Comparing Self-Monitoring Strategies for Weight Loss: Does Developing Mastery Before Diet Tracking Enhance Engagement?

by

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Dissertation submitted in partial fulfillment of the requirements for the degree of Doctor of Philosophy in the Department of Psychology and Neuroscience in the Graduate School of Duke University

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ABSTRACT

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Abstract

Self-monitoring of dietary intake is a valuable component of behavioral weight loss treatment but engagement in self-monitoring declines quickly, resulting in suboptimal treatment outcomes. This dissertation examined a novel weight loss intervention that aims to lessen the decline in self-monitoring engagement by building mastery, self-efficacy, and self-regulatory skills—key constructs of behavior change—prior to self-monitoring diet. GoalTracker was a randomized controlled trial among 105 adults with overweight or obesity comparing three standalone 12-week weight loss interventions: (1) a Simultaneous arm with concurrent self-monitoring of weight and diet each day, along with weekly lessons, action plans, and tailored feedback via email; (2) a Sequential arm with the same components but that tracked only weight through week 4, then added diet tracking; and (3) an App-Only arm that only tracked diet, and did not receive additional behavior change components. All groups used the commercial app MyFitnessPal for self-monitoring and received a tailored calorie goal and a goal to lose 5% of initial weight by 12 weeks. Paper one examined the impact of the intervention on weight change and self-monitoring engagement (Aims 1-3) and found significant weight loss and engagement for all treatment arms, with no differences between arms. Paper two examined the relation between consistent self-monitoring and weight loss (Aim 4), revealing that consistent trackers lost significantly more weight than others. Lastly, paper three examined whether early weight loss predicts future
engagement and weight loss success (Aim 5), which was supported. Regardless of
the order in which diet is tracked, using tailored goals and a commercial app can
produce clinically significant weight loss. Consistent self-monitoring and early
weight loss should be emphasized. Standalone digital health treatments may be a
viable option for those looking for a lower intensity approach.
Dedication

This work is dedicated to my mother, Karen Braun Lanpher, PhD, a woman of many talents (psychologist, businesswoman, reliable editor, matriarch of the Lanpher clan) who is always ready with a cup of tea, encouraging words, and unmatched enthusiasm.
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<td>APP-ONLY</td>
<td>App-Only arm</td>
</tr>
<tr>
<td>ASA24</td>
<td>Automated Self-Administered 24-Hour Recall</td>
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<tr>
<td>BMI</td>
<td>Body Mass Index</td>
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<td>CI</td>
<td>Confidence Interval</td>
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<td>KG</td>
<td>Kilograms</td>
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<td>SEQ</td>
<td>Sequential self-monitoring arm</td>
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<td>SIM</td>
<td>Simultaneous self-monitoring arm</td>
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Acknowledgements

The execution and success of this dissertation would not have been possible without the support of many people on my team.

First, I am very appreciative of my committee – Kathy Sikkema, Rick Hoyle, and Bryan Batch – for providing their unique insight into this research project from an early stage. I am deeply grateful for members of my lab, the Duke Digital Health Science Center, for providing an incredibly supportive, engaging, and fun work environment. In particular, I thank Dori Steinberg for modeling what a dissertation is capable of entailing, and for providing advice and encouragement along the way. To Hallie Davis-Penders and Miriam Berger (and formerly, Perry Foley) for being graciously ready to help on the fly, no matter the task. To Martin Streicher for creating and operating the Prompt dashboard so that I could easily access engagement data. To Sandy Askew for her incredibly informative statistical support – always going above and beyond her role for the sake of learning. I sincerely thank my labmates, Christina Hopkins and Jack Brooks, for being eager and willing to assist and take charge of study visits when I moved to California, along with Tia Kelley, Azaria Anderson, Hira Ahmed, Maggie Wang, and Kendra Pallin for their dedication as research assistants. Importantly, I thank all who participated in the GoalTracker trial for undertaking in this experience with me and contributing to science. Further, I thank my advisor, Gary Bennett, whom I have had the pleasure to know now for eight years and who has graciously prepared me for each step in this
(non-linear) dissertation research process, and, just as importantly, inspired me to enjoy the journey and surround myself with positive, sharp, and hardworking people. I am honored to have worked with him and this Duke team, and hope future projects together are forthcoming.

I am also indebted to Duke University – and the Psychology & Neuroscience Department – for allowing me to become a triple Dukie, and providing a home-away-from-home for the past twelve years filled with passionate students and faculty, and the most beautiful & majestic campus, where I got married in June 2017.

There are also a number of other important individuals in my life who joined me in this graduate school journey: Jessica, Caitlin, and Marcus – I am grateful that we were paired together as a cohort in 2012. To Ilana Lane, who has served as a mentor and friend, and whose impromptu check-ins I always appreciate. To Karmel Choi for providing an ear at our regular tea breaks. And to Deshira Wallace, who started with me in Wilson Dorm as a freshman, and has remained a true friend, motivator, appreciator of the details, and late-night study partner.

Importantly, I am grateful for my husband, Nishant Patel (another Wilson Dorm hallmate), for being a steady force since Day 1 at Duke. Whether happily listening to my to do lists, providing impressive Excel expertise, or creatively getting through 7 years of bicoastal long distance before we could finally reunite, I sincerely appreciate your endless confidence that things will work out, and your ability to make me laugh. Finally, I thank my family – my mom, Ryan, Sarah, Brad, and
Francesca – for helping me persevere through this dissertation project, setting the bar high for achievement of goals, and making sure we celebrate each step of the way. While he is no longer here with us, it goes without saying that my father, Gregory Lanpher, is an unwavering light and inspiration, reminding me to aim for the stars and pursue science with both curiosity and compassion.
1. Introduction

1.1 Obesity Prevalence and Consequences

Obesity is a pervasive health concern in the United States that is detrimental to both physical and mental health. Excessive adiposity can increase one’s risk for developing adverse medical conditions such as type 2 diabetes, cardiovascular disease, sleep apnea, certain types of cancers, and all-cause mortality.\textsuperscript{1-5} It can also contribute to poor psychological health, particularly when experiencing feelings of stigma or shame; these factors can contribute to lower self-esteem, increased social avoidance, and binge-eating tendencies.\textsuperscript{6} At the societal level, the negative repercussions of obesity can drive healthcare costs and result in workplace absenteeism or presenteeism.\textsuperscript{7,8} Currently, 39.8\% of adults in the United States have obesity,\textsuperscript{9} while another one-third of adults in the United States are overweight.\textsuperscript{10} In light of the widespread nature of overweight and obesity and its multitude of repercussions, treatments to reduce body weight are needed. An increasing number of strategies exist to aid in weight loss, including surgical procedures (e.g., gastric bypass surgery), pharmacological approaches (e.g., orlistat), dietary methods (e.g., meal replacement programs, meal timing), and lifestyle interventions.

1.2 Traditional Lifestyle Interventions

In 2013, three prominent health associations—the Obesity Society, the American Heart Association, and the American College of Cardiology—jointly developed and published clinical treatment guidelines for adults with overweight
and obesity.\textsuperscript{3} As recommended by the clinical treatment guidelines and the United States Preventive Services Task Force,\textsuperscript{11} lifestyle interventions should be the first-line of treatment for adults who are overweight and have at least one comorbidity, and for adults with class 1 (BMI of 30.0-34.9) or class 2 obesity (BMI of 35.0-39.9). These comprehensive lifestyle interventions incorporate dietary changes, physical activity improvements, and behavioral therapy. Weight reduction of at least 2\% to 5\% has been shown to reduce cardiovascular disease risk.\textsuperscript{3,12} The guidelines do not endorse one particular dietary pattern; instead, diet should be tailored to meet an individual’s food preferences and risk factors. Caloric restriction is encouraged to produce desirable outcomes.

\textbf{1.3 Self-Monitoring Diet}

A common component of behavioral weight loss treatment involves self-monitoring diet, which frequently involves recording all foods and beverages consumed during the day, and tracking how many calories are in each item. Individuals are then able to compare their current caloric intake to a desired calorie goal or to their past performance.\textsuperscript{13,14} The majority of evidence-based behavioral obesity treatments use calorie tracking as their primary strategy.\textsuperscript{3,15-17}

The act of self-monitoring diet is useful because it allows individuals to become aware of how their lifestyle choices affect their health.\textsuperscript{18} By recording their calories each day, individuals are more likely to identify factors in the food environment that are impacting their progress, thus prompting better awareness of
what stimuli or behavioral patterns should be modified or maintained. For example, by self-monitoring their diet, individuals will likely have better insight into how certain eating patterns (e.g., skipping meals, choosing sugar-sweetened beverages over water, eating at restaurants) contribute to their caloric intake; moreover, they may be able to reflect on how fluctuations in meeting or exceeding their daily caloric budget correspond to their weight loss progress. Self-regulatory theories provide an explanation for why behavior change occurs in the context of self-monitoring dietary intake: self-monitoring diet can increase awareness of eating patterns and provide positive reinforcement for eating healthy, which can enhance self-efficacy for making healthy dietary changes. This enhanced awareness and self-efficacy can then encourage individuals to continue adapting their eating behavior in order to more closely attain their weight loss goal.

In a review of effective behavior change techniques for weight management, calorie tracking was highlighted as one of the most impactful strategies. Many interventions encourage daily self-monitoring of diet, since both higher frequency and consistency of self-monitoring diet have been linked to greater weight loss. Comprehensiveness of diet tracking has also been associated with weight loss, but not when frequency and consistency of self-monitoring are accounted for in the model. In an weight management intervention by Peterson et al. that examined all three of these facets of dietary self-monitoring, participants were instructed to monitor their diet in a paper diary at least 3 days each week.
The study demonstrated that increased frequency and consistency are both important for weight change, and – perhaps more intriguing – that frequent but inconsistent self-monitoring had a limited effect on outcomes. The authors concluded that consistency of self-monitoring is necessary, even among individuals who are frequent self-monitors. Consistency was defined in Peterson et al.’s trial as the number of weeks with at least 3 completed daily food records (the number that was the weekly target); high consistency was operationalized as consistently self-monitoring diet at least 50% of the total intervention weeks. There is no existing evidence regarding whether consistency in self-monitoring results in clinically significant weight loss when individuals are instructed to self-monitor diet every day. Other studies that examined consistency have instructed participants to self-monitor diet just 3 days a week or ad libitum or self-monitor other items daily, such as exercise or weight.

Despite its demonstrated efficacy, dietary self-monitoring engagement often declines over time, likely due to a multitude of factors such as time constraints, literacy and numeracy constraints, limited enjoyment from tracking, difficulty with tracking, changing perceptions of its usefulness, failure to develop a habit of self-monitoring, and heightened cognitive load, especially in the context of restricted eating. When the perceived costs of self-monitoring exceed the perceived benefits, engaging in dietary self-monitoring practices may become infrequent or discontinue.
This decline in self-monitoring engagement is often associated with suboptimal weight loss. Therefore, determining ways to delay or reverse this decline in engagement are needed. Initial self-monitoring practices are particularly important because they are associated with early weight loss success (i.e., outcomes at 4 weeks), which has been demonstrated to be a strong predictor of long-term weight loss. Few studies report weight loss outcomes or rates of self-monitoring early in treatment; one such study by Unick et al. investigated these process data in an internet-based intervention and categorized intervention participants as either ‘early responders’ (i.e., those who lost at least 2% of weight by week 4) or ‘early nonresponders (i.e., those who lost less than 2% weight, or gained weight by week 4). The study found that early responders had tracked their calories and body weight on a website more frequently over the first four weeks than did early nonresponders (p<0.001 and p=0.001, respectively), and were more likely to achieve clinically meaningful weight loss at 3, 6, and 12 months. Thus, enhancing intervention engagement in the first month of treatment may have long-lasting repercussions.

Taken together, the literature demonstrates that frequent and consistent self-monitoring of dietary intake are positively associated with improved weight loss outcomes. Consequently, there is a need to discover ways to improve self-monitoring engagement in the first month of treatment; strategies that prepare individuals before they engage in the meaningful, but effortful practice of self-
monitoring diet should be considered. We will next explore theoretical constructs that may help us identify a strategy to improve engagement.

1.4 Theoretical Constructs

Theories of self-regulation posit that developing self-efficacy and self-regulatory skills are fundamental to changing health behavior.\textsuperscript{20,46} Each will be reviewed below.

1.4.1 Self-Efficacy

Self-efficacy is a key construct of Social Cognitive Theory and is defined as one's confidence in his or her ability to initiate and maintain change in a certain behavior to produce a desired outcome.\textsuperscript{19,46,47} Improvements in self-efficacy for controlling diet predict both concurrent\textsuperscript{48-50} and future reductions in body weight,\textsuperscript{51,52} as well as reductions in caloric consumption.\textsuperscript{51} Changes in self-efficacy have also been shown to mediate the treatment effect on weight loss.\textsuperscript{53} In combination with initial weight loss, improvement in dietary self-efficacy was shown to be the best predictor of 12-month weight loss.\textsuperscript{54} In light of these findings, weight loss interventions should adopt strategies that increase self-efficacy for the purpose of facilitating behavior change.

Individuals with stronger self-efficacy are more likely to make behavioral changes because they have greater confidence in their efforts being worthwhile; thus, they tend to persist for longer, even for time-intensive or cognitively demanding tasks. Furthermore, self-efficacy is considered a malleable construct that
can be enhanced through intervention, as has been demonstrated in several behavioral weight management studies. By attending to this construct, theory-based interventions aim to promote greater change in their target behaviors and corresponding outcomes. However, several studies have demonstrated that self-efficacy actually decreases over the course of an intervention, which is attributed to initially being over-confident in one’s efforts to produce change. Specifically, individuals with limited experience in changing diet, or those who are highly motivated to change, may initially underestimate the difficulty of changing weight-control behaviors.

1.4.2 Mastery

Although there are several ways to strengthen self-efficacy, the most powerful mechanism is through mastery experiences (also known as enactive attainment or performance attainment). Mastery entails gaining a high degree of skill in a desired behavior. Accomplishing a desired behavior promotes self-efficacy because one’s effort and capabilities are judged to be the cause of success. Moreover, by focusing on one treatment target at a time and developing mastery for that task, self-efficacy can increase, leading to subsequent behavior change. Because adverse mastery experiences may attenuate one’s self-efficacy for that task, it may be useful to begin an intervention by engaging in tasks that are easier to accomplish. Starting with a simple task that can be easily mastered may be ideal.
Several studies have explored whether mastery or habit strength formation can be harnessed if individuals focus on one behavior at a time.\textsuperscript{62-65} Some findings suggest that focusing initially on only one behavioral domain may promote better outcomes in subsequent domains that are targeted; for example, developing exercise self-regulation skills initially has been demonstrated to promote subsequent diet-related self-regulation skills,\textsuperscript{63,66} and focusing on diet before adding physical activity goals demonstrated improvements in both domains at 6 months, though the effect subsided by 9 months.\textsuperscript{65} Therefore, future research is warranted to assess whether mastery can be more readily achieved if one behavior is addressed at a time.

Despite the potential for mastery experiences to enhance outcomes, few weight loss interventions have leveraged – or reported on – this psychological construct. Most behavioral obesity treatments instruct individuals to self-monitor multiple behaviors \textit{simultaneously} through the end of treatment. However, one weight loss trial focused on providing a mastery experience before beginning an intensive treatment.\textsuperscript{67} Participants were randomized to either a novel ‘Maintenance First’ group or a traditional ‘Weight Loss First’ group. In the Maintenance First group, individuals first completed an 8-week period where they were instructed to neither lose nor gain any weight. During this period, Maintenance First participants focused on learning about energy balance and healthy eating, self-weighing daily, monitoring fluctuations in weight, making small adjustments to behavior, and
overcoming disruptions. Ultimately, the purpose of this initial period was to achieve mastery of self-regulatory skills and foster self-efficacy before trying to change behavior; a high-intensity, 20-week weight loss intervention began at the end of the 8-week, skill-building period. By 18 months, the Maintenance First group had significantly less weight regain than did the Weight Loss First group (1.4 kg vs. 3.3 kg, respectively).67 This study provides support for developing mastery of self-regulatory skills before beginning a more intensive treatment.

1.4.3 Self-Regulation

Self-regulation involves acquiring skills for managing short-term costs that lead to long-term goals.68 Self-regulation includes setting a goal, self-monitoring current behavior, obtaining feedback about whether there is a discrepancy between current behavior and one’s goal, and changing behavior to make progress toward achieving one’s goal.69 Combining several self-regulation strategies into one treatment – specifically, goal setting, self-monitoring, and feedback on both the behavior and progress towards an outcome – promotes greater behavior change.70 For example, individuals in weight loss interventions may first establish a weight loss goal (e.g., 5% weight loss), then self-monitor their body weight or behaviors related to weight control (e.g., calorie consumption and physical activity), and review feedback on how proximal their current weight is to their target goal. During this process, they will likely gain awareness of how many calories they typically consume in a day and how different food items vary in caloric content. If insufficient
progress is made, they may seek to adapt their current eating pattern or physical activity level; if satisfied with their weight loss progress, they may aim to maintain their current daily caloric intake and physical activity regimen. This behavior change process is cyclical, such that individuals will positively reinforce behaviors that promote success and negatively reinforce behaviors that contribute to stagnant weight or weight gain.69

While individuals tend to have moderately stable self-regulatory capacity, they can improve their self-regulatory skills with practice; thus, it is possible for individuals to develop mastery of self-regulatory behavior.62 As opposed to sole nutrition education interventions, theoretically-based behavioral interventions are able to promote greater adoption of self-regulatory behaviors.70,71 Self-regulation theory supports the use of smaller changes that are less effortful and easier to initiate and maintain.69 Small change approaches have been used in prior weight loss trials to promote mastery and self-efficacy for small yet achievable behavior change.72,73 Implementing strategies that incorporate small, gradual changes should be considered in intervention development and experimentally tested.

1.4.4 Relation of Constructs

Self-efficacy and self-regulatory skills have been shown to be reciprocally related, such that improvement in self-regulatory skills has been linked to improvement in eating self-efficacy,48 and improvement in self-efficacy serves as an antecedent of dietary self-regulation.74,75 Indeed, self-regulation theory,20 suggests
that self-regulation can promote perceived self-efficacy. A recent study by Annesi (2016) found that greater change in self-regulatory skills for controlled eating predicted greater self-efficacy for controlling eating, and that changes in self-efficacy mediated the effect of self-regulatory skills on healthy behaviors (e.g., increasing fruit and vegetable intake). Moreover, Linde et al. (2006) demonstrated that greater eating self-efficacy at 4 weeks predicted greater frequency of self-monitoring calories in weeks 5 to 8. Further, weight-control behaviors, such as self-monitoring of calories, mediated the effect of self-efficacy on weight change. In sum, by developing self-efficacy and forming new habits, self-regulatory capacity may become enhanced; at the same time, developing self-regulatory skills can improve self-efficacy. Targeting both of these constructs may produce optimal behavior change.

This dissertation study aims to blend the literature on self-regulation and self-efficacy by determining whether developing mastery in self-monitoring practices enhances self-regulatory skills and self-efficacy in controlling diet, leading to greater long-term self-monitoring engagement, adoption of weight-control behaviors, and subsequent weight loss. In intervention development, it is important to remain cognizant that declines in self-monitoring engagement are common, leading to lost opportunity for strengthening self-regulatory skills and building mastery. Therefore, it is advisable to select an initial strategy that is easy to master and keeps individuals engaged in the intervention.
1.5 Daily Self-Weighing

When selecting a strategy that promotes self-regulatory capacity as well as provides an opportunity for mastery, interventionists need to consider demonstrated efficacy and ease of use. Daily self-weighing (i.e., self-monitoring of body weight) meets both of these needs.

1.5.1 Efficacy

First, daily self-weighing promotes weight loss when combined with other empirically supported behavioral components such as feedback and skills training. Most interventions that incorporate self-weighing also involve concurrent self-monitoring of other weight-control behaviors, including food intake or physical activity. Few studies have explored the efficacy of daily self-weighing without these other self-monitoring components. One such intervention by Steinberg et al. asked participants to weigh daily on a cellular-connected smart scale, and provided them with weekly lessons and feedback via email. No in-person meetings or telephone counseling were provided. Among intervention participants, the observed rate of daily self-weighing was 6.1 days per week, which was associated with 6.6% loss of body weight over 6 months – a magnitude that is as large as most efficacy trials that have a significantly higher treatment dose. In contrast, a study by Madigan and colleagues (2014) isolated the effect of daily self-weighing and found no difference in weight change between a group that self-weighed daily and a similar group that did not. Compared to the previous study by
Steinberg et al., this study did not incorporate skills training about dietary changes or provide additional feedback, reinforcing the notion that multiple behavior change techniques in a treatment are necessary to achieve change. Additionally, the importance of frequent and consistent self-monitoring of body weight has been confirmed.

Daily self-weighing is also found to foster changes in healthy eating patterns. Two recent studies found that individuals who self-monitor their weight daily are more likely to adopt a higher number of weight-control behaviors than are individuals who self-monitor their weight most days of the week. Likewise, in an analysis of baseline behavioral outcomes and psychosocial constructs, frequency of self-weighing was related to self-regulatory eating practices. Specifically, frequent self-weighing was associated with higher dietary restraint, while lower disinhibition was linked to self-weighing less than once per week.

Also important to note is that potential adverse psychological outcomes of daily self-weighing—such as binge eating, depressive symptoms, body dissatisfaction, and maladaptive eating behavior and cognitions—among adults with overweight and obesity have not been substantiated.

1.5.2 Ease of Use

Fortunately, interventions that incorporate daily self-weighing have typically found engagement to be high, likely because self-monitoring of body weight is easy to do and can be made habitual. Unlike traditional self-monitoring approaches
that involve many steps to completion, daily self-weighing can be completed in just a few steps and become a habit (e.g., step on scale after you shower every morning, then enter weight on app). In studies that included multiple self-monitored behaviors, engagement of self-weighing tends to be higher than that of dietary self-monitoring\textsuperscript{25,91,92} and of physical activity self-monitoring\textsuperscript{93,94} While daily self-weighing engagement tends to decline over time,\textsuperscript{78,95,96} long-term engagement tends to remain higher, and rates of decline more gradual, than that of dietary self-monitoring engagement\textsuperscript{13,29,56} and physical activity self-monitoring engagement.\textsuperscript{29}

This differential engagement has been demonstrated in several studies. In the SELF trial, an 18-month randomized controlled trial for weight loss, percent time of adherence to self-weighing was 44\% at 6 months, 37\% at 12 months, and 29\% at 18 months\textsuperscript{97}; in comparison, adherence to dietary tracking decreased from approximately 45\% at 3 months, to 25\% at 6 months, and 10\% at 12 months.\textsuperscript{56} In a secondary analysis of a separate behavioral intervention, Zheng and colleagues revealed that a majority of participants (75\%) consistently self-monitored their body weight over 6 days per week for the entire 12-month intervention, while 9\% of participants saw a drastic decline in self-weighing engagement.\textsuperscript{98} The authors concluded that the latter subset never established a habit of daily self-weighing from early on in the intervention. Nevertheless, these results illustrate that daily self-weighing is a skill that can be targeted in an intervention and can be considered
a means by which an individual can strengthen self-regulatory capacity and form habitual behavior.

### 1.5.3 Other Factors at Play

Daily self-weighing is a simple behavior that involves stepping on a scale and recording one’s weight every day. In addition to having high ease of use, self-weighing is shown to have high acceptability and perceived helpfulness among intervention participants. In a large, 24-month multicomponent behavioral weight loss intervention delivered over the internet, tracking weight was identified by intervention participants as one of the most helpful activities for weight control efforts. Moreover, almost all (91%) of participants who achieved weight loss of at least 5% (the study goal) identified tracking weight as a helpful activity; in comparison, 83% of such individuals identified calorie tracking as helpful for weight control. Another study found that satisfaction with a weight loss treatment was associated with greater frequency of self-weighing, confirming the importance of self-weighing for promoting intervention satisfaction.

Taken together, self-weighing is a viable self-regulatory technique in which mastery can be achieved and self-regulatory capacity can be strengthened.

### 1.6 A Sequential Approach

Behavioral weight loss interventions typically involve monitoring multiple behaviors or outcomes simultaneously during treatment. Different self-monitored behaviors have been shown to independently contribute to weight loss,
which enhances overall treatment success. Moreover, monitoring several behaviors simultaneously is efficient and provides multiple opportunities for mastery experiences in that there are more behaviors that can be mastered.

Despite these advantages, self-monitoring multiple items at the same time may detrimentally impede performance on each item or result in greater dropout of treatment.\textsuperscript{102,103} A problem arises when \textit{attempting} to change a behavior but \textit{failing} to develop mastery of that behavior, which can weaken self-efficacy,\textsuperscript{61} leading to negative downstream repercussions. In addition, rates of self-monitoring engagement are often similar across behaviors,\textsuperscript{98,104} so when an individual self-monitors one behavior less frequently, it is likely that he or she will also self-monitor the other behavior less frequently, as demonstrated in an analysis of self-monitoring patterns by Zheng et al.\textsuperscript{31} These issues highlight why it could be problematic to track two behaviors simultaneously for the duration of an intervention.

An alternative to simultaneous behavior change is to self-monitor items in a \textit{sequential} fashion. Interventionists have developed sequential interventions that still include multiple components but that stagger their introduction in the intervention,\textsuperscript{105,106} based on the premise that mastery is more easily obtained if one new behavior is targeted at a time. The order of behaviors being targeted in a sequential intervention may be important, especially when they differ in complexity. A study by Schulz et al. targeted multiple health behaviors and found that the
smoking cessation rate was higher in the sequential arm than the simultaneous arm, though there was no difference on other behavioral outcomes. Additionally, a study by King et al. compared two sequential interventions (diet-first, exercise-first) to a simultaneous intervention (diet and exercise concurrently), and found that only the exercise-first arm saw improvements in physical activity at 4 months, but that by 12-months the simultaneous arm also achieved significant improvements.

It is common in these trials for the first behavior in a sequential design to continue to be targeted for the duration of the study, instead of swapping one behavioral target for another. It is conceivable that sustained engagement in self-monitoring the first item will positively influence engagement in the second behavior that is self-monitored.

Despite support for sequential intervention approaches, no studies of behavioral weight loss interventions have compared a sequential self-monitoring approach to a simultaneous self-monitoring approach, nor have any studies examined an intervention that incorporates self-monitoring weight prior to self-monitoring diet. The current trial addresses these gaps in the field.

**1.7 Interventions for Weight Loss using Smartphone Apps**

We chose to test this sequential strategy in the context of a remotely delivered intervention that utilizes a commercially available mobile app – MyFitnessPal. Given the pervasiveness of obesity, strategies are needed that have high reach. Past studies have demonstrated that technology-based strategies for
self-monitoring dietary intake produce greater adherence and less pronounced declines in engagement than traditional paper-based self-monitoring methods.\textsuperscript{110,111} This increased engagement is likely due to greater automation resulting in reduced tracking time and burden, ability to capture behavior more proximal to actual time of eating or drinking, and immediate, tailored feedback. mHealth solutions hold promise given that 77\% of U.S. adults own a smartphone.\textsuperscript{112}

We reviewed the literature on weight loss interventions that utilized mobile phone applications ("apps") for self-monitoring dietary intake. We first examined interventions that used commercial apps for self-monitoring diet that did not include a counseling component (i.e., standalone interventions; Table 1), then reviewed those that included counseling (Table 2), as well as trials with researcher-designed apps (Table 3).

As demonstrated below and in recent reviews,\textsuperscript{113,114} most trials that used commercial apps lacked fully-powered designs and/or were considered pilot studies. In trials that utilized commercial apps with no counseling component, maximum weight loss was -4.7 kg at 3 months and -6.8 kg at 6 months.\textsuperscript{115} The trial with these findings included a weight loss goal, calorie goal, self-monitoring of steps, and skills training via podcasts.\textsuperscript{115} Only one study that was fully-powered and not a pilot trial examined commercial apps plus some level of counseling; this trial by Jospe et al. found no difference in weight loss between an arm that tracked diet in the app and other interventions (e.g., self-monitoring weight via SMS or hunger
training) that had the same dose of counseling and choice of three dietary plans.\textsuperscript{116} Of note, this study did not establish a weight loss goal, did not provide reminders to track, and participants were instructed to monitor diet daily in the first month only, then one week per month thereafter.

In studies that used researcher-designed apps for self-monitoring diet, maximum weight loss achieved was -5.2 kg at 3 months and -6.2 kg at 5 months; the study with these weight loss results included six counseling sessions, a weight loss goal, a step goal, self-monitoring of weight and steps, and app-based skills training.\textsuperscript{117} While efficacy was demonstrated, interventions with researcher-designed apps are less likely to be available in the commercial marketplace, and maintained and updated over time, thus making them a less favorable intervention strategy. Utilizing an already-existing commercial app would allow for greater scalability. We chose to use MyFitnessPal in the current trial given its high popularity and acceptability,\textsuperscript{118} free nature, and availability on both iOS and Android platforms.
Table 1: Weight Loss Interventions that Use Commercial Apps for Dietary Self-Monitoring, without Counseling

<table>
<thead>
<tr>
<th>Author (Year)</th>
<th>IX Length</th>
<th>App used for Self-Monitoring Diet</th>
<th>Additional Intervention Components</th>
<th>Weight Tracking</th>
<th>Diet Tracking</th>
<th>PA Tracking</th>
<th>Comparison Arm(s) Without App</th>
<th>Weight Change from Baseline in Standalone Arm</th>
<th>Significance Between Arms in Weight Loss</th>
</tr>
</thead>
<tbody>
<tr>
<td>Turner-McGrievy (2011) 35</td>
<td>6 months</td>
<td>(a) Calorie Counter by Fat Secret app</td>
<td>[core] 2 podcasts/wk (a) Twitter app – interact w/ study coordinator, participants; and told to post daily</td>
<td>unclear</td>
<td>unclear</td>
<td>freq rec</td>
<td>(b) calorie book</td>
<td>3 months: (a) -2.4 kg 6 months: (a) -2.6 kg</td>
<td>3mo: a = b 6mo: a = b</td>
</tr>
<tr>
<td>Laing et al. (2014) 34</td>
<td>6 months</td>
<td>(a) MyFitnessPal app</td>
<td>(a) pt choice of WL goal of .23-.90 kg/wk; tailored calorie goal generated by app</td>
<td>optional</td>
<td>optional</td>
<td>optional</td>
<td>(b) usual care</td>
<td>3 months: (a) -0.27 kg 6 months: (a) -0.03 kg</td>
<td>3mo: a = b 6mo: a = b</td>
</tr>
<tr>
<td>Wharton et al. (2014) 119</td>
<td>8 weeks</td>
<td>(a) Lose It! app</td>
<td>(core) PA expenditure of 150 cal/d (a) WL goal of 1 lb/wk; tailored calorie goal generated by app</td>
<td>daily</td>
<td>daily</td>
<td>--</td>
<td>(b) memo on phone to track diet + 1 F2F (c) paper to track diet + 1 F2F</td>
<td>8 weeks: (a) -1.6 kg</td>
<td>a = b = c (pilot – no power analysis)</td>
</tr>
<tr>
<td>Johnston &amp; Thompson-Felty (2015) 120</td>
<td>8 weeks</td>
<td>(a) MyDietitian app (b) MyDietitian app (c) MyDailyPlate app</td>
<td>(b) daily feedback from dietitian via SMS or MMS</td>
<td>daily</td>
<td>daily</td>
<td>--</td>
<td></td>
<td>8 weeks: (a) +0.7 kg (b) -0.2 kg (c) +0.2</td>
<td>a = b = c (no power analysis)</td>
</tr>
<tr>
<td>Hales et al. (2016) 121</td>
<td>12 weeks</td>
<td>(a) Calorie Counter by Fat Secret app (b) researcher-designed app</td>
<td>(core) podcasts w/ diet and exercise info via email 2x/wk (b) notifications to track, social support, incentives</td>
<td>daily</td>
<td>daily</td>
<td>daily</td>
<td>--</td>
<td>3 months: (a) -2.2 kg (b) -5.3 kg</td>
<td>b &gt; a</td>
</tr>
<tr>
<td>Burke et al. (2017) 122</td>
<td>12 weeks</td>
<td>(a) Lose It! app (b) Lose It! app (c) Lose It! app</td>
<td>(b) feedback (c) feedback + 3 F2F groups</td>
<td>daily</td>
<td>daily</td>
<td>daily</td>
<td>--</td>
<td>12 weeks: (a) -2.47 kg (b) -2.88 kg (c) -3.01 kg</td>
<td>a = b = c (pilot – no power analysis)</td>
</tr>
<tr>
<td>Turner-McGrievy et al. (2017) 115</td>
<td>6 months</td>
<td>(a) Calorie Counter by Fat Secret app</td>
<td>(core) 2 podcasts/wk sent via email; track steps (a) WL goal of 1-2lbs/wk; tailored calorie goal</td>
<td>daily</td>
<td>unclear</td>
<td>freq rec</td>
<td>(b) Bite Counter device</td>
<td>3 months: (a) -4.7 kg 6 months: (a) -6.8 kg</td>
<td>3mo: a = b 6mo: a &gt; b</td>
</tr>
</tbody>
</table>
Table 2: Weight Loss Interventions that Use Commercial Apps for Dietary Self-Monitoring, with Counseling

<table>
<thead>
<tr>
<th>Author (Year)</th>
<th>IX Length</th>
<th>App used for Self-Monitoring Diet</th>
<th>Additional Intervention Components</th>
<th>Weight Tracking</th>
<th>Diet Tracking</th>
<th>PA Tracking</th>
<th>Comparison Arm(s) Without App</th>
<th>Weight Change from Baseline in App Arm</th>
<th>Significance Between Arms in Weight Loss</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allen et al. (2013)</td>
<td>6 months</td>
<td>(b) Lose It! app</td>
<td>(core) ≥150 min MVPA/wk; 5% WL by 6mo; DASH diet; daily cal budget (from app)</td>
<td>weekly</td>
<td>daily</td>
<td>daily</td>
<td>(a) intensive counseling intervention</td>
<td>6 months: (b) -5.4 kg (c) -3.3 kg (d) -1.8 kg</td>
<td>a = b = c = d (pilot - no power analysis)</td>
</tr>
<tr>
<td>Hartman et al. (2016)</td>
<td>6 months</td>
<td>(a) MyFitnessPal app or website</td>
<td>(a) 12 calls; 10% WL goal WL 1-2 lbs/wk; ≥ 150min/wk MVPA; dietary goals; tailored calorie goal</td>
<td>unclear</td>
<td>daily</td>
<td>daily (w/Fitbit)</td>
<td>(b) usual care (2 15-min calls)</td>
<td>6 months: (a) -4.4 kg</td>
<td>6 mo: a &gt; b (pilot, no power analysis)</td>
</tr>
<tr>
<td>Rogers et al. (2016)</td>
<td>6 months</td>
<td>(c) BodyMedia Fit app</td>
<td>(core) tailored calorie goal, tailored fat goal (20-30%), 100min/wk Moderate intensity PA initially progressed to 200min/wk by week 9 (c) wearable device + 1 F2F + monthly 10min calls</td>
<td>daily</td>
<td>daily</td>
<td>daily</td>
<td>(a) weekly F2F groups + paper tracking of diet and PA, w/ weekly FB (b) wearable device w/ manual upload, web tracking of diet and weight + 1 F2F + monthly 10min calls</td>
<td>3 months: (c) -4.76 kg 6 months: (c) -6.25 kg</td>
<td>3mo: a = b = c 6mo: a = b = c (no power analysis)</td>
</tr>
<tr>
<td>Ross et al. (2016)</td>
<td>6 months</td>
<td>(b) Fitbit app (c) Fitbit app + 14 calls (10-15min)</td>
<td>(core) 1 F2F weight loss 101 session; tailored calorie goal (1200-1500 kcal/d); &lt;30% of cal from fat; gradually inc. moderate PA to 250min/wk and 10k steps/d</td>
<td>daily (WIFI scale)</td>
<td>daily (Fitbit Zip)</td>
<td>(a) paper logs and calorie reference book, pedometer, regular scale</td>
<td>3 months: (b) -4.6 kg (c) -5.7 kg 6 months: (b) -4.04 kg (c) -6.40 kg</td>
<td>3mo: not stated 6mo: c &gt; a; a = b; b = c (pilot)</td>
<td></td>
</tr>
<tr>
<td>Jospe et al. (2017)</td>
<td>12 months</td>
<td>(a) MyFitnessPal app</td>
<td>(core) 1 F2F group (30-45min); choose one of three possible dietary plans and one of two exercise programs (a) calorie goal</td>
<td>Daily mo1; 1 wk/mo in mo 2-12</td>
<td>(b) daily self-weighing via SMS or online, monthly FB email (c) monthly 1:1 F2F (10-15min) (d) hunger training (e) control</td>
<td>6 months: (a) -3.7 kg 12 months: (a) -2.0 kg</td>
<td>6mo: a = e 12mo: a = e; a = b</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Table 3: Weight Loss Interventions that Use *Researcher-Designed* Apps for Dietary Self-Monitoring

<table>
<thead>
<tr>
<th>Author (Year)</th>
<th>IX Length</th>
<th>App used for Self-Monitoring Diet</th>
<th>Additional Intervention Components</th>
<th>Weight Tracking</th>
<th>Diet Tracking</th>
<th>PA Tracking</th>
<th>Comparison Arm(s) Without App</th>
<th>Weight Change from Baseline in App Arm</th>
<th>Significance between Arms in Weight Loss</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carter et al. (2013)</td>
<td>6 months</td>
<td>(a) Researcher-designed app – <em>My Meal Mate</em></td>
<td>(a) WL goal of choice; calorie goal automatically generated by app; weekly FB via SMS</td>
<td>daily</td>
<td>optional</td>
<td>(b) commercial website tracking of diet</td>
<td>6 weeks: (a) -2.9 kg; 6 months: (a) -4.6 kg</td>
<td>6wks: not reported; 6mo: a &gt; c; a = b (pilot – no power analysis)</td>
<td></td>
</tr>
<tr>
<td>Svetkey et al. (2015)</td>
<td>24 months</td>
<td>(a) Researcher-designed app (b) Researcher-designed app</td>
<td>(a and b) Dash dietary plan, 1500-1800kcal/d, ≥180 min mod. PA/wk, personal goals (a) social support, tracking prompts (b) 6 weekly F2F groups then monthly calls by RDs</td>
<td>daily w/ smart scale</td>
<td>daily</td>
<td>(c) usual care</td>
<td>6 months: (a) -0.87 kg; (b) -3.07 kg; 12 months: (a) -1.48 kg; (b) -3.58 kg</td>
<td>6mo: a = c; b &gt; a; 12mo: a = c; b = c; b &gt; a</td>
<td>24mo: a = c; b = c; b = a</td>
</tr>
<tr>
<td>Fukuoka et al. (2015)</td>
<td>5 months</td>
<td>(a) Researcher-designed app</td>
<td>(a) WL goal of 10%, 6 F2F, home exercise program, 20% increase in steps/wk, up to 12k steps/d, in-app messages, video clips, and quizzes</td>
<td>≥2x/wk</td>
<td>daily</td>
<td>(b) control w/ pedometer</td>
<td>3 months: (a) -5.2 kg; 5 months: (a) -6.2 kg</td>
<td>3mo: a &gt; b; 6mo: a &gt; b (pilot, but powered)</td>
<td></td>
</tr>
<tr>
<td>Spring et al. (2017)</td>
<td>6 months</td>
<td>(a) Researcher-designed app</td>
<td>(core) 7% WL goal; 5-1kg/wk; 1200-2000 kcal/d; 32-55 g/day of fat; 45-175 min of MVPA (gradual) (a and b) 8 F2F groups (90min) + 12 calls, financial incentives (a) wireless accelerometer, social support, 2-4 tailored FB msg/wk</td>
<td>daily</td>
<td>daily</td>
<td>(b) self-guided: 12 DPP videos, 1 F2F group, paper tracking of diet and fat (c) paper tracking of diet and fat</td>
<td>3 months: (a) -4.1 kg; 6 months: (a) -4.7 kg; 12 months: (a) -3.1 kg</td>
<td>3mo: (a+b) &gt; c; a = c; 6mo: (a+b) &gt; c; a = c; 12mo: (a+b) = c; a = c</td>
<td></td>
</tr>
</tbody>
</table>

Abbreviations: BL, baseline; F2F, face-to-face counseling sessions; FB msg, feedback message; freq rec, frequency recommendation; IX, intervention; mo, month; MVPA, moderate-to-vigorous physical activity; PA, physical activity; wk, week; WL, weight loss
1.8 Rationale for the Present Study

The current study aims to investigate a novel research question: *Can we prepare individuals to self-monitor their diet by having them first achieve a mastery experience and develop self-regulatory skills during an initial daily self-weighing period?* No studies have examined whether altering the sequencing of intervention components in a digital health trial impacts weight loss outcomes. Thus, in a randomized trial design – the GoalTracker study – we compare a Sequential self-monitoring approach to a traditional Simultaneous self-monitoring approach in a behavioral weight loss intervention. By examining these approaches in the context of a lower-intensity intervention, we thought it easier to examine the effects of different self-monitoring strategies.

It is possible that self-monitoring of diet may be more helpful for adopting weight loss concordant behaviors, compared to simply self-monitoring body weight, because tracking foods and beverages consumed throughout the day allows individuals to become aware of how many calories are in each item, and prompts a reflection on how their daily caloric intake has impacted their subsequent body weight. Thus, we expected that the treatment arm that simultaneously self-monitors diet and body weight would have greater initial weight loss. However, we anticipated wider variability in self-monitoring engagement over the first month among this Simultaneous arm, due to the greater intensity and demands of this intervention. Accordingly, the Sequential self-monitoring arm was expected to have
greater mastery of self-monitoring in the first month, given the relative ease of use of daily self-weighing. We suspected that any reduction in initial weight loss would be offset by higher levels of sustained engagement, which, in turn, would promote larger weight loss over the long term, relative to the Simultaneous arm. To note, while we expected that not all participants randomized to the Sequential arm will be daily self-weighers over the initial 4-week period and, thus, the presumed benefits of the Sequential arm (i.e., developing mastery over self-weighing and enhancing self-regulatory skills) will not be exploited, we hypothesized that the majority of Sequential arm participants will adhere to daily self-weighing recommendations. This prediction is based on a lower-intensity self-weighing study that found that 94% of intervention participants self-weighed at least 5 days per week over six months, and 51% self-weighed every day.86

Our conceptual model, depicted in Figure 1, draws on constructs from self-regulation theories and Social Cognitive Theory to explain how enhanced engagement of dietary and weight self-monitoring produces greater weight loss. In line with these theories, past empirical evidence revealed that self-regulatory skills, self-efficacy, and mastery are important predictors of behavior change. Ultimately, this study allows us to examine whether developing mastery and self-regulatory skills by daily self-weighing produces high levels of self-monitoring engagement that are sustained even after dietary self-monitoring is added, and compare these
findings to a traditional intervention that includes a simultaneous approach to self-monitoring.

**Figure 1: Conceptual Model**

We also compared the novel sequential self-monitoring approach to an App-Only treatment arm that tracked diet. In order to examine the impact of the Sequential self-monitoring approach that included empirically supported behavior change components, we standardized across all arms the following components: the app used for self-monitoring (MyFitnessPal), the frequency of self-monitoring (daily), the receipt of a tailored weight loss goal and calorie goal, and the inclusion of reminders to track. We designed our App-Only arm to be consistent with a self-directed approach that is already freely available to the public on the commercial market. We devised the study so that it would be powered to detect an effect between the Sequential and App-Only arms, allowing us to determine whether this new sequential self-monitoring schedule produces significantly greater weight loss.
than an existing dietary tracking mobile app. These hypotheses are tested in paper one.

In paper two we examine the impact of consistent engagement in self-monitoring, which has never been studied in a standalone commercial app-based intervention. Finally, in paper three we investigate the impact of early weight loss success on future engagement and weight loss. Identifying individuals who do not respond early to treatment would allow for more informed decisions about whether to alter the course of treatment.

1.9 Specific Aims and Hypotheses

1.9.1 Primary Aims

Aim 1: to determine the effect of the Sequential self-monitoring arm, compared to the App-Only arm, on weight change and proportion of participants achieving clinically meaningful weight loss at 3 months

Hypothesis 1: The Sequential arm will have greater weight change and proportion of participants achieving 3% and 5% weight loss at the end of the 3-month intervention than the App-Only arm.

Aim 2: to determine the effect of the Sequential self-monitoring arm, compared to the Simultaneous self-monitoring arm, on weight change and proportion of participants achieving clinically meaningful weight loss at 3 months
**Hypothesis 2:** The Sequential arm will have greater weight change and proportion of participants achieving 3% and 5% weight loss at the end of the 3-month intervention than the Simultaneous arm.

1.9.2 Secondary Aims

**Aim 3:** to compare self-monitoring engagement by treatment arm at 1 months and 3 months

**Hypothesis 3a:** Sequential arm participants will have greater self-monitoring engagement than will Simultaneous arm participants over the initial 4 weeks and over the 3-month intervention.

**Hypothesis 3b:** Participants in the Sequential arm will have greater self-monitoring engagement than will App-Only arm participants over the initial 4 weeks and over the 3-month intervention.

**Aim 4:** to examine the relation between consistent engagement in self-monitoring and weight loss at 3 months and 6 months

**Hypothesis 4:** Consistent self-monitoring engagement will be positively related to weight loss, such that participants who consistently engage in self-monitoring will have greater weight loss at the end of the intervention (at 3 months) and beyond (at 6 months).

**Aim 5:** to investigate whether early weight loss success predicts weight loss at 3 months and 6 months, and intervention engagement
**Hypothesis 5:** Early weight loss responders will have greater weight loss at 3 months and 6 months, as well as greater intervention engagement, compared to early nonresponders.

Of note, we originally proposed to investigate theoretical mediators of 3-month weight change, including self-efficacy, mastery, and self-regulation behaviors at 4 weeks; however, these analyses were not conducted because weight change did not differ by treatment arm.
2. Study Methods

2.1 Study Design Overview

We conducted a randomized controlled trial – GoalTracker – comparing three 12-week standalone weight loss interventions: (1) an arm that simultaneously self-monitored body weight and diet and also received additional behavior change techniques, as described below (Simultaneous); (2) an arm that sequentially self-monitored body weight then added self-monitoring of diet after the first month and received the same behavior change techniques (Sequential); or (3) an arm that self-monitored only diet, and did not receive additional behavior change techniques (App-Only). Study evaluation visits were held at baseline, 1 month, and 3 months. Self-reported weight was collected at 6-months via email or text message. All study procedures were approved by the Duke University Institutional Review Board.

2.2 Participants

We recruited individuals who met the inclusion and exclusion criteria listed in Table 4. Exclusion criteria were predominantly intended to promote safety. Two criteria were amended during the trial in order to promote generalizability of findings: (1) the BMI criteria were expanded to include participants in the 40.0-45.0 kg/m² range and (2) the weight change criteria were adjusted to no longer exclude individuals who gained more than 10 lbs in the past 6 months. The IRB approved both amendments.
**Table 4: Eligibility Criteria**

<table>
<thead>
<tr>
<th>Inclusion criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>21-65 years old</td>
</tr>
<tr>
<td>BMI 25.0-45.0 kg/m² *</td>
</tr>
<tr>
<td>Interested in losing weight through dietary changes</td>
</tr>
<tr>
<td>Current use of an iPhone or Android smartphone and has an email address</td>
</tr>
<tr>
<td>If iPhone, updated iOS software (version 9.0 or later)</td>
</tr>
<tr>
<td>Willing to download the mobile app on their phone and self-monitor behaviors using the app for 3 months</td>
</tr>
<tr>
<td>Willing to not track diet or body weight using any other modality (e.g., other health or weight tracking mobile apps, websites, paper diaries) for the duration of the intervention</td>
</tr>
<tr>
<td>Willing to receive study-related messages via text message and email</td>
</tr>
<tr>
<td>Has regular access to a bathroom scale</td>
</tr>
<tr>
<td>Able to attend all study evaluation visits over the course of a 3-month period</td>
</tr>
<tr>
<td>Able to read and write in English</td>
</tr>
<tr>
<td>Willing to provide consent for the research team to monitor phone utilization</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Exclusion criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Currently pregnant, &lt;12 months postpartum, or planning to become pregnant within the study period</td>
</tr>
<tr>
<td>One of the following self-reported medical conditions that necessitates additional attention in a lifestyle modification intervention: history of a cardiovascular event (e.g., heart attack, stroke, heart failure), congestive heart failure, an eating disorder, diabetes mellitus, hypothyroidism; current uncontrolled hypertension</td>
</tr>
<tr>
<td><strong>History of a contraindicated condition (e.g., cancer, end stage renal disease) or medication (e.g., lithium, steroids, antipsychotics)</strong></td>
</tr>
<tr>
<td>---</td>
</tr>
<tr>
<td><strong>Has been hospitalized in a psychiatric facility in the past 5 years</strong></td>
</tr>
<tr>
<td><strong>Has profound cognitive, developmental, or psychiatric disorders</strong></td>
</tr>
<tr>
<td><strong>Current participation in another weight loss treatment</strong></td>
</tr>
<tr>
<td><strong>Use of the MyFitnessPal mobile app to track food intake in the past 6 months</strong></td>
</tr>
<tr>
<td><strong>Former or planned bariatric surgery (e.g., gastric bypass, lap band)</strong></td>
</tr>
<tr>
<td><strong>Current use of a weight loss medication or recent use in the past 6 months</strong></td>
</tr>
<tr>
<td><strong>Weight loss over the past 6 months (≥10 lbs)</strong> **</td>
</tr>
</tbody>
</table>

*The BMI criteria was originally 25.0-39.9. The new, expanded BMI range was approved by the IRB on 7/31/17.

**The weight change criteria originally excluded individuals who gained ≥ 10 lbs in the past 6 months. The more lenient weight change criteria were approved by the IRB on 5/30/17.

### 2.3 Study Procedures

#### 2.3.1 Recruitment

Participants were recruited between April-September 2017 via (1) a university affiliated community research recruitment website (i.e., Duke Behavioral Research SONA), (2) messages sent to Duke University listservs and digital flyers, (3) social media postings (e.g., posts on Twitter and Facebook), (4) paper flyers posted around the community, (5) ClinicalTrials.gov registry, (6) Craigslist, and (7) Nextdoor (a private social networking service, connecting individuals in surrounding neighborhoods). Advertisements provided a brief description of the study and eligibility criteria. Individuals interested in the study were directed to the
study website (www.goaltrackerstudy.com), which included additional information about the study and an online screening questionnaire (via Qualtrics).

### 2.3.2 Online Screening

The study website contained a screening questionnaire to assess initial eligibility based on current participation in a weight loss intervention, age, comfort reading and writing in English, height, weight, recent weight change, current smartphone ownership, recent app use, access to a bathroom scale, unstable medical conditions, current health status, bariatric surgery status, current medications, recent psychiatric hospitalization, availability over the next 3 months, willingness to receive study-related text messages and email, and recent pregnancy status, if applicable. If interested and eligible based on the initial screening, individuals were prompted to provide contact information and indicate their preferred time of being contacted (i.e., 8am-noon, noon-4pm, 4-8pm). Individuals recruited through the Duke Behavioral Research SONA website were able to sign up online for a baseline visit appointment if deemed initially eligible based on the online screen, obviating the need for a follow-up telephone call from study personnel.

### 2.3.3 Telephone Screening

Study personnel contacted eligible candidates within 3 business days of completing the online screening questionnaire. The telephone screen included an
overview of study details, confirmation of candidates’ interest in participating, and scheduling of an in-person baseline evaluation visit held at Duke University.

2.3.4 Baseline Screening and Randomization

During the baseline visit, study staff reviewed details of the study, confirmed age, answered participants’ questions, obtained written informed consent, and gathered height and weight to confirm BMI eligibility. After the completion of anthropometric measurements, study personnel assisted participants in installing the MyFitnessPal mobile app onto their smartphone (if not already installed) and participants completed an online survey. In order to collect self-monitoring data through our software engine (Prompt), study staff created both a MyFitnessPal account and a Fitbit account, and linked the two accounts so that we can view MyFitnessPal data using the Fitbit API. If a participant already had an account on either platform, he or she was asked to use a new account or change their login credentials and give our team access to the existing account. Then, participants briefly reviewed information with study personnel on how to access the MyFitnessPal app on their smartphone.

Participants were then randomized to one of three treatment arms using Excel’s random number generator, which allocated participants equally (1:1:1) across conditions. The allocation sequence was concealed to study staff. Randomization was revealed to participants by study personnel; as such, study staff were not blinded to treatment allocation. Participants were enrolled into the study
on a rolling basis until the target sample size was met. Lastly, participants reviewed written materials describing their treatment condition. Study staff then checked participants’ understanding of their treatment arms to reduce contamination and ensure that the treatment was delivered as intended. Items included types of goals prescribed, recommended frequency of tracking, length of the intervention, and date of follow-up visit.

2.3.5 Data Collection

Study evaluation visits were conducted in-person at baseline, 1 month, and 3 months post-randomization at Duke University in Durham, NC. The baseline visit lasted approximately 60 minutes, while the follow-up visits lasted 20-30 minutes. Trained study personnel performed assessments and adhered to a standardized protocol, completing all procedures in the same order. At 1-month, participants were provided with written materials detailing their goals for the second part of their treatment condition. As described below, only the Sequential arm received different goals.

At all evaluation visits, study personnel assess anthropometrics before administering the online questionnaire. Questionnaires were administered in English via a desktop computer using a secure, web-based survey system (i.e., Duke Qualtrics survey software). At 6 months post-baseline, study staff contacted participants via email and text message to collect self-reported body weight measure. Data collection ended March 2018.
2.3.6 Retention

We aimed to maximize study retention by reimbursing participants for their time and travel to study evaluation visits at baseline, 1 month, and 3 months. Participants were compensated with $12 Amazon electronic gift card at the baseline visit and a $6 Amazon electronic gift card for each follow-up evaluation visit. Eligible participants received an additional $5 Amazon electronic gift card for completing all 4 online dietary assessments. We asked permission to collect multiple phone numbers (e.g., cell phone, home phone, office phone), e-mail addresses, and family/friend contact information. We also provided reminder phone calls and text messages prior to study evaluation visits.

2.4 Intervention Design

Details about the intervention components are outlined below. See Appendix A for goal sheets provided to participants at the baseline visit and Appendix B for handouts on study information.

2.4.1 Similar Components Across the Three Treatment Arms

All three treatment arms used the same mobile app, received the same outcome-related goals, and were instructed to monitor their food intake (timing varied based on treatment arm).

2.4.1.1 Mobile App

All three groups were instructed to use the MyFitnessPal mobile app. MyFitnessPal is a free commercial app and web platform acquired by Under Armour.
in 2015. It has over 100 million worldwide users to date and is available to install on Android and iOS mobile devices from the Android Google Play store and the Apple iTunes App Store, respectively. This app continues to grow in popularity; among its monthly visitors, 25% of individuals access the app daily (over 1.5 million U.S. adults).

In a recent review of commercial mobile apps for weight loss, Bardus et al. found that MyFitnessPal included 11 of 34 behavior change techniques; this compares to a mean of 9.3+/-.4.0 techniques across all apps (range: 1 to 17). Among the 23 mobile apps evaluated in this review, MyFitnessPal received the highest customer ratings in both the iTunes App Store and the Google Play store.

During the account setup process, the app instructs users to input their current weight, identify a target end weight, and identify their preferred rate of weight loss. During the baseline visit, study staff calculated the participant’s target end weight and corresponding rate of weight loss. Then, they entered these values into the app during the account setup process. See additional details below.

### 2.4.1.2 Weight Loss Goal

During the baseline visit, study staff provided all three treatment arms with a goal to lose 5% of initial body weight by 3 months. Study staff presented participants with the following information: (a) their current weight (assessed earlier in the baseline visit), (b) their target weight at 3 months (calculated to achieve reduction of 5%), (c) how much weight they should aim to lose, and (d) the
corresponding target weekly rate of weight change (e.g., 1 lb of weight loss per week). Information was presented in pounds unless otherwise requested.

For instance, an individual with a starting weight of 200 lbs (a) would aim to lose 10 lbs (c) in order to reach the 5% weight loss goal of 190 pounds (b) by 3 months. To calculate the target rate of weekly weight loss, we multiplied the starting weight by 0.05, then divided the resulting value by the number of weeks in the intervention (i.e., 12). The app allows rates of 0.5 lbs/week, 1.0 lb/week, 1.5 lbs/week, and 2.0 lbs/week; thus, we rounded up to the nearest value. For example, an individual with a starting weight of 200 lbs would be given a weight loss goal of 1 lb per week ([200x0.05]/12=0.83 lbs/week, which rounds up to 1 lbs/week), over 12 weeks.

2.4.1.3 Calorie Goal

Upon account setup, the MyFitnessPal app creates a tailored daily calorie goal based on an individual’s height, current weight, gender, age, and normal activity level (i.e., sedentary, lightly active, active, very active), as well as their preferred rate of weight loss (i.e., lose 0.5 lbs per week, lose 1 lb per week, lose 1.5 lbs per week, lose 2 lbs per week). In doing so, MyFitnessPal is able to account for an individual’s basal metabolic rate, using the Mifflin-St. Jeor equation. MyFitnessPal sets a minimum caloric goal of 1200 kcal/day for women and 1500 kcal/day for men, based on recommendations by NIH. Activity levels were set at sedentary unless requested otherwise based on current exercise level, so as to reduce risk of
over-adjustment of their daily calorie goal. MyFitnessPal has demonstrated good validity for estimating caloric intake.\textsuperscript{130}

2.4.1.4 Self-Monitoring of Dietary Intake

Participants in all treatment arms were asked to track their food and beverage intake daily using the app. The app allows users to log foods according to the meal eaten (i.e., breakfast, lunch, dinner, or snack). Users can also rename their meals and add two meal categories via the companion website. Users can search for foods using the extensive in-app database with over 5 million foods (MyFitnessPal.com). Once a food item is selected, users are prompted to indicate the serving size and number of servings eaten. Users can also use the in-app barcode scanner to take a photo of a product with a barcode, which will automatically generate the food item and its nutrition information. Users can create their own foods and input or adjust nutrition information. The app remembers past food entries, and allows users to quickly select from recently tracked or frequently tracked items or meals.

2.4.1.5 In-App Dietary Feedback

Feedback denotes providing individuals with information about their behavioral performance.\textsuperscript{70} Feedback, like self-monitoring, is part of the self-regulatory process.\textsuperscript{69}

The MyFitnessPal app provides real-time feedback on one’s caloric and nutritional intake in both graphical and text formats. Once self-monitored data are
recorded in the app, the app automatically computes new totals and adjusts prior information. The app presents calorie data in several formats. Taking into account an individual's daily caloric goal, the app provides information about the number of calories consumed and the surplus or deficit for that day. The current day is set as the default page, but users can swipe to view data from previous days. The app also allows users to view a pie chart with a given day's breakdown of caloric intake by meal type, as well as a bar graph of weekly data on calories consumed by meal type. The current day is set as the default page, but users can swipe to view data from previous days. The app also allows users to view a pie chart with a given day's breakdown of caloric intake by meal type, as well as a bar graph of weekly data on calories consumed by meal type. The user can change the date to view data over any one-week period. Below this bar graph is text-based information on the daily average of calories consumed over any one-week period.

In addition, the app provides feedback on both macronutrients and micronutrients. Information about macronutrients (i.e., carbohydrates, fat, and protein) are presented in a similar format to that of caloric information: a pie chart displaying the proportion of any given day’s macronutrient intake (e.g., 50% carbohydrates, 30% fat, and 20% protein), a bar graph comparing the daily macronutrient proportions for any given week, and textual information about the average weekly proportion of each macronutrient. Lastly, the app presents textual information about the amount of micronutrients consumed (e.g., sugar, fiber, fat, sodium, calcium) for a given day or for any one-week period. The deficit or surplus amount is also presented.
2.4.1.6 Reminders to Self-Monitor in the App

Participants received in-app reminders to self-monitor. The app allows users to create customized reminders that can vary by item tracked (e.g., weight, breakfast, lunch, any item for 1 day, any item for 7 days), frequency of delivery (i.e., daily, weekly, or monthly), and time of day. During setup of a participant’s account, in-app push-reminders were programmed to be sent each day if tracking has not occurred by a pre-specified time of day. Specifically, reminders to self-monitor body weight were sent if body weight was not recorded in the app by 7:00 PM each day. Reminders to self-monitor food intake were sent if food entries were not recorded in the app by 9:00 PM each day (for Sequential participants, this feature was set up at the 1-month visit).

2.4.2 App-Only Arm

App-Only participants were instructed to self-monitor their food intake daily on the mobile app for the duration of the intervention. They did not receive a recommendation to weigh themselves, and did not receive any lessons or additional feedback. For our App-Only arm, we wanted to provide an ‘off-the-shelf’, self-guided approach that the general U.S. population can already access for free in the commercial marketplace. The MyFitnessPal app meets these criteria. Although we did not disallow use of other MyFitnessPal features such as fitness or weight tracking by App-Only participants, diet tracking is the main feature of MyFitnessPal.
2.4.3 Sequential Self-Monitoring Arm

Sequential group participants were asked to self-monitor body weight for 4 weeks. They were encouraged not to track dietary intake using any medium during this period. Accordingly, their weekly feedback pertained only to self-weighing engagement and weight loss outcomes. Beginning in week 5 of the intervention, Sequential participants were asked to begin self-monitoring diet, in addition to continuing to track body weight. Feedback then began including reports about one's engagement with self-monitoring of diet and one's progress with meeting daily calorie goals.

2.4.4 Both Simultaneous and Sequential Arms

Individuals in the Simultaneous and Sequential groups received the same intervention components, but the sequence in which self-monitoring occurred varied. The intervention components are described below.

2.4.4.1 Daily Self-Weighing

Intervention participants were asked to self-weigh daily and to record their body weight in the app each day. It was recommended that individuals weigh themselves at the same time each day, ideally in the morning upon waking, to enhance habit-forming of self-weighing.

2.4.4.2 Tailored Feedback

When individuals monitor their behavior, they can evaluate their progress using either personal cues or environmental sources. According to Social Cognitive
Theory, feedback can lead to goal attainment by increasing motivation and self-efficacy for making behavior change. In a 2016 review of internet-based weight loss interventions, treatments that delivered personalized feedback produced 2.05 kg greater weight loss than internet interventions receiving no personalized feedback.

**In-app weight feedback.** The MyFitnessPal app provides real-time feedback on one’s body weight. Once weight is recorded in the app, the app automatically adjusts prior information. Specifically, the app displays a line graph of one’s weight loss progress, and allows the user to adjust the corresponding time period (e.g., a period of 1 week, 1 month, or since the starting weight was entered). Based on the time period selected, the app presents a comparison of the beginning weight, the current weight, and the change in weight over that period (in pounds and percent change). The app also provides a list of all weight entries recorded in MyFitnessPal.

**Email summary feedback.** Each week (on Mondays), study staff sent intervention participants an email with tailored feedback regarding their progress on each goal in the past week (see Appendix C for example report). Feedback was presented in both text and pictorial formats. It was automatically generated using Word’s Mail Merge feature. The purpose of the weekly feedback email was to provide additional progress data that were not presented in the app, as well as to reiterate feedback that appears in the app in order to call attention to key data points. See Table 5, below, for the criteria used for each goal in order to determine if
a goal was met, somewhat met, or not met. A total count of goals met in the past week (possible range: 0-4) was provided, and motivational messages were used based on that count. Then, based on a participant's weight loss progress in the past week, motivational messages were provided to reinforce positive behaviors or to highlight behaviors that could be improved upon in the following week. The following is an example: “It looks like you lost weight last week! What went well? It is likely that your weight loss was due to the following: -tracking your weight frequently, controlling your calories.” Of note, Sequential arm participants did not receive any feedback related to diet tracking or the calorie goal until week 5 of the intervention when they began tracking foods.

Table 5: Criteria for Each Goal

<table>
<thead>
<tr>
<th>Goal</th>
<th>Met</th>
<th>Somewhat Met</th>
<th>Not Met</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tracking body weight</td>
<td>If tracked 6-7 days in past week</td>
<td>If tracked 2-5 days in past week</td>
<td>If tracked 0-1 days in past week</td>
</tr>
<tr>
<td>Tracking food &amp; drinks</td>
<td>If tracked 6-7 days in past week</td>
<td>If tracked 2-5 days in past week</td>
<td>If tracked 0-1 days in past week</td>
</tr>
<tr>
<td>Weight loss progress</td>
<td>If met or exceeded weekly weight loss goal</td>
<td>If maintained weight or lost weight but did not meet weekly weight loss goal</td>
<td>If gained weight in past week, or did not track weight at least once</td>
</tr>
<tr>
<td>Calorie goal progress</td>
<td>If average daily calories consumed was &lt;150 kcal above daily calorie goal</td>
<td>If average daily calories consumed was ≥150 and &lt;300 kcal above daily calorie goal</td>
<td>If average daily calories consumed was ≥300 kcal above daily calorie goal, or did not track diet at least once</td>
</tr>
</tbody>
</table>
Self-monitoring engagement. Feedback covered several topics, including an individual’s self-monitoring engagement. This type of feedback included the number of days weight and food intake were tracked in MyFitnessPal in the past week and whether these goals were met, somewhat met, or not met.

Weight outcomes. Data were provided on an individual’s amount of weight change (in lbs) in the past week, and whether their weekly weight loss goal was met. This value was computed by calculating the average weight in the past week and in the prior week and taking the difference. Information about one’s overall weight change during the entire intervention period was also presented, along with progress toward reaching the overall weight loss goal (e.g., “Your goal weight is 210 lbs by September 1, 2017. You are 2.5 pounds away from your goal”). Weight outcomes feedback was provided as long as one weight was recorded in the past week. Individuals who did track their weight in the past week received a message stating “Make sure to enter your weight in MyFitnessPal so that we can give you helpful insights!”

Calorie outcomes. Data were provided on an individual’s average caloric intake during the past week (e.g., 1850 calories on average), and whether their average daily calorie goal was met. Feedback included only days with at least 800 kilocalories recorded, as used in a previous study.\textsuperscript{119}
2.4.4.3 Skills Training

Behavioral skills training is an important component of lifestyle interventions. More frequent lesson completion has been associated with greater weight loss. Developing new skills promotes positive behavior change in part due to its impact on self-efficacy. Structured weekly lessons have been used in effective weight loss interventions. Gaining knowledge is considered a prerequisite for the establishment of other behavioral principles. Indeed, an intervention that included self-monitoring of body weight without a skills training component, produced no significant weight loss, in spite of the strong line of literature demonstrating the efficacy of self-monitoring approaches. Weekly lessons can be paired with action plans to aid in self-evaluation and promote adherence to behavioral principles.

Intervention participants were sent weekly skills training materials via email (on Thursdays). Each skills training email included the following: (1) a tip about using different features of the app, (2) a lesson pertaining to a nutrition topic or a behavioral modification strategy, and (3) an action plan prompting individuals to identify ways to apply this lesson to their life. Immediately after their baseline visit, intervention participants were emailed an initial tip, which focused on how to use the MyFitnessPal app to track weight and/or food, and how to view progress in the app. See Table 6 for lesson topics and Table 7 for app usage tips.
The Sequential arm received the same lessons and action plans in the same order as the Simultaneous arm, with only slight variation in language on two lessons and on the initial action plan based on differences in what was being self-monitored. They also received the same app usage tips as the Simultaneous arm, but in a different order, such that tips pertaining to food tracking features began at week 5 of the intervention for the former group. No structured dietary advice (e.g., follow a low carbohydrate diet) was given to participants; instead, participants were encouraged to choose their own dietary strategy.

**App usage tips.** Users were provided with tips on how to use different features of the app. Examples include learning how to log restaurant food items and how to use the barcode scanner. The tips were predominantly visual in nature, such that participants could view screenshots of the app, which were accompanied with brief text that described the actions needed to utilize this feature. See Appendix D for an example tip.
Table 6: Topics of Structured Lessons

<table>
<thead>
<tr>
<th>Week</th>
<th>Lesson Topic</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Overview of the program (losing 5% weight, self-monitoring); calorie balance*</td>
</tr>
<tr>
<td>2</td>
<td>Red zone foods; green zone foods</td>
</tr>
<tr>
<td>3</td>
<td>Reading food labels*</td>
</tr>
<tr>
<td>4</td>
<td>Reducing sugar</td>
</tr>
<tr>
<td>5</td>
<td>Portion control</td>
</tr>
<tr>
<td>6</td>
<td>Preparing meals at home; shopping tips</td>
</tr>
<tr>
<td>7</td>
<td>Eating out</td>
</tr>
<tr>
<td>8</td>
<td>Social support</td>
</tr>
<tr>
<td>9</td>
<td>Environmental cues; vacations and holidays</td>
</tr>
<tr>
<td>10</td>
<td>Emotional eating</td>
</tr>
<tr>
<td>11</td>
<td>Slippery slope; weight loss maintenance; relapse prevention</td>
</tr>
</tbody>
</table>

*These lessons differ slightly between the Simultaneous and Sequential arms, such that there was no discussion of a calorie goal for the latter arm.
Table 7: Tips for Using the MyFitnessPal App

<table>
<thead>
<tr>
<th>Week</th>
<th>Tips for Simultaneous Arm</th>
<th>Tips for Sequential Arm</th>
</tr>
</thead>
</table>
| Sent after baseline visit | A: how to track body weight  
B: how to view weight progress  
C: how to track a food item  
D: how to view your calorie goal and the foods you've tracked | A: how to track body weight  
B: how to view weight progress |
| 1 | how to use the barcode scanner | how to delete a weight entry |
| 2 | how to use multi-add to speed up food tracking | how to add progress photos |
| 3 | how to view nutrition progress | how to change reminders to track (weight) |
| 4 | A: how to delete a weight entry  
B: how to add progress photos | how to recruit a friend to use MyFitnessPal |
| Sent after 1MV | -- | A: how to track a food item  
B: how to view your calorie goal and the foods you've tracked |
| 5 | how to track food from a restaurant | how to use the barcode scanner |
| 6 | A: how to create a meal  
B: how to log a meal | how to use multi-add to speed up food tracking |
| 7 | A: how to add a recipe  
B: how to log a recipe | how to view nutrition progress |
| 8 | how to use the 'Complete Diary' feature | how to track food from a restaurant |
| 9 | how to change reminders to track (weight and food) | A: how to create a meal  
B: how to log a meal |
| 10 | how to customize meal names | A: how to add a recipe  
B: how to log a recipe |
| 11 | how to recruit a friend to use MyFitnessPal | A: how to use the 'Complete Diary' feature  
B: how to customize meal names |
Nutrition knowledge and behavioral modification lessons. Lessons were adapted from the gold standard curriculums of the Diabetes Prevention Program,\textsuperscript{134,135} the Look AHEAD trial,\textsuperscript{16} and two behavioral technology-based weight loss interventions (Track and WEIGH) conducted by several members of the Duke Digital Health Science Center.\textsuperscript{79,136} Some lesson content focused on a nutrition topic, such as reducing sugar, avoiding unhealthy “Red Zone” foods (e.g., sugary drinks), or increasing “Green Zone” foods (e.g., protein-rich foods, healthy grains, low-calorie seasonings). Other lesson content pertained to strategies for increasing healthy behaviors and decreasing unhealthy behaviors. Examples include reading food labels, reducing emotional eating, adjusting the eating environment, and planning for meals. See Appendix E for an example lesson.

Action plans. Action planning involves outlining the steps needed to achieve a goal. This process incorporates establishing the \textit{when}, \textit{where}, and \textit{what} of each action. The \textit{when} step includes detailing the frequency (e.g., daily) or duration (for 3 months) of an action, while the \textit{what} step details the content of the behavior to be performed. Similarly, problem solving is a technique that refers to identifying barriers to change and ways to overcome these barriers. Action planning and problem solving strategies are frequently incorporated into behavioral weight loss interventions to foster behavior change.\textsuperscript{23} Findings demonstrate that prompting individuals to create an action plan helped achieve greater weight loss\textsuperscript{137}; having
multiple iterations of action plans (e.g., weekly rather than once at the beginning of an intervention) further promotes success.\textsuperscript{138}

Participants were asked to complete a brief action plan (via Qualtrics) each week identifying strategies to help apply the weekly lesson. Elements of motivational interviewing and problem solving were included given the utility of these empirically-supported techniques in obesity treatment.\textsuperscript{139,140} This survey included the following types of components: identification of current behaviors or beliefs, the creation of action plans that prompt individuals to think about the \textit{when}, \textit{where}, and \textit{what} of each action, an assessment of potential barriers that may arise and potential solution to address each barrier.

Action plans often included a review of past goals and questions pertaining to why a goal was met or not met. Survey items included a mix of free-response items, checklists, Likert scales, brief quizzes to assess understanding and accompanying explanations of answers. For instance, in the weekly action plan pertaining to reducing added sugar, participants were provided with two quizzes assessing knowledge of how much sugar is added to two common food items, then, were shown lists of common sugary foods and drinks and were asked to select items they consume at least once a week. Then in free-response format, they were prompted to record potential barriers to reducing these sugary items (e.g., eating at social engagements, time limitations, food availability) and brainstorm ways to address these challenges. Lastly, participants were prompted to identify an individual with
whom they could share their weekly action plan. Participants were encouraged to complete the action plans in the structured order in which they were presented, but they were allowed to return to former ones at any time. See Appendix F for an example action plan.

2.4.4.4 Reminders about Intervention Goals

In every feedback email, intervention participants were provided with their list of goals for the upcoming week, including the goal to track their weight every day in the app, their weekly weight loss goal, and their overall weight loss goal (equating to losing 5% of initial weight). They were also reminded to review their weekly lesson and complete their weekly action plan. The daily calorie goal and the goal to track food intake via the app every day were included in this list for the duration of the intervention for the Simultaneous participants; in comparison, Sequential participants were shown these goals starting at week 5. The purpose of this component was to ensure that all participants understand the components of their treatment arm, in hopes of minimizing contamination.

2.5 Measures

2.5.1 Anthropometric Data

Participants were asked to wear light clothing (e.g., remove sweaters, hats) and to remove shoes prior to measurement of anthropometrics. Body weight was measured using a calibrated electronic scale (SECA 876). Height was measured to the nearest 0.1 cm using a calibrated, wall-mounted stadiometer (SECA 222). BMI
was calculated as the body weight in kilograms divided by the height squared in meters (kg/m²). Baseline height was used for calculation of BMI at subsequent evaluation time points. Self-reported body weight was collected at 6-months. For better verification, participants were asked to send a photo with their feet on the scale displaying the value in either kg or lbs; if not possible, participants could simply send the value.

2.5.2 Survey Measures

Surveys assessed information related to sociodemographic and clinical characteristics in order to describe the sample; they also assessed relevant constructs that may act as mediators of the treatment effect on weight change. See Table 8 for the assessment schedule.

Sociodemographic characteristics. We collected information regarding participants’ demographics, socioeconomic status, marital status, and employment status.

Dietary intake. The National Cancer Institute’s Automated Self-Administered 24-Hour Recall (ASA24) web-based system was used to assess caloric intake. We collected two separate 24-hour dietary recalls (one unannounced weekday and one unannounced weekend day) at baseline and 3 months. Participants were sent a link and unique login credentials to complete the ASA24 online.
<table>
<thead>
<tr>
<th>Data Collected</th>
<th>Collection Time Point</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>BL</td>
</tr>
<tr>
<td></td>
<td>1 Month</td>
</tr>
<tr>
<td></td>
<td>3 Months</td>
</tr>
</tbody>
</table>

**Physical Measurements**

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Height</td>
<td>X</td>
</tr>
<tr>
<td>Weight</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>X</td>
</tr>
</tbody>
</table>

**Self-Report Measures**

<table>
<thead>
<tr>
<th>Construct</th>
<th>Questionnaire Name or Type of Questions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sociodemographics</td>
<td>13 items assessing age, gender, race/ethnicity, marital status, number of people living in household, highest level of education, employment status, annual household income, health insurance status and type</td>
</tr>
<tr>
<td>Prediabetes history</td>
<td>1 item</td>
</tr>
<tr>
<td>Hypertension history and prescription medication</td>
<td>4 items</td>
</tr>
<tr>
<td>Technology use</td>
<td>PEW Research Center &amp; researcher-created</td>
</tr>
<tr>
<td>Self-weighing history</td>
<td>1 item adapted from Linde et al. 2006</td>
</tr>
<tr>
<td>Calorie tracking history</td>
<td>1 item adapted from Linde et al. 2006</td>
</tr>
<tr>
<td>Health literacy</td>
<td>Newest Vital Sign</td>
</tr>
</tbody>
</table>

X: Included at BL, 1 Month, 3 Months
<table>
<thead>
<tr>
<th>Category</th>
<th>Measure</th>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dietary intake</td>
<td>Automated 24-Hour (ASA24) Dietary Assessment Tool(^{143})</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>Paffenbarger Activity Questionnaire</td>
<td>7 items(^{144})</td>
</tr>
<tr>
<td>Physical activity</td>
<td>Paffenbarger Activity Questionnaire</td>
<td>7 items(^{144})</td>
</tr>
<tr>
<td>Mastery for diet tracking(^*)</td>
<td>Automaticity subscale of The Self-Report Habit Index (SRHI)</td>
<td>4 items(^{145})</td>
</tr>
<tr>
<td>Mastery for weight tracking(^**)</td>
<td>Automaticity subscale of The Self-Report Habit Index (SRHI)</td>
<td>4 items(^{145})</td>
</tr>
<tr>
<td>Self-efficacy for eating</td>
<td>Weight Efficacy Lifestyle Questionnaire (WEL)</td>
<td>20 items(^{21})</td>
</tr>
<tr>
<td>Self-efficacy for diet tracking</td>
<td>Adapted from Bandura self-efficacy measure</td>
<td>14 items(^{146})</td>
</tr>
<tr>
<td>Self-efficacy for weight tracking(^**)</td>
<td>Adapted from Bandura self-efficacy measure</td>
<td>14 items(^{146})</td>
</tr>
<tr>
<td>Self-regulation for controlling eating</td>
<td>Three Factor Eating Questionnaire-R18 (TFEQ-R18)</td>
<td>18 items(^{147,148})</td>
</tr>
<tr>
<td>Self-regulation for weight tracking(^**)</td>
<td>Adapted from Self-Control Short Scale</td>
<td>10 items(^{149})</td>
</tr>
<tr>
<td>Self-regulation for diet tracking(^*)</td>
<td>Adapted from Self-Control Short Scale</td>
<td>10 items(^{149})</td>
</tr>
<tr>
<td>Mood</td>
<td>Patient Health Questionnaire (PHQ-8)</td>
<td>8 items and 1 follow-up item(^{150})</td>
</tr>
<tr>
<td>Perceived stress</td>
<td>Perceived Stress Scale</td>
<td>10 items(^{151})</td>
</tr>
<tr>
<td>Sleep quality</td>
<td>Medical Outcomes Study (MOS) Sleep</td>
<td>12 items(^{152})</td>
</tr>
<tr>
<td>Negative life events</td>
<td>Adapted</td>
<td>16 items</td>
</tr>
<tr>
<td>Test</td>
<td>Description</td>
<td>Abbreviation: BL, baseline.</td>
</tr>
<tr>
<td>------</td>
<td>-------------</td>
<td>-----------------------------</td>
</tr>
<tr>
<td><strong>Personality</strong></td>
<td>Ten-Item Personality Inventory (TIPI)</td>
<td></td>
</tr>
<tr>
<td><strong>MyFitnessPal usage</strong>*</td>
<td>Items assessing how MyFitnessPal was used (app or website); whether wearables were synced with the app; what was liked or not liked about the app; whether participants upgraded to Premium version or are interested in Premium version</td>
<td></td>
</tr>
<tr>
<td><strong>Type of body scale</strong>*</td>
<td>Created</td>
<td></td>
</tr>
<tr>
<td><strong>Frequency of reading progress report email</strong>*</td>
<td>Created</td>
<td></td>
</tr>
<tr>
<td><strong>Frequency of reading lessons and which ones read and most helpful</strong>*</td>
<td>Created</td>
<td></td>
</tr>
<tr>
<td><strong>Frequency of completing action plan</strong>*</td>
<td>Created</td>
<td></td>
</tr>
<tr>
<td><strong>Frequency of reviewing tip and which ones read and most helpful</strong>*</td>
<td>Created</td>
<td></td>
</tr>
</tbody>
</table>

*Not administered to Sequential arm at 1 month.

**Not administered to App-Only arm at 1- or 3-months.

***Not administered to the App-Only arm.
2.5.3 Intervention Engagement Data

We used a software engine developed at Duke (“Prompt”) to collect participants’ MyFitnessPal self-monitoring data. Specifically, after study staff linked participants’ MyFitnessPal and Fitbit accounts, Prompt was able to retrieve this data using Fitbit’s application programming interface (API). Each week, Prompt collated and stored participants’ objective daily self-monitoring weight and calorie data. Data from all three treatment arms was extracted. Primary outcomes for self-monitoring engagement cover the duration of the intervention period, that is, from day 1 to day 83. Day 1 corresponds with the day after the participant’s baseline visit. We categorized engagement in several time intervals: the first 4 weeks in the intervention (day 1 to 28), the final two months of the intervention (day 29-83), and the entire 83-day intervention period.

For exploratory purposes, we also examined engagement data after the intervention ended up to 6 months (i.e., day 84 to day 183). Food records were considered complete if at least 800 kilocalories are recorded for a given day, a threshold used in a previous intervention with dietary self-monitoring.\footnote{119}

To examine overall self-monitoring engagement, we examined the percentage of days that entries were recorded (i.e., number of days with entries recorded divided by number of days asked to record an entry, multiplied by 100). We expected that the Simultaneous arm track both diet and body weight every day for the entire 12-week intervention (i.e., 83 days), and that the App-Only arm track
diet during this period (i.e., 83 days). For individuals assigned to the Sequential arm, we expected that they track body weight every day for the entire 12-week intervention (i.e., 83 days) and that they track food intake every day after week 4 of the intervention (i.e., for 55 days). We also examined the average number of days per week that participants self-monitored weight, and the average number of days per week that participants self-monitored diet (with a complete entry). We also explored contamination between arms by assessing whether participants self-monitored when they were not expected to do so: i.e., whether participants in the Sequential arm self-monitored food intake during the initial part of the intervention and whether participants in the App-Only arm self-monitored weight at any point during the intervention.

*Action plan completion.* Through an examination of objective data in Qualtrics, we measured the percentage of action plans completed.

### 2.6 Sample Size Determination

Sample size was calculated based on power to detect a 3.5 kg difference in weight change at 3 months (the primary outcome) between the App-Only arm and the Sequential intervention arm.\(^{34,79}\) Our power analysis determined that 93 participants were needed to achieve 80% power for a two-sided test with an alpha level of 0.05. To account for attrition of 10% and to obtain equal-size groups, we aimed to recruit 105 participants (35 per group). Power analyses were conducted in G*Power 3.1.9.2.\(^{154}\)
3. Comparing Self-Monitoring Strategies for Weight Loss in a Randomized Controlled Trial

3.1 Introduction

Self-monitoring of dietary intake is a cornerstone of behavioral weight loss treatment, and past research has demonstrated that frequency of self-monitoring is positively associated with weight loss. Despite its utility, self-monitoring of diet typically declines over the course of treatment. Novel strategies are needed to improve dietary self-monitoring engagement. One strategy involves enriching self-monitoring with other theoretically and empirically supported behavior change techniques, such as tailored goals and feedback, action plans, and skills training. Past studies have shown the utility of these features in enhancing weight loss outcomes.

A second strategy includes building mastery, self-efficacy, and self-regulation – key constructs of behavior change in Carver’s Control Theory and Bandura’s Social Cognitive Theory – before engaging in dietary self-monitoring. Fostering self-regulatory skills may provide an opportunity for mastery and, in turn, strengthen self-efficacy, which has been linked to greater weight reduction. We propose a novel solution that aims to attenuate the decline in engagement by employing a sequential self-monitoring approach, wherein individuals track only body weight for a period of time and then begin to track diet. Tracking body weight was chosen as it requires minimal effort, provides an opportunity for habit
formation (e.g., track every morning upon waking), and is efficacious for weight loss.\textsuperscript{79,164} We focused on only self-monitoring of body weight during the first month, based on prior research demonstrating that enhanced engagement in the first month of treatment may have long-lasting repercussions.\textsuperscript{43}

We tested this sequential strategy using a remotely-delivered intervention that utilizes a popular commercially available mobile app – MyFitnessPal. Given the pervasiveness of obesity among U.S. adults (40\%),\textsuperscript{9} strategies are needed that have high dissemination potential. Utilizing technology for self-monitoring dietary intake has been shown to produce greater adherence and less-pronounced declines in engagement than traditional paper-based tracking methods.\textsuperscript{110,111} This increased engagement is likely due to greater automation resulting in reduced tracking time and burden, ability to capture behavior more proximal to actual time of eating or drinking, and immediate, tailored feedback. mHealth solutions hold promise given that 77\% of U.S. adults own a smartphone.\textsuperscript{112} Recent studies have demonstrated that interventions without counseling that utilize commercially available digital solutions for self-monitoring of diet (e.g., a mobile application “app” or website) can produce weight losses of 2.5-5.5 kg at 3 months and 3.9-5.4 kg at 6 months or later.\textsuperscript{92,115,122,160,165-167} These findings are clinically meaningful given that weight reduction of at least 2-5\% has been shown to reduce cardiovascular disease risk.\textsuperscript{3,12}

In a randomized trial, we tested a weight loss intervention that targeted the aforementioned strategies of including empirically supported behavior change
techniques, promoting mastery and self-efficacy through self-monitoring of body weight prior to dietary self-monitoring, and utilizing a free commercially available app (MyFitnessPal) for self-monitoring that has high acceptability. We hypothesized that a sequential approach would produce greater weight loss and self-monitoring engagement at 3 months, compared to a traditional simultaneous self-monitoring approach and to an “off-the-shelf” app.

3.2 Methods

3.2.1 Study Design Overview

GoalTracker was a 3-arm randomized controlled trial comparing three standalone weight loss interventions: (1) a Simultaneous self-monitoring arm in which participants simultaneously tracked body weight and dietary intake each day, and received additional empirically-supported behavior change techniques (weekly lessons, action plans, tips, tailored feedback) via email for the entirety of the intervention; (2) a Sequential arm, consisting of identical intervention components, but that tracked only body weight through week 4, then added tracking of diet; and (3) an App-Only arm that tracked only diet with no additional behavior change components. Study evaluation visits were held at baseline, 1 month, and 3 months. Self-reported weight was collected at 6 months via email or text message. All study procedures were approved by the Duke University Institutional Review Board.
3.2.2 Participants

Inclusion criteria comprised men and women ages 21-65 years old with a body mass index (BMI) between 25.0-45.0 kg/m² who were interested in losing weight through dietary change. We required participants to have an iPhone or Android smartphone, email address, and access to a bathroom scale, as well as written English fluency. We excluded participants if they were enrolled in another weight loss intervention, used MyFitnessPal to track diet in the past 6 months, lost ≥10 lbs or used a weight loss medication in the past 6 months, had previous or planned bariatric surgery, had a medical or psychiatric condition that contraindicates weight loss or necessitates additional attention in a lifestyle intervention (e.g., cancer, diabetes mellitus, cardiovascular disease, eating disorder, uncontrolled hypertension), or were currently pregnant or <12 months postpartum. Exclusion criteria were predominantly intended to promote safety.

Two criteria were amended during the trial in order to promote generalizability of findings during the trial: (1) the BMI criteria were expanded to include participants in the 40.0-45.0 kg/m² range and (2) the weight change criteria were adjusted to no longer exclude individuals who gained more than 10 lbs in the past 6 months. The IRB approved both amendments.

3.2.3 Recruitment

Recruitment occurred between April-September 2017 in central North Carolina. We recruited participants via (1) a university affiliated community
research recruitment website, (2) messages sent to university listservs and digital flyers, (3) social media postings (e.g., Twitter and Facebook), (4) paper flyers posted around the community, (5) ClinicalTrials.gov registry, (6) Craigslist, and (7) Nextdoor. Advertisements provided a description of the study and eligibility criteria.

### 3.2.4 Procedure

We directed interested individuals to a study website with descriptive information and an online screening questionnaire that assessed eligibility criteria, including participants’ current height and weight. Study personnel contacted eligible candidates within 3 business days of completing the screening questionnaire to schedule an in-person baseline visit.

During the baseline visit, trained study staff confirmed participants’ age, obtained written informed consent, and gathered height and weight to confirm BMI eligibility. After collecting anthropometric measurements, study personnel assisted participants in installing and navigating the MyFitnessPal mobile app; participants then completed an online survey. In order to collect self-monitoring data through our software engine (“Prompt”), study staff created both a MyFitnessPal account and a Fitbit account, and linked the two accounts in order to view MyFitnessPal data using the Fitbit API. If participants already had an account on either platform, they were asked to use a new account or change their login credentials and give study staff access to the existing account. Then, participants briefly reviewed information with study personnel on how to access the MyFitnessPal app on their smartphone.
Using simple random sampling, participants were then randomized by study staff to one of three treatment arms using Excel’s random number generator, which allocated participants equally (1:1:1) across conditions. The allocation sequence was concealed to study staff. Randomization was revealed to participants by study personnel; as such, study staff were not blinded to treatment allocation. Participants were enrolled into the study on a rolling basis until the target sample size was met. Lastly, participants reviewed written materials describing their treatment condition. Study staff then checked participants’ understanding of their treatment arms to reduce contamination and ensure that the treatment was delivered as intended.

In-person follow-up visits occurred at 1 month and 3 months. At 1 month, study staff provided participants with information detailing their goals for the remainder of the intervention. We compensated participants with Amazon electronic gift cards ($12 at the baseline visit; $6 for each follow-up visit; an additional $5 bonus for completing all 4 online dietary measures). Trained study personnel performed assessments and adhered to a standardized protocol, completing all procedures in the same order. Questionnaires were administered in English via a desktop computer using a secure, web-based survey system. There was no contact of any kind with participants between months 3 and 6. At 6 months post-baseline, study staff contacted participants via email and text message to collect self-reported body weight measure. Data collection ended March 2018.
3.2.5 Intervention Design

Participants were randomized to one of three conditions: (1) Simultaneous; (2) Sequential; or (3) App-Only, as outlined below. The intervention period lasted 12 weeks. Details about the intervention components are described in Table 9.
Table 9: Differences in Intervention Components Between Treatment Arms

<table>
<thead>
<tr>
<th>Intervention Component</th>
<th>Sim</th>
<th>Seq</th>
<th>App-Only</th>
<th>Theoretical Construct</th>
<th>Behavior Change Technique\textsuperscript{158}</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight loss goal: 0.5-2.0 lbs/week (tailored) and 5% by 12 weeks</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>Self-regulation</td>
<td>- Goal setting (outcome)</td>
</tr>
<tr>
<td>Calorie goal: tailored based on individual factors and rate of weight loss; minimum 1200 kcal for women, 1500 kcal for men</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>Self-regulation</td>
<td>- Goal setting (behavior)</td>
</tr>
<tr>
<td>Self-monitoring of body weight: daily via the app</td>
<td>X</td>
<td>X</td>
<td></td>
<td>Self-regulation</td>
<td>- Prompt self-monitoring of behavioral outcome</td>
</tr>
<tr>
<td>Self-monitoring of dietary intake: daily via the app</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>Self-regulation</td>
<td>- Prompt self-monitoring of behavior</td>
</tr>
<tr>
<td>Facilitate mastery experience by first tracking weight then tracking diet</td>
<td>X</td>
<td></td>
<td>(delayed)</td>
<td>Self-efficacy; Self-regulation; mastery</td>
<td>- Set graded tasks</td>
</tr>
<tr>
<td>In-app real-time feedback</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>Self-regulation; Self-efficacy</td>
<td>- Provide feedback on performance</td>
</tr>
<tr>
<td>Out-of-app summary feedback via weekly email (tailored)</td>
<td>X</td>
<td>X</td>
<td></td>
<td>Self-regulation; Self-efficacy</td>
<td>- Provide feedback on performance</td>
</tr>
</tbody>
</table>

\textsuperscript{158} Values are: X = Present, X = Absent.
<table>
<thead>
<tr>
<th>Skills Training via weekly email with structured behavioral lesson and tips on how to use features of the app</th>
<th>X</th>
<th>X</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outcome expectancies; Self-efficacy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Provide information on consequences of behavior in general</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Prompt generalization of a target behavior</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Provide information on when and where to perform the behavior</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Provide instruction on how to perform the behavior</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Environmental restructuring</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Plan social support/social change</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Relapse prevention/coping planning</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Action Plans via weekly email</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Self-regulation; Self-efficacy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Action planning</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Motivational interviewing</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Barrier identification/problem solving</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Prompt practice</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Plan social support/social change</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reminder of goals</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Self-regulation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Prompt review of outcome goals</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Prompt review of behavioral goals</td>
<td></td>
<td></td>
</tr>
<tr>
<td>In-app reminders to track</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Self-regulation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Teach to use prompts/cues</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Abbreviations: Sim, Simultaneous self-monitoring intervention arm; Seq, Sequential self-monitoring intervention arm; App-Only, App-Only arm
3.2.5.1 Common Intervention Components

All three treatment arms self-monitored dietary intake using MyFitnessPal, a free commercial app that allows users to log food and beverages, and provides nutritional information from a database with over 5 million foods (myfitnesspal.com).\(^{169}\) In-app feedback in both graphical and text format provides users with a real-time snapshot of their progress updates. Participants received a goal to lose 5% of their initial body weight by 12 weeks. Based on this goal and the participant’s current weight, a weekly weight loss goal between 0.5 lbs and 2.0 lbs was calculated, and inputted into the app during the account set up process in order to determine a daily calorie goal. Other variables impacting the calorie goal include an individual’s height, gender, age, and normal activity level (i.e., sedentary, lightly active, active, very active). MyFitnessPal is able to account for an individual’s basal metabolic rate, using the Mifflin-St. Jeor equation. MyFitnessPal sets a minimum caloric goal of 1200 kcal/day for women and 1500 kcal/day for men. During setup of a participant’s account, in-app push-reminders were programmed to be sent each day if tracking had not occurred by a pre-specified time of day. MyFitnessPal has good relative validity for estimating caloric intake.\(^{130}\) No structured dietary advice (e.g., follow a low carbohydrate diet) was given to participant.

3.2.5.2 Both Simultaneous and Sequential Arms

In addition to the common intervention components, participants in the Simultaneous and Sequential arms were asked to self-weigh and enter their body
weight in the app each day. Each week, participants received an automated email with tailored feedback. The email described a participant’s progress on each goal in the past week. A total count of goals met in the past week (possible range: 0-4) was provided, along with motivational messages, tips to reinforce positive behaviors or highlight areas to improve upon, and their total weight loss progress and pounds from their goal. See Table 5 for the criteria used for each goal in order to determine if a goal was met, somewhat met, or not met. Weight outcomes feedback was provided as long as one weight was recorded in the past week. Feedback pertaining to the calorie goal included only days with complete food diaries (≥800 kcal/day).119

Participants in both the Simultaneous and Sequential arms were also sent weekly skills training materials via email on a different day. Each email included (1) a tip on using different features of the app (e.g., using the barcode scanner) accompanied by screenshots of the app, (2) a lesson pertaining to a nutrition topic or a behavioral modification strategy, and (3) an online action plan that encourages individuals to identify ways to apply the lesson. Lessons were adapted from the gold-standard curriculum of the Diabetes Prevention Program,135 and the Look AHEAD trial,16 as well as from two behavioral technology-based weight loss interventions (Track and WEIGH).79,136 Action plans included motivational interviewing and problem solving approaches,139,140 and included the following types of components to reinforce the weight loss curriculum: identification of current behaviors or beliefs, confidence in and reasons for change, the creation of
action plans that prompt individuals to think about the *when*, *where*, and *what* of each action, an assessment of potential barriers that may arise and potential solution to address each barrier, prompts to identify a support person, and a review of past action plans. See Table 6 and Table 7 for lesson and app tip topics for each arm.

### 3.2.5.3 Sequential Arm’s Self-Monitoring and Feedback

Individuals in the Sequential arm received the same intervention components as the Simultaneous arm, but they did not begin self-monitoring dietary intake until after week 4 of the intervention. The Sequential arm did not receive any feedback related to diet tracking or the calorie goal until they began tracking diet.

### 3.2.5.4 App-Only Arm

App-Only arm participants were instructed to self-monitor their food intake daily on the MyFitnessPal app for the duration of the intervention. Participants did not receive a recommendation to weigh themselves and did not receive weekly email messages with feedback or skills training. For this arm, we wanted to provide an ‘off-the-shelf’, self-guided approach that the general U.S. population can already access for free in the commercial marketplace.

### 3.2.6 Outcome Measures

The primary outcome was weight change at 3 months.
3.2.6.1 Sociodemographic and Clinical Characteristics

At baseline, we collected data on participant age, gender, marital status, race, ethnicity, educational attainment, employment status, and annual household income. We also assessed whether participants had ever been told by a doctor or other health professional that they had prediabetes or hypertension. Frequency of self-monitoring weight and diet in the month prior to baseline were measured with a 7-point scale ranging from *several times per day* (7) to *never* (0).\(^{79,136}\) One question pertained to self-weighing and a separate question pertained to self-monitoring calories.

3.2.6.2 Technology Use

At baseline, we assessed type of smartphone and names of health apps currently on participants' phones. At 3-months, we assessed "Did you ever use the MyFitnessPal website during the past 3 months?" Response options were no, yes-regularly, and yes-infrequently. For those who indicated ever using the website, we asked "During the past 3 months when you used MyFitnessPal, did you use it mostly on the app or on the website?" We also assessed whether participants upgraded to the Premium version of the MyFitnessPal app in the past 3 months, and whether they synced any wearables to their app.

3.2.6.3 Anthropometric Data

We asked participants to remove heavy clothing (e.g., coats, hats) and to remove shoes prior to measurement of anthropometrics. We measured body weight
using a calibrated electronic scale (SECA 876). Height was measured to the nearest 0.1 cm using a calibrated, wall-mounted stadiometer (SECA 222). We calculated BMI as the body weight in kilograms divided by the height squared in meters (kg/m²). Baseline height was used for calculation of BMI at subsequent evaluation time points. We collected self-reported body weight at 6-months. For better verification, participants were asked to send a photo with their feet on the scale displaying the value in either kg or lbs. We assessed the proportion of participants at 3 months who achieved weight loss of ≥3% and ≥5% from baseline.

3.2.6.4 Caloric Intake

Via a web interface, we administered the Automated Self-Administered 24-Hour Dietary Assessment Tool (ASA24, version 2016) that was developed by the National Cancer Institute to assess average caloric intake. At both baseline and 3 months, we instructed participants to complete two 24-hour recalls (one weekday and one weekend day), which were averaged.

3.2.6.5 Self-Monitoring Engagement Data

We used a software engine developed at Duke ("Prompt") to collect participants’ objective MyFitnessPal self-monitoring data. After study staff linked participants’ MyFitnessPal and Fitbit accounts, Prompt was able to retrieve this data using Fitbit’s application programming interface (API). Each week, Prompt collated and stored participants’ objective daily self-monitoring weight and calorie data from all three treatment arms. We used this data in creating tailored feedback reports for
intervention participants each week. Primary outcomes for self-monitoring engagement cover the duration of the intervention period, that is, from day 1 to day 83. Day 1 corresponds with the day after the participant’s baseline visit. We report engagement outcomes for the first 4 weeks in the intervention (day 1 to 28), for the final two months (day 29-83), and for the entire 83-day intervention period. In exploratory analyses, we examined engagement data after the intervention ended up to 6 months post-randomization (i.e., day 84 to day 183).

We also examined the median number of days per week that participants self-monitored weight, and self-monitored diet (with a complete entry). Food records were considered complete if at least 800 kilocalories are recorded for a given day, as utilized in a previous intervention using dietary self-monitoring. To examine overall self-monitoring engagement, we examined the percentage of days that entries were recorded (i.e., number of days with entries recorded divided by number of days asked to record an entry, multiplied by 100). We expected that the Simultaneous arm track both diet and body weight every day for the entire 12-week intervention (i.e., 83 days), and that the App-Only arm track diet during this period (i.e., 83 days). For individuals assigned to the Sequential arm, we expected that they track body weight every day for the entire 12-week intervention (i.e., 83 days) and that they track food intake every day after week 4 of the intervention (i.e., for 55 days).
3.2.6.6 Engagement in Action Plans and Feedback Email

Percentage of action plans completed was examined through objective survey data. In the 3-month survey, we measured participants’ frequency of reading their weekly feedback email, with five response options *(Several times per week, One time per week, Less than 1 time per week, Less than 1 time per month, or Never).*

3.2.6.7 Intervention Satisfaction

Modeled after questions from the Laing et al. 2014 trial,34 we asked at the 3-month visit “What did you like about MyFitnessPal?” We also asked “If you stopped using MyFitnessPal during the past 3 months, why did you stop using it?” For both questions, participants could choose multiple options or provide their own response.

3.2.7 Statistical Analysis

Sample size was calculated based on power to detect a 3.5 kg difference in weight change at 3 months between the Sequential arm and the App-Only arm (our primary comparison).34,79 Our power analysis determined that 93 participants were needed to achieve 80% power for a two-sided test with an alpha level of 0.05. To account for attrition of 10% and to obtain equal-size groups, we aimed to recruit 105 participants (35 per group). Power analyses were conducted in G*Power 3.1.9.2.154 In exploratory analyses, we compared weight change between the Sequential arm and the Simultaneous arm, though we were not adequately powered to detect a significant effect.
For the sociodemographic and clinical characteristics assessed at baseline, we computed descriptive statistics (mean, SD for continuous variables; N, % for categorical variables) to help characterize the sample, stratified by treatment arm. We examined whether completers differed from noncompleters in these baseline characteristics. For categorical variables, the Pearson chi-square test was used, while analysis of variance (ANOVA) was used for continuous variables. We used Fisher’s exact tests when small cell counts existed. $P < .05$ was considered statistically significant. All analyses were two-tailed. To compare retention rates among treatment arms, we used the Pearson chi-square test. Participants who became ineligible (e.g., became pregnant) during the study period up to the primary end point (12 weeks) were excluded from analyses. Investigators remained blinded to outcomes until the completion of the 6-month trial. Data was analyzed using SAS 9.4 (SAS Institute, Cary, NC).\textsuperscript{171}

We used intent-to-treat (ITT) analyses to test our primary aim using linear mixed modeling with an unstructured covariance matrix and restricted maximum likelihood estimates to examine changes in weight and caloric intake over time by treatment arm.\textsuperscript{172} We assumed missing at random and used SAS 9.4 PROC MIXED (SAS Institute) for these analyses.\textsuperscript{173} We also conducted a completers’ analysis with all eligible participants who attended the 3-month evaluation visit. For 6-month weight values sent via photo, we subtracted 0.172 kg (.4 lbs) to account for participants holding a device on the scale to take the photo. To account for the 6-
month self-reported weight data without photos, we used a regression model from Jain et al. 2010 to adjust for age, gender, and race/ethnicity for values without photos. Participants who sent a photo did not differ on any measured sociodemographic characteristics from those who sent their 6-month weight without a photo (data not shown). To assess differences in proportion of participants achieving a clinically significant weight loss (≥3% and ≥5% of initial weight by 3 months), we used chi-square tests; we assumed noncompleters did not achieve this clinical threshold.

Given that the intervention engagement data were non-normally distributed, we reported medians and interquartile ranges (IQR). To examine differences between treatment arms, we used Wilcoxon Mann-Whitney U tests (if two arms) and the Kruskal-Wallis tests (if three arms). We used Spearman rank correlation coefficients ($r_s$) to examine the relation between self-monitoring engagement and change in weight. We also assessed for contamination by exploring whether participants self-monitored when they were not expected to do so.

### 3.3 Results

#### 3.3.1 Participant Enrollment and Retention

Figure 2 displays the flow of participants through the trial. Of the 670 individuals who completed the online screen for eligibility, 58.3% were ineligible, while 23.7% were invited to attend the baseline visit. We enrolled 105 participants and randomized them equally to each of three treatment arms: Simultaneous
(n=35), Sequential (n=35), or App-Only (n=35). During the trial, five participants became ineligible. Of the remaining 100 participants, 84.0% completed the 1-month visit and 76.0% completed the 3-month visit. Participant retention did not differ significantly by treatment arm (1 month: \( p=0.84 \), 88%, 82%, 82%, respectively; 3 months: \( p=0.23 \), 75%, 85%, 68%, respectively). Between 3 and 6-months, one additional participant became ineligible due to pregnancy. At 6-months, 77.8% of participants self-reported their weight; response rates did not differ between arms at 6 months (\( p=0.32 \); 78%, 85%, 70%, respectively). We had no missing self-monitoring engagement data.

### 3.3.2 Baseline Characteristics

Table 10 illustrates the baseline characteristics of GoalTracker participants. At baseline, participants had a mean (SD) age of 42.7 (11.7) years and BMI of 31.9 (4.5) kg/m\(^2\), and were predominantly female (84%) and employed (78%). One-third were racial/ethnic minorities, and most had obesity (60%), were married or living with a partner (64.0%), and had at least a college education (83%). Few participants had been told by a health care professional that they had prediabetes (9.0%) or hypertension (10.0%). The majority (56%) had never tracked diet though most had experience tracking body weight (87%). Completers at 3 months differed from noncompleters in race/ethnicity (\( p=0.03 \)), with 16% of non-Hispanic white participants and 39% of racial/ethnic minority participants missing the visit.
Figure 2: CONSORT Flow Diagram
Table 10: Baseline Characteristics by Treatment Arm

<table>
<thead>
<tr>
<th></th>
<th>Total (N = 100*)</th>
<th>Simultaneous (n = 32)</th>
<th>Sequential (n = 34)</th>
<th>App-Only (n = 34)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, mean (SD), y</td>
<td>42.7 (11.7)</td>
<td>43.8 (12.6)</td>
<td>42.1 (11.0)</td>
<td>42.3 (11.8)</td>
</tr>
<tr>
<td>Gender, No. (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>16 (16.0)</td>
<td>8 (25.0)</td>
<td>4 (11.8)</td>
<td>4 (11.8)</td>
</tr>
<tr>
<td>Female</td>
<td>84 (84.0)</td>
<td>24 (75.0)</td>
<td>30 (88.2)</td>
<td>30 (88.2)</td>
</tr>
<tr>
<td>Marital status, No. (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Married or living w/ partner</td>
<td>64 (64.0)</td>
<td>22 (68.8)</td>
<td>18 (52.9)</td>
<td>24 (70.6)</td>
</tr>
<tr>
<td>Not married or living w/ partner</td>
<td>36 (36.0)</td>
<td>10 (31.3)</td>
<td>16 (47.1)</td>
<td>10 (29.4)</td>
</tr>
<tr>
<td>Race/ethnicity, No. (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-Hispanic White</td>
<td>67 (67.0)</td>
<td>21 (65.6)</td>
<td>23 (67.7)</td>
<td>23 (67.7)</td>
</tr>
<tr>
<td>Non-Hispanic Black</td>
<td>22 (22.0)</td>
<td>9 (28.1)</td>
<td>6 (17.7)</td>
<td>7 (20.6)</td>
</tr>
<tr>
<td>Hispanic (all races)</td>
<td>3 (3.0)</td>
<td>0 (0.0)</td>
<td>2 (5.9)</td>
<td>1 (2.9)</td>
</tr>
<tr>
<td>Non-Hispanic other</td>
<td>8 (8.0)</td>
<td>2 (6.3)</td>
<td>3 (8.8)</td>
<td>3 (8.8)</td>
</tr>
<tr>
<td>Education, No. (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Less than college graduate</td>
<td>17 (17.0)</td>
<td>7 (21.9)</td>
<td>6 (17.7)</td>
<td>4 (11.8)</td>
</tr>
<tr>
<td>College graduate or above</td>
<td>83 (83.0)</td>
<td>25 (78.1)</td>
<td>28 (82.4)</td>
<td>30 (88.2)</td>
</tr>
<tr>
<td>Employment status, No. (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Employed, full-time</td>
<td>67 (67.0)</td>
<td>20 (62.5)</td>
<td>27 (79.4)</td>
<td>20 (58.8)</td>
</tr>
<tr>
<td>Employed, part-time</td>
<td>11 (11.0)</td>
<td>3 (9.4)</td>
<td>1 (2.9)</td>
<td>7 (20.6)</td>
</tr>
<tr>
<td>Not employed</td>
<td>22 (22.0)</td>
<td>9 (28.1)</td>
<td>6 (17.7)</td>
<td>7 (20.6)</td>
</tr>
<tr>
<td>Annual household income, No. (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>$0-$49,999</td>
<td>26 (26.0)</td>
<td>8 (25.0)</td>
<td>9 (26.5)</td>
<td>9 (26.5)</td>
</tr>
<tr>
<td>$50,000-$99,999</td>
<td>36 (36.0)</td>
<td>14 (43.8)</td>
<td>12 (35.3)</td>
<td>10 (29.4)</td>
</tr>
<tr>
<td>$100,000 or greater</td>
<td>34 (34.0)</td>
<td>9 (28.1)</td>
<td>11 (32.4)</td>
<td>14 (41.2)</td>
</tr>
<tr>
<td>Unknown/not reported</td>
<td>4 (4.0)</td>
<td>1 (3.1)</td>
<td>2 (5.9)</td>
<td>1 (2.9)</td>
</tr>
<tr>
<td>----------------------</td>
<td>---------</td>
<td>---------</td>
<td>---------</td>
<td>---------</td>
</tr>
<tr>
<td>Weight, mean (SD), kg</td>
<td>89.6 (16.0)</td>
<td>89.3 (17.0)</td>
<td>90.8 (16.9)</td>
<td>88.6 (14.6)</td>
</tr>
<tr>
<td>Body mass index, mean (SD), kg/m²</td>
<td>31.9 (4.5)</td>
<td>31.3 (4.2)</td>
<td>32.6 (5.1)</td>
<td>31.7 (4.4)</td>
</tr>
<tr>
<td>BMI category, No. (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Overweight, 25-29.9 kg/m²</td>
<td>40 (40.0)</td>
<td>13 (40.6)</td>
<td>12 (35.3)</td>
<td>15 (44.1)</td>
</tr>
<tr>
<td>Class I obesity, 30-34.9 kg/m²</td>
<td>38 (38.0)</td>
<td>14 (43.8)</td>
<td>13 (38.2)</td>
<td>11 (32.4)</td>
</tr>
<tr>
<td>Class II obesity, 35-39.9 kg/m²</td>
<td>17 (17.0)</td>
<td>4 (12.5)</td>
<td>6 (17.7)</td>
<td>7 (20.6)</td>
</tr>
<tr>
<td>Class III obesity, 40+ kg/m²</td>
<td>5 (5.0)</td>
<td>1 (3.1)</td>
<td>3 (8.8)</td>
<td>1 (2.9)</td>
</tr>
</tbody>
</table>

Self-monitoring of diet frequency, No. (%)

| Daily | 6 (6.0) | 1 (3.1) | 2 (5.9) | 3 (8.8) |
| 1-6 times/week | 14 (14.0) | 6 (18.8) | 4 (11.8) | 4 (11.8) |
| Less than 1 time/week | 24 (24.0) | 4 (12.5) | 11 (32.4) | 9 (26.5) |
| Never | 56 (56.0) | 21 (65.6) | 17 (50.0) | 18 (52.9) |

Self-monitoring of weight frequency, No. (%)

| Daily | 11 (11.0) | 6 (18.8) | 2 (5.9) | 3 (8.8) |
| 1-6 times/week | 35 (35.0) | 6 (18.8) | 14 (41.2) | 15 (44.1) |
| Less than 1 time/week | 41 (41.0) | 13 (40.6) | 16 (47.1) | 12 (35.3) |
| Never | 13 (13.0) | 7 (21.9) | 2 (5.9) | 4 (11.8) |

Type of smartphone, No. (%)

| iPhone | 54 (54.0) | 17 (53.1) | 16 (47.1) | 21 (61.8) |
| Android | 46 (46.0) | 15 (46.9) | 18 (52.9) | 13 (38.2) |
| MyFitnessPal already on phone prior to study | 20 (20.0) | 6 (18.8) | 9 (26.5) | 5 (14.7) |

*aFive participants omitted due to becoming ineligible during the intervention period
3.3.3 Technology Use

Slightly more participants (54%) owned an iPhone than an Android smartphone (46.0%). One-fifth (20.0%) of participants indicated that MyFitnessPal was already downloaded on their phone prior to the study. Among the 75 participants who completed the 3-month survey, 32.0% of participants reported using the MyFitnessPal companion website regularly during the 3-month intervention, while 20.0% used it infrequently, and 48.0% never used the website; website use did not differ by treatment arm ($p=0.41$). Among those who used the website, few (8.1%) participants reported using the website more than the app. One-quarter (24.0%) of participants indicated that they synced a wearable to the MyFitnessPal app during the 3-month intervention, which did not differ by treatment arm ($p=1.00$). No participants reported upgrading to the Premium version of the MyFitnessPal app during the intervention.

3.3.4 Weight Loss

3.3.4.1 Primary Outcomes

Figure 3 and Figure 4 display weight change over time by treatment arm. Weight change at 1 month was significant over time for all arms ($ps<0.025$); in this period, the Sequential arm had average weight change of -0.80 kg (95% CI: -1.49, -0.10), compared to the App-Only arm, with change of -1.76 kg (95% CI: -2.48, -1.05; $p=0.06$) and the Simultaneous arm, with change of -1.25 kg (95% CI: -1.97, -0.53; $p=0.36$).
Weight change at 3 months was significant over time for all arms ($ps<0.001$), with no difference between the Sequential arm (-2.67 kg; 95% CI: -3.85, -1.49) and either the App-Only arm (-2.43 kg; 95% CI: -3.69, -1.16; $p=0.78$) or the Simultaneous arm (-2.75 kg; 95% CI: -4.01, -1.49; $p=0.92$).

Weight change at 6 months was significant over time for all arms ($ps<0.001$), with no difference between the Sequential arm (-2.25 kg; 95% CI: -3.66, -0.85) and either the App-Only arm (-1.88 kg; 95% CI: -3.41, -0.34; $p=0.72$) or the Simultaneous arm (-3.05 kg; 95% CI: -4.57, -1.52; $p=0.45$). See Table 11 for mean differences between arms.

### 3.3.4.2 Secondary Outcomes

The proportion of participants achieving at least 3% weight loss at 3 months was similar between arms ($p=0.43$; Simultaneous: 40.6%, Sequential: 44.1%, App-Only: 29.4%). Likewise, weight loss of at least 5% at 3-months did not significantly differ among arms ($p=0.26$) and occurred in 31.3%, 20.6%, and 14.7%, respectively.

There were no significant differences in BMI between arms (see Table 11). In a sensitivity analysis of only participants who completed the 3-month visit (n=76), weight change outcomes were similar (mean difference at 3 months between Simultaneous and Sequential, -0.41 kg [95% CI: -2.17 to 1.35 kg], $p=0.65$; between App-Only and Sequential, 0.21 kg [95% CI: -1.57 to 1.99 kg], $p=0.82$).
### Table 11: Between-Group Differences (intent to treat)

<table>
<thead>
<tr>
<th></th>
<th>Sim vs. Seq&lt;sup&gt;a&lt;/sup&gt;</th>
<th>App-Only vs. Seq&lt;sup&gt;a&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Weight change from baseline (kg)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 month</td>
<td>-0.46 (-1.45 to 0.54)</td>
<td>-0.97 (-1.97 to 0.03)</td>
</tr>
<tr>
<td>3 months</td>
<td>-0.08 (-1.81 to 1.64)</td>
<td>0.24 (-1.49 to 1.97)</td>
</tr>
<tr>
<td>6 months</td>
<td>-0.79 (-2.87 to 1.29)</td>
<td>0.38 (-1.71 to 2.46)</td>
</tr>
<tr>
<td><strong>BMI change from baseline (kg/m&lt;sup&gt;2&lt;/sup&gt;)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 month</td>
<td>-0.17 (-0.52 to 0.18)</td>
<td>-0.35 (-0.69 to 0.00)</td>
</tr>
<tr>
<td>3 months</td>
<td>-0.04 (-0.65 to 0.57)</td>
<td>0.08 (-0.53 to 0.69)</td>
</tr>
<tr>
<td>6 months</td>
<td>-0.24 (-0.98 to 0.49)</td>
<td>0.15 (-0.59 to 0.88)</td>
</tr>
<tr>
<td><strong>Caloric intake change from baseline (kilocalories)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3 months</td>
<td>271 (-131 to 673)</td>
<td>230 (-182 to 642)</td>
</tr>
</tbody>
</table>

Abbreviations: Sim, Simultaneous self-monitoring intervention arm; Seq, Sequential self-monitoring intervention arm; App-Only, App-Only arm

Note: One additional participant was omitted in analyses (App-Only arm) at 6-months due to becoming ineligible after the intervention period and before 6-months.

<sup>a</sup>Sequential is the reference group
Figure 3: Weight Change Over Time by Treatment Arm

Figure 4: Weight Change for All Participants who Attended the 3-Month Visit
3.3.5 Caloric Intake

Mean (SD) baseline caloric intake was 1734 (531) kcal/day. Most (90.0%; n=90) participants completed at least one recall at baseline, while 54.0% (n=54) completed at least one recall at 3 months. Change in caloric intake at 3 months was not significant over time for any treatment arms. The Sequential arm had a reduction of 266 calories ($p=0.07$), while the App-Only arm had a reduction of 36 calories ($p=0.81$), and the Simultaneous arm had an increase of 5 calories ($p=0.97$). There was no difference between the Sequential arm and either the App-Only arm ($p=0.27$) or the Simultaneous arm ($p=0.18$). See Table 11 for mean differences between arms.

3.3.6 Self-Monitoring and Other Intervention Engagement

Table 12 displays self-monitoring engagement and action plan completion outcomes for the following time intervals: baseline to 4 weeks, 5 to 12 weeks, all 12 weeks of the intervention, and 12 weeks to 6 months (i.e., the post-intervention period).

3.3.6.1 Self-Monitoring of Body Weight

Over the 12-week intervention, the median [IQR] number of days per week of self-monitoring body weight was 5.08 [4.50] in the Simultaneous arm and 4.83 [4.33] in the Sequential arm. Over the 12-week intervention, the frequency of days participants self-monitored weight did not differ between the Simultaneous and
Sequential arms (median [IQR]: 73.5% [64.5%] vs. 69.9% [62.7%], p=0.92). See Figure 5 for weekly self-monitoring data.

### 3.3.6.2 Self-Monitoring of Diet

Diet was tracked a median of 5.33 [4.83] days per week in the Simultaneous arm and 2.92 [4.00] days per week in the App-Only arm. Once instructed to track diet beginning in week 5, the Sequential arm tracked diet for 1.88 [5.25] days per week. There were no significant differences in frequency of days of self-monitoring diet between the Simultaneous and App-Only arms over the intervention period (median [IQR]: 76.5% [69.3%] vs. 42.2% [57.8%], p=0.10). Once the Sequential arm began tracking diet, they tracked a median of 27.3% [76.4%] of days. See Figure 6 for weekly self-monitoring data.
Table 12: Self-Monitoring Engagement by Treatment Arm

<table>
<thead>
<tr>
<th></th>
<th>Simultaneous (n=32)</th>
<th>Sequential (n=34)</th>
<th>App-Only (n=34)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Baseline to 4 Weeks</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td># Days/ Week Tracked Weight</td>
<td>6.25 [4.13]</td>
<td>5.75 [3.00]</td>
<td>0.00 [0.75]</td>
<td></td>
</tr>
<tr>
<td># Days/ Week Tracked Diet</td>
<td>6.50 [3.13]</td>
<td>0.00 [0.00]</td>
<td>5.38 [4.75]</td>
<td></td>
</tr>
<tr>
<td>% of Days Tracked Weight</td>
<td>89.29% [58.93%]</td>
<td>82.14% [42.86%]</td>
<td>0.00% [10.71%]</td>
<td>0.52 a</td>
</tr>
<tr>
<td>% of Days Tracked Diet</td>
<td>92.86% [44.64%]</td>
<td>0.00% [0.00%]</td>
<td>76.79% [67.86%]</td>
<td>0.37 b</td>
</tr>
<tr>
<td><strong>5 to 12 Weeks</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td># Days/ Week Tracked Weight</td>
<td>4.50 [5.44]</td>
<td>4.06 [5.88]</td>
<td>0.00 [0.25]</td>
<td></td>
</tr>
<tr>
<td>% of Days Tracked Weight</td>
<td>64.55% [79.09%]</td>
<td>59.09% [83.64%]</td>
<td>0.00% [3.64%]</td>
<td>0.95 a</td>
</tr>
<tr>
<td>% of Days Tracked Diet</td>
<td>70.00% [88.18%]</td>
<td>27.27% [76.36%]</td>
<td>20.91% [61.82%]</td>
<td>0.17 c</td>
</tr>
<tr>
<td><strong>Entire Intervention</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td># Days/ Week Tracked Weight</td>
<td>5.08 [4.50]</td>
<td>4.83 [4.33]</td>
<td>0.08 [0.58]</td>
<td></td>
</tr>
<tr>
<td># Days/ Week Tracked Diet</td>
<td>5.33 [4.83]</td>
<td>n/a</td>
<td>2.92 [4.00]</td>
<td></td>
</tr>
<tr>
<td>% of Days Tracked Weight</td>
<td>73.49% [64.46%]</td>
<td>69.88% [62.65%]</td>
<td>1.20% [8.43%]</td>
<td>0.92 a</td>
</tr>
<tr>
<td>% of Days Tracked Diet</td>
<td>76.51% [69.28%]</td>
<td>n/a</td>
<td>42.17% [57.83%]</td>
<td>0.10 b</td>
</tr>
</tbody>
</table>

86
<table>
<thead>
<tr>
<th>% Action Plans Completed</th>
<th>69.70%</th>
<th>27.30%</th>
<th>n/a</th>
<th>0.21 a</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>[77.25%]</td>
<td>[72.70%]</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**13 Weeks to 6 Months (Post-Intervention)**

<table>
<thead>
<tr>
<th></th>
<th># Days/ Week</th>
<th># Days/ Week</th>
<th>% of Days Tracked</th>
<th>% of Days Tracked</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tracked Weight</td>
<td>0.32</td>
<td>0.43</td>
<td>5.05%</td>
<td>2.53%</td>
</tr>
<tr>
<td></td>
<td>[0.89]</td>
<td>[1.64]</td>
<td>[13.64%]</td>
<td>[17.17%]</td>
</tr>
<tr>
<td>Tracked Diet</td>
<td>0.14</td>
<td>0.00</td>
<td>0.00%</td>
<td>0.00%</td>
</tr>
<tr>
<td></td>
<td>[1.18]</td>
<td>[0.29]</td>
<td>[0.43]</td>
<td>[5.05%]</td>
</tr>
</tbody>
</table>

Abbreviation: n/a, not applicable given that this treatment arm was not asked to track this item in this time period.

Notes: the table displays p-values comparing treatment arms that were instructed to track during the given time period; One additional participant was omitted in analyses (App-Only arm) at 6-months due to becoming ineligible after the intervention period and before 6-months.

a Simultaneous arm versus Sequential arm
b Simultaneous arm versus App-Only arm
c All arms
Figure 5: Mean Number of Days per Week of Self-Monitoring Body Weight During the Intervention, by Treatment Arm

Figure 6: Mean Number of Days per Week of Self-Monitoring Diet During the Intervention, by Treatment Arm
3.3.6.3 Relation Between Self-Monitoring Frequency and Weight Change

The percentage of days weight was tracked was significantly associated with 3-month weight change in both the Simultaneous arm ($r_s=-0.48$, $p=0.02$) and the Sequential arm ($r_s=-0.47$, $p=0.01$). In the same time period, the association between weight change and the percentage of days with complete diet entries was significant in the App-Only arm ($r_s=-0.58$, $p=0.003$), but not for the Simultaneous arm ($r_s=-0.25$, $p=0.24$). The percentage of days diet was tracked starting in week 5 for the Sequential arm was significantly associated with weight change from baseline to 3 months ($r_s=-0.44$, $p=0.02$). See Table 13 for additional correlations between intervention engagement and weight change.

Table 13: Spearman Rank Correlation Between Engagement and Weight Change

<table>
<thead>
<tr>
<th>Engagement Metric</th>
<th>Weight Change by 1 Month</th>
<th>Weight Change by 3 Months</th>
</tr>
</thead>
<tbody>
<tr>
<td>% Action Plans Completed</td>
<td>--</td>
<td>Both: -0.41 **</td>
</tr>
<tr>
<td></td>
<td></td>
<td>SIM: -0.07</td>
</tr>
<tr>
<td></td>
<td></td>
<td>SEQ: -0.60 **</td>
</tr>
<tr>
<td>Baseline to 4 Weeks</td>
<td></td>
<td></td>
</tr>
<tr>
<td>% days tracked weight</td>
<td>Both: -0.35 **</td>
<td>Both: -0.40 **</td>
</tr>
<tr>
<td></td>
<td>SIM: -0.40 *</td>
<td>SIM: -0.51 *</td>
</tr>
<tr>
<td></td>
<td>SEQ: -0.29</td>
<td>SEQ: -0.34</td>
</tr>
<tr>
<td>% days tracked diet</td>
<td>Both: -0.42 **</td>
<td>Both: -0.40 **</td>
</tr>
<tr>
<td></td>
<td>SIM: -0.36</td>
<td>SIM: -0.30</td>
</tr>
<tr>
<td></td>
<td>APP: -0.51 **</td>
<td>APP: -0.48 *</td>
</tr>
</tbody>
</table>

5 to 12 Weeks
<table>
<thead>
<tr>
<th></th>
<th>% days tracked</th>
<th>% days tracked diet</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>weight</td>
<td>ALL: -0.37 **</td>
</tr>
<tr>
<td>Both:</td>
<td>Both: -0.44 **</td>
<td>ALL: -0.42 **</td>
</tr>
<tr>
<td>SIM:</td>
<td>SIM: -0.37</td>
<td>SIM: -0.24</td>
</tr>
<tr>
<td>SEQ:</td>
<td>SEQ: -0.54 **</td>
<td>SEQ: -0.50 **</td>
</tr>
<tr>
<td></td>
<td></td>
<td>APP: -0.52 **</td>
</tr>
<tr>
<td></td>
<td></td>
<td>APP: -0.44 *</td>
</tr>
</tbody>
</table>

### Entire Intervention

<table>
<thead>
<tr>
<th></th>
<th>% days tracked</th>
<th>% days tracked diet</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>weight</td>
<td>ALL: -0.35 **</td>
</tr>
<tr>
<td>Both:</td>
<td>Both: -0.44 **</td>
<td>ALL: -0.42 **</td>
</tr>
<tr>
<td>SIM:</td>
<td>SIM: -0.40 *</td>
<td>SIM: -0.25</td>
</tr>
<tr>
<td>SEQ:</td>
<td>SEQ: -0.50 **</td>
<td>SEQ: -0.52 **</td>
</tr>
<tr>
<td></td>
<td></td>
<td>APP: -0.58 **</td>
</tr>
</tbody>
</table>

### 13 Weeks to 6 Months (Post-Intervention)

<table>
<thead>
<tr>
<th></th>
<th>% days tracked</th>
<th>% days tracked diet</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>weight</td>
<td>ALL: -0.29 **</td>
</tr>
<tr>
<td>Both:</td>
<td>Both: -0.50 **</td>
<td>ALL: -0.35 **</td>
</tr>
<tr>
<td>SIM:</td>
<td>SIM: -0.49 **</td>
<td>SIM: -0.27</td>
</tr>
<tr>
<td>SEQ:</td>
<td>SEQ: -0.59 **</td>
<td>SEQ: -0.42 *</td>
</tr>
<tr>
<td></td>
<td></td>
<td>APP: -0.20</td>
</tr>
</tbody>
</table>

**Abbreviations:** SIM, Simultaneous self-monitoring intervention arm; SEQ, Sequential self-monitoring intervention arm; App, App-Only arm

**Notes:** The table displays correlations and p-values for the treatment arms that were asked to track during the given time period. At 3 months: SIM: n=24, SEQ: n=29, APP-Only: n=23. At 6 months, one additional participant was omitted in analyses (App-Only arm) due to becoming ineligible after the intervention period and before 6-months.

**P<0.01; *P<0.05**

### 3.3.6.4 Contamination

To assess contamination across treatment arms, we explored the frequency of self-monitoring when not instructed to do so. The median [IQR] frequency of days
that App-Only participants tracked weight during the 3-month intervention was 1.20% [8.43%], and the median [IQR] frequency of days that Sequential participants tracked diet during month 1 was 0.00% [0.00%].

### 3.3.6.5 Action Plan Completion

In the Simultaneous arm, the median [IQR] number of action plans completed was 69.7% [77.3%], compared to 27.3% [72.7%] in the Sequential arm; this difference was not statistically significant ($p=0.21$). Percent action plan completion was significantly related to weight change at 3-months in the Sequential group ($r_s=-0.60$, $p=0.0006$), but not in the Simultaneous group ($r_s=-0.07$, $p=0.75$).

### 3.3.6.6 Review of Feedback Email

Most participants (67.3%) reported reading their weekly feedback email at least once per week, while 11.5% participants reported never reading them; there were no significant differences between the Simultaneous and the Sequential arms ($p=0.90$).

### 3.3.7 Intervention Satisfaction

Among the 75 participants who responded to the question “What did you like about MyFitnessPal?” 87% of participants indicated it was easy to use, and 32% endorsed that they liked receiving feedback on progress, and 33% reported they liked the reminders. See Figure 7 for additional response items. Of the 74 participants who answered the question “If you stopped using MyFitnessPal during the past 3 months, why did you stop using it?,” 27% indicated it is tedious and 14%
indicated “other” (stating reasons such as forgetting to track, feeling discouraged, and life issues). Of note, 59% of participants selected “I did not stop using it.” See Figure 8 for additional responses.

**Figure 7: Satisfaction with MyFitnessPal**

**Figure 8: Dissatisfaction with MyFitnessPal**
3.4 Discussion

A low-intensity intervention utilizing a commercial app for self-monitoring resulted in comparable weight loss at 3 months, with no variability by treatment arm. These findings are important because weight loss of 3-5% has been linked to improved health outcomes.\textsuperscript{3,12} GoalTracker’s Simultaneous arm had a comparable or higher proportion of participants achieving 5% weight loss, compared to other weight loss interventions that used mobile apps for self-monitoring dietary intake (range of 26-35\textsuperscript{\%};\textsuperscript{12,26,127,175}), but lower rates than some interventions that include counseling (range of 42-44\textsuperscript{\%};\textsuperscript{92,117,124}). Interestingly, we found sustained weight loss at 6 months despite no intervention occurring after 3 months, with trends suggesting continued weight loss in the Simultaneous arm, relative to weight gain in the other two arms.

There was no added benefit of evidence-based features like weekly action plans, behavioral lessons, and tailored feedback, over-and-above the core intervention (i.e., self-monitoring and in-app feedback), which parallels findings from several digital health weight loss trials,\textsuperscript{160,165,176,177} but not others.\textsuperscript{29,161} Although most commercial weight loss apps do not include many evidence-based features,\textsuperscript{157,178} we suspect that weight loss might still occur with the inclusion of a weight loss goal, daily self-monitoring of diet, and a daily reminder to track. To note, although not statistically significant, the App-Only arm had greater attrition, lower
self-monitoring adherence in months 2 and 3, and less pronounced weight loss, compared to the other two treatment arms.

Notably, GoalTracker is the first weight loss trial to compare a sequential self-monitoring approach to a traditional approach that asks participants to track multiple components simultaneously. A 2016 review by James et al. examined this comparison in the context of multiple behavior change interventions and concluded that both simultaneous and sequential approaches were equally efficacious, with limited evidence to support one approach over another. In comparison, a review that compared a single behavior (diet or exercise) to simultaneous behaviors determined that a simultaneous intervention was most efficacious for long-term weight loss; a study by Ma et al. found that simply focusing on a single component (fiber) resulted in comparable weight loss at 12 months with a group that focused on the multicomponent AHA diet. None of these studies focused on digital health interventions for weight loss, nor the self-monitoring aspect. Simultaneous interventions delivered in a digital health context may differ from traditional approaches in that working on multiple behavioral targets may be easier to do in the former; for instance, digital health interventions are able to send immediate feedback to relay information about one’s progress towards multiple behavioral goals, which may increase awareness about how each behavior differentially impacts outcomes. Also, the possibility of having in-the-pocket reminders about
several behavioral goals may promote greater engagement to multiple behaviors concurrently. Future research should investigate mechanisms at play.

We were surprised that the App-Only arm in GoalTracker performed better than expected, which may have masked the effects of the additional behavior change components and of daily self-weighing. Intervention participants in Laing et al.’s trial used the same MyFitnessPal app for diet tracking and lost 0.27 kg at 3 months and 0.03 kg at 6 months, in contrast to weight loss of 2.43 kg at 3 months and 1.88 kg at 6 months in the comparable arm in our trial. Laing et al.’s intervention also had poor intervention engagement. Both trials helped participants download the app on their phones, did not have a run-in period or kickoff session, had many participants endorse that the app was easy to use, and had comparable attrition at final follow-up in these two arms (30-32%). A possible explanation for the difference in weight loss, between Laing et al.’s trial and the GoalTracker trial include GoalTracker’s use of specific goals to track diet daily and to lose 5% of initial weight by a specified end date, and usage of phone-based reminder notifications – components found to have added value in eHealth interventions. It is also possible that our sample was more motivated, given that people interested in joining the study proactively completed our online eligibility survey, whereas Laing et al.’s participants were recruited through their routine primary care visits.

We found that self-monitoring engagement was high despite no counseling component, and that greater frequency of self-monitoring was related to greater
weight loss. Although not statistically significant, the Sequential arm demonstrated less engagement (e.g., fewer completed action plans and days of diet tracking) than the App-Only or Simultaneous arms. It is possible that the Sequential arm participants’ minimal first month weight loss may have negatively impacted their future engagement. It is also possible that they already developed a habit of daily self-monitoring of weight and were not able to smoothly incorporate tracking of diet into that daily habit. The latter pattern has been observed when individuals are asked to begin dietary change after a period of only focusing on exercise.\textsuperscript{103}

In comparison to other randomized trials that used commercial apps for self-monitoring of diet,\textsuperscript{92,116,122,123,125} GoalTracker’s Simultaneous arm tended to have greater adherence to diet tracking, while the Sequential arm had lower adherence. This differential pattern was similar when compared to weight loss trials that used researcher-designed apps for self-monitoring diet.\textsuperscript{111,117,127} Given that most weight loss trials of commercial apps are pilot studies and/or were not powered to detect an effect in weight change between treatment arms,\textsuperscript{92,119,122-125,181} more fully-powered studies are needed that examine the efficacy of commercial apps for weight loss.

Strengths of this trial include the collection of objective self-monitoring data for all participants via an API, use of a popular commercially available smartphone app, and ability to isolate the effect of a sequential vs. simultaneous self-monitoring approach. In addition, this trial mimicked real-world weight loss experience, with no
run-in period, pre-baseline visit, or orientation session; consequently, it is possible that removal of these treatment barriers allowed for inclusion of participants with lower motivation and readiness to change. This design may have greater external validity but may make it harder to detect an effect between arms. Another strength was that the trial had little contamination between arms, which has been a problem in past app-based trials where up to 50% of participants in two no-treatment control arms were found to have used commercial apps during the study period.\textsuperscript{34,116,126}

Because this study was powered on superiority rather than equivalency, we cannot definitively assert that the treatment arms produce comparable weight loss. In addition, we collected self-reported weight at 6-months due to logistical reasons; however, we were encouraged to find that no additional attrition occurred between 3 and 6 months, despite no contact occurring during that period and no incentive given to provide a weight value. Only half of participants (54%) completed the ASA-24 dietary measure at follow-up, which limits the validity of this data; we attribute this low response rate to the inability to administer this measure at the in-person evaluation visit and the measure being viewed as burdensome and too timely. Additionally, neither study staff nor participants were blinded to treatment arm, and we required participants to have access to a bathroom scale, though this mimics the real-world population who would track weight; interestingly, no participants who were instructed to track weight reported using a WIFI or cellular connected
scale. Comparing a passive self-monitoring approach (of simply stepping on the scale that automatically transmits weight to the app) to a more active approach of also having to enter one’s weight into the app would allow a more nuanced understanding of the pros and cons of these strategies, as highlighted by Thomas et al. 2017.165 Lastly, this study did not include a pure control arm without an intervention, which may have led to an underestimation of treatment effects, as could the possibility of data not actually missing at random.

Future research should consider framing the initial period prior to self-monitoring diet as a time to build self-regulatory skills rather than as a weight loss period, as has been proposed previously;67,182,183 this reframing may allow individuals to change their expectations of losing weight prior to tracking diet. Further, the optimal time point in which the second behavior in a sequential self-monitoring intervention is added should be assessed in an experimental manner. Additionally, having a longer study period may allow more time to see differential effects materialize; though not statistically significant, we found that App-Only participants had a more rapid decline in self-monitoring engagement, which may have eventually resulted in reduced weight loss; in contrast, it is also possible that this arm would continue to do just as well in the long-term by gaining self-regulatory skills from frequent tracking of diet for several weeks. Thus, future studies could assess if there is added benefit of continuing to track for long periods,
and whether having intermittent refresher periods of tracking leads to better outcomes.

In addition, it would be worthwhile to investigate the impact of self-monitoring physical activity, given mixed evidence of combining dietary and physical activity goals as beneficial\textsuperscript{179} or disadvantageous\textsuperscript{177} to weight loss. In addition, using an adaptive or optimization design\textsuperscript{184} would allow researchers to further investigate the unique impact of features known to contribute to weight loss, such as social support or social comparison,\textsuperscript{14,23} delivery modality of feedback, provision of connected scales, participant choice of goals or order of tracking, and primary care provider buy-in; these designs would allow researchers to better examine for whom a remotely-delivered weight loss intervention is most effective.

\textbf{3.5 Conclusion}

This study adds to the limited literature of randomized trials that assess the efficacy of commercially available mobile apps for weight loss\textsuperscript{114,185} and it sought to answer the question of how to optimize weight loss and engagement in a standalone intervention. In the GoalTracker trial, all three versions of the remotely-delivered intervention produced weight loss and had high self-monitoring engagement, with no significant impact of enhanced behavior change features nor differential findings between a sequential vs. simultaneous approach to self-monitoring. These results suggest that regardless of the order in which diet is tracked, using tailored goals and a commercial app can produce clinically significant weight loss in one-third of
individuals. Standalone digital health treatments may be a viable option for those looking for a lower intensity approach, who are willing and able to track.
4. Consistent Self-Monitoring in a Commercial App-Based Intervention for Weight Loss: Results from a Randomized Trial

4.1 Introduction

Self-monitoring is the strongest predictor of success in behavior change interventions and is considered an essential component of weight loss treatment. In accordance with self-regulation theory, the act of self-monitoring allows individuals to become aware of how their lifestyle choices impact their goals, and through observation of discrepancies, promotes greater self-regulation. Traditional behavioral weight loss interventions often instruct participants to self-monitor their food and body weight concurrently, which can promote better understanding of how greater caloric intake leads to weight gain, thereby prompting adjustments to eating behavior.

While there are several ways to examine the impact of self-monitoring on treatment outcomes (e.g., frequency, timeliness, comprehensiveness), consistent self-monitoring—whereby individuals self-monitor for most or all of the weeks in the intervention—has been demonstrated to be advantageous for weight management. A 2014 obesity treatment study by Peterson et al. compared three facets of self-monitoring; participants were instructed to track dietary intake at least 3 days per week using paper-based tracking logs. Results revealed that high comprehensiveness of food records did not predict weight loss,
whereas high frequency predicted weight loss only when coupled with high consistency (defined in this study as ≥50% of weeks).\textsuperscript{28} Accordingly, participants who frequently tracked but were inconsistent across weeks did not produce significant weight loss.

Given the utility of consistency in self-monitoring, we wanted to extend past research to a digital health context and examine predictors of consistency. Few studies have examined baseline predictors of consistent self-monitoring; finding predictors would allow interventionists to better prepare individuals for treatment or align them with treatments that match their resources, skills, and current health.

Digital health modalities for self-monitoring are increasingly being used in behavioral weight loss treatment.\textsuperscript{156} In addition to providing access to easily searchable and comprehensive food databases, digital health facilitates passive collection of self-monitoring data by study staff, whereas paper-based self-monitoring methods necessitate that participants submit their food diaries in order to receive feedback. Freely-available commercial products, such as MyFitnessPal, allow users to receive instantaneous feedback via graphically-engaging interfaces, making them a well-accepted and scalable treatment option.

While a few trials that incorporated self-monitoring via websites have examined consistency,\textsuperscript{29,188,189} it remains unknown how consistently participants self-monitor in a smartphone app. App-based interventions are different from web-based ones in that the portability of the smartphone allows for self-monitoring to
occur more proximal to the actual behavior being tracked (e.g., eating or exercise behavior). Determining whether consistent self-monitoring in a standalone, app-based intervention leads to greater weight loss will guide interventionists and clinicians in making recommendations to individuals seeking to lose weight.

In the GoalTracker trial, we examined the efficacy of a 12-week standalone weight loss intervention that focused on self-monitoring in a commercial app (MyFitnessPal). We randomized 105 participants equally to 1 of 3 arms to assess the impact of delaying self-monitoring of dietary intake until after a month of developing self-regulatory skills through self-monitoring of weight (“Sequential” vs. “Simultaneous”) and to evaluate the impact of behavior change components over-and-above an off-the-shelf self-monitoring arm (“App-Only”) (M.L.P., unpublished data, June 2018). Weight change at 3 months and 6 months did not vary by treatment arm, nor did frequency of self-monitoring. We found the median [IQR] number of days per week of self-monitoring weight was 5.1 [4.5] in Simultaneous and 4.8 [4.3] in Sequential. Diet was tracked 5.3 [4.8] days per week in Simultaneous and 2.9 [4.0] days in App-Only. Once self-monitoring of diet began, the Sequential arm averaged 1.9 [5.3] days per week. Frequency of self-monitoring was positively correlated with weight loss.

In line with the recent shift in weight loss treatment to focus on adherence outcomes,190-192 the current study addresses the following aims:
1. To describe what proportion of participants consistently self-monitor in a standalone, commercial app-based intervention

2. To examine sociodemographic and clinical predictors of consistent self-monitoring

3. To assess whether weight loss outcomes differ by self-monitoring consistency

4.2 Methods

This is a secondary analysis of the GoalTracker trial, which was described previously (M.L.P., unpublished data, June 2018). GoalTracker was a randomized controlled trial (n=105) that examined the efficacy of three 12-week standalone behavioral interventions for weight loss. Participants were randomized to either (1) a Simultaneous self-monitoring arm (n=35) in which participants simultaneously tracked body weight and dietary intake daily, and received weekly lessons, action plans, tips, and tailored feedback via email, (2) a Sequential self-monitoring arm (n=35) in which participants received all of the same components but delayed diet tracking until week 5, and (3) an App-Only arm (n=35) in which participants self-monitored diet daily but did not receive additional behavior change techniques. Evaluation visits occurred at baseline, 1 month, and 3 months. Compensation included Amazon electronic gift cards of $12, $6, and $6, respectively, with a $5 bonus for completing dietary measures. At 6 months, study staff collected self-reported weight via email or text message. Participants provided written informed
consent at baseline. The study was conducted between April 2017 and March 2018 and the Duke University Institutional Review Board approved study procedures.

4.2.1 Participants

Participants included in this secondary analysis were those who remained eligible during the 12-week intervention (n=100/105). To be eligible to participate in the GoalTracker trial, participants were required to have overweight or obesity (BMI 25.0-45.0 kg/m²), be 21-65 years old, own an iPhone or Android smartphone, have access to a bathroom scale, have English fluency, and have no medical or psychiatric contraindications that may necessitate more intensive treatment (e.g., cancer, uncontrolled hypertension, eating disorder, pregnancy or <12 months postpartum).

4.2.2 Intervention

All participants received MyFitnessPal—a popular and free commercial smartphone app—for self-monitoring, along with a goal to lose 5% of initial weight by 3 months, a corresponding weekly weight loss goal ranging from 0.5 to 2 lbs, and an in-app daily push reminder that was programmed to be sent if self-monitoring had not occurred by 7:00pm. Participants in the Simultaneous and Sequential arms received weekly feedback on their self-monitoring engagement and weight loss progress. They were told they met their tracking goal if they tracked at least 6 out of 7 days in the previous week. They had separate goals for weight and diet (n.b., for
Sequential participants, diet tracking and corresponding feedback started in week 5), and received separate feedback on each goal.

4.2.3 Measures

4.2.3.1 Anthropometric Data

We asked participants to remove heavy clothing and shoes prior to measurement of anthropometrics. We measured body weight using a calibrated electronic scale (SECA 876). At 6 months, we collected self-reported body weight, asking participants to send a photo with their feet on the scale displaying the value in either kg or lbs. Height was measured at baseline to the nearest 0.1 cm using a calibrated, wall-mounted stadiometer (SECA 222). BMI was calculated as the body weight in kilograms divided by the height squared in meters (kg/m$^2$). We assessed two thresholds of clinically meaningful weight loss$^{3,12}$: weight loss of ≥3% and ≥5% from baseline.

4.2.3.2 Baseline Participant Characteristics

As reported previously, (M.L.P., unpublished data, June 2018) we collected sociodemographic and clinical characteristics at baseline. For example, we collected age, marital status, race/ethnicity, socioeconomic status, health literacy, and depressive symptoms. Limited health literacy was defined as scores of 0-3, while adequate health literacy was defined as scores of 4-6.$^{142,193}$ Depression was assessed using the 8-item Patient Health Questionnaire (PHQ-8), which ranges from 0 to 24; scores ≥10 are indicative of clinically meaningful depression.$^{150}$ We also assessed
smartphone type, whether the MyFitnessPal app was downloaded on the phone prior to the study (participants were not told prior to randomization what app would be using), and frequency of self-monitoring weight and diet in the month prior to baseline (using a 7-point scale ranging from several times per day to never).

4.2.3.3 Self-Monitoring Engagement

Using a Duke-developed software engine (Prompt), we collected participants’ objective self-monitoring data from MyFitnessPal. By connecting MyFitnessPal with Fitbit, we were able to use Fitbit’s API to retrieve this data. Given that what the Sequential arm self-monitored changed over time (i.e., only body weight in month 1, then added diet), we categorized data by month 1 (day 1 to 28), the final two months of the intervention (days 29-83), and the entire intervention period (day 1-83). Diet entries were considered complete if at least 800 kilocalories were tracked on a given day.

**High engagement.** We first assessed the number of days in each week in which self-monitoring occurred. We then operationalized high engagement as a week with at least 6 out of 7 days of all expected self-monitoring entries.

**Consistency in self-monitoring.** We operationalized Consistent Trackers as individuals with high engagement (i.e., ≥6 of 7 days per week) in self-monitoring all items they were instructed to track, for at least 75% of the weeks when asked to track. This criterion number of weeks was derived from a previous eHealth trial, which defined high consistency in self-monitoring as tracking for at least 75% of the
total number of intervention weeks. Participants who did not meet these criteria were considered Inconsistent Trackers.

Specifically, for participants in the Simultaneous arm, Consistent Trackers were individuals who consistently self-monitored both weight and diet for at least 75% of weeks (i.e., ≥9) in the 12-week intervention; for Sequential arm participants, Consistent Trackers were those who tracked weight consistently for at least 75% of weeks (i.e., ≥9) in the 12-week intervention and consistently tracked diet (once asked to do so) at least 75% of weeks (≥6) in the final 8 weeks of the intervention; for participants in the App-Only arm, Consistent Trackers were those who consistently tracked diet at least 75% of weeks in the 12-week intervention.

**Categories of consistency in self-monitoring in month 1.** Given that high engagement in the first month of treatment is associated with weight loss success,\textsuperscript{189,194} in exploratory analyses, we established three categories of consistency in self-monitoring: Consistent for 3 Months, Consistent for 1st Month Only, and Not Consistent.

**4.2.4 Statistical Analysis**

Because self-monitoring weight or diet did not differ between treatment arms, we collapsed data across treatment arms in these secondary analyses. We excluded five participants who became ineligible during the intervention period; in 6-month analyses, we excluded one additional participant who became ineligible between 3 and 6 months. To account for underestimation of self-reported weights at
6 months, we used a regression model from Jain et al. 2010 to adjust for age, gender, and race/ethnicity for values without photos. For 6-month weight values sent via photo, we subtracted 0.172 kg (.4 lbs) to account for participants holding a device on the scale to take the photo.

Given the non-normal distributions of self-monitoring engagement data, we reported medians and interquartile ranges (IQR). To characterize the sample, we computed descriptive statistics stratified by treatment arm. We used the Pearson chi-square test for categorical variables, analysis of variance for continuous variables, and Fisher's exact tests with small cell counts. All analyses were two-tailed. $P<.05$ was considered statistically significant. Analyses were conducted using SAS 9.4 (SAS Institute, Cary, NC).

To examine differences between Consistent Trackers and Inconsistent Trackers in changes in weight and BMI over time, we used linear mixed models with random intercepts and slopes and restricted maximum likelihood estimates. We used chi-square tests and Fisher's exact tests (for small cell sizes) to examine differences in clinically meaningful weight loss between Consistent Trackers and Inconsistent Trackers. Similar analyses were used in exploratory analyses that compared three categories of consistency in self-monitoring.
4.3 Results
4.3.1 Baseline Participant Characteristics and Retention

In this secondary analysis of the GoalTracker trial, we included the 100 participants (out of 105) who remained eligible during the intervention period. In this sample, at baseline, participants had a mean (SD) age of 42.7 (11.7) years, weight of 89.6 (16.0) kg, and BMI of 31.9 (4.5) kg/m². Most participants were female (84%), married or living with a partner (64%), had a college education (83%), worked full-time (67%), and had adequate health literacy (95%). One-third (33%) of participants were non-white. Few (11%) scored above the clinical threshold for depression. In the month prior to the baseline visit, 56% had never tracked diet while 20% tracked diet at least once per week. In comparison, 13% never tracked weight in the month prior to baseline, while 46% did so at least once per week. One-fifth (20%) indicated they had the MyFitnessPal app already downloaded on their phone prior to the study. Further details have been described previously (M.L.P., unpublished data, June 2018).

Retention was 84.0% and 76.0% at the 1-month and 3-month evaluation visits, respectively, and did not differ between treatment arms ($p > 0.05$). One participant became ineligible between 3-6 months and was excluded from 6-month analyses. The response rate for submitting a self-reported weight at 6 months was 77.8%, which did not differ between arms ($p=0.32$).
4.3.2 High Engagement in Self-Monitoring

Briefly, among all participants instructed to track weight, high self-monitoring engagement occurred a median [IQR] of 6 [9.0] weeks out of the 12 weeks in the intervention. Among participants asked to track diet, high self-monitoring engagement occurred a median [IQR] of 3 [4.0] out of 4 weeks in month 1, and 1 [6.5] out of the final 8 weeks of the intervention. Self-monitoring engagement did not differ between treatment arms, so we collapsed data across treatment arms in these secondary analyses.

As presented in Figure 9, the proportion of participants who were highly engaged in self-monitoring each week ranged from a high of 68% (in week 1) to a low of 21% (in week 12); a transition to fewer than half of participants with high self-monitoring engagement occurred between weeks 3 and 4. Overall, participants were highly engaged in self-monitoring a median [IQR] of 4.0 [8.5] weeks in the 12-week intervention (Table 14).

Figure 9: Proportion of Participants with High Engagement in Self-Monitoring each Week

111
Table 14: Median [IQR] Number of Weeks of High Engagement in Self-Monitoring, by Consistent vs. Not Consistent Trackers

<table>
<thead>
<tr>
<th></th>
<th>Total</th>
<th>Consistent Trackers (n=25)</th>
<th>Inconsistent Trackers (n=75)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weeks 1-4</td>
<td>3.00 [4.00]</td>
<td>4.00 [0.00]</td>
<td>2.00 [3.00]</td>
</tr>
<tr>
<td>Weeks 5-12</td>
<td>0.50 [5.00]</td>
<td>8.00 [1.00]</td>
<td>0.00 [1.00]</td>
</tr>
<tr>
<td>Weeks 1-12</td>
<td>4.00 [8.50]</td>
<td>11.00 [2.00]</td>
<td>2.00 [5.00]</td>
</tr>
</tbody>
</table>

Abbreviation: IQR, interquartile range.
Note: high engagement in self-monitoring defined as a week with at least 6 days of tracking data; for diet entries, a complete entry is ≥800 kilocalories.

4.3.3 Consistent vs. Inconsistent Trackers

One-fourth (25%) of participants were Consistent Trackers, compared to 75% who were Inconsistent Trackers. Consistent Trackers were highly engaged in self-monitoring a median of 11 weeks, compared to just 2 weeks of high engagement among Inconsistent Trackers (Table 14).

4.3.4 Consistency in Self-Monitoring by Baseline Participant Characteristics

As shown in Table 15, compared to Inconsistent Trackers, Consistent Trackers were more likely to be married or living with a partner (84% vs. 57%) and had a higher average health literacy score. No participants with limited health literacy were Consistent Trackers (0 out of 5). Further, 30% of non-Hispanic white participants were Consistent Trackers compared to 15% of participants who are racial/ethnic minority.
Table 15: Baseline Characteristics by Consistent vs. Inconsistent Trackers

<table>
<thead>
<tr>
<th></th>
<th>Consistent Trackers*</th>
<th>Inconsistent Trackers</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(n = 25)</td>
<td>(n = 75)</td>
<td></td>
</tr>
<tr>
<td>Age, mean (SD), y</td>
<td>44.5 (11.2)</td>
<td>42.1 (11.9)</td>
<td>0.37</td>
</tr>
<tr>
<td>Gender, No. (%)</td>
<td></td>
<td></td>
<td>0.75</td>
</tr>
<tr>
<td>Male</td>
<td>3 (12.0)</td>
<td>13 (17.3)</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>22 (88.0)</td>
<td>62 (82.7)</td>
<td></td>
</tr>
<tr>
<td>Marital status, No. (%)</td>
<td></td>
<td></td>
<td>0.017</td>
</tr>
<tr>
<td>Married or living w/ partner</td>
<td>21 (84.0)</td>
<td>43 (57.3)</td>
<td></td>
</tr>
<tr>
<td>Not married or living w/ partner</td>
<td>4 (16.0)</td>
<td>32 (42.7)</td>
<td></td>
</tr>
<tr>
<td>Race/ethnicity, No. (%)</td>
<td></td>
<td></td>
<td>0.015</td>
</tr>
<tr>
<td>Non-Hispanic White</td>
<td>20 (80.0)</td>
<td>47 (62.7)</td>
<td></td>
</tr>
<tr>
<td>Non-Hispanic Black</td>
<td>1 (4.0)</td>
<td>21 (28.0)</td>
<td></td>
</tr>
<tr>
<td>Hispanic (all races)</td>
<td>0 (0.0)</td>
<td>3 (4.0)</td>
<td></td>
</tr>
<tr>
<td>Non-Hispanic other</td>
<td>4 (16.0)</td>
<td>4 (5.3)</td>
<td></td>
</tr>
<tr>
<td>Education, No. (%)</td>
<td></td>
<td></td>
<td>0.09</td>
</tr>
<tr>
<td>Less than college graduate</td>
<td>7 (28.0)</td>
<td>10 (13.3)</td>
<td></td>
</tr>
<tr>
<td>College graduate or above</td>
<td>18 (72.0)</td>
<td>65 (86.7)</td>
<td></td>
</tr>
<tr>
<td>Employment status, No. (%)</td>
<td></td>
<td></td>
<td>0.83</td>
</tr>
<tr>
<td>Employed, full-time</td>
<td>18 (72.0)</td>
<td>49 (65.3)</td>
<td></td>
</tr>
<tr>
<td>Employed, part-time</td>
<td>2 (8.0)</td>
<td>9 (12.0)</td>
<td></td>
</tr>
<tr>
<td>Not employed</td>
<td>5 (20.0)</td>
<td>17 (22.7)</td>
<td></td>
</tr>
<tr>
<td>Annual household income, No. (%)</td>
<td></td>
<td></td>
<td>0.35</td>
</tr>
<tr>
<td>$0-$49,999</td>
<td>4 (16.7)</td>
<td>22 (30.6)</td>
<td></td>
</tr>
<tr>
<td>$50,000-$99,999</td>
<td>9 (37.5)</td>
<td>27 (37.5)</td>
<td></td>
</tr>
<tr>
<td>$100,000 or greater</td>
<td>1 (45.8)</td>
<td>23 (31.9)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
<td>P value</td>
</tr>
<tr>
<td>--------------------------------</td>
<td>---------------</td>
<td>---------------</td>
<td>---------</td>
</tr>
<tr>
<td>Weight, mean (SD), kg</td>
<td>85.6 (16.2)</td>
<td>90.9 (15.9)</td>
<td>0.15</td>
</tr>
<tr>
<td>Body mass index, mean (SD), kg/m²</td>
<td>31.0 (4.6)</td>
<td>32.2 (4.5)</td>
<td>0.25</td>
</tr>
<tr>
<td>BMI category, No. (%)</td>
<td></td>
<td></td>
<td>0.84</td>
</tr>
<tr>
<td>Overweight, 25-29.9 kg/m²</td>
<td>12 (48.0)</td>
<td>28 (37.3)</td>
<td></td>
</tr>
<tr>
<td>Class I obesity, 30-34.9 kg/m²</td>
<td>9 (36.0)</td>
<td>29 (38.7)</td>
<td></td>
</tr>
<tr>
<td>Class II obesity, 35-39.9 kg/m²</td>
<td>3 (12.0)</td>
<td>14 (18.7)</td>
<td></td>
</tr>
<tr>
<td>Class III obesity, 40+ kg/m²</td>
<td>1 (4.0)</td>
<td>4 (5.3)</td>
<td></td>
</tr>
<tr>
<td>Self-monitoring of diet frequency, No. (%)</td>
<td></td>
<td></td>
<td>0.20</td>
</tr>
<tr>
<td>Daily</td>
<td>3 (12.0)</td>
<td>3 (4.0)</td>
<td></td>
</tr>
<tr>
<td>1-6 times/week</td>
<td>3 (12.0)</td>
<td>11 (14.7)</td>
<td></td>
</tr>
<tr>
<td>Less than 1 time/week</td>
<td>3 (12.0)</td>
<td>21 (28.0)</td>
<td></td>
</tr>
<tr>
<td>Never</td>
<td>16 (64.0)</td>
<td>40 (53.3)</td>
<td></td>
</tr>
<tr>
<td>Self-monitoring of weight frequency, No. (%)</td>
<td></td>
<td></td>
<td>0.14</td>
</tr>
<tr>
<td>Daily</td>
<td>5 (20.0)</td>
<td>6 (8.0)</td>
<td></td>
</tr>
<tr>
<td>1-6 times/week</td>
<td>10 (40.0)</td>
<td>25 (33.3)</td>
<td></td>
</tr>
<tr>
<td>Less than 1 time/week</td>
<td>6 (24.0)</td>
<td>35 (46.7)</td>
<td></td>
</tr>
<tr>
<td>Never</td>
<td>4 (16.0)</td>
<td>9 (12.0)</td>
<td></td>
</tr>
<tr>
<td>Type of smartphone, No. (%)</td>
<td></td>
<td></td>
<td>0.82</td>
</tr>
<tr>
<td>iPhone</td>
<td>13 (52.0)</td>
<td>41 (54.7)</td>
<td></td>
</tr>
<tr>
<td>Android</td>
<td>12 (48.0)</td>
<td>34 (45.3)</td>
<td></td>
</tr>
<tr>
<td>Health literacy score, mean (SD)</td>
<td>5.8 (0.6)</td>
<td>5.3 (1.1)</td>
<td>0.048</td>
</tr>
<tr>
<td>Health literacy, No. (%)</td>
<td></td>
<td></td>
<td>0.33</td>
</tr>
<tr>
<td>Limited health literacy</td>
<td>0 (0.0)</td>
<td>5 (6.7)</td>
<td></td>
</tr>
<tr>
<td>Adequate health literacy</td>
<td>25 (100.0)</td>
<td>70 (93.3)</td>
<td></td>
</tr>
<tr>
<td>Depression, No. (%)^</td>
<td>1 (4.0)</td>
<td>10 (13.3)</td>
<td>0.28</td>
</tr>
</tbody>
</table>

- ° indicates missing data.
MyFitnessPal app already on phone prior to study, No. (%)  
4 (16.0)  16 (21.3)  0.77

* Consistent Trackers defined as participants who self-monitored ≥6 days per week for at least 75% of weeks when asked to track (for Simultaneous arm: both consistent tracking of weight and diet in ≥9 of 12 weeks; for Sequential arm: consistent tracking of weight in ≥9 of 12 weeks and consistent tracking of diet in ≥6 of last 8 weeks; for App-Only arm: consistent tracking of diet in ≥9 of 12 weeks)

^Scores ≥10 on the PHQ-8 measure are indicative of clinically significant depression

4.3.5 Consistency in Self-Monitoring and Clinical Outcomes

As depicted in Figure 10, Consistent Trackers had greater weight change than Inconsistent Trackers at 1 month (mean difference [95%CI]: -1.11 kg [-2.12, -0.10]), 3 months (-2.42 kg [-3.80, -1.04]), and 6 months (-2.13 kg [-3.99, -0.27]). BMI change demonstrated similar patterns (see Table 16 for details). At both 3- and 6 months, significantly more Consistent Trackers achieved ≥3% and ≥5% weight loss than did Inconsistent Trackers (ps<.01; Table 16); for instance, 80% of Consistent Trackers had weight loss of at least 3% at 3 months, compared to only 24% of Inconsistent Trackers.

Figure 10: Mean Percent Weight Change Over Time between Consistent and Inconsistent Trackers
### Table 16: Outcomes of Consistent vs. Inconsistent Trackers

<table>
<thead>
<tr>
<th></th>
<th>Consistent Trackers* (n = 25)</th>
<th>Inconsistent Trackers (n = 75)</th>
<th>Between-Group Difference</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight change from baseline, mean (95% CI), kg</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 month</td>
<td>-2.04 (-2.89, 0.19)</td>
<td>-0.93 (-1.47, -0.39)</td>
<td>-1.11 (-2.12, -0.10)</td>
<td>0.03</td>
</tr>
<tr>
<td>3 months</td>
<td>-4.35 (-5.51, -3.19)</td>
<td>-1.93 (-2.68, -1.18)</td>
<td>-2.42 (-3.80, -1.04)</td>
<td>0.0007</td>
</tr>
<tr>
<td>6 months</td>
<td>-3.22 (-4.80, -1.65)</td>
<td>-1.09 (-2.08, -0.10)</td>
<td>-2.13 (-3.99, -0.27)</td>
<td>0.03</td>
</tr>
<tr>
<td>BMI change from baseline, mean (95% CI), kg/m²</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 month</td>
<td>-0.73 (-1.04, -0.43)</td>
<td>-0.34 (-0.53, -0.14)</td>
<td>-0.39 (-0.76, -0.03)</td>
<td>0.03</td>
</tr>
<tr>
<td>3 months</td>
<td>-1.57 (-1.97, -1.16)</td>
<td>-0.69 (-0.95, -0.42)</td>
<td>-0.88 (-1.37, -0.40)</td>
<td>0.0005</td>
</tr>
<tr>
<td>6 months</td>
<td>-1.47 (-2.02, -0.93)</td>
<td>-0.61 (-0.96, -0.27)</td>
<td>-0.86 (-1.50, -0.21)</td>
<td>0.009</td>
</tr>
</tbody>
</table>

**Proportion achieving weight loss of ≥3% of initial weight, No. (%)^**

|                          |                               |                               |                          |         |
| 3 months                 | 20 (80.0)                     | 18 (24.0)                     | --                       | <0.0001 |
| 6 months                 | 14 (58.3)                     | 19 (25.3)                     | --                       | 0.003   |

**Proportion achieving weight loss of ≥5% of initial weight, No. (%)^**

|                          |                               |                               |                          |         |
| 3 months                 | 12 (48.0)                     | 10 (13.3)                     | --                       | 0.0003  |
| 6 months                 | 13 (54.2)                     | 11 (14.7)                     | --                       | <0.0001 |

Note: One additional participant was omitted in analyses (App-Only arm) at 6-months due to becoming ineligible after the intervention period and before 6-months; Inconsistent Trackers is the reference group.

^Analyses assume that individuals who did not attend the given follow-up visit did not achieve clinically meaningful weight loss (≥3%)

* Consistent Trackers defined as participants who self-monitored ≥6 days per week for at least 75% of weeks when asked to track (for Simultaneous arm: both consistent tracking of weight and diet in ≥9 of 12 weeks; for Sequential arm: consistent tracking of weight in ≥9 of 12 weeks and consistent tracking of diet in ≥6 of last 8 weeks; for App-Only arm: consistent tracking of diet in ≥9 of 12 weeks)
4.3.6 Consistency in Self-Monitoring by Month 1

Almost half (47%) of participants did not consistently engage in the first month or beyond (Table 17). Approximately one-quarter (28%) of participants consistently self-monitored in the first month only. This group engaged highly in self-monitoring a median [IQR] of only 1.0 [2.5] weeks out of the 8 remaining weeks in the intervention.

Table 17: Median [IQR] Number of Weeks of High Engagement in Self-Monitoring, by Consistent vs. Not Consistent Trackers

<table>
<thead>
<tr>
<th></th>
<th>Consistent for 3 Months (n=25)</th>
<th>Consistent for 1st Month Only (n=28)</th>
<th>Not Consistent (n=47)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weeks 1-4</td>
<td>4.00 [0.00]</td>
<td>4.00 [1.00]</td>
<td>0.00 [1.00]</td>
</tr>
<tr>
<td>Weeks 5-12</td>
<td>8.00 [1.00]</td>
<td>1.00 [2.50]</td>
<td>0.00 [0.00]</td>
</tr>
<tr>
<td>Weeks 1-12</td>
<td>11.00 [2.00]</td>
<td>5.00 [2.50]</td>
<td>0.00 [2.00]</td>
</tr>
</tbody>
</table>

Weight change at 3 months was significantly greater for participants who were Consistent for 3 Months, compared to those who were Consistent for the 1st Month Only (mean difference [95%CI]: -1.65 kg [-3.28, -0.01]), but this pattern was no longer significant at 6 months (-1.82 kg [-4.03, 0.39]). Weight change between participants Consistent for the 1st Month Only and those Not Consistent did not significantly differ at any time point (ps>0.05; see Table 18 for details). As presented in Figure 11, there was a significant difference in achieving clinically meaningful weight loss between these three groups.
at 3 months, with 48% of participants in the Consistent for 3 Months group losing ≥5% of weight, compared to 21% in the Consistent for 1st Month Only group, and 9% in the Not Consistent group ($p=0.01$).

**Table 18: Between-Group Differences in Weight Change from Baseline (kg), by Three Categories of Consistency in Self-Monitoring (intent to treat)**

<table>
<thead>
<tr>
<th></th>
<th>Consistent for 3 Months vs. Not Consistent$^a$</th>
<th>Consistent for 3 Months vs. Consistent for 1st Month Only$^a$</th>
<th>Consistent for 1st Month Only vs. Not Consistent$^a$</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean (95% confidence interval)</td>
<td>p=0.17</td>
<td>p=0.02</td>
</tr>
<tr>
<td>1 month</td>
<td>-1.31 (-2.42, -0.21)</td>
<td>-0.82 (-2.00, 0.36)</td>
<td>-0.49 (-1.58, 0.60)</td>
</tr>
<tr>
<td></td>
<td>$p=0.02$</td>
<td>$p=0.17$</td>
<td>$p=0.37$</td>
</tr>
<tr>
<td>3 months</td>
<td>-3.02 (-4.55, -1.50)</td>
<td>-1.65 (-3.28, -0.01)</td>
<td>-1.38 (-2.89, 0.14)</td>
</tr>
<tr>
<td></td>
<td>$p=0.0001$</td>
<td>$p=0.048$</td>
<td>$p=0.08$</td>
</tr>
<tr>
<td>6 months</td>
<td>-2.35 (-4.40, -0.31)</td>
<td>-1.82 (-4.03, 0.39)</td>
<td>-0.53 (-2.55, 1.49)</td>
</tr>
<tr>
<td></td>
<td>$p=0.02$</td>
<td>$p=0.11$</td>
<td>$p=0.60$</td>
</tr>
</tbody>
</table>

Note: One additional participant was omitted in analyses (App-Only arm) at 6-months due to becoming ineligible after the intervention period and before 6-months.

$^a$The second group listed is the reference group
Figure 11: Proportion of Participants who Achieved Clinically Meaningful Weight Loss at 3 Months and 6 Months, by 3 Categories of Consistent Self-Monitoring

Note: Overall $p$-value: $<0.0001$; $p$-value at $\geq3\%$ weight loss$=0.0003$; $p$-value at $\geq5\%$ weight loss$=0.01$

4.4 Discussion

We found that one quarter of participants consistently engaged in self-monitoring via a commercial app throughout the 12-week GoalTracker intervention. This study is the first weight loss intervention to examine consistency in self-monitoring via a commercial mobile app. As such, this addresses an important gap given the potential for commercial apps to deliver portable, free, and engaging self-monitoring tools for weight loss with instantaneous tailored feedback.

Past trials have examined consistency via other digital health strategies. For example, in a web-based study that used a similar operationalization of high consistency (≥75% of weeks with at least 3 self-monitoring entries per week), Hutchesson et al. found that individuals who were most consistent had the greatest amount of weight loss at 12 weeks.29 Similar patterns were found in other digital
health trials, including a study that used interactive voice response (IVR) for self-monitoring behavioral goals among those who consistently tracked for 80% of week,\textsuperscript{195} a study where body weight was tracked on WiFi-enabled scales for over 6 days per week for the majority of weeks,\textsuperscript{31} and a pilot trial with a researcher-designed app for self-monitoring diet daily for the first week then ad libitum.\textsuperscript{30} Together with the current trial’s findings, technology-based self-monitoring modalities demonstrate that consistency and weight loss go hand-in-hand.

However, given the vastly different operationalizations of self-monitoring consistency across behavioral weight loss trials, we are unable to make direct comparisons with other trials as to whether the standalone GoalTracker intervention resulted in a comparable proportion of participants who consistently self-monitored. For instance, while we operationalized Consistent Trackers as individuals who completed all required self-monitoring entries at least 6 days a week for $\geq 75\%$ of weeks of the intervention, prior trials defined consistency in less rigorous terms as $\geq 3$ days per week or once per week, and earlier studies defined consistency as what is now referred to as frequency (i.e., the number of days of self-monitoring entries).\textsuperscript{24,196} Direct comparisons are also complicated to make because the number of days participants are instructed to track varies (e.g., daily, a few days per week, weekly, or optional tracking). In fact, to our knowledge, the current study is the first to investigate consistency in self-monitoring when individuals are instructed to self-monitor diet \textit{every day}. 

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We found that marital status, race/ethnicity, and health literacy were baseline predictors of consistency in self-monitoring. These findings are in line with past research that demonstrated that individuals who are married or living with a partner,\textsuperscript{188} those who are white,\textsuperscript{31,155} or individuals with adequate health literacy\textsuperscript{197} engage more in self-monitoring. Given that no participants with limited health literacy were Consistent Trackers in our study, more simplified or abbreviated self-monitoring approaches should be investigated for this population. Further, our trial did not lend support for other sociodemographic and behavioral characteristics that have been found to be predictors in past trials, including gender,\textsuperscript{189} age,\textsuperscript{188,195} education,\textsuperscript{188,195} income,\textsuperscript{188} BMI,\textsuperscript{188} and previous self-weighing frequency,\textsuperscript{188} though this is consistent with findings from other trials that also did not find any of these predictors.\textsuperscript{30,31} It is possible that the sample size in our study precluded detection of a small but significant effect.

Importantly, Consistent Trackers lost twice as much weight as Inconsistent Trackers at 1- and 3 months, and almost 3 times as much weight at 6 months. Further, over 3 times as many Consistent Trackers than Inconsistent Trackers achieved clinically meaningful weight loss at end of treatment. These findings demonstrate that engagement and weight loss are highly linked in a standalone commercial app-based intervention – a platform that could serve as a highly scalable strategy for individuals with overweight or obesity who are seeking to lose weight. Further, the current study provides a window into how much weight loss is
expected if individuals are adherent to self-monitoring recommendations in this lower intensity intervention (i.e., ~4 kg by 3 months), which could be useful for providers and patients alike to understand upfront what to expect before using self-monitoring tools for weight loss. In light of these promising findings, we understand that standalone interventions are not a good fit for everyone seeking to lose weight.

To promote scalability and focus efforts on assessing a standalone digital health treatment for weight loss, GoalTracker had no in-person skills training component nor telephone-based calls. However, we recognize that individuals may benefit more from self-monitoring when weekly counseling sessions are included or there exists social support from peers in treatment.185,191,198

Further, for promoting efficient treatments, it is useful to determine if weight loss success varies depending on whether high consistency in self-monitoring is maintained beyond the first month of treatment. We found that roughly half of participants engaged consistently in the first month, and those who maintained highly consistent had greater weight loss at 3 months than did individuals who no longer consistently engaged in self-monitoring after the first month. In fact, over twice as many of the long-term Consistent Trackers achieved 5% weight loss at 3 months, compared to Consistent Trackers for the 1st Month Only. It remains unknown why this latter group decreased engagement over time, given that their weight loss at 1 month did not differ from those who consistently tracked all 3 months. Because we did not randomize participants to different durations of
consistent self-monitoring, (e.g., all 3 months vs. 1st month only) we are unable to make causal conclusions. Nevertheless, we suspect that continuing to engage in dietary self-monitoring until a short-term weight loss goal is met (e.g., 5% of initial weight) will promote better outcomes, because individuals will remain highly aware of how their eating behaviors impact their weight, which in turn could reinforce self-regulatory skills and self-efficacy for making healthy dietary choices – consistent with self-regulatory theories.20,47

Strengths of this study include the collection of objective self-monitoring data from MyFitnessPal, a fully-powered randomized trial design, and collection of objective weight at 1 month, which is seldom done. We recognize limitations of having to rely on self-reported weights at 6 months and no follow-up beyond 6 months. Having a longer follow-up may allow more time to see differential effects materialize between treatment arms. In addition, week 12 engagement rates may be artificially low because some participants completed their evaluation visit a few days prior to the official end of the 12th week, which likely prompted them to stop tracking.

Because our three treatment arms varied in what we asked participants to self-monitor, the sequence of self-monitoring, and the receipt of additional behavior change techniques (lessons, action plans, tailored feedback), we were not able to isolate the effect of self-monitoring weight versus self-monitoring diet. Future dismantling studies are needed that isolate different behaviors or behavioral
outcomes being self-monitored so that determinations can be made about whether consistency in self-monitoring matters more for certain types of self-monitoring.

4.5 Conclusion

In a standalone, remotely delivered intervention, a quarter of participants consistently engaged in self-monitoring, and Consistent Trackers produced significantly greater weight loss than everyone else. In fact, tracking consistently resulted in the vast majority or individuals achieving clinically meaningful weight loss whereas never tracking consistently resulted in few individuals doing so. In clinical practice, providers should encourage weight loss-seeking patients who own a smartphone to track in a commercial app (any combination of body weight and dietary intake) all or almost all days per week, every week, to allow for the greatest chance of success with weight loss.
5. Early Weight Loss in a Standalone mHealth Intervention Predicting Treatment Success

5.1 Introduction

Behavioral weight loss treatment delivered via technology are efficacious, with roughly 25-44% of participants achieving clinically significant weight loss of 5%113,114,113,198; these rates tend to be higher with counseling,92,117,123,124 but still do not typically exceed 50% of participants. The evidence repeatedly points to early weight loss as a predictor of clinically meaningful weight loss.43-45 In fact, several studies have used early outcomes as a trigger in stepped-care behavioral interventions to implement rescue efforts for individuals not responding early to obesity treatment.43,199-202

A 12-week internet-based weight loss study by Unick et al. found a strong positive relation of early weight loss at 1-month predicting weight loss at 3-, 6-, and 12-months. However, no mobile health (“mHealth”) studies have examined the ability of early weight loss success to predict longer term weight loss. Given the increasing evidence-base for obesity treatment delivered via mHealth strategies, research is needed that examines whether early weight loss success predicts future weight loss and intervention engagement.

We conducted the GoalTracker trial to compare self-monitoring strategies for weight loss in a mobile application (“app”) - based intervention. In intent-to-treat analyses, we found no differences between treatment arms in weight change at 3
months (range: -2.4 kg to -2.7 kg) or 6 months (range: -1.88 kg to -3.05 kg). Further, we found that self-monitoring engagement of both weight and diet were high, with no difference between arms, and that frequency of self-monitoring was positively associated with weight loss.

The current study aims to examine early weight loss and its predictive ability in the GoalTracker trial. We hypothesized that early weight loss at 1 month would predict greater weight loss at 3 months and 6 months, as well as greater frequency of completed action plans and days of self-monitoring both weight and diet.

5.2 Methods

GoalTracker was a randomized controlled trial designed to promote weight loss via a 12-week standalone intervention delivered via a smartphone app. Details of the study design and outcomes have been described previously (M.L.P., unpublished data, June 2018). Briefly, participants (N=105) were randomized to one of three treatment arms: (1) a Simultaneous self-monitoring arm (n=35) in which participants simultaneously tracked body weight and dietary intake daily, and received weekly lessons, action plans, tips, and tailored feedback via email, (2) a Sequential self-monitoring arm (n=35) that included all of the same components but that delayed diet tracking until week 5 in order to promote mastery and self-efficacy, and (3) an App-Only arm (n=35) in which participants tracked diet daily but did not receive additional behavior change techniques.
Evaluation visits occurred at baseline, 1 month, and 3 months. Compensation included Amazon electronic gift cards of $12, $6, and $6, respectively, with a $5 bonus for completing dietary measures. At 6 months, self-reported weight was collected via email or text message. Written informed consent was collected at baseline. The study was conducted between April 2017 and March 2018 and the Duke University Institutional Review Board approved study procedures.

5.2.1 Participants

Participants with a 1-month weight and who remained eligible during the intervention period were included in this secondary analysis (n=84) – an approach that has been used previously. Briefly, participants were deemed eligible if they were 21-65 years with a BMI 25.0-45.0 kg/m², owned an iPhone or Android smartphone, had access to a bathroom scale, had English fluency, and had no medical or psychiatric contraindications that may necessitate more intensive treatment (e.g., cancer, uncontrolled hypertension, eating disorder, pregnancy or <12 months postpartum).

5.2.2 Intervention

All three treatment arms used MyFitnessPal – a free and popular commercial app for self-monitoring. We provided each participant with a goal to lose 5% of initial body weight by 12 weeks, a tailored weekly weight loss goal ranging from 0.5 lbs to 1.5 lbs, and a tailored daily calorie goal. In-app daily push-reminders were programmed to be sent if tracking had not occurred by 7:00pm. Participants in both
the Sequential and Simultaneous arms received additional behavior change techniques via email each week: lessons on a nutrition or behavior change strategies, corresponding online action plans, tips on using the app (e.g., how to scan a barcode on a food package), and tailored feedback on weight loss progress and goal achievement.

The Sequential arm differed from the Simultaneous arm in that only body weight was tracked in the first month to promote mastery and self-efficacy, before adding diet tracking.

5.2.3 Measures

5.2.3.1 Anthropometric Data

We asked participants to remove heavy clothing and shoes prior to measurement of anthropometrics. We measured body weight using a calibrated electronic scale (SECA 876). At 6 months, we collected self-reported body weight, asking participants to send a photo with their feet on the scale displaying the value in either kg or lbs. Height was measured at baseline to the nearest 0.1 cm using a calibrated, wall-mounted stadiometer (SECA 222). We calculated BMI as the body weight in kilograms divided by the height squared in meters (kg/m²). We assessed the proportion of participants at 3 months and at 6 months who achieved weight loss of ≥3% and ≥5% from baseline, thresholds used to define clinically meaningful weight loss.⁸,¹²
5.2.3.2 Baseline Participant Characteristics

As reported previously, (M.L.P., unpublished data, June 2018) we collected sociodemographic and clinical characteristics at baseline. Health literacy was measured at baseline using the Newest Vital Sign, a 6-item screening measure that asks individuals to read and interpret information on a nutrition label; limited health literacy was defined as scores of 0-3, while adequate health literacy was defined as scores of 4-6.

5.2.3.3 Intervention Engagement

We collected objective self-monitoring data from MyFitnessPal using Fitbit’s API. We examined the percentage of days that self-monitoring entries were recorded during the first month (i.e., days 1-28), during the second and third months (i.e., days 29-83), and during the entire 12-week intervention (the denominator included only days instructed to track a given item). Entries were considered complete if they contained ≥800 kcal/day. Through objective online survey data, we also assessed percentage of action plans completed during the intervention.

5.2.4 Statistical Analysis

Given that weight change at 1 month and at 3 months did not differ between treatment arms (M.L.P., unpublished data, June 2018), we collapsed data across treatment arms in the current analysis. Five participants who became ineligible during the trial were excluded from analysis (pregnancy: n=3; cancer diagnosis:
n=1; previously undisclosed eating disorder: n=1). Among those remaining, 84 participants had a 1-month weight and were included, which consisted of 28 in each treatment arm. In line with previous behavioral weight loss research, we categorized participants into early responders (i.e., those who achieved weight loss ≥2% of initial weight at 1 month) and early nonresponders (i.e., those with <2% weight loss at 1 month). In exploratory analyses, we also assessed achievement of ≥1% weight loss, as has been done previously. We used chi-square tests and analysis of variance (ANOVA) to examine differences in baseline characteristics and 1-month attrition by early weight loss status. Fisher’s exact tests were used with small cell counts.

Linear regression and Pearson correlation were used to examine the association between 1-month percent weight loss and percent weight loss at 3- and 6-months, controlling for baseline weight. For 6-month weight values sent via photo, we subtracted 0.172 kg (.4 lbs) to account for participants holding a device on the scale to take the photo. To account for underestimation of self-reported weights at 6 months, we used a regression model from Jain et al. 2010 to adjust for age, gender, and race/ethnicity for values without photos.

We used linear mixed models with random intercepts and slopes and restricted maximum likelihood estimates to examine changes in percent weight over time, by early weight loss status. Logistic regression with firth correction was used to examine the odds of achieving clinically significant weight loss (i.e., ≥3% or ≥5%).
at 3- or 6- month weight loss by early weight loss status. To examine whether early weight loss success correctly classified participants’ later weight loss success, we examined the following:

True Negative (achieved weight loss threshold at month 1, and achieved weight loss threshold at 3 months)

False Negative (achieved weight loss threshold at month 1, but failed to achieve weight loss threshold at 3 months)

False Positive (failed to achieve weight loss threshold at month 1, but achieved weight loss threshold at 3 months)

True Positive (failed to achieve weight loss threshold at month 1, and failed to achieve weight loss threshold at 3 months)

Sensitivity (the proportion of true nonresponders correctly identified as nonresponders; True Positive / (True Positive + False Negative))

Specificity (the proportion of true responders correctly identified as responders; True Negative / (True Negative + False Positive))

Positive Predictive Value (True Positive / (True Positive + False Positive))

Negative Predictive Value (True Negative / (True Negative + False Negative))

Given the non-normal distributions of intervention engagement data, we reported medians and interquartile ranges (IQR) and used the Wilcoxon Mann-Whitney U test to examine differences by early weight loss status. For each time interval, only participants who were instructed to self-monitor an item during that
period were included; for instance, App-Only participants were excluded from weight tracking data analyses since they were never instructed to track weight. We also conducted a sensitivity analysis with all participants who completed the 1-month visit (n=84) with the assumption that participants who missed the 3-month visit (n=11) or 6-month time point (n=13) did not achieve a clinically significant weight loss. \( P < .05 \) was considered statistically significant. Analyses were conducted using SAS 9.4 (SAS Institute, Cary, NC).

### 5.3 Results

Baseline characteristics and main outcomes have been described in detail previously (M.L.P., unpublished data, June 2018). The 84 participants in the current analysis were predominantly female (81%) and college educated (85%), with a mean (SD) age of 43.7 years (11.6) and weight of 89.8 kg (16.8). A majority of the sample had obesity (58%) and had adequate health literacy (95%). Roughly one-third (36%; n=30) of participants were categorized as early weight loss responders (i.e., achieving \( \geq 2\% \) weight loss at 1 month), while 64% (n=54) were early nonresponders. Baseline characteristics did not differ by early weight loss status (see Table 19). Attrition at the 1-month visit differed by racial/ethnic background \( (p=.03) \) and age \( (p=0.04) \); 10% of non-Hispanic white participants missed this visit, compared to 27% of racial/ethnic minority participants, and participants who were younger were more likely to miss the 1-month visit (mean 37.2 years among those who missed vs. 43.7 years among those who attended this visit).
Table 19: Baseline Characteristics by 1-Month Weight Loss

<table>
<thead>
<tr>
<th></th>
<th>Total (N = 84)</th>
<th>Early Responders ≥2% at 1-Month (n = 30)</th>
<th>Early Nonresponders &lt;2% at 1-Month (n = 54)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age, mean (SD), y</strong></td>
<td>43.7 (11.6)</td>
<td>43.0 (12.3)</td>
<td>44.1 (11.4)</td>
<td>0.66</td>
</tr>
<tr>
<td><strong>Gender, No. (%)</strong></td>
<td></td>
<td></td>
<td></td>
<td>0.78</td>
</tr>
<tr>
<td>Male</td>
<td>16 (19.1)</td>
<td>5 (16.7)</td>
<td>11 (20.4)</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>68 (81.0)</td>
<td>25 (83.3)</td>
<td>43 (79.6)</td>
<td></td>
</tr>
<tr>
<td><strong>Marital status, No. (%)</strong></td>
<td></td>
<td></td>
<td></td>
<td>0.42</td>
</tr>
<tr>
<td>Married or living w/ partner</td>
<td>57 (67.9)</td>
<td>22 (73.3)</td>
<td>35 (64.8)</td>
<td></td>
</tr>
<tr>
<td>Not married or living w/ partner</td>
<td>27 (32.1)</td>
<td>8 (26.7)</td>
<td>19 (35.2)</td>
<td></td>
</tr>
<tr>
<td><strong>Race/ethnicity, No. (%)</strong></td>
<td></td>
<td></td>
<td></td>
<td>0.46</td>
</tr>
<tr>
<td>Non-Hispanic White</td>
<td>60 (71.4)</td>
<td>22 (73.3)</td>
<td>38 (70.4)</td>
<td></td>
</tr>
<tr>
<td>Non-Hispanic Black</td>
<td>16 (19.1)</td>
<td>4 (13.3)</td>
<td>12 (22.2)</td>
<td></td>
</tr>
<tr>
<td>Hispanic (all races)</td>
<td>1 (1.2)</td>
<td>0 (0.0)</td>
<td>1 (1.9)</td>
<td></td>
</tr>
<tr>
<td>Non-Hispanic other</td>
<td>7 (8.3)</td>
<td>4 (13.3)</td>
<td>3 (5.6)</td>
<td></td>
</tr>
<tr>
<td><strong>Education, No. (%)</strong></td>
<td></td>
<td></td>
<td></td>
<td>0.40</td>
</tr>
<tr>
<td>Less than college graduate</td>
<td>13 (15.5)</td>
<td>6 (20.0)</td>
<td>7 (13.0)</td>
<td></td>
</tr>
<tr>
<td>College graduate or above</td>
<td>71 (84.5)</td>
<td>24 (80.0)</td>
<td>47 (87.0)</td>
<td></td>
</tr>
<tr>
<td><strong>Employment status, No. (%)</strong></td>
<td></td>
<td></td>
<td></td>
<td>0.07</td>
</tr>
<tr>
<td>Employed, full-time</td>
<td>55 (65.5)</td>
<td>15 (50.0)</td>
<td>40 (74.1)</td>
<td></td>
</tr>
<tr>
<td>Employed, part-time</td>
<td>11 (13.1)</td>
<td>6 (20.0)</td>
<td>5 (9.3)</td>
<td></td>
</tr>
<tr>
<td>Not employed</td>
<td>18 (21.4)</td>
<td>9 (30.0)</td>
<td>9 (16.7)</td>
<td></td>
</tr>
<tr>
<td><strong>Annual household income, No. (%)</strong></td>
<td></td>
<td></td>
<td></td>
<td>0.32</td>
</tr>
</tbody>
</table>

133
<table>
<thead>
<tr>
<th>Income Range</th>
<th>Weight, mean (SD), kg</th>
<th>Body mass index, mean (SD), kg/m²</th>
<th>BMI category, No. (%)</th>
<th>Prediabetes, No. (%)</th>
<th>Limited health literacy, No. (%)</th>
<th>MyFitnessPal app already on phone prior to study, No. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>$0-$49,999</td>
<td>19 (23.5)</td>
<td>31.7 (4.5)</td>
<td>35 (41.7)</td>
<td>7 (8.3)</td>
<td>4 (4.8)</td>
<td>17 (20.2)</td>
</tr>
<tr>
<td>$50,000-$99,999</td>
<td>30 (37.0)</td>
<td>31.7 (4.3)</td>
<td>32 (38.1)</td>
<td>4 (13.3)</td>
<td>1 (3.3)</td>
<td>4 (13.3)</td>
</tr>
<tr>
<td>$100,000 or greater</td>
<td>32 (39.5)</td>
<td>31.8 (4.7)</td>
<td>13 (15.5)</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
<td>13 (24.1)</td>
</tr>
</tbody>
</table>

### 5.3.1 Weight Change

Percent weight change at 1 month was positively associated with percent weight change at 3 months ($r=0.77$) and at 6 months ($r=0.51$), with 58% and 25% of the variance accounted for by 1-month percent weight change, respectively. For every 1% weight loss at 1 month, there is a 1.50% and 1.38% increase in weight loss at 3 months and 6 months, respectively (Table 20).
Table 20: Prediction of Percent Weight Loss at Follow-up from Percent Weight Loss at 1 Month, Controlling for Baseline Weight

<table>
<thead>
<tr>
<th></th>
<th>B (regression coefficient)</th>
<th>F</th>
<th>$R^2$</th>
<th>Adj $R^2$</th>
<th>P-value</th>
<th>Pearson correlation (P-value)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight loss at 3 months (n=73)</td>
<td>1.50</td>
<td>50.84</td>
<td>0.59</td>
<td>0.58</td>
<td>&lt;0.0001</td>
<td>0.77 (&lt;0.0001)</td>
</tr>
<tr>
<td>Weight loss at 6 months (n=71)</td>
<td>1.38</td>
<td>12.65</td>
<td>0.27</td>
<td>0.25</td>
<td>&lt;0.0001</td>
<td>0.51 (&lt;0.0001)</td>
</tr>
</tbody>
</table>

As depicted in Figure 12: Mean Percent Weight Change Over Time by Early Weight Loss Status, early responders had significantly greater percent weight loss at 1 month, 3 months, and 6 months, compared to early nonresponders ($p$s<.0001; see mean values in Table 21). The odds of achieving ≥3% and ≥5% weight loss at 3 months were 21.9 (95% CI: 5.83, 81.99) and 9.7 (95% CI: 3.02, 31.34) times higher, respectively, among early responders, compared to early nonresponders. Similarly, at 6 months, the odds of achieving ≥3% and ≥5% weight loss were significantly greater (6-7 times higher) among early responders than early nonresponders (Table 22).
Most (89%) participants who were early responders went on to achieve ≥3% weight loss at 3 months, compared to 24% of those who were early nonresponders; In terms of ≥5% weight loss at 3 months, 57% of early responders and 11% of early nonresponders achieved this threshold (see Figure 13). Similar patterns were observed at 6 months. Sensitivity, specificity, positive predictive value, and negative predictive value in predicting achievement of clinically significant weight loss at 3 months and 6 months are presented in Table 23. Sensitivity was best with a 1-month threshold of ≥2% weight loss (range of 77% to 92%), while specificity was best with a ≥1% weight loss threshold (range of 83% to 91%). In a sensitivity analysis of all participants who completed the 1-month visit regardless of retention status at the 3-month or 6-month time point (n=84), the predictive ability of early weight loss was similar, with slightly higher positive predictive value and sensitivity, and slightly lower negative predictive value (see Table 24 and Table 25).
5.3.2 Intervention Engagement

As shown in Table 21, early responders completed more action plans than did early nonresponders ($p=0.02$), and self-monitored body weight and dietary intake more frequently ($p<0.01$). For instance, during the 12-week intervention, early responders tracked weight 90% of days and tracked diet 83% of day, compared to 74% and 46% of days, respectively, among early nonresponders. In the first month, early responders tracked weight more often than did early nonresponders (96% vs. 86% of days), as well as diet (100% vs. 79% of days).
Table 21: Outcomes of Early Responders vs. Early Nonresponders

<table>
<thead>
<tr>
<th></th>
<th>Early Responders (≥2% at 1 month) (n=30)</th>
<th>Early Nonresponders (&lt;2% at 1 month) (n=54)</th>
<th>P-value of between group difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>% weight change from baseline, mean (95% CI), kg</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 month</td>
<td>-3.37% (-3.88%, -2.85%)</td>
<td>-0.43% (-0.81%, -0.04%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>3 months</td>
<td>-5.93% (-6.82%, -5.03%)</td>
<td>-1.45% (-2.15%, -0.75%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>6 months</td>
<td>-5.91% (-7.33%, -4.48%)</td>
<td>-1.28% (-2.37%, -0.19%)</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

Intervention engagement, median [IQR]

| % action plans completed* | 72.7% [27.3%] | 45.5% [72.7%] | 0.02 |
| % of days tracked weight* |                                           |                                            |     |
| Weeks 1-4                | 96.4% [10.7%] | 85.7% [42.9%] | 0.0018 |
| Weeks 5-12               | 92.7% [29.1%] | 67.3% [76.4%] | 0.0063 |
| Weeks 1-12               | 90.4% [19.3%] | 73.5% [57.8%] | 0.0027 |

% of days tracked diet

|                      |                                           |                                            |     |
| Weeks 1-4^            | 100% [5.4%]                               | 78.6% [71.4%]                              | 0.0006 |
| Weeks 5-12            | 73.6% [50.9%]                             | 27.3% [78.2%]                              | 0.0027 |
| Weeks 1-12~           | 82.5% [34.3%]                             | 46.4% [66.9%]                              | 0.008  |

* among participants in the Simultaneous and Sequential arms only (n=56) since App-Only arm not asked to track body weight or complete action plans

^ among participants in the Simultaneous and App-Only arms only (n=56) since Sequential arm not asked to track dietary intake during this period

~ among participants in the Simultaneous and App-Only arms only (n=56) since Sequential arm not asked to track dietary intake during the entire period
Table 22: Odds (95% Confidence Interval) of Achieving 3% or 5% Weight Loss

<table>
<thead>
<tr>
<th></th>
<th>Achieved 3% Weight Loss at Month 3</th>
<th>Achieved 5% Weight Loss at Month 3</th>
<th>Achieved 3% Weight Loss at Month 6</th>
<th>Achieved 5% Weight Loss at Month 6</th>
</tr>
</thead>
<tbody>
<tr>
<td>Early nonresponders</td>
<td>1.0 (ref)</td>
<td>1.0 (ref)</td>
<td>1.0 (ref)</td>
<td>1.0 (ref)</td>
</tr>
<tr>
<td>(≤2% at month 1)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Early responders</td>
<td><strong>21.86</strong> (5.83, 81.99)</td>
<td><strong>9.72</strong> (3.02, 31.34)</td>
<td><strong>6.26</strong> (2.14, 18.28)</td>
<td><strong>6.93</strong> (2.33, 20.62)</td>
</tr>
<tr>
<td>(≥2% at month 1)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Notes: Bold indicates statistically significant result compared to reference group. In 3 month analyses: n=73; in 6 month analyses: n=71.

Figure 13: Proportion of Participants Achieving Clinically Significant Weight Loss, by Early Weight Loss Status
Table 23: Sensitivity and Specificity in Early Weight Loss Identifying 3% or 5% Weight Loss

<table>
<thead>
<tr>
<th>Met 1 Month Weight Loss Threshold</th>
<th>True Negative</th>
<th>False Negative</th>
<th>False Positive</th>
<th>True Positive</th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>Positive Predictive Value</th>
<th>Negative Predictive Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Achieving ≥ 3% at 3 months</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
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<td>10</td>
<td>8</td>
<td>37</td>
<td>78.7%</td>
<td>66.7%</td>
<td>82.2%</td>
<td>61.5%</td>
</tr>
</tbody>
</table>

Notes: in 3 month analyses: n=73; in 6 month analyses: n=71.

Table 24: Sensitivity Analysis: Odds (95% Confidence Interval) of Achieving 3% or 5% Weight Loss

<table>
<thead>
<tr>
<th>Achieved 3% Weight Loss at Month 3</th>
<th>Achieved 5% Weight Loss at Month 3</th>
<th>Achieved 3% Weight Loss at Month 6</th>
<th>Achieved 5% Weight Loss at Month 6</th>
</tr>
</thead>
<tbody>
<tr>
<td>Early nonresponders (&lt;2% at month 1)</td>
<td>1.0 (ref)</td>
<td>1.0 (ref)</td>
<td>1.0 (ref)</td>
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<tr>
<td>Early responders (≥2% at month 1)</td>
<td>17.54 (5.59, 55.04)</td>
<td>10.24 (3.27, 32.09)</td>
<td>5.21 (1.98, 13.70)</td>
</tr>
</tbody>
</table>

Notes: Bold indicates statistically significant result compared to reference group; N=84.
Table 25: Sensitivity Analysis: Sensitivity and Specificity in Early Weight Loss Identifying 3% or 5% Weight Loss

<table>
<thead>
<tr>
<th>Met 1 Month Weight Loss Threshold</th>
<th>True Negative</th>
<th>False Negative</th>
<th>False Positive</th>
<th>True Positive</th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>Positive Predictive Value</th>
<th>Negative Predictive Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Achieving ≥ 3% at 3 months</td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
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<td>≥ 1%</td>
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<td>83.3%</td>
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<td>83.3%</td>
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<tr>
<td>Achieving ≥ 5% at 3 months</td>
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<td>≥ 1%</td>
<td>19</td>
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<td>90.7%</td>
<td>53.3%</td>
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<tr>
<td>Achieving ≥ 3% at 6 months</td>
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<td>66.7%</td>
<td>85.2%</td>
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</tbody>
</table>

Note: N=84.
5.4 Discussion

On average, we found that in a standalone app-based intervention focused on self-monitoring, early responders met their goal of losing 5% of initial weight by 3 months, and maintained this clinically significant weight loss at 6 months. In contrast, over 8 in 10 participants who did not respond early to treatment were not successful at achieving 5% weight loss at 3 months or at 6 months. These findings illustrate the importance of early weight loss in promoting clinically meaningful weight loss at the end of treatment and beyond. These findings are consistent with past studies of behavioral interventions for weight loss, but extend previous findings to digital health interventions. The GoalTracker trial is the first study to demonstrate this relation in the context of a standalone mHealth intervention, which holds promise as a less resource-intensive and more scalable initial intervention strategy in stepped-care approaches.

Interestingly, the GoalTracker trial found very similar findings as an internet-based weight loss intervention that had the same operationalization of early weight loss; both trials found that early responders achieved roughly 6% weight loss at 3 months and 6 months while early nonresponders maintained less than 2% weight loss, which further strengthens the evidence of the predictive nature of the 2% weight loss threshold at 1 month. While later time points of assessing early weight loss (e.g., in months 2 and 3) are predictive of overall weight loss, past trials have found that intervening with nonresponders at 3 months post-randomization
does not translate to improved outcomes,\textsuperscript{200,206} perhaps reflecting that waiting longer to intervene may not be effective among individuals who feel discouraged about poor early treatment response. No gold standard exists for when and at what threshold to intervene with nonresponders in behavioral weight loss interventions; it is possible that 1 month would be an advantageous time point at which to intervene, though no study has experimentally tested it yet.

Engagement likely drives early weight loss success. We found that intervention engagement differed by early weight loss status, which is consistent with findings in past trials.\textsuperscript{41,194,204} After the first month, early responders tracked diet almost three times as frequently, which may suggest satisfaction with their initial weight loss. Our findings are consistent with those of Unick et al., who also found that self-monitoring engagement in the first month of treatment is associated with early weight loss success.\textsuperscript{194} These findings highlight the importance of early engagement, though our study design precludes the determination of a causal relationship.

A strength of our study was the collection of objective self-monitoring data from a commercial mobile app, as well as objective action plan completion data. A limitation of our data is that the smaller sample size yielded wide confidence intervals in the odds of achieving 3\% or 5\% weight loss by early response status; future studies with larger sample sizes and longer follow-up should replicate these analyses. Given that the current study was a secondary analysis of a randomized
trial, we were not able to causally determine that greater intervention engagement and clinically significant weight loss at 3 and 6 months were caused by early weight loss success; it is possible that a third factor (e.g., a participant’s personality, stress level, nutrition knowledge) was at play. Further, due to logistical constraints, we were unable to collect in-person weights at 6 months, and instead relied on self-reported weights. It is also possible that asking participants to attend a 1-month visit with study staff may have impacted outcomes, given the potential for performance to improve when being evaluated (i.e., the Hawthorne effect).\textsuperscript{207} Future studies should examine whether capturing weights solely via cellular- or WIFl-enabled smart scales would change the predictive nature of early weight loss response. Likewise, while past studies of behavioral interventions have examined predictors of overall weight loss,\textsuperscript{45,208} future studies are needed to determine predictors of early weight loss.

\textbf{5.5 Conclusion}

Overall, we found that early weight loss success in a standalone smartphone app-based intervention predicted clinically significant weight loss and intervention engagement among adults with overweight or obesity. These findings highlight the utility of keeping individuals engaged in the first month of treatment, which may serve as a point at which to intervene among early nonresponders in future trials. Having upfront discussions of the importance of early weight loss as well as discussing realistic weight loss expectations in standalone interventions may help
reduce nonengagement or dropout. In clinical settings, measuring and discussing patients’ early weight loss response would allow providers and patients to make informed decisions together about whether to continue, stop, or alter treatment.
6. Discussion

6.1 Summary of Findings

This dissertation aimed to employ a novel strategy for attenuating the decline in self-monitoring engagement commonly seen in behavioral weight loss treatment. To examine this question, we developed a randomized controlled trial that compared three theoretically- and empirically-supported self-monitoring strategies for weight loss over the course of a 12-week intervention and at 6-month follow-up. We studied these effects in the context of a standalone commercial app-based intervention, which has high dissemination potential, but has been infrequently tested in fully-powered, randomized weight loss trials. Below, we address each specific aim, review strengths and limitations, and consider research and clinical implications.

6.1.1 Aim 1

The GoalTracker trial addressed several gaps in the behavioral weight loss literature, including whether a sequential self-monitoring approach, which also includes additional behavior change components such as weekly skills training and tailored feedback, performs better than an “off-the-shelf” app. Both arms lost significant weight at 3- and 6 months, with no difference between arms, nor differences in the proportion of participants achieving clinically significant weight loss of ≥3% or ≥5%.
These findings illustrate that a standalone app-based intervention is efficacious for weight loss, and that there was no added benefit of empirically-supported behavior change components of weekly action plans, behavioral lessons, and tailored feedback, over-and-above the core intervention. However, it is likely that the specific instruction to track diet daily, along with programming of an in-app reminder to track, and provision of a specific weight loss goal contributed meaningfully to treatment success, as these have been demonstrated to be key components of eHealth interventions in a recent review.\textsuperscript{159} Indeed, a past study by Laing et al. using the same app for self-monitoring diet but that did not include these components resulted in poor app engagement and limited weight loss.\textsuperscript{34} Thus, the App-Only arm’s better-than-expected weight loss holds promise as a lower intensity intervention approach that is scalable.

6.1.2 Aim 2

We also examined whether this sequential self-monitoring approach produces greater weight loss than an intervention that simultaneously self-monitors weight and diet and receives identical behavior change components. Similar to results from Aim 1, we found a significant decrease in weight for the Simultaneous arm at 3- and 6 months, with no difference between arms. Given a trend of the Simultaneous arm continuing to lose weight at 6 months while the other arms slightly gained weight, it remains unknown whether an extended length of follow-up would eventually reveal significant differences between arms. These findings add to
the limited weight loss literature comparing Sequential versus Simultaneous interventions that are delivered via digital health modalities, and confirm recent research by Spring et al. demonstrating that success in an mHealth treatment can be achieved with either Simultaneous or Sequential interventions.65

6.1.3 Aim 3

We also sought to examine whether self-monitoring engagement differed between treatment arms. Across all arms, we found frequency of self-monitoring to be high. In line with expectations, the vast majority of participants achieved mastery in self-monitoring body weight in month 1. Meanwhile, frequency of self-monitoring diet in the first month was high for both the Simultaneous and App-Only arms, indicating that, in contrast to our expectations, tracking both weight and diet concurrently did not impede each other for Simultaneous participants.

Contrary to our hypothesis, the Sequential arm had relatively low engagement in dietary self-monitoring despite demonstrating mastery in self-monitoring of body weight, which may be the result of minimal weight loss in month 1; it is possible that this poor performance, on average, resulted from participants feeling discouraged from engaging highly in self-weighing yet still not losing significant weight. This disappointment may have translated into failure to adopt a more intensive dietary tracking regimen. Perhaps a sole focus on fostering self-regulatory strategies in the first month without the intent to lose weight – as has been suggested previously67,182,183 – would promote greater subsequent uptake of
dietary self-monitoring among Sequential participants, and, consequentially, greater weight loss. Future trials should conduct qualitative interviews with participants to better understand decisions to engage or not engage in the intervention along with perceptions of barriers, in order to better inform intervention design.

6.1.4 Aim 4

Results from a secondary analysis indicate that consistently engaging in self-monitoring was associated with improved weight loss outcomes at 1 month, 3 months, and 6 months. These findings are in line with past studies that examined this relation in the context of other digital health modalities (e.g., websites and smart scales) or more intensive interventions with counseling. Over 3 times as many Consistent Trackers (i.e., those who highly engaged ≥75% of weeks) than Inconsistent Trackers achieved clinically meaningful weight loss at the end of treatment. Interestingly, individuals who consistently self-monitored in the first month of the intervention but not afterward were not as successful at achieving weight loss goals, though this should be explored further in a prospective, randomized design. These findings illustrate that regardless of what is being tracked, consistent engagement and weight loss success go hand-in-hand. However, as only a quarter of participants were Consistent Trackers, it remains to be determined whether other intervention components, such as counseling or social comparison, could increase one’s likelihood of achieving this threshold.
6.1.5 Aim 5

Lastly, this study was the first commercial-app based trial to examine whether early weight predicts future weight loss and intervention engagement. We found that individuals who responded early to treatment (i.e., ≥2% weight loss by the end of the first month) had significantly greater subsequent weight loss at 3- and 6 months than those who did not respond early to treatment. Additionally, early responders tracked everything they were asked to track almost all days in the first month and over 70% of days in months 2 and 3, which was significantly greater than that of early nonresponders. This research suggests that early weight loss success in a standalone intervention is highly predictive of future weight loss success.

6.2 Strengths and Limitations

Strengths of our trial include the fully-powered randomized experimental design with *a priori* power analyses and follow-up data beyond the end of the intervention. We also were able to collect objective self-monitoring data from MyFitnessPal via the Fitbit API, which allows us to more confidently state the true rate of self-monitoring. We acknowledge that our study was limited in that we collected self-reported weight at 6 months and study staff were not blinded to treatment allocation, due to limited resources. While we were pleasantly surprised to find that the App-Only arm lost a significant amount of weight, this higher-than-expected weight loss therefore resulted in a smaller magnitude between treatment
arms, which would require a larger sample size or the use of a ‘no treatment’ control arm to better examine the efficacy of our novel sequential self-monitoring approach.\textsuperscript{210} Further, we intended to investigate the impact of the intervention on changes in caloric intake, but due to poor response rates at follow-up, we could not reliably examine this behavioral domain. In addition, we did not collect objective measures of whether participants reviewed their weekly feedback reports, lessons, or app-usage tip sheets; acquiring this information would allow interventionists to elucidate what aspects of treatment are being used as they were intended, which is important in refining intervention design.\textsuperscript{211}

We initially proposed conducting a mediation analysis of whether theoretical constructs serve as mediators of the effect of treatment arm on weight change, but chose not to examine this analysis once results indicated no differential effect by treatment arm. We thought it more interesting and timely to thus examine early treatment response given a recent prioritization in obesity research toward the use of adaptive designs to alter treatment among individuals responding sub-optimally.\textsuperscript{212,213} Nevertheless, because we collected data on these theoretical constructs, future analyses could be conducted to investigate whether they serve as baseline predictors of engagement and weight loss, or even to examine whether changes over time in these constructs are found.
6.3 Recommendations for Future Research

In light of our findings, we provide several recommendations for researchers devising behavioral weight loss treatments. To improve standardization in terminology across the field, refer to *consistency* in self-monitoring when talking about number of weeks whereas *frequency* should refer to number of days with self-monitoring entries. Further, to allow for more direct comparisons, researchers should report the number of days participants were instructed to self-monitor, and, if possible, investigate whether self-monitoring engagement was related to weight loss outcomes. Interventionists seeking to employ an adaptive approach should consider using the 1-month mark point as a time point for when to intervene with early nonresponders; for standalone digital health trials, the ≥2% weight loss cutoff could serve as a meaningful predictor of future weight loss success.

More research is needed to determine whether a commercial app-based dietary self-monitoring intervention is efficacious in other populations, including teens with overweight and obesity, women seeking to prevent excessive gestational weight gain, older adult populations who may be less comfortable with using technology, and individuals with limited health literacy. Lastly, this study was not designed to isolate the impact of self-monitoring diet only vs. weight only vs. both (or physical activity); obesity researchers could employ dismantling designs to examine the unique impact of different targets of self-monitoring on treatment outcomes. Randomizing participants to varying durations of consistent self-
monitoring (e.g., 1 month only vs. 3 months vs. intermittent) would elucidate the optimal dose of self-monitoring for weight loss.214

6.4 Implications for Clinical Practice

The GoalTracker trial resulted in clinically significant weight change for roughly one-third of participants, indicating that a commercial app-based self-monitoring intervention could be leveraged as a viable treatment option for patients seeking to lose weight. Clinicians could recommend this approach as either a standalone solution or as an adjunct to a more-intensive treatment that involves counseling – or perhaps prior to initiating an intensive treatment, as has been recommended previously.215

In clinical practice, a free commercial mobile app with high acceptability, such as MyFitnessPal, could be downloaded with the help of a clinical team member. At the same time, in-app push reminders to track could be easily set up, and patients could receive instruction to self-monitor daily, and establish a realistic weight loss goal by a specified time point (e.g., 3 months), a weekly weight loss goal, and a tailored daily calorie goal. While we recognize that daily self-monitoring of dietary intake in an app will not be suitable for everyone, this low-cost approach may be a good fit for many individuals with overweight or obesity who own a smartphone and have adequate health literacy. Emphasizing to patients the importance of consistent engagement in self-monitoring, particularly in the first month, will likely enhance weight loss success. Given no difference in outcomes between treatment
arms, clinicians and patients could jointly decide whether to begin self-monitoring dietary intake right away or delay it after a period of gaining comfort using an app on a daily basis for tracking something simpler and less time-intensive.
7. Conclusion

Overall, findings from this dissertation improve understanding of a novel sequential self-monitoring strategy for weight loss among adults with overweight or obesity. It is the first study to compare a sequential versus simultaneous self-monitoring intervention for weight loss, and the first commercial-app based trial to assess consistency in self-monitoring as well as the impact of early treatment response on future success. Our focus on self-monitoring engagement addresses recent calls for a shift in adherence outcomes.\textsuperscript{105,190-192} We find our results promising and hope they substantively add to the obesity treatment field given the increasingly high prevalence of obesity and corresponding need for effective treatment options of varying intensities and forms.
Appendix A

Goal Sheet Provided to Simultaneous Arm Participants at Baseline

You are in Group A!

Here are your goals this week:

Step on your scale, and **track** your weight **every day** in the MyFitnessPal app.

**Aim to lose** ______ lbs in the next week. Your current weight is ______ lbs.  
Your goal weight is ______ lbs by _____________, 2017.  
You are ______ lbs away from your goal.

**Track** your foods & drinks for every meal, **every day** in the MyFitnessPal app.

**Aim to eat** ______ calories each day.

**Review** Tip 0, which describes how to use important features of the MyFitnessPal app. Then, review the Lesson and **complete** the Action Plan, which will be emailed to you later this week.

Good luck this week!  
Shelley

Questions? Email us at goaltracker@duke.edu
Goal Sheet Provided to Sequential Arm Participants at Baseline

You are in Group B!

Here are your goals this week:

- Step on your scale, and track your weight every day in the MyFitnessPal app.

- Aim to lose _____ lbs in the next week. Your current weight is ______ lbs. Your goal weight is ______ lbs by ____________, 2017. You are _____ lbs away from your goal.

- Review Tip 0, which describes how to use important features of the MyFitnessPal. Then, review the Lesson and complete the Action Plan, which will be emailed to you later this week.

Good luck this week!
Shelley

Questions? Email us at goaltracker@duke.edu
Goal Sheet Provided to App-Only Arm Participants at Baseline

You are in Group C!

Here are your goals this week:

- Aim to lose ______ lbs in the next week. Your current weight is ______ lbs. Your goal weight is ______ lbs by ______________, 2017. You are ______ lbs away from your goal.

- Track your foods & drinks for every meal, every day in the MyFitnessPal app.

- Aim to eat ________ calories each day.

Good luck this week!
Shelley
Appendix B

Handout Provided to Simultaneous and Sequential Participants at Baseline

---

### STUDY VISITS

- You will have **three study visits** at the IBRC: today’s baseline visit, a visit 1 month from today, and a visit 3 months from today.
  - The IBRC is located in the Erwin Mill Building at 2024 W. Main Street
  - Before your next 2 visits, we’ll send a **reminder email or text message**. Please respond so that we can confirm that the time works for you.
  - Please note that attending the study visits is *incredibly important* to us. Without your help, we wouldn’t be able to contribute to science on what is the best approach to losing weight and getting healthy. **We thank you in advance for your help!**

- **6 months from today**, we will contact you via text, phone call, or email to ask you for your current weight.

- We will ask you to complete **4 online dietary recall surveys**. These will ask you about everything you ate and drank over the prior 24 hours.
  - Stay tuned for our email, and please complete the dietary survey on the same day that you receive the email.
  - We expect this survey to take 15-30 minutes.
  - To thank you for your time, we will provide an additional $5 Amazon electronic gift card if you complete all 4 dietary recall surveys.

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<table>
<thead>
<tr>
<th>MyFitnessPal Account Email:</th>
<th>Pw:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fitbit Account Email:</td>
<td>Pw:</td>
</tr>
<tr>
<td>Date of One-Month Visit:</td>
<td>Time:</td>
</tr>
</tbody>
</table>

**Questions?** Email us at goaltracker@duke.edu
THE GOALTRACKER WEIGHT LOSS PROGRAM

- The purpose of GoalTracker is to help you lose weight and become healthier over the next 3 months.
- This weight loss program includes components that have been demonstrated by research to enhance weight loss. These include:

  ○ Completing your goals
    - See the *Getting Started with GoalTracker* handout for your weekly goals
    - Please use only MyFitnessPal for tracking

  ○ Reviewing personalized progress reports
    - You will be emailed a progress report every Monday
    - Your first progress report should arrive to your inbox in 7-13 days

  ○ Trying out tips on how to use MyFitnessPal
    - These tips will visually illustrate how to utilize different features of the MyFitnessPal app on your iPhone or Android smartphone
    - On Thursdays or Fridays, you’ll receive an email with weekly tips

  ○ Reading lessons on healthy eating and behavior
    - These lessons will describe information on healthy eating, as well as ways to modify your behavior or environment
    - The same Thurs/Fri email will also include your weekly lesson

  ○ Creating action plans to plan ahead for success
    - These action plans will give you a chance to think strategically about how you can follow each week’s lesson
    - The same Thurs/Fri email will also include your weekly action

Questions? Email us at goaltracker@duke.edu
Appendix C

Example Weekly Feedback Report Sent to a Simultaneous Arm Participant

Hi Shelley,

Here is your progress report #1 of GoalTracker. Overall, you met 2 of your 4 goals last week – It looks like some goals are easier to meet than others. What can you do differently this week? Since you started GoalTracker, you’ve lost 2.6 pounds.

<table>
<thead>
<tr>
<th>In the past week, you…</th>
<th>Did you meet your goal?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tracking body weight</td>
<td>tracked 5 days</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>Weight loss progress</td>
<td>lost 2.2 pounds</td>
</tr>
<tr>
<td>Tracking food &amp; drinks</td>
<td>tracked 4 days</td>
</tr>
<tr>
<td>Calorie goal progress</td>
<td>consumed 1460 calories per day, on average</td>
</tr>
</tbody>
</table>
It looks like you lost weight last week! What went well? It is likely that your weight loss was due to the following:
- **controlling your calories**

---

**In order to lose more weight, complete these goals this week:**

1. **Step on your scale,** and **track** your weight every day in MyFitnessPal.

2. **Aim to lose** 1 pound in the next week. As a reminder, your goal weight is 190 lbs by May 31, 2017. You are 7.4 pounds away from your goal.

3. **Track** your foods/drinks for every meal, every day in MyFitnessPal.

4. **Aim to eat** 1560 calories each day.

   A lesson on **red zone & green zone foods** will be heading to your inbox in the next few days. **Review** the lesson and fill out your weekly action plan!

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Good luck this week!

Shelley
Appendix D

Example Weekly Tip

Tips for how to use MyFitnessPal!

***Note that for each tip iPhone images are displayed on the left, and Android images are on the right.

**Tip: how to use the barcode scanner**

1. Open the MyFitnessPal app on your phone.

2. Tap the large blue “+” button on the bottom of the screen.

3. Tap the orange “Food” button.
4. Select a meal.

5. Once you are at the point to search for a food, tap the barcode icon in the top right corner.
6. A camera screen will pop up; take a picture of the barcode. *You may need to allow MyFitnessPal to access your camera before being able to use this feature.

Place the red line in the center of the barcode to scan.

7. Once the photo of the barcode is taken, the calorie/nutrition page will appear for the food product.
8. As you’ve done previously, adjust the Number of Servings and/or Serving Size to reflect the amount of the item you’ve eaten.

9. Don’t forget to tap the check mark at the top right of the screen, to add the food item to your Diary.
Appendix E

Example Weekly Lesson

EMOTIONAL EATING

It is common for us to eat based on an emotion rather than hunger.

For instance, you may have felt bored, and then wandered into the kitchen. Or perhaps you felt celebratory and ate a huge slice of cake even though you were full. Or maybe, you felt sad and picked up a jar of ice cream.

Many emotions - both negative AND positive - can lead us to (1) eat more than we would have done, and (2) eat foods that are high in sugar or fat and low in nutritional quality.

This lesson will focus on recognizing different emotions that may play a role in your eating experience, and brainstorming ways you can make change.

IDENTIFY WHAT EMOTIONS YOU ARE EXPERIENCING

Emotion and Examples
- Feeling Stressed or Overwhelmed - When we engage in mindless eating when feeling like we have a lot going on
- Feeling Bored - When we turn to our refrigerator when we don’t know what else to do
- Feeling Sad or Lonely - When we order an unhealthy takeout when we feel alone
- Feeling Tired - When we turn to soda instead of a nap or a walk outside
- Feeling Tense or Anxious - When we are waiting anxiously for test results and decide to nibble on a bag of chips
- Feeling Fearful of Failure or Criticism - When we procrastinate on a project, we often turn to food to justify our delay
- Feeling Celebratory - When we meet up with a friend whom we haven’t seen in a long time and decide to indulge at dinner despite our weight loss goals
- Feeling Motivated - When we motivate ourselves on a task by promising that we can eat food while doing the task or having food as a reward for completion of the task

**Remember!** Many times we turn to eating when we are trying to improve our mood. The problem with this tendency is two-fold:
1. We tend to eat unhealthy foods when we are eating based on emotions
2. We tend to overeat. Often, our emotions aren’t linked to our hunger level, so when we eat in order to try to improve our mood, we find ourselves eating when we actually aren’t hungry.

**STEPS TO MANAGE EMOTIONAL EATING**

1. Learn to recognize true hunger
   a. Not sure? Emotions usually lead to specific cravings (think ice cream, brownies, French fries) and an intense desire to eat now. Physical hunger tends to be more gradual

2. Recognize your emotional triggers - know which emotions you encounter tend to promote unhealthy eating or overeating

3. Then...
   a. Distract yourself
   b. Pick another activity to do
   c. or, Accept that you have this emotion.
      Let the emotion pass without changing anything else

**GENERATE IDEAS TO COPE WITH SUCH EMOTIONS**

As mentioned above, when facing emotions that trigger us to eat, it is often helpful to engage in a different activity. Ask yourself these 3 questions to help generate ideas.
Ask yourself:

1. Is this an emotion I want to reduce?
   - If YES - Think about a way to cope with the emotion.
   - If NO - Think about another way to maintain or enhance this emotion without food.

2. What has worked in the past?

Example activities for different emotions:

- Feeling stressed
  - Take a brief walk
  - Engage in 10 minutes of deep breathing
  - Make a to do list of a few items that are most important to do now. Hold off on writing down anything else on your list

- Feeling bored
  - Do something productive, such as washing dishes, checking mail, or organizing your closet
  - Set new goals
  - Start a new book
  - Work out while watching a tv show you haven’t seen

- Feeling lonely
  - Contact a friend to meet up and workout together or do something fun that does not involve food
  - Meet people: take a class, join a team/club, volunteer
  - Start a video chat with a relative you haven’t talked to in the past week

- Feeling tired
  - Plan your day so that you can get more sleep tonight
  - Take a short (15-20 minute) nap

- Feeling celebratory
  - Plan something fun to do now that does not involve food, such as taking a bubble bath, or playing mini-golf
  - Post about your success on social media or a blog
  - Book a special event for the near future, such as a spa trip, beach outing, or jazz concert
- Feeling motivated
  - When working on a task, play energizing music and take small breaks
  - Set a non-food reward for completing the task, such as playing a video game, watching a movie, or buying an item on your wish list

**IMPLEMENT ONE OR MORE OF YOUR IDEAS**

- **Select**
  - Select a strategy that is easy-to-do and realistic

- **Maintain**
  - Stay with the strategy until you feel you have coped with the emotion

- **Evaluate**
  - Evaluate how this strategy worked. *How do you feel now? Would you use this strategy again?*
Appendix F

Example Weekly Action Plan in Qualtrics (researcher view)
What was one way you managed the food cue?

Now let’s take a look at this week’s topic — managing emotional eating!

Think about the last time you had a “slip” with your goals, where you overate or ate unhealthy food. What were you feeling?

- stressed/overwhelmed
- sad/lonely
- angry
- tired
- bored
- tense/anxious
- fearful of failure or criticism
- happy/celebratory

What food/drink item did you turn to when faced with this emotion?

Now let’s plan ways to manage emotional eating tendencies.

There are 3 steps for managing emotional eating.

Which of these steps will be the easiest for you to do?

1. Learning to recognize true hunger
2. Recognizing my emotional triggers (the emotions that tend to promote unhealthy eating or overeating)
3. Picking another activity to do instead of eating, distracting myself, or accepting my emotional state
Why do you think this step is the easiest for you?

Which of these steps will be the hardest for you to do?

» (1) learning to recognize true hunger
» (2) recognizing my emotional triggers (the emotions that tend to promote unhealthy eating or overeating)
» (3) Picking another activity to do instead of eating, distracting myself, or accepting my emotional state

How can you get better at this step?

Now, select an emotion that is commonly linked to food for you. Write it down here.

Is this an emotion you want to reduce?

  yes
  no

Have you ever been successfully at managing this emotion without food?

  yes
  no

Have you ever been successful at maintaining this emotion without food?

  yes
  no

What has worked for you in the past?
What is 1 NEW activity that you could try to manage this emotion (without food)? Make sure it is easy enough and realistic enough that you would actually do it.

You have finished your action plan. Let's recap:

- **An emotion that commonly promotes unhealthy eating or overeating for you:** $\text{Your selected emotion}$
- **What has worked for you in the past:** $\text{Your selected activity}$
- **A new activity that you could try to help manage this emotion:** $\text{Your selected new activity}$

Remember that after you try this activity, evaluate it. That means: (1) assess how you feel after doing it, and (2) decide whether you would use it again. If not, pick a new activity.

*Feel free to copy or print this text so you can remember it throughout your weight loss journey!*

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Biography

Michele Lanpher Patel — Shelley — was born on February 11, 1988 in Baltimore, MD to Karen and Gregory Lanpher. After growing up in York, PA with older siblings Ryan and Sarah, she attended Duke University and received her bachelor’s degree in 2010, majoring in Psychology and completing the Markets & Management Certificate. Shelley was a recipient of the Karl E. Zener Award for Outstanding Performance of a Major in Psychology, for her senior thesis entitled The Positive Effects of Extended Volunteerism. In 2012, Shelley began her doctoral degree in clinical psychology at Duke, continuing work with her advisor, Gary G. Bennett, PhD, and the Duke Digital Health Science Center. Her master’s thesis (MA ’14), entitled Using Digital Health Technology to Self-Monitor Behavior for Weight Loss: A Systematic Review of Randomized Trials, was awarded the inaugural Master’s Thesis Award by The Obesity Society. For her dissertation, Shelley devised a 3-arm RCT (GoalTracker) to examine how to optimize self-monitoring engagement in a standalone digital health intervention for weight loss. She received the Dissertation Research Award from the American Psychological Association, Duke’s Aleane Webb Dissertation Research Fellowship, and Duke’s E. Bayard Halsted Scholarship. In August 2018, Shelley will complete her clinical internship in behavioral medicine at the VA Palo Alto and will begin a postdoctoral research fellowship at the Stanford Prevention Research Center, where she plans to continue researching obesity treatment strategies at the intersection of behavioral medicine and digital health.