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Primary Care Physician Delivered Brief Behavioral Intervention for Adult Obesity and Associated Health Conditions

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PRIMARY CARE PHYSICIAN DELIVERED BRIEF BEHAVIORAL INTERVENTION FOR
ADULT OBESITY AND ASSOCIATED HEALTH CONDITIONS

by

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Western Michigan University, 2018

Obesity is a chronic health condition with prevalence rates that have continued to rise steadily over the past 30 years to the point that it has now been declared a global epidemic and a serious public health concern. Obesity is associated with significant physical and economic costs, primarily resulting from co-occurring health conditions that increase the risk of morbidity including type II diabetes, hypertension, dyslipidemia, stroke, coronary heart disease, and respiratory problems. Despite the dissemination of several obesity treatments, including pharmacotherapy, lifestyle modification, and bariatric surgery, the prevalence and severity of obesity continues to rise. Federal guidelines recommend the use of lifestyle interventions involving behavioral strategies to reduce caloric intake and increase physical activity, yet there is limited research examining the effectiveness and feasibility of delivering these interventions in community settings, particularly within primary care medical offices. Primary care providers (PCPs) play a critical role in diagnosing, monitoring, and treating obesity and co-morbid health conditions, yet there are many barriers to implementing lifestyle interventions in primary care including time, resource, and knowledge constraints.

The current study evaluates the effectiveness and feasibility of a brief behavioral intervention for obesity delivered by PCPs in an outpatient internal medicine office. Physician

training and regular electronic between visit check-ins are utilized to address commonly cited barriers to the delivery of lifestyle interventions in primary care. Outcome variables included weight and BMI as well as severity measures of common obesity-related health conditions including sleep quality, depression, diabetes, hypertension, and hyperlipidemia.

Participants (N = 31) received either brief behavioral intervention (n = 15) or usual care (n = 17) for obesity, depending on their pre-existing PCP, over a 12-month period. Linear mixed modeling analysis revealed a statistically significant difference in rates of change for hemoglobin A1c over time between participants in the behavioral intervention and usual care conditions. Specifically, A1c values decreased for those in the intervention group and increased for those in the usual care group. No other statistically significant results were found and data trends revealed mixed results for the remaining outcome variables. Consumer satisfaction data for the behavioral intervention revealed high feasibility and usefulness ratings from PCPs and patients.

These findings reveal that the brief behavioral intervention, though viewed as valuable and feasible by both PCPs and patients, resulted in statistically significant improvement in only one obesity associated health condition over time relative to usual care. The current study is limited by a small sample size and inconsistent data collection across participants and time points, however, these results have implications for the development of a population-based tiered model of care for obesity. It is possible that the brief behavioral intervention used in the current study could be a first level intervention that might be particularly effective for specific sub-populations, whereas others may need additional levels of intervention. Future research should continue investigating effective implementation of behavioral interventions for obesity in community settings including primary care.

ACKNOLWEDGMENTS

TABLE OF CONTENTS

Table of Contents - Continued

LIST OF TABLES

LIST OF FIGURES

INTRODUCTION

Scope and Significance of the Problem

Obesity can be defined as abnormal or excessive fat accumulation in the body's adipose

tissue (WHO, 2000). Body mass index (BMI) is an easily obtained and commonly used

screening measure for obesity, though it does not measure body fat directly. BMI is calculated as

the ratio of a person's weight (kg) to the square root of their height (m) and has been shown to be

correlated with measures of body fat and adverse health outcomes (Flegal & Graubard, 2009;

National Institutes of Health, 1998). When a person's weight is higher than what is considered to

be healthy for their height, they are considered to be overweight or obese. Within this

categorization, there are varying levels of severity: overweight is defined as having a BMI

between 25 and 29.9, class 1 obesity entails having a BMI between 30 to 34.9, class 2 obesity

involves a BMI between 35 and 39.9, and class 3 (severe) obesity is identified by a BMI greater

than or equal to 40 (National Institutes of Health, 1998; WHO, 2000).

Obesity is a chronic health condition that is increasing in prevalence around the world. In

2012, there were over 78 million obese adults in the United States alone (Ogden, Carroll, Kit, &

Flegal, 2014). The age-adjusted percentage of U.S. adults with obesity has increased from 22.9%

to 37.89% between 1988 and 2014 (U.S. Department of Health and Human Services, 2017).

These steadily rising rates over the past 20 years have resulted in obesity being declared a global

epidemic and a serious public health concern. In 2000, poor diet and physical inactivity together

accounted for the second highest number of deaths in the United States; 400,000 deaths, making

up 16.6% of total U.S. deaths (Mokdad, Marks, Stroup, & Gerberding, 2004).

Obesity is also associated with many other health conditions that increase an individual's risk of morbidity including: hypertension, dyslipidemia, type II diabetes mellitus, stroke, coronary heart disease, gallbladder disease, sleep apnea, respiratory problems, osteoarthritis, and some types of cancer (e.g., liver, kidney, endometrial, breast, prostate, and colon; Aronne, 2001; Must et al., 1999; National Institutes of Health, 1998; U.S. Department of Health and Human Services, 2013). In 2015, heart disease, cancer, stroke, and diabetes were all listed within the top 10 leading causes of death in the United States (U.S. Department of Health and Human Services, 2017). Additionally, obese individuals experience psychosocial problems including stigmatization, discrimination, and reduced quality of life, which increases risk for premature mortality (National Institutes of Health, 1998; WHO, 2000).

A cohort study conducted in Washington on 73,003 adults, aged 50 to 76 years, examined the relationship between BMI and over 40 other health conditions. The results revealed that 90% and 71% of the conditions examined were associated with increased BMI in females and males, respectively (Patterson, Frank, Kristal, & White, 2004). Of particular concern is the fact that among the subcategories of obesity, the prevalence of severe obesity is increasing at the highest rate in the U.S. population. This is especially concerning because the most severe health conditions that tend to be comorbid with obesity are most likely to occur in individuals who are severely obese (Arterburn & Courcoulas, 2014; Sturm, 2007; U.S. Department of Health and Human Services, 2017). Additionally, increased mortality has been found to be particularly associated with higher levels of obesity, relative to normal weight categories (Flegal, Graubard, Williamson, & Mitchell, 2005).

There are significant economic costs associated with the many medical consequences of obesity. Finkelstein, Trogdon, Cohen, and Dietz (2009) report that rising rates of obesity have

been linked to increases in medical spending. In 1995, the total cost attributable to obesity and associated health conditions was $99.2 billion, with more than half resulting from direct medical costs which comprised 5.7% of the national health expenditure (Wolf & Colditz, 1998). Additionally, in 1994 there were 39.2 million lost work days, 239 million restricted activity days, 89.5 million bed days, and 62.6 million physician visits attributable to obesity, resulting in an extra $3.9 billion in lost productivity costs. In comparison to 1988 data, by 1994 lost work days increased by 50%, restricted activity days increased by 36%, bed days increased by 28%, physician visits increased by 88%, all attributable to obesity (Wolf & Colditz, 1998). There is no reason to assume that the economic impact of obesity has slowed or reversed in recent years.

As of 2009, the annual medical burden of obesity accounted for almost 10% of all medical spending. Across all payers in 2006, the per capita medical spending for obese individuals was 42% greater than the per capital medical spending of non-obese individuals. On average, each obese beneficiary cost Medicare $600 more per year than each non-obese beneficiary. This economic burden to public and private payers results almost entirely from the treatment of the many health conditions associated with obesity (Finkelstein, Trogdon, Cohen, & Dietz, 2009). The pharmacotherapy costs for obesity attributable diseases constitute a much larger percentage of total treatment costs than for other diseases and non-obese patients. The greatest costs among obese patients are for drugs to treat comorbid conditions including hypertension, diabetes, and cardiovascular diseases, as well as antidepressants and respiratory and ulcer medications (Aronne, 2001).

Obesity Treatment

A nationally representative sample revealed that 64.3% of U.S. adults have a desire to lose weight, however, only 48.4% reported pursuing some form of weight control (Yaemsiri,

Slining, & Agarwal, 2011). Treatment guidelines recommend medically-directed weight loss for individuals who are obese (BMI ≥ 30) and those who are overweight (BMI between 25-30) if comorbid health conditions are also present (Ryan, 2016). Weight loss among obese individuals is known to be associated with decreased incidence of obesity related health conditions and death (Moyer, 2012). The majority of individuals with obesity report health improvement as a primary motivator for weight loss (Doyle et al., 2012).

Despite continued increases in prevalence and the many physical, psychological, and economic costs of obesity and associated health conditions, few evidence-based treatments exist to target the growing obesity epidemic, and there is little agreement on the best treatment approach (Arterburn, & Courcoulas, 2014). The limited success of treatments thus far is likely due in part to the fact that obesity is a complex problem with a multifactorial etiology that involves the interaction of both genetic and environmental factors, including culture (Comuzzie & Allison, 1998; Hill & Peters, 1998; National Institutes of Health, 1998; WHO, 2000).

The genetic component of obesity involves predispositions mediated by many different molecules involved in the regulation of food intake, energy expenditure, and fat storage (Comuzzie & Allison, 1998; WHO, 2000). Contributing environmental factors include sedentary lifestyle, energy dense food intake, and cultural factors that support an obese lifestyle. The evolutionary drive to consume energy dense foods is no longer adaptive in the current environment of abundance, yet modern society does not readily support the negative energy balance needed to produce weight loss (Hill & Peters, 1998; WHO, 2000).

Although relatively little progress has been made with respect to successfully treating obesity, there are several treatment modalities that have demonstrated effectiveness. These include: bariatric surgery, pharmacotherapy, and lifestyle modification (Arterburn & Courcoulas,

2014). A comprehensive approach to treatment involving components of several different therapeutic techniques is likely to produce the best results (Wadden et al., 2005). Most major guidelines for obesity management suggest that comprehensive lifestyle intervention should be the core treatment modality with other adjunctive treatments added for individuals who are at higher risk and those who have failed to benefit from previous lifestyle interventions (Ryan, 2016). Unfortunately, both short and long-term success rates are still relatively low, and research reveals that patients often have unrealistic expectations and prefer treatments that do not require them to make substantial lifestyle changes (Doyle, 2012).

A review conducted by Aronne in 2001 suggested the following guidelines for utilizing various weight loss treatment options: diet, exercise, behavioral therapy, and pharmacotherapy are appropriate for obese individuals and those with a BMI less than 30 if comorbid health conditions are also present. However, surgical interventions should be reserved for those patients falling in the highest BMI categories who also have associated health complications. Current U.S. guidelines recommend the consideration of bariatric surgery procedures for individuals who have not responded to non-surgical treatments and who also have BMI of at least 40, or at least 35 if they are also suffering from serious comorbid health conditions (Arterburn & Courcoulas, 2014; Ryan, 2016). The U.S. Preventive Services Task Force recommends multicomponent, intensive behavioral intervention for individuals with a BMI of 30 or higher (Moyer, 2012).

Currently, bariatric surgery is the treatment with the most definitive research support for both significant and sustained weight loss and remission of obesity associated health conditions, including type II diabetes (Arterburn, & Courcoulas, 2014; WHO, 2000). Refinements in the efficacy and safety of bariatric surgery procedures have led to a twenty-fold increase in the number of procedures performed annually in the U.S. over the past two decades (Arterburn &

Courcoulas, 2014). There are several risks associated with bariatric surgery procedures, though the risks have decreased as the techniques have been refined. Reported incidence of short-term post-surgery complications ranges from 4-25%, depending on a variety of patient and procedural factors, but the overall risk of perioperative mortality is relatively low (0.3%). Reoperation as a result of insufficient weight loss or complications occurs in some cases. There is also evidence for increased long-term risk of suicide, nutritional deficiencies, and substance use disorders, possibly due to changes in the way alcohol is absorbed by the body following bariatric surgery (Arterburn & Courcoulas, 2014). Although bariatric surgery is beneficial for some individuals with obesity, it is expensive and inappropriate for most individuals and, therefore, should not be a first line treatment. There are risks and major lifestyle changes involved, including modifications to the frequency, quantity, and content of food intake, as well as efforts to increase energy expenditure through exercise, that should be carefully considered.

Pharmacotherapy is another available intervention option. There have been many different weight loss medications introduced over the past 30 years for both short and long-term obesity treatment, though some have since been withdrawn from the market due to safety concerns. In general, obesity medications seek to promote weight loss through some combination of the following mechanisms: increasing energy wastage, increasing energy expenditure, or decreasing food intake. Many medications introduced solely to increase energy wastage or expenditure have proved to be ineffective and are often associated with significant side effects including malabsorption and a compensatory rise in food intake (Wilding, 2018). Many newer weight loss medications seek to increase satiety and reduce food intake. There are currently a handful of medications approved for either short-term (≤ 12 weeks) or long-term (≥ 12 weeks) use in obesity management, though significant side effects, limited effectiveness, high out-of-

pocket costs, and lack of prescription guidance for providers remain barriers to widespread use (Yanovski & Yanovski, 2014).

An analysis of prescription antiobesity medication use conducted by Hampp, Kang, and Borders-Hemphill (2013) revealed that use of antiobesity drugs peaked in 1996, then sharply declined, and over the past 10 years has begun to slowly increase again. The most common users of antiobesity medications are women between 17 and 44 years of age. Phentermine, a noradrenergic agent approved by the FDA for short-term use, was the most commonly prescribed weight loss medication in the U.S. from 1991 through 2011. In addition to medications introduced specifically for weight loss, there is some evidence supporting the use of medications approved for the management of other conditions, such as diabetes (i.e. metformin, liraglutide, pramlintide), epilepsy (i.e. zonisamide), and mood disorders (i.e. fluoxetine, bupropion), in the treatment of obesity (Appolinario, Bueno, & Coutinho, 2004; Wilding, 2018; Yanovski & Yanovski, 2014). Most medications have been found to produce maximum weight loss, as well as additional improvements in obesity associated health conditions, when used in combination with lifestyle modification (Ryan, 2016; Yanovski & Yanovski, 2014).

The final intervention modality with demonstrated effectiveness in treating obesity is lifestyle modification. Comprehensive lifestyle interventions are those that include three main components: a moderately reduced-calorie diet, increased physical activity, and the use of behavioral strategies, including self-monitoring, goal setting and reinforcement, to facilitate adherence to diet and exercise recommendations. These interventions can be delivered in low ($\leq$ 5 visits in 6 months), moderate (6-13 visits in 6 months), or high ($\geq$ 14 visits in 6 months) intensity formats (Ryan, 2016; U.S. Department of Health and Human Services, 2013). While pharmacological and surgical interventions produce weight loss by modifying internal bodily

cues and systems that regulate appetite and satiety, lifestyle interventions produce weight loss by

teaching skills for managing the external environment as it relates to food consumption and

energy expenditure. Lifestyle modification is widely applicable and can be individually tailored

and delivered by a variety of professionals in many different formats and settings. Additionally,

behavioral interventions have shown demonstrated benefit and typically involve minimal risk

(Moyer, 2012).

Federal guidelines for managing overweight and obesity in adults reveal that, in

comparison to usual care involving limited provision of advice or educational materials,

comprehensive lifestyle interventions have demonstrated greater short, intermediate, and long-

term weight loss. Additionally, electronically delivered comprehensive lifestyle interventions,

including both self-monitoring and individualized feedback from a trained professional, have

been shown to produce greater weight loss than the use of no intervention or knowledge gained

from widely available print or electronic materials (U.S. Department of Health and Human

Services, 2013). Intensive, multicomponent behavioral interventions have been shown to

produce not only weight loss among obese adults, but also improvement in glucose tolerance and

other cardiovascular risk factors (Moyer, 2012; Ryan, 2016). Additionally, there is evidence that

40-60% of overweight and obese adults maintain weight loss of at least 5% of initial body weight

two or more years after participating in a high-intensity, long-term, comprehensive lifestyle

intervention (U.S. Department of Health and Human Services, 2013).

Treating Obesity in Primary Care

Obesity and its associated health conditions often present first in primary care and are

typically managed by primary care physicians. In 2012, there were 11 million physician office

visits for obesity by adults age 20 and over. The majority of these visits (73%) included an

additional chronic condition, the most common of which were: hypertension, hyperlipidemia, diabetes, and depression. Health education was offered at less than half of these visits (Talwalkar & McCarty, 2016). Therefore, there is both an opportunity and a need for the provision of information regarding the effects of excess weight on health and the delivery of lifestyle interventions in primary care settings. One main advantage to providing interventions in primary care is the fact that primary care physicians (PCPs) have contact with diverse segments of the population and their advice is generally highly respected by patients. However, many PCPs are uncomfortable providing behavioral recommendations and creating weight loss plans with patients for a variety of reasons.

A study examining the attitudes and practices of over 1,000 physicians revealed that while 75% of the physicians sampled reported that dietary counseling is a high priority for them, 65% reported that they spend five minutes or less discussing dietary concerns with their patients. Additionally, more than two-thirds of the physicians sampled reported that less than 40% of the patients seen in their practice actually receive nutritional counselling from their physician. Lack of time was the most commonly cited barrier, followed by lack of patient compliance, inadequate teaching materials, lack of knowledge and training in nutritional counseling, lack of adequate reimbursement, and lack of confidence in ability to improve patient diet (Kushner, 1995).

Another more recent study (Smith et al., 2011) examined the practices of over 1,200 physicians and found that the practice of discussing energy balance in clinical care remains low among primary care physicians. Less than half of the PCPs sampled reported calculating BMI for their patients. The majority of PCPs reported providing some counseling to patients but less than half reported always providing specific guidance, even to patients with weight related chronic health conditions. Additionally, few PCPs reported consistently referring patients for further

9

management or systematically tracking patient behavior over time. In contrast to the low number of physicians providing lifestyle counselling to their patients, almost 75% of PCPs reported prescribing pharmacological treatments for weight control and almost 90% reported having referred patients for bariatric surgery. The physicians sampled reported being more likely to guide patients on exercise or diet specifically and less likely to provide guidance on overall weight control (Smith et al., 2011).

A study examining the attitudes of medical residents at Louisiana State University Health Sciences Center-Shreveport identified several barriers to physician provision of weight loss counselling to patients. The barriers included pessimism about patient's desire to lose weight and the effectiveness of weight loss counselling, lack of obesity management resources, insufficient time, deficits in brief counselling skills, and a lack of knowledge about best clinical practices in this area. Patient surveys revealed that the majority of patients (60-65%) believe that their weight affects their health and recognize that losing 10% of their weight would improve their health. Additionally, 89% of patients reported a need to lose weight, 88% reported the desire to lose weight, and 90% reported previous weight loss attempts (Huang, Marin, Brock, Carden, & Davis, 2004). These data suggest that patients are invested in losing weight and would likely be receptive to weight loss recommendations from their physicians.

However, while 79% of patients reported being counselled by their physician to lose weight, only 28% reported being given specific weight loss recommendations concerning modifications to their diet and/or activity or information about pharmacological or surgical weight loss options. Only 5% of these patients recalled being given the combined weight loss strategy of diet and exercise. Not surprisingly, patients who reported receiving weight loss counselling from their physicians were more likely to have a better understanding of obesity

10

associated health problems and the benefits of weight loss, a stronger desire and increased

readiness for weight loss, and were more likely to be engaged in current or past weight loss

activities (Huang, Marin, Brock, Carden, & Davis, 2004). These data suggest that specific diet

and exercise recommendations, though infrequently provided by physicians, can positively

impact patient levels of motivation and accountability as well as their understanding of obesity.

Few research studies have found evidence to support the delivery of low to moderate

intensity lifestyle interventions, in person or over the phone, to overweight or obese adults by

primary care staff alone (Carvajal, Wadden, Tsai, Peck, & Moran, 2013; U.S. Department of

Health and Human Services, 2013). There is some support for the delivery of moderate-intensity

lifestyle interventions by trained professionals in group or individual formats on a bi-weekly to

monthly basis over a period of 6-12 months (U.S. Department of Health and Human Services,

2013). There is also evidence that weight loss medication or collaboration from other health

professionals, in addition to brief PCP counseling, produces increased weight loss (Carvajal,

Wadden, Tsai, Peck, & Moran, 2013). However, more intensive interventions may not be

feasible in primary care settings and additional health professionals and services may not be

easily accessible or available for many patients.

Tsai and Wadden (2009) reviewed 10 randomized controlled trials (RCTs) evaluating the

delivery of behavioral weight loss interventions alone or in combination with pharmacotherapy

in primary care settings. None of the four studies involving only mild to moderate intensity

lifestyle counseling delivered by a PCP resulted in weight loss that reached the threshold of

clinical significance, which is generally considered to be 3kg. These interventions involved the

creation of individualized behavioral goals through PCP visits occurring every 1-3 months,

however, none of them included any patient feedback or additional follow-up contact between

office visits. Two of the studies reviewed were able to achieve clinically significant weight loss by combining low intensity lifestyle counseling by a PCP with pharmacotherapy. Another study attained clinically significant weight loss by adding meal replacements and additional counseling with a registered dietician.

Another review of 12 RCTs examining behavioral treatment of obesity in primary care settings was conducted by Wadden, Butryn, Hong, and Tsai (2014). In all trials, lifestyle counseling (including diet, exercise, and behavioral strategies) was provided for at least 3 months with at least 6 months of follow-up. Interventions were delivered by PCPs and/or trained interventionists in person, by phone, or over the internet. Interventions involving only PCP delivered diet and/or exercise focused counseling, and the use of motivational interviewing strategies to assess patient readiness for change, did not achieve significant weight loss (>3kg) at 6 months. The interventions that were successful in achieving significant weight loss at 3 months, and maintenance at 6 months, were those in which comprehensive lifestyle interventions were delivered by trained professionals with little PCP collaboration and supported by additional resources. Many of the interventions that were able to achieve clinically significant weight loss also involved additional participant contact between physician office visits. This review highlights the fact that behavioral counseling, delivered by a variety of different trained professionals (e.g., medical assistants, dieticians) in a variety of different formats (e.g., phone, internet, in person), can produce clinically significant weight loss for primary care patients.

One pilot study combining behavioral counseling with pharmacotherapy demonstrated initial support for structured lifestyle modification provided by PCPs during regular office visits. Twenty-six obese women were prescribed two weight loss medications and assigned to receive either 32 (75-minute) sessions of group behavior modification with a nutritionist or 10 (15-20

minute) physician visits that included lifestyle modification. After one year, both groups had achieved significant and equivalent weight loss (30-34 pounds) and 96% of study participants had lost 5-25% of their initial body weight. Treatment was also associated with significant improvements in triglycerides, total cholesterol, HDL and LDL, resulting in decreased risk for coronary heart disease. Additionally, participants reported significant improvements in mood, attention, appetite, and eating behavior (Wadden, Berkowitz, Vogt, Steen, Stunkard, & Foster, 1997). These results suggest that frequent, structured, lifestyle modification provided by PCPs, in combination with medication, may produce clinically significant weight loss and improvement in obesity related health conditions. However, without the inclusion of a control group, it is not clear which, if any, intervention components were actually responsible for the observed results.

The POWER-UP studies, conducted by the National Heart, Lung, and Blood Institute, found that PCPs working with Medical Assistants (MAs) can deliver effective weight management interventions to some obese patients in primary care settings. The delivery of brief education and handouts provided by PCPs every three months resulted in ≥5% weight loss for 22% of participants. In comparison, the most intensive intervention, which included the addition of monthly 10-15 minute phone calls with an MA and the choice of either meal replacement or weight loss medication, resulted in ≥5% weight loss for 35% of participants (Wadden et al., 2013). These results suggest that lifestyle modification delivered by PCPs in primary care settings can result in significant weight loss for a subset of obese patients. More research is needed to assess the feasibility of delivering these interventions in primary care and to determine which patients are most likely to benefit.

A recent study conducted by Tsai et al. (2013) examined the cost effectiveness of primary care treatment of obesity. Six primary care practices were examined and 390 patients with BMIs

between 30 and 50, elevated waist circumference, and the presence of at least one metabolic condition (high blood pressure, elevated triglycerides, low HDL cholesterol, impaired fasting glucose/diabetes) were randomized to receive one of three treatments. The usual care (UC) condition involved quarterly PCP visits. The brief lifestyle counseling (BLC) condition involved quarterly PCP visits plus monthly weight loss counseling visits. Finally, the enhanced brief lifestyle counseling (EBLC) condition involved the addition of the participant's choice of either weight loss medication or meal replacements. Participant weight and the cost for all intervention components and concomitant medication use and other health care costs were measured. Intervention costs were $3092 for EBLC, $1323 for BLC, and $837 for UC. The UC condition had significantly higher costs associated with concomitant medications than the other groups, however, no cost differences were observed between groups for other health care costs. Average weight loss after two years was 1.7kg for UC participants, 2.9kg for BLC participants, and 4.6kg for EBLC participants. Incremental cost-per-kilogram year lost for EBLC over UC was $292. Incremental cost per QALY (quality adjusted life years) was $115,397 (no difference between groups). These data suggest that primary care obesity treatment could be cost effective long-term (Tsai et al., 2013).

Federal guidelines recommend the delivery of comprehensive lifestyle interventions, yet there is limited research examining the effectiveness and feasibility of delivering these interventions within primary care settings. Thus far, limited success has been achieved through the provision of behavioral weight loss counseling by PCPs and other health providers in primary care practices (Carvajal, Wadden, Tsai, Peck, & Moran, 2013). The best results have been found with interventions involving frequent, face-to-face contact, however, this is difficult to achieve in primary care settings (Ryan, 2016). In-person low intensity or remotely delivered high-intensity

behavioral interventions typically result in less weight loss, however, they are also less resource intensive and more accessible (Carvajal, Wadden, Tsai, Peck, & Moran, 2013).

Current Study

The currently available research evidence provides only limited data to support the efficacy, feasibility, and cost-effectiveness of mild to moderate intensity behavioral interventions delivered by PCPs. Most interventions involving only PCP delivered behavioral counseling, without the addition of weight loss medication, additional resources, or interventions provided by other trained professionals, have not achieved clinically significant weight loss. However, while effective, the addition of these extra services requires increased time, cost, and staff demands, which may not be feasible for many primary care practices.

PCPs play a critical role in identifying obesity, evaluating its causes, prescribing and monitoring medications, assessing and treating co-morbid health conditions, and monitoring the resulting outcomes. PCPs have the ability to reach large and diverse segments of the population and prevent increasingly severe obesity and associated health conditions. Therefore, additional research on the effectiveness of brief, structured lifestyle interventions delivered by PCPs is warranted. However, consideration must also be given to feasibility, considering the limitations of primary care practice and the barriers currently impacting the delivery of lifestyle interventions by PCPs. Self-monitoring and regular feedback/follow-up are components known to be effective in enhancing behavioral change and can be delivered electronically between office visits to reduce burden. There is some research support for the electronic delivery of obesity interventions and the potential to reduce time, cost, and resource burdens, which is especially important in primary care settings.

The current study examines both the feasibility and effectiveness of a brief behavioral intervention for obesity and associated health conditions delivered by PCPs during scheduled office visits and supported by at home participant behavior tracking and regular electronic feedback from physicians. Brief physician training in the delivery of behavioral lifestyle modification was provided to minimize the frequently cited barriers of knowledge and confidence deficits. Electronic physician-patient between visit check-ins were utilized as a cost and time effective alternative to high intensity face-to-face interventions to increase patient compliance and outcomes. The use of brief, low-intensity, PCP delivered behavioral interventions for obesity creates the base for a tiered model of care involving the widespread use of available and accessible lifestyle interventions with minimal intrusiveness and risk as first-line treatments. This would reserve the use of more intensive, costly, and risky interventions for more severe and treatment resistant cases of obesity, in accordance with existing treatment guidelines.

METHOD

Participants

All participants were recruited from an outpatient internal medicine primary care office. All obese or overweight patients (BMI of 25+), who were at least 18 years of age, fluent in English, and active members of the electronic communication system (MyChart) utilized in the office as part of the electronic medical record (EMR), were eligible to participate. Patients meeting these eligibility criteria, whose PCP was one of the physicians involved in the study, and who were scheduled for an obesity related chronic health condition (i.e. diabetes, hypertension, hyperlipidemia, sleep, depression, chronic pain) follow-up visit or yearly physical during the recruitment period were contacted regarding participation in the study. All women who were known to be pregnant were excluded from participating due to the potential risks associated with weight loss during pregnancy.

All participants meeting the above criteria were sent an electronic message via the MyChart system. The recruitment message (Appendix D) provided general information about the study. Patients were asked to respond to this initial message if they were interested in receiving additional information about study participation. Patients who did not wish to participate could either send a message back declining participation or simply choose not to respond to the recruitment message. Only patients who expressed explicit interest in participating via a reply message were sent the full informed consent document (Appendix A) via MyChart. Potential participants were given the opportunity to ask any questions they had about the study via MyChart prior to providing consent. Additionally, the office manager, hospital risk management

17

staff, and HSIRB staff were involved as needed to address participant questions and concerns. Consent for participation was obtained through a MyChart message response to the informed consent document that included a statement of understanding and intent to participate as well as the patient's full typed name. Once consent was received, participants were notified electronically that they would be asked to complete a few brief questionnaires at their upcoming office visit. All relevant future office visits were then flagged in the EMR (using documentation in the appointment notes section) to alert office staff of study participation.

Procedures

All eligible participants who consented to participate in the study completed a brief questionnaire assessing sleep quality and a PHQ-9 to assess depression symptoms while waiting to be seen by their physician for their regularly scheduled office visit occurring during the study recruitment period. Data were then collected at all relevant office visits occurring over a 13-month period between April 2017 and May 2018 with the goal of obtaining data at two different time points for each participant. At each office visit participants completed the sleep quality questionnaire and the PHQ-9 while waiting to be seen by their physician. All relevant physiological measures (weight, BMI, blood pressure, cholesterol, hemoglobin A1c) collected at office visits as part of routine clinical care were retrieved from the EMR.

All standard office policies were followed in the event of medical or mental health emergencies. There was a social worker available in the office at all times to assist in the event that significant mental health symptoms or suicidal ideation were endorsed by participants on the PHQ-9. This did not occur during the course of the study. In keeping with standard care, physicians reviewed participant PHQ-9 data at each office visit and referred patients with significant depression symptoms to the medical social worker for follow-up care as appropriate.

Two physicians (one male and one female) were selected to provide a brief behavioral intervention to their consenting patients who met the inclusion criteria, and two different physicians (one male and one female) were selected to continue providing their usual level of patient care to their consenting patients who met the inclusion criteria. Usual physician care for obesity involved checking BMI at every office visit and offering BMI counseling once/year. Participant assignment to receive either brief behavioral treatment or usual care was determined by the role assigned to their pre-existing PCP. Participants in the behavioral intervention condition were compared to participants who continued to receive usual physician care without modification during the data collection period. All physicians consented to their role in the research study and were instructed in how to perform their role prior to study initiation.

Behavioral Intervention

The same physiological and self-report data were collected for participants in both the usual care and behavioral intervention conditions at all scheduled office visits occurring during the data collection period. However, participants in the behavioral intervention condition also completed a brief questionnaire assessing their current eating and exercise habits (Appendix C) at their initial office visit as well as all subsequent office visits during the study. Physicians administering the behavioral intervention spent five minutes during the initial visit reviewing the completed diet and exercise habits questionnaire with participants and utilizing it to assist them in collaboratively setting one specific behavioral goal for improving diet and one specific behavioral goal for improving physical activity. Goals were recorded in visit progress notes and check-out instructions, using standardized templates, to track PCP treatment adherence and to serve as a reminder for participants.

Following the initial office visit, participants in the behavioral intervention condition were sent a MyChart message containing instructions about completing behavioral tracking and regular electronic reporting of progress to PCPs (Appendix F). Participant progress towards diet and exercise goals was reviewed with physicians during all subsequent office visits occurring during the data collection period. Between office visits, patients in the behavioral intervention condition were asked to track their diet and physical activity and send their physician brief summaries of their progress towards their behavioral goals and a current weight via MyChart. Physicians, with the help of medical assistants as needed, provided brief responses to patient updates either encouraging continued progress or troubleshooting barriers and suggesting modifications. Physicians were able to use response templates within the EMR system to respond to participant check-in messages. Physician-patient exchanges were scheduled to occur once/week following the first office visit, once every two weeks following the second office visit or after three months of weekly check-ins, and once/month following any additional office visits that occurred during the data collection period or after three months of bi-weekly check-ins.

Participants were prompted via MyChart to send progress summaries to their physicians at the specified time points. If on any occasion participants failed to send progress summaries to their physician by the appropriate date, up to three reminder prompts were sent via MyChart. Any participants who failed to provide MyChart check-ins at three consecutive time points, despite receiving multiple reminders, were no longer prompted to send MyChart check-ins at future time points. In person self-report and physiological data continued to be collected at all office visits regardless of whether or not participants were compliant in providing regular between visit MyChart updates.

The two physicians delivering the behavioral intervention attended a brief training prior to the start of data collection. This training involved a review of possible diet and exercise goals and behavioral principles/strategies involved in setting, modifying, and troubleshooting specific diet and exercise goals as outlined in the physician decision guide (Appendix E). If physicians delivering the behavioral intervention failed to document participant goals in the chart or failed to respond to participant MyChart check-in messages within one week they were reminded to engage in these practices.

At the conclusion of the data collection period, consumer satisfaction data were collected from both PCPs and patients who delivered and/or received the brief behavioral intervention. Participants were asked to complete a brief 3-item questionnaire assessing the utility and feasibility of the behavioral intervention (Appendix G) either during their final office visit or via MyChart. Physicians were asked to complete either a paper and pencil or electronic version of the questionnaire at the end of the study.

<div align="center">Measures</div>

Primary Outcomes: Obesity and Associated Health Conditions

Physiological measures. Prior to many yearly physical or chronic health condition follow-up appointments patients will have relevant lab work done (in keeping with standard clinical practice), including hemoglobin A1c and cholesterol. Additionally, at every office visit height, weight, BMI, and blood pressure are recorded. These routine progress measures were retrieved from the EMR and used to measure the presence/severity of obesity related health conditions (e.g. hypertension, diabetes, hyperlipidemia). Usual physician care was not modified with respect to medications, procedures, lab work, or scheduling. Thus, there were no additional costs to participants that would not ordinarily be part of usual physician care outside of the study.

Mood. Depression is known to be prevalent among obese individuals seeking weight loss treatment (Anderson, & Wadden, 1999) and previous research has shown that decreases in depression can occur alongside successful weight loss (Wadden, Berkowitz, Vogt, Steen, Stunkard, & Foster, 1997). Therefore, depression levels were measured at all office visits occurring during the data collection period using the PHQ-9. This is a 9-item questionnaire designed to measure depression levels in medical settings. The PHQ-9 was already being used in the office as a depression screening tool prior to study initiation so it was easily available, familiar to staff, and part of the existing office work flow. It takes less than 5 minutes to complete and has been found to have diagnostic validity (Spitzer, Kroenke, & Williams, 1999). Participants completed the PHQ-9 while waiting to be seen by their physician at each office visit. Total PHQ-9 scores were used as an outcome measure in the current study.

Sleep. Sleep issues have been found to commonly co-occur with obesity (Aronne, 2001; Must et al., 1999; National Heart, Blood, and Lung Institute, 2001). Twelve questions, derived from evidence-based recommendations for assessing sleep (Bloom et al., 2009), were utilized to assess the quality of participant sleep throughout the study (Appendix B). This questionnaire was administered at all office visits occurring during the data collection period. Participants completed the sleep questionnaire at each visit while waiting to be seen by their physician. The total number of items endorsed as a "yes" (out of a possible 9 questions) was used as an outcome measure of overall sleep quality, with higher numbers indicating poorer sleep quality.

Secondary Outcomes: Behavioral Intervention

Diet and exercise habits. At the initial office visit occurring during the recruitment period, participants in the behavioral intervention condition completed a questionnaire assessing their current level of motivation and willingness to try a variety of different diet modification

22

strategies and physical activity changes (Appendix C). This information was used to assist physicians in selecting specific diet and exercise goals that were individually relevant for each participant. This questionnaire was also completed at all additional follow-up visits that occurred during the data collection period to assist PCPs in monitoring participant progress towards existing goals and establishing new goals as needed. Data were not used in any formal analyses.

Treatment adherence. Physicians were asked to record the specific diet and exercise goals set with participants receiving the behavioral intervention during the initial office visit in their EMR notes. The percentage of initial office visit notes including specific goals was used as a measure of treatment adherence for PCPs delivering the behavioral intervention. The number of MyChart follow-up messages exchanged between participants and PCPs was used as an additional measure of treatment adherence for the behavioral intervention group.

Consumer satisfaction. At the completion of the data collection period, both physicians and participants in the treatment condition were asked to complete a brief 3-item measure assessing the utility and feasibility of the behavioral intervention (Appendix G). Each question was rated on a 1 (strongly disagree) to 5 (strongly agree) scale, resulting in 15 total possible points. Both paper and pencil and electronic versions of the questionnaire were available. Numerical ratings as well as qualitative comments were recorded and analyzed.

Study Design

The first stage of the study involved the recruitment of participants. All regularly scheduled obesity related chronic health condition follow-up or yearly physical visits occurring over a one-month period were screened for eligible participants who met study inclusion criteria. Treatment condition (usual care or behavioral intervention) was determined by the pre-existing assigned PCP for each participant. Participants were followed for up to 12 months after their

initial office visit and entry into the study. Relevant and available physiological measures as well as mood, sleep quality, and diet/exercise habits (behavioral intervention condition only) questionnaires were completed at all office visits occurring during the data collection period. Data was collected at all office visits for participants in the behavioral intervention condition regardless of compliance with the between visit MyChart physician check-ins.

Data Analysis

Descriptive statistics were utilized to characterize participant demographics, treatment adherence, and consumer satisfaction data. Pretreatment differences between the usual care and behavioral intervention conditions were analyzed using Pearson's chi-square tests and independent measures t-tests.

Between group outcome analyses were conducted on an intent-to-treat sample using the Linear Mixed Models procedure in SPSS, version 24. A mixed models framework was selected because it does not require repeated measures data to be collected at equal timepoints across all participants and it allows for the inclusion of cases with missing data. A correlated random effects model was utilized with participant I.D. entered as the subject variable. Treatment condition, time, and treatment condition*time interactions were entered as fixed factors. Random factors included participants entered as a subject grouping. Time was recorded as number of months since baseline which resulted in rates that reflect the amount of change/month for all outcome variables. All outcome measures were analyzed individually using an unstructured covariance model.

Effect size analyses were calculated using Cohen's d for all dependent variables to assess the amount of clinically significant change achieved. Last available outcome data from the behavioral intervention group were contrasted with last available outcome data from the usual

care group. For participants in the behavioral intervention condition only, bivariate Pearson product-moment correlations were used to analyze the relationship between outcome variables and degree of treatment adherence, as measured by the number of MyChart messages exchanged between participants and providers.

All participants were included in analyses as long as they received either the behavioral intervention or usual care and contributed outcome data during at least one time point throughout the study. Every effort was made to obtain outcome data at two or more time points from as many participants as possible. Of the 291 eligible patients contacted about participation in the study during the recruitment period, 33 (11.34%) consented to participate (see Figure 1). The majority of those who did not participate, never responded to the initial MyChart message about the study. Of the 33 participants who consented to participate, data from 32 were used in final analyses. One participant was excluded from receiving the behavioral intervention due to PCP concerns regarding the appropriateness of weight loss given the patient's age and BMI.

Over the course of the 12-month data collection period, data were obtained at two or more time points from 29 participants. Data were obtained only during an initial office visit for the remaining three participants. One of these three participants chose to voluntarily withdraw following the initial office visit, and thus no further data was collected. The other two participants never attended a follow-up visit during the data collection period. Additionally, one participant received bariatric surgery and another became pregnant during the course of the study so only data collected prior to these events were utilized in analyses.
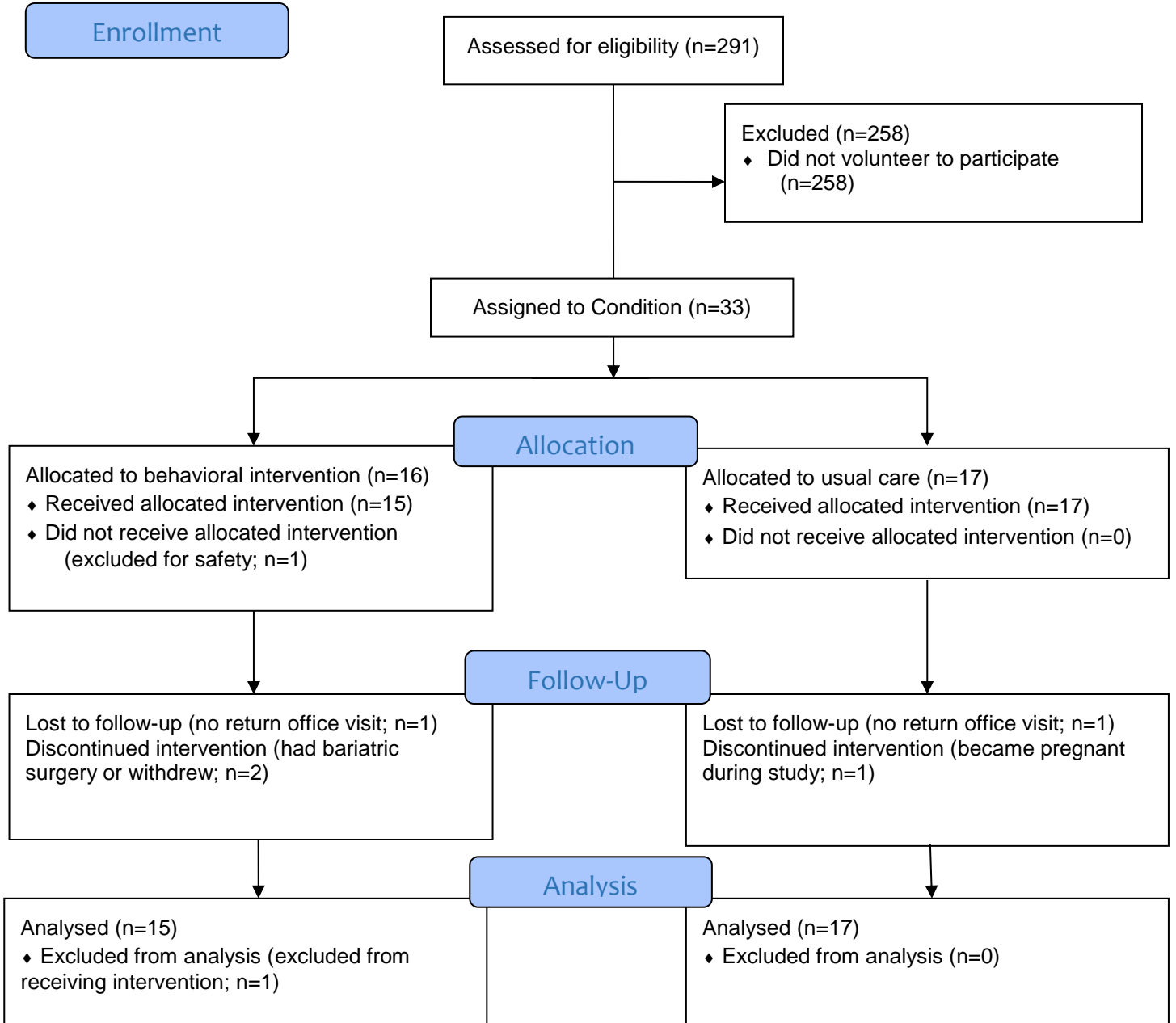
Participant Flow Diagram

Figure 1. Participant Flow Diagram

RESULTS

Demographics and Pre-Treatment Variables

Of the final sample of 32 participants, 15 (47%) received the brief behavioral intervention and 17 (53%) received usual care. At baseline, 25% of the total sample was overweight and 75% was obese (see Figure 2). There were a total of 9 (28%) male (n = 5 intervention; n = 4 usual care) and 23 (72%) female participants (n = 10 intervention; n = 13 usual care). The average age of the entire sample was 54.69 years (SD = 14.85, range = 27–78). Participants in the intervention group were slightly older (M = 57.53, SD = 14.69) than participants in the usual care group (M = 52.18, SD = 14.97). Male participants (M = 62.22, SD = 15.44) were also slightly older than female participants (M = 51.74, SD = 13.84). There were no statistically significant differences between participants in the behavioral intervention and usual care conditions on any of the demographic or outcome variables at baseline (see Table 1).

Table 1
Pre-treatment Differences for Demographic and Outcome Variables

Variable	t	p	Variable	t	p
Age	-1.019	0.316	LDL Cholesterol	2.151	0.051
Weight	0.696	0.492	Cholesterol Ratio	1.736	0.106
BMI	-0.417	0.680	Systolic BP	-1.670	0.105
Hemoglobin A1c	-0.400	0.703	Diastolic BP	1.368	0.181
Total Cholesterol	1.660	0.121	Sleep Quality	0.697	0.491
Triglycerides	0.862	0.404	Depression	0.532	0.599
HDL Cholesterol	-1.269	0.227	*Gender	0.379	0.538

Note. *=nominal variable for which Pearson chi-squared (x^2) analysis was used instead of independent measures t-test analysis; BP = blood pressure; BMI = body mass index.
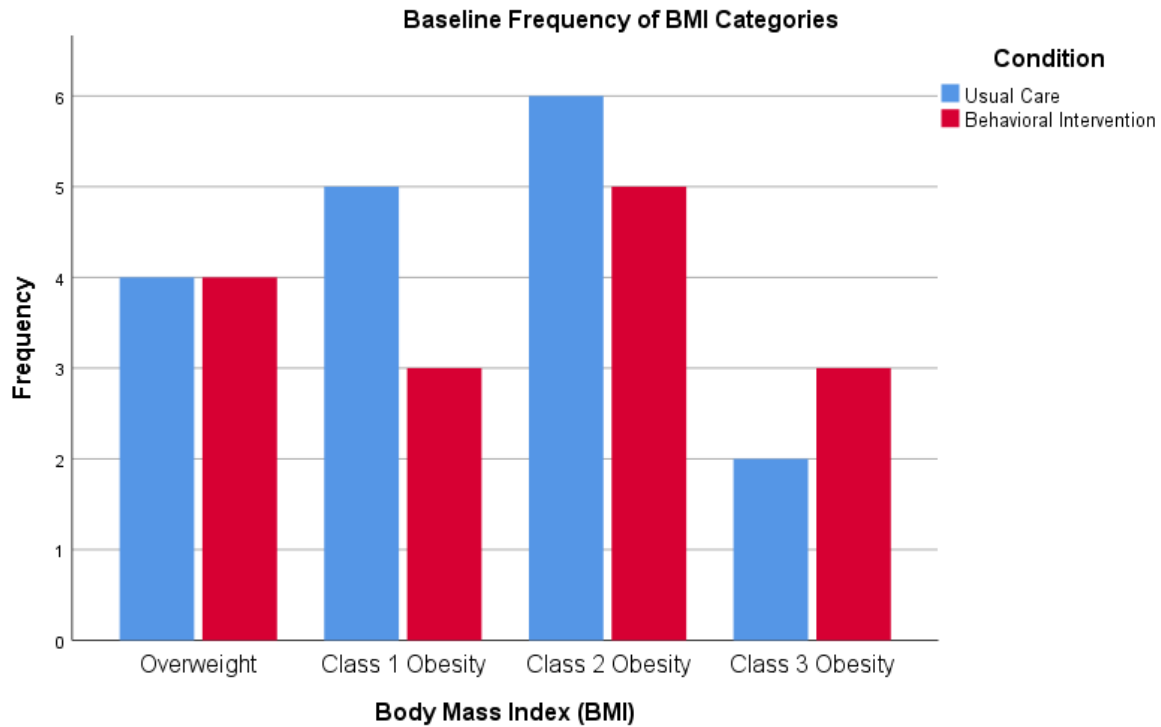
Figure 2. Baseline Frequency of BMI Categories

Treatment Adherence

The number of office visits attended by participants during the course of the study was similar across both the behavioral intervention and usual care groups (see Figure 3). Treatment adherence data was collected in order to monitor the degree to which participants in the behavioral intervention condition received important additional intervention components. Specific diet and exercise goals were recorded by physicians in EMR visit notes for all but one (14/15) eligible initial office visit with participants in the behavioral intervention group. This represents a 93.3% adherence rate. Participants in the intervention group sent their physicians an average of 7.6 (SD = 9.66) MyChart message updates regarding weight loss and progress towards diet and exercise goals during the course of the data collection period. The number of MyChart messages sent by individual participants ranged from zero to 28.

28
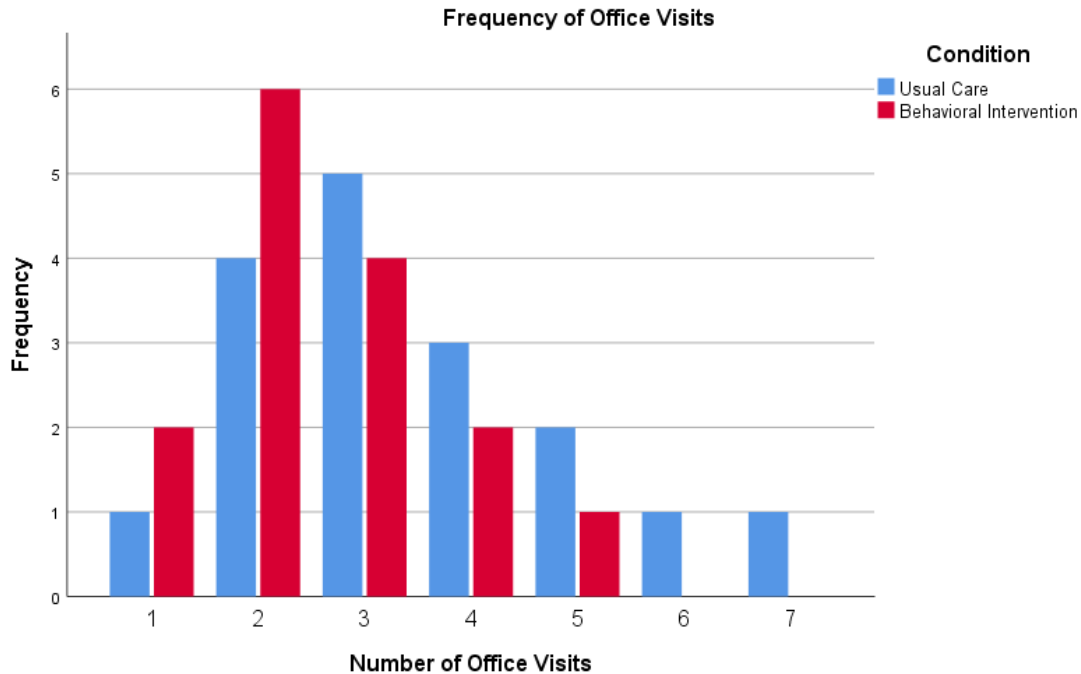
Figure 3. Number of Office Visits Attended by Participants Throughout the Study

In order to evaluate whether a dose-response relationship was present in the behavioral intervention condition between any of the outcome variables and the number of MyChart exchanges that occurred, bivariate Pearson product-moment correlation analyses were conducted (see Table 2). No relationship was found between weight, BMI, triglycerides, or diastolic blood pressure and number of MyChart messages exchanged. A weak relationship was found between HDL cholesterol, systolic blood pressure, sleep quality, depression and MyChart messages indicating that as the number of MyChart messages increased, depression, sleep quality, and HDL cholesterol improved, whereas systolic blood pressure worsened. A medium strength relationship was found between total cholesterol, cholesterol ratio, LDL cholesterol and MyChart messages, indicating that as the number of MyChart exchanges increased, scores on these variables improved (decreased). Finally, a strong relationship was observed between hemoglobin A1c and MyChart messages ($r = -0.589$), indicating improvement (decrease) in A1c values as the

29

number of MyChart exchanges increased. Specifically, the number of MyChart messages sent explains 34.7% of the variation in A1c values ($r^2 = 0.347$).

Table 2
Pearson Correlation Coefficients for Number of MyChart Messages and Outcome Variables in the Behavioral Intervention Group

Variable	r	Variable	r
Weight	0.072	*LDL Cholesterol*	*-0.501*
BMI	-0.034	*Cholesterol Ratio*	*-0.426*
Hemoglobin A1c	**-0.589**	Systolic BP	0.198
Total Cholesterol	*-0.413*	Diastolic BP	0.090
Triglycerides	0.041	Sleep Quality	-0.275
*HDL Cholesterol	0.136	Depression	-0.255

Note. Boldface values indicate strong correlations ($r = 0.5$-1.0); italicized values indicate medium strength correlations ($r = 0.3$-0.5); BP = blood pressure; BMI = body mass index; *=higher scores indicate improved outcomes (higher scores indicate worse outcomes for all other variables).

Linear Mixed Modeling

There were no statistically significant main effects of time, however, one statistically significant treatment*time interaction effect was found in the linear mixed modeling analyses. There was a statistically significant difference in the rate of change for A1c in the intervention group relative to the usual care group (F = 5.20; *p* = .047). Specifically, A1c decreased over time in the intervention group and increased over time in the usual care group (see Figure 4). The overall numerical pattern of results is mixed across the remaining outcome variables (see Table 3). Decreased scores are associated with improvement across all outcome measures except for HDL cholesterol where increased scores are associated with improvement.

For weight (see Figure 5), and to a lesser degree BMI (see Figure 6), rates of change indicate numerical reduction (improvement) over time in both the intervention and usual care

groups, with a trend towards greater improvement in the usual care group. The following descriptive data was also obtained regarding clinically significant (≥3kg) weight loss over the course of the study. In the intervention group, 4 participants (30.77% of those who had data collected at multiple time points) achieved clinically significant weight loss. One of these four participants lost more than 10% of initial body weight. In the usual care group, 5 participants (31.25% of those who had data collected at multiple time points) achieved clinically significant weight loss. Four of these five individuals also lost 5-10% of their initial body weight.

Numerical rates of change for total cholesterol (see Figure 7) indicate relative stability/ slight reduction (improvement) over time for the usual care group compared with a trend towards more substantial reduction in the intervention group. Numerical rates of change for triglycerides (see Figure 8) indicate an upward (worsening) trend over time in the usual care group compared with a downward (improving) trend over time in the intervention group. Numerical rates of change for systolic blood pressure (see Figure 9) and depression (see Figure 10; approaching statistical significance) indicate relative stability/slight increase (worsening) over time for the usual care group compared to a trend towards reduction (improvement) in the intervention group.

For HDL cholesterol (see Figure 11) and diastolic blood pressure (see Figure 12), the numerical rates of change indicate a trend towards worse outcomes over time, more so in the intervention group than the usual care group. Numerical rates of change for cholesterol ratio (see Figure 13) reveal overall stability with a very slight trend towards worse outcomes for both groups over time, particularly the usual care group. Rates of change for LDL cholesterol (see Figure 14) and sleep quality (see Figure 15) reveal a numerical upward (worsening) trend for the intervention group and a downward (improving) trend for the usual care group.

31
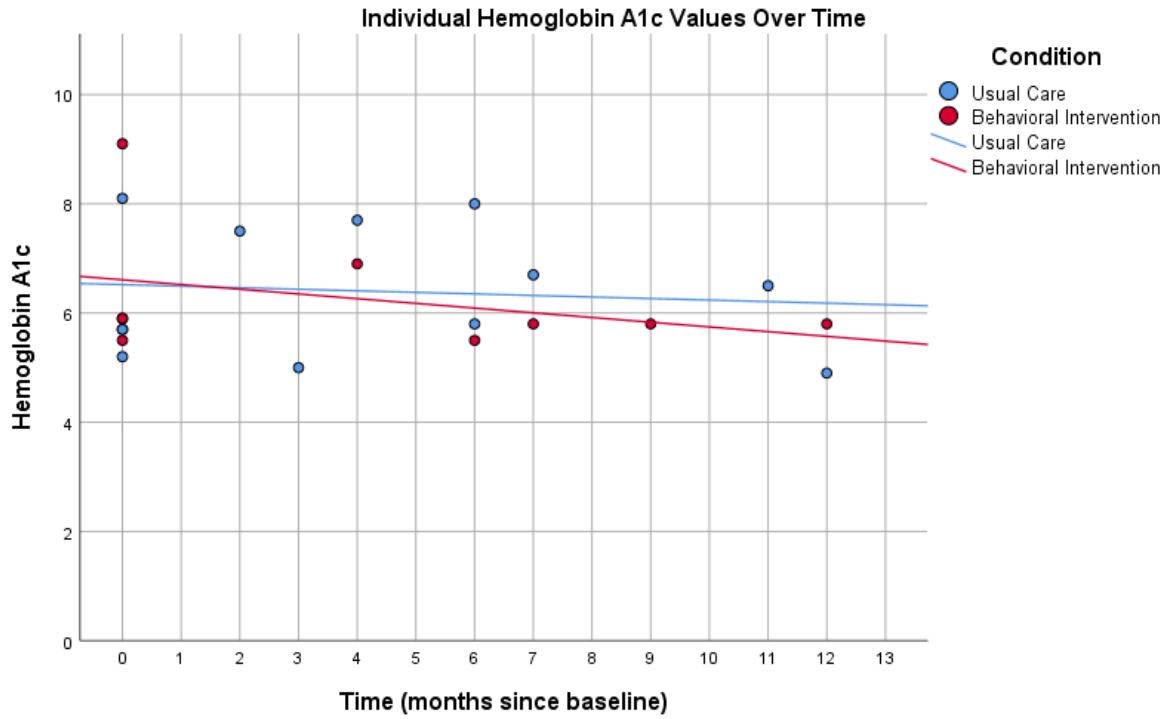
Figure 4. Individual Hemoglobin A1c Values Over Time
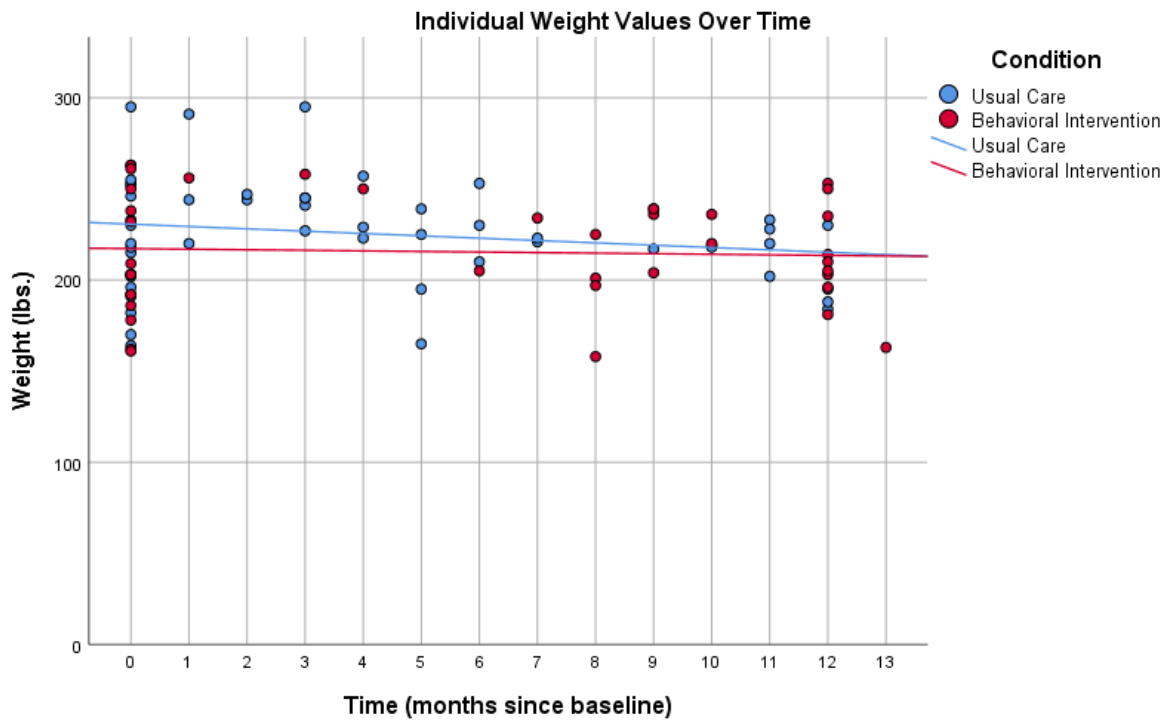
Figure 5. Individual Weight Values Over Time

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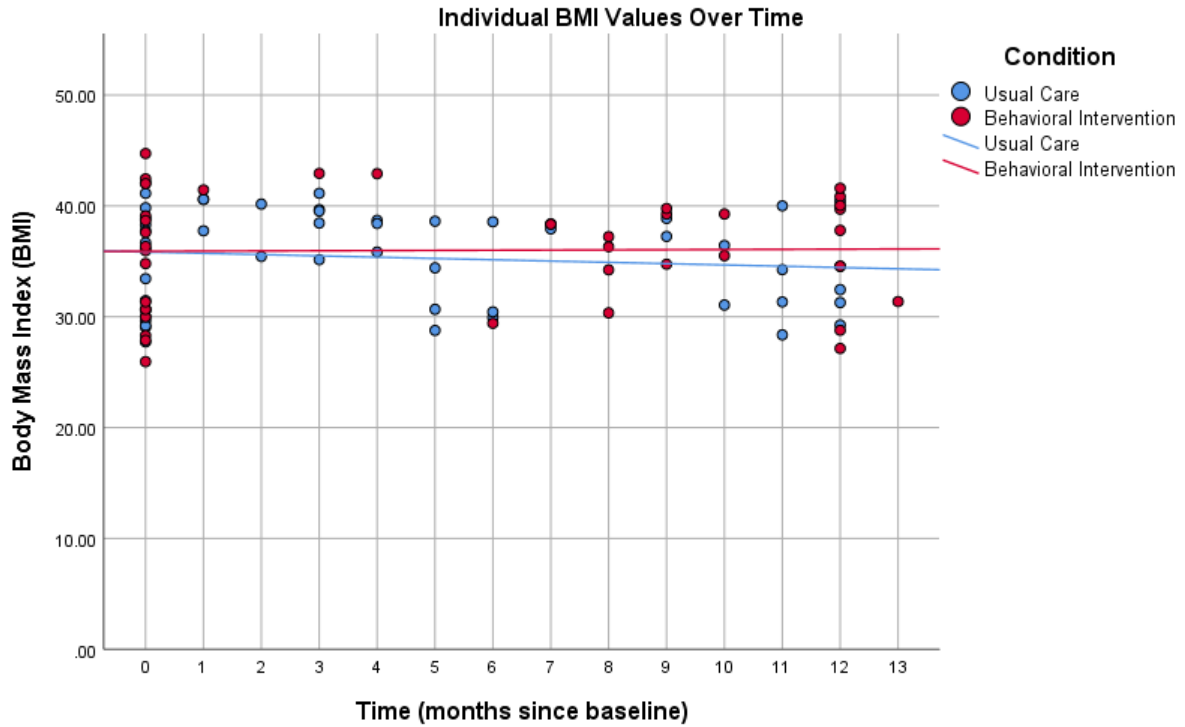
Figure 6. Individual BMI Values Over Time
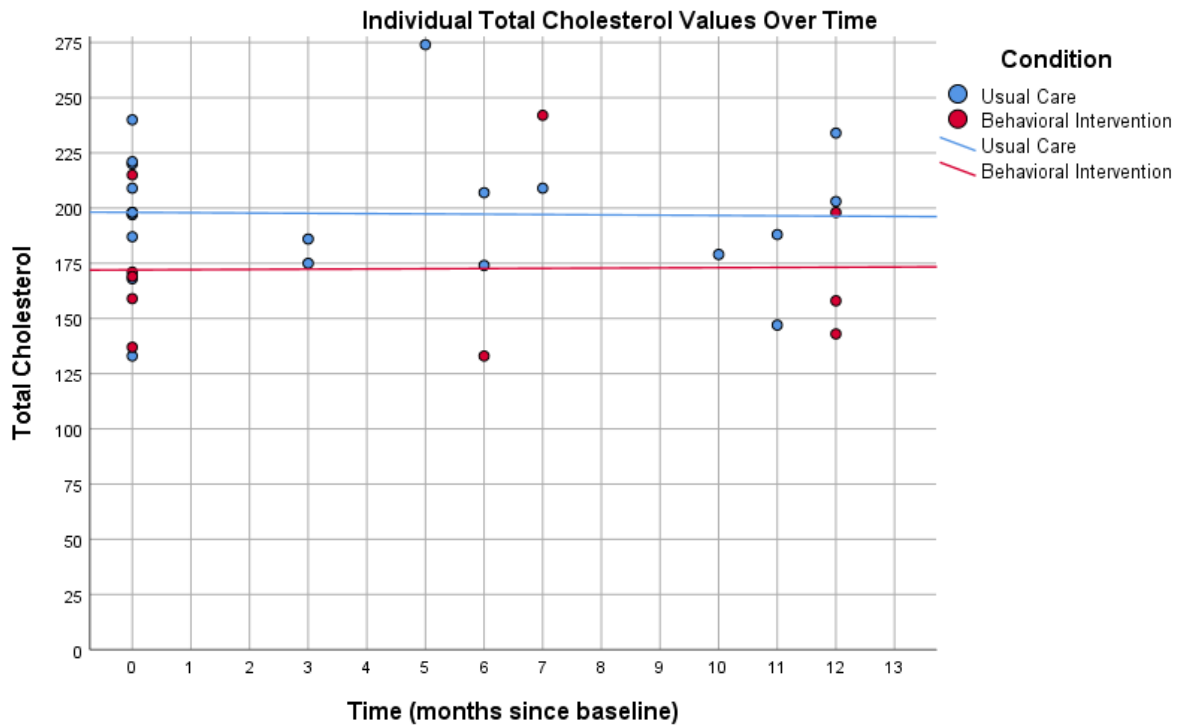
Figure 7. Individual Total Cholesterol Values Over Time

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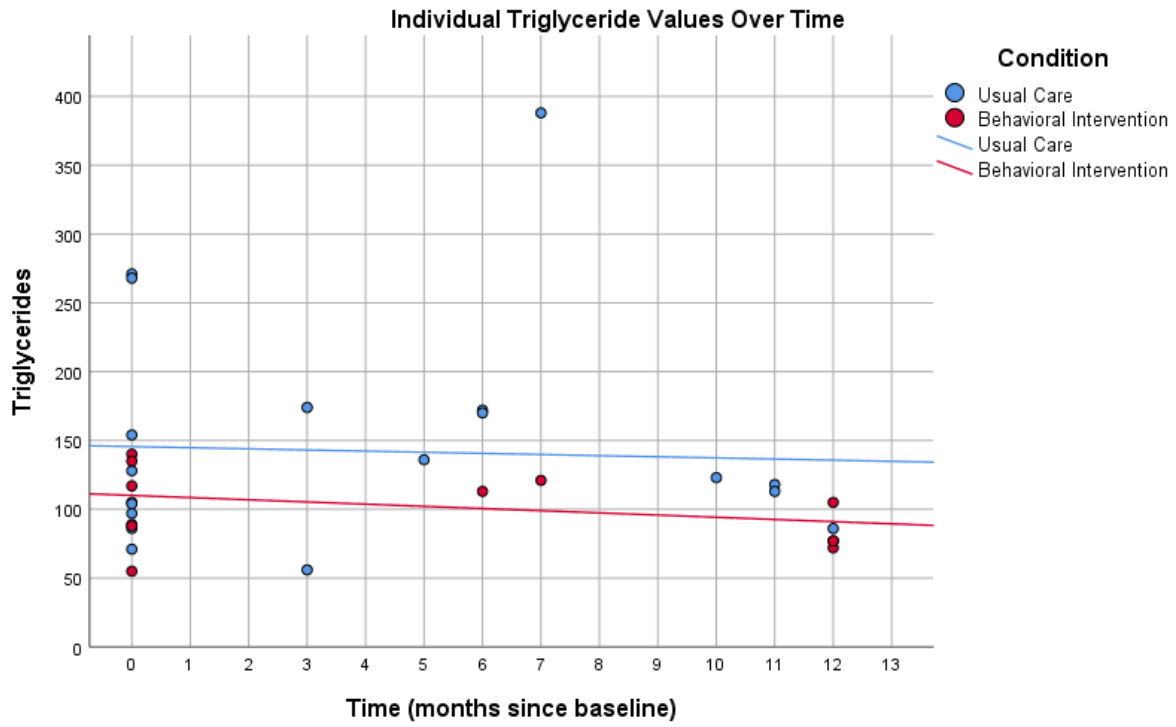
Figure 8. Individual Triglyceride Values Over Time

Figure 9. Individual Systolic Blood Pressure Values Over Time
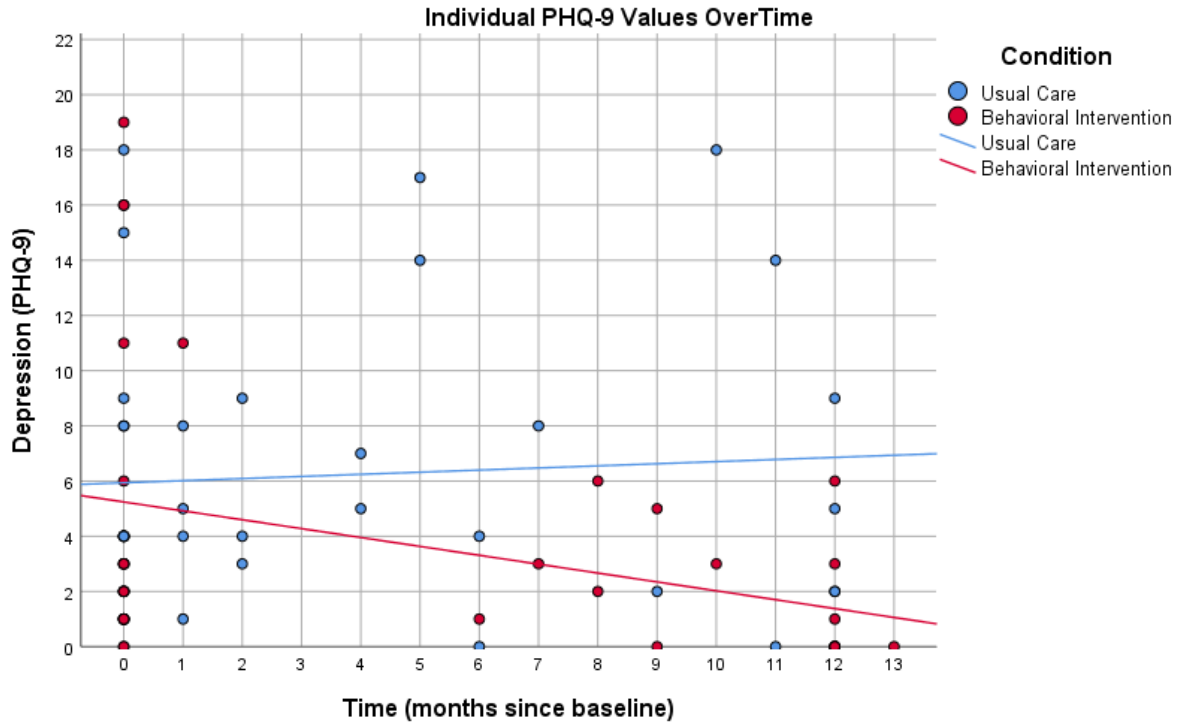
Figure 10. Individual PHQ-9 Values Over Time
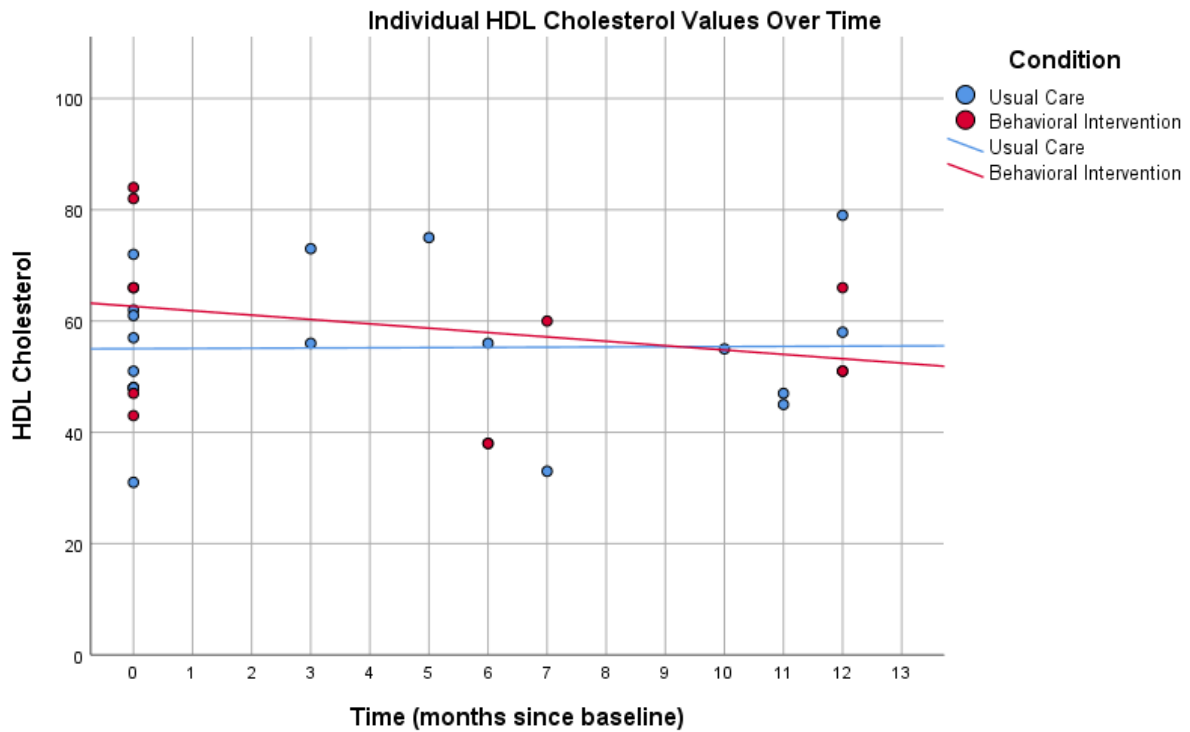
Figure 11. Individual HDL Cholesterol Values Over Time

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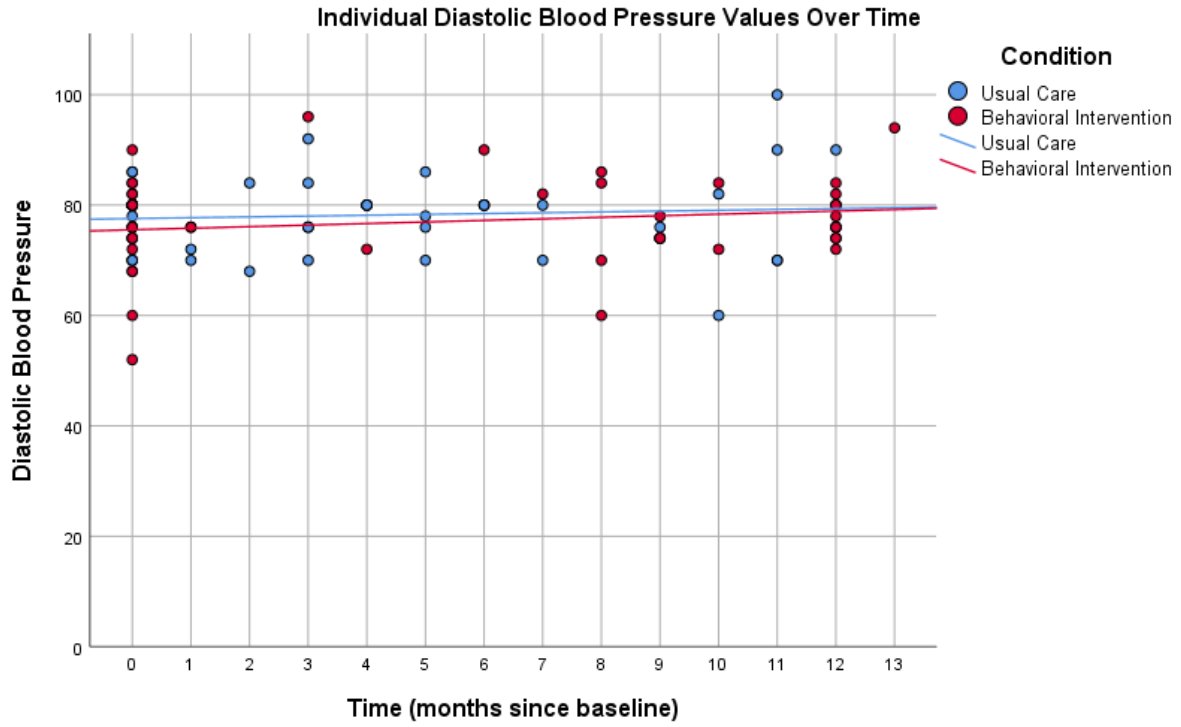
Figure 12. Individual Diastolic Blood Pressure Values Over Time
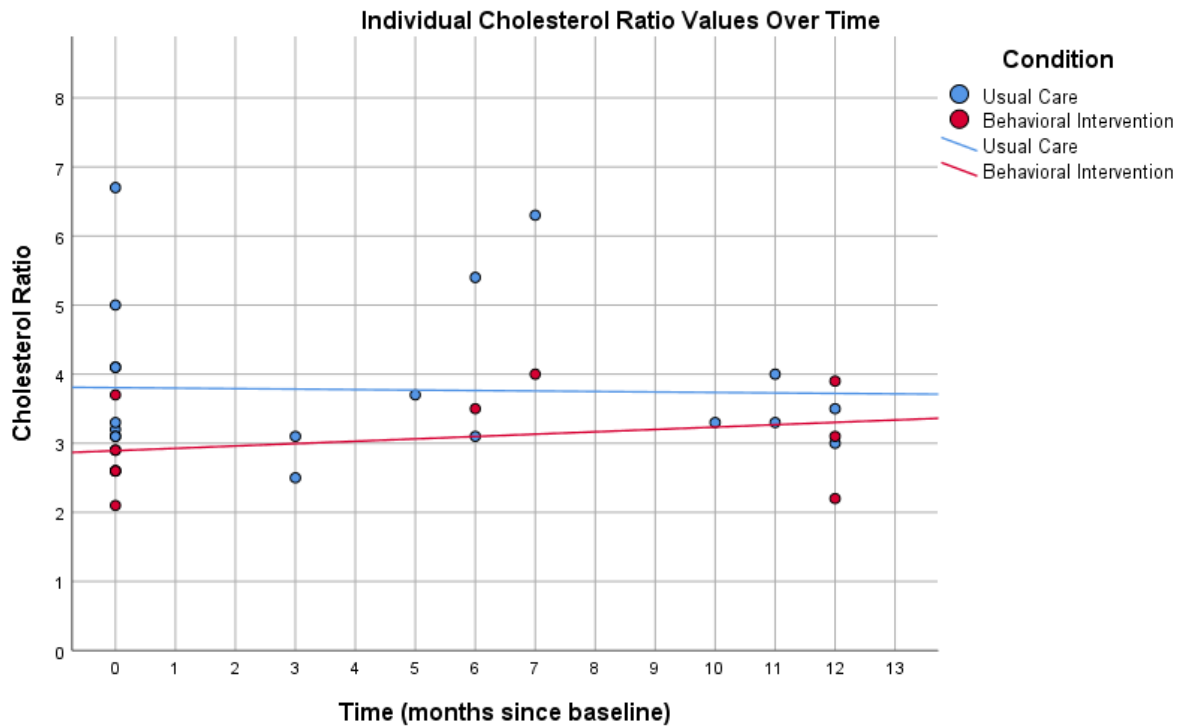
Figure 13. Individual Cholesterol Ratio Values Over Time
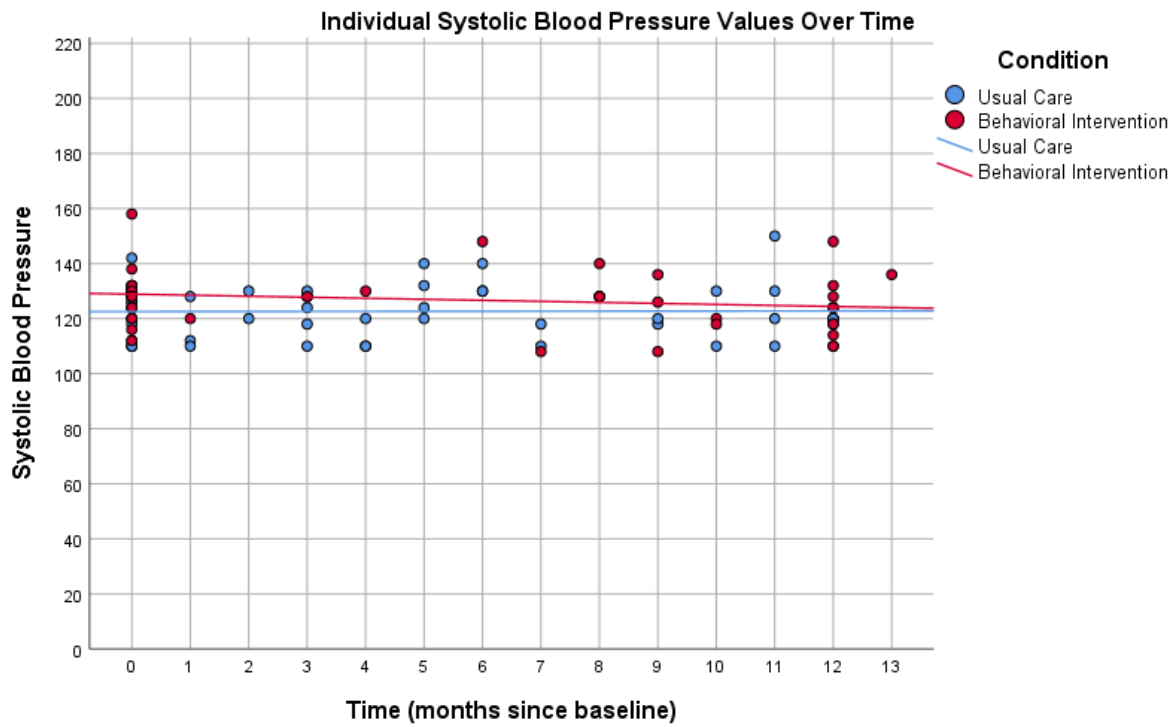
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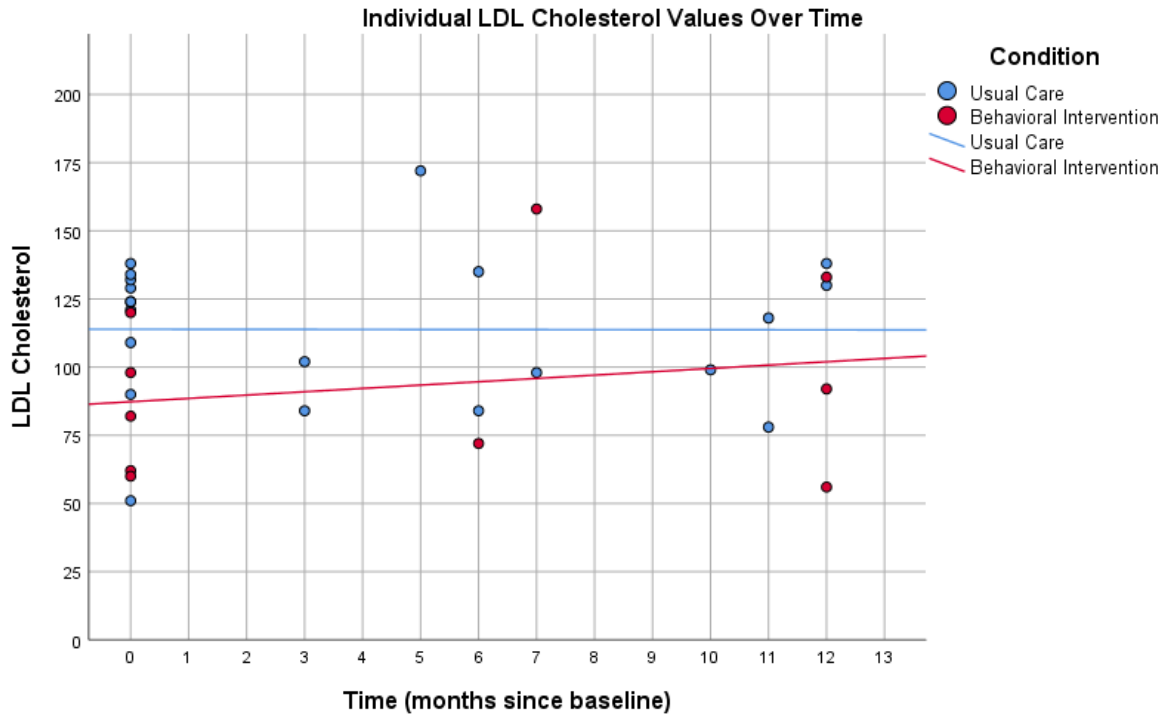
Figure 14. Individual LDL Cholesterol Values Over Time
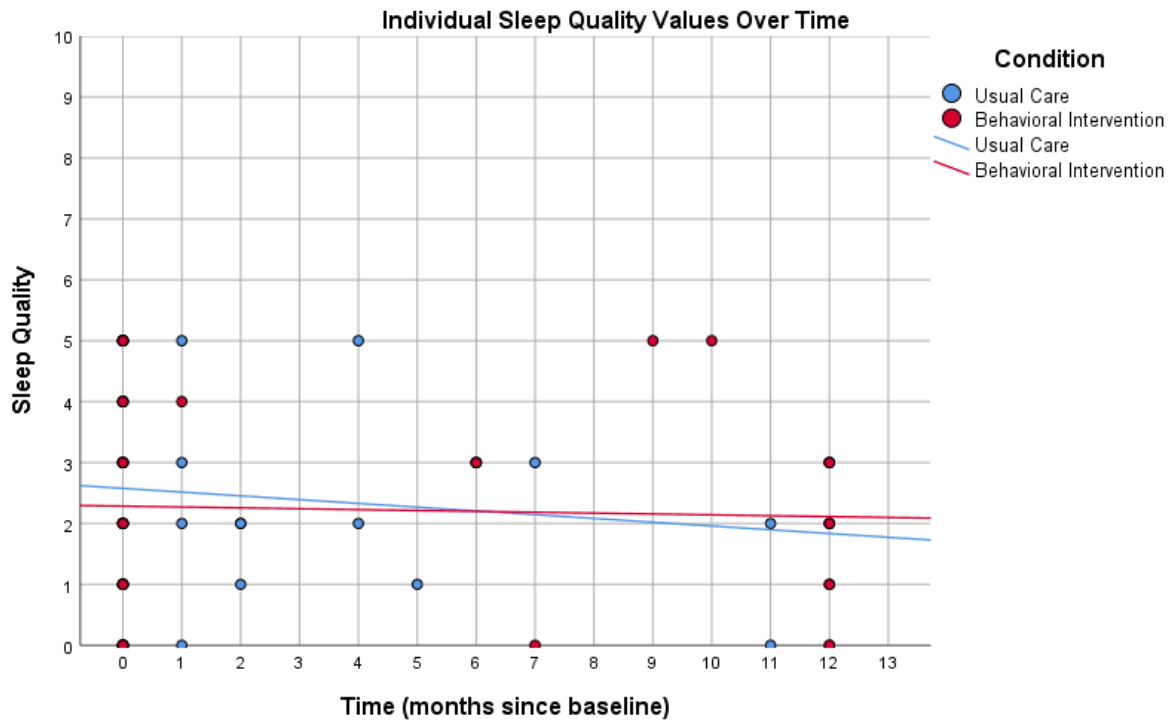
Figure 15. Individual Sleep Quality Values Over Time

37

Two representative case examples of participants in the behavioral intervention group (with the same PCP) are presented to illustrate changes in weight and associated health conditions over the course of the study. The first is a 69-year-old female who attended three office visits (baseline, 3 months, and 12 months) and exchanged 28 MyChart messages with her PCP. Her weight dropped from 261 lbs. at baseline to 250 lbs. 12 months later at her final office visit. This represents an overall weight loss of 11 lbs. or just over 4% of her initial body weight. Her BMI went from 44.73 at baseline to 41.6 at 12 months. While she remained in the most severe category of obesity throughout the study (BMI ≥40), she was able to lower her BMI by several points. Additionally, her cholesterol values at baseline were: total:169, triglycerides: 135, HDL: 82, LDL: 60, and ratio: 2.1. At her 12-month follow-up visit her cholesterol values were: total: 143, triglycerides: 105, HDL: 66, LDL: 56, and ratio: 2.2. These values reflect a decrease across total cholesterol, triglycerides, and LDL, all of which reflect improvement and decreased risk of heart disease. While HDL cholesterol also decreased, and her ratio increased slightly, which reflect changes in the undesired direction, all cholesterol values were within normal range. Blood pressure was 130/84 at baseline and 124/74 at 12 months, revealing improvement in both systolic and diastolic blood pressure throughout the study. No A1c values were collected. Sleep quality and depression scores both decreased from a value of 1 at baseline to a value of 0 at 12 months, revealing an absence of sleep and depression concerns. She completed the consumer satisfaction survey at the conclusion of the study and gave the intervention the highest rating of 5 across all categories, resulting in a total score of 15/15. Additionally, she commented: "I became more focused and motivated to change my behavior."

Another case is that of a 37-year-old female who had two office visits (baseline and 12 months) but did not send any between-visit MyChart check-ins to her PCP during the course of

the study. Her weight went from 203 lbs. at baseline to 210 lbs. at 12 months. This reflects an overall weight gain of 7 lbs. or 3.4% of her initial body weight. BMI went from 35.96 at baseline to 37.8 at 12 months, moving her closer to the severe obesity range. Her blood pressure went from 112/74 to 128/84, demonstrating worsening of both systolic and diastolic blood pressure from baseline to 12-month follow-up. No A1c data was collected. Cholesterol values were not collected at baseline, however, values at 12 months were: total: 198, triglycerides: 72, HDL: 51, LDL: 133, ratio: 3.9. These values reveal low HDL and elevated LDL and ratio values. In contrast to poor physical health outcomes, both sleep quality and depression scores improved over the course of the study, moving from 4 to 2 and 3 to 0 respectively. She also completed the consumer satisfaction survey and rated the intervention 3/5 in terms of usefulness/helpfulness, 4/5 in terms of feasibility, and 3/5 in terms of likelihood of recommending this intervention to others. This resulted in a total score of 10/15 accompanied by the following comment: "I lacked follow through." In summary, these case studies provide additional qualitative evidence for the important role that participant engagement and frequent between-visit check-ins can play in improving outcomes.

Table 3
Fixed Effect Estimates from Intent-to-Treat Analyses Using SPSS Linear Mixed Modeling

Variable	Intercept	Condition	Time Main Effect		Condition*Time Interaction		
			F	p		F	p
Weight (n = 90)	220.075	-8.114	-0.322	7.754	0.191	0.139	0.174	0.678
BMI (n = 90)	34.265	0.874	-0.040	0.660	0.420	0.008	0.012	0.912
Hemoglobin A1c (n = 21)	5.859	0.849	0.048	2.731	0.132	**-0.104**	**5.200**	**0.047**
Total Cholesterol (n = 31)	198.391	-21.462	-0.015	0.000	0.990	-0.357	0.032	0.862
Triglycerides (n = 31)	136.201	-25.947	1.452	0.511	0.487	-3.105	0.808	0.383

39

Table 3 – continued

Variable								
*HDL Cholesterol (n = 31)	56.239	4.425	-0.160	0.231	0.640	-0.320	0.310	0.588
LDL Cholesterol (n = 31)	115.144	-20.742	-.0175	0.032	0.862	0.623	0.140	0.715
Cholesterol Ratio (n = 31)	3.711	-0.622	0.010	0.109	0.746	-0.004	0.007	0.934
Systolic BP (n = 90)	122.768	6.169	0.031	0.011	0.917	-0.341	0.715	0.401
Diastolic BP (n = 90)	77.711	-2.114	0.188	0.601	0.441	0.177	0.285	0.595
Sleep Quality (n = 62)	2.442	-0.299	-0.085	2.433	0.128	0.090	1.596	0.215
Depression (n = 71)	6.099	-1.226	0.011	0.011	0.917	*-0.260*	*3.321*	*0.076*

Note. Boldface values reflect statistical significance ($p<.05$); italicized values reflect approaching statistical significance; BP = blood pressure; BMI = body mass index; n = sample size; * = higher scores indicate improved outcomes (higher scores indicate worse outcomes for all other variables)

Table 4
Effect Sizes for Dependent Variables

Variable	Usual Care		Behavioral Intervention		Cohen's d
	n	Mean (SD)	n	Mean (SD)	
Weight	17	217.18 (34.23)	15	210.33 (30.60)	-0.21
BMI	17	33.86 (4.40)	15	34.92 (5.56)	0.21
Hemoglobin A1c	5	6.26 (1.25)	5	6.42 (1.51)	0.12
Total Cholesterol	12	196.42 (37.82)	8	174.63 (39.92)	**-0.56**
Triglycerides	12	144.25 (83.27)	8	100.00 (28.94)	**-0.71**
*HDL Cholesterol	12	55.33 (13.80)	8	57.88 (14.28)	0.18
LDL Cholesterol	12	112.17 (32.59)	8	96.88 (36.50)	-0.44
Cholesterol Ratio	12	3.72 (1.07)	8	3.10 (0.65)	**-0.69**
Systolic BP	17	123.18 (11.73)	15	127.07 (12.00)	0.33
Diastolic BP	17	80.12 (8.96)	15	80.00 (6.76)	-0.01
Sleep Quality	17	1.82 (1.55)	15	2.20 (1.74)	0.23
Depression	17	6.06 (6.15)	15	2.40 (3.29)	**-0.74**

Note. Boldface values indicate medium effect size (Cohen's d: 0.2 = small, 0.5 = medium, 0.8 = large effect); BP = blood pressure; BMI = body mass index; SD = standard deviation; n = sample size;*=higher scores indicate improved outcomes (higher scores indicate worse outcomes for all other variables)

Effect size analyses (see Table 4) revealed no effect for Hemoglobin A1c, HDL cholesterol, or diastolic blood pressure and only a small effect for weight, BMI, LDL cholesterol, systolic blood pressure, and sleep quality. Medium sized effects were found for total cholesterol, triglycerides, cholesterol ratio, and depression. No large effect sizes were found for any of the dependent variables measured in the study.

<div align="center">Consumer Satisfaction</div>

Qualitative and quantitative (see Table 5) consumer satisfaction data was obtained from both physicians and participants involved in the behavioral intervention. Each of three questions was rated on a 1 (strongly disagree) to 5 (strongly agree) scale, resulting in a total of 15 possible points. Ratings from the two physicians who delivered the intervention revealed an average rating of 4.0 (SD = 1.41) for the degree to which they found the intervention to be useful, 4.5 (SD = 0.71) for the degree to which the intervention was manageable in terms of time requirements, and 4.0 (SD = 1.41) for the likelihood that they would recommend this intervention to others. The average of their overall total satisfaction ratings was 12.5 (SD = 3.54). Individual comments revealed that it took approximately 15-30 seconds to respond to individual patient MyChart messages. One physician reported feeling that the intervention "helped to keep in touch with patients who were motivated and working toward a behavioral goal." This physician also noted that the individual follow-up was not burdensome due to the low number of patients who participated in the study.

Data was obtained from eight participants (53%) in the behavioral intervention group. One participant answered only the first two questions, and another provided qualitative feedback but no quantitative ratings. Therefore, complete data was obtained from 6 participants (40%). Ratings revealed an average of 3.57 (SD = 1.13) for the degree to which they found the

intervention to be useful, 4.29 (SD = 0.49) for the degree to which the intervention was

manageable in terms of time requirements, and 4.0 (SD = 0.89) for the likelihood that they would

recommend this intervention to others. The average of their overall total satisfaction ratings was

12.17 (SD = 2.32); however, these data are interpreted cautiously given the low response rate.

Individual comments revealed that the intervention was "painless, interesting, and beneficial" as

well as being helpful with "focus and motivation to change behavior." One patient stated:

"talking to my doctor weekly, biweekly, or monthly was a great way to maintain an ongoing

conversation regarding goals, expectations, and successes." Another patient acknowledged, "I

lacked follow through on this intervention."

Table 5
Consumer Satisfaction Data from Physicians and Participants in the Behavioral Intervention Group

Respondent	Q1: Helpful/Valuable M(SD)	Q2: Reasonable/Manageable M(SD)	Q3: Recommend M(SD)	Total M(SD)
Physicians (n = 2)	4.0(1.41)	4.5(0.71)	4.0(1.41)	12.5(3.54)
Participants (n = 7)	3.57(1.13)	4.29(0.49)	4.0(0.89)*	12.17(2.32)*

Note. Each question was rated on a 1 (strongly disagree) to 5 (strongly agree) scale; Total score is out of 15; M = mean; SD = standard deviation; n = sample size; * = only 6 participant responses were recorded.

DISCUSSION

Obesity is a chronic health condition that continues to increase in prevalence around the world, despite the existence of several effective treatments. Obesity often presents first in primary care and is typically managed by PCPs. Therefore, the current study examined both the feasibility and effectiveness of a brief behavioral intervention for obesity and associated health conditions that was delivered by PCPs during scheduled office visits and supported by at home participant behavior tracking and regular electronic between-visit check-ins. Prior research has provided only limited data to support the efficacy, feasibility, and cost-effectiveness of mild to moderate intensity behavioral interventions delivered by PCPs (Carvajal, Wadden, Tsai, Peck, & Moran, 2013). Though more effective, the delivery of high intensity behavioral interventions requires additional time, cost, and staff demands, which may not be feasible for many primary care practices (Ryan, 2016).

PCPs play a critical role in obesity management and thus consideration must be given to the feasibility of delivering comprehensive lifestyle interventions in primary care. The current study attempted to overcome many commonly cited barriers including lack of time, resources, and knowledge (Kushner, 1995), through the use of brief physician training and regular electronic check-ins. The low-intensity, brief behavioral intervention utilized in the current study was designed as a first-tier treatment for obesity aimed at producing benefit while being low-risk and using minimal resources. Weight loss among obese individuals is known to be associated not only with decreased incidence of obesity but also a reduction in the incidence of obesity-related health conditions (Moyer, 2012). Thus, the chronic health conditions most likely to present

43

alongside obesity during PCP visits: hypertension, hyperlipidemia, diabetes, and depression (Talwalkar & McCarty, 2016) were also targeted by the current intervention.

Though participants were not randomized to study conditions, sample size and participant demographics (gender, age) were roughly equivalent across the behavioral intervention and usual care groups in the current study. Overall, there were substantially more female than male participants, however, participants were diverse in terms of age. There were no statistically significant differences found between participants in the behavioral intervention and usual care groups on any demographic or pre-treatment variables.

At baseline, 25% of the total sample had a BMI in the overweight range and 75% had a BMI in the obese range. This suggests that, in additional to lifestyle modification, nearly all study participants could likely be considered for the addition of other treatment components, including pharmacotherapy or bariatric surgery, given their BMI and the presence of associated health conditions, in accordance with national treatment guidelines (Arterburn & Courcoulas, 2014; Moyer, 2012; Ryan, 2016).

Treatment adherence data revealed that the behavioral intervention was implemented with good fidelity by PCPs, though participants varied widely in completion of regular MyChart check-ins as prescribed by the study. This variability could have impacted results, as regular electronic follow-up with PCPs between office visits was conceptualized as an important component of the behavioral intervention utilized in the current study. Correlational analyses evaluating the degree to which variability in treatment adherence, as measured by quantity of MyChart exchanges, explained any of the variation in outcome measures found mixed results. Number of MyChart messages was found to have little to no relationship with weight, BMI, triglycerides, HDL cholesterol, blood pressure, sleep, and depression. However, there was a

medium strength negative relationship found for some cholesterol variables (total, LDL, and ratio), and a strong negative relationship between MyChart messages and A1c values. This suggests that an increase in the number of between visit check-ins between participants and their PCPs is related to improvement on some outcome variables. Future studies should therefore consider ways of increasing participant adherence to study requirements, such as providing incentives, utilizing electronic tracking to monitor behavioral progress towards goals, or investigating alternative forms of communication between participants and PCPs.

Linear mixed modeling analyses revealed mixed results overall with some evidence of improved outcomes in the behavioral intervention group relative to the usual care group. Most notably, a statistically significant improvement was observed in the rate of change over time for hemoglobin A1c in the intervention group compared to the usual care group. This could be due to the strong role of diet and exercise in diabetes management and the responsiveness of A1c values to modifications in diet and physical activity. No other significant differences were found among the rates of change over time for weight or other obesity-associated health conditions between the behavioral intervention and usual care groups. However, some consistent trends can be described among the pattern of results.

Weight and BMI demonstrated numerical trends towards improvement over time across both groups, more so in the usual care group than in the intervention group, though there was not a statistically significant time effect. Additionally, several variables, including systolic blood pressure, triglycerides, total cholesterol, and depression, demonstrated numerical trends towards improvement in the intervention group relative to the usual care group. However, the variables of diastolic blood pressure, HDL cholesterol, LDL cholesterol, and sleep quality revealed numerical trends towards worse outcomes in the intervention group relative to the usual care group.

45

Interestingly, effect size analyses revealed no effect for HDL cholesterol, diastolic blood pressure, and hemoglobin A1c. This suggests that, although a statistically significant difference was found for hemoglobin A1c in the rates of change over time between the usual care and behavioral intervention groups, this difference may not be clinically meaningful. However, the number of available A1c values used in this analysis was very small. Small effect sizes were found for: weight, BMI, LDL cholesterol, systolic blood pressure, and sleep quality and medium sized effects were found for: total cholesterol, triglycerides, cholesterol ratio, and depression. This indicates that, although statistically significant differences in rates of change over time between the usual care and behavioral intervention groups were not found for these variables, it is possible that the observed differences could be clinically meaningful. This is especially relevant for depression scores, as linear mixed modeling analyses almost reached the level of statistical significance and effect size analyses revealed a medium to large effect.

Descriptive statistics revealed that approximately the same percentage of participants achieved clinically significant (≥3kg) weight loss across both groups (30.8% behavioral intervention; 31.3% usual care), though more weight was lost overall in the usual care group. This suggests that there were factors operating in the usual care group that were equally as powerful as the individualized behavioral goal setting that occurred in the intervention group. It also suggests that the brief behavioral intervention may produce significant weight loss and improvement in a subset of the primary care population.

In comparison to the POWER-UP studies (Wadden et al., 2013), where 22% of participants lost ≥5% of their initial body weight with brief education delivered by PCPs every 3 months, in the current study 1 participant in the behavioral intervention group (6.7%) and 4 participants in the usual care group (23.5%), or a total of 5 participants across both groups

(15.6%), were able to achieve ≥5% weight loss. The lower percentages in the current study could be a result of reduced visit frequency, as only 28% of participants in the current study attended an office visit at least once every 3 months. Additionally, it appears that the usual care and behavioral intervention conditions in the current study may not have been different enough from each other, as they resulted in similar rates of clinically significant weight loss. In order to maximize resources, future research should investigate for which subgroups brief behavioral intervention is likely to be most effective.

Consumer satisfaction data obtained from both physicians and patients revealed a relatively high degree of feasibility and acceptability for the brief behavioral intervention utilized in the current study. Participant data was obtained both from those who were highly adherent and sent their PCPs frequent MyChart check-in messages and those who were less adherent and sent their PCP zero or very few MyChart messages throughout the study. This variability is also reflected in participant comments (e.g., "I became more focused and motivated to change my behavior" and "I lacked follow-through on this intervention"). Participant ratings ranged from 2 to 5 for the degree to which they found the intervention to be helpful/useful, however, all participants rated the intervention highly (ratings of 4 or 5) in terms of feasibility. This is an important consideration for future studies as it suggests that perhaps more intensive interventions would be more helpful and also still be reasonably feasible for patients. However, it is notable that majority of the participants in the behavioral intervention group did not complete the consumer satisfaction survey, so the obtained data should be interpreted somewhat cautiously. Those that chose to complete the survey may represent a biased or unrepresentative sample.

Physicians reported that the level of time required to respond to regular individual patient messages was manageable and that the intervention was helpful in terms of staying in

touch with patients. Of note, the PCP who had a larger number of patients participating in the active treatment condition over the course of the study, provided slightly lower satisfaction ratings on all items. This indicates that the degree to which physicians feel that the time required to implement the intervention is feasible depends on the number of patients with whom they are implementing the intervention at a given point in time. This is an important consideration in terms of targeting the intervention to those patients who are most likely to be adherent and to benefit in order to maximize physician time and resources and patient outcomes.

One strength of the current study is the degree to which the behavioral intervention was viewed as acceptable and feasible by both patients and providers and could be easily adopted by many primary care practices. It required no additional staff or resources and only minimal training. By streamlining the behavioral weight loss counseling process through training and materials to help guide individualized physician decision making, existing time and resources are maximized. If obesity is more effectively managed with lifestyle modification in primary care, many patients may not need medications, surgery, or referrals to specialty providers. Therefore, they may avoid incurring extra costs and additional risk. A tiered model of care would reserve the use of weight loss medications, specialized nutritional or exercise counseling, and bariatric surgery for individuals who need more intensive care or are not responding to more basic physician assisted interventions. This would also allow basic weight loss interventions to be individualized and accessible to a larger portion of the population. Future research should continue to support the development of a tiered model of care for obesity.

The widespread use of lifestyle modification as a first-tier treatment for obesity, with additional interventions added as needed, is consistent with national treatment guidelines (Ryan, 2016) and has significant economic implications in addition to direct patient health benefits.

Those who aren't able to achieve significant weight loss or improvement in obesity-related

health conditions through brief behavioral intervention are at least gaining skills and knowledge.

For those patients who are successful in losing weight and/or reducing the severity of obesity-

related health conditions, there would likely be a reduction in the amount of money being spent

on medications and procedures for managing obesity and associated health conditions, thus

reducing overall medical spending. Additionally, if individuals are healthier, they will miss less

work and be less restricted in their activities, which will increase overall productivity. Having a

healthier population would decrease the demand on PCPs. If each individual patient required less

intensive care, then PCPs would be able to provide care to a larger population of individuals.

Indeed, previous research has found primary care behavioral interventions for obesity to be cost-

effective long-term (Tsai et al., 2013).

Limitations to the current study include the inconsistency of data collected across time

and participants, and also a lack of control over some extraneous variables, which may have

impacted the results. Standardization of time intervals and consistent physiological data

collection across participants were sacrificed in the current study in order to maximize time,

resource, and cost efficiency. Future studies should evaluate the feasibility and acceptability of

more intensive interventions that include standardization across time, participants, and measures,

and control over potentially confounding variables such as medication changes. Additionally,

the sample used in the current study was a recruited sample for research purposes, so it is unclear

whether or not the results are generalizable to a non-research patient population.

Another limitation of the current study is small sample size, which was largely the result

of abbreviated recruitment. It is also worth noting that, while the pool of eligible participants was

quite large among the patient population sampled, the number of eligible patients who ultimately

consented to participate was low (11%), even in comparison to other similar research studies. For example, a systematic review of 17 studies in which researchers asked for access to data contained in participant medical records revealed active consent rates ranging from 36.6% to 92.9% (Kho, Duffett, Willison, Cook, & Brouwers, 2009). In light of the low consent rate in the current study, future research should consider alternative recruitment methods which might elicit a higher response rate. Future studies should also attempt to replicate the current study with a larger sample of participants, as a larger sample size would likely allow for the detection of more consistent and robust effects.

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52

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Appendix A

Informed Consent

Western Michigan University
Department of Psychology and Homer Stryker School of Medicine

Principal Investigator: Wayne Fuqua, Ph.D.
Student Investigator: Julia Huston, M.A.
Title of Study: Primary Care Physician Delivered Brief Behavioral Intervention for Adult Obesity and Associated Health Conditions

You have been invited to participate in a research project titled "Primary Care Physician Delivered Brief Behavioral Intervention for Adult Obesity and Associated Health Conditions". This project will serve as Julia Huston's dissertation research project for the requirements of the Doctoral degree. This consent document will explain the purpose of this research project and will go over all of the time commitments, the procedures used in the study, and the risks and benefits of participating in this research project. Please read this consent form carefully and completely and please contact the researcher with any questions.

What are we trying to find out in this study?
Obesity is a chronic health condition with increasing prevalence rates worldwide. There are many physical, mental, and economic costs associated with obesity and the many associated health conditions that often accompany it. This study will evaluate the feasibility and effectiveness of a brief, structured, lifestyle intervention for obesity and associated health conditions delivered by primary care physicians.

Who can participate in this study?
You may participate if you are at least 18 years old, fluent in English, coming in for a chronic health condition follow-up or yearly physical visit during the recruitment period, active on Bronson MyChart, and have a BMI of at least 25. Women known to be pregnant will be excluded from participating in the study due to the potential risks associated with weight loss during pregnancy. If you become pregnant during the course of the study your participation will be stopped immediately for your safety.

Where will this study take place?
The study will take place at Bronson Internal Medicine Oshtemo outpatient primary care office within the context of your routine medical appointments.

What is the time commitment for participating in this study?
The time commitment for completing this study will involve spending about 10 minutes completing questionnaires before regularly scheduled physician visits occurring over the course of up to 12 months. Additionally, you may be asked to spend approximately 15 minutes per day tracking your behavior at home and sending periodic MyChart updates to your physician.

What will you be asked to do if you choose to participate in this study?
If you choose to participate, you will be asked to complete a questionnaire about your current exercise and eating habits, as well as measures assessing depression and sleep quality at regularly scheduled physician visits occurring over a 12-month interval. Some of the questions on these measures may cause you to feel upset. You may skip any questions that you do not wish

to answer. It is possible that significant symptoms of depression may be identified through these questionnaires. Your responses will be reviewed by your physician at each office visit and appropriate follow-up care will be provided as needed. Additionally, you may be asked to discuss weight, diet, and exercise with your physician during your regularly scheduled visits. Finally, you may be asked to track your diet and exercise habits at home and send periodic updates to your physician via MyChart.

What information is being measured during the study?
Physiological data collected during routine physician visits that occur during the data collection period will be obtained from your EPIC medical record including:
- Weight
- BMI
- Blood pressure
- Cholesterol
- Hemoglobin A1c

Additionally, the following symptoms will be measured via self-report questionnaires which will be completed via MyChart or in-person at all routine physician office visits that occur during the data collection period:
- Sleep quality
- Depression
- Diet and exercise habits

Finally, treatment compliance and acceptability will be measured by:
- Frequency of physician-patient MyChart exchanges relevant to specific diet and exercise goals created during office visits
- Consumer satisfaction questionnaires completed by patients and office staff

What are the risks of participating in this study and how will these risks be minimized?
One possible risk that you may experience is psychological distress produced by failure to lose weight or follow through on exercise and diet goals. To minimize this risk, you will be offered additional weight loss resources at the conclusion of the research study. Another potential risk is the sharing of data collected during the research study. To minimize this risk all identifiable participant data will be maintained at the Bronson Internal Medicine Office. Once collected, all data will be de-identified and stored on a password protected external hard drive.

What are the benefits of participating in this study?
Direct benefits of the study may include weight loss, reduction in BMI and the severity of obesity related health conditions, as well as improvements in mood and sleep quality.

Are there any costs associated with participating in this study?
Costs may include the effort necessary to modify daily habits and the time that it takes to complete daily behavior tracking and report progress to physicians. To minimize this cost, goals will be specific and realistic and tracking will be individualized.

Is there any compensation for participating in this study?
There is no monetary compensation for participating in this study.

Who will have access to the information collected during this study?
Only the student investigator will have direct access to identifiable patient information collected from questionnaires or the Bronson EPIC system. All Identifiable patient data will be maintained at the Bronson Internal Medicine office. Both the primary and student investigators will have access to de-identified participant data which will be maintained on a password-protected external hard drive and stored in a locked cabinet in the WMU Behavioral Medicine Lab for at least three years after the research study has ended. It is the intent of the researchers to present this data at a professional conference and/or publish it in a journal article. At any point you may choose to withdraw your permission for study investigators to access your previously collected data. If you choose to do this, please contact either the primary (Wayne Fuqua) or student (Julia Huston) investigators using the contact information provided below and your data will be removed from all identifiable and de-identified data records associated with the research study.

What if you want to stop participating in this study?
Participation in this study is completely voluntary. There are no consequences for choosing not to participate and your medical care will not be altered if you choose not to participate. If you decide to participate, you can choose to withdraw from the study at any time for any reason. You will not suffer any prejudice or penalty for choosing to stop your participation. You will experience NO consequences if you choose not to participate or to withdraw from this study. If you would like to withdraw from the study you may notify your physician in person or via MyChart or the student investigator via MyChart at any time. The investigators can also decide to stop your participation in the study without your consent.

Should you have any questions about your rights or any study procedures please contact the primary investigator, Wayne Fuqua at 269-387-4474 or wayne.fuqua@wmich.edu or the student investigator, Julia Huston at 740-603-2328 or julia.c.konkler@wmich.edu. Please let the study investigators know immediately if you believe you have been injured in any way as a result of your participation in the study. You may also contact the Chair of the WMU Human Subjects Institutional Review Board at 269-387-8293 or the WMU Vice President for Research at 269-387-8298 if questions or concerns about the research arise during the course of the study. You may also contact the WMed Institutional Review Board by phone at 269-337-4345 or by e-mail at wmedirb@med.wmich.edu.

This consent document has been approved for use for one year by both the WMU and WMed Human Subjects Institutional Review Boards (HSIRB) as indicated by the stamped dates and signatures of the board chairs in the upper right corner. Do not participate in this study if the stamped date is older than one year.

I have read this informed consent document. The risks and benefits have been explained to me. I agree to take part in this study.

Please type your full name below if you agree and send a message back containing a copy of the complete document with your name typed below, or choose not to type your name below if you do not agree and send a message back declining to participate. If you do not agree to participate, you will experience no consequences for choosing not to participate.

_____

Please Type Your Name

Appendix B

Sleep Quality Questionnaire

Sleep Quality Questionnaire

1. What time do you normally go to bed at night? What time do you normally wake up in the morning?

2. Do you often have trouble falling asleep at night?   YES   NO

3. About how many times do you wake up at night?

4. If you do wake up during the night, do you usually have trouble falling back asleep?

   YES   NO

5. Does your bed partner say (or are you aware) that you frequently snore, gasp for air or stop breathing?   YES   NO

6. Does your bed partner say (or are you aware) you kick or thrash about while asleep?

   YES   NO

7. Are you aware that you ever walk, eat, punch, kick, or scream during sleep?

   YES   NO

8. Are you sleepy or tired during much of the day?   YES   NO

9. Do you usually take 1 or more naps during the day?   YES   NO

10. Do you usually doze off without planning to during the day?   YES   NO

11. How much sleep do you need to feel alert and function well?

12. Are you currently taking any type of medication or other preparation to help you sleep?

    YES   NO

Appendix C

Diet and Exercise Habits Questionnaire

Diet and Exercise Habits Questionnaire

1. Please rank the following dietary changes in order of importance/relevance to you based on changes that could reasonably be made to your current diet.
    *   Overall reduction in caloric intake (shoot for 1,600 calories daily to promote weight loss but any reduction is better than no reduction)
    *   Reduction in fats consumed (increase fruits, vegetables, fiber, protein)
    *   Reduction in carbohydrates consumed (increase fruits, vegetables, fiber, protein)
    *   Reduction in sugars/sweets consumed (increase fruits, vegetables, fiber, protein)
    *   Reduction in portion sizes
    *   Eating several small, healthy meals/snacks throughout the day (every 2-3 hours) rather than 2-3 large meals (this is especially helpful for people who are always on the go or in the car for a large part of the day)
    *   Reduction in consuming fast food/eating out at restaurants
    *   Reduction in unhealthy snacking
    *   Increased water consumption
    *   Decreased consumption of sugary or alcoholic beverages (empty calories)

2. Please rank the following exercise changes in order of importance/relevance to you based on changes that could reasonably be made to your current level of physical activity.
    *   Increase the frequency of exercise (more days/week)
    *   Increase the duration of current exercise efforts
    *   Increase the intensity of current exercise efforts (jogging instead of walking)`
    *   Include both strength and cardio in workouts (add in the missing component)
    *   Increase exercise during daily life activities (taking the stairs instead of the elevator, lifting weights while watching TV, etc.)

3. On a scale from 1 (not motivated at all) to 10 (incredibly motivated) how motivated are you to make the above changes to your diet/exercise habits?

Appendix D

MyChart Recruitment Script

MyChart Recruitment Script

I am a clinical psychology doctoral student who has also been working as a Behavioral Health Specialist at the Bronson Internal Medicine office. I am currently doing my dissertation research project on obesity and its associated health conditions. I am recruiting participants for a study that will examine the effectiveness and feasibility of a brief behavioral intervention for obesity delivered by primary care physicians. If you are at least 18 years old, fluent in English, MyChart active, and have a BMI of 25+ you are eligible to participate. Your participation would involve filling out brief questionnaires assessing your diet and exercise habits, depression symptoms, and sleep quality. It would also involve the collection of physiological data stored in your EPIC chart such as weight, BMI, blood pressure, cholesterol, and hemoglobin A1c. Your participating may also involve setting diet and exercise goals during regularly scheduled physician visits occurring over a 12 month period, engaging in home behavior tracking, and sending periodic updates to your physician via MyChart. I would greatly appreciate your help in gaining information about effective treatment for obesity and its associated health conditions. Please reply to this message and indicate whether or not you are interested in participating in this research project.

Thank you,
Julia Huston

Appendix E

Physician Decision Guide

Physician Decision Guide

Diet modification strategies:
1. Overall reduction in caloric intake (shoot for 1,600 calories daily to promote weight loss but any reduction is better than no reduction)
2. Reduction in fats consumed (increase fruits, vegetables, fiber, protein)
3. Reduction in carbohydrates consumed (increase fruits, vegetables, fiber, protein)
4. Reduction in sugars/sweets consumed (increase fruits, vegetables, fiber, protein)
5. Reduction in portion sizes
6. Eating several small, healthy meals/snacks throughout the day (every 2-3 hours) rather than 2-3 large meals (this is especially helpful for people who are always on the go or in the car for a large part of the day)
7. Reduction in consuming fast food/eating out at restaurants
8. Reduction in unhealthy snacking
9. Increased water consumption
10. Decreased consumption of sugary or alcoholic beverages (empty calories)

Exercise modification strategies:
1. Increase the frequency of exercise (more days/week)
2. Increase the duration of current exercise efforts
3. Increase the intensity of current exercise efforts (jogging instead of walking)`
4. Include both strength and cardio in workouts (add in the missing component)
5. Increase exercise during daily life activities (taking the stairs instead of the elevator, lifting weights while watching TV, etc.)

Behavioral goal setting tips:
- Goals should be specific (what foods will be eaten and when, what types of exercises and when will they occur)
- Goals should fit within daily routines (work within time and scheduling constraints)
- Goals should be accomplishable (for someone not exercising at all, the next step might be walking once/week)
- Patients should be encouraged to reward themselves for meeting goals (rewards can be small, inexpensive, and frequent or larger and more infrequent)
- Patient should be encouraged to engage in daily behavior tracking to monitor progress

Appendix F

Participant Information Sheet

Participant Information Sheet

As a part of your participation in the current research project, you will be receiving a brief behavioral weight loss intervention delivered by your primary care physician. As a part of this intervention, you will be asked to complete a few tasks.

1. Please use some form of at home tracking to monitor your daily food intake and physical activity as appropriate according to your specific diet and exercise goals. Below is a link to one possible type of tracking sheet that you may find helpful. Depending on your specific goals, all parts of this form may not be relevant. Please utilize the pieces that are relevant or find a different tracking form or electronic app (my fitness pal, etc.) that you find more helpful. (http://www.webmd.com/diet/printable/food-fitness-journal).

2. Once every week/two weeks/month (depending on the stage of the study) you will be prompted to send a MyChart message to your physician briefly summarizing:
   - Progress towards the specific diet and exercise goals established collaboratively with your physician during your office visit (utilize the information from your tracking forms/app to assist you in monitoring your progress towards your goals).
   - Any areas where you are struggling to reach your goals.
   - Current weight (it is important to weight yourself at approximately the same time each day wearing approximately the same clothing).

   Your physician will provide you with feedback on your progress via MyChart.

Appendix G

Consumer Satisfaction Questionnaire

Consumer Satisfaction Questionnaire

Please answer the following questions on a scale from 1 (strongly disagree) to 5 (strongly agree).

The word intervention refers to specific behavioral goal setting during office visits plus regular between visit MyChart check-ins.

1. I found this intervention to be helpful/valuable.

Strongly Disagree	Disagree	Undecided	Agree	Strongly Agree
(1)	(2)	(3)	(4)	(5)

2. I found the time required to participate in this intervention reasonable and manageable.

Strongly Disagree	Disagree	Undecided	Agree	Strongly Agree
(1)	(2)	(3)	(4)	(5)

3. I would recommend this intervention to others.

Strongly Disagree	Disagree	Undecided	Agree	Strongly Agree
(1)	(2)	(3)	(4)	(5)

Please provide any additional comments that you may have about the intervention below.

Appendix H

Western Michigan University Human Subjects Institutional
Review Board Letter of Approval

WESTERN MICHIGAN UNIVERSITY

Date: March 14, 2017

To: Wayne Fuqua, Principal Investigator
Julia Huston, Student Investigator for dissertation

From: Amy Naugle, Ph.D., Chair

Re: HSIRB Project Number 16-05-02

This letter will serve as confirmation that your research project titled "Primary Care Physician Delivered Brief Behavioral Intervention for Adult Obesity and Associated Health Conditions" has been **approved** under the **expedited** category of review by the Human Subjects Institutional Review Board. The conditions and duration of this approval are specified in the Policies of Western Michigan University. You may now begin to implement the research as described in the application.

Please note: This research may **only** be conducted exactly in the form it was approved. You must seek specific board approval for any changes in this project (e.g., *you must request a post approval change to enroll subjects beyond the number stated in your application under "Number of subjects you want to complete the study")*." Failure to obtain approval for changes will result in a protocol deviation. In addition, if there are any unanticipated adverse reactions or unanticipated events associated with the conduct of this research, you should immediately suspend the project and contact the Chair of the HSIRB for consultation.

Reapproval of the project is required if it extends beyond the termination date stated below.

The Board wishes you success in the pursuit of your research goals.

Approval Termination: **March 13, 2018**

Appendix I

Homer Stryker School of Medicine/Bronson Hospital Human Subjects
Institutional Review Board Letter of Approval

DATE: March 20, 2017
TO: Wayne Fuqua, PhD
FROM: IRB Office
SUBMISSION TYPE: Response to IRB Conditions
PROTOCOL NUMBER: WMed-2016-0114
IRB ACTION: **APPROVED**
FINAL APPROVAL DATE: March 17, 2017
EXPIRATION DATE: March 16, 2018

Thank you for your submission responding to the Western Michigan University Homer Stryker M.D. School of Medicine (WMed) Institutional Review Board's (IRB) request for changes to secure approval of your study "Primary Care Physician Delivered Brief Behavioral Intervention for Adult Obesity and Associated Health Outcomes", IRB number WMed-2016-0114. The IRB has approved your submission using an Expedited review procedure, Category 5 and 7 as a minimal risk study.

Your responses have been reviewed and determined to satisfy the conditions placed by the IRB. Your study is now fully approved.

Please note this study has been approved with the following:

- Waiver of Consent under 45 CFR 46.116(d) for Appendix G survey
- Online Survey Informed Consent, WMU IRB approval date 3.14.2017 WMed IRB approval date 3.17.17
- Online Survey Informed Consent, non-stamped version for electronic use.

The IRB-stamped consent form is attached for your files. You may use the non-stamped consent form since this is an electronic survey.

All research must be conducted in accordance with this approved submission. Any changes to the approved study, including to the consent form, must be reviewed and approved by the WMed IRB prior to implementation, except when necessary to eliminate an apparent immediate hazard to the subject. If you must implement a change prior to WMed IRB approval to eliminate an apparent immediate hazard, the change must be promptly reported to the IRB.

You are reminded that you must apply for, and undergo review, and be granted continued IRB approval for this study before March 16, 2018 to be able to conduct your study in an uninterrupted manner. Please apply for renewal using the "Continuing Review Form" available on the WMed IRB website. If you do not receive approval before this date, you must stop all research activities associated with this study until approval is granted. The IRB office will send you reminder notices to help ensure that you submit in sufficient time to avoid a lapse in approval. Alternatively, if your study has concluded please complete the "Study Closure Form" and forward to the WMed IRB office. For additional information on WMed IRB requirements, including continuing review and interim reporting responsibilities, please refer to the WMed HRPP Handbook.

If you have any questions or comments about this correspondence, please contact the IRB Office at 269-337-4345.

Sincerely,

Kelly M. Quesnelle, PhD
IRB Chair
Western Michigan University Homer Stryker M.D. School of Medicine

1