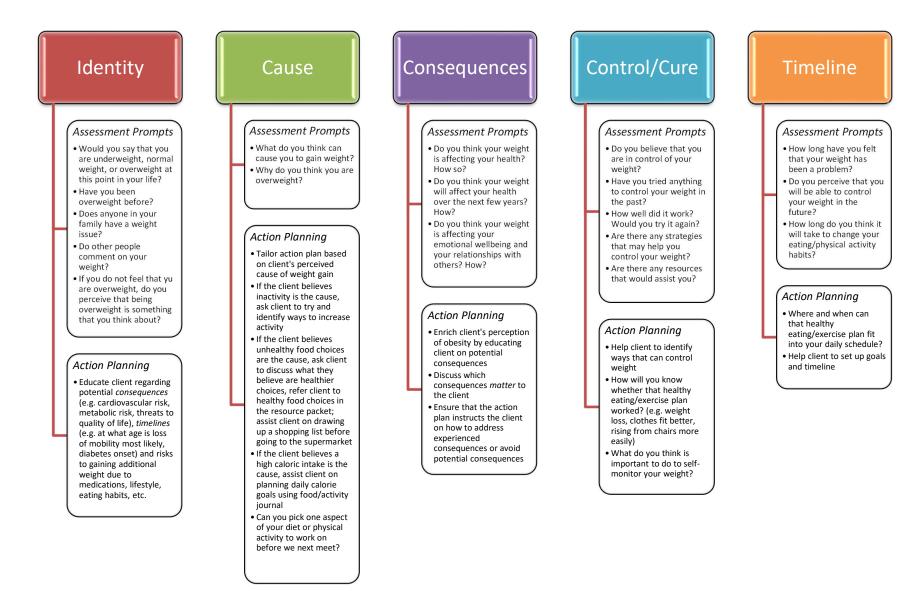
Chowing how to lose weight or knowing that you can do something to lose weight

Chowing that a healthy lifestyle can fit into your schedule; Having time to exercise and diet

□ None of these

KCS Health Center

APPENDIX D



APPENDIX E

TABLE OF EVIDENCE

Lifestyle Education

Purpose	Design & Key Variables	Sample & Setting	Measures	Results	Conclusion; Limitations; Notes
Can a lifestyle intervention tailored for people with serious mental illness be more effective than usual care in reducing weight and diabetes risk? (Green et al., 2015)	Randomized Control Trial IV: STRIDE Core Intervention (Awareness enhanced through monitoring, weekly 2-hour group meetings, including 20 minutes of physical activity, delivered over 6 months, then maintenance phase of motivational group sessions for another 6 months). Lifestyle education emphasized calorie reduction, diet, physical activity, and improved sleep	200, all adults and taking antipsychotic meds, with BMI ≥ 27 96 CG for usual care, 104 IG for STRIDE intervention Participants recruited by purposive sampling from community mental health centers (mostly low-income) and from a Kaiser Permanente in the Pacific Northwest	Height and weight measurements, fasting blood sample, BP and waist circumference. Fasting labs to measure insulin, plasma glucose, triglycerides, cholesterol levels BMI calculated using Quetelet index (kg/m ²) Collected at baseline, 6 months, and 12 months	 Baseline: groups not different on gender and clinical characteristics, stratified blocking was done based on gender and BMI IG: lost 4.4 kg more than CG at 6 months; 2.6 kg more than CG at 12 months. Lost 4.5% of baseline weight at 12 months (p=0.03); decline in fasting glucose (106.3 mg/dL to 100.4 mg/dL) CG: ↑fasting glucose (106.0 mg/dL at baseline to 109.5 mg/dL at 12 months) No statistically significant difference in BP, triglycerides 	Comprehensive weight-loss and lifestyle-change program tailored for mental health clients may help reduce weight and improve fasting glucose significantly for individuals taking antipsychotic meds. Group sessions may have increased camaraderie, support, and motivation to attain health-related goals. Unlike Usher et al. (2012), cognitive barriers were addressed through repetition and multiple teaching modalities

Purpose	Design & Key Variables	Sample & Setting	Measures	Results	Conclusion; Limitations; Notes
	DV: body measurements (BMI, weight), fasting glucose, BP, triglycerides, cholesterol (LDL, HDL)			and cholesterol in groups at 12 months	
To determine the effectiveness of a 12- month healthy living intervention to reduce weight gain in overweight and obese patients with first episode psychosis (Lovell et al. 2013)	Randomized Control Trial IV: 7 individual face-to-face sessions over 6 months containing behavioral and motivational components, optional group activities covering healthy living topics DV: BMI, waist circumference CG received some level of support from case managers to undertake healthy activities, but no systematic	105 participants diagnosed with SMI within the past 3 years, overweight or obese CG=51, IG=54 88.6% of participants completed the 12-month study All participants recruited from 2 early intervention services in England	Participants weighed using the same set of SECA model 864 scales Anthropometric measurements taken at baseline and each assessment	Baseline: groups similar in demographic variables, weight, BMI, waist circumference At 12 months, mean decrease in BMI from baseline for IG was 0.31; no changes in CG; difference was not significant difference between IG and CG in weight and waist circumference at both 6 and 12 months	12-month healthy living intervention with behavioral components was associated with a small reduction in BMI Discussion section states that they might have overestimated the effect of the intervention, since weight gain is more marked in the early course of psychosis Researchers questioned whether BMI change is the appropriate outcome measure – cardiovascular and metabolic

Purpose	Design & Key Variables	Sample & Setting	Measures	Results	Conclusion; Limitations; Notes
	approach to weight control				parameters should have been measured
To test the efficacy of a lifestyle-change program for controlling weight gain for individuals with schizophrenia under antipsychotic treatment (Attux et al., 2013)	Randomized Control Trial IV: 12-week weight management intervention (one- hour weekly sessions covering healthy lifestyle topics) with use of diaries, role playing, visual aids DV: weight in kg and BMI changes Unique design feature is inclusion of relatives in one session of the intervention (study was done in Brazil where most patients live wit families)	 160, adults using antipsychotic meds in past 3 months with dx of schizophrenia, clinically stable; 79 in CG (standard care), 81 in IG At three-month follow-up, CG 66; IG 60 At six-month follow-up, CG=41; IG=44, response rate of 53.1% Purposive sampling done in outpatient programs and community centers in Sao Paulo, Brazil 	Weight monthly on same scale, patients without shoes Fasting plasma, insulin, total cholesterol, HDL/LDL, height, weight, BMI, and abdominal girth at baseline, 3 and 6 months Blinded investigators used validated scales to evaluate severity of schizophrenia (PANSS is used to assess positive/negative symptom severity), patients used self-rated scales to assess diet and physical activity	Baseline: BMI of CG is slightly higher. No difference on other variables, including type of antipsychotic (p=0.254) IG: at 3 mos: weight loss of 0.48 kg, BMI decrease of 0.14 kg/m ² At 6 mos: weight loss of 1.15 kg (CI 95%) CG: at 3 mos: weight increase of 0.48 kg, BMI increase of 0.16 kg/m ² At 6 mos: weight increase of 0.5 kg (CI 95%) Non-significant difference in weight between groups at 3 mos. but significant at 6 mos.	A lifestyle-change program did not result in clinically significant weight loss at 3 months, but difference was significant at 6 months Lifestyle interventions learned during 12- weekly sessions may have long-term benefits on weight management AEB statistically significant weight loss x 6 months Low-cost, safer alternative that pharmacological measures to reduce weight

Purpose	Design & Key Variables	Sample & Setting	Measures	Results	Conclusion; Limitations; Notes
To examine the effectiveness of a cognitive-behavioral intervention for weight loss in individuals with schizophrenia or schizoaffective disorder taking antipsychotics (Weber & Wyne, 2006)	Randomized Control Trial IV: 1 hour cognitive- behavioral group sessions, weekly x 16 weeks DV: weight, BMI, waist-hip ratios, fasting glucose Group sessions promote healthy lifestyle, provided by a psychiatric nurse practitioner CG received care as usual Subjects given 5 dollars for each completed visit to assist with transportation expenses	 17 adults with schizophrenia or schizoaffective disorder, overweight or obese Participants take only one oral antipsychotic Majority of subjects are female and African-American Mean BMI for both groups = 33 2 CG subjects dropped off due to worsening psychosis All participants recruited from a large urban public mental health clinic in Dallas. Convenience sampling was used. 	Pre- and post- intervention weight, BMI, waist-hip ratio and blood sugar measured by a blinded graduate research assistant Blood glucose measured by finger-stick method, same glucometer Same scale and height measurement tool used throughout the study	Baseline: groups similar in weight, BMI, waist-hip ratio, drug, gender, ethnicity At 16 weeks, mean weight loss from baseline for IG was 5.4 lb; CG was 1.3 kg. Difference was not statistically significant Post fasting blood sugar could not be analyzed as 2 subjects did not fast prior to glucose check	Weight-loss is possible with cognitive- behavioral interventions for populations with psychotic disorders Small-sample size 100% retention rate for treatment group

Fitness Training

Purpose	Design & Key Variables	Sample & Setting	Measures	Results	Conclusion; Limitations; Notes
Effect of a nurse-led weight-loss intervention on the weight of mental health patients taking second generation antipsychotics (Usher, Park, Foster, & Buettner, 2012)	Randomized Control Trial IV: 12-week nutrition and exercise education, exercise education, exercise sessions, nurse support DV: body measurements (BMI, abdominal girth, weight) Not a drug-based intervention unlike most single mode intervention studies. In past studies, greater weight reduction found in lifestyle intervention groups > pharmacological intervention groups	 101, all adults and taking antipsychotic meds; 51 in CG, 50 in IG 89 had BMI above the normal range. Mean BMI=33.71 kg/m² Used convenience sampling. Recruitment via posters at local community mental health centers and NGOs, word of mouth. All participants from North Queensland, Australia. 	Survey instruments measuring drug compliance and self- evaluation of general health. Compliance was measured using a 7- point scale ranging from 'complete refusal' to 'active participation' 51-item Likert type side effect rating scale to check patient views on antipsychotic tolerability. Height, weight, BMI, and abdominal girth were collected, at baseline, 12 weeks.	Baseline: groups not different on any variable IG: mean weight loss o0.74 kg (p=0.167) CG: mean weight loss 0.17 kg (p=0.729) No statistically significant difference in BMI in groups at 12 weeks	Lifestyle, education, and weight loss intervention with motivational interviewing x 12 weeks did not resul in clinically significant weight loss. 12 weeks is short time to produce significant weight loss, but results indicated change in predicted direction (including ↓BMI and ↓girth). Possibly, longer duration = significant results. Ability of participants to comprehend educational booklet was not tested.
To determine the impact of a 24-week program of diet, exercise and counseling in	Quasi- experimental study	17 obese, chronically psychotic patients (10 women, 7 men)	Weekly monitoring of weight and BMI	By 24 weeks, mean weight loss per patient was 6.0 kg;	Labor-intensive weight-loss interventions

Purpose	Design & Key Variables	Sample & Setting	Measures	Results	Conclusion; Limitations; Notes
weight loss for chronically psychotic patients (Centorrino et al. 2006)	IV: 24-week weight loss program, includes exercise sessions, low-fat/low- calorie food plan DV: weight, BMI, BP, serum cholesterol and triglycerides Intervention was 90 mins long, divided into 2 phases: first 45 min spent assisting with issues of adherence with diet and meal planning, 2 nd 45 min spent on individualized fitness training	Inclusion criteria include reported weight gain of ≥4.5 kg and an increase in BMI of ≥5% since starting antipsychotic treatment All are taking only psychiatric medications, doses of all meds held constant throughout study Settings include a small gym, weight-lifting room, kitchen, and meeting rooms Study used convenience sampling to recruit participants	Clinical laboratory measurements of serum glucose, triglycerides, cholesterol, hepatic enzymes, creatinine, urea nitrogen and ECG were obtained at baseline and at the end of the study	BMI decreased to 34.5 (by 5.7%) BP decreased from 130/83 to 116/74 (11% improvement) No significant difference in cholesterol and triglyceride concentrations pre and post intervention	integrating exercise and diet planning may yield clinically promising benefits for individuals taking antipsychotic meds Medication doses were held constant – this may not be applicable in real world scenarios when patient is unstable on meds Intensive interventions may be both feasible and effective for the chronically, mentally ill Study reported poor adherence to exercise component, however weight loss remained significant. Could diet planning have a bigger impact?

	Nutritional	Counsel	ling
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Purpose	Design & Key Variables	Sample & Setting	Measures	Results	Conclusion; Limitations; Notes
To determine the effectiveness of a behavioral weight-loss intervention modified for individuals with SMI in decreasing the weight of veterans who suffer from antipsychotic medication- associated obesity (Erickson et al. 2016)	Randomized Control Trial IV: "Lifestyle Balance" modified from the Diabetes Prevention Program, consists of weight management classes and individual nutritional counseling with a dietician Optional group exercise sessions DV: weight, waist circumference, body fat percentage DPP is the gold standard for behavioral weight loss in the general population	 121 veterans with SMI, overweight or obese, reported 7% weight gain while on antipsychotics Age = 49.6 ± 8.0 years CG=59, IG=62 CG received less intensive usual care (encouragement to improve lifestyle habits) Participants stratified by antipsychotic weight gain risk (high: clozapine/olanzapine; medium: quetiapine/risperidone; low: aripiprazole/ziprasidone; negligible: haloperidol/other) All participants recruited from four southern CA VA locations. Study used convenience sampling. 	Weekly anthropometric checks (weight, BMI, vital signs, body fat percentage and waist circumference) x 8 weeks Quarterly laboratory tests of metabolic and lipid parameters Average daily caloric intake measured through food journals Treatment adherence questionnaire, Lifestyle habits questionnaire	Both CG and IG lost weight at 12 months $(\geq 5\%)$; more participants in IG had weight loss, but difference was not significant IG had a significantly greater decrease in waist circumference (mean loss of 1.04 cm) and percent body fat Average daily caloric intake decreased from 2055 to 1650 for IG (p <0.001)	Individuals with SMI who are taking antipsychotics are capable of making lifestyle changes, AEB significant improvements in anthropometric parameters and decreased caloric intake Self-monitoring through food and activity journals increases likelihood of intervention success LB participants with more insight into both psych illness and weight problem experienced the most weight loss

Purpose	Design & Key Variables	Sample & Setting	Measures	Results	Conclusion; Limitations; Notes
To assess the effectiveness of an adapted blood pressure management intervention in decreasing the weight of overweight/obese individuals taking antipsychotic medications (Green, Janoff, Yarborough, & Yarborough, 2014)	Randomized Control Trial IV: PREMIER intervention with DASH diet (a lifestyle intervention originally intended for people with elevated blood pressure) DV: weight in lbs. Designed to promote weight loss through dietary changes (↑ fruit and vegetables, ↑lean protein, ↓fat and sodium), a behavioral intervention, and clinical advice	36 adults, taking at least one antipsychotic med x 30 days, overweight or obese (BMI 25-44.9) CG=18, IG=18 Mean age is 48.5 (SD=13.3) years, 81% female, 94% white. Only one participant lost to follow-up, from the IG. Had achieved normal BMI after first session All participants recruited within a large, not-for-profit, integrated health plan. Purposive sampling was used.	Height, weight and BP measured by blinded staff Weight measured without shoes on a digital scale, height measured using a wall mounted stadiometer, BP measured using a digital sphygmomanometer Baseline and post- treatment questionnaires (Eating Habits Confidence and Exercise Confidence) Psychiatric medication information (names and doses) collected through questionnaires	Baseline: groups similar in sociodemographic characteristics, medication types, weight and BMI. In 12 weeks, mean weight for IG declined from 213.3 to 206.6 lbs; CG essentially unchanged from 209.6 to 209.3 lbs. Statistically significant difference in mean weight (difference of 6.5 lbs) at follow-up between groups (p=0.004)	This study also found that this particular weight loss and lifestyle intervention is feasible and acceptable for individuals with SMI who are taking antipsychotic meds Significant weight loss after only 12 weeks, very close to those reported (about seven pounds) following an 18-month intervention study by Daumit et al. (2013) May not be representative of individuals receiving care in community health settings

Purpose	Design & Key Variables	Sample & Setting	Measures	Results	Conclusion; Limitations; Notes
To determine the effectiveness of an 18- month weight-loss	Randomized Control Trial	291 adults with SMI, overweight or obese	Height, weight and BP measured by blinded staff	Baseline: groups similar in sociodemographic	Weight-loss intervention which incorporated weight
intervention in decreasing the weight of overweight/obese	IV: group and individual weight- management	Mean number of psychotropic meds is 3.1	Weight measured with the subject wearing only	characteristics, psychiatric diagnoses, weight and BMI.	management counseling and group exercise
individuals with SMI (Daumit et al. 2013)	sessions, group exercise sessions	CG=147, IG=144 After 18 months,	indoor clothing, without shoes, on a high-quality, calibrated digital scale	At 6 months, mean weight loss from	significantly reduced weight in 18 months
	DV: weight in kg. Designed to	CG=137, IG=142	0	baseline for IG was -1.8 kg; CG was -0.3 kg. At 18 months,	Weight-loss did not peak early on, but
	promote weight loss through a reduction in caloric intake	CG received standard nutrition and physical activity information at baseline		mean weight loss from baseline for IG was -3.4 kg; CG was - 0.2 kg.	progressed gradually during the trial
	(avoiding sugar- sweetened beverages and	Mean age is 45.3 years, 49.8% male, 38.1% black		Statistically significant difference	Long-term study, one of the first large scale trials of
	junk food), five total servings of fruits and	All participants recruited from 10 community psychiatric rehabilitation		in mean weight (difference of -3.2 kg) at 18-month follow-	behavioral weight loss for persons with SMI
	vegetables, portion control, and moderate-intensity aerobic exercise	programs in central Maryland. Purposive sampling was used.		up between groups (p=0.002)	People with SMI can also make substantial LMs

Use of Technology

Purpose	Design & Key Variables	Sample & Setting	Measures	Results	Conclusion; Limitations; Notes
To determine the feasibility of a behavioral weight loss intervention enhanced with peer support and mobile technology for individuals with SMI (Aschbrenner, Naslund, Shevenell, Meuser, & Bartels 2016)	Mixed-method exploratory design 24-week enhanced behavioral weight loss intervention consisting of 3 variables (1) 90-min weight mgmt. sessions (2) Optional 1- hour exercise session (3) Use of mHealth tech and social media to increase motivation Use of mobile technology also helps with self-monitoring dietary intake Participants wore Fitbit activity tracking devices	13 obese adults with SMI (mean weight = 243.5 lbs) Required to be stable on psych meds (defined as receiving the same psych meds over the prior 2 months) Conducted in an urban community mental health setting in southern New Hampshire	Quantitative measures: program attendance, weight, cardiorespiratory fitness tracked by a research assistant Weight measured on a flat, even surface using a high-quality, calibrated digital scale Cardiorespiratory fitness assessed by the 6-min Walk Test Participant satisfaction assessed using a questionnaire with Likert rating scales Qualitative measure: Participant feedback interviews	No overall significant changes in mean weight or cardiorespiratory fitness At 6-month follow-up, 45% of participants were below baseline weight, 45% improved 6-MWT scores 89% reported program satisfaction Participants suggested: More active and engaging learning activities, and to focus more on overall positive changes in dietary behavior and less on counting calories and fat	Participants were generally satisfied with the technological component, although attendance for the weekly weight management sessions was poor (56%) Participants commented that weight management sessions had a lot of "lectures" with little opportunity to interact mHealth technologies could effectively support health behavior change

Contingency Management

Purpose	Design & Key Variables	Sample & Setting	Measures	Results	Conclusion; Limitations; Notes
Can positive reinforcement through financial rewards be effective in facilitating weight loss in patients taking antipsychotic medications? (Ratliff, Palmese, Tonizzo, Chwastiak, & Tek, 2012)	Randomized Control Trial IV: 8-week LM with CM, patients randomized to 3 conditions: LM with CM for attendance, LM with CM for weight loss, and a waitlist control, who after the waiting period received payment (food reimbursement) for behavioral change (healthy food purchases).		Weight measured in light clothing, without shoes Height measured using a calibrated, portable scale BP measured using a	Baseline: groups not different in weight or BMI, but antipsychotic medication dose was different. Controlled using statistical analysis with chlorpromazine equivalent In 8 weeks, CM _{attendance} : weight loss (- 1.16 kg)	CM is effective in any form for weight loss, but the greatest weight loss achieved through behavioral change. High cost of healthy foods to blame?
	DV: weight in kgCG was eventually included in the three-fold CM interventionCM was proven to be effective in prior studies to facilitate behavior change in individuals with substance abuse disorders	Used convenience sampling. Recruitment via advertisement or referral. Study was conducted at a mental health center at New Haven, CT	calibrated wrist monitor Plasma glucose, insulin HgbA1C and lipid profile 24-hour dietary recall done to get food consumption	CM _{weight} : weight loss (-1.23 kg) CG: weight gain (0.68 kg) After another 8 weeks, CM _{behavior} : Statistically significant weight loss (-2.54 kg) p=0.02	CG crossed over to an IG, less confounding if there are 4 separate groups Not cost-effective

Notes. AEB = As Evidenced By; BMI = Body Mass Index; BP = Blood Pressure; CG = Control Group; CI = Confidence Interval; CM = Contingency Management; DV = Dependent Variable; HDL = High Density Lipoprotein; IG = Intervention Group; IV = Independent Variable; LB = Lifestyle Balance; LDL = Low Density Lipoprotein; LM = Lifestyle Modification; NGO = Non-Government Organization; PANSS = Positive And Negative Symptom Scale; SMI = Serious Mental Illness.