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A Novel Approach to Reducing Adiposity Among Young Men

Jean M. Reading
Virginia Commonwealth University

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By

Jean M. Reading
Master of Art in Applied Psychological Research, Pennsylvania State University, 2014
Bachelor of Science in Psychology, Pennsylvania State University, 2012

Director: Jessica Gokee LaRose, Ph.D.
Associate Professor, Department of Health Behavior and Policy

Virginia Commonwealth University
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"Find a group of people who challenge and inspire you, spend a lot of time with them, and it will change your life"

– Amy Poehler

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Dedication

This dissertation is dedicated to the research participants in these studies—who provided their time and effort to advance not just science, but my training.

Abstract

Background

The prevalence of obesity among young adults increased fivefold over the last 40 years. Further, men with obesity during young adulthood have double the mortality risk than young men with a healthy weight. Indeed, there is a critical need to treat obesity during early adulthood to mitigate the development of co-morbid conditions such as cardiovascular disease and certain related cancers and reduce mortality risk among young men. Lifestyle intervention is the first line treatment for obesity. Yet, young men are underrepresented in lifestyle interventions, which is posited to be the result of a combination of unmet needs and overall low concern for weight management. Therefore, the overarching aim of this dissertation was to inform a viable model for reducing adiposity among young men. The aims of this dissertation are to:
Papers 1 and 2: Test the preliminary efficacy, feasibility, and acceptability of a novel lifestyle intervention (self-guided + health risk messaging) for young men (ACTIVATE).
Paper 3: Explore the behavioral and physiological factors associated with changes in adiposity among young men and women enrolled in a more intensive, but primarily digital, lifestyle intervention (REACH).

Results

Papers 1 and 2: Recruitment for the ACTIVATE lifestyle intervention was successful as evidenced by achieving 109% of target enrollment in a 2-month period. The self-guided intervention produced modest weight loss at 3-months compared to slight gains in the control group (-1.6% vs. +0.31, p=0.04). Change in perceived risk was not associated with weight change, but young men found the health risk focus as a motivator for joining the program, along with the age and gender focus. Certain components of the intervention were rated as more favorable than others (e.g., Bluetooth scale over the self-guided aspect), but there was some variation in preferences by treatment response. Social support and increased personalization were preferred for future programming. Overall, online delivery was preferred, specifically focusing on physical activity; less preference for in-person delivery was noted among those achieving clinically significant weight loss.
Paper 3: Young men exhibited greater reductions in adiposity (weight, waist circumference, body fat percentage) compared to women at 3-months (all p's <0.05). Baseline resting metabolic rate was associated with changes in percent body fat at 3-months (p=0.001) but no other outcomes. More frequent objective dietary self-monitoring was associated with greater weight loss (p=0.004) and reductions in body fat (p=0.004) at 3-months. No physiological or behavioral factors associated with changes in adiposity differed by sex.

Conclusions

A self-guided approach to weight loss, paired with an age- and gender-targeted program, might enhance enrollment and initial engagement of young men in lifestyle interventions. To improve the clinical significance of a self-guided lifestyle intervention among young men, additional evidence-based components are warranted. Based on these dissertation findings, social support and self-monitoring might particularly benefit young men. Though, these components should be tested within a self-guided lifestyle intervention for young men.

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CHAPTER 1

Background

OBESITY

The prevalence of obesity[1] underscores the need for effective prevention and treatment of this urgent public health issue. Epidemiologic data estimate over 13% of the world population[2] and 42% of the U.S. population[1] meet criteria for obesity (Body Mass Index $\geq$ 30 kg/m^2). Obesity increases the risk for a host of adverse health outcomes including cardiovascular disease[3,4] and associated complications[5] (e.g., atrial fibrillation), type 2 diabetes,[5] metabolic disorders,[6] and certain cancers[7-9]—in addition to increasing the risk of all-cause mortality.[10] Further, obesity is linked with poorer quality of life[11] and a number of negative psychological health outcomes, including depression and anxiety.[12] The economic costs associated with obesity are also staggering—in fact, data indicate the cost of obesity-related medical expenditures amount to over $172 billion annually in the United States, and it is estimated that individuals with obesity have an additional cost of ~$1,800 in medical expenses annually.[13]

PREVENTION AND TREATMENT OF OBESITY

There are a number of predisposing factors thought to increase the risk of developing obesity including sociodemographic (e.g., living in obesogenic environment) behavioral (diet, physical activity), and genetic factors.[14] While there are several approaches to treating obesity including prescription medications[15] and surgical procedures (e.g., bariatric surgery),[16] comprehensive lifestyle intervention (i.e., behavioral treatment) is the first-line treatment per recommendations of the American Heart Association and The Obesity Society.[17,18] The U.S. Preventive Services Task Force (USPSTF) outlines the current standard of intensive behavioral treatment of obesity as healthy meal planning and physical activity, along with adherence to

prescribed behavioral interventions.[19] These guidelines are consistent with seminal findings from the Diabetes Prevention Program (DPP)[20], a large trial comparing non-pharmacological approaches (e.g., lifestyle interventions, behavioral weight loss interventions) to pharmacological approaches for the treatment of obesity and co-morbid conditions. The main finding of this landmark trial was that lifestyle intervention, alone, was nearly twice as effective in reducing the risk of developing type 2 diabetes compared to pharmacological treatment.[21]

Lifestyle interventions for the management of obesity are grounded in the energy balance model.[22] A large emphasis is placed on diet, given the wealth of evidence showing that diet alone is more effective at promoting initial weight loss compared to physical activity alone.[18,23,24] Though, it should be noted that diet and physical activity together is recommended, with physical activity yielding other important cardiometabolic benefits.[24] For diet, the recommendations typically focus on promoting adherence to reduced caloric intake.[25] In addition to calorie reduction, improvement to diet quality is also recommended for healthy weight management and overall health benefits. The Centers for Disease Control recommends following the dietary guidelines for healthy weight management outlined by the United States Department of Agriculture and United States Department of Health and Human Services.[26] These recommendations include limiting intake of foods and beverages with added sugar and eating nutrient-dense foods that are low in saturated fat and sugar (e.g., lean meats, fruits, vegetable, beans, whole grains, etc.).[26] These recommendations are consistent with dietary recommendation specific to weight loss.[17] To enhance energy expenditure and support weight loss maintenance, 250 to 300 minutes per week of moderate-intensity physical activity is recommended—participants receive personalized progressions based on their baseline level of activity to assist them in gradually working toward this goal.[27] Within gold standard behavioral treatment, participants receive training in evidence-

based behavioral strategies to support their changes to diet and physical activity. The behavioral approach is grounded in an understanding of how one's environment—physical, interpersonal, and internal—influences diet and physical activity behaviors. Thus, behavioral treatment programs teach a variety of strategies for modifying one's environment when possible (e.g., stimulus control, pre-planning), as well as strategies for navigating situations and environmental stimuli that cannot be changed (e.g., assertive communication, stress management).[28] At its core, adult behavioral treatment is an individual-level intervention—firmly rooted in the self-regulation framework—that includes goal setting, self-monitoring of diet, physical activity, and weight, as well as adherence to recommended programs.[29] The model of self-regulation is based on 3 basic tenants: 1) self-monitoring one's behavior and the conditions involved with adopting the behavior; 2) goal setting and implementing strategies to achieve the established goal; and 3) considering influencers (e.g., motivators, social support, physical environment) that might sustain the behavior change.[30,31]

Core Behavioral Change Techniques

Behavioral treatment for obesity typically includes training in a host of different behavior change techniques. For the purpose of this literature review and aims of this dissertation, focus will be narrowed primarily self-regulatory techniques including self-monitoring, goal setting, problem-solving techniques, and stimulus control. While there are a number of different behavior change techniques implemented across health interventions (social support, relapse prevention),[32] common techniques and those most reliably associated with successful weight management[33] include the aforementioned self-regulatory techniques—all of which fall under the model of self-regulation.

Self-Monitoring

Self-monitoring is a core element of self-regulation and occurs when an individual provides attention to a certain behaviors and records details about the behavior in order to make a positive change and track progress in pursuit of an pre-determined benchmark of success.[34] Within the context of a lifestyle intervention, self-monitoring diet and weight is a commonly recommended behavior change technique, and is consistently associated with greater weight loss.[33-36] It is generally recommended to track daily or weekly, with majority of programs recommending daily self-monitoring of diet.[35] In the early years of weight loss research, self-monitoring consisted of recording diet and physical activity using paper diaries.[37] However, given the vast changes in technology over the last decade, focus has shifted from self-monitoring via a paper diary to self-monitoring using a technology-based platform in lifestyle interventions.[35] A considerable body of literature shows that self-monitoring through technology-based applications is associated with larger weight reduction[38,39] and higher adherence to self-monitoring.[35,40]

Goal Setting

Another core element of self-regulation is the concept of goal setting. This behavior change technique is a cognitive and behavioral process that guides individuals to achieve the desired outcome or health behavior.[31] Based in Locke and Latham's goal-setting theory[41], the goal setting process starts with goal selection and then moves into active goal pursuit.[31] Within active goal pursuit and goal process cognition, there are different processes to consider. Active goal pursuit starts with planning which typically draws on implementation intentions or strategies, which establishes a roadmap for how the individual will handle certain situations. For instance, when an individual joins a lifestyle intervention, an initial goal might be to self-weigh for a certain number of days each week. To achieve success, implementation strategies might include stimulus control

strategies such as keeping the scale in a place that is visible at the start of the day or setting reminders to self-weigh.

Coinciding with planning, there are cognitive processes that should occur in order to achieve the set goal. Ford and Nichols suggest that feedback is central to goal attainment, in that monitoring and evaluating progress is the basis of a behavioral outcome.[42] Feedback in a lifestyle intervention might involve evaluating weight trends over the course of the program and mapping them onto dietary patterns to discern which behavioral patterns might be leading to decreases or increases in weight. Feedback is particularly important to reinforce and/or reward desired behaviors within the context of lifestyle interventions since it can improve intervention adherence.[43] Lastly, these outcomes are suggested to be contingent on outcome expectancies and efficacy expectations, which may feedforward into progress and behavioral outcomes.[44]

Problem Solving

The last core element of self-regulation is problem solving, which is a technique that helps individuals identify potential barriers that might impede their goal progress or attainment, and formulate realistic solutions and an action plan to overcome those barriers. Problem solving is considered an active ingredient for lifestyle interventions[45] and beneficial for weight loss.[46] Most programs incorporate problem solving techniques through in-person sessions. However, more recent research has incorporated problem solving into mobile health apps that include problem solving tools to mitigate barriers to diet and exercise.[47] Findings from a recent feasibility study found incorporating problem solving techniques through a behavioral weight loss mobile app is acceptable and facilitates modest weight loss; though, more research is needed to understand whether or not an app can enhance problem solving skills and reduce weight.[48]

Stimulus Control

A stimulus is a basic tenant of operant conditioning and is thought to be a triggering action of the environment, which then in turn produces a response.[49] Stimulus control is a critical component in lifestyle interventions, which involves understanding and adjusting environmental cues that might influence eating and exercise behaviors.[50] The main goal of stimulus control is creating an optimal environment that will support weight loss goals—this involves both removing unhelpful environmental cues as well as adding cues to support the desired behavior. For instance, if an individual desires to reduce their consumption of sugar, one stimulus control strategy they might adopt is to remove foods high in added sugar from the home or place them in a less visible location. Whereas if an individual sets a goal to walk four times over the coming week, they might choose to add a reminder on their phone and place their sneakers in a visible location—that is, adding cues that might remind them of the valued behavior / goal.

THE HIGH-RISK DEVELOPMENTAL PERIOD OF YOUNG ADULTHOOD

Young adults are vulnerable to major life transitions that often occur during this developmental period.[51] Some of these life transitions include moving away from home, living independently, marriage, starting or completing school, starting a new job, or family planning. These life stressors and transitions can be associated with risky health behaviors that contribute to weight gain including sedentary behavior,[52] poor diet quality,[53] and irregular sleep patterns.[54-56] Moreover, risky health behaviors such as high consumption of sugar sweetened beverages,[57] take away meals[58], as well as low consumption of fruit and vegetables[59] are particularly common among young adults—all of which can contribute to weight gain.[60,61] Coupled with poor diet, adults also experience declines in resting energy expenditure during young adulthood.[62] That said, these behaviors are likely to contribute to the increasing obesity prevalence among young adults—which have increased from 6% to over 30% in the last 40 years.[63] Weight gain particularly during young

adulthood is associated with the development of number of health issues later in life including type 2 diabetes, hypertension, cardiovascular disease.[64] Hence, reducing excess unhealthy weight prior to midlife (45 years old) can reduce all-cause mortality by 50%, yet little relatively work has been done in this area to promote weight loss during young adulthood.[65] Thus, there is a dire need for additional work focused on the prevention and treatment of obesity during this critical developmental period.

LIFESTYLE INTERVENTIONS WITH YOUNG ADULTS

While early adulthood is an opportune time to promote positive health behaviors, young adults are particularly challenging to recruit into lifestyle interventions and have poorer weight loss outcomes than older adults.[66] For the most part, behavioral weight loss samples include middle- to older-aged adults, with an age range of 37-57 years old[67] and median age of 49 years old.[68] Growing interest in developing lifestyle interventions for young adults led to the funding of the EARLY trials (Early Adult Reduction of weight through LifestYle intervention). The EARLY trials included a consortium of 7 randomized controlled trials funded by NIH to test primarily technology-driven weight control interventions for young adults.[69] Only 5 of the 7 EARLY trials are reported in this review (2 weight gain prevention, 3 weight loss). The 2 trials not described are not broadly generalizable to weight management among young adults—1) Treating Adults at Risk for Weight Gain with Interactive Technology (TARGIT)[70] aimed to reduce smoking and weight management) and 2) eMoms targeted pregnant women with excessive gestational weight gain.[71]

Two of the EARLY trials addressing weight gain prevention included the Choosing Healthy Options in College Environment Settings (CHOICES) and Study of Novel Approaches to Weight Gain Prevention (SNAP) trials. The CHOICES trial was a 24-month intervention targeting diet/nutrition, physical activity/sedentary behavior, sleep, and stress management in college

students.[72] The intervention involved a 1-credit course that offered either a face-to-face version, online, or a hybrid option. Following the course, participants were provided access to a website that included education on the 4 key targets mentioned above, adapted to address areas (e.g., screen time, mindful eating, sleep, sugar sweetened beverage consumption) specific to this age group. There were no significant differences between the groups on reductions in weight, BMI, waist circumference, or body fat percentage at any of the follow-up time points (4, 12, 24 months).[73] While this was not a pre-specified outcome, the intervention group experienced significant reductions in the prevalence of overweight or obesity compared to the control group at 24 months (46.5% vs. 57.6%).[73]

The SNAP study was a 3-arm trial comparing two self-regulation approaches (large changes vs. small changes) to a self-guided control arm. The main difference between the two approaches was the large changes approach taught participants to make larger changes up front to produce a weight loss buffer against anticipated future gains, as opposed to the small changes approach which promoted small daily changes to eating and activity as a model to be maintained indefinitely. The intervention consisted of 10-in person sessions over 4 months. Following the in-person sessions, the interventions was delivered remotely (wireless scales, text messages, and web-based refresher courses).[74] At the 2-year follow-up, both the large changes (-1.5 kg) and small changes (-0.77 kg) showed significantly less weight gain than the control arm (+0.54 kg). At the primary endpoint, which was the change from baseline to a mean follow up of 3-years, both the large changes (-2.4 kg) and small changes (-0.56 kg) group exhibited significantly less weight gain than the control arm (+0.26 kg), but the large changes arm was more effective than small changes.[75]

The three weight loss interventions from the EARLY trials included the Cell Phone Intervention for You (CITY), Intervention Approaches to Diet Exercise and Activity (IDEA), and

Social Mobile Approaches to Reduce Weight (SMART) project. The CITY trial was a 3-arm trial comparing the effects of a mobile app, personal coaching, and control group. The mobile app arm included digital self-monitoring, goal setting, challenges, and social support through a mobile app.[76] Whereas, the personal coach involved six in-person group sessions with a personal coach and monthly phone calls, in addition to self-monitoring using a mobile app. The control group received 3 handouts about nutrition and physical activity. At 6-months, the personal coaching arm experienced greater reductions in weight (-3.1 kg) compared to the mobile app (-0.87 kg) and control group (-1.14 kg). At 12-month, the personal coaching arm experienced greater reductions in weight (-3.6 kg) compared to the mobile app (-1.5 kg) and control group (-2.3 kg). At the trial primary endpoint of 24-months, there were no differences between any of the arms: personal coaching (-2.5 kg), mobile app (-1.4 kg), and control group (-0.99 kg).[77]

The IDEA trial was a 2-arm trial comparing the effects of adding wearable technology (device worn on the upper arm, which connected to a web-based interface to provide feedback on energy expenditure and physical activity) to a standard lifestyle intervention during the maintenance phase. All participants received an intensive 24-month lifestyle intervention, which consisted of weekly in-person group sessions for the first 6 months and then followed by telephone contact and weekly text messages.[78] At 6-months, there were no differences between the standard lifestyle intervention and wearable technology group (-8.6% vs. -8%). Contrary to the hypotheses, the standard lifestyle group exhibited significantly larger reductions in weight compared to the wearable technology group at 12-month (-8.3% vs. -6.7%) and 24-months (-5.9% vs. -3.5%), respectively.[79]

SMART was a 24-month intervention that was implemented across 3 college campuses and was remotely delivered using several different modalities (e.g., mobile apps, Facebook, text

message, email, website, technology-mediated health coaching). At 6- and 12-months, the intervention arm was associated with modest weight losses, which were statistically significant from the control group (-1.1 kg vs. +0.3 kg at 6 months; -1.0 kg vs. +0.3 kg at 12 months). Notably, these differences diminished between the digital intervention and control group over longer periods of follow-up at 18-months (-0.3 kg vs. +0.4 kg), and at the trial primary endpoint of 24-months no group differences were observed (+0.3 kg vs. +1.1 kg), respectively.[80]

Overall, digital lifestyle interventions, which hold great potential for reach among young adults, produced modest weight loss compared to more intensive in-person and hybrid approaches. Taken together, findings from the EARLY trials are consistent with more recent findings from a digital lifestyle intervention—Healthy Body Healthy U—which was designed for young adults and implemented across two college campuses via social media (i.e., Facebook). The goal of the trial was to compare tailored vs. targeted messaging within the context of the digital intervention. No significant differences in weight outcomes were found between the intervention groups and control at 6-, 12-, or 18-months.[81] At 6-months, the tailored had about -1% difference in weight loss compared to both the targeted and control group. It should also be noted that highly engaged participants receiving tailored feedback lost significantly more weight than the control at both 6- and 12-months.[81]

One weakness that holds consistent across most of these trials targeting young adults, is the relatively homogeneous samples, particularly with respect to gender. As demonstrated in the EARLY trials, young men were particularly challenging to recruit into these lifestyle interventions and were vastly underrepresented (~20-30%) in majority of the samples from these trials. Furthermore, differences in treatment response between young men and women is unclear. Only

1 trial reported outcomes by gender, but no differences were found.[77] Thus, there are gaps that remain unaddressed with respect to engaging young men in weight management.

WEIGHT MANAGEMENT AMONG YOUNG MEN: A CRITICAL GAP

Young men (18-35) are particularly at high-risk, with over 40% meeting criteria for obesity.[1] Surveillance data from the last decade show sharp increases in obesity among men aged 20-39, with the prevalence rising to 46% after the age of 40.[1] This is especially concerning since cardiovascular disease and cancer—the two leading causes of death among men past the age of 45—are associated with obesity.[82] In fact, young men with obesity double their mortality risk later in life compared to young men with a healthy weight.[83] Furthermore, young men are prone to behaviors that contribute to weight gain—consuming more processed meats and alcohol,[84] as well as less fruits and vegetables compared to women.[85] This is especially concerning, since weight not only tends to increase over the life span,[86] but has the potential for setting ominous conditions for early health complications and premature death.

Some studies have begun to address the issues in recruiting men by using male-targeted recruitment ads but have shown mixed results. One study found that male-targeted recruitment ads produced similar rates of enrollment as studies that were not targeting young adults.[87] However, another study found larger yields in recruiting younger men by using targeted recruitment ads.[88] Moreover, a quasi-experimental study found improvements in enrollment rates of young men using male-targeted ads, but these improvements were modest.[89] As such, it appears that male-targeted ads are necessary for recruiting young men, but not sufficient enough to improve enrollment of young men. In light of these recruitment challenges, further adapting programs for young men might help to circumvent some of the issues surrounding the enrollment of young men in lifestyle

interventions. Yet, more research is needed to improve our understanding about the factors that might be contributing to young men's low enrollment in lifestyle interventions.

Factors Contributing to Low Enrollment among Young Men

Identifying factors that might contribute to this low enrollment could help to improve lifestyle interventions for young men. An explanation for the low enrollment among young men could be the workings of several factors including gender norms, unmet needs specific to men's health,[90] low perception of health risks,[91] and perceiving lifestyle interventions as feminine.[90] The role of masculinity, as it relates to health, is well-documented[92-97] and can impede health seeking services.[97] One qualitative study used online focus groups to examine young men's help-seeking behavior within the context of health services—young men in this study agreed that masculinity can often interfere with seeking medical advice, and that men prefer tailored advice that promotes autonomy, choice, and non-directive communication.[97] However, when men seek health information it tends to be related to physical activity information related to muscle gain, which is consistent with recent evidence showing that popular health norms presented in social media tend to promote muscular appearances in men.[98]As it relates to weight loss behaviors, the interference of masculinity starts from a young age. A large longitudinal study found that higher levels of masculinity is related to higher levels of weight gain attempts in adolescent boys.[99] Furthermore, in one study young men showed lower concern about weight gain relative to young women and reported they would need to gain more weight before taking action.[100] It is not entirely clear as to why men have lower concern about losing weight, but some research has identified that women tend to have lower satisfaction with weight and a fear of gaining weight[101]—which could be driven by the societal norms and pressure for women to be "thin" and men to achieve a muscular appearance.[102] There is also some evidence that young men are more likely to misperceive their

own weight status downward (i.e., a BMI in the overweight range but not perceiving oneself as overweight) whereas young women are more likely to consider themselves overweight when they are not.[100] Given the role gender can play in health, specifically weight management, it is worth examining young men's specific preferences for managing their weight.

Young Men's Preferences for Lifestyle Interventions

The aforementioned issues with enrolling men into lifestyle interventions has led to an emerging area of research that has begun testing the efficacy and effectiveness of male-only lifestyle interventions.[103-106] Though, this burgeoning area mainly enrolls men between the ages of 40-60.[107] Thus, it is even less clear as to whether or not young adult men might have unique needs when it comes to weight loss. A systematic review of weight loss interventions among young adults revealed men had greater enrollment in exercise-based programs than diet-based programs.[108] This lower enrollment in diet-based programs among men is consistent with a systematic review that found men show a lack of overall interest towards diet.[109] In addition, young men report that barriers to eating healthy are often the result of a lack of time, money, resources, and skillset to plan and prepare healthy meals.[109,110] While young men have an overall lack of interest in diet, young men are motivated to improve physical health, appearance, and sport-related skills.[109,110] With respect to preferences for a lifestyle interventions, data show that young adult men want programs that encompass tips for eating healthy on a budget, skill development, personalized feedback, resistance training, and a combination of face-to-face and online delivery.[110,111] Young men also prefer intense muscle strengthening exercise compared to women, and prefer to exercise on their own with minimal guidance from a program.[112] Taken together, extant evidence suggests that not only are young men underrepresented in lifestyle interventions, but young men have different needs and preferences for managing their weight. Therefore, a male-

targeted lifestyle intervention that meets young men's specific needs might have more success in engaging this high-risk population than a gender-neutral lifestyle intervention.

Male-targeted Lifestyle Interventions

While there is no evidence to indicate that gender-specific interventions are more effective at reducing weight compared to gender-neutral interventions,[113] there is evidence to support the utilization of male-targeted interventions, especially as a means to engage this population in lifestyle interventions. Exit-interviews from a male-adapted National Diabetes Prevention Program found that men felt more open to share about their experience losing weight, changing eating habits, masculinity, and body image with other men—within the context of a lifestyle intervention.[114] Furthermore, male-only lifestyle interventions are also effective in reducing weight—recent finding from a systematic review show that over three-quarters of the male-targeted weight loss interventions reviewed produced clinically meaningful weight loss of >5%.[115] Despite this promising evidence of male-targeted lifestyle interventions, there is still a need for larger and more rigorous testing of male-targeted approaches.

The approaches used in male-targeted lifestyle interventions tend to vary. The REFIT trial, which was primarily promoted autonomy, tested the use of an approach that included recommendations for making self-selected, modest calorie reductions (small changes [Six 100 calorie changes per day]).[103] At 3-months, the small changes group lost significantly more weight compared to the control group (-4.9% vs. -0.6%), with similar findings exhibited at 6-months as well (-5.2% vs. -0.6%).[103] A second similar study, which compared the effectiveness of these small changes alone versus small changes paired with financial incentives, found that men lost more weight when provided financial incentives.[116] Similar results were found in another study that incorporated narrative text messages with financial incentives—both groups achieved clinically

meaningful weight loss (>3%), but the group receiving financial incentives outperformed the text message only group.[104] In addition to the use of financial incentives to promote weight loss, evidence-based strategies such as self-monitoring has also been tested to promote weight loss among men. A feasibility trial, comparing the effectiveness of using self-monitoring via mobile technology versus enhanced self-monitoring program (text message reminders, peer support), found that men experienced clinically meaningful weight loss in both groups (>3%) at 3-months, but men receiving the additional text reminders and peer support had greater weight losses at the 6-months (-6% vs. -4%).[117] Thus, it appears that men perform well in a less intensive approach where simple reminders or text messages are incorporated, despite the fact that most traditional lifestyle interventions are intensive and typically involve weekly meetings and/or support from a professional coach.[118-120] Men also appear to lose significant weight loss in programs that encourage autonomy (e.g., personalized exercise, non-directive language)[103] or when only provided with evidence-based resources and/or educational materials about weight loss.[77,106]

The results from these male-targeted programs show promise for engaging men to lose weight. Yet, the average age range for these male-only trials was late-forty to mid-fifty. Thus, suggesting a need for developing and testing age- and male-targeted lifestyle interventions. Nevertheless, lifestyle interventions targeted for both gender and age are nearly absent, at least in the United States. One pilot trial tested the feasibility of a healthy lifestyle intervention (HEYMAN) incorporating common motivators, barriers, and preferences among young men—findings demonstrated high retention rates (>90%), acceptability, satisfaction, and significant improvements on adiposity (weight, waist circumference).[121] Emerging evidence indicates that young men could benefit from a self-guided lifestyle intervention,[122] but such an approach has yet to be tested among young men. Furthermore, it is unclear if other additional components, might

help to bolster weight loss and engagement during this developmental period. Considering young men's low concern about weight gain, an approach that enhances their awareness of the link between obesity and chronic disease might be warranted.

THEORETICAL FRAMEWORK: EXTENDED PARALLEL PROCESS MODEL

Health risk messages or fear appeal messaging have played a central role in public health campaigns aimed at changing health behaviors and perceptions. Importantly, theory-based interventions have shown to have powerful effects in changing behavior.[123] A useful theory for developing health risk messages is the Extended Parallel Process Model (EPPM). This theory posits that the perception of a health threat interacts with our belief that the recommended strategy will prevent the health threat and influences our intention to adopt the recommended health behavior.[124] EPPM is comprised of four constructs and proposes that in order to change a behavior, the individual must: 1) perceive that they are at risk for a negative health outcome (*perceived susceptibility*) and that the outcome would be severe (*perceived severity*) and can result in negative health outcomes and 2) believe that they have the ability to change the given health behavior (*self-efficacy*) and that the changes produce positive health outcomes (*response efficacy*). In order to develop a health risk message based in EPPM, these 4 constructs should be included. Once an individual is presented with an EPPM-based message, the individual will first, appraise the message in which perceived threat will either be activated or there will be no response. If perceived threat is activated, the individual will then appraise the message, wherein either 1 of 2 processes is activated: fear control processes or danger control processes. Danger control processes occurs when the individual accepts the message. Fear control processes occurs when efficacy is low and the message is rejected by the individual.

EPPM is a useful theory and has been applied to a number of different health campaigns and interventions including safe sex practices, vaccination, smoking cessation and prevention, and breast cancer screening.[125-127] Most commonly, EPPM has been applied to different messaging in education materials aimed to prevent disease. Early work with EPPM includes a fear appeal campaign that promoted condom use to prevent the spread of genital warts among college students.[128] Although this work did not find the fear appeal messages to effectively change condom use behaviors, this study did show that fear appeal messages are effective at changing attitudes and intention to use condoms. One randomized controlled trial demonstrated that providing educational materials surrounding the risks of breast cancer was effective at changing women's attitude and intention to attend an annual breast exam.[125] It should be noted that, while the EPPM educational materials were not effective in changing women's behavior to attend a breast exam, this study was limited to a short follow-up assessment of behaviors (3-months). Thus, it's possible EPPM is indeed effective at changing behaviors, but demands a longer-term follow-up. Other work involving cigarette smoking found that EPPM-based educational materials were effective at reducing smoking behaviors among adolescents.[127]

The obesity-related research with EPPM is minimal, but burgeoning. A more recent health campaign, that fosters the tenants of EPPM, is the Let's Move! Campaign rolled out by Michelle Obama. This major public health campaign coincided with the establishment of the Task Force on Childhood Obesity by the White House in 2009.[129] This campaign brought health risk awareness to the public of the growing obesity epidemic among children and the severe health consequences that can result from obesity. In addition, this campaign provided parents, families, and communities with information on ways to eat healthy and get active. This large public health campaign, that utilizes EPPM, has led to a number of positive outcomes including updated

nutritional standards for school meals,[130] thus resulting in increases in the percentage of elementary schools offering fruits, vegetables, and whole grains for lunch.[131] While this campaign has led to positive changes at both the policy and community level, the impact of this public health campaign on individual behavior is not entirely clear. In fact, little work has been conducted on how EPPM can be applied to an intervention to change individual-level behaviors that promote weight loss. One study shows that communicating the risk of obesity to individuals can enhance intention and motivation to eat healthy,[132] and that perceiving obesity as a health risk is associated with intention to maintain a healthy weight.[133] Moreover, one study demonstrated that health risk messages grounded in EPPM can effectively motivate men to engage in physical activity.[134] Another recent study examining the efficacy of an EPPM-based training on young men enlisted in the military in Iran. This study found significant effects on perceived severity, susceptibility, knowledge, and response efficacy toward obesity management.[135] Despite these promising findings for using EPPM-based health messages to change health behaviors, it is still unclear if EPPM can promote weight loss. To date, EPPM has not been applied within a lifestyle intervention for weight management.

Given the utility of EPPM, it is surprising that this framework has not been used in lifestyle interventions—not only can these health risk messages prompt an individual to change a behavior (e.g., physical activity, diet), but the actual lifestyle intervention itself is a resource for activating self-efficacy, thus resulting in behavior change. Young men are at high risk for developing health issues related to obesity—particularly cardiovascular disease, the leading cause of death among men.[136] However, young men show low concern about weight[100] and enroll at low rates in lifestyle interventions[137] that could aid in weight management. Thus, there is an overarching need for developing and testing lifestyle interventions for young men, specifically interventions that can

enhance their motivation to join and raise awareness of the potential risks and health implications of excess adiposity.

Effectively intervening early can mitigate disease risk over the life course. Yet, very little is known about young men with respect to lifestyle interventions. More specifically, given that young men are markedly underrepresented in lifestyle interventions, there is a need for more male-targeted programming to promote weight loss. Notably, an approach that meets the particular needs of young men. Considering research indicates that men are responsive to health risk messaging[134] and fair well with self-guided lifestyle intervention,[122] it is plausible that pairing a self-guided lifestyle intervention with the EPPM framework could be a viable approach to promoting weight loss among this population. Yet, this type of approach has not been tested within the context of a lifestyle intervention, particularly targeting young men. Lastly, relatively little is known about the factors associated with weight loss for young men. Therefore, additional work is needed to further explore if different factors might be differentially driving weight loss for young men and women. Taken together, addressing these research gaps can further expand our knowledge of weight management approaches that might offer clinically meaningful benefits to young men.

DISSERTATION AIMS

This dissertation research is based on the premise that young men with obesity are at high risk for developing co-morbid conditions, resulting in part from risky health behaviors (e.g., high consumption of alcohol, sugar sweetened beverages, and processed meat intake). Yet, young men are markedly underrepresented in lifestyle interventions, which is potentially due to low concern about weight, coupled with unmet needs in non-targeted programs. Thus, developing a lifestyle intervention specific to young men's needs—one that is targeted to both age and gender—shows promise in engaging this population, but research is minimal and has been conducted in the United

States. Such a program, that intervenes in early adulthood, has the potential to reduce obesity burden and prevent potential health complications later in life for men.

The overarching purpose of this dissertation is to inform the development of gender and age targeted lifestyle interventions that appeal to young men and will engage them in weight loss. Specifically, the goals of this research were twofold: 1) to examine whether a self-guided intervention that integrates male-targeted health risk messages is a viable approach for weight loss in young men; and 2) to explore whether the behavioral and physiological factors associated with weight loss treatment response differ for young men and women. These aims were accomplished by using data from two randomized controlled trials targeting young adults. Papers 1 and 2 presents findings from a small pilot randomized controlled trial examining the preliminary efficacy, feasibility, and acceptability of a self-guided lifestyle intervention, grounded in EPPM, that targets young men (ACTIVATE). Paper 3 explores behavioral and physiological factors associated with weight loss by sex, using data from a larger trial that enrolled emerging adults into a more intensive lifestyle intervention (REACH).

Aim 1
To determine the preliminary efficacy and feasibility of ACTIVATE (self-guided + EPPM) on changes in weight among young men
Hypothesis
Men in the intervention arm will manifest greater reductions in percent of initial body weight at 3-months compared to the delayed treatment control group.

Aim 2
To explore young men's perceived experience and satisfaction with recruitment strategies and materials, intervention content, and delivery mode of ACTIVATE (self-guided + EPPM).

Aim 3
To compare weight loss treatment response for young men and women, and explore whether the behavioral and physiological factors associated with changes in adiposity differ by sex.
Hypothesis
We anticipate that men will manifest greater reductions to adiposity compared to women.

CHAPTER 2

Paper 1

A self-guided lifestyle intervention for young men: Findings from the ACTIVATE randomized pilot trial

Abstract

Objective

To examine the feasibility and preliminary efficacy of a lifestyle intervention (self-guided + health risk messaging) targeting young men.

Methods

35 young men (Age=29.3±4.27; BMI=30.8±4.26; 34% racial/ethnic minority) were randomly assigned to the intervention or delayed treatment control. The intervention (ACTIVATE) included 1 virtual group session, digital tools (wireless scale, self-monitoring app), access to self-paced content via a secure website, and 12 weekly texts to reinforce health risk messaging. Fasted objective weight was assessed remotely at baseline and 12-weeks. Perceived risk was assessed via survey at baseline, 2-weeks, and 12-weeks. T-tests were used to compare weight outcomes between arms. Linear regressions examined the association between percent weight change and perceived risk change. All outcome analyses adhered to the Intent-to-Treat (ITT) approach, using multiple imputation with 5 imputed datasets for missing cases at follow-up.

Results

Recruitment was successful as evidenced by 109% of target enrollment achieved in a 2-month period. Retention was 86% at 12 weeks, with no differences by arm (p=.17). Participants in the intervention arm experienced modest weight loss at 12 weeks, whereas slight gains were observed in the control arm (-1.6%±2.5 vs. +0.31%±2.8, p=.04). Change in perceived risk was not associated with change in percent weight (p>.05).

Conclusion

A self-guided lifestyle intervention showed initial promise for weight management among young men, but these findings are limited by small sample size. More research is needed to bolster weight loss outcomes while retaining the scalable self-guided approach.

Introduction

Nearly 40% of men between 20-39 years of age meet criteria for obesity (Body Mass Index [BMI] > 30 kg/m^2), with the prevalence increasing to over 46% after the age of 40.[1] This is concerning given the links between obesity and cardiovascular disease[138] and cancer[139]—the two leading causes of death among men.[82] Young men in particular engage in a number of obesity-related health risk behaviors including high consumption of processed meats and alcohol[84] and low consumption of fruits and vegetables.[85] Considering the risk of obesity among men, it is imperative to promote weight loss during young adulthood (age 18-35 yrs). However, despite the prevalence of obesity among this population, young men are underrepresented in weight management trials—even those adapted specifically for young adults.[77,78] Therefore, more work is needed to close these gaps in enrollment and improve outcomes for men during this critical window in the developmental life course.

The challenge of enrolling men of all ages into lifestyle interventions has led to a burgeoning area of research testing the effects of male-only lifestyle interventions.[103,104,116,117] Formative data supporting male-only interventions indicate that men are more open to share weight loss experiences with other men and are more comfortable in programs designed specifically for them.[114] In addition, extant evidence suggests that the intensity and delivery mode of gold standard weight management programs might not be appealing to young men.[77,87] A recent systematic review by the US Preventive Services Task Force found that approximately 95% of behavioral counseling programs, addressing diet and physical activity to reduce cardiometabolic risk, involve either a high- (>360-minutes) or medium-level (3- to 360-minutes) of contact from a behavioral counselor.[140] Indeed, this level of intensity is at odds with time and convenience barriers reported by young men.[110] A lower intensity, male-only intervention might be more appealing to young men and limited available data suggest that men perform well in weight management programs

that are self-guided (e.g., provide evidence-based content with none to minimal support).[77,106,122] Yet, to our knowledge, this type of approach has not been designed for or tested among young men specifically—and young men remain underrepresented in male-only lifestyle interventions.[116,117] As such, there remains a need for weight loss interventions designed to meet both gender preferences and developmental needs of young men.

Given young men have low concern about weight,[91,100] employing theory-based messaging within a self-guided lifestyle intervention, to raise health concerns associated with obesity, might be a natural fit. Health risk messages have played a key role in public health campaigns to alter health behaviors and increase perception of health risks.[125,129] One specific theory used to develop health risk messages is the extended parallel process model (EPPM). The EPPM suggests that our perception of a health threat interacts with the belief that a recommended behavior change strategy is effective at preventing the given health threat. When coupled with the confidence to carry out the given behavior, this will in turn, influence our intent to adopt the recommended behavior.[124] EPPM has been applied to a number of different health areas including smoking cessation[127] and breast cancer screening.[125] Nevertheless, obesity-related research with EPPM is minimal—though, EPPM shows some promise for changing risky health behaviors among young men. Limited evidence indicates that EPPM-based messaging can motivate young men to engage in physical activity and enhance their perceived risk of obesity.[134,135] Despite these promising findings, EPPM has not yet been applied to a male-targeted self-guided lifestyle intervention. EPPM might be a particularly appropriate framework to integrate into a lifestyle intervention designed for young men, given evidence that shows young men in particular have lower concern about weight gain relative to young women.[100]

It is plausible that an intervention that is not only male-targeted, but also self-guided and grounded within the EPPM framework, could be a viable approach to promoting weight loss among young men. Not only could using this type of programming improve enrollment among this high-risk population, it also has the potential to promote awareness of health risks associated with obesity, as well as equip young men with the necessary skills to effectively manage their weight throughout the life course. To that end, the primary aim of the present study is to test the feasibility and preliminary efficacy of a male-targeted lifestyle intervention (self-guided intervention + EPPM) on weight change among young men. We will assess feasibility via retention and satisfaction data, and anticipate that young men in the intervention arm will manifest greater reductions in weight at 12-weeks compared to the delayed treatment control arm. We also aim to explore potential changes in perceived risk in response to the intervention and whether change in perceived risk is associated with weight loss.

Methods

Sample

Participants were eligible if they were between 18 and 35 years of age, with a body mass index (BMI) between 25-45 kg/m^2. Exclusion criteria were selected primarily for safety reasons and included: an uncontrolled medical condition that might make it unsafe to engage in exercise without medical supervision, diagnosis of type 1 or type 2 diabetes, report of a heart condition or chest pain during rest, history of anorexia or bulimia nervosa, report of compensatory behaviors within last 3 months, or hospitalization for psychiatric condition in the last 12 months. Additional exclusion criteria included potential confounds or reasons that would prevent participants from being able to benefit from the treatment: participation in another program promoting weight loss,

loss of ≥ 5% body weight within the last 3 months, not able to read/speak English, does not possess a mobile device or unwilling to receive text messages, or lives/resides outside of North America.

Recruitment and Screening

Recruitment and screening occurred between January-March 2021 throughout North America. Both national and local recruitment strategies were adopted and included unpaid advertisements through VCU listservs, unpaid posts on social media, flyers distributed in VCU buildings and residence halls, and postings to research recruitment sites (e.g., researchmatch.org). Recruitment materials included an image of a young man engaging in physical activity paired with a male-targeted health risk message based in the EPPM. Messaging emphasized the risk of heart disease among men and that the program was a self-guided lifestyle program (See Figure 1). A link to a recruitment website was included on all recruitment materials. The recruitment website provided interested individuals with a brief overview of the study, inclusion criteria, a BMI calculator, contact information, and a link to a secure online eligibility screener. Based on screening information, individuals who appeared eligible were contacted to attend a one-on-one virtual orientation session via Zoom. The interactive orientation session included a brief PowerPoint presentation with text/visuals and covered the study purpose and goals, study procedures, and time commitment. Time was also allotted for questions throughout and at the end. Following the brief presentation, those who remained interested began the informed consent process and were given the opportunity to review the consent form and ask questions. Participants who chose to enroll signed an informed consent form electronically.

Design

Eligible participants were stratified by BMI (25-35 kg/m^2 or 36-45 kg/m^2) and randomly assigned to 1 of 2 groups (ACTIVATE intervention or delayed treatment control). Blocks of four

were used for the allocation sequence, which was generated by online software designed for this purpose and uploaded to REDCap. A trained research assistant (no role in either intervention or assessments) assigned and notified participants of assignment via phone. The trial protocol was approved by the institutional review board at Virginia Commonwealth University. The study had a target sample size of 32. The purpose was not to be a fully powered trial, but rather to obtain stable estimates of standard deviations and to determine if this self-guided model was a feasible approach to promote weight loss. The study had 80% power to detect a 3% between group comparison of change in weight from baseline to 12 weeks. All investigators and assessors were blinded until after the final data collection visit for this trial.

All protocol changes are reported using the CONSERVE Guidelines for reporting trial protocols (CONSERVE-SPIRIT Extension).[141] The original in-person protocol was modified in May 2020, prior to the enrollment of the first participant, due to the global COVID-19 pandemic. These modifications were reviewed and approved by the study investigators and VCU IRB. Mitigating strategies included modifications that allowed for remote recruitment, data collection, intervention implementation, and measurement. Recruitment was expanded to all of North America given that in-person outcome assessments were no longer required. The protocol was revised to only examine weight change, as opposed to multiple measures of adiposity, given weight could be measured via a remote protocol that aligned with our clinic-based protocol (i.e., fasted state, serial objective measures on a study issued scale). Scale selection was based on data collected from reliability and validity testing of 4 different scales (Renpho, Taylor, Healthometer, Withings). A 15-pound hand weight was used during testing. The hand weight was placed on the scale 3 consecutive times and the weight was recorded. Measurements were also collected across 3 separate time points (approximately 1 week between each time point). Error for each scale was

compared to a research grade clinic scale (Tanita BWB 800) and 3 other similar bathroom scales, and across time. The Renpho scale had 0lb error within timepoint measurements. The error across timepoints was 0.2lb, which was the same compared to all scales except the Taylor (0 error). The Renpho scale was selected based on cost, availability, and its Bluetooth capability. The intervention group kick-off session was adapted for delivery via Zoom instead of in-person.

Assessment visits occurred via Zoom (baseline and 12-weeks) and were identical to how assessments occur in clinic (e.g., fasted conditions, serial measures). Remote assessment visits were conducted by a blinded assessor in a private room. Video was only required to be on for the assessment of weight, in order for the assessor to see the weight shown on the scale. Participants were given the option to turn video off for the remaining measures.

Intervention

All participants received the 12-week ACTIVATE intervention that included 1 group kick-off session delivered via Zoom, access to a private intervention website with self-paced content, wireless/Bluetooth capable scale, 12 weekly text messages, and feedback reports at baseline and 12-weeks. Intervention content, text messages, and feedback reports included health risk messaging based on the 4 constructs of EPPM. Perceived threat is defined as perceived susceptibility (*belief one is vulnerable to a specific disease*) and perceived severity (*belief the disease is serious*). Efficacy is defined as self-efficacy (*confidence to carry out recommendations to avoid risk of disease*) and response efficacy (*belief the proposed recommendation is effective at mitigating the disease risk*).[124] Health risk messaging emphasized the link between obesity and cardiovascular disease specific to young men, as well as the research evidence for the behavioral strategies taught to promote weight loss, and for weight loss to mitigate cardiovascular disease risk.

The virtual group session was facilitated by a licensed clinical psychologist with expertise in behavioral weight loss treatment in young adults. The session provided an overview of health risks and a brief review of the principles of behavioral self-regulation for weight management.[29] During the session, participants received psychoeducation, training in evidence-based behavior change techniques, and engaged in skills practice to enhance self-efficacy. The intervention website provided participants with additional psychoeducation about healthy weight management practices including diet and meal prep strategies and physical activity recommendations. The website also provided content focused on evidence-based behavior change techniques associated with weight loss, including self-monitoring and goal setting.[34,142] All intervention content was adapted to enhance relevance and meet the needs and preferences of young men.[110,112] This included an emphasis on fitness and reducing consumption of alcohol, sugar-sweetened beverages, fast foods and processed meals, and foods high in fat content. The website also provided links to publicly available videos and apps for physical activity, with recommendations for free apps to facilitate self-monitoring of dietary intake, weight, and physical activity. To reinforce EPPM messaging across the 12-weeks, participants received weekly text messages that included EPPM constructs. See Figure 2.

Measures

Demographic information was self-reported by participants via an online questionnaire.

Satisfaction

Overall satisfaction with the program was assessed via self-report at 12-weeks. Two items are reported on a 7-point Likert scale (1=Very Dissatisfied, 7=Very Satisfied). “How satisfied were you with the overall ACTIVATE program.” “How satisfied were you with what you achieved in the ACTIVATE program.”

Weight/Height

Weight was collected via video using a study-issued Bluetooth scale (Renpho). Participants refrained from eating or drinking, except water, for 8 hours and wore light gym clothes and a t-shirt without shoes, socks, and jewelry. Height was assessed via self-report but was not measured directly.

Perceived Risk

The Risk Behavior Diagnosis Scale (RBDS) is 12-item scale that was designed to measure constructs based in the EPPM. The RBDS has demonstrated good internal consistency and predictive validity.[143] Cardiovascular disease was used as the defined health threat and weight loss as the defined recommended response to the health threat. For example, "It is likely that I will get cardiovascular disease if I do not lose weight." Participants rated each statement on a 5-point scale (*1=Strongly disagree*, *5=Strongly agree*).

Statistical Analyses

All outcome analyses adhered to the Intent-to-Treat (ITT) approach, using multiple imputation with 5 imputed datasets for missing cases (n=5) at follow-up. T-tests were used to assess between group differences (intervention vs. control) in percent weight change from 0- to 12-weeks and change in EPPM constructs at 2- and 12-weeks. Linear regression was used to examine the association between percent weight loss and changes in EPPM constructs. Chi-square analyses were conducted to compare between group differences in the proportion of participants achieving a clinically significant weight loss (>3%).[17] An alpha level of .05 was used. All analyses were conducted using (JMP 15.0, SAS, Inc.).

Results

Detailed demographics are displayed overall and by arm in Table 1. The mean age was 29.3±4.27, with an average BMI of 30.8±4.26, and 34% of participants identifying as racial or ethnic minority. Recruitment and enrollment occurred in a 2-month period. Retention was 86% at 12-weeks, with no statistically significant differences by arm (p=.17; see Figure 3 for CONSORT flow diagram). Attendance at the virtual group kick-off session was 83%; the 3 participants who missed the live session received a pre-recorded video that covered the same concepts. Overall satisfaction with the ACTIVATE program was 4.2±1.1 on a 7-point scale. Participants overall satisfaction with results they achieved in the intervention was 3.9±.83 on a 7-point scale.

Weight Change

Participants in the ACTIVATE intervention arm manifested larger reductions in weight compared to the control group (-1.6%±2.5 vs. +0.31%±2.8, p=.04). See Table 2.

Perceived Risk

Changes in EPPM constructs (response efficacy, self-efficacy, perceived severity, perceived susceptibility) were not associated with percent weight change at 12-weeks (all p's > .05) for the intervention or control group. There were no statistically significant differences between participants in the ACTIVATE intervention and control group in changes to EPPM constructs at 12-weeks (all p's > .05). See Table 2.

Discussion

The present study sought to determine the feasibility and preliminary efficacy of a self-guided intervention that integrates male-targeted health risk messages on weight loss among young men. Data indicate that participants were moderately satisfied with the intervention and experienced modest weight losses during the 12-week intervention. These findings are consistent with another recent trial that targeted young men in Australia, wherein modest weight loss

differences were found between the intervention and control group (-1.3% vs. +0.6%).[121] The prior study was also 12-weeks in duration but was more intensive compared to the current intervention thus supporting the notion that young men may not need high-levels of intensive support in a lifestyle intervention. Instead, men might need an intervention that can potentially be used at their own discretion to meet the demands of this developmental period and preferences of men.

Notably, this trial exceeded recruitment and enrollment goals within the short time span of two months. Remote implementation may have mitigated some of the common barriers reported among young men (time and convenience)[110] that otherwise would have occurred with in-person assessments. Given the notorious challenges recruiting young men in lifestyle interventions,[137] these enrollment data are particularly encouraging and suggest this type of male-targeted self-guided program, with remote delivery, might be a promising approach for reaching young men. Furthermore, how the intervention is advertised to young men might be central to engaging this population in weight management. This intervention was designed to meet the specific needs and preferences of young men[110] and used recruitment materials to include various images of young men and messaging (e.g., health risk messages, no health risk message). Though, these recruitment strategies were not experimentally manipulated in this study and varied by outlet. As such, we cannot know which elements of the recruitment ads might have been most effective. Indeed, future studies should consider testing different recruitment strategies that might be effective at engaging this hard-to-reach population.

Lastly, significant changes in EPPM constructs were not observed in the current study. Due to ceiling effects and low variability of these constructs, it is challenging to interpret the association between these constructs with weight change. It is possible that the high perceived risk scores observed at baseline could be due to bias in this treatment-seeking sample wherein the

young men who enrolled had greater concern about their weight than young men in the general population. This could also reflect the need for increased dose or tailoring EPPM messaging to enhance these constructs in young men. More research is needed to understand if health risk messaging might be better suited for recruitment materials and whether or not EPPM constructs moderate weight change. One study conducted with Iranian soldiers found that EPPM constructs increased after men received educational training about obesity and weight management, but weight was not assessed as an outcome.[135] Given these findings, along with the challenges of recruiting men into lifestyle interventions, it is worth examining different elements of recruitment materials that might bolster enrollment in this population.

Limitations

Findings should be interpreted in light of several limitations. First, our sample size was small. Thus, caution should be taken when interpreting and generalizing these results. Additionally, the intervention period was brief and there was only a post-treatment assessment. Therefore, there is a need for replicating these findings in a larger sample over a longer follow-up period. Although 34% of the sample self-identified as racial/ethnic minority, there were no Black men enrolled—even with some advertisements that included an image of a young Black man. This underscores the need to improve reach among this population and that superficial adaptations to recruitment ads are insufficient. This sample was also highly educated, which coupled with limited racial and ethnic minority enrollment, raises concerns about generalizability. Third, due to the global COVID-19 pandemic, this study was limited to one measure of adiposity because a remote protocol was implemented to minimize risk to participants and study team members. This study would have benefited from collecting body composition and waist circumference, which was originally proposed. As a result, the full cardiometabolic health benefits of this type of self-guided

intervention remain unknown. Given the self-guided nature of the program without behavioral targets, combined with the global pandemic and goal of keeping the assessment battery minimal, no self-reported or objective behavioral adherence data were collected. Finally, EPPM messaging was used in recruitment materials, which may have improved enrollment, but might have also increased these constructs prior to the intervention period and contributed to ceiling effects, thereby limiting our ability to differentially promote change in these constructs through this low touch intervention relative to the control arm.

Implications Moving Forward

Our data provides evidence that a brief, self-guided intervention can produce modest weight loss and prevent weight gain among young men. Given the rate of accruing men over a short period of time (2 months) relative to previous work with young adults, these pilot findings suggest that recruiting nationally with a remote protocol is feasible for recruiting this hard-to-reach population. Moreover, the combination of a male-targeted program and health risk messaging shows promise for promoting weight management in this population. However, more research is needed to better understand the specific elements that engage men to lose weight—for incorporation into both recruitment and intervention materials. Overall, these findings highlight that self-guided lifestyle interventions might be a useful, low-cost, and scalable approach for promoting initial weight loss among young men. More testing is needed to better understand which evidence-based components should be added to produce clinically meaningful weight loss among young men, while at the same time, retaining a self-guided approach.

Figure 1. Example of Male-Target Recruitment Advertisement Based in Extended Parallel Process Model

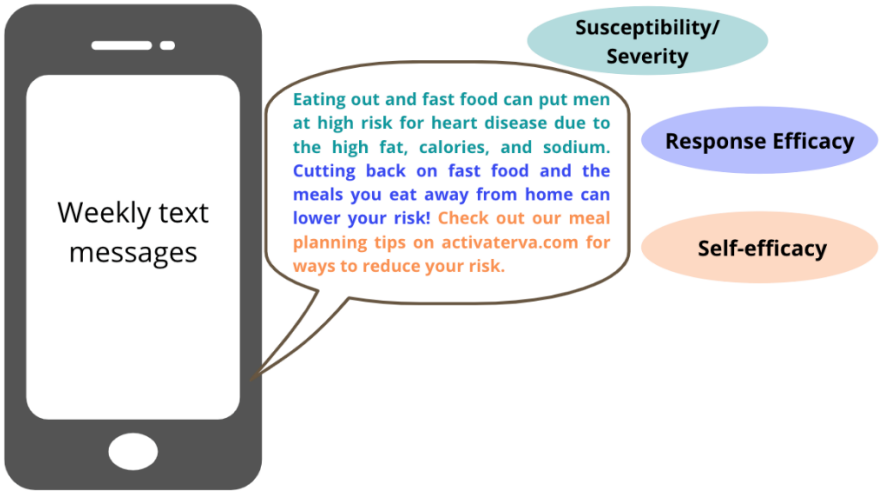

Figure 2. Example of a Weekly Text Message Based in Extended Parallel Process Model

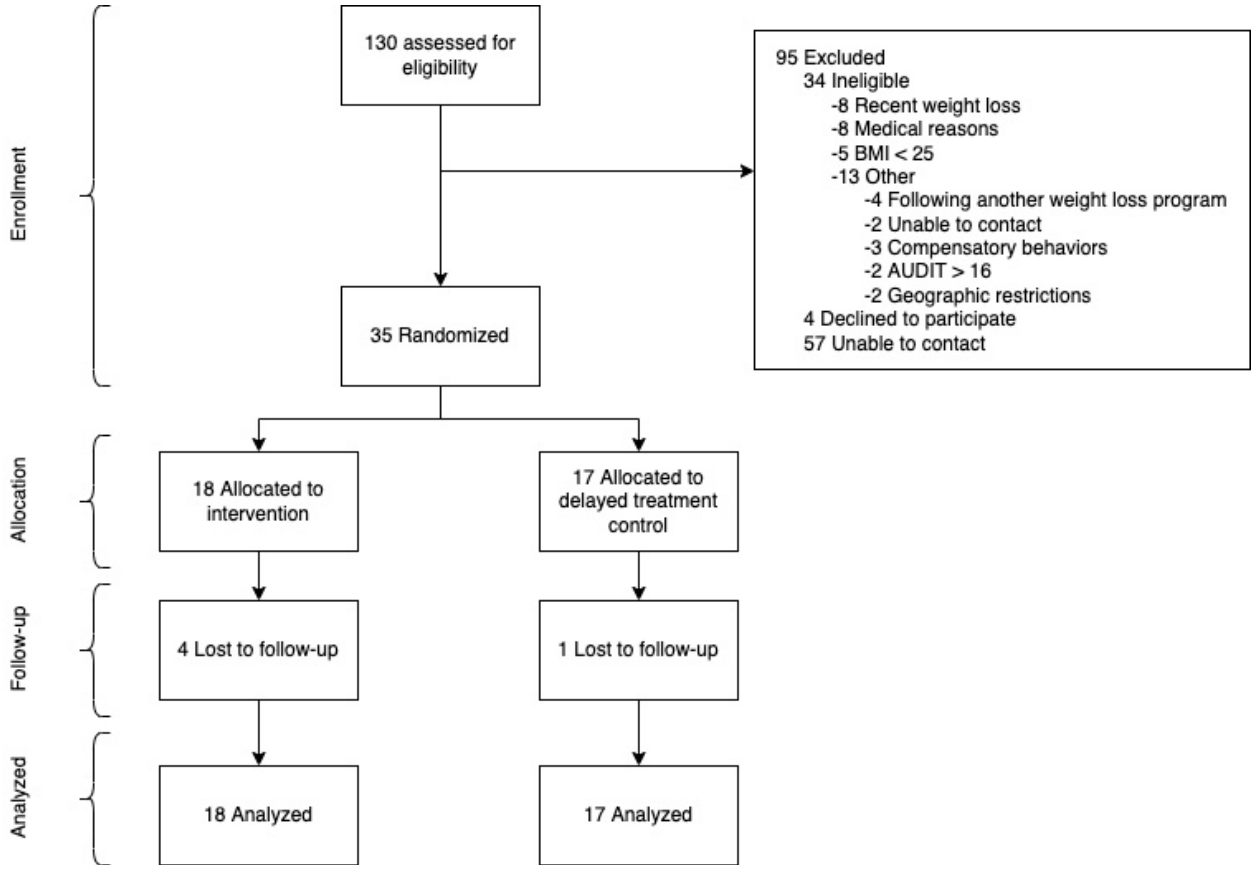

Figure 3. CONSORT Flow Diagram

Table 1. Participant characteristics (%[n] for categorical variables and mean ± SD for continuous variables)

	Full Sample (N=35)	Treatment (n=18)	Control (n=17)
Age	29.6±4.3	29.6±3.8	29.0±4.8
Race/Ethnicity			
American Indian/Alaskan Native	5.9 (2)	5.6 (1)	6.3 (1)
Asian	11.8 (4)	11.1 (2)	12.5 (2)
Black	0	0	0
Native Hawaiian/Pacific Islander	0	0	0
Non-Hispanic White	65.7 (23)	72.2 (13)	58.8 (10)
Other	8.8 (3)	5.6 (1)	12.5 (2)
Latino	21.2 (7)	22.2 (4)	20.0 (3)
Multiracial	14.7 (5)	16.7 (3)	12.5 (2)
Work/School Status			
Working Full-Time	73.3 (22)	78.6 (11)	68.8 (11)
Working Part-Time	13.3 (4)	14.3 (2)	12.5 (2)
Student Full-Time	16.7 (5)	14.3 (2)	18.8 (3)
Student Part-Time	0	0	0
Hours Worked Weekly	39.9±9.5	41.3±10.5	38.5±8.6
Level of Education			
Some College	13.3 (4)	14.3 (2)	12.5 (2)
College Graduate	46.7 (14)	57.1 (8)	37.5 (6)
Postgraduate Degree	40.0 (12)	13.3 (4)	50.0 (8)
Relationship Status			
Married	48.3 (14)	46.2 (6)	50.0 (8)
Single	34.5 (10)	46.2 (6)	25.0 (4)
Living with Partner	17.2 (5)	7.7 (1)	25.0 (4)
Baseline Outcomes			
Baseline BMI	30.8±4.2	30.9±4.7	30.7±3.9
Baseline Weight (kg)	96.8±15.5	98.3±18.1	95.1±14.2
Response Efficacy	4.6±0.7	4.7±0.5	4.6±0.8
Self-Efficacy	3.7±0.8	3.7±0.8	3.7±0.8
Perceived Severity	4.7±0.5	4.7±0.4	4.7±0.5
Perceived Susceptibility	3.7±1.0	3.9±0.9	3.5±1.1

Table 2. Change in Outcomes by Arm (mean ± SD [95% Confidence Interval)

	Treatment	Control	p-value	Cohen's d
Weight Change (%)	-1.6%±2.5 [-2.8, -0.36]	0.31%±2.8 [-1.3, 1.7]	.042	0.72
2-Week Perceived Risk Change				
Perceived Severity	0.13±0.38 [-0.06, 0.31]	0.05±0.35 [-0.13, 0.23]	.551	0.16
Perceived Susceptibility	-0.04±0.58 [-0.33, 0.25]	-0.05±0.70 [-0.42, 0.30]	.921	0.04
Response Efficacy	0.07±0.59 [-0.22, 0.36]	-0.01±0.38 [-0.22, 0.18]	.583	0.19
Self-Efficacy	0.22±0.85 [0.20, 0.64]	0.11±0.59 [-0.19, 0.41]	.661	0.22
12-Week Perceived Risk Change				
Perceived Severity	0.08±0.41 [-0.12, 0.28]	-0.18±1.4 [-0.90, 0.54]	.640	0.64
Perceived Susceptibility	-0.10±1.1 [-0.67, 0.45]	0.02±1.1 [-0.56, 0.60]	.317	0.32
Response Efficacy	0.05±0.44 [-0.17, 0.27]	0.02±0.36 [-0.16, 0.21]	.829	0.07
Self-Efficacy	0.19±0.59 [-0.11, 0.48]	0.13±.73 [-0.24, 0.50]	.810	0.13

CHAPTER 3

Paper 2

Acceptability of a self-guided lifestyle intervention designed for young men: A mixed method analysis

Abstract

Background
Young men are challenging to recruit into behavioral weight loss interventions. Thus, there is a need for developing appealing and effective programing for this population.

Objective
A convergent mixed methods design was used to examine young men's experience and satisfaction with specific elements of a self-guided weight management intervention that incorporated male-targeted health risk messaging.

Methods
Fourteen young men (aged 29.9±4.9 yrs, BMI 31.0±4.5 kg/m^2, 29% ethnic/racial minority) completed semi-structured interviews and satisfaction surveys following the completion of a 12-week intervention. The intervention included 1 virtual group session, digital tools (wireless scale, self-monitoring app), access to self-paced content through a secure website, and 12 weekly health risk text messages. Qualitative data were coded, using a directed content analysis, and integrated with satisfaction survey scores using a joint display. Experience and satisfaction were compared by treatment response (clinically significant weight loss, non-clinically significant weight loss, no weight loss).

Results
Age and gender were described as primary reasons for joining the program. The Bluetooth scale was described and rated favorably in aiding weight loss, but only among those achieving clinically significant weight loss (≥ 3%). The text messages were described as helpful reminders, but not sufficient for sustaining motivation. Young men did not prefer a group session for weight loss, but did recommend adding a peer support to help with motivation and accountability. The self-guided aspect was less appealing to men and majority of men preferred monthly check-ins. Overall, online delivery was preferred, specifically focusing on physical activity. However, in-person and virtual muscle strengthening classes were preferred among men who did not lose weight.

Conclusions
A self-guided weight management intervention designed for young men was found acceptable. This study demonstrates a need for designing behavioral weight loss programs in a way that is responsive to individuals needs and preferences. Including a social component in a male-targeted intervention and other ways to sustain motivation, such as periodic coach check-ins and / or automated tailored feedback should also be further examined.

Introduction

Men with obesity during young adulthood have double the mortality risk compared to men with a healthy body mass index ([BMI] kg/m^2).[83] Thus, highlighting the need for effective management of obesity among young men (ages 18-35 years). Despite this risk, men of all ages are underrepresented in behavioral weight loss interventions[144]—representing approximately one-quarter of enrolled participants.[137] Young men in particular are all but absent in behavioral weight loss trials—in fact, a systematic review revealed that the age range for men enrolled in behavioral weight loss trials is 39 to 62 years.[144] Young men's low enrollment in weight loss interventions might be related to the intersection of gender and age. Men in general have low concern about weight gain[91,100] and health risks linked to obesity,[91] and there is a lack of behavioral weight loss programming designed to meet the specific needs of men.[90] When considering age, young adulthood presents with its own developmental characteristics[145] which are thought to add to low enrollment of this population[66] such as life transitions including moving away from home or starting work or school. Therefore, tailoring for both age[87,146] and gender[137,144,147] has the potential to bolster engagement among young men. Work has been done to adapt weight loss programs for young women, [148-150] and men with no age limitations[103,106,116,117]. However, limited research exists pertaining to young men's needs as it relates to losing weight, despite their obesity-related health risks.

Behavioral weight loss interventions targeting men show promise in engaging men to lose weight and include different features appealing to men—such as a sports-based or self-guided approach.[103,110,117,122] Implementing a male-targeted self-guided approach appears efficacious in producing initial weight loss and satisfaction among young men.[104,122,151] Moreover, using a self-guided approach is also consistent with formative data indicating that young men have a preference

for interventions that are convenient and mitigate time constraints.[110] With respect to age, formative data found that young adults demonstrate preference for programs with reduced intensity and that promote autonomy.[87] Despite this, it is unclear if a self-guided approach alone can enhance young men's concern about weight. Framing messages to raise men's health risk awareness about obesity might be suitable for weight loss. Young men in particular appear responsive to health risk messaging.[134,135] In a weight loss trial targeting young men, we found that implementing a self-guided approach, paired with health risk messaging, demonstrated initial efficacy for promoting modest weight loss among young men compared with a control arm.[152] However, it remains unclear which specific elements are perceived as most helpful in supporting weight loss for young men.

To improve young men's engagement with weight loss, it is critical to adapt behavioral weight loss interventions based on young men's preferences and experience with the intervention. Existing guidelines for behavioral intervention development are outlined through the ORBIT model and recommend being flexible via an iterative process, as a way to reach optimal treatment outcomes for the target population.[153] The ORBIT model specifically recommends the use of mixed method approaches for defining and refining interventions, as well as during feasibility pilot testing.[153] Prior to a rollout of a behavioral weight loss program, it is important to determine acceptability of the program among users, which is often captured quantitatively through measures of satisfaction, attendance, and efficacy.[48,154-156] Satisfaction is a key construct to consider when developing an intervention, given that higher levels of satisfaction with a program is associated with favorable weight loss outcomes.[157] Though, qualitative measures of satisfaction with programs is limited in behavioral weight loss trials,[157-159] especially as it relates to young men. As a result, this limits our full understanding of the experience and satisfaction of the actual end-user,

in this case, young men. To promote favorable weight outcomes among young men, new approaches should be adopted that incorporate both quantitative and qualitative user feedback and experience with the intervention.

To address this gap in the literature, we used a mixed methods approach to explore the experiences of young men who completed a 12-week digital weight loss intervention (self-guided + male-targeted health risk messaging). The objectives of this paper were to: 1) explore young men's satisfaction with specific components of the self-guided lifestyle intervention (digital tools, health risk text messages); and 2) compare satisfaction and preferences by response to treatment.

Methods

A convergent mixed methods design was used to examine the user experiences and acceptability of a digital weight loss intervention (self-guided + male-targeted health risk messaging). Both the consolidated criteria for reporting qualitative studies (COREQ)[160] and guidelines for reporting mixed methods studies[161] were followed in the current study.

Parent study

Men between the age of 18-35, with a BMI of 25-45 kg/m^2, were recruited and enrolled during a 2-month period. Recruitment occurred throughout North America and locally using unpaid recruitment advertisements, which were distributed using email listservs, University postings, and researchmatch.org. Recruitment advertisements included an image of a man exercising and a male-targeted health risk message, emphasizing the link between cardiovascular disease and obesity. Interested participants completed an online study screener to determine initial eligibility and were contacted by a member of the study team to schedule an orientation to learn more about the study. Following orientation, interested individuals engaged in an informed consent process, and those who chose to consent provided electronic signatures. Thirty-five men were

randomly assigned to either the intervention or a delayed intervention control group. Men assigned to intervention and who completed the 3-month follow-up visit (n=14) were asked to participate in an exit-interview following completion of the 12-week assessment visit. Assessments occurred remotely and involved collection of fasted weight in serial via video at 0 and 12-weeks, as well self-administered surveys completed through a secure website (REDCap). A remote protocol was implemented due to the global COVID-19 pandemic. The protocol and exclusion criteria are detailed elsewhere.[152]

Intervention

Men received a 12-week behavioral weight loss intervention that was primarily self-guided. The intervention incorporated male-targeted health risk messaging throughout the materials. The messages were grounded in the extended parallel process model (EPPM)[124] and linked obesity to cardiovascular disease. EPPM, a health communication theory, proposes that in order to a change a health behavior, the individual must perceive that they are at risk for a poor health outcome (perceived susceptibility) and that the consequences must be severe (perceived severity). The individual must also believe they possess appropriate skills and strategies to address the health outcome (self-efficacy) and believe that the recommended solution is effective (response efficacy). The intervention was delivered remotely and included 1 virtual group session with a licensed clinical psychologist, access to a private website with evidence-based content (psychoeducation and behavioral skills), digital tools (Bluetooth scale, apps for self-monitoring), feedback reports at baseline and 12-weeks, and 12 weekly text messages. Details of the intervention are described elsewhere.[152]

Acceptability and Satisfaction

Acceptability and satisfaction were operationalized using a combination of user feedback from both semi-structured interviews and satisfaction surveys.

Satisfaction Survey

Satisfaction with the intervention components was assessed via self-report at 12-weeks. Items were reported on a 7-point Likert scale. Participants were asked to rate aspects of the intervention they found appealing upon joining the program (e.g., male only, young adult only, self-guided, etc.) on a scale wherein higher scores reflected higher satisfaction (1=Strongly disagree, did not help, not appealing at all, very dissatisfied; 7=Strongly agree, very helpful, very appealing, very satisfied). Participants also rated program components (group session, text messages, website) perceived as helpful with weight loss, as well as certain features (length, frequency, relevance) of each component. In addition, participants were asked about intervention components and delivery method that were not offered but they felt would have been helpful (e.g., in-person meetings focused on physical activity, online meetings about diet).

Interviews

Interviews (N=14) were conducted over the phone, in a private setting, by a female Ph.D. student (first author/student investigator) with extensive interviewing experience (both focus groups and semi-structured interviews). Interviews were an average length of 15-minutes (range = 8-29 minutes) in duration. The interview guide was developed by 3 of the authors (JMR, JGL, MDT), all with qualitative research experience, and included questions about motivations for joining the study, overall satisfaction with the intervention, challenges and successes with the intervention, and suggested changes for future interventions. Standardized probes were used to extract detailed comments about intervention components that were helpful or unhelpful in reaching intervention goals. Interviews also asked participants to describe the intervention as if

they were talking to a friend interested in joining as a way to understand how best to present the program in the recruitment process. All interviews were audio recorded and transcribed verbatim.

Analysis

Quantitative Analysis

Data were classified into 3 categories for treatment response: 1) clinically significant weight loss (≥ 3%); 2) non-clinically significant weight loss (<3%); or 3) no weight loss. The threshold for categorizing participants is based on guidelines by the American Heart Association, where 3% weight loss is indicated as the minimal amount of weight loss determined to have clinical significance given reliable associations with improvement in cardiometabolic risk factors.[18]

Descriptive statistics were computed for each item on the satisfaction survey. The means for each item were then compared by treatment response to note trends. Acceptability with program components were deemed satisfactory if the mean score for each item was ≥ 5 (1 point above the central point of scale) and unsatisfactory for scores < 5.[162] No inferential statistics were conducted to compare differences between treatment response groups, given the small cell sizes for each treatment response group and the aim of the study was characterizing participant experience through data integration with the qualitative data. Descriptive statistics were computed using SPSS, Version 27 (IBM Corporation).

Qualitative Analysis

A directed content analysis was used to qualitatively code the semi-structured interviews. The codebook definitions and codes were developed based on the literature review and evidence-based intervention.[163] Standard coding recommendations were followed.[164] The coders consisted of 2 men with education in public health and behavioral medicine (MPH, B.S.). Both coders were trained through 2 weekly trainings by the student investigator with education in psychology

and behavioral sciences (M.A.), and extensive experience in qualitative research. First, four transcripts were reviewed by the student investigator (JMR) to develop an initial codebook, which consisted of primary and secondary codes. Next, two coders then coded the same four transcripts using the initial codebook. Coding discrepancies were discussed over weekly meetings to refine the codebook. Then, four additional transcripts were coded by both coders and discrepancies were discussed to further refine and finalize the codebook. Transcripts were analyzed in batches of 2 to 4 by both coders, with reliability checks throughout. Over half of the transcripts (n=8) were reviewed by both coders and maintained inter-coder reliability[165] (Kappa >0.80) and fidelity to the codebook. Incongruent codes were flagged, discussed, and reviewed at weekly meetings with the student investigator. All discrepancies were resolved through group consensus. Data achieved saturation after 10 coded interviews, in that no new categories emerged and sufficient information was acquired to explain the quantitative data.[166] Coded categories were grouped into pre-identified themes based on intervention components and aspects of participant satisfaction. Subcategories of each pre-identified theme was cross-compared for word similarities to identify overlap in responses. Data were coded using NVivo 12.0 (QSR International). No participant checking or feedback was provided on the findings from participants.

Data Integration

A convergent mixed methods analysis[167] was used following standard guidelines.[161] Quantitative and qualitative data sets were integrated using a joint display.[168] Specific items from the satisfaction survey were integrated with corresponding themes related to intervention materials, in which qualitative data was embedded into quantitative data to explain satisfaction scores for intervention components and response to treatment. Frequency of themes were

compared by treatment response using a crosstab query in NVivo 12.0, (QSR International) and then cross-compared to quantitative satisfaction scores to identify noteworthy trends.

Results

Participants (N=14) mean age was 29.9±4.9 with a BMI of 31.0±4.5 kg/m^2, and 29% identifying as racial/ethnic minority. Demographic characteristics of the participants completing the interview and satisfaction questionnaires are displayed in Table 1. Retention for the treatment arm was 78% (14/18), which was not statistically significant compared to the control group (p=.17).

On average, participants lost -1.8%±2.8 (range= -9.5 to +1.3) of initial body weight over the course of 12-weeks. Within the treatment group, majority of the participants lost weight (n=9, 64.3%) compared to participants who did not lose weight (n=5). Of those who lost weight in the treatment group, over one-third of the treatment group (n=5) achieved a weight loss ≥ 3% and 29% achieved less than 3% weight loss (n=4).

Appealing Aspects of the Program / Motivations for Joining

Participants reported multiple reasons for joining the program in the interviews. Losing weight was the most common reason for joining the program (57%). Other reasons for joining included meeting the age and gender demographic (50%), gain knowledge (43%), get in shape (36%), or for the self-guided aspect (29%). Half of participants discussed that a major reason for joining was meeting the demographic. Participants often mentioned age and gender together as a reason for joining. Age (5.0±1.1) and gender (5.0±1.4) were also among the top 5 aspects rated as appealing to men. See Table 2.

"I think what specifically, uh, got me into it was the fact that it targeted young men [sic], my age group."

Most participants did not report hesitations for joining the program. However, a few participants (21%) reported reluctancies about joining the program—mainly about having enough time.

All aspects of the program, except for one (self-guided), had an overall rating ≥ 5. The three highest ranked reasons for joining the program included general lifestyle changes (5.9±1.0), focus on health risk (5.8±0.73), and weight loss (5.4±1.0). The lowest ranked aspect was the self-guided component (3.8±1.8). See Table 2. This was ranked as less appealing (< 5) among those who achieved clinically significant weight loss (3.8±2.2) and maintained/gained weight (3.2±1.6). Those achieving non-clinically significant weight loss found the self-guided aspect as slightly more appealing (4.5±1.7).

Acceptability of Program Components

Majority of the participants in the interviews mentioned the Bluetooth scales (79%), the recommended apps (64%), and text messages (71%) were helpful with weight loss, which was consistent with survey ratings for these items. Details of each program component are described below.

Bluetooth scale

Participants specifically discussed finding the scale's features, which included an app to track metrics and progress, helpful and had an average satisfaction of 5.1±1.4.

"The scale was really, really useful, actually, especially starting out because I could see, like, all the different metrics that I had no idea of before."

The scale was reported as particularly helpful in aiding weight loss for all participants who achieved clinically significant weight loss (5/5) and received a rating of 6.0±0. However,

satisfaction with the scale for participants was lower among those who gained or maintained weight (3.8±1.6).

"One thing I really liked was the scale that you gave. I use that as kind of a daily start off for my morning, so I downloaded the Renpho app. And I did check my weight. I usually did it morning and night. [sic] 90 percent of the time I would get a morning and an evening weight and my BMI and I would kind of track that. And that would kind of be a jump start to my day."

Recommended Apps

The recommended food tracking apps had a slightly lower satisfaction rating (4.0±1.6) than apps for physical activity (4.5±1.6). Satisfaction ratings were also similar when comparing individuals' response to treatment.

"I already use some of the nutrition tracking apps, but there was a workout app specifically, Fit On is the one that I kind of latched on to and I hadn't heard of it before. And I use that as my primary source for exercise and kind of coming up with an actual exercise plan. And I use My Fitness Pal a little bit as well to check diet."

Health Risk Text Messages

The qualitative data indicate participants found the weekly text messages served as good reminders. However, quantitative data show that overall satisfaction with the health risk text messages was modest (4.3±1.8). Participants rated the strategies suggested in the text messages less helpful (4.2±1.6) compared to other aspects of the text messages, such as increasing awareness of health risks (5.4±1.6) and serving as motivation (5.0±1.5). Satisfaction was higher among participants who achieved non-clinically significant weight loss compared to participants who achieved clinically significant weight loss or did not lose weight. See Table 3.

"The text messages like the cardiovascular information. I thought that was helpful."

"The text messages I found helpful [sic], as a reminder of the ultimate reason why I was doing this."

Half of the qualitative interviews indicate that participants found the text messages of benefit. The other half either did not find the messages helpful or had mixed feelings about them—some felt the content of the text messages didn't have enough variety or were something that could be easily disregarded.

"I mean, uh, the uh, the text message that we got, it was good accountability, but it was also, that I can see how that could also just be something that you just kind of slough off because we just like, a here's a fact."

Of note, participants who either gained or maintained weight (4/5) or reached non-clinically significant weight loss (4/4) distinctly reported that the text messages were helpful compared to those who achieved clinically significant weight loss (2/5). This qualitative finding is particularly consistent with quantitative data, where men who achieved clinically meaningful weight loss did not find the health risk text messages particularly helpful with weight loss. See Table 4.

Virtual group session

The group session was rated as less helpful (3.7$\pm$1.9) compared to the other components of the program. The length of the group session was rated higher among those who achieved clinically significant weight loss (5.6$\pm$0.89) than those achieving non-clinically significant weight loss (3.5$\pm$0.58). Participants rated the strategies taught during the class as less helpful (4.1$\pm$1.3). The information provided during the group session was rated as less motivating (4.3$\pm$1.1) and relevant (4.6$\pm$1.2). Scores were consistent across treatment response groups with the exception that those who did not lose weight rated the group session with slightly higher satisfaction

(4.0±1.9) compared to those achieving clinically significant weight loss (3.8±1.6) and non-clinically significant weight loss (3.3±2.6).

Intervention Website

Overall satisfaction with the intervention website was rated as less helpful (3.6±1.6). Participants found the website information less relevant (4.1±1.2), less helpful with building skills to aid weight loss efforts (4.1±1.2), and that the website was not motivating (3.4±1.3). There were slight differences in satisfaction across treatment response groups for certain components of the website. Participants who achieved non-clinically significant weight loss rated the website as slightly more motivating (4.0±0.82) compared to those who achieved clinically significant weight loss (2.8±1.3) and the participants who did not lose weight (3.4±1.7). The participants who did not lose weight also found the website information less relevant (3.6±1.5) compared to those who achieved some clinically significant (4.4±1.3) and non-clinically significant weight loss (4.5±1.7).

Preferences for an Ideal Program

Participants discussed components and aspects they would have preferred to see in future programming. Preferences for future program components did not differ by treatment response category.

Social aspect

All but 4 participants would have liked to have a group or social aspect to the program and provided this component with the highest rating for components that would have helped achieve greater weight loss (5.6±1.4). Particularly, participants rated online group meetings focusing on physical activity as an important component that would have helped with weight loss (5.6±1.3). Participants discussed the want for a message board or some sort of ongoing discussion with other participants to help with motivation or accountability through the duration of the program.

"Maybe a social component, more so than the accountability part, you know. Just like a shared experience kind of thing."

Several participants (5/14) also mentioned wanting the program to be a little more personalized to their experience and to receive more feedback (5/14).

"I also think little pop, pop-ups like that input into the website. I think achievements of showing like, hey, I took 10,000 steps on average every week. Here's, like, that achievement. Um, and I, I get that from the Fitbit. Like I get, oh, you did 20, 10,000 steps, good job. Oh you did 20,000 steps, good job. It's like a little thing on my phone that does, like, fireworks. And I think that's a good incentive to, like, hey, you know, it's a validation framework."

"Maybe adding in a few suggestions as to what can be done, instead of saying that this is sort of the sort of thing that just like foods high in fat, sugar or being inactive are things that cause this maybe also provide a suggestion of a small change you could make throughout the week sort of thing."

Frequency of contact

Majority (8/14) participants commented that they would have preferred more contact from the program. The frequency of contact varied among participants and did not differ by treatment response. For the most part, participants would have preferred online group check-ins monthly or mid-way through the program (6/8), opposed to weekly check-ins (2/8).

"I would say like having, like, another check-in would maybe be good, like midway through or a couple of check-ins."

Delivery

Participants did not comment during the interviews about preferences for in-person or online meetings. Overall, online group meetings, focusing on diet (5.4±1.4) and physical activity,

(5.6±1.3) were rated the highest compared to in-person meetings on diet (4.9±1.7) and physical activity (4.6±1.6). When examining trends in modality preference by treatment response, data show that men who achieved clinically significant weight loss preferred online meetings for diet (5.2±1.9 vs. 3.6±2.1), physical activity (5.0±1.9 vs. 3.4±1.8), or muscle strengthening (4.4±1.8 vs. 3.0±1.6) over in-person meetings. Participants who did not lose weight showed no preference for either online or in-person delivery of meetings related to physical activity or diet, but did show higher preference for in-person muscle strengthening classes (5.6±0.89) compared to men who lost clinically significant weight loss (3.0±1.6) and men achieving non-clinically significant weight loss (4.5±1.0). See Table 5.

Discussion

This convergent mixed methods analysis provides comprehensive insight into young men's experience with a male-targeted lifestyle intervention. Certain components of the lifestyle intervention were met with higher satisfaction among young men, while other components had lower satisfaction. As a way to begin adapting a scalable behavioral weight management program for young men, based on user experience, three key areas were explored: motivations for joining/appealing aspects of the program, acceptability of specific program components, and preferences for an ideal program. Integration of the data showed consistency between satisfaction survey data and the qualitative subthemes. Differential patterns in acceptability for certain program components were found between those who received clinically meaningful treatment benefit and those who did not, suggesting that a stepped care approach might be a way to improve treatment for young men. Though, these differences should be approached with caution, considering the small sample size and exploratory nature of this study.

Motivations for joining and appealing aspects of weight loss programming was a key area

explored in this study. Qualitative data and quantitative data surrounding motivations for joining and appealing aspects of the program were fairly consistent. First, qualitative data indicated that men's interest in joining the program was related to meeting the demographic criteria (age and gender), which was also among the highest rated aspects in the quantitative data. This specific aspect of the program underscores the need for designing programs specifically for young men—as a way to increase enrollment in behavioral weight loss interventions.[144] Second, perceived health risk and lifestyle changes were the two of the highest rated aspects of the program found to be appealing among young men. Though, perceived health risk and lifestyle changes, as a motivator for joining, did not emerge from the qualitative data. The health risk piece is somewhat consistent with recent findings showing fear of health complications[90] and improving health[104] is a motivator for men to engage with weight loss behaviors. Indeed, focus group data also show that men are motivated to lose weight when prompted by a family member's experience with obesity.[90] Third, our findings suggest that framing behavioral weight loss programs as a lifestyle program, opposed to a weight loss intervention, may also be more appropriate for engaging young men to lose weight. This finding is consistent with past research, where young adults report that making healthy lifestyle changes was viewed as more important than weight loss.[87] Fourth, recent research indicate that men are less likely to view diet and weight loss related content on social media compared to women.[169] Instead, men tend to engage with fitness-related content[169] and show an overall preference for muscle strengthening[112] and enhancing fitness as a motivator for engaging with weight loss.[110] Therefore, in order to engage young men to lose weight, further examination of effective message framing—in both recruitment and intervention materials—is needed.

Young men were satisfied with certain components of the program, particularly the study-issued scale which included a mobile app to track weight and other metrics. The integration of

quantitative responses supports this overall interpretation. Though, satisfaction with the scale was not evident among men who did not lose weight. However, it should be noted that men who did not lose weight had a higher desire for muscle strengthening classes. This might be an indicator that these men had more interest in physical activity or strength training initially, opposed to an initial interest in weight loss. It's possible that more support or training is needed for men on how to effectively interpret weight change when engaging with strength training, which might promote changes in body composition. It might also suggest that a single group session is insufficient to teach young men how to use the scale to promote self-regulation in a helpful way (e.g., not weighing multiple times a day or in the evening). There is also a need to ensure no negative effects occur from self-weighing within the context of a self-guided intervention. Thus, additional evaluation to better understand user experience with self-weighing—when not meeting weight loss goals—should be further examined.

Men found that the health risk text messages served as a good reminder for continuing weight loss efforts, but did not sustain motivation—and in particular, those young men who achieved clinically significant weight loss found them to be less helpful. This was consistent with men's experience with the self-guided aspect, in that the program was a little too "hands-off" and less personalized. While men perform well in self-guided weight loss programs,[122] young men in this study reported preference towards more check-ins (i.e., monthly) to help with accountability. The self-guided aspect was rated as more helpful with weight loss among those who achieved modest weight loss. As such, it might be worth considering using a self-guided approach during the initial phase of the program, and then depending on performance at a check-in, either increase the intensity of the program or remain steady with a self-paced program.

Overall, young men highlighted, both quantitatively and qualitatively, preference for

adding a social aspect in future programming. Men particularly called out a need to have a shared similar experience—which is a reported benefit of using online platforms for sharing weight loss experiences.[170] Some findings indicate that peer support produces significantly more weight loss than treatment without peer support,[171] but in older adults, the majority of whom are women. While including a social component in behavioral weight loss programs is not uncommon, these preferences for a shared similar experience could be somewhat negated since most behavioral weight loss programs are comprised of women.[137,172] Previous research indicate that men do not feel comfortable discussing men's health issues and weight loss around women.[114] Thus, building a platform for young men to discuss relevant health issues might be one strategy for improving this population's engagement with weight management. In addition to the desire for an online social platform, young men also showed preference for an online component related to physical activity compared to other components such as diet. This finding is consistent with formative data suggesting young men have a greater desire for programs to focus on physical activity than young women, particularly as it relates to peer support and accountability.[87] While physical activity is less effective at producing weight loss compared to diet alone,[173] promoting physical activity upfront—as a way to engage men—could potentially have a ripple effect on other behaviors such as diet.

Lastly, these findings suggest that modality of treatment delivery might depend on treatment response. Young men who achieved clinically significant weight loss had a lower preference for in-person meetings compared to those who did not achieve clinically significant weight loss. This is not surprising—given that majority of young adults use smart phones[174] to obtain health information.[175] As such, if participants are meeting weight loss goals, delivering behavioral weight loss intervention remotely should be given priority to improve accessibility and

convenience.[176] Recent findings show that remote delivery of a behavioral weight loss program produced similar weight loss outcomes as in-person delivery.[177] Taken together, it appears that programs should be flexible in the modality of program delivery (in-person, online), depending on response to treatment. It might be that some participants start online and then, depending on performance, participants either continue online or move to in-person sessions to mitigate time constraints in this population.[87]

Limitations

This study had several limitations. First, the small sample size limits our ability to make comparisons within the sample due to small cell sizes. Second, the sample was mostly non-Hispanic white with a college education. Given the racial and education disparities in both enrollment in behavioral weight loss interventions and obesity prevalence,[178,179] more research is warranted to investigate the needs and experiences of weight loss programs among young men from minoritized racial/ethnic backgrounds. Third, these data were collected during COVID-19. Considering the rapid shift towards digital health interventions and unique context of a global health pandemic, this may have impacted the findings in numerous ways (desire for weight management, social connection). Fourth, we are limited to a treatment seeking sample which might not be reflective of young men broadly. Therefore, selection bias may contribute to a higher risk awareness of obesity and cardiovascular disease, thus adding to higher levels of satisfaction with health risk messages. Fifth, interviews were of shorter duration than a typical qualitative interview. However, given the specific goals and deductive design (directed content analysis) of the qualitative components and pairing of quantitative data, the depth of the participant responses was sufficient in addressing the paper objectives. Lastly, men who completed the interviews were slightly older than men who were lost to follow-up (30 vs. 26). Therefore, more work is needed to

understand the preferences and experiences of emerging adult men specifically.

Strengths

This study had several strengths. First, to our knowledge, this is the first study to report young men's experience and satisfaction with a behavioral weight loss program. In future work, fully embracing user-centered design in behavioral weight loss programs will better allow us to identify elements that ultimately improve the participant's experience and the quality of programs.[180] In this case, these findings can inform future programming targeting this hard-to-reach and high-risk population, as a means to improve enrollment. Second, there was a high percentage of agreement between coders. Kappa was calculated, which follows ICR guidelines,[165] and accounts for chance agreement. While Kappa isn't necessarily equipped to account for multiple coders like Krippendroff's alpha, only two coders were used and Cohen's Kappa has been found to produce nearly identical values as alpha.[181] Third, we followed standard guidelines for the best practice of integrating the qualitative and quantitative findings.[161] One of the major strengths of this study is the use of mixed methods. Behavioral weight loss trials can benefit from a mixed methods design by using qualitative and quantitative data to compliment inherent weakness in each, generate robust findings, and enhance the validity of weight loss programs.[182]

Conclusions and future directions

In conclusion, our findings suggest a need to be flexible in adapting intensive behavioral weight loss programs to meet the specific needs of young men. During the early phase of weight loss, programs could enhance engagement among young men by using a self-guided approach with optional online group fitness classes. These classes might also be a poignant time to emphasize the importance of physical activity and fitness—as it relates to men's health—and include elements of health risk messaging. As a way to enhance user experience and promote accountability,

programs should consider including a social component that allows men to connect with other men in order to share their weight loss journey. While our findings address the user experience of young men enrolled in a 12-week digital weight loss program, more research is needed to expand our understanding of young men's experience after initial engagement with weight loss (beyond 12-weeks). More specifically, research should determine if men and women differ in response to motivational enhancements, as a way to identify the best way for men to sustain motivation when attempting weight loss. Last, self-weighing was only met with satisfaction among young men achieving weight loss. As such, more research is needed to better understand young men's user experience with self-weighing when weight loss goals are not achieved, in order optimize treatment outcomes.

Table 1. Summary of Selected Characteristics of Intervention Users Interviewed (n [%])

Age	
18-25	3 (21.4)
26-35	11 (78.6)
Race/Ethnicity	
American Indian/White	1 (7.1)
Asian	1 (7.1)
Mexican	1 (7.1)
White	11 (78.6)
Relationship Status	
Married	6 (42.9)
Single	6 (42.9)
Living with Partner	1 (7.1)
Education	
Some College	2 (14.3)
College Graduate	8 (57.1)
Postgraduate Degree	5 (35.7)
Treatment Response	
Clinically Significant Weight Loss	5 (35.7)
Non-Clinically Significant Weight Loss	4 (28.6)
No Weight Loss	5 (35.7)

Table 2. Overall Scores of Reasons for Joining the Program

Motivations for joining the program	**Overall Score**
General Lifestyle Changes	5.9 (1.0)
Focus on health risk	5.8 (.73)
Weight loss	5.4 (1.0)
Diet	5.1 (1.1)
Fitness	5.0 (1.6)
Age focused	5.0 (1.1)
Male focused	5.0 (1.4)
Minimal in-person requirements	4.4 (1.7)
Self-guided	3.8 (1.8)

Table 3. Satisfaction with Health Risk Text Messages by Response to Treatment

	Clinically Significant Weight Loss	**Non-Clinically Significant Weight Loss**	**No Weight Loss**
The messages were **motivating** to me	4.8 (1.8)	5.5 (1.3)	4.8 (1.5)
The messages suggested strategies that were **helpful** to me.	3.2 (2.2)	5.3 (.30)	4.4 (.89)
The messages made me **aware** of the risks associated with weight gain	5.0 (1.9)	6.5 (1.0)	5.0 (1.6)
The messages made me **aware** that I am at risk for cardiovascular disease	4.6 (1.9)	5.8 (1.5)	4.4 (.89)

Table 4. Acceptability of Program Components by Response to Treatment

Program Components	Exemplar by Response to Treatment	Satisfaction Score
Bluetooth Scale and application	Clinically significant weight loss *"The scale was really, really useful, actually, especially starting out because I could see, like, all the different metrics that I had no idea of before."*	6.0±0
	No weight loss *"I haven't used it like in the past week, but I use that less often for weight tracking just because there was even a time where I decided to write it down instead."*	3.8±1.6
Recommended applications	Clinically significant weight loss *"Probably the most helpful would be the, uh, just, just the resources. The calorie tracking app, and the, uh, the scale, just to have all that data myself. You know, I never really, I guess, compiled all that information, you know, before."*	4.0±2.1
	No weight loss *"I think it was a little hard for me because I don't have a smartphone. It's hard for me to kind of use the apps and check the apps on the desktop and, uh, you know, I don't know if there's a, I just can't think of another way without a smartphone to do this."*	3.8±1.6
Text Messages	Clinically significant weight loss *"The text messages, like, you know, they were sort of like kind of throw in your face kind of things, which was nice because it's just that a nice little reminder of, like, you know, think about the outcomes of, or the consequences of things"*	4.0±2.2
	No weight loss *"The text message that we got, it was good accountability, but it was also, that I can see how that could also just be something that you just kind of slough off because we just like, a here's a fact."*	4.2±2.2

Table 5. Modality Preference by Treatment Response

	Clinically Significant Weight Loss	**Non-Clinically Significant Weight Loss**	**No Weight Loss**
Online group component	5.2 (2.0)	5.8 (1.0)	6.0 (1.0)
Online meetings – Diet Focused	5.2 (1.9)	6.0 (.82)	5.0 (1.2)
Online meetings – Physical Activity Focused	5.0 (1.9)	6.0 (.82)	5.8 (.89)
Online meetings – Muscle Strengthening	4.4 (1.8)	4.8 (1.3)	5.4 (.89)
In-person meetings – Diet Focused	3.6 (2.1)	5.5 (1.3)	5.6 (1.1)
In-person meetings – Physical Activity Focused	3.4 (1.8)	4.8 (.96)	5.6 (.89)
In-person meetings – Muscle Strengthening	3.0 (1.6)	4.5 (1.0)	5.6 (.89)

CHAPTER 4

Paper 3

Sex differences in behavioral and physiological factors associated with weight loss among emerging adults

Abstract

Background
During a weight loss program, men generally lose more weight than women, but this has not been examined among emerging adults (18-25). It is also unclear whether young men and women differ in behavioral and physiological factors associated with reductions in adiposity.

Purpose
This study explored the behavioral and physiological factors associated with early treatment response among emerging adult men and women enrolled in a primarily digital lifestyle intervention.

Methods
Participants (N=382, 17% men, 21.9 years, BMI 33.5kg/m^2, 58% racial/ethnic minority) all received a BWL intervention. Weight, waist circumference, and body fat were objectively assessed at 0 and 3-months; resting metabolic rate was objectively assessed at baseline only. Behavioral factors were assessed via the Weight Control Strategies Survey (WCSS) at 0 and 3-months, as well as continuous self-monitoring data captured via digital tools. Linear models were used to examine factors associated with adiposity change, using sex as an interaction term and controlling for treatment arm.

Results
At 3-months, men had greater reductions in weight, (-4.4% vs. -3.0%; p=.010), waist circumference (-5.33cm vs. -2.8cm; p<.001), and body fat (-2.3% vs. -1.2%; p=.001) compared to women. Baseline resting metabolic rate was only associated with changes in percent body fat at 3-months (p=.001). More dietary self-monitoring was associated with greater reductions in weight (p=.004) and body fat (p=.004) at 3-months. Sex did not interact with physiological or behavioral factors associated with changes in adiposity.

Conclusions
Observed sex differences in treatment response were not associated with physiological or behavioral factors. Consistent with previous findings, self-monitoring diet is critical for weight loss. However, it is unclear which other factors might be driving differences in weight loss between emerging adult men and women.

Introduction

Emerging adulthood (age 18-25 years) is a distinct developmental period involving major life transitions, such as changes in work, school, and living situations.[66,145] These years are also associated with an increase in behavioral risk factors for obesity including declines in physical activity,[183] irregular sleep[54] and eating patterns,[184] and high consumption of sugar sweetened beverages,[185] meals away from home, and processed food.[186,187] Furthermore, the prevalence estimate of overweight and obesity is over 50% among this age group.[63] Thus, there is a crucial need to intervene and promote weight management during this development period.

Emerging adult men are particularly at heightened risk, yet relatively little work has focused on this population. In fact, emerging adult men with obesity have a two-fold mortality risk later in adulthood compared to emerging adult men with a healthy weight.[83] Though, men only represent approximately 24-36% of samples in lifestyle interventions targeting the general adult population.[137,144] When considering age, most lifestyle interventions include adults with a mean age range of 40-60 years old.[107] Similar age-related trends occur in commercially available lifestyle interventions, where the mean age across trials ranged from 37-57 years old.[188] However, even when lifestyle interventions are adapted to meet the developmental needs of this age group, there is still low enrollment of men.[36,73,77,79] Interestingly, there is ample evidence—in the general adult population—to suggest men lose more weight than women once they enroll.[77,189,190] Whether or not these sex differences in treatment response hold true among emerging adults has not been examined. There are distinct differences between emerging adults and middle- and older-aged adults—emerging adults have higher overall lean muscle,[191] lower calorie consumption,[192] and increases in daily energy expenditure.[62] Given the unique features of early adulthood, it is

important to examine if similar sex differences are observed during emerging adulthood and which behavioral and physiological factors might be associated with reductions in adiposity.

Lifestyle interventions generally aim to impact energy balance through changes in diet and physical activity.[25] In order to support individuals in meeting their energy balance goals, programs include training in evidence-based behavior change strategies.[29,33,193,194] This includes self-monitoring, goal setting, problem solving, stimulus control, and psychological coping. Self-monitoring is an important behavioral strategy to consider and a quintessential component associated with weight loss.[34,195-198] Self-monitoring is based on 3 basic tenants: 1) self-monitoring one's behavior and the conditions involved with adopting the behavior; 2) goal setting and implementing strategies to achieve the established goal; and 3) considering influencers (e.g., motivators, social support, physical environment) that might sustain the behavior change.[30,31] In the context of lifestyle interventions, self-monitoring encompasses tracking diet, weight, and physical activity. Some research demonstrates that self-weighing generally tends to be higher among women compared to men.[199] Available data in adults indicate that men generally self-weigh and log food less than women, yet demonstrate greater weight loss than women.[198] These differences have also been observed during adolescence, such that girls are found to self-monitor more than boys.[200] To our knowledge, these potential sex differences in self-monitoring and their association with treatment response has not been examined in emerging adults.

Problem solving and psychological coping[201] are also key features of lifestyle interventions and generally include strategies for managing emotions,[202] negative/positive thoughts and behaviors,[203] and stress[204] surrounding weight loss setbacks and progress. Problem solving and psychological coping are particularly relevant areas to address during emerging adulthood, given the risk of depression and anxiety during this developmental period.[205] Within the context of

weight loss, it is unclear whether or not differences in psychological coping exist between men and women. Though, some evidence suggests that men and women use different strategies to regulate emotions.[206] For instance, women and girls tend to score higher in rumination (i.e., focusing on negation emotions) compared to men and boys.[207]

Physiological differences between men and women might also play a role in weight loss—specifically resting metabolic rate which is the amount of energy or calories expended by an individual at a resting state.[208] Men have a higher resting metabolic rate compared to women,[209] and while these differences do not appear to contribute to weight loss differences between men and women,[210] it is not known if this is the case in emerging adulthood. Of note, evidence suggests that resting metabolic rate increases at a greater rate among men during early adulthood compared to women.[211,212] Thus, it's possible that resting metabolic rate could contribute to greater weight loss among men in early adulthood.

Addressing these gaps might improve lifestyle interventions for this age group[213] and has the potential to reduce the risk of health complications later in life. More importantly, it is imperative to understand potential sex differences in early treatment response, given the association between early treatment response[214] and long-term weight loss.[215] Identifying these potential sex differences in early treatment response could optimize treatment response and mitigate the sharp declines in engagement exhibited during the first 3-months of treatment among this age group.[216] To that end, the primary aim was to determine whether emerging adult men and women differ in changes to adiposity (weight, waist circumference, body fat). This is a secondary analysis using data from the mid-point (3-months) of a primarily digital lifestyle intervention adapted for emerging adults. Based on previous research,[217-219] we hypothesize that emerging adult men will experience greater reductions on all indicators of adiposity compared to emerging adult

women. The secondary aim explored potential sex differences in behavioral and physiological factors associated with treatment response. Since little work has examined sex differences in behavioral factors associated with weight loss among emerging adults, no a priori hypotheses were stated.

Methods

Participants

Participants were 382 adults (18-25 years of age with a body mass index 25-45 kg/m^2). Detailed exclusion criteria have been published previously.[220] Exclusions were based primarily on participant safety (e.g., an uncontrolled medical condition that would make it unsafe to change dietary patterns or be physically active without supervision; lifetime diagnosis of anorexia or bulimia nervosa; psychiatric hospitalization in the last 12 months), with additional exclusions related to possible confounds (e.g., currently participating in another weight loss program) and feasibility (e.g., living outside of a 30-mile radius of study sites).

Procedures

This is a secondary data analysis of a large-scale randomized clinical trial comparing the efficacy of 3 approaches to behavioral obesity treatment among emerging adults. Detailed trial procedures and descriptions of the interventions have been previously reported.[220] Data collection was completed in February 2020. All study procedures were approved by the VCU Institutional Review Board.

Recruitment and Screening

Participants were recruited using a multi-method, community-based approach. A mix of active and passive methods (e.g., in-person events, paid advertisements) and outlets (e.g., digital and print ads, listservs, radio, social media) were utilized. Targeted efforts were made to enroll

men and racial / ethnic minority participants; strategies included adapted images and language grounded in our formative work[87] and previous pilot trials[221,222] with this population. A male research assistant was also involved in the recruitment process (e.g., drafting materials, attending recruitment events, screening/scheduling participants). Recruitment occurred in 6 waves and recruitment yield and source were monitored on an ongoing basis; additional resources were allocated to those sources which reached the greatest number of men in an effort to enhance enrollment rates among young men. All recruitment materials included a link or QR code to a mobile responsive recruitment website that served as the initial point of study contact. The website included a brief overview of the trial in both text and video format, a list of inclusion criteria, a BMI calculator, and contact information. Interested individuals were directed from the recruitment website to a secure site to complete an eligibility prescreen or were given the option to complete the prescreen via phone. Based on the prescreen, eligible individuals were invited to attend an interactive group orientation session, where the study and requirements were explained in greater detail. The orientation consisted of a combination of didactic and experiential activities, including the use of talk back methods and an opportunity for question and answer with the trial PI. Individuals who remained interested following the orientation were guided through the informed consent process, in which key portions of the consent form was read aloud, risks and benefits were reviewed, and individuals could ask any remaining questions. At the completion of the consent process, individuals who chose to participant in the trial signed the consent form and scheduled a baseline assessment visit.

Intervention

Participants were randomized to one of three arms which have been previously detailed (intrinsic motivation vs. extrinsic motivation vs. no motivational manipulation).[220] All groups

received a 6-month lifestyle intervention grounded in formative work[87,221,222] and extant gold standard lifestyle interventions,[20,75,223] but adapted to meet the unique needs of this developmental stage. Intervention content included a mix of psychoeducation and behavioral skills training. All participants received personalized calorie goals based on objective assessment of resting metabolic rate and personalized physical activity goals based on objective accelerometry data. Energy intake goals were designed to produce a 1-2lb weight loss per week. Participants attended 1 in-person group session which included an overview of the intervention and evidence-based weight management strategies. Participants also received 1 in-person individual session with their lifestyle coach to facilitate personalized goal setting and problem solving specific to each person's context. The remainder of the program was delivered via a digital platform. Digital tools were provided to facilitate self-monitoring, which included a premium Lose It! subscription and wireless scale. Participants were asked to track calories and physical activity via the app, and self-weigh at least 4 days per week using the wireless scale. These data were directly imported into the study database and used by the participant's coach to provide weekly tailored feedback. Participants also received weekly content adapted to this age group, and two automated text messages per week. Opt-in Facebook groups were also created for to provide opportunities for social support.

Data Collection

This secondary analysis includes all randomized participants (N=382), and reports findings using data from only the baseline and 3-month assessment visits. Prior to the scheduled assessment visit, participants refrained from eating or drinking (except water) for 12 hours, vigorous physical activity (8 hours), and smoking and caffeine (2 hours). During the visit, participants wore light gym shorts and a t-shirt without shoes, socks, and jewelry. Measures were collected by a masked assessor in a private exam room. Questionnaire data were collected and managed in REDCap

(Research Electronic Data Capture), a secure web-based platform designed to support data capture for research studies.[224,225]

Measures

Demographics

Participants self-reported demographic characteristics at baseline including age, biological sex, gender, race, ethnicity, work status (full- or part-time), number of working hours per week, and student status (full- or part-time).

Adiposity

Weight. A digital scale, Tanita BWB 800 (Tanita Corp., Arlington Heights, IL) was used to assess body weight to the nearest 0.1 kg. Weight was measured two times. If the two measurements had more than a 0.2 kg difference, a third measurement was collected. The average of the measurements was used in analyses.

Height. A wall-mounted stadiometer was used to measure height to the nearest 0.1 cm. Height was measured two times. If the two measurements had more than a 0.5 cm difference, a third measurement was collected. The average of the measurements was used in analyses.

Waist circumference. A Gulick tape measure was used to assess waist circumference to the nearest 0.1 cm. If the two measurements had more than a 0.5 cm difference, a third measurement was collected. The average of the measurements was used in analyses.

Body fat. Bioelectrical impedance analysis (BIA) was used to assess body fat using the Tanita BC-418 Segmental Body Composition Analyzer.

Resting metabolic rate

Resting metabolic rate was collected at baseline by using indirect calorimetry (Fitmate GS, Cosmed USA, Inc.) with canopy hood. Participants remained steady for 20 minutes during the

assessment period and refrained from physical activity for 8 hours prior to the measurement of resting metabolic rate. Assessors were trained to monitor air flow and make adjustments accordingly.

Objective self-monitoring

Self-weighing. Weights were objectively captured via Withings wireless scales. The outcome of interest was frequency of self-weighing, which was calculated using the total number of days the participant stepped on their study-issued scale over the initial 3-months of treatment (90 possible days).

Dietary self-monitoring. Data were imported into our database on a daily basis from LoseIt!, a mobile application and web-based platform that allows for streamlined dietary self-monitoring. Based on pre-specified criteria, a day of dietary self-monitoring was counted if >500 calories were logged. The outcome of interest was the total number of dietary self-monitoring days over 3 months (90 possible days).

Weekly adherence. For self-weighing and dietary self-monitoring, an adherence variable was created that summed the total number of days per week (7 possible days) where self-monitoring occurred.

Weight control strategies

The Weight Control Strategies Scale (WCSS) was used to measure self-reported weight loss behaviors used by participants. The WCSS is comprised of 30-items (0-4, 0=Never uses WCS, 4=Always uses WCS) and 4 constructs: dietary choices, self-monitoring, physical activity, and psychological coping. The WCSS demonstrates good internal consistency and content and discriminant validity.[226]

Statistical Analyses

Descriptive statistics were computed to capture enrollment rates and demographics. Primary analyses adhered to the intent-to-treat principle and multiple imputation was used to handle missing data for all measures of adiposity at 3-months. The primary outcome of weight change is reported as a percentage from baseline to 3-month follow-up (percentage of weight [(3-month weight – baseline weight) / baseline weight x 100] to account for baseline level while also allowing for comparison to established thresholds for clinical significance.[17] Change in waist circumference and body composition are both reported as absolute change, controlling for baseline values. Self-monitoring variables (self-weighing, diet) were summed as total days where weight or diet was monitored (possible range=0-90 days). QQ-plots of all outcomes were evenly distributed. A Brown Forsythe test revealed equal variances for both men and women on all outcomes. T-tests were conducted to compare men and women on changes in adiposity (weight change, waist circumference, body fat percentage), changes in weight control strategies at 3-months, baseline resting metabolic rate, and objective self-monitoring of weight and diet. Fisher's exact test was used to compare men and women on proportion self-monitoring 4 or more times within a week. A total of 3 linear models were fit to investigate the interaction of sex on physiological and behavioral factors associated with changes in adiposity (Model 1, percent weight change; Model 2, change in waist circumference; Model 3, body fat percentage). Treatment arms were collapsed for the purposes of this secondary analysis since randomization was stratified by sex and there were no differences in retention by sex; treatment arm was included as a covariate for all comparisons. Statistical analyses were conducted using JMP for Macintosh (Version 15, SAS Institute Inc), with an alpha level of .05 for the outcome comparison by sex. A corrected alpha level of .007 was used for models examining behavioral and physiological factors associated with changes in adiposity.

Results

Participants (N=382) were 21.9±1.2 years, 58% racial/ethnic minority, with an average BMI of 33.5±4.9 kg/m^2 and 45% of the sample reported both working and attending school. A total of 17% of the sample were men. Participant demographics are presented in Table 1 for the full sample.

Baseline physiological and behavioral factors

Baseline resting metabolic rate differed significantly between men and women (1909.3±362.2 vs. 1530.0±299.6; p<.001). At baseline, there were no significant differences between men and women in weight control strategies for diet (1.6±0.83 vs. 1.9±0.9, p=.992), self-monitoring (0.5±0.6 vs. 0.7±0.7, p=.993), physical activity (1.1±0.9 vs. 1.2±1.0, p=.821) and psychological coping (0.9±0.8 vs. 1.2, p=.986).

Change in behavioral factors at 3 months

At 3-months, there were no differences between men and women in changes to any of the subscales on the weight control strategies survey (all p's>.007).

Men and women did not differ in total days of self-weighing (43.3±24.8 vs. 46.4±24.2, p=.296). See Table 2. Frequency of self-weighing across the 12 weeks is displayed by sex in Figure 1. Compared to women, the proportion of men self-weighing 4 or more times per week was lower for all weeks except Weeks 1 and 3. See Figure. 3. The 3 largest differences between the proportion of men and the proportion of women self-weighing 4 or more days occurred at week 5 (59% vs. 68%, p=.196), week 6 (56% vs. 66%, p=.159), and Week 7 (50% vs. 59%, p=.173).

Men and women did not differ in total days of dietary self-monitoring (37.6±24.9 vs. 43.1±23.2, p=.076). See Table 2. Frequency of dietary self-monitoring across the 12 weeks is displayed by sex in Figure 2. Compared to the women, the proportion of men engaging with dietary

self-monitoring 4 or more times per week was lower across weeks 2-12. See Figure 4. The 3 largest differences between the proportion of men and proportion of women engaging with dietary self-monitoring 4 or more days per week occurred at week 5 (50% vs. 66%, p=.024), 6 (49% vs. 62%, p=.039), and 12 (23% vs. 41%, p=.007).

Changes in adiposity at 3 months

Men manifested greater reductions in weight (-4.4%±4.3 vs. -3.0%±3.9; p=.001), waist circumference (-5.1cm±4.9 vs. -2.9cm±3.8; p<.001), and changes in percent body fat (-2.3%±2.4 vs. -1.3%±2.1; p=.001). See Table 2.

Factors associated with change in adiposity at 3 months

There were no interactions by sex for the association between behavioral / physiological factors and adiposity change (all p's >.007). See Table 3. Overall, more objective dietary self-monitoring was associated with greater weight loss (p=.004, η^2=.03) and greater reduction of body fat percentage (p=.004, η^2=.03). Greater self-monitoring via the WCSS was associated with greater reductions in waist circumference (p=.001, η^2=.04). No other behavioral factors were associated with changes in adiposity. See Table 3-5. Baseline resting metabolic rate was not associated with greater weight change (p=.910, η^2=.00) or reductions in waist circumference (p=.212, η^2=.01), but was associated with reductions of body fat percentage (p=.001, η^2=.04).

Discussion

This secondary data analysis sought to understand behavioral and physiological factors associated with adiposity changes among emerging adult men and women with overweight or obesity. Consistent with our hypotheses, emerging adult men experienced greater reductions in adiposity than emerging adult women. Of note, however, the behavioral and physiological factors associated with reductions in adiposity did not vary by sex.

The significant differences between men and women in resting metabolic rate did not appear to play a role in larger weight losses exhibited among men. The larger weight loss experienced by emerging adult men compared to emerging adult women is similar to patterns found among the general adult population.[227] Our findings are also consistent with findings from the general adult weight loss literature suggesting resting metabolic rate does not play a role in weight loss differences between men and women.[210] Given that our findings show resting metabolic rate played a role in body fat change for both men and women, it is possible that men's larger reductions in weight could be explained by differences in body composition among men and women. Men tend to have more lean muscle mass compared to women,[228] which is known to increase resting metabolic rate.[212] Though, caution should be used when interpreting these findings given that our measurement of body composition was not the gold standard measurement.

Evidence also shows that men tend to have different preferences in exercise compared to women, which could play a part in some of the initial differences in weight loss observed.[112] Relatedly, the Look AHEAD trial found that men exercised more minutes than women, which is one measure of treatment adherence thought to explain the larger weight losses exhibited among men.[120] Interestingly, additional evidence suggests that, compared to women, physical activity has a greater effect on weight loss in men.[227] Taken together, future studies should further examine the role of physical activity on these weight loss differences observed between men and women using objective assessments of physical activity.

Greater self-monitoring of diet was associated with larger reductions in weight at 3-months—regardless of sex. This finding is not surprising given the favorable effect that dietary self-monitoring has on weight when included in a lifestyle intervention.[229] Overall, men had lower adherence in meeting the self-monitoring recommendations of 4 days per week and disengaged

earlier than women. It remains unclear why men disengaged from dietary self-monitoring earlier in the program than women. Focus group data show that men, after self-monitoring for 21 days, perceived dietary self-monitoring as tedious and preferred a simpler approach to dietary self-monitoring.[230] Even abbreviated approaches to dietary self-monitoring, such as color categorizing food based on caloric density, is rated less important for weight loss among men.[231] That said, more research is needed to understand and test different simplified or abbreviated approaches that might keep men engaged with dietary self-monitoring.

Another potential approach that might encourage men to self-monitor is through nudges. Different types of nudges include reminders, feedback, peer support, or incentives. Nudges have been found to be effective at promoting early weight loss,[232] self-management of chronic disease,[233] including medication adherence.[234] However, little is known on what might work best for reengaging emerging adult men with self-monitoring within the context of a lifestyle intervention, as majority of lifestyle intervention trials are comprised of women.[137,144] For that reason, more research is needed to determine which nudges are effective and the most suitable timing of delivering these nudges, as a means to preventing self-monitoring behaviors from receding in early weight loss treatment.

These findings highlight that emerging adult men experienced larger reductions on all measures of adiposity compared to women despite slightly lower rates of self-monitoring than women. It is plausible that emerging adult men might fare well in a less intensive weight loss approach. One large-scale lifestyle intervention trial, targeting young adults, found that young men lost the most weight in the control group, which only provided handouts and educational materials for losing weight.[77] That said, it is worth considering and testing approaches that garner men's interest to enroll. Men report time constraints as a major barrier for healthy eating and engaging in

physical activity.[111] Moreover, recent qualitative findings suggest that men view weight loss services as female dominated and incompatible with men's needs.[90] Taken together, it's possible a gender-specific or self-guided approach to weight management could be appealing and sufficient for promoting clinically meaningful weight loss among emerging adult men. Recent pilot findings show that a self-guided weight loss intervention for young men able to meet enrollment targets in a 2-month period and also promote modest weight loss at 12-weeks.[152]

The current findings should also be interpreted in light of several important limitations. First, we did not collect resting metabolic rate at 3-months, which restricts our understanding of adaptive thermogenesis or the full role of resting metabolic rate on weight loss. Further research should examine possible sex differences in factors contributing to weight loss maintenance and adaptive thermogenesis over a longer period of exhibited weight loss. One potential limitation is the decision to use sex, instead of gender, for comparisons. We selected sex since 1) it was used for stratification in the main trial and 2) literature indicates sex differences in resting metabolic rate.[209] It is possible that behavioral factors might vary by gender, but concordance between sex and gender was >99% in this sample. Therefore, showing indication that the results would not differ. Another limitation was our use of segmental bio-electrical impedance analysis to assess body composition, as opposed to the gold standard dual-energy absorptiometry. As a result, findings related to body fat should be interpreted with caution. A minor limitation of this study is the low enrollment of young men. Given the historical challenges recruiting this population, those who did enroll in this trial might not be representative of the larger population of emerging adult men. Yet, this is a persistent sampling issue within lifestyle intervention trials.[137] Furthermore, given this was a secondary data analysis, we were not powered to examine sex as a moderator. Although generalizability is limited to a treatment seeking sample, these results can inform future

efforts for approaching weight loss during early adulthood, a particularly important time to promote weight loss in order to reduce mortality risk.[65]

Despite these limitations, this study also has numerous strengths. This is the first study to examine whether the behavioral and physiological factors associated with weight loss vary by sex—during the high-risk period of emerging adulthood. The collection of objective measurements (weight, waist circumference, resting metabolic rate, objective self-monitoring), using gold standard procedures, is one of this study's greatest strength and mitigates the potential for error and bias in measurement. Specifically, objective self-monitoring was measured along with self-report data on weight control strategies, which provided a more comprehensive assessment and allowed for us to examine the use of behavioral strategies beyond self-monitoring. Retention was also quite strong in this trial, and appropriate techniques were employed to handle missing outcome data, which adds to the rigor of this work. Finally, despite the exploratory nature of this study, these analyses adjusted the significance level for multiple comparisons, thus minimizing the potential for Type I error.

In conclusion, findings from this study confirm that emerging adult men experience greater reductions in adiposity compared to women when enrolled in a primarily digital lifestyle intervention. However, no measured behavioral factors appeared to be differentially associated with weight loss for emerging adult men and women. Resting metabolic rate was also only associated with change in body fat, which did not vary by sex. In sum, the mechanisms through which young men are losing more weight than young women remain unclear, which underscores the need for additional work in this area, including robust assessments of diet, physical activity, and other factors which may promote and / or interfere with treatment response. Moving forward, more research is needed to optimize lifestyle interventions for emerging adult men.

Table 1. Participant characteristics (%[n] for categorical variables and mean ± SD for continuous variables)

	Total Sample (N=382)
Age	21.9±2.2
Race	
American Indian/Alaskan Native Only	0.8 (3)
Asian Only	5.8 (22)
Black Only	33.8 (129)
Multiracial	7.9 (30)
White Only	47.1 (180)
Another race not listed	4.5 (17)
Missing	0.3 (1)
Ethnicity	
Hispanic / LatinX	12.8 (49)
Work/School Status	
Working Only	31 (118)
School Only	22 (85)
Work and School	45 (170)
Non-working / Non-student	2 (8)
Hours Worked Weekly	30.2±13.9
Baseline Adiposity	
Baseline BMI	33.5±4.9
Baseline Weight (kg)	93.1±17.1
Baseline Waist Circumference (cm)	100.8±12.0
Baseline Body Fat %	40.7±7.2
Baseline Resting Metabolic Rate	1600.7 ± 332.3
Baseline Weight Control Strategies	
Diet	1.8±0.8
Self-monitoring	0.6±0.7
Psychological Coping	1.6±0.8
Physical Activity	1.6±0.8

Table 2. Behavioral Factors and Treatment Response by Sex, adjusted for treatment arm (least square means [95% CI])

	Men	Women	p-value	Cohen's d
Days of self-monitoring weight	43.3±24.8 (37.3, 49.3)	46.4±24.2 (43.6, 49.2)	.296	0.14
Days of self-monitoring diet	37.6±24.9 (31.4, 43.8)	43.1±23.2 (40.4, 45.7)	.076	0.25
Diet	1.6±0.83 (0.5, 0.9)	1.9 ±1.1 (0.5, 0.7)	.541	0.09
Self-monitoring	1.6±1.1 (1.3, 1.9)	1.7±1.1 (1.5, 1.8)	.599	0.08
Psychological coping	1.0±0.82 (0.8, 1.2)	0.9±1.3 (0.7, 1.1)	.667	0.06
Physical activity	0.5±1.1 (0.2, 0.8)	0.6±1.1 (0.4, 0.7)	.605	0.07
Weight change (%)	-4.4±4.3 (-5.3, -3.4)	-3.0%±3.9 (-3.4, -2.5)	.010*	0.35
Waist circumference change (cm)	-5.1±4.9 (-6.4, -4.2)	-2.9±3.8 (-3.3, -2.3)	.000**	0.56
Change in absolute body fat (%)	-2.3±2.4 (-3.1, -1.6)	-1.3%±2.1 (-1.7, -0.7)	.001**	0.46

*$p < .05$, **$p < .001$*

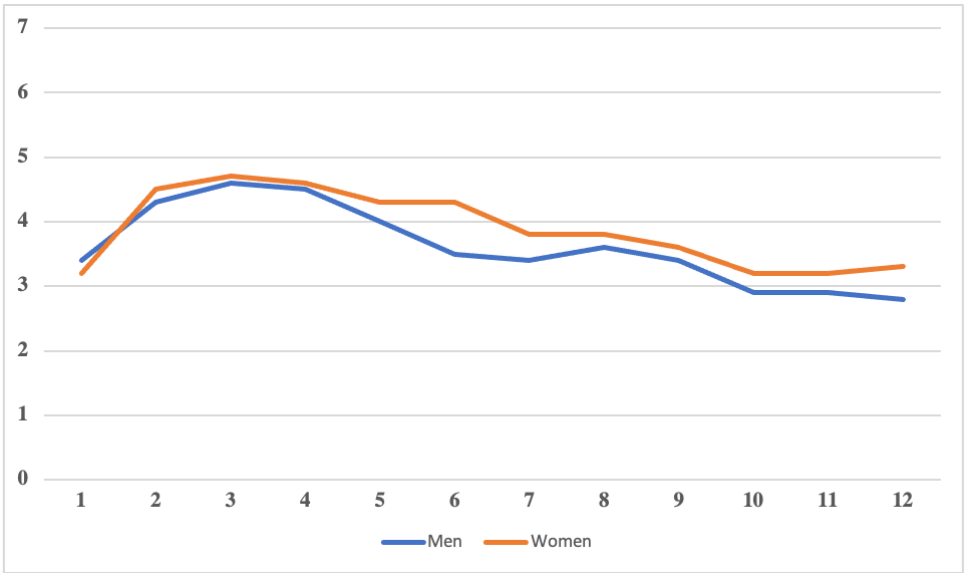

Figure 1. Frequency of self-weighing days over the first 12 weeks of treatment by sex

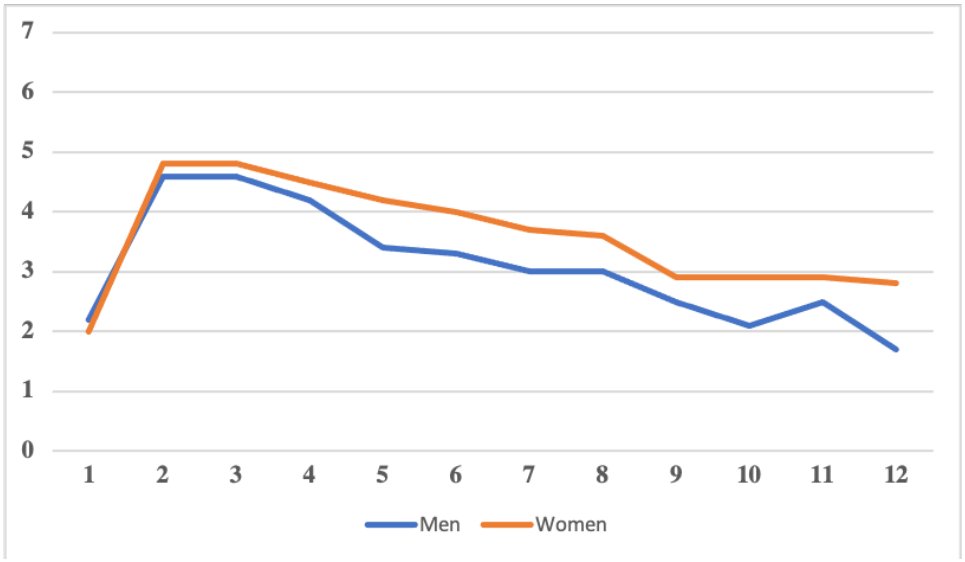

Figure 2. Frequency of dietary self-monitoring days over the first 12 weeks of treatment by sex

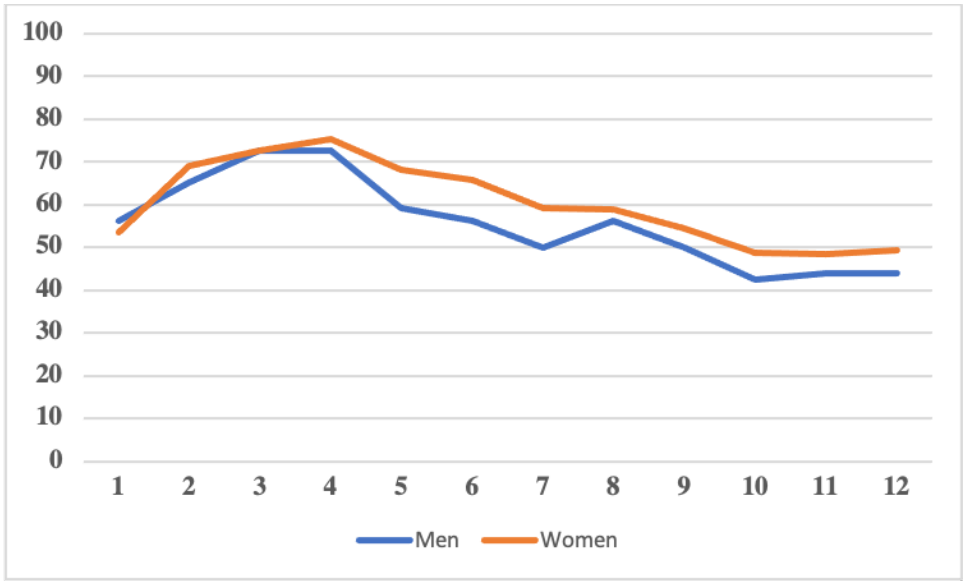

Figure 3. Percent of participants self-weighing 4 or more days over 12 weeks by sex

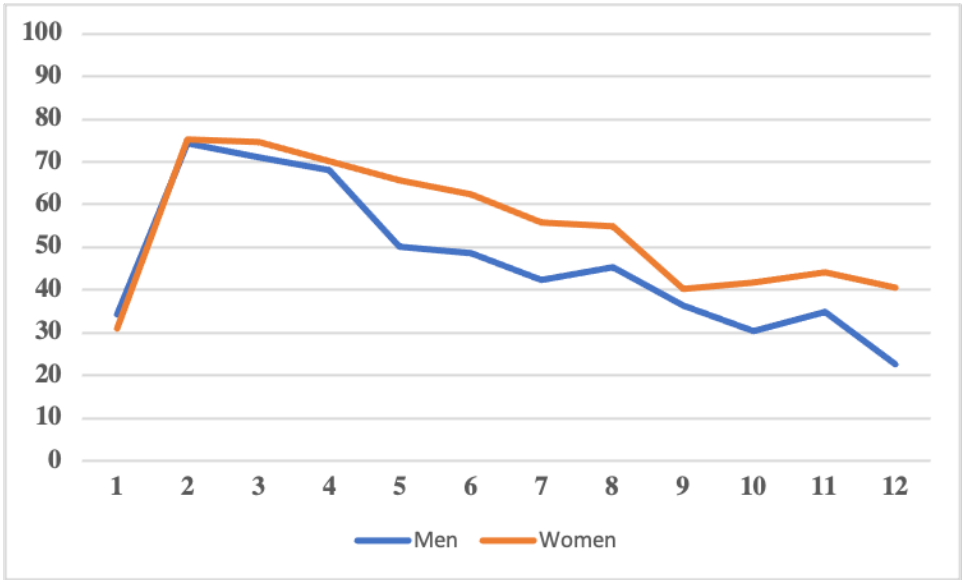

Figure 4. Percent of participants dietary self-monitoring diet 4 or more days over 12 weeks by sex

Table 3. Behavioral and Physiological Factors Associated with Weight Outcomes, Effects of Sex

	B (Standard Error)	p-value	Partial Eta Squared
Main Effects			
Baseline Resting Metabolic Rate	0.00 (0.00)	0.225	0.01
Objective Self-Weighing	-0.04 (0.02)	0.047	0.02
Objective Dietary Self-Monitoring	-0.05 (0.02)	0.004	0.03
WCSS Dietary Choices	-0.55 (0.42)	0.196	0.01
WCSS Self-Monitoring	-1.05 (0.41)	0.011	0.03
WCSS Physical Activity	0.20 (0.37)	0.586	0.00
WCSS Psychological Coping	0.13 (0.49)	0.794	0.00
Interactions by Sex			
Baseline Resting Metabolic Rate	0.00 (0.00)	0.910	0.00
Objective Self-Weighing	0.01 (0.02)	0.655	0.00
Objective Dietary Self-Monitoring	-0.01 (0.02)	0.754	0.00
WCSS Dietary Choices	-0.02 (0.42)	0.969	0.00
WCSS Self-Monitoring	-0.77 (0.41)	0.061	0.01
WCSS Physical Activity	0.22 (0.37)	0.552	0.00
WCSS Psychological Coping	0.46 (0.49)	0.352	0.00

Table 4. Behavioral and Physiological Factors Associated with Waist Circumference Outcomes, Effects of Sex

	B (Standard Error)	p-value	Partial Eta Squared
Main Effects			
Baseline Resting Metabolic Rate	0.00 (0.00)	0.211	0.01
Objective Self-Weighing	-0.03 (0.02)	0.072	0.01
Objective Dietary Self-Monitoring	-0.03 (0.02)	0.055	0.01
WCSS Dietary Choices	-0.65 (0.42)	0.121	0.01
WCSS Self-Monitoring	-1.37 (0.40)	0.001	0.04
WCSS Physical Activity	0.05 (0.37)	0.899	0.00
WCSS Psychological Coping	0.26 (0.49)	0.590	0.00
Baseline Resting Metabolic Rate	-0.00 (0.00)	0.463	0.00
Interactions by Sex			
Objective Self-Weighing	-0.01 (0.02)	0.614	0.00
Objective Dietary Self-Monitoring	0.01 (0.02)	0.715	0.00
WCSS Dietary Choices	-0.29 (0.42)	0.491	0.00
WCSS Self-Monitoring	-1.10 (0.40)	0.007	0.03
WCSS Physical Activity	0.54 (0.37)	0.146	0.01
WCSS Psychological Coping	0.43 (0.49)	0.382	0.00

Table 5. Behavioral and Physiological Factors Associated with Body Fat % Outcomes, Effects of Sex

	B (Standard Error)	p-value	Partial Eta Squared
Main Effects			
Baseline Resting Metabolic Rate	0.00 (0.00)	0.001	0.04
Objective Self-Weighing	-0.01 (0.01)	0.216	0.01
Objective Dietary Self-Monitoring	-0.03 (0.01)	0.004	0.03
WCSS Dietary Choices	-0.49 (0.25)	0.054	0.01
WCSS Self-Monitoring	-0.17 (0.24)	0.483	0.00
WCSS Physical Activity	-0.02 (0.22)	0.935	0.00
WCSS Psychological Coping	0.30 (0.30)	0.313	0.00
Interactions by Sex			
Baseline Resting Metabolic Rate	0.00 (0.00)	0.194	0.01
Objective Self-Weighing	-0.00 (0.01)	0.936	0.00
Objective Dietary Self-Monitoring	-0.01 (0.01)	0.495	0.01
WCSS Dietary Choices	-0.37 (0.25)	0.145	0.01
WCSS Self-Monitoring	-0.00 (0.24)	0.986	0.00
WCSS Physical Activity	0.06 (0.22)	0.784	0.00
WCSS Psychological Coping	0.33 (0.30)	0.266	0.00

CHAPTER 5

Overall Discussion

Excess adiposity during young adulthood is associated with a heightened risk of mortality later in life, specifically among men.[83] Thus, intervening during young adulthood has the potential to mitigate the development of chronic illness and mortality later in adulthood. Yet, men have low enrollment in lifestyle interventions,[137] even those adapted for young adults specifically. This low enrollment among young men suggests a need for redesigning existing evidence-based lifestyle interventions to meet the needs of young men.

Despite this clear need, relatively little work has been done to improve lifestyle interventions for young men. Therefore, the overarching aim of this dissertation was to inform a viable model for enhancing engagement and reducing adiposity among young men with overweight or obesity. These aims were achieved across three papers using a mix of quantitative and qualitative data from two lifestyle interventions designed for young adults. Papers 1 and 2 present findings from a pilot randomized trial targeting young men (ACTIVATE). The goal of this trial was to determine the preliminary efficacy, feasibility, and acceptability of a self-guided lifestyle intervention that incorporated health risk messaging grounded in the extended parallel processing model. Paper 3 was a secondary data analysis from a large-scale lifestyle intervention trial for young adults (REACH). The aim was to explore potential sex differences in the behavioral and physiological factors associated with treatment response. Taken together, this dissertation provides important insights that can be used to inform the development of lifestyle interventions for this high-risk population. Four key contributions to the literature are highlighted in an integrated discussion of findings below.

Integration of Findings

Young men receive clinically meaningful benefits from extant lifestyle interventions, but gender- and age-targeted interventions might improve recruitment and enrollment

The premise of this dissertation is based upon the historical challenges of recruiting and enrolling young men into lifestyle interventions. We found that implementing an age- and gender-targeted lifestyle intervention (ACTIVATE) mitigated some of the challenges faced when recruiting young men. Of note, enrollment goals were exceeded within the short period of 2-months. Further, the ACTIVATE program accrued 35 young men over the course of 2-months, whereas the REACH trial accrued just 66 young men across a total of 15 months of recruitment—even with the use of gender-targeted ads (i.e., images, text). Given the dissertation study design, we can't isolate which components played the largest role in motivating young men to join the ACTIVATE lifestyle intervention. However, these differences in enrollment yield suggest that using gender-targeted ads, without a gender-targeted lifestyle intervention, is not optimal for enrolling young men. Hence, to bolster men's interest in making healthy lifestyle changes, we recommend developing lifestyle interventions specific to both age and gender and drawing attention to this in recruitment materials.

The importance of implementing an age- and gender-specific lifestyle intervention is further supported by qualitative findings from Paper 2. Young men described meeting the demographic characteristics as a salient reason for joining and highlighted that both age and gender were considered when deciding to join. Of note, there is no evidence to suggest that gender-neutral lifestyle interventions are inferior to gender-specific lifestyle interventions in producing desired weight loss outcomes.[235] This is further supported by findings from Paper 3, where we observed young men in REACH experienced greater treatment benefit across all measures of adiposity than young women. Though, it might be that a gender-specific lifestyle intervention is necessary to reach young men and improve recruitment efforts with this hard-to-reach population. It should be

noted that ACTIVATE enrollment of emerging adults (under 25 years old) was low. Only 17% of the participants enrolled in ACTIVATE were emerging adults, which might suggest that a gender-specific program might not mitigate recruitment issues among emerging adult men specifically. Given the risky health behaviors exhibited during early adulthood, coupled with the increasing prevalence of obesity during these years,[63] there is a need for more focus on emerging adult men.

Health risk messages might enhance young men's motivation to join lifestyle interventions and serve as a useful reminder to change health behaviors

Young men found the weekly health risk text messages—emphasizing the link between obesity and cardiovascular disease— served as useful reminders throughout the program for why they were attempting weight loss. However, the health risk messages did not enhance perceived health risk. It should be noted that young men enrolled in the ACTIVATE intervention had high perceived health risk scores initially. Thus, we believe we were limited in our ability to detect change in perceived health risk, which then limited our ability to detect whether or not perceived risk was related to reductions in weight. It is also possible more testing is needed to develop a more rigorous and comprehensive measure of perceived risk.

Given these dissertation findings, more research is needed to explicate how health risk messages best fit into lifestyle interventions targeting young men. Overall, the health risk text messages were not met with ideal levels of satisfaction. Men also wanted more variety in the messages. Though, it should be noted that satisfaction with the health risk messages varied by treatment response—satisfaction was higher among participants who achieved non-clinically significant weight loss. Moreover, those who achieved clinically significant weight loss found the strategies for addressing health risks as less helpful. Additionally, the health risk messages were found to be a high contender for motivating men to join the lifestyle interventions. Taken together, it's possible that these health risk messages are better suited in recruitment materials—to enhance

perceived risk at the outset of a lifestyle intervention—and then as periodic reminders throughout treatment. Moving forward with the health risk messages, one approach might be to vary the weekly text messages, where health risk messages are deployed monthly, opposed to weekly, to avoid diminished effects and redundancy. Another approach might be to link other areas of disease and mortality, such as cancer,[236-238] with relevant health behaviors pronounced among young men (e.g., high consumption of processed meat, low consumption of fruits and vegetables). Overall, more research is needed to test different types of message framing with different diseases and health behaviors relevant to young men, as well as the dosage of these messages.

Self-guided approach shows promise for preventing weight gain, but young men might need additional support to achieve clinically meaningful weight loss

While young men in the self-guided intervention experienced modest weight losses, which were significantly different from the control (Paper 1), the magnitude of the weight losses did not reach established thresholds for clinical significance as they did within a more intensive lifestyle intervention (Paper 3). This underscores that young men can lose weight in a self-guided program, but might need more support to experience clinically meaningful weight loss. This is consistent with preferences and feedback from young men following participation in the self-guided intervention. In Paper 2, men expressed a desire for more contact (e.g., monthly check-ins) or feedback from the self-guided program. It is plausible that young men might experience greater treatment benefit and overall satisfaction if the self-guided program was adapted to include additional support.

One possible addition that could enhance motivation and still maintain the essence of a self-guided program, is a nudge. Over the last decade, nudges have been increasingly integrated into health interventions aiming to change a range of behaviors including eating practices,[239] vaccine literacy,[240] and medication adherence.[241] Nudges are particularly effective in reducing

weight among young adults when included in lifestyle interventions, with the most common nudges being feedback, reminders, financial incentives, and social support.[232] As such, integrating nudges into a self-guided behavioral lifestyle intervention, might be well-received among young men and have the potential to enhance weight loss outcomes. In Paper 2, young men expressed three types of nudges that would have helped with weight loss (social support, feedback, reminder)—all of which are commonly included in lifestyle interventions.[232] Recommendations for integrating these nudges in future intervention research is described below.

Peer Support/ Messenger

The vast majority of men described the need for social support, particularly from men with similar experiences. Recent research indicates that peer support[171] or group-based interventions[242] are effective in promoting weight loss. Young men also indicate a preference for peer support[110] within the context of physical activity or fitness.[87] However, given sampling limitations with existing lifestyle intervention research, little is actually known about the most effective types of social support needed for weight loss among young men, and how social support should be delivered within these interventions. For instance, it's unclear if young men prefer receiving social support online or in-person. Online support groups or discussion boards are beneficial to women, [170] but it is unknown if online support would also benefit men. More recent evidence suggests that in-person group comradery is beneficial for men to make lifestyle changes[19] and enhances motivation particularly among young men.[243,244] Sports-[245,246] and work-based programs[247,248] are becoming popular avenues for promoting weight management and reducing disease risk among men. Given the challenges of recruiting men into lifestyle interventions, places of work or recreation might be an opportune setting to implement lifestyle interventions. To expand on this

work, future research should determine if peer support mediates engagement or weight loss among young men specifically, and identify appropriate type of peer support and mode of delivery.

Personalized Feedback / Reminders

Young men described a particular preference for personalized feedback or brief reminders. This is a common element in lifestyle interventions designed for young adults[249] and is particularly beneficial to weight loss when feedback is based on progress related to self-monitoring.[250-253] Considering our data shows men disengaged from self-monitoring earlier than women, it is possible that integrating nudges, such as automated feedback might enhance engagement and the clinical benefit among young men. Moreover, using algorithms to tailor automated feedback on goal progress, based on self-monitoring behaviors, would coincide with men's preferences while still retaining the primarily self-guided approach. However, it's unclear when and how feedback should be delivered. Of note, the user experience with self-weighing varied by treatment response, which might indicate a need for varied or different intensities of personalized feedback on goal progress. It might be that men who are not achieving weight loss might need additional support or human e-coaching on goal progress to enhance motivation and satisfaction with progress. This is of particular note, considering findings from Paper 3 where men disengaged from self-monitoring earlier than women. Though, considering little is known about men's user experience with self-monitoring and feedback, yet the cornerstone of behavioral weight loss treatment,[34] there is a critical need to explore young men's experience with self-monitoring and feedback using mixed method approaches. Integrating more qualitative data specifically could better capture how to best deliver feedback on goal progress to young men.

Young men's preferences varied by treatment response, suggesting the need for applying a precision medicine approach to lifestyle interventions

In both the self-guided (ACTIVATE) and intensive (REACH) lifestyle intervention, the data show marked variability in treatment response. Interestingly, preferences for the degree of preferred support within the program varied by treatment response in ACTIVATE. In that, men who were not achieving clinically significant weight loss preferred a different delivery modality (in-person meetings over online meetings for both physical activity and diet) than men who achieved clinically significant weight loss. These differences in program preference, based on treatment response, underscore the need to move away from a "one-size fits all" approach to lifestyle interventions. Indeed, these findings support the call for precision medicine to move beyond the bench and to be applied to other areas such as the behavioral sciences—to prevent and treat obesity and other related diseases such as cardiovascular disease and cancer.[254,255]

Potential intervention approaches that utilize a personalized experience, while still retaining a standard of care, are the stepped-care approach. The stepped-care approach is a cost-effective approach adopted to treat depression—and embraces the idea of using the least intensive treatment prior to moving to a more intensive treatment.[256,257] Available evidence in obesity suggests that while a stepped-care approach does not produce as much weight loss at 18 months as the standard approach, the stepped-care approach did produce clinically significant weight loss at 18-months and was less costly. Though, it should be noted these trial samples have been largely women and appropriate timing and intensity have yet to be drilled down.[258,259] Therefore, more testing using a sequential multiple assignment randomized trial (SMART) design is needed to improve lifestyle interventions among young men. Drawing from findings across all 3 papers, it is plausible that young men could start with the self-guided approach which involves a less time-intensive self-regulation strategy, such as self-weighing paired with a set of discrete strategies to influence energy balance (e.g., cutting portions, limiting red foods). This first step could also

include automated but tailored feedback on goal progress. Then, depending on treatment response, young men could step-up to a more time-intensive approach such as dietary self-monitoring or different motivational enhancements such as e-coaching or peer support from someone also enrolled in the program. A stepped-care approach not only has the potential to be low-burden and low cost,[259] but could be a resource-efficient way to minimize heterogeneity in treatment response. However, more testing using a factorial experiment or a SMART design is needed to examine which and when these components will be of most clinical benefit to young men.

Moving forward, multiphase optimization strategy (MOST) could be used as a framework to systematically evaluate the distinct effects of each component to optimize lifestyle interventions for young men. MOST is a three phase framework for intervention development, optimization, and evaluation of health interventions.[260] The inherent goal of optimization is to reach the best process for intervention implementation, subject to constraints (i.e., cost).[260] To our knowledge, no research exists using the MOST framework to determine suitable intervention components to reduce adiposity among young men. Therefore, more pilot testing and subsequent revisions of the intervention components, as described in this dissertation, is needed to establish optimization criterion[260] for future lifestyle interventions targeting young men.

Limitations

Overall, there were several limitations across the 3 papers. First, the sample size was small in Papers 1 and 2. However, the sample sizes were appropriately aligned with the goals of the pilot study, which was to examine preliminary efficacy, feasibility, and acceptability of the self-guided program. Second, Paper 3 was a secondary analysis and was not powered to determine differences between men and women.

All three papers have some limitations in terms of generalizability. The three papers were mostly comprised of a college educated sample, with Papers 1 and 2 having limited racial/ethnic minority representation. In addition, all participants studied were treatment seeking. As such, these results might not be reflective of the broader population of young adult men. Further, the ACTIVATE trial was conducted within the context of COVID-19. It's possible that men had a heightened interest in weight loss due to the weight gain observed during the pandemic.[261] Furthermore, men's preferences for a program, specifically the online delivery and social aspect, could have been driven by concerns over in-person requirements and social isolation during the pandemic.

Last, there were some limitations in our assessment measures. Due to COVID-19, we transitioned ACTIVATE to a remote protocol which limited outcome assessment to one measure of adiposity (i.e., weight). Therefore, we lack an understanding of the full cardiometabolic health benefits men might have received from the program. In addition, weight data was collected remotely using a Bluetooth scale, as opposed to a clinic grade scale. However, this concern was mitigated through validity and reliability testing of different scales to minimize measurement error. In Paper 3, body composition was not measured per the gold standard, dual-energy absorptiometry. In addition, resting metabolic rate was not measured at 3-months, which limits our understanding of the potential role of adaptive thermogenesis. Thus, caution should be used when interpreting the findings. Lastly, the end points were relatively short-term—just 3 months—across the 3 papers. Therefore, more research is needed to understand if findings are consistent over longer-term follow up.

Strengths

Despite some limitations, overall, this dissertation had a number of strengths worth highlighting. Most notably, the rigorous approach to addressing the overall research question—

including randomized controlled trials, objective outcome assessments, integration of quantitative and qualitative data, as well as inclusion of racially/ethnically diverse samples. Findings provide future directions for the development of lifestyle interventions targeting young men—a high-risk and hard-to-reach population.

Conclusions

Given young men with obesity have high mortality and disease risk later in life,[83,262] it is critical to promote effective weight management during early adulthood—prior to the development and progression of disease. However, research is limited on how best to engage young men in weight management efforts to prevent mortality and disease risk. To that end, this work serves to address notable gaps in the field and provide insights into future directions for lifestyle interventions targeting young men. This dissertation found that a self-guided lifestyle intervention produced modest weight loss, but did not surpass the clinically relevant levels produced in the more intensive lifestyle intervention. Even so, the self-guided approach, paired with an age- and gender-specific program, might be better suited to engage young men in lifestyle interventions initially, especially when comparing the recruitment accrual of the self-guided and intensive lifestyle intervention. To maximize the clinical benefit of a self-guided approach, more work is needed to identify which specific components should be added to a lifestyle intervention for young men, as well as the mode and timing of delivery. In sum, these findings have important implications for health interventions and underscore the need for adopting a precision medicine framework in the behavioral sciences to minimize treatment variability and enhance the overall health benefits of lifestyle interventions for young men.

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APPENDICES

Paper 1. Appendix 1. Perceived Risk Measurement

RISK BEHAVIOR DIAGNOSIS SCALE

Define Threat=_Cardiovascular Disease__

Define Recommended Response: Weight Loss_____

	Strongly Agree				Strongly Disagree
RE 1. Weight loss is effective in preventing cardiovascular disease:	1	2	3	4	5
RE 2. Weight loss works in preventing cardiovascular disease:	1	2	3	4	5
RE 3. If I lose weight, I am less likely to get cardiovascular disease:	1	2	3	4	5
SE 4. I am able to lose weight to prevent getting cardiovascular disease:	1	2	3	4	5
SE 5. I have the skills to lose weight to prevent cardiovascular disease:	1	2	3	4	5
SE 6. I can easily lose weight to prevent cardiovascular disease:	1	2	3	4	5
SEV 7. I believe that cardiovascular disease is severe:	1	2	3	4	5
SEV 8. I believe that cardiovascular disease has serious negative consequences:	1	2	3	4	5
SEV 9. I believe that cardiovascular disease is extremely harmful:	1	2	3	4	5
SUSC 10. It is likely that I will get cardiovascular disease if I do not lose weight:	1	2	3	4	5
SUSC 11. I am at risk for getting cardiovascular disease:	1	2	3	4	5
SUSC 12. It is possible that I will get cardiovascular disease:	1	2	3	4	5

Paper 2. Appendix 1. Quantitative Satisfaction Survey

Program Feedback: ACTIVATE

1. How satisfied were you with the overall ACTIVATE program that you received during the past 12-weeks?

①	②	③	④	⑤	⑥	⑦
Very Dissatisfied						Very Satisfied

2. How satisfied were you with what you achieved in the ACTIVATE Program?

①	②	③	④	⑤	⑥	⑦
Very Dissatisfied						Very Satisfied

3. Would you recommend the ACTIVATE program to other young men?

①	②	③	④	⑤	⑥	⑦
Would strongly **not** recommend						Would strongly recommend

4. The information I learned in this program would be relevant to other men of my age who want to lose weight.

①	②	③	④	⑤	⑥	⑦
Strongly disagree						Strongly agree

5. The length of the program was sufficient for a weight loss program targeting men my age (18-35).

①	②	③	④	⑤	⑥	⑦
Strongly disagree						Strongly agree

6. Did you join any other weight loss programs within the past 3-months?

⓪ No ① Yes – what program(s) did you join?

_____

7. What parts of the program did you find appealing?	Not appealing at all						Very appealing

a. Male only	①	②	③	④	⑤	⑥	⑦
b. Young adult only	①	②	③	④	⑤	⑥	⑦
c. Minimal in-person	①	②	③	④	⑤	⑥	⑦
d. Self-guided	①	②	③	④	⑤	⑥	⑦
e. Focus on health risk specific to men of my age	①	②	③	④	⑤	⑥	⑦
f. Focus on fitness	①	②	③	④	⑤	⑥	⑦
g. Focus on diet	①	②	③	④	⑤	⑥	⑦
h. Focus on weight loss	①	②	③	④	⑤	⑥	⑦
i. Focus on general lifestyle changes	①	②	③	④	⑤	⑥	⑦
j. Other							

8. How much did each of the following help you lose weight?	Did not help						Very helpful
k. Attending **initial** group kick off session with a trained lifestyle coach	①	②	③	④	⑤	⑥	⑦
l. Program **website**	①	②	③	④	⑤	⑥	⑦
m. Program **meal plans**	①	②	③	④	⑤	⑥	⑦
n. Weekly **text messages**	①	②	③	④	⑤	⑥	⑦
o. Receiving feedback on measures from baseline visit	①	②	③	④	⑤	⑥	⑦
p. Using the scale to monitor my weight	①	②	③	④	⑤	⑥	⑦
q. Using an app to track my eating	①	②	③	④	⑤	⑥	⑦
r. Using an app to monitor my physical activity	①	②	③	④	⑤	⑥	⑦
s. Other							

9. Please rate the content of the **website**:	Strongly disagree						Strongly agree
a. The skills taught in the handouts helped me with my weight loss efforts.	①	②	③	④	⑤	⑥	⑦
b. The handouts were motivating to me.	①	②	③	④	⑤	⑥	⑦
c. The information in the handouts was relevant to me.	①	②	③	④	⑤	⑥	⑦

10. Please rate the following features of the initial group session class:	Strongly disagree						Strongly agree
a. The **length** of the class was the right amount of time.	①	②	③	④	⑤	⑥	⑦
b. The strategies taught in the group session were **helpful** to me.	①	②	③	④	⑤	⑥	⑦
c. The information in the group session was **motivating** to me.	①	②	③	④	⑤	⑥	⑦
d. The information in the group session was **relevant** to me.	①	②	③	④	⑤	⑥	⑦

11. Please rate the content of the weekly **text messages** you received during the program.	Strongly disagree						Strongly agree
a. The messages were **motivating** to me	①	②	③	④	⑤	⑥	⑦
b. The messages suggested strategies that were **helpful** to me.	①	②	③	④	⑤	⑥	⑦
c. The messages made me **aware** of the risks associated with weight gain	①	②	③	④	⑤	⑥	⑦
d. The messages made me **aware** that I am at risk for cardiovascular disease	①	②	③	④	⑤	⑥	⑦

12. How would you change the program to help you achieve greater weight loss?	This would <u>not</u> improve the program						This would improve the program
a. Add an **online group** component for discussion.	①	②	③	④	⑤	⑥	⑦
b. Add **in-person** group meetings focusing on **diet**.	①	②	③	④	⑤	⑥	⑦
c. Add **online** group meetings focusing on **diet**.	①	②	③	④	⑤	⑥	⑦
d. Add **in-person** group meetings focusing on **physical activity**.	①	②	③	④	⑤	⑥	⑦
e. Add **online** group meetings focusing on **physical activity**.	①	②	③	④	⑤	⑥	⑦
f. Add **in-person** group meetings focusing on **muscle strengthening**	①	②	③	④	⑤	⑥	⑦
g. Add **online** group meetings focusing on **muscle strengthening**	①	②	③	④	⑤	⑥	⑦
h. Other:							

13. How would you improve the **initial group session** in the future?
14. How would you improve the program **handouts**?
15. How would you improve the **weekly text messages**?
16. Is there anything else that could improve the **ACTIVATE program** in the future?

17. Please describe what you liked best about this program.
18. Please describe what you liked least about this program.

Paper 2. Appendix 2. Qualitative Interview Guide

Semi-Structured Interview Guide

Thanks for your participation in the study. I just have a few questions to ask about your experience participating in the study. As a reminder, I will be audio-recording our conversation—this is only so that we can properly analyze the data later. The only individuals with access to these interviews are study staff. Identifying information will not be connected to transcripts of the interview and all audio recordings will be password protected. We value your responses. There are no right or wrong answers. We really are interested in both positive and negative feedback because this will help us to improve the program in the future. Do you have any questions before we begin?

[If yes: address participant questions / concerns.]
[If no: Okay, well if it's alright with you then we will go ahead and get started.]

Motivations to Join

Thinking back to when you first joined the study, what was appealing about the program that motivated you to join?
[Probe for aspects of the study that were appealing to them]
[Male-only]
[Young adult only]
[Minimal in-person]
[Self-guided]
[Health risks—obesity, cardiovascular disease]
[Focus on fitness]
[Focus on diet]
[Focus on weight loss]

Thinking back to when you first heard about the program, what questions did you have about the program?

*[*Probe: *Please describe anything that made you hesitate or think twice about joining.]*

[Probe: *What could we say or do differently that would make the program more appealing to join?]*

What do you think would be the most effective ways of advertising the program to other young men your age?

Intervention Content/Delivery

How satisfied were you with the program overall?

[Probe for details about their experience with the program components]

[Probe for satisfaction with what they achieved in the program (i.e., their goals / outcomes) and which things were most meaningful / important to them]

Thinking about the intervention program, what parts of the program did you find the most helpful in meeting your goals? The least helpful? Anything else?

[Probe for all program details—group session, toolkit (scale, self-monitoring, resources / apps, sample meal plans), handouts and videos on website, text messages, duration, time commitment, delivery mode]

Which of the program recommendations did you struggle with while working towards your goals?

[Probe for behaviors (self-monitoring diet, physical activity, or weight, meal planning, purchasing fruits and vegetables, reducing calorie intake, reducing alcohol, reducing how often I eat out)]

What were some of the strategies used in your day-to-day living that helped you when trying to reach your goals?

[Probe for behaviors (self-monitoring diet, physical activity, or weight, meal planning, purchasing fruits and vegetables, reducing calorie intake, reducing alcohol, reducing how often I eat out)]

What were some of the suggested changes you found surprisingly challenging?

What aspects about the program would you suggest changing?

[Probe for suggestions that would be personally important]

If you were to talk to a friend interested in joining the program, what would you tell them about the program?

Paper 3. Appendix 1. Weight Control Strategies Scale

Instructions: The following statements describe strategies and behaviors that individuals may engage in when they are trying to lose weight or maintain their weight loss. Using the scale below, circle the number that best describes how often you did each of the following **during the past month**. Please respond to every item.

0 = Never
1 = Occasionally
2 = About half the time
3 = Most of the time
4 = Always

	Never	Occasionally	About half the time	Most of the time	Always
1. I set a daily calorie goal for myself.	0	1	2	3	4
2. I had several servings of fruits and/or vegetables each day.	0	1	2	3	4
3. I kept a record of the type and amount of food I ate.	0	1	2	3	4
4. I set exercise goals for myself.	0	1	2	3	4
5. If I overate, I thought about what led up to my overeating.	0	1	2	3	4
6. I kept high calorie, high fat foods (e.g., chips, cookies, cakes) out of sight so they would not tempt me.	0	1	2	3	4
7. I avoided fried foods.	0	1	2	3	4
8. I had a plan for getting my exercise in if the weather was bad and I couldn't exercise outside.	0	1	2	3	4
9. If I overate on one day, I made up for it by eating less the next	0	1	2	3	4

10. I kept low-calorie foods (e.g., fruit, raw vegetables, unbuttered popcorn) accessible for a healthy snack.	0	1	2	3	4
11. I engaged in moderate-intensity exercise like brisk walking or something similar to brisk walking for at least 30 minutes a day.	0	1	2	3	4
12. I weighed and/or measured the foods I ate.	0	1	2	3	4
13. I limited my intake of regular soda.	0	1	2	3	4