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Washington University in St. Louis

The Brown School

Social Work

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The Physical Health of People with Co-occurring Serious Mental Illness and Substance
Use Disorders

By

Mark R. Hawes

A dissertation presented to the Brown School of Washington University in St. Louis in
partial fulfillment of the requirements for the degree of Doctor of Philosophy

June 2023

St. Louis, Missouri

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Dedication

To Jie, Grace, and my parents Russell and Judy

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Abstract

The Physical Health of People with Co-occurring Serious Mental Illness and Substance
Use Disorders

By

Mark R. Hawes

Doctor of Philosophy in Social Work

The Brown School, Washington University in St. Louis, 2023

Leopoldo J. Cabassa, Ph.D., Chair

People with serious mental illness (SMI; e.g., schizophrenia) die 10–25 years earlier than people in the general population largely due to chronic medical conditions (e.g., cardiovascular disease [CVD]), and having a co-occurring substance use disorder (SUD) increases this risk even further compared to having either disorder alone. This is concerning since 50% of people with SMI will be diagnosed with a co-occurring SUD in their lifetime and 40%-80% are current tobacco smokers. Healthy lifestyle interventions can improve the health of people with SMI by offering a package of services aimed at improving physical activity, dietary habits, and engagement in health promoting activities, but little is known about how substance use and tobacco smoking affect healthy lifestyle intervention mechanisms of change (e.g., diet, physical activity) and outcomes (e.g., weight loss).

The proposed study sought to understand how tobacco smoking and substance use among people with SMI impacts healthy lifestyle intervention factors (e.g., improvements in diet and physical activity) and health outcomes (e.g., weight loss). Understanding this impact is an important step in the development of personalized

interventions directed at reducing CVD risk factors, the leading cause of early mortality among people with co-occurring disorders. Further, despite a national push to integrate behavior and physical healthcare, there is limited research into the multimorbidity of substance use disorders and chronic diseases among people with SMI. Advancing knowledge in this area will provide information important to the integration of behavioral and physical healthcare.

This dissertation study uses data from a recently completed National Institute of Mental Health (NIMH) funded trial testing the effectiveness of a peer-led healthy lifestyle intervention for 314 participants with SMI and overweight/obesity ($BMI \geq 25$) living in supportive housing. The intervention helped participants achieve clinically significant weight loss ($\geq 5\%$) through changes in dietary practices and physical activity. The present study addresses the following aims: 1) examine the baseline sociodemographic (e.g., education), mental health (e.g., SMI diagnosis), physical health (e.g., physical health conditions), and healthy lifestyle factor (e.g., diet) correlates of substance use and tobacco smoking, 2) examine how the impact of receiving either the peer-led healthy lifestyle intervention or usual care on weight loss throughout the trial was moderated by participants' baseline tobacco smoking or substance use status, and 3) explore how tobacco smoking and substance use at baseline moderate the mediating effects that improvements in diet and physical activity over the course of the trial have on weight loss at 18-months.

Most participants were from racial/ethnic minoritized groups (82%) and 42% were female. The mean age of participants was 49. Approximately 57% were diagnosed with schizophrenia or a schizoaffective condition, 50% anxiety related conditions, 47%

bipolar, and 63% were taking an antipsychotic medication. At baseline, 17% had cardiovascular disease, 32% diabetes, 31% arthritis, and on average, participants had 3.7 different chronic medical conditions. The average BMI of participants was 33. At baseline, 63% (N=197) of participants were current tobacco smokers and 25% (N=79) were using substances (i.e., alcohol or drugs).

The aim 1 results indicated that the odds of being a current smoker was significantly higher for females, people with fewer years of education, and those with lower BMI's. Poor – fair self-rated health (compared to good – excellent) was consistently related to any substance use, more days of substance use, and more problematic substance use. Additionally, a higher number of medical conditions was related to more days of substance use and more problematic substance use. Fewer sitting minutes per day was significantly associated with any substance use and more days of substance use at baseline. Any substance use and more days of substance use were related to younger age and more years of education. Also, females were less likely to have problematic substance use than those who identified as male. Additionally, racial and ethnic minoritized participants had a higher risk of more substance use days and having bipolar disorder was significantly associated with more days of substance use.

Aim 2 results found that the main effects of baseline weight and tobacco smoking were important predictors of weight loss over the course of the trial, but these did not moderate the effect of the intervention. Additionally, the main effect of total days of substance use was a predictor of weight loss over the course of the trial but did not moderate the effect of the intervention. Aim 3 results found that neither baseline tobacco

smoking nor substance use influenced weight loss indirectly through diet or physical activity.

An important finding of this study was that more days of substance use and more problematic substance use were significantly associated with worse self-rated health and a higher number of medical conditions. In addition, this study challenges researchers to take substance use and tobacco smoking into account when testing healthy lifestyle interventions since smoking and total days of substance use at baseline were significantly associated with more weight loss over the course of the trial. The potential impact of substance use on diet, physical activity, and weight loss and the known association of smoking cessation and weight gain, have important implications for the personalization of healthy lifestyle interventions.

In conclusion, the proposed study sought to understand how tobacco smoking and substance use among people with SMI impacted their physical health at baseline and how it impacted their diet, physical activity, and weight loss during a healthy lifestyle intervention. Even though there is a national push to integrate behavioral and physical healthcare, there is limited research into the multimorbidity of substance use disorders and chronic diseases among people with SMI. This study advances knowledge in this area and provides information important to the integration of behavioral and physical healthcare. This study also provides information critical for the development of personalized interventions directed at reducing CVD risk factors, the leading cause of early death among people with SMI and co-occurring disorders. Health interventions can no longer be siloed into weight loss, diet, PA, tobacco smoking, substance use, coordinated care, etc. It is becoming increasingly clear that there is an integral connection

between all aspect of physical and mental health and intervening in one area while ignoring another will make it difficult to move the needle and improve quality of life and life expectancy for people with SMI.

Chapter 1: Introduction

Problem Statement

People with serious mental illness (SMI; e.g., schizophrenia) die 10–25 years earlier than people in the general population largely due to chronic medical conditions (e.g., cardiovascular disease [CVD]) (Correll et al., 2015; Walker et al., 2015), and having a co-occurring substance use disorder (SUD) increases this risk even further compared to having either disorder alone (Batki et al., 2009; Bruckner et al., 2017; Dickey et al., 2002; Heiberg et al., 2018; Rosenberg et al., 2005; Schmidt et al., 2011). This is concerning since 50% of people with SMI will be diagnosed with a co-occurring SUD in their lifetime and 40%-80% are current tobacco smokers (Callaghan et al., 2014; Mueser & Gingerich, 2013). Healthy lifestyle interventions can improve the health of people with SMI by offering a package of services aimed at improving physical activity, dietary habits, and engagement in health promoting activities, but little is known about how substance use and tobacco smoking affect healthy lifestyle intervention mechanisms of change (e.g., diet, physical activity) and outcomes (e.g., weight loss) (Firth et al., 2019; Naslund et al., 2017).

Substance use and tobacco smoking among people with SMI are associated with higher mental illness severity, more positive symptoms (e.g., delusions), impaired cognition and social interaction skills, and worse functional outcomes (e.g., personal care skills), all of which could impact the ability to engage in and benefit from healthy lifestyle interventions (Buckley & Brown, 2006; Depp et al., 2015; Dickerson et al., 2013, pp. 1999–2011; Mueser & Gingerich, 2013; Oluwoye et al., 2019; Priester et al., 2016; Velligan et al., 2017). Particularly relevant to health lifestyle intervention

outcomes, quitting smoking is associated with weight gain, and smokers with SMI tend to engage in less physical activity while consuming diets less healthy than non-smokers with SMI (Bobes et al., 2010; Dipasquale et al., 2013; Tian et al., 2015). A systematic review quantified weight gain after smoking cessation and found that quitting smoking led to a mean weight gain of 9 pounds (4.10 kg) (Tian et al., 2015). Additionally, some studies show that smokers are overall a lower weight than non-smokers, although some reviews of the literature indicate that heavy smokers tend to have greater body weight compared to light smokers or nonsmokers, which could reflect a clustering of risky behaviors (e.g., less physical activity, unhealthy diet, and smoking) (Chiolero et al., 2008). Smoking also increases insulin resistance which can cause weight gain. (Tian et al., 2015).

Data on the association between substance use, diet, and physical activity among people with SMI is scarce. The proposed study seeks to understand how tobacco smoking and substance use among people with SMI impacts healthy lifestyle intervention factors (e.g., improvements in diet and physical activity) and health outcomes (e.g., weight loss). Understanding this impact is an important step in the development of personalized interventions directed at reducing CVD risk factors, the leading cause of early mortality among people with co-occurring disorders. Further, despite a national push to integrate behavior and physical healthcare, there is limited research into the multimorbidity of substance use disorders and chronic diseases among people with SMI. Advancing knowledge in this area will provide information important to the integration of behavioral and physical healthcare.

This dissertation study uses data from a recently completed National Institute of Mental Health (NIMH) funded trial testing the effectiveness of a peer-led healthy lifestyle intervention for 314 participants with SMI and overweight/obesity (BMI ≥ 25) living in supportive housing (Cabassa et al., 2015). The intervention helped participants achieve clinically significant weight loss ($\geq 5\%$) through changes in dietary practices and physical activity. Most participants were from racial/ethnic minoritized groups (82%). At baseline, 63% (N=197) of participants were current tobacco smokers and 25% (N=79) were using substances (i.e., alcohol or drugs). This dataset is ideally situated to examine the relationship between tobacco smoking/substance use and healthy lifestyle intervention factors (i.e., diet and physical activity) and health outcomes (e.g., weight loss) since smoking status, substance use, dietary intake, physical activity, and health outcomes were systematically examined among a large sample of participants (usual care = 157; intervention = 157). The present study will address the following aims.

Study Aims

1. Examine the baseline sociodemographic (e.g., education), mental health (e.g., SMI diagnosis), physical health (e.g., physical health conditions), and healthy lifestyle factor (e.g., diet) correlates of substance use and tobacco smoking. Hypothesis: Compared to non-smokers and non-substance users, tobacco smoking and substance use at baseline will be related to worse mental and physical health and lower levels of fruit/vegetable intake and physical activity at baseline.
2. Examine how the impact of receiving either the peer-led healthy lifestyle intervention or usual care on weight loss throughout the trial was moderated by participants' baseline tobacco smoking or substance use status. Hypothesis: Tobacco smoking and

substance use will moderate the effect of the intervention, resulting in tobacco smokers and substance users losing less weight loss over the course of the PGLB trial.

3. Explore how tobacco smoking and substance use at baseline moderate the mediating effects that improvements in diet and physical activity over the course of the trial have on weight loss at 18-months. Hypothesis: Tobacco smoking and substance use at baseline will moderate the mediating effects of the healthy lifestyle intervention on improvements in diet and physical activity on weight loss at 18-months.

Significance of Research

The study expands the knowledge base on how people with SMI who smoke tobacco and use substances respond to healthy lifestyle interventions that address health disparities and will impact the way healthy lifestyle services are provided to people with co-occurring disorders by evaluating the mechanisms and processes of change using moderation analysis and conditional process analysis (i.e., moderated mediation), which is a rigorous approach to understanding how these interventions work and for whom (A. F. Hayes & Rockwood, 2020).

Understanding how tobacco smoking and substance use among people with SMI effects key aspects of healthy lifestyle interventions and intervention outcomes is important as the field moves towards personalized interventions. No prior studies have systematically examined the effect of tobacco smoking and substance use on healthy lifestyle intervention factors and outcomes in people with SMI. The findings from this project will be an important step in the development of tailored multifaceted interventions directed at reducing CVD-risk factors for people with co-occurring disorders.

Chapter 2: Literature Review

Prevalence and Physical Health of People with Co-occurring Disorders

Worldwide substance use disorders ([SUD] i.e., alcohol and illicit drugs) and psychiatric disorders (e.g., schizophrenia, bipolar disorder) are considered among the most disabling health problems, comparable to cancer, cardiovascular disease, and diabetes (Whiteford et al., 2013). In 2021 approximately 5.5% of adults in the U.S., some 14.1 million people, reported a serious mental illness (SMI) in the past year (SAMHSA, 2022). Results from the 2021 NSDUH estimated that 6.4 million people (2.5% of adults) in the U.S. had a past year co-occurring SMI and SUD, corresponding to 45% of people with SMI (SAMHSA, 2022).

The prevalence of co-occurring SMI and SUD varies by SMI diagnosis. A meta-analysis found that the prevalence of any SUD among people with schizophrenia spectrum disorders was 41.7%, followed by illicit drug use disorder (27.5%), cannabis use disorder (26.2%), alcohol use disorder (24.3%), and stimulant use disorder (7.3%) (Hunt et al., 2018). Further, males with schizophrenia had a 2-3 times greater risk of SUD compared to females with schizophrenia. Another meta-analysis found that 33% of people with bipolar disorder had any SUD, followed by alcohol use disorder (24%) and illicit drug use disorder (17%) (Hunt et al., 2016). Around 50% of people with SMI will be diagnosed with a SUD in their lifetime compared to 15% of the general population (Mueser & Gingerich, 2013). A U.S. based study of a large multiethnic sample of 9,142 individuals found that people with severe psychotics disorders have a 4.6 greater odds of recreational drug use, 4.0 greater odds of heavy alcohol use (e.g., >4 drinks per day), and

3.5 greater odds of heavy marijuana use (e.g., >21 times per year) compared to the general population (Hartz et al., 2014).

Substance use disorders and SMI independently place people at increased risk of chronic disease and premature death (Meszaros et al., 2011). Substance use disorders increase the risk of developing cardiovascular disease (CVD) and cancer and some studies have shown that people with SUD have a life expectancy 17 years less than people in the general population (Frishman et al., 2003; R. D. Hayes et al., 2011; Roerecke & Rehm, 2014).

People with SMI are at increased risk of chronic disease and premature mortality compared to the general population. While life expectancy increased in the general population over the past decades, people with SMI have not realized these gains (Walker et al., 2015). People with SMI die up to 25 years earlier than people in the general population largely due to chronic medical conditions (Parks et al., 2006). It is estimated that 67% of deaths in people with SMI are due to cardiovascular disease (CVD), cancer, and diabetes (Walker et al., 2015). For example, CVD is the leading cause of death among people with SMI with a prevalence 2 to 3 times higher than the general population (De Hert et al., 2011). Cancer mortality is also elevated in this population. People with schizophrenia are more likely to die of cancer, particularly lung cancer, than the general population (Olfson et al., 2015). The prevalence of diabetes mellitus (DM) is 2 to 3 times higher in people with SMI which contributes to reduced functioning, lower quality of life, heart attacks, strokes, and premature death (De Hert et al., 2011).

The prevalence of co-morbid physical health conditions and the risk of premature death seems to be greater for people with co-occurring SMI and SUD (Dickey et al.,

2002). For instance, some studies demonstrate that people with co-occurring schizophrenia and alcohol use disorder have significantly more medical illness (e.g., hypertension, coronary artery disease) compared to people with schizophrenia alone. Similarly, Bruckner et al. (2017) found that having a co-occurring disorder increases the risk of CVD death by 24% compared to SMI alone (Batki et al., 2009; Bruckner et al., 2017). Additionally, Bruckner et al. (2017) found non-Hispanic Blacks with co-occurring disorders were more likely to die of CVD than non-Hispanic Whites with co-occurring disorders (Bruckner, 2017). Also, people with co-occurring disorders also have greater risk of contracting HIV and hepatitis C virus than people with SMI alone (Rosenberg et al., 2005).

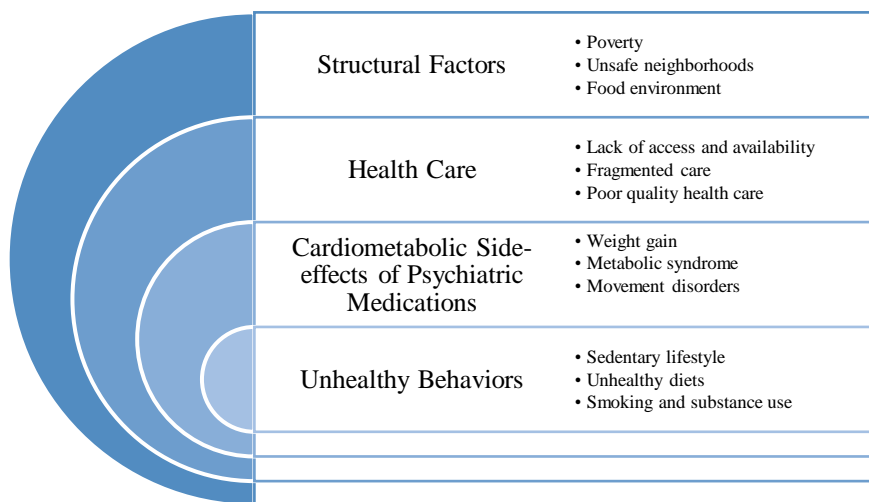
A large study from Norway found a standardized mortality ratio (SMR) of 4.4 for people with schizophrenia but not SUD; 6.6 for those with SUD only, and a SMR of 7.4 for people with co-occurring schizophrenia and SUD. The reference population was Norwegian residents aged 20-79 (Heiberg et al., 2018). Another large register-based cohort study conducted in Denmark found an SMR of 8.46 in those with schizophrenia and a lifetime SUD (i.e., alcohol, cannabis, hard drugs) compared to an SMR of 3.63 in those with schizophrenia without a lifetime SUD (Hjorthøj et al., 2015). The authors found similar findings for bipolar disorder and unipolar depression. An additional large population-based register study found that people with alcohol use disorder die 24-28 earlier than people in the general population (Westman et al., 2015). In closing, over 3 million U.S. adults with SMI have a co-occurring SUD which increases mental illness severity and places this group at higher risk for chronic disease and premature mortality compared to the general population and to people with SMI alone.

Contributing Factors

Many factors contribute to the excess morbidity and mortality that disproportionately impacts people with SMI and co-occurring disorders. These factors include a combination of health behavior risk factors (e.g., smoking, alcohol use, diet), cardiometabolic side-effects of psychiatric medications, interactions between psychiatric medications and substance use, and disparities in social determinants of health, such as health care access and quality, stigma, incarceration, employment, income, homelessness, housing instability, food security, and built environment (De Hert et al., 2011) [See Figure 1]. These factors converge to create an almost perfect storm that negatively effects the health of people with SMI and co-occurring disorders.

Figure 1

Factors Contributing to Health Disparities Among People with SMI



Since this dissertation project will focus on the effect of tobacco smoking and substance use on healthy lifestyle intervention mechanisms (e.g., diet and physical activity) and outcomes (e.g., weight loss), this chapter will discuss health behaviors such as unhealthy diet, physical inactivity, tobacco smoking, and substance use. Structural

factors, health care factors, and cardiometabolic side-effects of psychiatric medications are also important contributing factors but are beyond the scope of this dissertation.

Health behavior risk factors

Substance Use

As discussed in chapter one, there is some evidence that people with co-occurring disorders have a higher risk of death due to CVD compared to people with SMI alone, but the connection between co-occurring disorders and physical health is vastly understudied. While we know that SMI and SUD individually increase the risk of chronic disease, we do not know how or if the combination of these disorders affects the prevalence of chronic diseases. For instance, there is limited to no data examining if substance use disorders among people with SMI contribute to a higher prevalence of diabetes, hypertension, high cholesterol, cancer, or CVD.

What we know about the effects of substance use on physical health and chronic disease largely comes from the general population (i.e., those without SMI). There are several pathways through which SUD may increase the risk of death due to chronic disease. Physiological mechanisms include: alcohol increases hypertension, opiates increase risk for arrhythmia and pulmonary edema, and cocaine increases risk for myocardial ischemic events (Frishman et al., 2003; Hollander & Hoffman, 1992).

A study by Wu et al. (2018) indicated that people with a higher number of chronic diseases are more likely to have a substance use disorder. The study used the electronic health record data (EHR) of 211,800 participants to examine the association between SUDs and nine chronic disease categories. The chronic disease categories were: those with one condition, two to three conditions, and four to nine conditions (L.-T. Wu et al.,

2018). They found that a higher number of chronic diseases was associated with a higher prevalence of SUD. For instance, among patients with one condition, 14.3% had SUD, 21.2% had a SUD among people with two to three conditions, and 32.5% had SUD among people with four to nine conditions (Frishman et al., 2003; Hollander & Hoffman, 1992).

These findings indicate that substance use treatment cannot be separated from physical health treatment in the same way that mental health treatment cannot be separated from physical health treatment.

Tobacco Smoking

Tobacco smoking is a major driver of premature death and chronic disease in people with SMI and co-occurring disorders and is the CVD risk factor with the greatest disparity between people with SMI and the general population. Smoking rates declined in the general population from 42% in 1964 to 12.5% in 2020, but people with SMI have not experienced similar reductions (Cornelius et al., 2022). The prevalence of smoking among people with SMI is 2 to 4 times higher than in the general population with estimates ranging from 40% to 80% depending on the sample and psychiatric diagnosis (Callaghan et al., 2014; Dickerson et al., 2018).

Smoking among people with SMI is associated with having a co-occurring SUD, but specific data comparing smoking rates of people with SMI to those with co-occurring SMI and SUD is sparse (Cooper et al., 2012; Dickerson et al., 2013). The high prevalence of smoking among people with SMI and co-occurring disorders is concerning since the leading causes of death in people with SMI (e.g., CVD, cancer) are causally linked to tobacco smoking, and smoking among people with SMI is associated with lower quality

of life, poorer mental health, worse cognitive functioning, higher levels of positive symptoms, and worse functional outcomes (e.g., financial and personal care skills) compared to nonsmokers with SMI (Callaghan et al., 2014; Depp et al., 2015; Dickerson et al., 2013; Oluwoye et al., 2019). Additionally, smokers with SMI tend to be heavy smokers (i.e., smoke ≥ 25 cigarettes per day) and to extract more nicotine with each cigarette than those without SMI further exacerbating the negative health effects (Evins et al., 2015).

The high prevalence of smoking among people with SMI is multicausal. Historically, smoking cessation treatment has not been offered to people with SMI because behavioral health staff have viewed smoking as a secondary concern compared to more immediate problems and have believed that smoking provides therapeutic benefits and quitting might cause psychiatric symptoms to worsen (Das & Prochaska, 2017; Schroeder & Morris, 2010). Further compounding this problem, the tobacco industry targeted this population by providing free cigarettes in behavioral health settings, marketing, research funding designed to push the self-medication hypothesis (i.e., cigarettes reduce psychiatric symptoms), and by offering assistance with blocking hospital smoking bans (Das & Prochaska, 2017; Prochaska et al., 2008; Schroeder & Morris, 2010). Additionally, there is evidence that tobacco use screening by psychiatrists declined from 1993 to 2010 (Rogers & Sherman, 2014). This is concerning because quitting without appropriate supports may be more difficult for people with SMI since evidence suggests that tobacco smoke normalizes cognitive deficits and temporarily lowers blood-levels of antipsychotic medications thus reducing medication side-effects (Das & Prochaska, 2017; Schroeder & Morris, 2010; Sharma et al., 2016). Despite these

challenges, people with SMI want to reduce or quit smoking and combined pharmacotherapy and behavioral interventions can be equally as effective as they are in the general population (Aschbrenner et al., 2015; Ashton et al., 2013; Banham & Gilbody, 2010; Evins et al., 2015; Hall & Prochaska, 2009; SAMHSA, 2019).

Unhealthy Diets

Poor dietary health is another behavioral risk factor that negatively impacts the health of people with SMI and co-occurring disorders. Compared to the general population, people with SMI consume more calories per day and eat more obesogenic foods (i.e., energy dense; nutrient-poor) (Firth et al., 2019).

Studies comparing the dietary intake of people with SMI to those with co-occurring disorders is scarce. There is some data to indicate that alcohol use among people without SMI is linked to disinhibited eating (Chao et al., 2019), so it is possible that having a co-occurring disorder could increase the risk for having unhealthy dietary practices compared to people with SMI alone. A systematic review of the dietary patterns of people with schizophrenia found that people with schizophrenia consume diets high in sugar and saturated fat and low in fiber, fruits, and vegetables (Dipasquale et al., 2013). The same review found that smokers with schizophrenia consumed fewer portions of fruits and vegetables and diets higher in caffeine, salt, and saturated fats compared to nonsmokers with schizophrenia (Dipasquale et al., 2013).

This is concerning given the high rates of smoking among people with SMI and co-occurring disorders. While it is established that people with SMI consume unhealthy diets, findings regarding the dietary patterns of subpopulations with SMI are underexplored. For instance, little has been published on if or how dietary patterns differ

among racial and ethnic groups with SMI, and the findings regarding gender differences are mixed. For example, a review of dietary patterns of people with schizophrenia reported that some studies found that females consumed diets higher in fat, carbohydrates, and calories and ate less fruits, vegetables and nuts than males, while other studies found that males consumed less fruits and vegetables than females (Dipasquale et al., 2013).

There is some evidence that antipsychotic medications may influence diet, particularly in regard to reduced satiety and increased appetite, but this is underexplored as well (Dipasquale et al., 2013; Firth et al., 2019). Exploring differences among subpopulations with SMI could be an important factor for personalizing interventions designed to improve the health of people with SMI. Aim 1 of this dissertation proposal will add knowledge in this area by exploring differences in dietary patterns, physical activity, and health conditions among people with SMI who use substances (i.e., tobacco, alcohol, drugs) compared to those who do not.

Reduced Physical Activity

In addition to poor dietary health, reduced physical activity levels in people with SMI contribute to disparities in chronic disease prevalence. Physical activity guidelines in the U.S. recommend 150 - 300 minutes of moderate physical activity or 75 - 150 minutes of vigorous physical activity per week (Piercy et al., 2018). People with SMI are significantly less physically active, less likely to meet physical activity guidelines, and more sedentary than people without mental illness (Stubbs, Firth, et al., 2016; Stubbs, Williams, et al., 2016; Vancampfort et al., 2017). A meta-analysis looking at the physical activity levels of people with schizophrenia reported that only 56% of people with

schizophrenia met the guidelines of 150 minutes of moderate physical activity per week, which was significantly less than controls (Stubbs, Firth, et al., 2016). Another meta-analysis of people with schizophrenia, bipolar disorder, and major depressive disorder reported that people with schizophrenia were the least physically active and people with bipolar disorder were the most physically active, although people with bipolar disorder were also the most sedentary (Vancampfort et al., 2017). People with psychotic disorders spend an average of 11 hours per day being sedentary, which is approximately three hours more than the general population (Stubbs, Firth, et al., 2016).

Studies looking at physical activity levels of people with co-occurring disorders compared to those with SMI alone are scarce. One study of people with schizophrenia in outpatient psychiatric clinics in Spain looked at the effect of smoking on exercise habits and found that smokers were significantly less likely to exercise habitually compared to non-smokers (Bobes et al., 2010). It is possible that smoking decreases cardiorespiratory fitness (CRF) making physical activity more difficult. The detrimental effects of physical inactivity coupled with the lack of information about the effect of smoking and substance use on physical activity among people with SMI highlights the importance of conducting new research in this area. Aim 1 of this dissertation proposal will examine the physical activity levels of people with SMI who smoke and use substances compared to those with SMI alone.

The dietary and physical activity patterns of people with SMI is concerning since they increase the risk of developing metabolic abnormalities and are two primary drivers for obesity which is present in up to 55% of people with SMI (Firth et al., 2019; Janssen et al., 2015). Metabolic abnormalities and obesity are risk factors for many of the health

conditions linked to premature mortality among people with SMI, particularly CVD, cancer, and diabetes (Firth et al., 2019). Further investigation is needed to see if smoking and substance use further negatively impact dietary and physical activity patterns of people with SMI to inform future interventions and services.

Interventions to Improve Physical Health

There is increased urgency to address health disparities experienced by people with SMI and those with co-occurring disorders. Healthy lifestyle interventions are an important approach for improving the health of people with SMI. These interventions help people with SMI achieve improvements in body weight and cardiometabolic indicators by offering a package of services aimed at increasing physical activity, improving dietary health, and increasing engagement in health promoting activities (Firth et al., 2019; Naslund et al., 2017). These interventions are delivered in a variety of settings (e.g., outpatient clinics supportive housing) by a range of providers, including case managers, peer specialists (i.e., people with lived experiences recovering from SMI), social workers, nurses, dietitians, and fitness instructors (Bartels et al., 2018; Cabassa et al., 2021; Daumit et al., 2013; Green et al., 2015; Speyer et al., 2016).

Most lifestyle interventions include behavioral strategies that incorporate elements of motivational interviewing and cognitive behavioral therapy. Behavioral strategies include motivational counseling, skills training, goal setting, feedback, problem solving, relapse prevention, risk and benefit comparisons, and assertiveness training (Cabassa et al., 2010; Naslund et al., 2017). To improve dietary intake, lifestyle interventions tend to provide education on reading food labels, counting calories, keeping food diaries, practicing portion control, and meal planning with the goal of increasing

intake of fruits, vegetables, and water and decreasing consumption of sugar sweetened beverages, high fat foods, sodium, and sugar (Cabassa et al., 2010). Interventions may also include experiential exercise or in-vivo training such as trips to the grocery store and cooking demonstrations to model and practice healthy dietary behaviors.

Lifestyle interventions also provide physical activity classes, such as warmup, stretching, and aerobic classes, as well as walking groups with the goal of helping participants achieve the physical activity guidelines of ≥ 150 minutes of moderate to vigorous physical activity per week (Cabassa et al., 2010; Naslund et al., 2017). Participants may also receive pedometers and heart rate monitors to assist in monitoring their physical activity (Cabassa et al., 2010). Other components of lifestyle interventions include monitoring of weight through regular weighing, counting steps and physical activity minutes with activity trackers, and mindfulness eating (Bartels et al., 2018; Cabassa et al., 2021; Daumit et al., 2013; Green et al., 2015; Speyer et al., 2016).

A systematic review of health lifestyle interventions for people with SMI provided an evaluation of their effectiveness in improving physical health (Naslund et al., 2017). Naslund et al. (2017) conducted a systematic review of randomized trials of lifestyle interventions for people with SMI who were classified as overweight or obese (i.e., BMI ≥ 25). Seventeen studies met the inclusion criteria and included 1,968 participants of which 50% were males. Sixty-six percent of participants had schizophrenia spectrum disorders and 22% had bipolar disorder. The review did not extract the percentage of participants with co-occurring SUD. Studies were conducted in the United States (n=11), Spain (n=2), China (n=2), Thailand (n=1), and the United Kingdom (n=1). The review aimed to assess the effect of participation in healthy lifestyle

interventions on weight loss and on promoting physical activity and healthy eating. The methodological quality of studies was assessed with the Methodological Quality Rating Scale (MQRS). Findings from this review found that the methodological quality of included studies was generally high since all studies were RCTs, used manuals, collected objective outcomes, and reported details that enabled replication. MQRS metrics that were not met by all studies were follow-up length of 12-months or greater, follow-up rate of 85% or greater, use of blinded assessors, and parallel replication at more than one study site.

Results indicated that among the ten lifestyle interventions lasting 6 months or less, lifestyle intervention participants were more likely to lose weight compared to controls, although there was a high degree of statistical heterogeneity. Among the six studies of lifestyle interventions lasting 12 months or greater, lifestyle intervention participation resulted in more weight loss compared to controls and statistical heterogeneity was very low. Five lifestyle interventions lasting 12 months or longer measured clinically significant weight loss (i.e., 5% or greater reduction in weight). Results indicated that lifestyle intervention participants had significantly greater odds of achieving clinically significant weight loss compared to controls. Clinically significant weight loss is an important outcome because achieving this level of weight loss has shown to be associated with clinically significant improvements in physical health (e.g., blood pressure) (Benjamin et al., 2019).

Both Speyer et al. (2019) and Naslund et al. (2017) evaluated the effectiveness of health lifestyle interventions for people with SMI, although Speyer et al. (2019) evaluated a larger number of interventions than Naslund et al. (2017) (41 versus 17, respectively).

The systematic review by Speyer et al. (2019) focused on the clinical significance of weight loss among healthy lifestyle intervention participants while Naslund et al. (2017) primarily focused on whether healthy lifestyle interventions could help participants achieve significantly more weight loss than the control condition. Both systematic reviews found that healthy lifestyle interventions could help people with SMI lose significantly more weight than the control condition. Although, Speyer et al. (2019) found the mean effect of the reviewed healthy lifestyle interventions was of little clinical relevance since the mean 0.63 kg/m² BMI reduction was unlikely to substantially reduce future risk of CVD.

While healthy lifestyle interventions have shown some promise in improving the health of people with SMI, little is known about how substance use and tobacco smoking among people with SMI affects healthy lifestyle intervention mechanisms of change (e.g., changes in diet) and health outcomes (e.g., weight loss). Particularly relevant to health lifestyle intervention outcomes, quitting smoking is associated with weight gain (Tian et al., 2015), and evidence suggests that smokers with SMI engage in less physical activity and consume diets less healthy than non-smokers with SMI (Bobes et al., 2010; Dipasquale et al., 2013).

Data on the association between substance use, diet, and physical activity among people with SMI is scarce. Given that 50% of people with SMI will be diagnosed with a SUD in their lifetime, understanding how substance use affects healthy lifestyle intervention mediators and outcomes is necessary for understanding what adaptations need to be made for people with SMI who use substances.

This dissertation study uses data from a recently completed NIMH-funded clinical trial testing the effectiveness of a peer-led group life-style balance (PGLB) program, a healthy lifestyle intervention for people with SMI (Cabassa et al., 2015). The PGLB trial found that a larger proportion of participants randomized to the PGLB intervention compared to usual care (UC) achieved clinically significant weight loss (32% vs. 31%), clinically significant increases in CRF (29% vs. 25%) and clinically significant reduction in CVD risk (49% vs. 48%) at 18 months, but none of these differences were statistically significant. Achieving clinically significant reductions in weight and CRF are important because studies show that achieving these goals can lead to a decrease in the risk for premature mortality. Despite the null findings, the intervention achieved similar outcomes to other U.S. based healthy lifestyle trials of people with SMI. Past clinical trials in the U.S., including PGLB, have found that between 30% to 40% of participants with SMI who participated in these healthy lifestyle interventions achieve clinically significant weight loss, improvements in CRF, and reductions in CVD risk.

Conceptual Model

The high morbidity and premature mortality rates experienced by people with SMI, as well as high rates of tobacco smoking and substance use among this population, necessitates a better examination of the impact of tobacco and substance use on healthy lifestyle interventions. The conceptual model informing this study examines how substance use and tobacco smoking moderate the impact of a healthy lifestyle intervention through its impact on two critical health behaviors directly linked to weight loss: improvements in physical activity and diet (mediators) (see Figures 1 and 2 in the data analysis plan section). The theory of the group lifestyle balance intervention is that

to achieve weight loss participants need to increase their physical activity and improve their dietary habits.

While data suggests that tobacco smokers and substance users eat less healthy diets and engage in less physical activity than non-smokers and non-substance users with SMI, the influence of tobacco and substance use on these mechanisms of change during a healthy lifestyle intervention is unknown (Bobes et al., 2010; Dipasquale et al., 2013; Tian et al., 2015). It is possible that tobacco smoking and substance use decrease cardiorespiratory fitness making exercise more difficult. Smoking and substance use may also affect appetite causing eating patterns to differ from non-smokers and non-substance users. Tobacco and substance use may moderate healthy lifestyle intervention outcomes, as well as moderate the potential mediating effects of diet and physical activity on healthy lifestyle intervention outcomes.

Despite PGLB trial null findings, recent literature indicates that mediation effects can exist in the absence of a statistically significant total intervention effect (A. F. Hayes & Rockwood, 2020; O'Rourke & MacKinnon, 2018). Testing for mediation in the absence of an intervention effect can provide valuable information on which parts of a program were successful and which need to be strengthened, and provides a way to assess the consistency of intervention effects on mediators across different studies (O'Rourke & MacKinnon, 2018).

Moderator analyses are critical for several reasons. Conducting moderator analysis identifies subgroups that the intervention worked for, even if there was no whole group effect (MacKinnon, 2011). Moderator analyses examine if an intervention worked the same across different groups, identifying for which groups the intervention had the

greatest effect or no effect (MacKinnon, 2011). In a null trial it is critical to conduct moderator analysis because if the intervention had opposite effects on two groups, the total group result may be insignificant and valuable information will be missed (MacKinnon, 2011). It may be that the intervention works for non-substance users but not for substance users. This would provide the information needed to then modify the intervention for substance users.

Chapter 3: Methods

Study Overview

This study analyzes secondary quantitative data from a NIH funded trial testing the effectiveness of a peer-led group life-style balance (PGLB) program, a healthy lifestyle intervention for people with SMI. The trial is registered in clinicaltrials.gov (NCT02175641) and a detailed description can be found in the PGLB study protocol (Cabassa et al., 2015). The trial was conducted in three supportive housing agencies in two U.S. cities. One agency uses a Housing First model (Stefancic & Tsemberis, 2007) and the other two agencies use a treatment-first model (Padgett et al., 2011). The Housing First model provides housing and social services regardless of participants' willingness to stop using substances or engage in substance use or psychiatric treatment. Treatment-first models require participants to participate in substance use or psychiatric treatment before they become eligible for housing.

Research assistants (RAs) recruited participants (e.g., flyers, staff referrals) and conducted face-to-face interviews with interested participants (Cabassa et al., 2015). Eligibility was broad to capture a sample that resembled the racially/ethnically diverse people with SMI served in supportive housing. Eligible participants were active clients at their supportive housing agencies, male or female, aged 18 or older, any race/ethnicity, English or Spanish speaking, and had a chart diagnosis of a SMI. Participants had to have a BMI ≥ 25 (kg/m²) at the time of screening to be eligible for the study (Cabassa et al., 2015). Participants were excluded if at the time of recruitment they needed substance use detoxification services, posed a danger to themselves or others, failed a capacity-to-consent questionnaire (Zayas et al., 2005), or self-reported medical conditions that

contraindicated their participation (e.g., active cancer treatment) (Cabassa et al., 2015). RAs conducted face-to-face baseline interviews with eligible participants at their supportive-housing agencies within four weeks of their screening interview. Interviews were approximately 1.5 hours and participants were reimbursed \$25 for their time (Cabassa et al., 2015).

Study recruitment took place between June 2015 and January 2018. RAs screened 448 individuals, and 340 were eligible to participate. A total of 314 participants were enrolled and then randomized to usual care (N= 157) or the PGLB intervention (N = 157) after they completed their baseline interview. Randomization was conducted at the participant level in blocks of four and stratified by site. Because there were imbalances in baseline weight between the usual care and PGLB groups, the original RCT main analysis conducted sensitivity analysis that employed the inverse probability of treatment weighting estimator to correct for selection biases that may have been caused by group assignment (Cabassa et al., 2021). No differences were found between the primary and sensitivity analyses. The most common reasons people were excluded from the trial were not having a BMI ≥ 25 (kg/m²), no SMI diagnosis, and having a medical condition that was contraindicative for a weight loss intervention (Cabassa et al., 2015). Data was collected at baseline, 6, 12, and 18-months. The sample for this dissertation proposal includes the 314 participants enrolled in the PGLB trial.

Peer-led Group Lifestyle Balance Program (PGLB)

PGLB was adapted from the Group Lifestyle Balance Program, a healthy lifestyle intervention derived from the Diabetes Prevention Program (Kramer et al., 2009). PGLB is a 12-month, 22-session, manualized program consisting of 3-months of weekly

sessions, followed by 3-months of bi-weekly sessions, and monthly sessions for the remaining 6-months. Sessions were delivered in group and one-on-one formats, lasted approximately one hour, and consisted of physical activity recommendations, nutrition education (e.g., reading food labels), and behavioral strategies (e.g., self-monitoring). Participants received a bathroom scale, pedometer, food log, and calorie reference book. PGLB was delivered by peer specialists (i.e., people with lived experiences recovering from SMI) who were employed by their respective housing agencies and trained and supervised by the study team (Cabassa et al., 2015). Training included a 2-day GLB certification program delivered by a GLB master trainer and a 3-month session-by-session training that included using intervention elements (e.g., food logs) in their everyday lives and delivering mock sessions to supervisors before facilitating the intervention. Throughout the trial, the study team monitored fidelity by reviewing session audio recordings and rating the degree to which key PGLB elements were present. Weekly supervision meetings occurred in person or by telephone to avoid intervention drift.

Usual Care (UC)

All participants received UC for general physical health throughout the trial. UC services consisted of health promotion groups (e.g., cooking groups), linkages to medical care, and community resources (e.g., gyms). Health promotion groups were not manualized interventions and focused on health education. Agency staff at study sites helped clients connect with medical care as needed.

Measures

The following measures were used in the current dissertation study (see Table 1).

Baseline Correlates

Demographic correlates were self-reported age, years of education, gender, and racial/ethnic minority status. *Physical health conditions* included self-reported lifetime physician-confirmed diagnosis of high cholesterol, diabetes, CVD, and cancer. Our CVD variable was defined as anyone who had a diagnosis of coronary heart disease, stroke, arteriosclerosis, heart attack, or congestive heart failure (Cabassa et al., 2017; Goodwin et al., 2009). Mental health conditions included self-reported lifetime physician-confirmed SMI diagnosis, including depression, schizophrenia/schizoaffective disorder, and bipolar disorder.

Covariates

The PGLB study took place at three separate sites. Study site will be included as a covariate in all analysis. Baseline weight will be included as a covariate in Aims 2 and 3.

Moderators

Tobacco smoking was assessed using a single question asking participants if they currently smoke tobacco. Recent substance use (i.e., alcohol and illicit drugs) was measured with a subset of questions from the Addiction Severity Index (ASI) (Cacciola et al., 2007). Participants were asked how many days in the past 30 days they used each substance. A continuous substance use variable was created by summing the total number of days the participant used each substance. An “any substance use” variable was created by dichotomizing participant substance use into 0 = no days of substance use; 1 = even one day of substance use in the past 30 days. The Behavior and Symptom Identification (BASIS-24) substance use subscale measured urges to drink alcohol or take drugs and problems from drinking alcohol or drug use (Cameron et al., 2007). The BASIS-24

substance use subscale questions are scored on a 0-4 rating scale. The lowest possible score is 0 and the highest possible score is 4. There are no cutoff scores on the BASIS-24 substance use subscale and higher scores indicate more problematic substance use.

Mediators

Physical activity: walking, moderate, vigorous, total minutes of physical activity per day, and the MET total score were assessed using the International Physical Activity Questionnaire-Short Form (IPAQ), a self-report measure that captures participants' levels of PA (Craig et al., 2003). The IPAQ asks questions such as, "During the last 7 days, on how many days did you do moderate physical activities for at least 10 minutes at a time?", and "how much time did you usually spend doing moderate physical activities on one those days?"

Dietary intake: fruit and vegetable servings per day were measured using the Block fruit and vegetable screeners (Block et al., 2000). Sugar-sweetened beverage servings per day were measured using questions from the 2013 Centers for Disease Control and Prevention Behavioral Risk Factors Surveillance System Questionnaire (BRFSS) (CDC, 2013).

Health Outcome

Research assistants measured participants' body weight (in pounds) using a calibrated digital scale. Participants wore indoor clothing without shoes. The aim 2 outcome is weight change at each time point. Weight change was calculated by subtracting participants' weight at each timepoint from their baseline weight. The aim 3 outcome is change in weight from baseline to 18-months, which was created by subtracting participants' 18-month weight from their baseline weight.

Table 1*Measure Descriptions*

Variable Type	Construct	Measure Description	Timepoint
Baseline Correlates	Socio-demographics	Race/ethnicity, age, gender, education, and marital status.	b
	Physical health conditions	Self-reported lifetime physician-confirmed diagnosis of high cholesterol, diabetes, CVD, and cancer.	b
	Mental health conditions	Self-reported lifetime physician-confirmed behavioral health diagnosis, including depression, schizophrenia/schizoaffective disorder, and bipolar disorder	b
Moderators	Current tobacco smoking	Assessed using a single question asking participants if they currently smoke tobacco	b, 6, 12, 18
	Days of substance use	A composite days of substance use variable was created by summing the number of days the participant used each substance in the past 30-days.	b, 6, 12, 18
	Any past 30-day substance use (including alcohol)	0 = no days of substance use; 1 = even one day of substance use	b, 6, 12, 18
	Any past 30-day alcohol use	0 = no days of alcohol use; 1 = even one day of alcohol use	b, 6, 12, 18
	BASIS-24 substance use subscale	There are no cutoff scores on the BASIS-24 substance use subscale and higher scores indicate more problematic substance use.	b, 6, 12, 18
Mediators	Physical Activity	Physical activity (e.g., walking, moderate, vigorous, and total physical activity per day) was assessed using the IPAQ.	b, 6, 12, 18
	Fruit and vegetable intake	Fruit and vegetable servings per day were measured using the Block fruit and vegetable screeners.	b, 6, 12, 18
	Sugar-sweetened beverage intake	Sugar sweetened beverage intake per day was measured using questions from the 2013 Centers for Disease Control and Prevention Behavioral Risk Factors Surveillance System Questionnaire (BRFSS).	b, 6, 12, 18
Health Outcome	Body weight	Measured using a digital scale	b, 6, 12, 18
Covariant	Site	The study took place at three separate sites	b, 6, 12, 18

Note: b = baseline; IPAQ = International Physical Activity Questionnaire-Short Form

Data Preparation and Analytical Approach

All analysis used an intent-to-treat approach. Aims 1 and 2 were conducted using Stata 17.0 (Stata Corp LP, College Station, TX, USA). Aim 3 was conducted using SPSS, version 28, and model 7 of the PROCESS macro (A. F. Hayes, 2022). Distributions of

continuous variables were checked for normality. Tests were 2-sided with critical value $\alpha = 0.05$. A categorical indicator for study site and continuous baseline weight were included as control variables in all models since substance use and smoking differed significantly by site and baseline weight differs significantly between the intervention and usual care conditions.

Statistical Analysis

Aim 1

Aim 1: Examine the baseline sociodemographic (e.g., education), mental health (e.g., SMI diagnosis), physical health (e.g., physical health conditions), and healthy lifestyle factor (e.g., diet) correlates of substance use and tobacco smoking.

Frequencies, percentages, and measures of central tendencies and dispersions were used to describe sample characteristics. Bivariate analysis was used to explore the relationships between our correlates and tobacco smoking and our three dimensions of substance use. Continuous variables were compared using t-tests, Pearson correlation, or corresponding nonparametric tests based on distributional properties. Categorical variables were compared using chi-square or Fisher exact test.

Multivariate logistic regression analysis was used to examine the associations of sample correlates with our two binary outcome variables, tobacco smoking and any substance use. Demographic, physical health, mental health, dietary, physical activity, and quality of life indicators were chosen based on the study aims. The same set of predictors were used for each tobacco and substance use outcome. The Link test was used to detect specification error. A significant linear predicted value and nonsignificant linear predicted value squared indicated a correctly specified link function and that the relevant

variables were included in both logistic regression models (Institute for Digital Research and Education, 2018). We used Hosmer–Lemeshow methods to test model fit. A non-significant statistic indicated a good model fit for both models. VIF with the excess of 10 was used to detect any multicollinearity problems. No problems with multicollinearity were detected in either model. Pregibon’s dbeta, which provides summary information of the influence on parameter estimates of each case, was used to identify influential cases. No influential cases were detected. Two-sided p-values of 0.05 was used to identify statistical significance.

A negative binomial regression model with robust standard error estimator was used to identify correlates of participants’ total days of substance use at baseline. A count model was chosen since the outcome variable was skewed, and the use of OLS regression violates the assumption of normality. Preliminary analysis using the likelihood ratio (LR) test of the overdispersion parameter showed that the overdispersion parameter alpha was not zero, indicating that overdispersion was a problem. The over dispersed nature of the total days of substance use data suggested that negative binomial regression would provide a better approximation to the data than a Poisson model (Long & Freese, 2014). The average marginal effects (AMEs) were used to interpret the regression coefficients and the incident rate ratios (IRRs) were used as a sensitivity analysis.

Poisson regression with robust standard error estimator was used to identify correlates of the BASIS-24 substance use subscale score. Poisson regression was used because the outcome variable has a non-normal distribution and is not over dispersed. Inverse normal transformation (INT) was considered as a method to transform the outcome variable, but the outcome variables has too few categories for this method to be

effective. The average marginal effects (AMEs) were used to interpret the regression coefficients and the incident rate ratios (IRRs) were used as a sensitivity analysis.

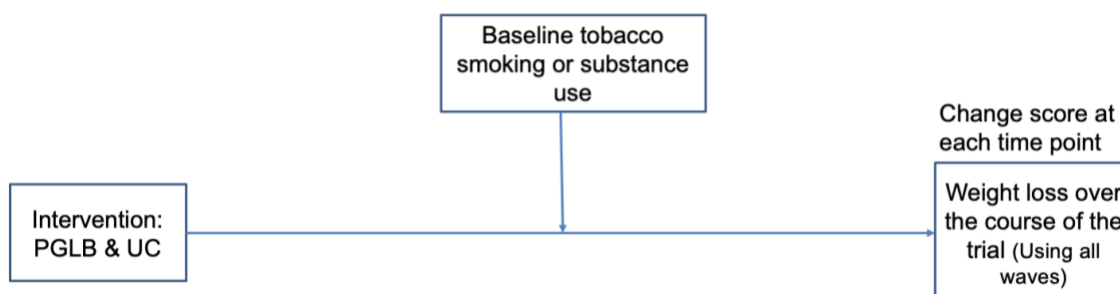
Aim 2

Aim 2: Use mixed effects models to examine how the impact of receiving either the peer-led healthy lifestyle intervention or usual care on weight loss throughout the trial was moderated by participants' baseline tobacco smoking or substance use status (see Figure 2).

An intent-to-treat approach was used to examine how participants' smoking status, substance use status, total days of substance use, and BASIS-24 substance use subscale scores moderated the impact of receiving either PGLB or UC on weight loss throughout the trial. Given the longitudinal data structure, meaning the same subjects were observed across four time points, the association between the continuous outcome (weight change) and its predictors were analyzed using mixed-effects models. Mixed effects models were also used since they employ random effects to accommodate extra heterogeneity. Separate mixed effects models were conducted for each moderator variable: tobacco smoking, any substance use, total days of substance use, and the BASIS-24 substance use subscale score. For each moderator variable, we first ran one model with only the main effects of site, baseline weight, the two treatment conditions (PGLB vs. UC), time (e.g., 6, 12, and 18 months), and the moderator variable. Next, we ran a second model that included the main effects plus the following two-way interaction term: moderator variable \times treatment condition.

Figure 2

Aim 2 Moderation Model



Aim 3

Aim 3: Explore how tobacco smoking and substance use at baseline moderate the mediating effects that improvements in diet and physical activity over the course of the trial have on weight loss at 18-months (see Figure 3).

The conditional indirect effect will reveal the amount by which the total effect of healthy lifestyle intervention is influenced when the mediators (fruit and vegetables servings per day; sugar sweetened beverage (SSB) servings per day, MET total score) and moderators (tobacco smoking, any substance use) are included in the analysis (A. F. Hayes & Rockwood, 2020). This method will test for significant differences in regression coefficients for mediated relationships at varying levels of the moderating variable (Krull et al., 2016). To test for moderated mediation:

“Hayes proposes an index of moderated mediation as a formal inferential test of whether the moderated mediational model is statistically different from zero.

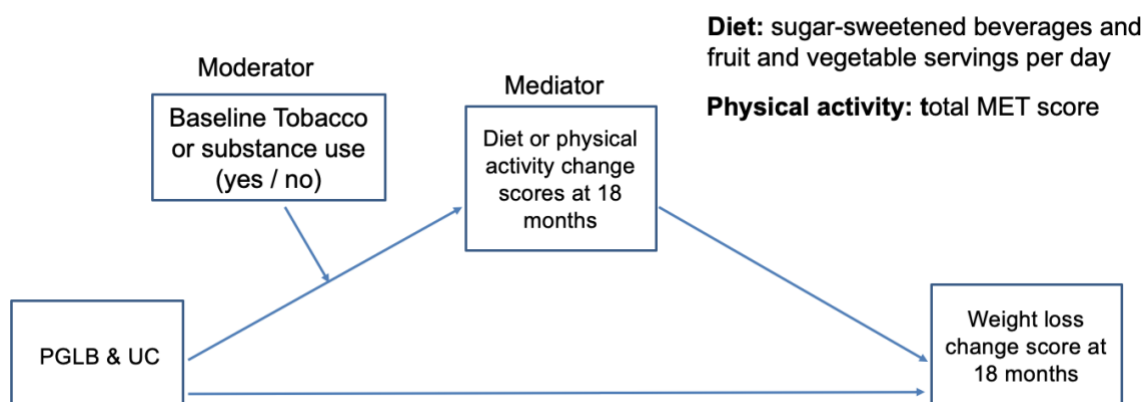
Hayes states that a significant index of moderated mediation is evidence that the conditional indirect effects estimated at different values of the moderator are significantly different from each other, thus indicating moderated mediation.

Assessing conditional indirect effects and calculating the index of moderated mediation is conducted via bootstrapping techniques.” (Torres & Taknint, 2015)

Separate conditional process models (i.e., moderated mediation) were run to test each mediator (SSB per day, fruits and vegetable servings per day, and MET total score) with each moderator (smoking status and any substance use). The outcome is weight change at 18-months (change score: baseline minus 18-months weight). The diet and physical activity mediators are a change score that calculates changes in diet (e.g., changes in number of servings per day in fruits and vegetables) and physical activity (e.g., changes in MET total score) from baseline to 18-months. The moderators are dichotomous smoking and substance use variables that categorize participants as either not using tobacco or substances or using tobacco or substances at baseline. Site and baseline weight were entered as control variables.

Figure 3

Aim 3 Conditional Process Model



Power analysis

A statistical power analysis was conducted using the Optimal Design software (Raudenbush & Liu, 2000). With a sample of 314 participants (i.e., 157 receiving PGLB

and 157 receiving UC) and four time-points (i.e., an outcome variable collected from baseline, 6, 12, and 18 months), the mixed effects model can detect a medium effect size of .529 with an adequate statistical power of .80 and statistical significance of .05. The mixed effects model shows that the current data only had a small effect size of .263 on the outcome of weight, which is associated with a power of 0.29. The current study may have limited capacity to deny a false hypothesis.

Human Subjects

An exempt IRB application (IRB # 202204085) was approved by the Washington University in St. Louis IRB office. All data for this secondary analysis are deidentified.

Chapter 4: Results

Aim 1 Results

This chapter presents results for aim 1. First, baseline sample characteristics for the total sample are presented. Next, results of the bivariate analysis of the tobacco smoking and substance use outcomes and the main study variables are presented. Lastly, the results from the multivariate analysis of each tobacco smoking and substance use variable and various correlates are summarized.

Participant Characteristics

Participant baseline characteristics are presented in Table 2. The mean participant age was 48.65 (SD= 11.56). More than half were male (57.32%) and most were racial/ethnic minoritized groups (81.21%), particularly non-Hispanic Blacks (57.64%). The average years of education was 11.91 (SD=2.48) and only 10.19% were employed. Participants' mean weight was 218.79 pounds (SD = 54.01) and mean waist circumferences was 111.59 centimeters (SD = 15.54). Participants walked an average of 318.42 meters (SD = 96.87) during the six-minute walking test (6MWT). Participants reported having an average of 3.66 (SD = 2.41) medical conditions. Based on blood pressure (BP) measurements taken at baseline, 38.06% of participants had hypertension. The most common reported lifetime physical health diagnoses were CVD (17.20%), high cholesterol (36.31%), arthritis (31.85%), diabetes (32.48%), and cancer (4.46%). More participants rated their health as good – excellent (60.19%) than fair – poor (39.81%). The most common reported lifetime mental health diagnoses were depression (75.88%), schizophrenia / schizoaffective disorder (57.23%), and bipolar disorder (46.95%). Most participants (63%) were taking an antipsychotic medication. On average, participants

reported eating 3.38 (SD = 2.13) servings of fruits and vegetables per day and drinking 1.75 (SD = 2.10) sugar-sweetened beverages per day. On average, participants spent 551.57 (SD = 202.74) minutes per day sitting and 37.58% reported getting 150 minutes or more per week of moderate or vigorous physical activity. The mean SF12 mental health component score was 47.58 (SD = 10.66) and the mean SF12 physical component score was 45.30 (SD = 8.90). More than half of participants were current smokers (62.74%) and 25.24% reported using any substances (i.e., alcohol or drugs). On average, participants total days of substance use in the past 30 days was 3.34 (SD = 8.86) and the mean BASIS substance use subscale score was 0.35 (SD = 0.61).

Table 2
Baseline Sample characteristics of study sample

	Total Group (N=314)			
	N	%	Mean	SD
Demographics				
Age			48.65	11.56
Female	133	42.36		
Race-ethnicity				
Non-Hispanic Black	181	57.64		
Non-Hispanic White	57	18.15		
Hispanic	39	12.42		
Non-Hispanic Other	35	11.15		
Total years of education			11.91	2.48
Employed	32	10.19		
Objective Health Indicators				
Mean weight (pounds)			218.79	54.01
Waist Circumference (centimeters)			111.59	15.54
Six-minute walking test (meters)			318.42	96.87
Number of medical conditions			3.66	2.41
Hypertension	118	38.06		
Lifetime self-reported physician-confirmed general medical conditions				
Cardiovascular Disease Indicator	54	17.20		

	N	%	Mean	SD
High Cholesterol	114	36.31		
Arthritis	100	31.85		
Diabetes	102	32.48		
Cancer	14	4.46		
Self-rated health				
Fair – Poor	125	39.81		
Good – Excellent	189	60.19		
Lifetime self-reported physician-confirmed diagnosis of psychiatric disorders				
Depression	236	75.88		
Schizophrenia / schizoaffective disorder	178	57.23		
Bipolar	146	46.95		
Taking any antipsychotic medications	197	63.00		
Dietary Intake				
Fruits and vegetable servings per day ^a			3.38	2.13
Sugar-sweetened beverages per day ^b			1.75	2.10
Physical Activity^c				
Sitting minutes per day			551.57	202.74
Greater than or equal to 150 minutes of moderate or vigorous physical activity per week	118	37.58		
Quality of Life Indicators^d				
SF12 Mental health component score			47.58	10.66
SF12 Physical health component score			45.30	8.90
Substance Use and Smoking				
Any smoking	197	62.74		
Any substance use	79	25.24		
Total days of substance use			3.34	8.86
BASIS substance use subscale score ^e			0.35	0.61
MET Total Score			2075.80	2266.79

Note: ^aFruit and vegetable intake were measured using the Block fruit, vegetable, and dietary fat screeners.

^bSugar-sweetened beverage (SSB) intake was measured using questions from the 2013 Centers for Disease Control and Prevention Behavioral Risk Factors Surveillance System Questionnaire (BRFSS).

^cThe International Physical Activity Questionnaire-Short Form (IPAQ) was used to measure sedentary behavior and physical activity.

^dScores on the SF-12 composite measures for physical and mental health range from 0 to 100 with higher scores indicating better health or mental health related quality of life, respectively.

^eThe summary score on the Behavior and Symptom Identification Scale (BASIS-24) Substance Use Subscale ranges from 0 to 4, with higher scores representing higher symptom severity.

Bivariate Analyses of Tobacco Smoking and Each Dimension of Substance Use at Baseline

We examined the relationship between each dimension of tobacco smoking and substance use and our correlates (Tables 3 - 6).

Smoking

Full results are presented in Table 3. We found that being a current smoker was associated with younger age ($p = .048$), female gender ($p = .015$), and less years of education ($p < .001$). Smoking was associated with a lower mean baseline weight ($p=0.003$) and smaller waist circumference ($p=0.009$). Smoking was also associated with having a lifetime diagnosis of arthritis ($p = 0.038$). Being a current smoker was associated with any substance use ($p = 0.022$), higher total days of substance use ($p = 0.021$), and a higher BASIS-24 substance use subscale score ($p = 0.004$).

Table 3

Bivariate analysis of smokers compared to non-smokers

	Non-Smoker (N=117)				Smoker (N=197)				P ^f
	Mean	SD	N	%	Mean	SD	N	%	
Demographics									
Age	46.98	12.63			49.65	10.79			0.048
Gender									
Female			39	29.32			94	70.68	0.015
Male			77	42.78			103	57.22	
Race-ethnicity									
Non-Hispanic Black			64	35.36			117	64.64	0.298
Non-Hispanic White			21	36.84			36	63.16	
Hispanic			20	51.28			19	48.72	
Non-Hispanic Other			12	34.29			23	65.71	
Total years of education	12.63	2.46			11.48	2.39			0.0001

	Non-Smoker (N=117)				Smoker (N=197)				P ^f
	Mean	SD	N	%	Mean	SD	N	%	
Depression									
No			26	34.67			49	65.33	0.634
Yes			89	37.71			147	62.29	
Schizophrenia									
No			56	42.11			77	57.89	0.158
Yes			61	34.27			117	65.73	
Bipolar									
No			66	40.00			99	60.00	0.357
Yes			51	34.93			95	65.07	
Taking Any Antipsychotic medications									
No			47	40.17			70	59.83	0.411
Yes			70	35.35			127	64.47	
Dietary Intake									
Fruits and vegetable servings per day ^a	3.60	2.07			3.25	2.16			0.161
Sugar-sweetened beverages per day ^b	1.59	2.12			1.85	2.09			0.300
Physical Activity^c									
Sitting minutes per day	560.90	195.14			545.98	207.47			0.533
Greater than or equal to 150 minutes of moderate or vigorous physical activity per week			43	37.07			73	62.93	0.957
No			74	37.37			124	62.63	
Yes			43	37.07			73	62.93	
Quality of Life Indicators^d									
SF-12 Mental health component score	47.89	10.13			47.40	10.98			0.698
SF12 Physical health component score	46.39	8.70			44.65	8.98			0.095
Substance Use									
Any substance use									
No			96	41.03			138	58.97	0.022
Yes			21	26.58			58	73.42	
Total days of substance use	1.85	6.41			4.23	9.95			0.021
BASIS substance use subscale ^e	0.22	0.48			0.42	0.66			0.004
Site									
Site 1			18	23.08			60	76.92	0.008

	Non-Smoker (N=117)				Smoker (N=197)				P ^f
	Mean	SD	N	%	Mean	SD	N	%	
Site 2			50	44.64			62	55.36	
Site 3			49	39.52			75	60.48	

Note:

^aFruit and vegetable intake were measured using the Block fruit, vegetable, and dietary fat screeners.

^bSugar-sweetened beverage (SSB) intake was measured using questions from the 2013 Centers for Disease Control and Prevention Behavioral Risk Factors Surveillance System Questionnaire (BRFSS).

^cThe International Physical Activity Questionnaire-Short Form (IPAQ) was used to measure sedentary behavior and physical activity.

^dScores on the SF-12 composite measures for physical and mental health range from 0 to 100 with higher scores indicating better health or mental health related quality of life, respectively.

^eThe summary score on the Behavior and Symptom Identification Scale (BASIS-24) Substance Use Subscale ranges from 0 to 4, with higher scores representing higher symptom severity.

^fContinuous variables were compared using t-tests, Pearson correlation, or corresponding nonparametric tests based on distributional properties. Categorical variables were compared using chi-square or Fisher exact test.

Any Substance Use

Full results are presented in Table 4. Any substance use was associated with more years of education ($p = 0.041$), smaller waist circumference ($p = 0.004$), and not taking an antipsychotic medication ($p = 0.009$). Any substance use was also associated with less sitting minutes per day ($p = 0.009$) and with getting 150 minutes or more of moderate or vigorous physical activity per week ($p = 0.037$). Any substance was associated with being a current smoker ($p = 0.022$), with more total days of substance use ($p < .001$), and with higher BASIS-24 substance use subscale scores ($p < .001$).

Table 4*Bivariate analysis of substance users compared to non-substance users*

	No Substance Use (N=234)				Any Substance Use (N=79)				P ^f
	Mean	SD	N	%	Mean	SD	N	%	
Demographics									
Age	49.16	11.73			47.30	11.00			0.217
Gender									
Female			104	78.20			29	21.80	0.218
Male			129	72.07			50	27.93	
Race-ethnicity									
Non-Hispanic Black			130	71.82			51	28.18	0.164
Non-Hispanic White			41	71.93			16	28.07	
Hispanic			32	84.21			6	15.79	
Non-Hispanic Other			30	85.71			5	14.29	
Total years of education	11.77	2.40			12.42	2.54			0.041
Employment									
Unemployed			211	75.36			69	24.64	0.416
Employed			22	68.75			10	31.25	
Objective Health Indicators									
Mean weight (pounds)	220.95	56.22			213.21	46.56			0.272
Waist Circumference (cm)	113.11	15.60			107.23	14.65			0.004
Six-minute walking test (m)	313.65	93.57			332.46	105.96			0.137
Number of medical conditions	3.63	2.33			3.75	2.63			0.706
Hypertension									
No			71	68.93			32	31.07	0.297
Yes			40	76.92			12	23.08	
Lifetime self-reported physician-confirmed general medical conditions									
CVD Indicator									
No			193	75.69			62	24.31	0.414
Yes			38	70.37			16	29.63	
High Cholesterol									
No			142	73.58			51	26.42	0.290
Yes			90	78.95			24	21.05	

	No Substance Use (N=234)				Any Substance Use (N=79)				P ^f
	Mean	SD	N	%	Mean	SD	N	%	
No			155	78.68			42	21.32	0.037
Yes			79	68.10			37	31.90	
Quality of Life Indicators^d									
SF-12 Mental health component score	47.91	10.49			46.50	11.17			0.308
SF12 Physical health component score	45.86	8.75			43.89	9.02			0.086
Tobacco Smoking and Substance Use									
Current Smoker									
No			96	41.03			138	58.97	0.022
Yes			21	26.58			58	73.42	
Total days of substance use	0	0			13.28	13.47			0.000
BASIS substance use subscale ^e	0.18	0.39			0.83	0.83			0.000
Site									
Site 1			35	44.87			43	55.13	
Site 2			95	84.82			17	15.18	0.000
Site 3			104	84.55			19	15.45	

Note:

^aFruit and vegetable intake were measured using the Block fruit, vegetable, and dietary fat screeners.

^bSugar-sweetened beverage (SSB) intake was measured using questions from the 2013 Centers for Disease Control and Prevention Behavioral Risk Factors Surveillance System Questionnaire (BRFSS).

^cThe International Physical Activity Questionnaire-Short Form (IPAQ) was used to measure sedentary behavior and physical activity.

^dScores on the SF-12 composite measures for physical and mental health range from 0 to 100 with higher scores indicating better health or mental health related quality of life, respectively.

^eThe summary score on the Behavior and Symptom Identification Scale (BASIS-24) Substance Use Subscale ranges from 0 to 4, with higher scores representing higher symptom severity.

^fContinuous variables were compared using t-tests, Pearson correlation, or corresponding nonparametric tests based on distributional properties. Categorical variables were compared using chi-square or Fisher exact test.

Total Days of Substance Use

Full results are presented in Table 5. More days of substance use was negatively correlated with mean weight ($p = 0.015$), waist circumference ($p < 0.001$), and sitting minutes per day ($p = 0.013$). More days of substance use was positively correlated with number of medical conditions ($p = 0.015$) and the BASIS substance use subscale score ($p = P < 0.001$). More days of substance use was also associated with having bipolar

disorder ($p = 0.007$), not taking an antipsychotic medication ($p = 0.009$), and with being a current smoker ($p = 0.021$).

Table 5

Bivariate analysis of total days of substance use

	Mean	SD	Corr ^f	P ^g
Demographics				
Age			0.01	0.862
Gender				
Female	3.16	9.43		0.741
Male	3.49	8.46		
Race-ethnicity				
Non-Hispanic Black	4.36	10.43		
Non-Hispanic White	3.09	7.56		0.099
Hispanic	0.82	2.78		
Non-Hispanic Other	1.37	5.25		
Total years of education			-0.01	0.889
Employment				
Unemployed	3.26	8.79		0.574
Employed	4.19	9.71		
Objective Health Indicators				
Mean weight (pounds)			-0.14	0.015
Waist Circumference (cm)			-0.21	0.000
Six-minute walking test (m)			0.07	0.199
Number of medical conditions			0.14	0.015
Hypertension				
No	3.26	8.16		0.946
Yes	3.33	9.75		
Lifetime self-reported physician-confirmed general medical conditions				
CVD Indicator				
No	3.19	8.27		0.433
Yes	4.24	11.54		

	Mean	SD	Corr^f	P^g
High Cholesterol				
No	3.31	8.36		
Yes	2.38	6.69		0.309
Arthritis				
No	3.20	8.96		
Yes	3.65	8.68		0.673
Diabetes				
No	3.58	8.66		
Yes	2.92	9.37		0.543
Cancer				
No	3.05	7.97		
Yes	5.00	10.35		0.378
Self-rated health				
Fair – Poor	4.19	10.50		
Good – Excellent	2.78	7.57		0.167
Lifetime self-reported physician-confirmed diagnosis of psychiatric disorders				
Depression				
No	3.53	10.25		
Yes	3.32	8.45		0.858
Schizophrenia				
No	3.45	8.30		
Yes	2.93	7.97		0.578
Bipolar				
No	1.99	6.11		
Yes	4.47	9.75		0.007
Taking Any Antipsychotic medications				
No	5.03	10.00		
Yes	2.34	7.97		0.009
Dietary Intake				
Fruits and vegetable servings per day ^a			-0.06	0.310
Sugar-sweetened beverages per day ^b			0.01	0.805

	Mean	SD	Corr ^f	P ^g
Physical Activity^c				
Sitting minutes per day			-0.14	0.013
Greater than or equal to 150 minutes of moderate or vigorous physical activity per week				
No	2.63	7.56		
Yes	4.56	10.66		0.062
Quality of Life Indicators^d				
SF-12 Mental health component score			-0.04	0.524
SF12 Physical health component score			-0.11	0.056
Substance Use and Smoking				
Any smoking				
No	1.85	6.41		
Yes	4.23	9.95		0.021
Any substance use				
No	0.00	0.00		
Yes	13.28	13.47		0.000
BASIS substance use subscale ^e			0.46	0.000
Site				
Site 1	8.87	13.01		
Site 2	1.59	5.91		0.000
Site 3	1.44	6.05		

Note:

^aFruit and vegetable intake were measured using the Block fruit, vegetable, and dietary fat screeners.

^bSugar-sweetened beverage (SSB) intake was measured using questions from the 2013 Centers for Disease Control and Prevention Behavioral Risk Factors Surveillance System Questionnaire (BRFSS).

^cThe International Physical Activity Questionnaire-Short Form (IPAQ) was used to measure sedentary behavior and physical activity.

^dScores on the SF-12 composite measures for physical and mental health range from 0 to 100 with higher scores indicating better health or mental health related quality of life, respectively.

^eThe summary score on the Behavior and Symptom Identification Scale (BASIS-24) Substance Use Subscales ranges from 0 to 4, with higher scores representing higher symptom severity.

^fPearson correlation

^gVariables were compared using t-tests, Pearson correlation, or corresponding nonparametric tests based on distributional properties.

BASIS-24 Problematic Substance Use Subscales

Full results are presented in Table 6. A higher BASIS-24 substance use subscale score was negatively correlated with mean weight ($p = 0.015$), waist circumference ($p <$

0.001), and the SF12 mental health component score. A higher BASIS substance use subscale score was positively correlated with the 6MWT ($p = 0.049$), number of medical conditions ($p = 0.045$), and total days of substance use ($p < 0.001$). A higher BASIS substance use subscale score was also associated with fair – poor self-rated health ($p = 0.47$), getting 150-minutes or more of moderate/vigorous physical activity per week, with being a current smoker ($p = 0.021$), and with using any substances in the past 30 days ($p < 0.001$).

Table 6
Bivariate analysis of the BASIS substance use subscale score^e

	Mean	SD	Corr ^f	P ^g
Demographics				
Age			-0.02	0.630
Gender				
Female	0.29	0.65		0.154
Male	0.39	0.65		
Race-ethnicity				
Non-Hispanic Black	0.37	0.61		
Non-Hispanic White	0.35	0.58		0.781
Hispanic	0.25	0.54		
Non-Hispanic Other	0.35	0.73		
Total years of education			-0.09	0.129
Employment				
Unemployed	0.34	0.41		0.523
Employed	0.41	0.70		
Objective Health Indicators				
Mean weight (pounds)			-0.10	0.068
Waist Circumference (cm)			-0.13	0.019
Six-minute walking test (m)			0.11	0.049
Number of medical conditions			0.11	0.045
Hypertension				
No	0.38	0.63		0.352
Yes	0.31	0.57		
Lifetime self-reported physician-confirmed general medical conditions				

	Mean	SD	Corr^f	P^g
CVD Indicator				
No	0.31	0.58		0.040
Yes	0.50	0.72		
High Cholesterol				
No	0.34	0.59		0.811
Yes	0.35	0.60		
Arthritis				
No	0.37	0.64		0.370
Yes	0.30	0.53		
Diabetes				
No	0.35	0.58		0.862
Yes	0.34	0.65		
Cancer				
No	0.34	0.60		0.657
Yes	0.27	0.48		
Self-rated health				
Fair – Poor	0.43	0.62		0.047
Good – Excellent	0.29	0.59		
Lifetime self-reported physician-confirmed diagnosis of psychiatric disorders				
Depression				
No	0.25	0.51		0.099
Yes	0.38	0.63		
Schizophrenia				
No	0.31	0.52		0.443
Yes				
Bipolar				
No	0.29	0.53		0.108
Yes	0.40	0.65		
Taking Any Antipsychotic medications				
No	0.39	0.60		0.350
Yes	0.32	0.61		
Dietary Intake				
Fruits and vegetable servings per day ^a			-0.07	0.198
Sugar-sweetened beverages per day ^b			0.06	0.307
Physical Activity^c				
Sitting minutes per day			-0.11	0.067

	Mean	SD	Corr ^f	P ^g
Greater than or equal to 150 minutes of moderate or vigorous physical activity per week				
No	0.29	0.53		
Yes	0.44	0.71		0.049
Quality of Life Indicators^d				
SF-12 Mental health component score			-0.15	0.008
SF12 Physical health component score			-0.02	0.745
Substance Use and Smoking				
Any smoking				
No	0.22	0.48		
Yes	0.42	0.66		0.004
Any substance use				
No	0.18	0.39		
Yes	0.83	0.83		0.000
Total days of substance use			0.46	0.000
Site				
Site 1	0.64	0.77		
Site 2	0.24	0.54		0.001
Site 3	0.27	0.48		

Note:

^aFruit and vegetable intake were measured using the Block fruit, vegetable, and dietary fat screeners.

^bSugar-sweetened beverage (SSB) intake was measured using questions from the 2013 Centers for Disease Control and Prevention Behavioral Risk Factors Surveillance System Questionnaire (BRFSS).

^cThe International Physical Activity Questionnaire-Short Form (IPAQ) was used to measure sedentary behavior and physical activity.

^dScores on the SF-12 composite measures for physical and mental health range from 0 to 100 with higher scores indicating better health or mental health related quality of life, respectively.

^eThe summary score on the Behavior and Symptom Identification Scale (BASIS-24) Substance Use Subscale ranges from 0 to 4, with higher scores representing higher symptom severity.

^fPearson correlation

^gVariables were compared using t-tests, Pearson correlation, or corresponding nonparametric tests based on distributional properties.

Multivariate Analyses of Tobacco Smoking and Each Dimension of Substance Use at Baseline

Results for the smoking and four dimensions of substance use models are presented in Tables 7 – 10.

Smoking

Logistic regression was used to identify correlates of being a current smoker at baseline (see Table 7). The model has a good fit to data (Hosmer-Lemeshow $\chi^2 = 8.2$, $p = 0.404$), as shown by a model χ^2 of 50.77 (df=26, $p=.003$). The pseudo- R^2 is 0.14, or about 14% of the variation in the dependent variable (non-smoker or smoker) is explained by the correlates included in the model. After adjusting for all variables, the odds of being a smoker were significantly higher for female participants (OR 2.40 [95% CI 1.28, 4.51]) and being a tobacco smoker was associated with having less years of education (OR 0.82 [95% CI 0.73, 0.93]) and a lower BMI (OR 0.94 [95% CI 0.90, 0.99]).

Table 7

Logistic Regression of Any Smoking^h

	OR ^a	SE	95% CI	
Demographics				
Age at Baseline	1.027	0.016	0.997	1.058
Female (Ref: Male)	2.398	0.772	1.276	4.508
Race/Ethnicity (Ref: Non-minority)	0.914	0.361	0.421	1.983
Total years of education	0.822	0.052	0.726	0.932
Objective Physical Health Measures				
BMI	0.943	0.023	0.898	0.989
Six-minute walking test (meters)	0.999	0.002	0.995	1.002
Hypertension (Ref: No)	1.002	0.313	0.543	1.846
Physical Health Conditions^b				
CVD Indicator (Ref: No)	0.655	0.283	0.281	1.526
High Cholesterol (Ref: No)	1.366	0.478	0.688	2.710
Arthritis (Ref: No)	0.548	0.205	0.263	1.143
Diabetes (Ref: No)	1.571	0.618	0.726	3.399
Cancer (Ref: No)	0.609	0.505	0.120	3.094
Number of Medical Conditions	0.964	0.100	0.786	1.182
Good – excellent self-rated health (Ref: poor-fair)	1.129	0.398	0.565	2.254

	OR^a	SE	95% CI	
Mental Health Conditions and Medications^c				
Depression (Ref: No)	0.992	0.366	0.482	2.044
Bipolar (Ref: No)	1.174	0.341	0.664	2.075
Schizophrenia/schizoaffective disorder (Ref: No)	1.673	0.566	0.862	3.248
Antipsychotic medication (Ref: No)	1.128	0.398	0.565	2.252
Dietary and Physical Activity Measures				
Fruits and Vegetable Servings Per Day ^d	0.910	0.061	0.798	1.038
Sugar Sweetened Beverages Per Day ^e	0.975	0.070	0.848	1.122
Sitting Minutes Per Day ^f	1.000	0.001	0.999	1.002
≥ 150 moderate or vigorous physical activity per week (Ref: No) ^f	0.904	0.293	0.479	1.707
Quality of Life Indicators^g				
SF-12MCS	0.982	0.015	0.953	1.012
SF12-PCS	0.969	0.020	0.930	1.009
Control Variable				
Site				
Site 2 (Ref: Site 1)	0.381	0.161	0.167	0.872
Site 3 (Ref: Site 1)	0.521	0.243	0.209	1.301
Analytic N	282			
Pseudo R ²	0.137			
Likelihood Ratio χ^2 (df =26)	50.77**			
*p<0.05; **p<0.01; ***p<0.001				

Note:^aCalculated using logistic regression.^bLifetime self-reported physician-confirmed general medical conditions^cLifetime self-reported physician-confirmed diagnosis of psychiatric disorder^dFruit and vegetable intake were measured using the Block fruit, vegetable, and dietary fat screeners.^eSugar-sweetened beverage (SSB) intake was measured using questions from the 2013 Centers for Disease Control and Prevention Behavioral Risk Factors Surveillance System Questionnaire (BRFSS).^fThe International Physical Activity Questionnaire-Short Form (IPAQ) was used to measure sedentary behavior and physical activity.^gScores on the SF-12 composite measures for physical and mental health range from 0 to 100 with higher scores indicating better health or mental health related quality of life, respectively.^hSelf reported any tobacco smoking in the past 30-days at baseline***Any Substance Use***

Logistic regression was used to identify correlates of using any substances at baseline (see Table 8). The model has a good fit to the data (Hosmer-Lemeshow $\chi^2 =$

13.73, $p = 0.089$), as shown by a model χ^2 of 86.62 ($df=26$, $p<.001$). The pseudo- R^2 is 0.27, or about 27% of the variation in the dependent variable (no substance use vs any substance use) is explained by the correlates included in the model. After adjusting for all variables, any substance use was significantly predicted by younger age (OR 0.96 [95% CI 0.93, 0.99]), more years of education (OR 1.37 [95% CI 1.17, 1.61]), not having hypertension (OR 0.40 [95% CI 0.18, 0.89]), poor-fair self-rated health (OR 0.42 [95% CI 0.18, 0.98]), and less sitting minutes per day (OR 0.99 [95% CI 0.99, 0.99]).

Table 8

Logistic Regression of Any Substance Use

	OR ^a	SE	95% CI	
Demographics				
Age at Baseline	0.964	0.018	0.930	0.999
Female (Ref: Male)	0.774	0.304	0.359	1.670
Race/Ethnicity (Ref: Non-minority)	1.697	0.817	0.660	4.362
Total years of education	1.370	0.111	1.168	1.607
Objective Physical Health Measures				
BMI	0.968	0.028	0.915	1.024
Six-minute walking test (meters)	0.999	0.002	0.995	1.003
Hypertension (Ref: No)	0.404	0.164	0.182	0.894
Physical Health Conditions^b				
CVD Indicator (Ref: No)	1.320	0.672	0.487	3.578
High Cholesterol (Ref: No)	0.766	0.336	0.324	1.809
Arthritis (Ref: No)	1.168	0.592	0.432	3.157
Diabetes (Ref: No)	0.679	0.325	0.266	1.735
Cancer (Ref: No)	0.970	0.936	0.147	6.423
Number of Medical Conditions	1.074	0.136	0.838	1.376
Good – excellent self-rated health (Ref: poor-fair)	0.420	0.180	0.181	0.975
Mental Health Conditions and Medications^c				
Depression (Ref: No)	1.107	0.509	0.450	2.726
Bipolar (Ref: No)	1.742	0.629	0.858	3.537
Schizophrenia/schizoaffective disorder (Ref: No)	1.117	0.458	0.500	2.494

	OR^a	SE	95% CI	
Antipsychotic medication (Ref: No)	0.485	0.199	0.216	1.086
Dietary and Physical Activity Measures				
Fruits and Vegetable Servings Per Day ^d	0.963	0.083	0.812	1.141
Sugar Sweetened Beverages Per Day ^e	1.084	0.088	0.925	1.271
Sitting Minutes Per Day ^f	0.998	0.001	0.996	0.999
≥ 150 moderate or vigorous physical activity per week (Ref: No) ^f	0.803	0.311	0.376	1.714
Quality of Life Indicators^g				
SF-12MCS	0.980	0.018	0.947	1.015
SF12-PCS	0.969	0.025	0.921	1.019
Control Variable				
Site				
Site 2 (Ref: Site 1)	0.109	0.054	0.041	0.287
Site 3 (Ref: Site 1)	0.092	0.051	0.031	0.273
Analytic N / Observations	282			
Pseudo R ²	0.274			
Likelihood Ratio χ^2 (df =26)	86.62***			

*p<0.05; **p<0.01; ***p<0.001

Note:

^aCalculated using logistic regression.

^bLifetime self-reported physician-confirmed general medical conditions

^cLifetime self-reported physician-confirmed diagnosis of psychiatric disorder

^dFruit and vegetable intake were measured using the Block fruit, vegetable, and dietary fat screeners.

^eSugar-sweetened beverage (SSB) intake was measured using questions from the 2013 Centers for Disease Control and Prevention Behavioral Risk Factors Surveillance System Questionnaire (BRFSS).

^fThe International Physical Activity Questionnaire-Short Form (IPAQ) was used to measure sedentary behavior and physical activity.

^gScores on the SF-12 composite measures for physical and mental health range from 0 to 100 with higher scores indicating better health or mental health related quality of life, respectively.

^hSelf reported any tobacco smoking in the past 30-days at baseline

Total Days of Substance Use

A negative binomial model with robust standard errors was used to identify correlates of total days of substance use (see Table 9). Total Days of Substance Use had a non-normal distribution (see appendix: Figure 4). The mean days of substance use in the past 30 days was 3.3 (sd = 8.9). The model has good fit to the data, as shown by a model χ^2 of 185.96 (df=26, p<.0001). The pseudo-R² is 0.084, or about 8.4% of the variation in

the dependent variable (total days of substance use) is explained by the correlates included in the model. Using the AME's to interpret the findings, only age was statistically significant. Every standard deviation increase in age (sd = 11.6) predicted a 4.9 (p = 0.036) decrease in the expected number of substance use days.

As a sensitivity analysis, the IRR's were also used to interpret the findings. The results indicate that for every year increase in age, a participant's total days of substance use decreased by 8.3% (IRR 0.916 [95% CI 0.881, 0.954]). In our sample, being a racial/ethnic minority increases the expected number of substance use days by 187.3% (IRR 2.783 [95% CI 1.194, 6.485]). For every additional year of education, a participant's total days of substance use increased by 21% (IRR 1.210 [95% CI 1.035, 1.416]). Having hypertension decreases the expected number of substance use days by 64.6% (IRR 0.354 [95% CI 0.164, 0.767]). For every additional medical condition, a participant's expected number of total substance use days increased by 27.9% (IRR 1.279 [95% CI 1.001, 1.633]).

Having good to excellent self-rated health decreases the expected number of total substance use days by 79.4% (IRR 0.206 [95% CI 0.087, 0.486]). Having bipolar disorder increases the expected number of substance use days by 143.1% (IRR 2.431 [95% CI 1.218, 4.851]). Finally, every additional sitting minute per day was associated with a 0.2% decrease in the expected number of total substance use days (IRR 0.998 [95% CI 0.996, 0.999]).

Table 9*Negative Binomial Regression of Total Days of Substance Use*

	AME Change	P-value	IRR ⁱ	RSE	95% CI	
Demographics						
Age at Baseline	-4.960 ^j	0.036	0.917	0.019	0.881	0.954
Female (Ref: Male)	-5.671	0.204	0.482	0.202	0.212	1.096
Race/Ethnicity (Ref: Non-minority)	6.730	0.063	2.783	1.201	1.194	6.485
Total years of education	1.672	0.170	1.210	0.097	1.035	1.416
Objective Physical Health Measures						
BMI	-0.361	0.126	0.955	0.025	0.907	1.004
Six-minute walking test (meters)	-0.012	0.480	0.998	0.002	0.994	1.003
Hypertension (Ref: No)	-6.906	0.071	0.354	0.140	0.164	0.767
Physical Health Conditions^b						
CVD Indicator (Ref: No)	-1.370	0.711	0.838	0.416	0.317	2.217
High Cholesterol (Ref: No)	-3.808	0.382	0.623	0.303	0.240	1.615
Arthritis (Ref: No)	-0.667	0.862	1.511	0.657	0.644	3.544
Diabetes (Ref: No)	3.824	0.453	0.919	0.454	0.349	2.420
Cancer (Ref: No)	-5.896	0.073	0.309	0.207	0.083	1.153
Number of Medical Conditions	2.215	0.152	1.279	0.160	1.001	1.633
Good – excellent self-rated health (Ref: poor-fair)	-13.316	0.085	0.206	0.090	0.087	0.486
Mental Health Conditions and Medications^c						
Depression (Ref: No)	2.990	0.281	1.565	0.659	0.686	3.572
Bipolar (Ref: No)	6.495	0.077	2.431	0.857	1.218	4.851
Schizophrenia/schizoaffective disorder (Ref: No)	-3.936	0.319	0.609	0.284	0.244	1.519
Antipsychotic medication (Ref: No)	-5.669	0.121	0.435	0.187	0.188	1.008
Dietary and Physical Activity Measures						
Fruits and Vegetable Servings Per Day ^d	-0.225	0.773	0.972	0.096	0.801	1.179
Sugar Sweetened Beverages Per Day ^e	-0.327	0.683	0.959	0.097	0.786	1.169
Sitting Minutes Per Day ^f	-0.018	0.102	0.998	0.001	0.996	1.000
≥ 150 moderate or vigorous physical activity per week (Ref: No) ^f	-3.263	0.196	0.590	0.222	0.282	1.235
Quality of Life Indicators^g						
SF-12MCS	0.208	0.276	1.026	0.018	0.991	1.063

	AME Change	P-value	IRR ⁱ	RSE	95% CI	
SF12-PCS	-0.084	0.672	0.989	0.025	0.942	1.040
Control Variable						
Site						
Site 2 (Ref: Site 1)			0.096	0.049	0.035	0.262
Site 3 (Ref: Site 1)			0.027	0.015	0.009	0.079
Site 2 vs. Site 1	-34.481	0.110				
Site 3 vs. Site 1	-37.117	0.102				
Site 3 vs. Site 2	-2.637	0.180				
Analytic N / Observations			282			
Pseudo R ²			0.084			
Wald χ^2			185.95***			

*p<0.05; **p<0.01; ***p<0.001

Note:

^bLifetime self-reported physician-confirmed general medical conditions

^cLifetime self-reported physician-confirmed diagnosis of psychiatric disorder

^dFruit and vegetable intake were measured using the Block fruit, vegetable, and dietary fat screeners.

^eSugar-sweetened beverage (SSB) intake was measured using questions from the 2013 Centers for Disease Control and Prevention Behavioral Risk Factors Surveillance System Questionnaire (BRFSS).

^fThe International Physical Activity Questionnaire-Short Form (IPAQ) was used to measure sedentary behavior and physical activity.

^gScores on the SF-12 composite measures for physical and mental health range from 0 to 100 with higher scores indicating better health or mental health related quality of life, respectively.

^hSelf reported any tobacco smoking in the past 30-days at baseline

ⁱCalculated using negative binomial regression with robust standard errors

^jRepresents the predicted change for every standard deviation increase in age (sd = 11.6).

BASIS Problematic Substance Use Subscale

Poisson regression with robust standard errors was used to identify correlates of the BASIS substance use subscale score (see Table 10). The BASIS-24 substance use subscale score had a non-normal distribution (see appendix: Figure 5). The mean score was 0.35 (sd = 0.61). The model was significant ($Wald \chi^2 (26, 276) = 105.64, p < .0001$) and explained 11.5% (pseudo R²) of the variance in BASIS substance use subscale scores. Using the AME's to interpret the findings, female, number of medical conditions, and sitting minutes per day were statistically significant. On average, being female decreased the expected BASIS substance use subscale score by -0.158 (0.024), a one unit increase in the number of medical conditions a participant had increased the expected BASIS substance use subscale score by 0.057 (p = 0.025), and every standard deviation

(sd = 202.7) increase in sitting minutes per day predicted a 0.06 decrease in the BASIS score.

As a sensitivity analysis, the IRR's were also used to interpret the findings. The results indicate being female decreases the expected BASIS substance use subscale score by 36.3% (IRR 0.637 [95% CI 0.426, 0.952]), holding all other variables constant. For every additional medical condition, a participant's expected BASIS substance use subscale score increased by 15.5% (IRR 1.155 [95% CI 1.025, 1.302]). In addition, having good to excellent self-rated health is associated with a 34.5% decrease in the expected BASIS substance use subscale score (IRR 0.655 [95% CI 0.434, 0.988]).

Table 10

Poisson Regression of BASIS-24 Substance Use Sub-scale Score

	AME Change	P-value	IRR ^a	RSE	95% CI	
Demographics						
Age at Baseline	-0.002	0.577	0.995	0.009	0.977	1.013
Female (Ref: Male)	-0.158	0.024	0.637	0.131	0.426	0.952
Race/Ethnicity (Ref: Non-minority)	0.093	0.185	1.316	0.292	0.851	2.033
Total years of education	0.009	0.561	1.024	0.041	0.946	1.107
Objective Physical Health Measures						
BMI	-0.005	0.479	0.987	0.019	0.951	1.024
Six-minute walking test (meters)	0.000	0.510	1.001	0.001	0.999	1.003
Hypertension (Ref: No)	-0.105	0.153	0.740	0.160	0.484	1.131
Physical Health Conditions^b						
CVD Indicator (Ref: No)	0.043	0.648	1.122	0.273	0.696	1.808
High Cholesterol (Ref: No)	-0.099	0.256	0.760	0.190	0.466	1.239
Arthritis (Ref: No)	0.003	0.978	1.008	0.273	0.592	1.714
Diabetes (Ref: No)	0.003	0.978	0.638	0.158	0.392	1.037
Cancer (Ref: No)	-0.176	0.072	0.534	0.245	0.217	1.313
Number of Medical Conditions	0.057	0.025	1.155	0.070	1.025	1.302
Good – excellent self-rated health (Ref: poor-fair)	-0.159	0.051	0.655	0.138	0.434	0.988
Mental Health Conditions and Medications^c						

	AME Change	P-value	IRR ^a	RSE	95% CI	
Depression (Ref: No)	0.114	0.159	1.417	0.383	0.835	2.406
Bipolar (Ref: No)	0.050	0.476	1.149	0.225	0.782	1.686
Schizophrenia/schizoaffective disorder (Ref: No)	0.081	0.293	1.251	0.265	0.826	1.895
Antipsychotic medication (Ref: No)	-0.006	0.934	0.984	0.194	0.668	1.449
Dietary and Physical Activity Measures						
Fruits and Vegetable Servings Per Day ^d	-0.022	0.198	0.940	0.046	0.854	1.036
Sugar Sweetened Beverages Per Day ^e	0.016	0.284	1.044	0.041	0.966	1.129
Sitting Minutes Per Day ^f	-0.061 ⁱ	0.036	0.999	0.000	0.998	1.000
≥ 150 moderate or vigorous physical activity per week (Ref: No) ^f	0.049	0.591	1.135	0.251	0.736	1.752
Quality of Life Indicators^g						
SF-12MCS	-0.006	0.106	0.984	0.010	0.964	1.004
SF12-PCS	-0.001	0.881	0.998	0.016	0.967	1.029
Control Variable						
Site						
Site 2 (Ref: Site 1)			0.454	0.129	0.260	0.792
Site 3 (Ref: Site 1)			0.552	0.152	0.321	0.948
Site 2 vs. Site 1	-0.311	0.005				
Site 3 vs. Site 1	-0.255	0.038				
Site 3 vs. Site 2	0.056	0.547				
Analytic N / Observations				276		
Pseudo R ²				0.115		
Wald χ^2 (df = 26)				105.64***		

*p<0.05; **p<0.01; ***p<0.001

Note:

^aCalculated using Poisson Regression

^bLifetime self-reported physician-confirmed general medical conditions

^cLifetime self-reported physician-confirmed diagnosis of psychiatric disorder

^dFruit and vegetable intake were measured using the Block fruit, vegetable, and dietary fat screeners.

^eSugar-sweetened beverage (SSB) intake was measured using questions from the 2013 Centers for Disease Control and Prevention Behavioral Risk Factors Surveillance System Questionnaire (BRFSS).

^fThe International Physical Activity Questionnaire-Short Form (IPAQ) was used to measure sedentary behavior and physical activity.

^gScores on the SF-12 composite measures for physical and mental health range from 0 to 100 with higher scores indicating better health or mental health related quality of life, respectively.

^hSelf reported any tobacco smoking in the past 30-days at baseline

ⁱRepresents the predicted change for every standard deviation increase in age (sd = 202.7).

Aim 2: Moderator Results

See Appendix Figures 6 – 8 for distribution of the weight change outcomes at 6-, 12-, and 18-months. There were no statistically significant differences between the PGLB and UC conditions across any of the tobacco smoking or substance use moderator variables.

Smoking

The results of the mixed effects regression models are summarized in Table 11. Model 1 tested the direct effects. The findings indicate that baseline weight and baseline smoking status predicted mean weight loss over the course of the trial. For smokers, the predicted weight loss over the course of the trial is 4.52 pounds more than for non-smokers (95% CI -7.672, -0.585). In addition, baseline weight was negatively associated with weight change over the course of the trial (beta = -0.03 [95% CI -0.065, -0.003]), indicating that participants who started at a higher baseline weight lost more weight over the course of the trial. Model 2 found that participants' smoking status did not moderate the impact of receiving PGLB or UC on weight loss throughout the trial. After adding the interaction terms, baseline weight (beta = -0.03 [95% CI -0.064, -0.001]) and tobacco smoking (beta = -5.44 [95% CI -7.672, -0.585]) continued to predict weight loss throughout the trial.

Table 11*Mixed Effects Linear Regression Model for Mean Weight Change – Smoking Moderator*

	Model 1				Model 2			
	Coef	SE	95% CI		Coef	SE	95% CI	
Site (ref: Site 1)								
Site 2	1.43	2.26	-3.008	5.861	1.41	2.26	-3.020	5.840
Site 3	2.02	2.21	-2.308	6.347	2.04	2.21	-2.282	6.364
Treatment (Ref: Usual Care)								
PGLB	0.88	1.71	-2.476	4.236	-0.94	2.82	-6.462	4.577
Time	-0.13	0.07	-0.266	0.002	-0.13	0.07	-0.266	0.002
Baseline Weight (in Pounds)	-0.03	0.02	-0.065	-0.003	-0.03	0.02	-0.064	-0.001
Current Smoker (Ref: Non-smoker)	-4.13	1.81	-7.672	-0.585	-5.44	2.42	-10.173	-0.700
Current Smoker (Ref: Non-smoker) * Treatment (Ref: Usual Care)					2.87	3.52	-4.032	9.766
Variance estimates (SE)								
Participant ID	176.63	17.44	145.55	214.35	176.17	17.40	145.16	213.81
Residual	87.01	5.43	76.98	98.35	87.01	5.44	76.98	98.35
Analytic N / Observations			809				809	
(df) Wald chi2			(6) 12.67				(7) 13.35	
P Value			0.048				0.064	

Note:

Tobacco smoking was assessed using a single question asking participants if they currently smoke tobacco.

Any Substance Use

The results of the mixed effects regression models are summarized in Table 12.

All direct effects in Model 1, site, treatment condition, baseline weight, time, and any substance use were insignificant. The Model 2 findings indicate that any substance use at baseline did not moderate the impact of receiving PGLB or UC on weight loss throughout the trial.

Table 12

Mixed Effects Linear Regression Model for Mean Weight Change – Any Substance Use

Moderator

	Model 1				Model 2			
	Coef	SE	95% CI		Coef	SE	95% CI	
Site (ref: Site 1)								
Site 2	0.87	2.44	-3.917	5.656	0.88	2.45	-3.926	5.684
Site 3	1.38	2.40	-3.325	6.090	1.39	2.40	-3.326	6.101
Treatment (Ref: Usual Care)								
PGLB	0.23	1.72	-3.150	3.601	0.27	1.97	-3.602	4.138
Time	-0.13	0.07	-0.263	0.005	-0.13	0.07	-0.263	0.005
Baseline Weight (in Pounds)	-0.03	0.02	-0.058	0.004	-0.03	0.02	-0.058	0.004
Any Substance Use (Ref: No Substance Use)	-2.92	2.20	-7.234	1.385	-2.84	2.88	-8.487	2.803
Any Substance Use (Ref: No Substance Use) * Treatment (Ref: Usual Care)					-0.18	4.02	-8.064	7.708
Variance estimates (SE)								
Participant ID	179.40	17.69	147.86	217.67	179.40	17.69	147.86	217.67
Residual	87.05	5.44	77.01	98.41	87.05	5.44	77.01	98.41
Analytic N / Observations	807				807			
(df) Wald chi2	(6) 9.27				(7) 9.27			
P Value	0.159				0.234			

Note:

Recent substance use (including alcohol) was measured with a subset of questions from the Addiction Severity Index (ASI). Participants were asked how many days in the past 30 they used each substance. The any substance use variable was created by dichotomizing participant substance use into 0 = no days of substance use; 1 = even one day of substance use in the past 30 days.

Total Days of Substance Use

The results of the mixed effects regression models are summarized in Table 13.

Model 1 tested the direct effects and found that the number of days of substance use at baseline predicted mean weight loss over the course of the trial. For every additional day of substance use, a 0.14-pound reduction in weight throughout the trial was predicted (beta = -0.14 [95% CI -0.234, -0.033]). Model 2 found that the total days of substance use as baseline did not moderate the impact of receiving PGLB or UC on weight loss

throughout the trial. After adding the interaction terms, the direct effect of baseline total days of substance use on weight loss became insignificant.

Table 13

Mixed Effects Linear Regression Model for Mean Weight Change – Total Days of Substance Use Moderator

	Model 1				Model 2			
	Coef	SE	95% CI		Coef	SE	95% CI	
Site (ref: Site 1)								
Site 2	0.68	2.31	-3.854	5.221	1.56	2.37	-3.095	6.213
Site 3	1.06	2.27	-3.394	5.520	1.86	2.34	-2.728	6.453
Treatment (Ref: Usual Care)								
PGLB	0.21	1.71	-3.148	3.559	1.12	1.82	-2.444	4.686
Time	-0.12	0.07	-0.256	0.011	-0.13	0.07	-0.265	0.003
Baseline Weight (in Pounds)	-0.03	0.02	-0.059	0.003	-0.03	0.02	-0.058	0.004
Total Days of Substance Use	-0.14	0.05	-0.238	-0.033	0.01	0.14	-0.268	0.285
Total Days of Substance Use * Treatment (Ref: Usual Care)					-0.21	0.20	-0.590	0.176
Variance estimates (SE)								
Participant ID	179.81	17.70	148.27	218.08	179.10	17.63	147.67	217.22
Residual	87.01	5.44	76.98	98.34	86.98	5.43	76.97	98.32
Analytic N / Observations	809				809			
(df) Wald chi2	(6) 14.18				(7) 9.28			
P Value	0.028				0.233			

Note:

Recent substance use (including alcohol) was measured with a subset of questions from the Addiction Severity Index (ASI). Participants were asked how many days in the past 30 they used each substance. The total days of substance use variable created by summing the total number of days the participant used each substance.

BASIS-24 Substance Use Subscale

The results of the mixed effects regression models are summarized in Table 14.

Model 1 tested the direct effects. Neither the model nor any of the predictors were significant. In Model 2, baseline BASIS-24 substance use subscale scores did not moderate the impact of receiving PGLB or UC on weight loss throughout the trial.

Table 14*Mixed Effects Linear Regression Model for Mean Weight Change – BASIS Moderator*

	Model 1				Model 2			
	Coef	SE	95% CI		Coef	SE	95% CI	
Site (ref: Site 1)								
Site 2	2.04	2.36	-2.583	6.654	2.42	2.36	-2.215	7.051
Site 3	2.48	2.29	-2.010	6.977	2.80	2.30	-1.700	7.301
Treatment (Ref: Usual Care)								
PGLB	0.05	1.72	-3.316	3.417	1.19	2.52	-3.756	6.132
Time	-0.13	0.07	-0.269	0.0004	-0.16	0.11	-0.364	0.051
Baseline Weight (in Pounds)	-0.03	0.02	-0.059	0.003	-0.03	0.02	-0.059	0.002
BASIS SU Subscale	-1.73	1.52	-4.700	1.240	-0.18	2.45	-4.988	4.624
BASIS SU Subscale * Treatment (Ref: Usual Care)					-4.18	2.92	-9.905	1.544
Variance estimates (SE)								
Participant ID	175.3	17.5	144.2	213.2	173.9	17.4	143.0	211.5
Residual	86.3	5.5	76.2	97.7	86.3	5.5	76.2	97.6
Analytic N / Observations	791				791			
(df) Wald chi2	(6) 9.73				(7) 11.86			
P Value	0.136				0.105			

Note:

The summary score on the Behavior and Symptom Identification Scale (BASIS-24) Substance Use Subscale ranges from 0 to 4, with higher scores representing higher symptom severity.

Aim 3 Moderated Mediation Results

See Appendix Figures 9 – 11 for distribution of the mediation variables at 18-months. There were no statistically significant differences between the PGLB and UC conditions across any of the mediator or moderator variables.

The first conditional process model tested the ability of sugar-sweetened beverage (SSB) servings per day to mediate the relationship between RCT group and weight change at 18-months with smoking status moderating the RCT group and SSB servings per day path (see Table 15). RCT group was not significantly related to SSB servings per day and SSB servings per day was not significantly related to weight change at 18-

months. In addition, the RCT group x smoking status interaction term was not statistically significant in predicting SSB servings per day. With all the variables in the model, RCT group was not a significant predictor of weight change at 18-months. Finally, the index of moderated mediation was not significant indicating that smoking status did not moderate the mediating effect of SSB servings per day in the overall model.

Table 15

Conditional Process Analysis (Mediator = Sugar Sweetened Beverages; Moderator = Smoking Status; Outcome = Weight Loss at 18-Months)

	B	SE B	95% CI	
Sugar Sweetened Beverages (M)				
Predictor: RCT Group	0.671	0.632	-0.575	1.916
Moderator: Current Smoker (W)	-0.058	0.538	-1.119	1.003
Interaction: RCT Group x Current Smoker	0.121	0.791	-1.439	1.680
Baseline Weight	0.003	0.004	-0.004	0.010
Site	-0.170	0.241	-0.644	0.305
Model R = 0.161; R ² = 0.026; MSE = 7.49; F(5, 203) = 1.082; p = .372]				
Weight loss at 18-Months (Y)				
Mediator: Sugar Sweetened Beverages	-0.363	0.492	-1.333	0.607
Predictor: RCT Group	3.639	2.720	-1.724	9.001
Baseline Weight	-0.040	0.024	-0.087	0.008
Site	1.265	1.685	-2.056	4.587
Model R = 0.154; R ² = 0.024; MSE = 368.014; F(4, 204) = 1.231; p = 0.299]				
	Bootstrap indirect effect/index	Bootstrap SE	95% CI	
Moderator: Current Smoker				
No	-0.243	0.403	-1.300	0.388
Yes	-0.287	0.386	-1.203	0.319
Index of Moderated Mediation	-0.044	0.416	-0.923	0.889

Note:

Sugar-sweetened beverage (SSB) intake was measured using questions from the 2013 Centers for Disease Control and Prevention. Tobacco smoking was assessed using a single question asking participants if they currently smoke tobacco.

The second conditional process model tested the ability of fruit and vegetable servings per day to mediate the relationship between RCT group and weight change at

18-months with smoking status moderating the RCT group and fruit and vegetable servings per day path (see Table 16). RCT group was not significantly related to fruit and vegetable servings per day and fruit and vegetable servings per day was not significantly related to weight change at 18-months. In addition, the RCT group x smoking status interaction term was not statistically significant in predicting fruit and vegetable servings per day. With all the variables in the model, RCT group was not a significant predictor of weight change at 18-months. Finally, the index of moderated mediation was not significant, indicating that smoking status did not moderate the mediating effect of fruit and vegetable servings per day in the overall model.

Table 16

Conditional Process Analysis (Mediator = Fruit and Vegetable Servings Per Day; Moderator = Smoking Status; Outcome = Weight Loss at 18-Months)

	B	SE B	95% CI	
Fruit and Vegetable Servings (M)				
Predictor: RCT Group	0.249	0.469	-0.674	1.172
Moderator: Current Smoker (W)	0.288	0.409	-0.519	1.095
Interaction: RCT Group x Current Smoker	-0.430	0.597	-1.608	0.748
Baseline Weight	0.001	0.003	-0.004	0.006
Site	0.075	0.188	-0.297	0.445
Model R = 0.061; R ² = 0.004; MSE = 5.258; F(5, 245) = 0.183; p = 0.969]				
Weight loss at 18-Months (Y)				
Mediator: Fruit and Vegetable Servings	0.335	0.534	-0.717	1.387
Predictor: RCT Group	1.45	2.448	-3.374	6.271
Baseline Weight	-0.048	0.022	-0.091	-0.006
Site	1.025	1.570	-2.068	4.118
Model R = 0.149; R ² = 0.022; MSE = 368.323; F(4, 246) = 1.405; p = 0.233]				

	Bootstrap indirect effect/index	Bootstrap SE	95% CI	
Moderator: Current Smoker				
No	0.084	0.316	-0.405	0.916
Yes	-0.061	0.240	-0.669	0.342
Index of Moderated Mediation	-0.144	0.422	-1.257	0.441

Note:

Fruit and vegetable intake was measured using the Block fruit, vegetable, and dietary fat screeners.

Tobacco smoking was assessed using a single question asking participants if they currently smoke tobacco.

The third conditional process model tested the ability of the MET total score to mediate the relationship between RCT group and weight change at 18-months with smoking status moderating the RCT group and the MET total score path (see Table 17). RCT group was not significantly related to the MET total score and the MET total score per day was not significantly related to weight change at 18-months. In addition, the RCT group x smoking status interaction term was not statistically significant in predicting the MET total score. With all the variables in the model, RCT group was not a significant predictor of weight change at 18-months. Finally, the index of moderated mediation was not significant, indicating that smoking status did not moderate the mediating effect of the MET total score in the overall model.

Table 17

Conditional Process Analysis (Mediator = MET Total Score; Moderator = Smoking Status; Outcome = Weight Loss at 18-Months)

	B	SE B	95% CI	
MET Total (M)				
Predictor: RCT Group	-292.896	512.188	-1301.791	715.998
Moderator: Current Smoker (W)	-341.950	444.906	-1218.315	534.415
Interaction: RCT Group x Current Smoker	584.019	651.646	-699.577	1867.617
Baseline Weight	0.625	2.918	-5.1224	6.374
Site	164.847	206.630	-242.167	571.862
Model R = 0.081; R ² = 0.006; MSE = 6161178.18; F(5, 243) = 0.327; p = 0.896]				
Weight loss at 18-Months (Y)				
Mediator: MET Total	-0.0004	0.0005	-0.001	0.0006
Predictor: RCT Group	1.395	2.478	-3.487	6.277
Baseline Weight	-0.050	0.022	-0.093	-0.007
Site	1.047	1.604	-2.112	4.206
Model R = 0.155; R ² = 0.024; MSE = 374.054; F(4, 244) = 1.501; p = 0.202]				
	Bootstrap indirect effect/index	Bootstrap SE	95% CI	
Moderator: Current Smoker				
No	0.104	0.429	-0.650	1.177
Yes	-0.103	0.386	-1.111	0.526
Index of Moderated Mediation	-0.207	0.641	-1.871	0.837

Note:

The International Physical Activity Questionnaire-Short Form (IPAQ) was used to measure MET total score. MET scores represent the amount of energy expended while carrying out physical activity.

Tobacco smoking was assessed using a single question asking participants if they currently smoke tobacco.

The fourth conditional process model tested the ability of sugar-sweetened beverage (SSB) servings per day to mediate the relationship between RCT group and weight change at 18-months with any substance use moderating the RCT group and SSB servings per day path (see Table 18). RCT group was not significantly related to SSB servings per day and SSB servings per day was not significantly related to weight change

at 18-months. In addition, the RCT group x any substance use interaction term was not statistically significant in predicting SSB servings per day. With all the variables in the model, RCT group was not a significant predictor of weight change at 18-months. Finally, the index of moderated mediation was not significant, indicating that any substance use did not moderate the mediating effect of SSB servings per day in the overall model.

Table 18

Conditional Process Analysis (Mediator = Sugar Sweetened Beverages; Moderator = Any substance use; Outcome = Weight Loss at 18-Months)

	B	SE B	95% CI	
Sugar Sweetened Beverages (M)				
Predictor: RCT Group	0.702	0.439	-0.164	1.568
Moderator: Any substance use (W)	-0.546	0.602	-1.732	0.640
Interaction: RCT Group x Current Smoker	-0.090	0.924	-1.911	1.732
Baseline Weight	0.027	0.003	-0.004	0.009
Site	-0.289	0.260	-0.801	0.223
Model R = 0.181; R ² = 0.033; MSE = 7.438; F(5, 203) = 1.371; p = 0.237]				
Weight loss at 18-Months (Y)				
Mediator: Sugar Sweetened Beverages	-0.363	0.492	-1.333	0.607
Predictor: RCT Group	3.639	2.719	-1.724	9.001
Baseline Weight	-0.040	0.024	-0.086	0.008
Site	1.265	1.685	-2.056	4.586
Model R = 0.154; R ² = 0.024; MSE = 368.014; F(4, 204) = 1.231; p = 0.299]				
	Bootstrap indirect effect/index	Bootstrap SE	95% CI	
Moderator: Any substance use				
No	-0.255	0.330	-1.058	0.259
Yes	-0.222	0.492	-1.570	0.361
Index of Moderated Mediation	0.033	0.466	-1.149	0.863

Note:

Sugar-sweetened beverage (SSB) intake was measured using questions from the 2013 Centers for Disease Control and Prevention
Recent substance use (including alcohol) was measured with a subset of questions from the Addiction Severity Index (ASI). Participants were asked how many days in the past 30 they used each substance. The any substance use variable was created by dichotomizing participant substance use into 0 = no days of substance use; 1 = even one day of substance use in the past 30 days.

The fifth conditional process model tested the ability of fruit and vegetable servings per day to mediate the relationship between RCT group and weight change at 18-months with any substance use moderating the RCT group and fruit and vegetable servings per day path (see Table 19). RCT group was not significantly related to fruit and vegetable servings per day and the fruit and vegetable servings per day was not significantly related to weight change at 18-months. In addition, the RCT group x any substance use interaction term was not statistically significant in predicting fruit and vegetable servings per day. With all the variables in the model, RCT group was not a significant predictor of weight change at 18-months. Finally, the index of moderated mediation was not significant, indicating that any substance use did not moderate the mediating effect of fruit and vegetable servings per day in the overall model.

Table 19

*Conditional Process Analysis (Mediator = Fruit and Vegetable Servings;
Moderator = Any substance use; Outcome = Weight Loss at 18-Months)*

	B	SE B	95% CI	
Fruit and Vegetable Servings (M)				
Predictor: RCT Group	-0.187	0.334	-0.845	0.470
Moderator: Any substance use (W)	-0.044	0.471	-0.972	0.885
Interaction: RCT Group x Current Smoker	0.874	0.687	-0.479	2.227
Baseline Weight	0.001	0.003	-0.004	0.006
Site	0.133	0.202	-0.265	0.531
Model R = 0.105; R ² = 0.011; MSE = 5.219; F(5, 245) = 0.547; p = 0.741]				
Weight loss at 18-Months (Y)				
Mediator: Fruit and Vegetable Servings	0.335	0.534	-0.716	1.387
Predictor: RCT Group	1.448	2.448	-3.373	6.271
Baseline Weight	-0.048	0.022	-0.091	-0.006
Site	1.025	1.570	-2.067	4.118
Model R = 0.149; R ² = 0.022; MSE = 368.323; F(4, 246) = 1.405; p = 0.233]				

	Bootstrap indirect effect/index	Bootstrap SE	95% CI	
Moderator: Any substance use				
No	-0.063	0.215	-0.555	0.357
Yes	0.231	0.438	-0.483	1.281
Index of Moderated Mediation	0.293	0.531	-0.629	1.564

Note:

Fruit and vegetable intake was measured using the Block fruit, vegetable, and dietary fat screeners. Recent substance use (including alcohol) was measured with a subset of questions from the Addiction Severity Index (ASI). Participants were asked how many days in the past 30 they used each substance. The any substance use variable was created by dichotomizing participant substance use into 0 = no days of substance use; 1 = even one day of substance use in the past 30 days.

The sixth conditional process model tested the ability of the MET total score to mediate the relationship between RCT group and weight change at 18-months with any substance use moderating the RCT group and the MET total score path (see Table 20). RCT group was not significantly related to the MET total score and the MET total score per day was not significantly related to weight change at 18-months. In addition, the RCT group x any substance use interaction term was not statistically significant in predicting the MET total score. With all the variables in the model, RCT group was not a significant predictor of weight change at 18-months. Finally, the index of moderated mediation was not significant, indicating that any substance use did not moderate the mediating effect of the MET total score in the overall model.

Table 20

Conditional Process Analysis (Mediator = MET Total Score; Moderator

= Any substance use; Outcome = Weight Loss at 18-Months)

	B	SE B	95% CI	
MET Total Score (M)				
Predictor: RCT Group	91.328	363.082	-623.86	806.518
Moderator: Any substance use (W)	514.838	516.329	-502.216	1531.891
Interaction: RCT Group x Current Smoker	-22.546	749.365	-1498.628	1453.535
Baseline Weight Site	0.563	2.810	-4.972	6.099
Model R = 0.098; R ² = 0.009; MSE = 6143082.79; F(5, 243) = 0.471; p = 0.797]				
Weight loss at 18-Months (Y)				
Mediator: MET Total Score	-0.0004	0.0005	-0.001	0.0006
Predictor: RCT Group	1.395	2.478	-3.487	6.277
Baseline Weight	-0.050	0.021	-0.093	-0.007
Site	1.047	1.604	-2.112	4.206
	Bootstrap indirect effect/index	Bootstrap SE	95% CI	
Moderator: Any substance use				
No	-0.032	0.254	-0.649	0.451
Yes	-0.024	0.656	-1.739	1.145
Index of Moderated Mediation	0.008	0.688	-1.702	1.286

Note:

The International Physical Activity Questionnaire-Short Form (IPAQ) was used to measure MET total score. MET scores represent the amount of energy expended while carrying out physical activity. Recent substance use (including alcohol) was measured with a subset of questions from the Addiction Severity Index (ASI). Participants were asked how many days in the past 30 they used each substance. The any substance use variable was created by dichotomizing participant substance use into 0 = no days of substance use; 1 = even one day of substance use in the past 30 days.

As an additional sensitivity analysis, mediation analysis was conducted using the MEDSEM package in Stata to test whether fruit and vegetable servings per day, SSB servings per day, or the MET total score mediated the impact of the intervention on weight loss. The results from this analysis indicate that neither diet nor physical activity mediated the impact of the intervention on weight loss (See Tables 21 – 23).

Table 21*Mediation Analysis (Mediator = Fruit and Vegetable Serving Per Day)*

Direct effect of intervention on weight change	Direct effect of intervention on mediator	Direct effect of mediator on weight change	Indirect effect of intervention on weight change	Total effect of intervention on weight change	Proportion of effect mediated
0.76 (-3.99 to 5.51)	0.02 (-0.55 to 0.58)	0.31 (-0.73 to 1.36)	0.006 (-0.36 to 0.39)	0.76	1%; p = 0.755

Table 22*Mediation Analysis (Mediator = Sugar-Sweetened Beverage Servings Per Day)*

Direct effect of intervention on weight change	Direct effect of intervention on mediator	Direct effect of mediator on weight change	Indirect effect of intervention on weight change	Total effect of intervention on weight change	Proportion of effect mediated
3.06 (-2.17 to 8.30)	0.78 (0.05 to 1.52)	-0.42 (-1.38 to 0.53)	-0.33 (-1.15 to 0.48)	2.73	12%; p = 0.252

Table 23*Mediation Analysis (Mediator = MET Total Score)*

Direct effect of intervention on weight change	Direct effect of intervention on mediator	Direct effect of mediator on weight change	Indirect effect of intervention on weight change	Total effect of intervention on weight change	Proportion of effect mediated
0.64 (-4.17 to 5.45)	72.94 (-538.41 to 684.30)	-0.0004 (-0.001 to 0.0006)	-0.010 (-1.46 to 0.36)	0.617	4%; p = 0.793

Chapter 5: Discussion

The purpose of this study has been to understand how tobacco smoking and substance use among people with SMI impacts healthy lifestyle intervention mechanisms of change (e.g., diet and physical activity) and health outcomes (e.g., weight loss). It sought to describe the health profile of people with SMI who use tobacco, alcohol, or illicit drugs while participating in a healthy lifestyle intervention. Three questions were addressed: (1) What are the baseline sociodemographic (e.g., education), mental health (e.g., SMI diagnosis), physical health (e.g., physical health conditions), and healthy lifestyle factor (e.g., diet) correlates of substance use and tobacco smoking? (2) How does participants' baseline tobacco smoking or substance use moderate the impact of receiving either a peer-led healthy lifestyle intervention or usual care on weight loss throughout the trial? (3) Does tobacco smoking and substance use at baseline moderate the mediating effects that improvements in diet and physical activity over the course of the trial have on weight loss at 18-months?

The current study advances knowledge in two important ways. First, it adds knowledge about how tobacco smoking and substance use impact interventions designed to improve the physical health of people with SMI. Even though the prevalence of tobacco smoking and substance use are high among people with SMI, most health interventions do not account for tobacco smoking and substance use in their analysis of intervention mechanisms of change and outcomes. Identifying this is important because there is reason to believe that people with SMI who smoke tobacco or use substances may respond differently to healthy lifestyle interventions compared to people who do not smoke tobacco or use substances (Bobes et al., 2010; Dipasquale et al., 2013; Tian et al.,

2015). Understanding if these interventions benefit this population is an important step in the development of personalized interventions directed at reducing CVD risk factors.

Second, this study is one of the first to explore how tobacco smoking and substance use compound the physical health problems of a population (i.e., people with SMI) that already experiences profound inequities when it comes to prevalence of chronic disease and premature death. Understanding the additional health impacts of tobacco smoking and substance use among people with SMI will allow resources to be better targeted so they have the greatest impact on improving health and wellbeing.

Aim 1 Discussion

Smoking

The first question sought to identify baseline correlates of tobacco smoking and substance use among people participating in the healthy lifestyle intervention using a series of regression analyses. Overall, the hypothesis that smoking would be related to worse physical and mental health, less fruits and vegetable consumption, and lower levels of physical activity was not confirmed by the logistic regression findings. Consistent with current literature, the findings confirmed that fewer years of education and lower BMI was associated with being a current smoker (Hickling et al., 2018; Hiscock et al., 2012; Tian et al., 2015). In addition, female gender was associated with being a current smoker, which is contrary to findings in the general population and among people with SMI that indicates males are more likely to smoke than females (Dickerson et al., 2018; Wang et al., 2018). The high prevalence of smoking among females in our sample indicates that societal-level protective effects seen in the general population may not extend to populations with SMI and demonstrates the need for targeted smoking cessation

interventions among all people with SMI (Hartz et al., 2014). Additionally, since the participants in the current study were mostly non-Hispanic Black, there could be different racial/ethnic tobacco smoking patterns among people with SMI. More studies are needed to examine tobacco smoking by race/ethnicity and gender among people with SMI.

Substance Use

The hypothesis that substance use would be related to worse physical and mental health, less fruits and vegetable consumption, and lower levels of physical activity was partially confirmed by the regression findings, although ultimately findings differed across the different substance use variables. We had three substance use variables: 1) any substance use in the past 30 days, 2) total number of days of substance use, and 3) the BASIS-24 substance use subscale score. Total number of days of substance use helps to understand frequency and the BASIS-24 looks at problematic substance use.

One consistent finding across all substance use variables was that poor – fair self-rated health (compared to good – excellent) was related to any substance use, more days of substance use, and more problematic substance use. Self-rated health has consistently shown to be correlated with objective health status (S. Wu et al., 2013). Additionally, findings showed that a higher number of medical conditions was significantly related to more days of substance use and more problematic substance use. It is established that people with SUD have worse physical health than people without SUD, and studies among people with SMI indicated that people with co-occurring SMI and SUD have higher mortality rates than people with SMI or SUD alone, but exactly how substance use influences the physical health of people with SMI is underexplored (Frishman et al., 2003; R. D. Hayes et al., 2011; Heiberg et al., 2018; Roerecke & Rehm, 2014). The

current study offers evidence that substance use is compounding the already significant physical problems experienced by people with SMI. These findings highlight the importance of screening for substance use among all people with SMI and including people with SMI who use substance in health interventions. Given the increased complexity of having a SMI and SUD, care manager interventions designed specifically for this population may be needed.

The physical activity and sitting minutes per day variables showed mixed results. Fewer sitting minutes per day was significantly associated with any substance use and more days of substance use at baseline, although sitting minutes did not significantly predict the BASIS-24 substance use subscale. Achieving 150 minutes or more of moderate or vigorous physical activity was associated with no substance use, less days of substance use, and less problematic substance use, although these associations were not statistically significant. Even though using substances was associated with sitting less, it may be that their non-sitting activity was not as likely to rise to the level of moderate or vigorous physical activity compared to people not using substances. This is concerning because it is known that people with SMI are already less likely to meet physical activity guidelines compared to people without mental illness, so the addition of a SUD may exacerbate this problem (Stubbs, Firth, et al., 2016; Stubbs, Williams, et al., 2016; Vancampfort et al., 2017). This association will need to be tested in a larger sample of people with SMI because it may be that the current study didn't not have enough power which is why the results were not significant.

One of the hypotheses was that substance use would be associated with higher SSB consumption and lower levels of fruit and vegetable consumption. Fewer fruit and

vegetable servings per day were associated with any substance use, more total days of substance use, and higher BASIS-24 substance use subscale scores, although these findings were not statistically significant. In addition, SSB was not consistent across all substance use variables. Higher SSB consumption was associated with the use of any substances and with higher BASIS-24 substance use subscale scores, but lower SSB consumption was associated with more days of substance use. None of the findings regarding SSB consumption were statistically significant. Overall, more fruit and vegetable consumption and less SSB consumption were associated with less substance use, but the findings may not have been statistically significant due to sample size limitations. More work is needed to understand the impact of substance use on dietary habits among people with SMI. Prior research indicates that people with schizophrenia consume diets higher in sugar and saturated fats and lower in fiber, fruits, and vegetables compared to the general population, and there is some work linking co-occurring SMI and alcohol use disorder (AUD) to disinhibited eating (Chao et al., 2019; Dipasquale et al., 2013), but research is lacking into other substance use disorders and on the increased risk that people with co-occurring disorders face compared to people with SMI alone. This type of research can help drive future healthy lifestyle interventions for people with SMI. Until this research is conducted, providers working with people with co-occurring disorders should pay special attention to their fruit, vegetable, and SSB consumption because people with SUD may be a lower weight compared to those without SUD, which could mask their unhealthy diet.

The finding that any substance use and more days of substance use were related to younger age is consistent with the literature in the general population and among people

with SMI (SAMHSA, 2019). Among adults 18 years of age and older, the 18 – 25-year-old demographic has the highest rates of substance use (SAMHSA, 2019). Disturbingly, among people with SMI, the trend of younger age being related to higher levels of co-occurring substance use could be due to the fact that those with co-occurring SUD and SMI die at earlier ages than those with either disorder alone, so overall there will be less people with co-occurring disorders in higher age groups. Although, our sample trended older with a mean age of 49, and there were no significant differences in age among people who used substances compared to those who did not in bivariate analysis. This indicates that a significant portion of those considered middle- and late-age were using substances. Programs and services that support people with SMI need to ensure they are screening and intervening for substance use among all age ranges and should be careful not to think the risk is greatly reduced for those in middle and older age groups.

Contrary to what is known about education level and substance use, any substance use and more days of substance use were related to more years of education. Although, in the current sample the average years of education was 11.91 (SD 2.48), indicating that the sample overall had low educational attainment. This highlights the need for more educational training programs directed at people with SMI. In the current study females were less likely to have problematic substance use, although females were at a greater risk of being a tobacco smoker. This indicates that in samples with SMI, high risk groups may differ from the general population.

Additionally, racial and ethnic minoritized participants in our sample had a higher risk of more substance use days. Data looking at substance use among racial/ethnic minoritized subgroups with SMI is scarce. This is concerning since studies indicate that

Hispanic and non-Hispanic Blacks have seen the largest percentage increases in opioid overdoses compared to other racial groups (Drake et al., 2020; Lippold et al., 2019, pp. 2015–2017). In 2020, it was estimated that 41 millions people in the U.S. had a SUD, but only 2.7 million received treatment (SAMHSA, 2021). Further, it was found that among people who needed SUD treatment, non-Hispanic Black and Hispanic individuals were less likely to receive treatment than non-Hispanic Whites (SAMHSA, 2021). Although, the 2021 NSDUH did not find any significant differences among racial/ethnic groups in the percentage of people who needed SUD treatment compared to the percentage who actually received SUD treatment (SAMHSA, 2022). These findings should be investigated among people with SMI who are receiving care in community mental health centers. In addition to investigating potential racial/ethnic inequities in the provision of SUD treatment, SUD interventions should be analyzed by racial/ethnic subgroups to inform culturally tailored SUD treatments.

The hypothesis that substance use would be related to mental health conditions was only partially confirmed. Having bipolar disorder was significantly associated with more days of substance use. Although not statistically significant, depression was associated with more days of substance use and schizophrenia/schizoaffective was associated with less days of substance use. Bipolar disorder, depression, and schizophrenia/schizoaffective disorder were all associated with higher BASIS-24 substance use subscale scores, but these findings were not significant. Some studies find that people with Bipolar Disorder experience higher rates of substance use disorder compared to people with schizophrenia and major depression, although all serious mental illnesses are associated with a higher risk of SUD compared to the general population

(Hartz et al., 2014). One reason that schizophrenia/schizoaffective may have been associated with less days of substance use in the current study was that people with schizophrenia/schizoaffective were also more likely to be taking an antipsychotic medication, and taking an antipsychotic medication was associated with less substance use in the bivariate analysis. People with all subtypes of SMI should be screened and offered treatment for SUD, including medication treatments.

Aim 2 Discussion

Aim 2 sought to understand how tobacco smoking and substance use moderated a healthy lifestyle intervention for people with SMI.

Smoking

The hypothesis that tobacco smoking would moderate the impact of receiving either the peer-led healthy lifestyle intervention or usual care on weight loss throughout the trial was not confirmed by the findings. The main effects indicated that baseline weight and tobacco smoking were important predictors of weight loss over the course of the trial, but these did not moderate the effect of the intervention. Participants who started at a higher baseline weight, and those who were tobacco smokers at baseline, lost more weight over the course of the trial compared to those that started at a lower weight and those who did not smoke tobacco. Higher baseline body weight has been shown to predict greater rate of weight loss in studies of the general population (Finkler et al., 2012).

Since past studies have shown that tobacco smokers with SMI engage in less physical activity and consume diets less healthy than non-smokers with SMI, it was hypothesized that they might benefit less from the intervention or that there would be

wider disparities between smokers in the different intervention groups (Bobes et al., 2010; Dipasquale et al., 2013; Tian et al., 2015). However, in the current study tobacco smokers and non-smokers did not differ significantly at any time point on measures of diet and physical activity. It is widely known that quitting smoking can cause weight gain and that some people smoke tobacco as a weight control mechanism (Bush et al., 2016; Fulkerson & French, 2003; Seeley & Sandoval, 2011). It may be that tobacco smoking's physiological effects caused tobacco smokers to lose more weight over the course of the trial. Considering what is known about smoking cessation's impact on weight, future interventions should combine smoking cessation and weight loss treatments. Tobacco smokers with SMI may need additional support and counseling to help counteract the impact of weight gain while they are quitting smoking.

Substance Use

The hypotheses that substance use would moderate the effect of the intervention resulting in people who use substances losing less weight loss over the course of the trial was not confirmed by the findings. Although, the analysis of the main effects indicated that total days of substance use was a predictor of weight loss over the course of the trial but did not moderate the effect of the intervention. Participants who used substances on more days at baseline lost more weight over the course of the trial compared to those who used substances less days. Studies looking at the impact of substance use on healthy lifestyle interventions are scarce. Only one study among people with SMI participating in a healthy lifestyle intervention conducted a subgroup analysis of people with a history of substance use (Alexander et al., 2019). They found no significant differences in weight loss over the course of the trial for people who reported a history of substance use

compared to those with no history of substance use. The current study adds to this literature by going beyond looking at a history of substance use and instead looking at current past 30 day any substance use, total days of substance use, and problematic substance use (i.e., BASIS-24). Given that the study by Alexander et al. (2019) did not find any differential effects of substance use on intervention outcomes and the current study did not finding a moderating effect, it may be that people with SMI who are using substances may benefit equally as well from the intervention as those who do not use substances. Based on these findings, healthy lifestyle interventions should not exclude people who use substances if their substance use does not prevent them from participating in the intervention. Although, since the current study found that people with more days of substance use lost more weight, providers should be careful that substance use is not masking metabolic effects of antipsychotic medications, low levels of physical activity, or unhealthy diets, all of which might normally cause people to gain weight.

Aim 3 Discussion

Aim 3 sought to explore the possibility that tobacco smoking and substance use at baseline would moderate the mediating effects that improvements in diet and physical activity over the course of the trial have on weight loss at 18-months. Using Hayes conditional process analysis, the current study found that neither baseline tobacco smoking nor substance use influenced weight loss indirectly through diet or physical activity. In addition, results indicated that neither baseline smoking nor substance use predicted any of our dietary or physical activity outcomes at 18-months. As discussed in the previous section, there is some evidence that smoking negatively impacts diet and physical activity among people with SMI (Bobes et al., 2010; Dipasquale et al., 2013;

Tian et al., 2015), but there is still very limited research in this area, and what is known about the impact of substance use on diet and physical activity is even scarcer.

Teasing apart the potential pathways through which tobacco smoking and substance use could impact health interventions for people with SMI is important given the high percentage of people with SMI who smoke tobacco and use substances and the ongoing efforts to improve physical health through lifestyle interventions. Systematic reviews have found mixed findings in regard to the effectiveness of healthy lifestyle interventions to help people with SMI achieve clinically significant physical health improvements (Cabassa et al., 2010; Naslund et al., 2017; Speyer et al., 2019).

Understanding all the potential influencing factors could help tailor these interventions to increase their effectiveness, which will increase quality of life and life expectancy for people with SMI.

Chapter 6: Limitations

Several study limitations need to be considered. First, self-report measures were used to evaluate levels of physical activity, diet, smoking, substance use, and many of the correlates. These measures tend to over- or under-estimate the prevalence of variables and are subject to recall bias (Duncan et al., 2017; Lee et al., 2011). In addition to recall bias, self-report physical activity and dietary measures are imprecise. Future studies should try to use objective measures. To measure dietary intake studies should consider using a 24-hour food recall and physical activity can be measured with activity trackers. Future studies should also consider employing biochemically verified 7-day point prevalence abstinence combined with 30-day self-report to measure tobacco smoking. Nevertheless, while self-report measures are imperfect, they are commonly used in large community studies due to their feasibility and are used extensively in population-based studies for examination and surveillance of health.

Second, our substance use variables measured any substance use, total days of substance use, and problematic substance use, but having clinician evaluated DSM substance use disorder diagnoses would strengthen the study. While it would be helpful to have this additional dimension of substance use, our study is important because it includes people who use substance at many levels, including below the threshold of an official diagnosis. It is important to understand the impacts of all levels of substance use on physical health and on healthy lifestyle interventions among people with SMI.

Third, aim 1 used cross-sectional baseline data. These findings need to be replicated in long-term longitudinal studies that monitor the health impact of having a co-occurring substance use disorder compared to either disorder alone. Fourth, the findings

of the moderator and conditional process analyses should be interpreted with caution since this trial was not powered to examine treatment moderators or moderated mediation. Future studies should be powered to examine moderation effects and moderated mediation so studies can better understand who these interventions are working for and why.

Fifth, most of the participants in the sample belonged to racial-ethnic minoritized groups, particularly non-Hispanic Blacks, and the study was not powered to examine intervention differences among racial/ethnic groups. It will be important that studies include larger samples of diverse racial and ethnic groups so that differential treatment effects can be examined.

Lastly, this study is based on people with SMI living in supportive housing in New York City and Philadelphia. While this is an important group in need of services, these findings cannot be generalized to all people with SMI who smoke tobacco or use substances. The experiences of the current sample could be very different from people with SMI living in the community (i.e., non-supportive housing) or in rural areas. Future studies need to include more representative samples of people with SMI, particularly those living in a variety of community settings. This will provide a more comprehensive understanding of how tobacco smoking and substance use impact healthy lifestyle intervention mechanisms of change and outcomes among people with SMI.

Chapter 7: Implications and Conclusion

Despite these limitations, the study has several important contributions. People with SMI are dying much younger than people in the general population and their quality of life is further reduced by their increased risk of chronic disease. While it is known that people with SMI have a much higher prevalence of cardiovascular disease (CVD) due to high rates of tobacco smoking, metabolic effects of antipsychotics medications (e.g., increased weight), and inequities related to social determinants of health (e.g., health care access, incarceration, homelessness), if and how substance use further contributes to the poor health of people with SMI is underexplored (De Hert et al., 2011). This dissertation study helps to fill this gap and adds to the paucity of research into how tobacco smoking and substance use impact the health of people with SMI.

An important finding of this study was that more days of substance use and more problematic substance use were significantly associated with worse self-rated health and a higher number of medical conditions. There are numerous interventions designed to improve the physical health of people with SMI, including healthy lifestyle interventions and care managers interventions, but many do not screen and intervene for tobacco and substance use disorders. Additionally, interventions that do target smoking cessation often do not screen and intervene for substance use as part of the intervention. It is possible that clinicians, service providers, and researchers are not aware of the negative health impacts that less severe forms of substance use (i.e., not needing detox) can have on people with SMI, or that they are prioritizing other factors such as the lack of coordinated care or overweight and obesity. These findings give service providers some

evidence of the importance of screening and intervening when it comes to substance use among people with SMI.

In addition, this study challenges researchers to take substance use and tobacco smoking into account when testing healthy lifestyle interventions. Even though the multivariate findings were not significant, there was a trend of substance use being associated with less fruit and vegetable consumption, more sugar sweetened beverage consumption, and less moderate and vigorous physical activity. Additionally, smoking and total days of substance use at baseline were significantly associated with more weight loss over the course of the trial. The potential impact of substance use on diet, physical activity, and weight loss and the known association of smoking cessation and weight gain, have important implications for the personalization of healthy lifestyle interventions. For instance, for people with SMI who smoke tobacco, weight loss and smoking cessation interventions may need to be combined so that tailored approaches will ensure participants are able to quit smoking and still lose weight at the same time. In addition, more focus may need to be given to diet and physical activity for participants who smoke tobacco or use substances, and they will likely need tobacco cessation and substance use disorder medications to help them quit. More research is needed to learn about these associations and potential causal mechanisms. Researchers should ensure their trials are powered to look for moderation and moderated mediation effects and they must intentionally make a point of including people who use substances and analyzing these subgroups.

In conclusion, the proposed study sought to understand how tobacco smoking and substance use among people with SMI impacted their physical health at baseline and how

it impacted their diet, physical activity, and weight loss during a healthy lifestyle intervention. Even though there is a national push to integrate behavior and physical healthcare, there is limited research into the multimorbidity of substance use disorders and chronic diseases among people with SMI. This study advances knowledge in this area and provides information important to the integration of behavioral and physical healthcare. This study also provides information critical for the development of personalized interventions directed at reducing CVD risk factors, the leading cause of early death among people with SMI and co-occurring disorders. No longer can health interventions be siloed into weight loss, diet, PA, tobacco smoking, substance use, coordinated care, etc. It is becoming increasingly clear that there is an integral connection between all aspect of physical and mental health and intervening in one area while ignoring another will make it difficult to move the needle and improve quality of life and life expectancy for people with SMI.

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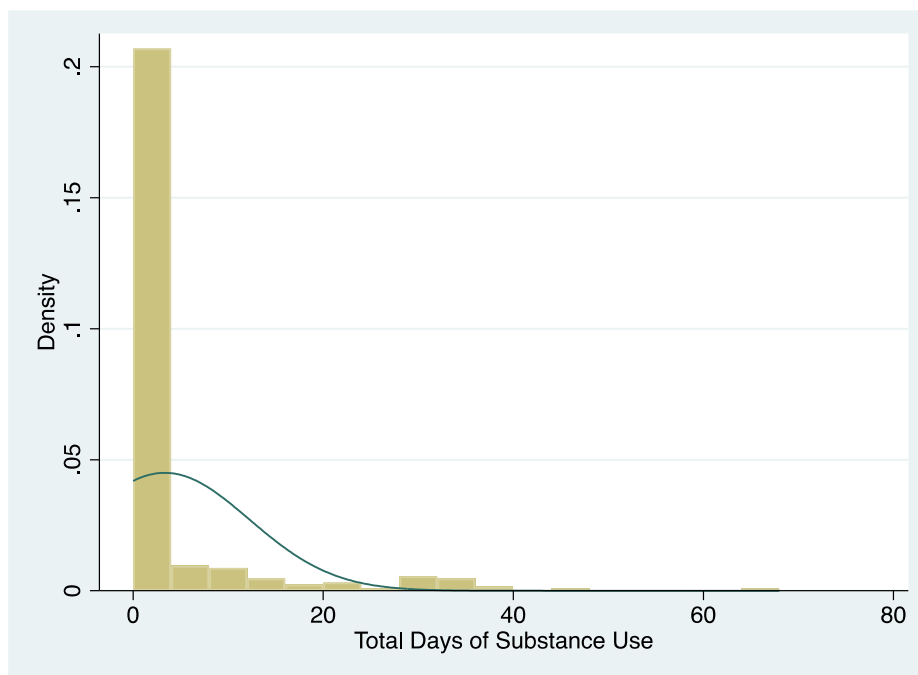
Appendix A: Distribution of Moderators, Mediators, and Outcome Variables**Figure A.1***Total Days of Substance Use Distribution*

Figure A.2

BASIS-24 Substance Use Subscale Score Distribution

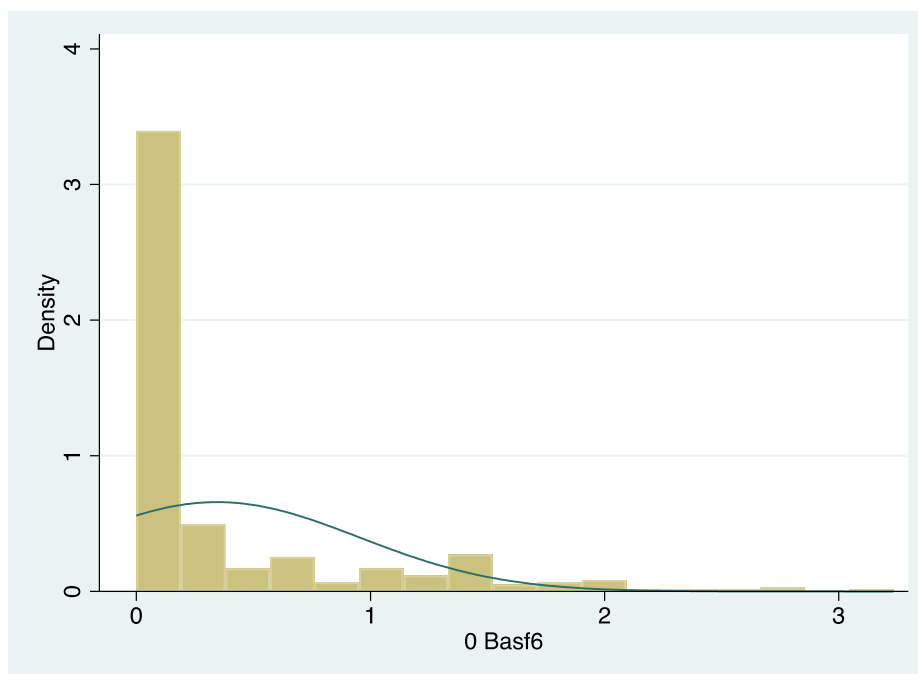


Figure A.3

Distribution of Mean Weight Change from Baseline to 6-Months

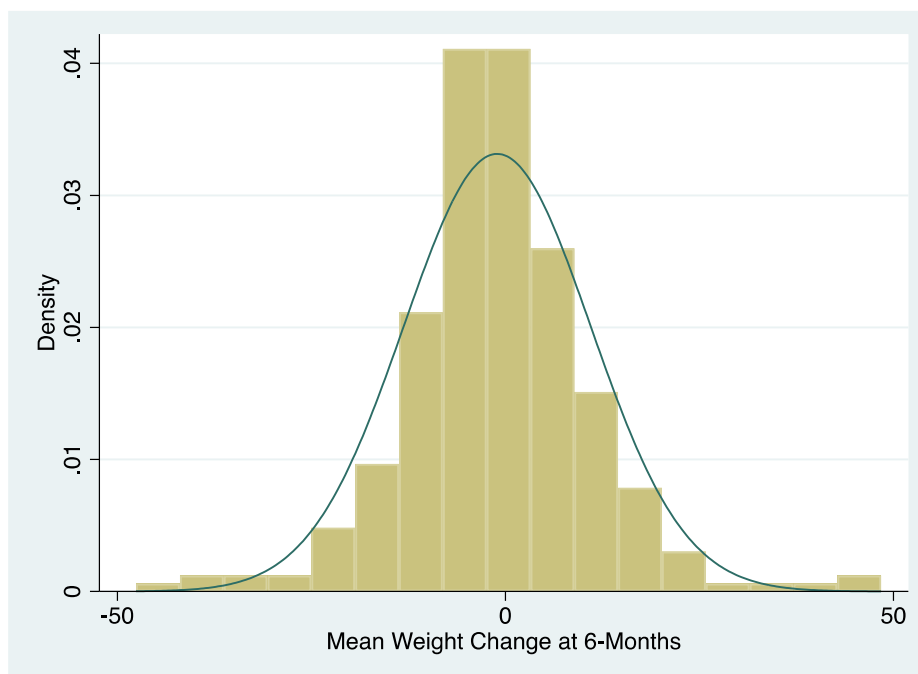


Figure A.4

Distribution of Mean Weight Change from Baseline to 12-Months

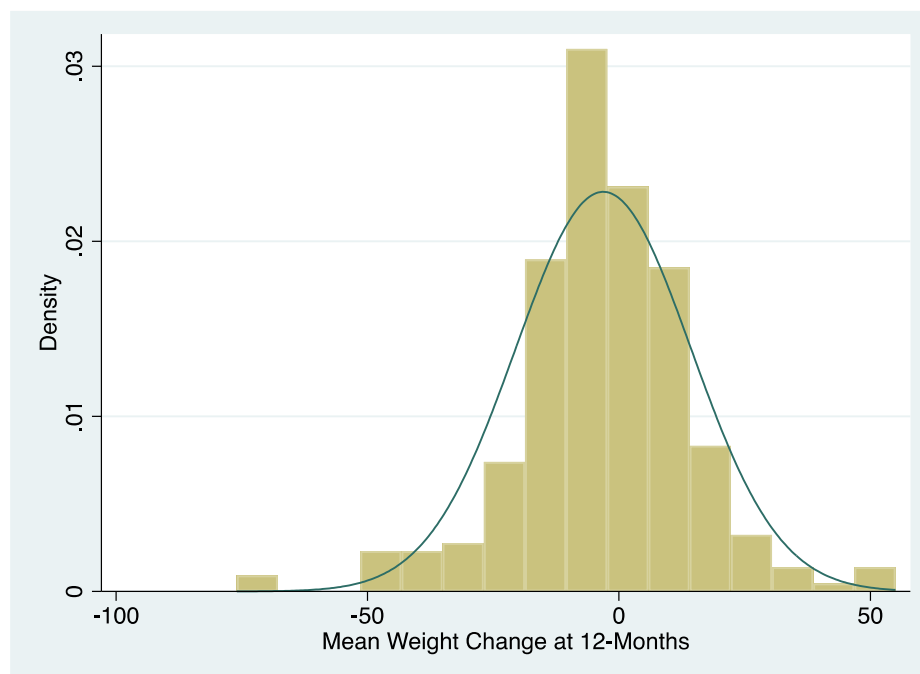


Figure A.5

Distribution of Mean Weight Change from Baseline to 18-Months

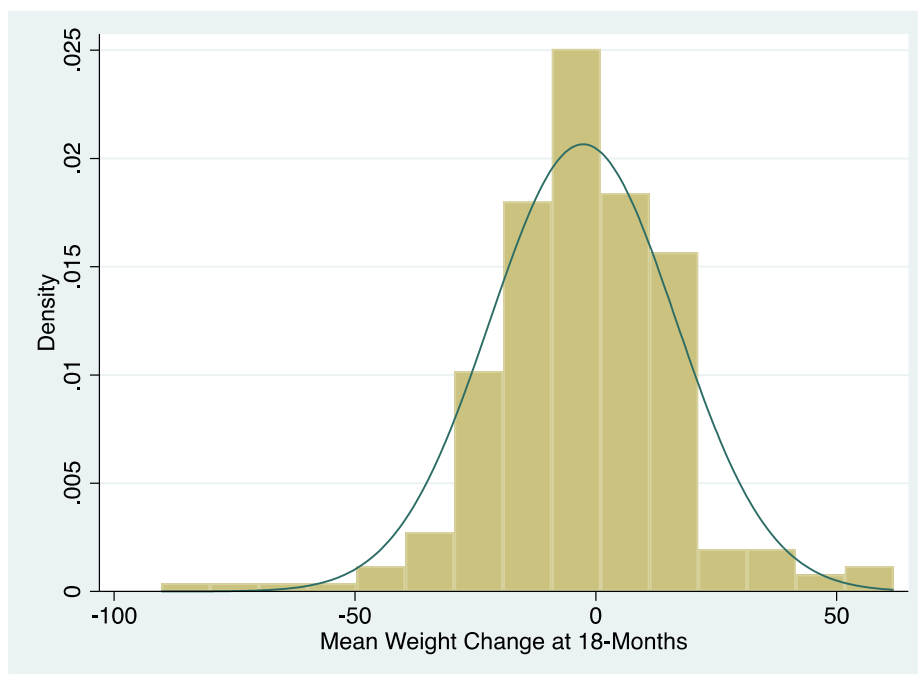


Figure A.6

Distribution of Mean Fruit and Vegetable Change from Baseline to 18-Months

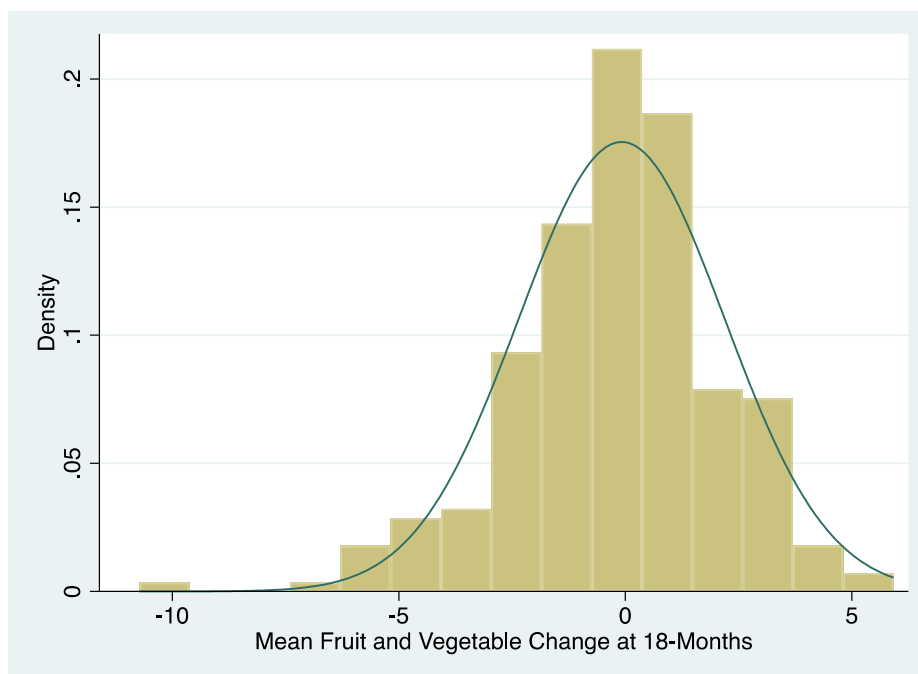


Figure A.7

Distribution of Mean Sugar Sweetened Beverage Change from Baseline to 18-Months

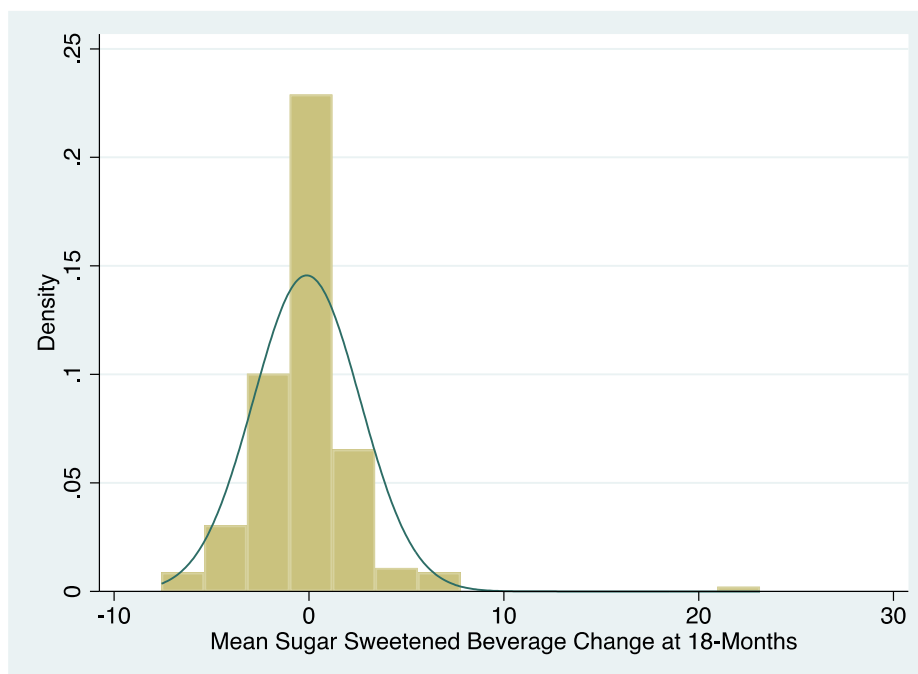
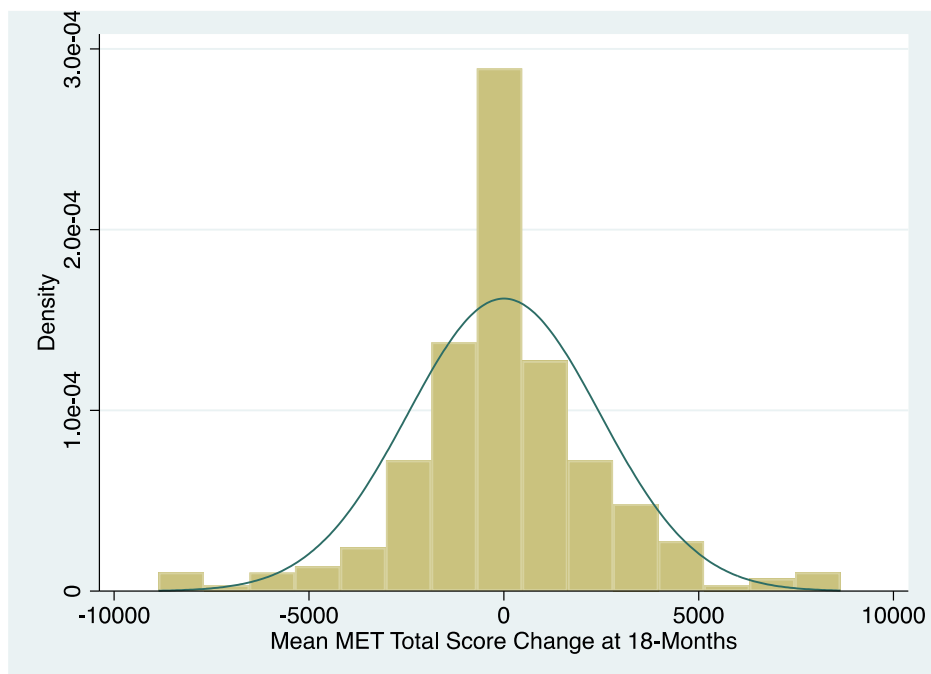


Figure A.8

Distribution of Mean MET Total Score Change from Baseline to 18-Months



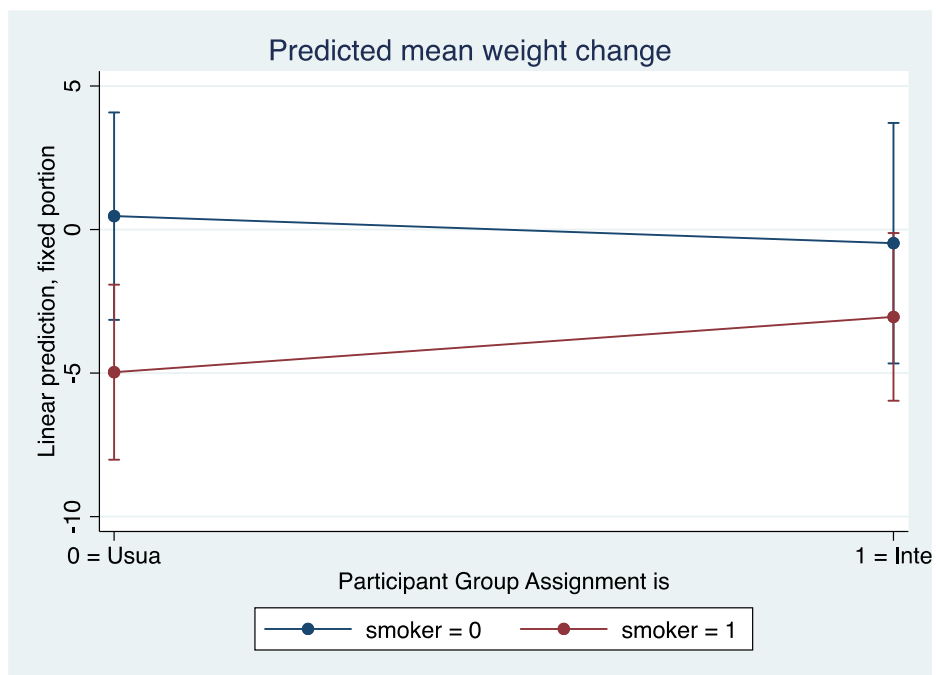
Appendix B: Graph of Aim 2 Interactions**Figure B.1***Tobacco Smoking x Treatment Group Interaction*

Figure B.2

Any Substance Use x Treatment Group Interaction

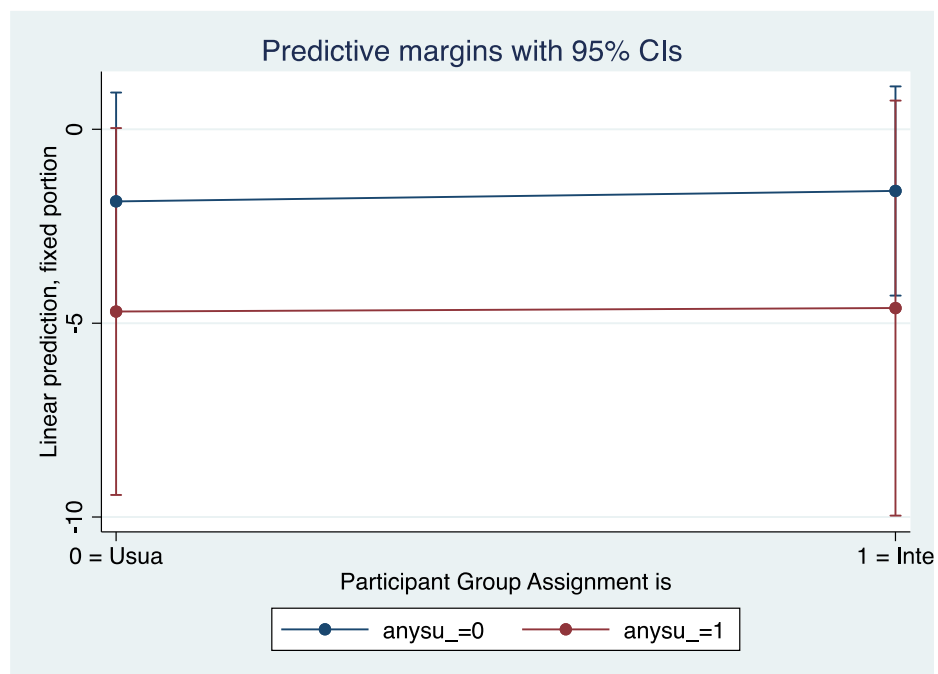


Figure B.3

Total Days of Substance Use x Treatment Group Interaction

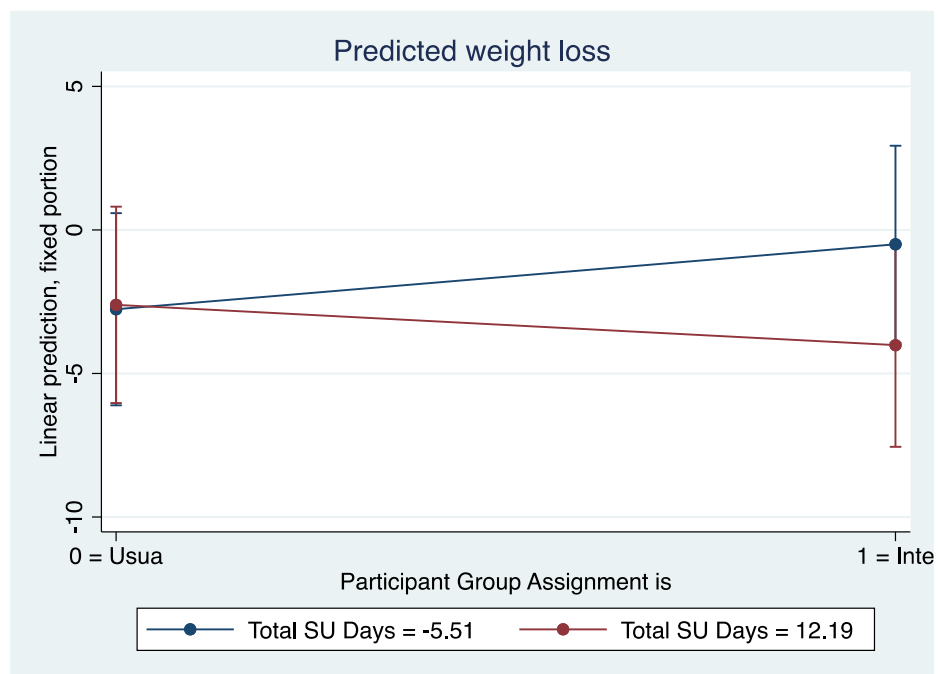


Figure B.4

BASIS-24 Substance Use Subscale Score x Treatment Group Interaction

