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The Tracking Study: Description of a randomized controlled trial of variations on weight tracking frequency in a behavioral weight loss program

Jennifer A. Linde^{a,*}, Robert W. Jeffery^a, Scott J. Crow^b, Kerrin L. Brelje^a, Carly R. Pacanowski^a, Kara L. Gavin^a, and Derek J. Smolenski^a

^aDivision of Epidemiology & Community Health, School of Public Health, University of Minnesota, 1300 S. 2nd St, Suite 300, Minneapolis MN 55454

^bDepartment of Psychiatry, Medical School, University of Minnesota, 2450 Riverside Ave, Minneapolis MN 55454

Abstract

Observational evidence from behavioral weight control trials and community studies suggests that greater frequency of weighing oneself, or tracking weight, is associated with better weight outcomes. Conversely, it has also been suggested that frequent weight tracking may have a negative impact on mental health and outcomes during weight loss, but there are minimal experimental data that address this concern in the context of an active weight loss program. To achieve the long-term goal of strengthening behavioral weight loss programs, the purpose of this randomized controlled trial (the Tracking Study) is to test variations on frequency of self-weighing during a behavioral weight loss program, and to examine psychosocial and mental health correlates of weight tracking and weight loss outcomes. Three hundred thirty-nine overweight and obese adults were recruited and randomized to one of three variations on weight tracking frequency during a 12-month weight loss program with a 12-month follow-up: daily weight tracking, weekly weight tracking, or no weight tracking. The primary outcome is weight in kilograms at 24 months. The weight loss program integrates each weight tracking instruction with standard behavioral weight loss techniques (goal setting, self-monitoring, stimulus control, dietary and physical activity enhancements, lifestyle modifications); participants in weight tracking conditions were provided with wireless Internet technology (Wi-Fi-enabled digital scales and touchscreen personal devices) to facilitate weight tracking during the study. This paper describes the study design, intervention features, recruitment, and baseline characteristics of participants enrolled in the Tracking Study.

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*Corresponding Author: Jennifer A. Linde, Division of Epidemiology & Community Health, School of Public Health, University of Minnesota, 1300 S. 2nd St, Suite 300, Minneapolis MN 55454. Phone: 612-624-0065; linde074@umn.edu..

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Keywords

Self-monitoring; self-weighing; weight tracking; psychosocial outcomes; weight loss

1. Introduction

Given the pernicious reach of obesity [1], efforts to improve approaches to weight loss intervention are crucial. Frequency of tracking body weight is potentially a prime target for behavioral enhancement during weight loss. Daily self-monitoring (e.g., of dietary intake and physical activity) is already well established as a central component of the behavioral weight loss process [2], and there has been work to suggest that frequent weighing may augment the weight loss process as well [3]. However, the current standard of care in behavioral weight loss for weight self-monitoring is weekly tracking of weight, and some programs caution against any weight tracking [4].

It has been suggested that frequent weighing may have a negative impact on mental health and outcomes during weight loss [5], but there are minimal data to address this concern experimentally in the context of an active weight loss program. Observational evidence from behavioral weight control trials and community studies suggests that greater frequency of weight tracking is associated with better weight outcomes [6-9]. Stronger experimental evidence is needed to establish a causal link between weight tracking and weight outcomes and to elucidate the impact of weight tracking, if any, on mental health during weight loss.

This paper describes the study design, intervention features, recruitment, and baseline characteristics of participants enrolled in the Tracking Study, a three-arm randomized controlled behavioral weight loss trial. The Tracking Study was designed to test variations on frequency of weight self-monitoring during a behavioral weight loss program, and to examine psychosocial and mental health correlates of weight tracking and weight loss outcomes.

2. Methods

2.1. Theoretical model

Given the associations of excess body weight with adverse health conditions [10,11] and with ever-increasing health care expenditures [12], it is crucial to provide evidence-based recommendations in weight loss programs. Social-ecological models emphasize the importance of considering health behavior changes within a broad framework that accounts for interactions with the environment [13-15]. Within this context, successful behavior change programs should enhance the environment to improve health outcomes. One way to accomplish this task is to modify the technological environment with enhancements that change perceptions of engagement in the behavior of interest, thus improving the culture around self-monitoring of that behavior [15]. Weight tracking is a good example to test within this framework, as it lends itself to technology and is in need of experimental data to solidify its value as a weight loss self-monitoring tool.

Behavior modification is critical to a social-ecological perspective on health behavior change [13]. Within this framework, weight tracking may act as a functional reinforcer that promotes weight control by providing an environmental cue (e.g., scale and tracking tool) during weight loss. In this sense, favorable weight changes, as tracked by weighing regularly, may reinforce continued behavior engagement to promote ongoing weight loss [13], thus positioning weight tracking as a central part of the feedback loop of behavior change [16]. Within the context of this self-regulation model, if weight is to be regulated, then weight tracking provides a reference from which to compare success or failure of actions to control weight, in terms of how weight has changed on the scale. This measure of progress then serves to maintain goal-driven behaviors enacted to improve weight status.

From another perspective, this highly personalized feedback (individual weight, recorded daily) may act as a cue to action that enhances motivation during weight loss, promoting healthy behavior changes to facilitate this process [17]. Unfortunately, little attention has been paid to collecting data on self-monitoring of weight in this context. A model illustrating a proposed mechanism of weight change via weight tracking, using a social cognitive theory (SCT) framework [18] is presented in Figure 1.

According to SCT, the relative simplicity of the skills associated with weight tracking instructions will promote knowledge acquisition and mastery of weight tracking skills, which will favorably influence self-efficacy [19,20]. Self-efficacy, knowledge, and mastery will work in concert to promote greater engagement in weight tracking behavior and, in turn, more effective weight control. Finally, provision of tools with which to enact behaviors will enhance adoption and related behavioral outcomes by enhancing the environment with regard to the skills to be performed [18,20,21].

2.2. Intervention description

The base weight loss intervention for all groups follows a standard behavioral weight loss protocol adapted from programs developed at the University of Minnesota over the past 30 years. This program has successfully produced weight loss in numerous randomized trials [22-25]; most recently, this program was delivered by the same intervention team in place for the present trial and produced sustained weight losses over 12 months [26]. Groups comprise approximately 15-20 and no more than 23 persons; groups meet weekly for the first six months, then biweekly for two months and monthly for the remaining four months of the 12-month treatment period. Interventionists were highly experienced weight loss counselors with nutrition training.

Session content was centered on behavioral goal setting and attention to caloric intake and physical activity. Each session contained didactic presentations, group interactions, and motivational messages to enhance behavior engagement, particularly around adherence to specified weight tracking instructions (see 2.3., *Weight tracking intervention protocol*). Participants were instructed to set caloric intake goals of no less than 1200 kilocalories per day, based on starting weight and appropriate to produce weight loss of one to two pounds per week. Participants were asked to restrict fat intake to 20-30% of daily caloric intake. Participants received structured meal plans and specific skills training in environmental stimulus control (e.g., not keeping high calorie snacks in the home). Physical activity goals

were increased in weekly increments, based on each individual's starting point, until a goal of at least 250 minutes per week of moderate to vigorous physical activity was reached. Some physical activity (e.g., light strength training) was directed during sessions with specific activity content; otherwise, participants were instructed to engage in activities of their choosing on their own or with partners outside of sessions. Participants were asked to keep daily dietary intake and physical activity logs that were reviewed by study interventionists.

Session content also addressed additional stimulus control techniques and ongoing modifications of the home or work environment to facilitate healthy eating at home or away (either at work, in restaurants, or at group events), increased physical activity, and prescribed scale use. Cognitive-behavioral content also focused on reducing barriers to behavior change, facilitating development of problem-solving skills, monitoring and reducing negative thinking and emotional eating, and developing relapse prevention plans to enhance maintenance of behavior changes. A representative timeline and brief overview of intervention content across the 32 scheduled sessions is presented in Table 1.

2.3. Weight tracking intervention protocol

For the weight tracking conditions, the first intervention session was dedicated to setting up the technology necessary to facilitate weight, dietary intake, and physical activity self-monitoring. At this session, each participant in a tracking condition was provided with an Apple iPod Touch, which was preconfigured by study staff with a unique study Apple ID and loaded with free apps required for study participation. Withings Wi-Fi-enabled body scales [27] were also issued to participants in the two weight tracking conditions at this session. These scales transmit weight data via home wireless network to the scale's free proprietary app on the iPod Touch; participants are also able to track weight using a web browser on a personal computer as needed. The scale interface was preconfigured by study staff to export weight data into LoseIt!, an electronic diet and physical activity tracking application that runs on mobile devices (i.e., iPod Touch) and interfaces with the Wi-Fi scale [27,28]. The LoseIt! interface was also preconfigured by study staff to establish a unique study account, which was set up to automate weekly email transmission of tracking logs to interventionists for review. Participants were contacted in advance of the first intervention session to determine preference for using the study-provided iPod or their own mobile device; for those who preferred to use their own device, intervention staff sent instructions for loading the necessary apps and configuring them for study use.

Interventionists instructed participants in the use of scales and iPods at the initial group intervention session, aided by laptops and iPods to assist with troubleshooting as needed. To minimize the effects of daily fluctuations in weight caused by intake and elimination, participants were instructed to weigh themselves once at the same time of day (each day for daily tracking; on the same day of the week for weekly tracking), preferably upon waking, at which time they are likely to weigh the least [29], either in light clothing or without clothes. Participants were sent home after the first session with written instructions to facilitate connection of the scale to a home wireless Internet network via home computer. Once scales were connected, participants were instructed to place the scale on a hard, even surface to

ensure accuracy, were encouraged to keep the scale in an accessible location to enhance ease of adherence to study recommendations, and were discouraged from letting others in the household use the scale for the first several weeks to ensure consistency with data capture while participants adjusted to study procedures. Interventionists promoted weight tracking accordingly as they presented didactic materials at each group session, reviewing tracking logs (on iPod, printed, or online) for adherence at sessions according to standard check-in protocols followed during the weight loss program.

The no weighing study condition was described as an alternative to weight tracking that has been proposed by weight loss experts [4], and one that this study would utilize for comparison of these different approaches to weight tracking to see which one might be most helpful during a weight loss program. The first session of the no weighing condition was spent orienting participants to the process of engaging in weight loss without weighing oneself, and encouraged discussion of alternate methods for monitoring progress without using a scale (e.g., size of clothes, energy level, feedback from others). Pre-printed paper logs and calorie information books were distributed to participants, with instructions to monitor dietary intake and physical activity in these paper diaries; participants were encouraged to bring completed diaries to each session for feedback from intervention staff.

For all conditions, the second session was dedicated to reinforcing the self-monitoring and weight tracking instructions, either via electronic tools or in paper diaries. From the third session onward, content proceeded in parallel across all groups with only minor modifications to reflect differing weight tracking instructions.

2.4. Study design

The Tracking Study is a two-year, three-arm randomized controlled trial (one year of intervention and one year of follow-up), in which eligible participants were randomized to one of three weight tracking conditions: daily, weekly, or none. The allocation sequences for randomization were generated by the principal investigator (PI) in consultation with the study data manager. Treatment condition was assigned by blocked randomization, with order of condition within blocks determined by random number generator; participants were also assigned at random to one of two assessment subprotocols (dietary intake via three-day recall or physical activity via accelerometers), using a random number generator and balanced across the three study conditions. The study project manager oversaw enrollment of participants and assignment to intervention conditions. Allocation information was maintained by the PI in a separate, secured file, which was not released to the project manager until consent had been obtained and baseline measures had been completed. Intervention groups were composed so that all participants in a given group had been randomized to the same weighing condition. Participants were recruited and randomized in three waves, with six months between waves; each wave held two groups per condition, and these two groups met on the same day of the week, at alternate times (12:00 and 5:30 PM in waves 1 and 3; 7:30 AM and 12:00 PM in wave 2). Participants were encouraged to attend their assigned group time as often as possible, though they were able to attend an alternate group time on the same day (i.e., within their same randomized condition) as needed to accommodate unforeseen schedule changes.

2.5. Recruitment and enrollment

The modified CONSORT diagram for the Tracking Study is presented in Figure 2. Participants were recruited in July and August 2012 for Wave 1, January and February 2013 for Wave 2, and July and August 2013 for Wave 3. A variety of recruitment methods were used. In Wave 1, a paid radio advertisement was placed on a commercial talk radio and music station with a largely female demographic; paid radio advertisements were placed on two sports talk radio stations with largely male demographics to facilitate gender balance in recruitment in Waves 2 and 3. Additional recruitment methods included online advertisement at ClinicalTrials.gov and Craigslist, participant lists from previous weight loss studies, flyers posted in buildings on and near the University of Minnesota campus, local newspaper advertisements, outreach to local employers in an area adjacent to the University, and word of mouth. To facilitate racial and ethnic minority recruitment, a study-run booth was placed at an African-American community festival, a research team presented information about the study to community leaders at a community-located University urban outreach center, an advertisement was placed in community newspapers with high racial and ethnic minority readership, and a presentation of study information was given by a pastor at a local church with a primarily African-American demographic.

All recruitment methods encouraged interested individuals to contact a study telephone number for further screening; over 1500 individuals called to express interest. Of these, study staff screened nearly 1200 individuals for eligibility based on age (18-64), self-reported height and weight [to determine self-reported body mass index (BMI) between 25 and 40 kg/m²], access to technology (to determine computer ownership and availability of wireless Internet access at home), proximity to campus (within 40-50 miles), history of bariatric surgery or weight loss greater than 10 pounds in the past three months (ineligible if yes), significant health conditions (e.g., diabetes, cancer, stroke, heart attack, pacemaker or other cardiac device, angina, inability to walk for 20 minutes or more; ineligible if yes to any of these), pregnant in the past 12 months, planning to become pregnant in the next two years, or currently breastfeeding (ineligible if yes), self-reported history of anorexia, bulimia, or other eating disorder, and availability for at least one intervention session meeting time across all potential study meeting days (Monday, Wednesday and Thursday in Waves 1 and 3; Tuesday, Wednesday, and Thursday in Wave 2), to ensure that participants would be able to attend at least one group on the day to which they were randomly assigned following successful eligibility screening, using the randomization protocol described above.

Of the 334 individuals who were not screened for study entry, most (n = 329) were not screened because they could not be reached by study staff, and two were not screened due to failure to follow up directly after a proxy individual contacted the study on their behalf. The remaining three individuals contacted the study after recruitment was closed.

Of the 1375 who were screened, 841 were excluded for a variety of reasons, including self-reported BMI ineligibility (n = 149 too high, n = 20 too low), health conditions including recent pregnancy or breastfeeding (n = 11) or history of bariatric surgery (n = 14), or lack of interest or availability once the study was described (n = 500; see Figure 2 for more information), leaving a total of 353 adults who were scheduled for baseline study visits. Fourteen adults were excluded following the baseline visit due to measured BMI

ineligibility ($n = 2$), elevated scores on measures of depression or binge eating ($n = 1$ for depression, $n = 9$ for binge eating, $n = 1$ for both depression and binge eating), or not having Wi-Fi at home ($n = 1$), leaving 339 adults who were randomized to one of three study conditions. Of those randomized, nine withdrew prior to the first intervention session due to dissatisfaction with the results of randomization, one withdrew after the first session to start a therapy program elsewhere, and five were determined ineligible due to pregnancy after the start of the study; one participant died during the course of intervention due to factors not related to the study.

2.6. Measures

Unless stated otherwise, all measures described below were administered to participants as follows: at baseline, 6 months, and 12 months (pre-intervention, intervention midpoint, end of active intervention), and at 18 months and 24 months (post-intervention follow-up, study endpoint). Participants were compensated \$15-25 for each questionnaire completed across the five measurement visits. All data collection visits took place at a University-run epidemiological clinical research facility; height and weight were measured in private rooms, and self-report measures were administered in a group setting, in the same rooms in which group intervention visits were held. Data collection staff were blinded to intervention assignment at the baseline measurement visit. However, staff were not blinded at subsequent visits, as measurement visits coincided with intervention group visits at 6 and 12 months, and were coordinated by intervention group at 18 and 24 months to facilitate retention. Study staff who measured height and weight and who processed self-reported questionnaires were independent of those who delivered intervention content.

Demographic Measures—Age, sex, education level, race/ethnicity, and marital status were assessed by self-report at baseline.

Weight and Height—The primary study outcome is change in body weight at 24 months, with measurement at baseline and intermediate endpoints (6, 12, and 18 months) to examine trends in weight change over time. Weight (in kilograms) was measured by study staff using a calibrated Tanita BWB-800A digital scale, with participants wearing light clothing and no shoes. Height (in centimeters) was measured by study staff at baseline only, using a Perspective Enterprises model PE-AIM-101 portable stadiometer. BMI (kg/m^2) was calculated from these measurements. Weight was also self-reported by participants at all assessment points by asking them to approximate their current weight, prior to measurement by study staff. Female participants were asked about pregnancy status prior to each weight measurement.

Health Habits—Participants completed items to assess smoking status, sedentary behavior (television viewing, media use, and sleep), current action to control weight, and frequency and duration of weight control behaviors (e.g., reducing calories, increasing exercise, decreasing fat intake, skipping meals). Self-weighing frequency (never, every other month, monthly, weekly, daily, or more than once a day) and number of bathroom scales at home were reported.

Intervention, Weight Tracking, and Self-Monitoring Adherence—During the intervention period, attendance was recorded by interventionists at each session and tracked in a FileMaker database. Weight tracking data from Wi-Fi-enabled scales and iPods (see section 2.3, *Weight tracking intervention protocol*, above) were reviewed by staff at each intervention session. Self-monitoring data on diet, physical activity, and weight from electronic or paper records were recorded by interventionists at each session. By compiling printouts of electronic records from websites supported by electronic monitoring tools, or by photocopying paper diaries for participants without electronic monitoring tools, trained study staff were able to determine and track the number of days per week that participants logged each behavior. Data were entered into a study database and quality-checked by research assistants to assure accuracy of data transfer from multiple sources by intervention staff. The data from scales and iPods or paper logs also will be used to validate self-reported weight tracking items from the Health Habits Questionnaire (see below).

Perceptions of Weight Tracking—At 6, 12, 18, and 24 months, participants in the two weighing conditions completed an 8-item questionnaire to assess beliefs about their weight tracking assignment during and after intervention. The measure asks participants to rate daily or weekly weight tracking in terms of ease, interest level, ability to remember, awareness, reward value, usefulness, understanding, and how motivated they are to engage in their assigned weight tracking frequency. These items measure aspects of cue strength (i.e., with questions of ease, awareness, reward value, and salience of instructions in the environment) and motivational value, both of which are important to the process of behavior modification within a social-ecological framework [13,17]; the items will provide feedback on acceptability of weight tracking instructions for future interventions. The scale demonstrated good internal consistency ($\alpha = .85-.93$ at 3 months, $.82-.94$ at 6 months) and retest reliability (3-month retest $r = .67-.79$) in pilot studies of a self-directed weight control intervention and of weight tracking feasibility conducted by the PI [30-32]. Each item is rated on a Likert scale (0 = not at all to 8 = extremely); higher scores indicate more favorable perceptions of weight tracking.

Barriers to Weight Tracking—To elucidate factors that may impede engagement in daily or weekly weight tracking, participants in weight tracking conditions completed an assessment of perceived barriers to tracking weight at 6, 12, 18, and 24 months; all participants completed this measure at baseline. Items were adapted from a measure of barriers to diet and exercise developed by a member of the research team and used in numerous weight loss studies; the original measure is sensitive to changes in behavior and weight over time [22]. The adaptation demonstrated good internal consistency ($\alpha = .85-.91$) and adequate retest reliability (3-month retest $r = .54$) in a pilot study of weight tracking feasibility conducted by the PI [32]; internal consistency reliability for this measure at baseline was consistent with previous findings ($\alpha = .90$). These items will provide feedback on factors that may interfere with weight tracking and will provide guidance for adaptation and use of weight tracking instructions for future interventions. Items are rated on a Likert scale (1 = not at all true for me to 5 = very true for me); higher scores indicate greater barriers to weight tracking.

Tracking of Weight Loss Behaviors—To assess non-weighing progress markers tracked by all participants, a 14-item form was developed for this study. The form assessed energy level, ease of getting around, meeting fitness goals, sleep quantity or quality, appearance, moods or emotions, body measurements, fit of clothes, compliments or recognition from others, and biomedical markers (antacid use, resting heart rate, blood pressure medication or other medication use), with an option to write in other markers as needed. Participants were asked to indicate the markers they were tracking, and to indicate whether each marker had improved since the start of the weight loss program. This measure was administered at 12, 18, and 24 months.

Dietary Intake—The online version of the Diet History Questionnaire-II [33] was used to assess usual dietary intake over the month prior to administration, including portion size. Responses were scored and analyzed using proprietary Diet*Calc software available at the DHQ website [33], which provides reasonable and valid estimates of macronutrient and caloric intake compared to 24-hour recall administrations [34] and alternate food frequency questionnaire (FFQ) protocols [35].

To enhance measurement of dietary intake during active weight loss and elucidate any changes in meal patterning or food sourcing (not assessed via FFQ) that might change with intervention, a subset of 165 participants (53 in daily condition, 50 in weekly condition, 62 in no weighing condition) were randomized at baseline to a 24-hour dietary recall protocol. Three recalls (2 weekdays, 1 weekend day) were collected at baseline and 12 months (end of active intervention). Dates and times of recalls were unscheduled so that participants would not change normal eating patterns. At baseline, participants were asked to indicate preferred days and times of day to be called and the telephone number(s) at which they preferred to be reached. Staff at the Nutrition Coordinating Center (NCC), University of Minnesota, Minneapolis, MN, contacted participants for telephone interviews. Data were analyzed using Nutrition Data System for Research software, developed by the NCC; mean dietary intake (kilocalories per day) was generated by averaging across the three recall days. Participants were compensated \$15 for completing dietary recalls at each time period.

Physical Activity—The Paffenbarger Activity Questionnaire (PAQ) [36] was administered to provide an estimate of calories expended per week in leisure time physical activities. The PAQ assesses activities performed in the previous week, including stairs climbed, blocks walked, and minutes of any other activities described using a free recall format. The open-ended responses were scored by categorizing activities as light (5 kilocalories/minute), moderate (7.5 kilocalories/minute), or vigorous (10 kilocalories/minute) intensity [37]. The PAQ has been associated with weight loss outcomes in intervention trials [38].

A subset of 174 participants (61 in daily condition, 59 in weekly condition, 54 in no weighing condition) were randomized to a 7-day accelerometer protocol at baseline and 12 months (end of active intervention), to enhance physical activity measurement during active weight loss, to elucidate any changes in daily patterning of activity that might occur during intervention. Actigraph model GT1M devices were used for the study; these devices have demonstrated low intra-instrument reliability (mean coefficient of variation = 0.66%), high

inter-unit reliability in lab testing situations (intraclass correlation = .91), and good concurrent validity ($r = .94$ for correlation with similar device) [39]. Likewise, reliability and validity of this monitor have been demonstrated in adult samples [40-43].

At baseline and 12-month evaluation visits, monitors and detailed instructions for use were distributed by study staff. Consistent with previous studies [44] participants were instructed to wear the monitor on the right hip during all waking times, using an attached elastic belt with a quick-release clip. At baseline, participants were instructed to return the monitor to staff at the first intervention session; at 12 months, monitors were distributed in a one-month window either before or after that evaluation visit. Monitors were mailed to select participants who did not attend a visit during this window, and addressed, postage-paid envelopes were provided to all participants with instructions to return the monitor after seven days of wear. Data were averaged across days and classified in inactive, mild, moderate, or vigorous activity by summing daily vector magnitude readings in counts per minute per day and averaging across days, as follows: 1-250 (sedentary/inactive), 251-2100 (light), 2101-5900 (moderate) or >5901 (vigorous). Counts greater than 16,000, any hour with zero counts, or days with fewer than 12 hours of activity were dropped; protocols with at least four days and up to seven days of valid data based on these criteria were retained for analysis [40,45-47]. Participants were compensated \$10 for completing each accelerometer protocol.

Psychosocial Measures—Although adverse effects of the intervention on psychosocial well-being are not anticipated, collection of these data will allow for examinations of the impact of weighing frequency, if any, on psychosocial factors that may disrupt behavior engagement [16,17]. Measures include:

Self-Efficacy for Weight Loss Behaviors—Self-efficacy for dietary intake, physical activity, and weight tracking were assessed using a 15-item scale developed by members of the research team [30]. Each item is rated on a Likert scale (0 = not at all confident to 8 = extremely confident); higher scores indicate greater self-efficacy for weight loss behaviors. The 10 dietary intake and physical activity self-efficacy items were internally consistent at baseline ($\alpha = .93$) and associated positively with corresponding behavior engagement and with weight loss outcomes [30]; five weight tracking self-efficacy items were adapted directly from existing items for use in the present study, and did not affect the internal consistency of the scale as a whole (5-item $\alpha = .92$; 15-item $\alpha = .94$).

Body Image—The Appearance Evaluation subscale of the Multidimensional Body-Self-Relations Questionnaire assessed body image; this measure is internally consistent ($\alpha = .88$) with good retest reliability ($r = .81$) [48] and sensitivity to changes associated with weight control [49]. Internal consistency reliability at baseline was $\alpha = .81$ in this sample. Items are rated on a Likert scale (0 = definitely disagree to 6 = definitely agree); higher scores indicate more positive body image ratings.

Self-esteem—The Rosenberg Self-Esteem Scale [50] was used to rate global self-esteem, which is associated strongly with overall psychosocial well-being [51]. The measure is typically highly internally consistent ($\alpha = .91$) [52]; internal consistency reliability at baseline

was $\alpha = .83$ in this sample. Items are rated on a Likert scale (0 = definitely disagree to 6 = definitely agree); higher scores indicate more positive self-perception.

Mood States—The Positive and Negative Affect Schedule – Expanded Form (PANAS-X) was used as a state measure of moods [53]. The measure, consisting of 60 adjectives rated on a five-point Likert scale (from 1=very slightly or not at all to 5=extremely), assesses positive and negative affect, basic negative emotions (fear, hostility, guilt, sadness), basic positive emotions (joviality, self-assurance, attentiveness), and additional mood states (shyness, fatigue, serenity, surprise). The PANAS-X has been validated in multiple samples as a short-term state measure, is sensitive to mood changes, and is highly internally consistent ($\alpha = .85-90$ across samples) [53]. Internal consistency reliability at baseline was $\alpha = .87$ in this sample. Items are rated on a Likert scale (1 = very slightly or not at all to 5 = extremely); higher scores indicate greater intensity of each mood state. As mood states may have a significant effect on the feedback process involved in behavior change attempts [16,17], these measures will be examined as related to tracking perceptions and adherence.

Life Events—Major life events are associated with illness, functional ability [54,55] or attention to health behaviors such as medication adherence [56] or weight gain [57]. Even minor stresses (e.g., daily hassles) may interfere with coping [58]. A possible model will be examined in which increased stress perceptions lead to decreased coping, which in turn may increase negative affect, which then might lead to decreased self-monitoring [16,17,58]. The Life Experiences Survey [55] assessed a broad range of life changes and events that could affect participation in weight tracking or other study recommendations. It is expected that participants who endorse a greater number of stressful life events will have poorer attendance and adherence to program recommendations, will be less able to maintain tracking diaries, and will experience greater negative affect relative to those with fewer life events during the study [55,58]. This measure has a retest reliability of $r = .63-.64$ over 5-6 weeks and is expected to be subject to fluctuations due to unpredictability of life events [55].

Depression—The Beck Depression Inventory (BDI-II) assessed depressive symptoms that may change over the course of the study period. The BDI-II has high internal consistency ($\alpha = .91$) and temporal stability (retest $r = .93$) [59]. Internal consistency reliability at baseline was $\alpha = .84$ in this sample. Items are rated from 0-3, with higher scores indicating greater depressive symptomatology (0-13 = minimal depression; 14-19 = mild depression; 20-28 = moderate depression, 29 = severe depression).

Anxiety—The Beck Anxiety Inventory (BAI) assessed anxiety symptoms that may change over the study. The BAI is reliable ($\alpha = .92$, retest $r = .75$) and valid in discriminating anxiety from depression [60]. Internal consistency reliability at baseline was $\alpha = .78$ in this sample. Items are rated from 0-3, with higher scores indicating greater anxiety symptomatology (0-7 = minimal anxiety; 8-15 = mild anxiety; 16-25 = moderate anxiety; 26 = severe anxiety).

Eating Disorder Symptoms—Measures used to screen participants prior to study entry will be repeated during the trial for ongoing monitoring. These include the Questionnaire on Eating and Weight Patterns [61] to assess binge eating, with two items from the SCOFF

Eating Disorder Screening Questionnaire (sensitivity = 84.6%, specificity = 89.6%, $\kappa = .82$) [62] added to assess presence of symptoms associated with body self-perception and preoccupation with food. Binge episodes were defined by self-report of eating an unusually large amount of food in a 2-hour period with corresponding feelings of loss of control while eating during the episode.

2.7. Power and sample size justification

Sample size calculations were based on expected associations between weight tracking frequency and weight change outcomes from observational data in the Weigh To Be (WTB) intervention study [6]. Based on 24-month WTB outcomes (the final endpoint in this comparable weight loss trial), in which mean weight change differences of 5 kg between never versus weekly weight trackers and 2.75 kg between weekly versus daily weight trackers were observed, a conservative mean weight change difference of 2.5 kg (SD = 5.0 kg) between participants assigned to each condition at 24 months in the present study. Using standard power and sample size calculation methods [63] and allowing for all pairwise mean comparisons between treatment conditions, approximately 112 participants were intended to be enrolled in each condition, with 80% power at the $\alpha = .05$ level to detect the expected treatment effect. This value also takes into account an estimated maximum attrition value of 25%, which is consistent with the experience of the research team [26].

2.8. Study hypotheses and statistical analysis plan

The primary outcome measure of the trial is weight in kilograms at 24 months. The study was designed to test the following hypotheses: a) A dose-response effect of weight tracking on weight loss will be observed, such that those who weigh daily will demonstrate the greatest weight loss relative to those who weigh weekly or those who do not weigh when compared at 24 months; b) Weight tracking will trigger an enhanced self-monitoring response for associated weight control behaviors (dietary intake and physical activity), mediated by self-efficacy, such that more frequent weight tracking will be associated with greater self-efficacy, which will generate better adherence to self-monitoring of all weight control behaviors during the 12 months of intervention; c) Based on previous work by the research team [30], the effects of weight tracking self-efficacy on weight loss outcomes will be mediated by weight tracking frequency; and d) Based on preliminary data collected for this trial [32], no detrimental effects of daily weighing on measures of depression, anxiety, self-esteem, or body image during weight loss will be observed.

For the intent-to-treat (ITT) analyses of the primary outcome, mean differences in weight will be examined first using a linear regression model with treatment assignment as a nominal explanatory variable and the weekly tracking condition as the referent category, with baseline weight as a covariate. The regression coefficients from these models will serve as effect sizes (mean differences), and the corresponding 95% confidence intervals will be used to evaluate both precision and statistical significance.

The three treatment arms will also be compared using a time-structured multilevel model for change [64] to take advantage of the repeated measures of the outcome. This model will produce parameter estimates of change for individual participants. Incorporation of

treatment assignment status will allow for comparisons in the intercept (baseline value) and slope parameters in an ITT fashion. This modeling option is preferred over repeated-measures ANOVA because of anticipated attrition over time, which would violate the balanced data assumption and would complicate the handling of missing data. For this model, all participants with data for at least one time point can be retained for analysis and parameters will be estimated using maximum likelihood. This modeling approach is useful under an assumption of data missing at random. We will evaluate patterns of missingness to determine the extent to which this assumption is reasonable. Any covariates associated with missingness will be included in the model to improve parameter estimation. Since baseline values of the measures will be included in the model, any differential missingness will be taken into account. For a sensitivity analysis, we will estimate a pattern mixture model to determine if an assumption of missing not at random produces changes to the overall study conclusions. Analyses will also be conducted using these models to look at a “per protocol” treatment effect among participants who adhered to the planned monitoring [65].

There are two statistical mediation models of interest: a) self-efficacy as a mediator of the association between weight tracking frequency and self-monitoring of weight loss behaviors, and b) weight tracking frequency as a mediator of the association between weight tracking-specific self-efficacy and weight loss (see Figures 3a and 3b). The analyses involve two steps: measurement modeling and mediation modeling.

For latent variables, confirmatory factor analyses will be conducted at baseline to assess model fit. Multi-group models will be used to compare the factor structure across treatment arms [66]. It is anticipated that due to the equalizing power of randomization across treatment arms, the models should be equivalent. Confirmation of this hypothesis will rule out measurement differences as an explanation for observed differences in latent means. In addition, temporal stability of the measurement structure will also be examined to rule out any changes in measurement due to treatment assignment. For each treatment condition, the same latent variable will be modeled simultaneously at each measurement point, and use parameter constraints to test equivalence of the factor structure over time. Fit for each measurement model will be assessed using standard indices, including the χ^2 , comparative fit index (CFI), the Tucker-Lewis index (TLI), and the root mean square error of approximation (RMSEA). For testing invariance, iterative constraints will be examined using a likelihood ratio test. Scale scores for each time point will be used as indicators for subsequent growth curve models.

MacKinnon [67] recommends the use of structural equation modeling to test hypotheses about statistical mediation. Within the structural equation framework, it is possible to estimate both direct and indirect effects of an exposure variable on an outcome. The product of the coefficients for the association between the explanatory variable and the mediator (α) and between the mediator and the outcome (β) estimate the indirect effect, while the coefficient for the remaining path between the explanatory variable and the outcome (τ') is the estimated direct effect. Precision and statistical significance are evaluated using bias-corrected bootstrap resampling with replacement of the observed data [68].

For psychosocial variables, scale scores will be calculated for each construct. To assess the effect of treatment condition on each of these outcomes, a seemingly unrelated linear regression model will be used, with treatment condition as a nominal predictor of mean differences. This procedure allows for simultaneous modeling of each of the psychosocial variables while accounting for intercorrelations. The result will be improved estimates of the effect of treatment assignment on each outcome independent of the other three.

3. Results

A description of the study sample at baseline is presented in Table 2, for the whole sample ($n = 339$, 65% women) and by randomized condition. Randomization was successful at allocating participants across groups. The sample was 46.5 ± 10.2 years of age on average, and predominately white (86%) and non-Hispanic (98%). Approximately two-thirds were married or partnered, and a comparable number were college educated. Only 8% were current smokers at the start of the study.

At baseline, mean BMI was 33.0 ± 3.6 kg/m², ranging from 25 kg/m² to 40.8 kg/m². Participants had approximately one bathroom scale at home, and the majority (56%) weighed themselves only once monthly or less. Their average score for barriers to weight tracking fell into the “not at all true” to “somewhat not true” range, indicating that they did not perceive significant barriers to monitoring their body weight. Participants reported low levels of physical activity at baseline.

With regard to eating and exercise self-efficacy, participants were only somewhat confident on average that they could follow an eating or exercise change plan, suggesting a need for intervention to improve dietary intake and physical activity behaviors. Baseline scores on the weight tracking self-efficacy measure indicated that participants felt confident that they could track their body weight under a variety of conditions. Mean scores on the body image scale indicate neutral to somewhat negative views of physical appearance, though mean scores on the self-esteem scale indicate an overall favorable view of self and self-worth. Mood state scores were indicative of relatively high positive affect and relatively low negative affect. Minimal significant life events were reported, with a mean of two events over the past year. On average, scores on the BDI-II and BAI were in the minimal symptom range at baseline, with 96% of participants endorsing minimal depressive symptoms and 90% endorsing minimal symptoms of anxiety. The study did screen out individuals who met criteria for binge eating disorder prior to baseline, and less than 5% of enrolled participants reported any binge eating episodes (at frequencies not meeting threshold for diagnosis) prior to the start of the study.

4. Discussion

The Tracking Study is positioned to make a significant contribution to the weight loss field because it provides needed data to strengthen weight tracking recommendations within behavioral weight loss programs, with the intent of improving weight loss outcomes. The simplicity of the study design (manipulating one critical component of weight control) allows for clear inference with regard to the effect of weight tracking on study outcomes,

and is an obvious strength of this trial. Furthermore, the ease with which this study attracted the attention of adults interested in weight control suggests that there is opportunity to change perceptions of weight tracking by providing a technological enhancement of the environment to promote better health [15]. The use of Wi-Fi scales allows for objective measures of weight tracking from participants in daily and weekly weight tracking conditions. Another strength of the Tracking Study is in measurement of a wide range of constructs, which allows for the study to examine the effects of weight tracking frequency on: a) weight loss outcomes, b) the weight loss process, and c) mental health and other psychosocial factors, providing an unprecedented and adequately powered contribution to the extant literature.

The primary challenges faced by launching this study were in recruitment. Recruitment in wave 1 was unexpectedly and heavily imbalanced in favor of women (95%); however, a modified approach to radio recruitment corrected this imbalance in subsequent waves, with no gender imbalance in randomization to conditions across all three waves. The end result was that the trial was successful in recruiting a sample that was 35% male, which is significantly higher than the average of 21% observed for weight loss trials without a disease target for study recruitment [69]. In addition, 30 individuals with interest in the study were excluded due to lack of Wi-Fi access at home, and given that recruitment materials stated the need for home wireless Internet access as a condition of study participation, it is possible that other prospective participants did not contact the study with interest in participation.

Despite multiple attempts by the research team, capitalizing on existing community-University partnerships and additional community networked connections, the final study sample was 86.4% white, compared to 75.1% reported for the seven-county metropolitan area from which the sample was recruited [70]; adults of Asian racial background and Hispanic ethnicity were also underrepresented compared to the metropolitan area population (1.5% in Tracking vs. 7% in metro area and 2.1% in Tracking vs. 6.1% in metro area, respectively). Although efforts to oversample from racial and ethnic minority groups fell short, the study was more successful in recruiting a population-representative sample of Black or African American and American Indian participants (8.0% in Tracking vs. 8.7% in metro area and 0.6% in Tracking vs. 0.6% in metro area, respectively).

An additional limitation of the study is that participants in the daily and weekly weighing conditions will have access to electronic monitoring to record eating, activity, and weight during intervention, whereas participants in the no weighing condition will rely on paper diaries to record eating and activity during intervention. At the time of study conception, the decision to provide electronic monitoring for all participants was considered in light of this potential confound; however, all commercially available electronic monitoring tools incorporate weight monitoring into their design, and the concern about prompting participants in the no weighing condition with a weight monitoring option on a regular basis outweighed concerns about confounding. Based on previous research establishing that paper and electronic monitoring tools are equivalent in terms of data generation, preference, and compliance [71], especially during weight loss [72], the design for the study was set with confidence that participants in all conditions would engage in recommended monitoring

during the trial. However, as adherence and outcome differences between electronic versus paper diary monitoring have been observed [73], interventionists were instructed to monitor participants carefully during the intervention to check and encourage adherence in all groups.

In sum, data collected by the Tracking Study will allow for direct investigation into conventional wisdom that weight tracking during weight loss should be limited to weekly frequency at most, or perhaps not employed at all. By testing this question in a randomized, controlled trial that takes the novel step of considering each of three debated weight tracking frequencies (never, weekly, or daily) during weight loss, we will be moving beyond the current observational evidence toward meaningful larger-scale experimental data to provide evidence on the optimal frequency of weight tracking for an improved standard of care in weight loss programs. The relatively recent availability of Wi-Fi-enabled scales as a new technology to support reliable and valid collection of weight tracking data will add precision to data collection and participant monitoring in this project, and has the potential to enhance the weight loss experience for study participants by capitalizing on the trend toward a “quantified self” mentality for managing health behaviors [74,75].

Researchers already have set dietary self-monitoring as necessary for successful weight loss [76]. At the conclusion of this study, we will be positioned to enhance the standard of care for weight loss with regard to weight tracking recommendations, elevating the potential for better weight control among nearly 150 million overweight and obese adults in the United States, and thus directly mitigating the public health impact of the obesity crisis. Next steps will be to work with community partners (e.g., medical professionals, public health agencies, consumer groups), to test this intervention approach in varied settings (e.g., community clinics or primary care facilities), and to evaluate its effectiveness as delivered by non-research weight loss counselors or adapted for use in self-directed programs.

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Figure 1.
Social-cognitive model of weight tracking and behavior change.

Figure 2.
Tracking Study modified CONSORT diagram.

Figure 3.
Mediational models for the Tracking Study.

Table 1

Tracking Study intervention sample timeline and session content.

Date	Session	Topic	Demonstrations/Incentives
		Weekly Sessions	
Sept 16	1	Introduction to the Tracking Study	iPod, scales, bag and stylus
Sept 23	2	Weight Loss Goals	Cups, spoons, scale Measuring demonstration
Sept 30	3	Increasing Your Physical Activity	
Oct 7	4	Fat Tracking	
Oct 14	5	Fiber	Food tasting
Oct 21	6	Lifestyle Exercise (Pedometers)	Pedometers
Oct 28	7	Menus / Meal Plans	Sample meals, Slimfast taste test, lunch bags
Nov 4	8	Barriers to Exercise	Pouch for iPod
Nov 11	9	Problem Solving	Winter clothing demonstration
Nov 18	10	Eating in Social Situations	
Nov 25		HOLIDAY WEEK OFF	
Dec 2	11	Eating in Restaurants	Sample menus
Dec 9	12	Eating and Exercise Cues	Blinking safety lights
Dec 16	13	Emotional Eating	
Dec 23		HOLIDAY WEEK OFF	
Dec 30		HOLIDAY WEEK OFF	
Jan 6	14	Volumetrics [77]	Food demonstration
Jan 13	15	Protein Power	Sample meals
Jan 20		HOLIDAY WEEK OFF	
Jan 27 EVAL	16	High Risk Situations	6 month evaluation
Feb 3	17	Re-evaluate Your Goals: Part 1	
Feb 10	18	Re-evaluate Your Goals: Part 2	Resistance bands
Feb 17	19	Advanced Activity Change	
Feb 24	20	Assertion and Eating	
Mar 3	21	Stop Light Diet [78] Part 1 Lifestyle Behaviors Forever	Recipe demonstration
Mar 10	22	Stop Light Diet [78] Part 2	
Mar 17		HOLIDAY WEEK OFF	
Mar 24	23	Finding Time for Activity How Much Physical Activity?	
Mar 31	24	Becoming a Weight Loss Expert	
		Biweekly Sessions	
April 7		OFF	
April 14		OFF	
Apr 21	25	Managing Slips and Lapses	

Date	Session	Topic	Demonstrations/Incentives
May 5	26	Negative Thinking	
May 19	27	Physical Activity Social Support Activity Fair	Equipment demonstration
May 26		HOLIDAY WEEK OFF	
June 9	28	Health News and Diet Myths	
June 23	29	Quick and Easy Meals	Recipe demonstration
		Monthly Sessions	
July 7	30	Alternative Eating Styles Vegetarian, Organic, Food Co-ops	Food tasting
Aug 4	31	Life Long Plan Give Self Credit for Success	
Sept 8 EVAL	32	Life Long Plan Part 2	12 month evaluation

Table 2

Baseline characteristics for the whole sample and by treatment condition.

	Total Sample (n = 339)		Daily Weighing (n = 114)	Weekly Weighing (n = 109)	No Weighing (n = 116)
Variable	M (SD) or %	Range	M (SD) or %	M (SD) or %	M (SD) or %
Sample Demographics					
Age (years)	46.5 (10.2)	18-64	47.0 (10.7)	46.3 (9.8)	46.3 (10.2)
Women Enrolled	64.9%		61.4%	66.1%	67.2%
Race					
American Indian	0.6%		0.9%	0.0%	0.9%
Asian	1.5%		0.9%	1.8%	1.7%
Black/African American	8.0%		13.2%	4.6%	6.0%
White	86.4%		81.6%	88.1%	89.7%
Other (more than one selected)	3.5%		3.5%	5.5%	1.7%
Ethnicity: Hispanic	2.1%		0.9%	4.6%	0.9%
Married or Partnered	67.9%		63.2%	67.9%	72.4%
College Graduate	63.7%		64.0%	67.9%	59.5%
Current Smokers	8.0%		7.9%	9.2%	6.9%
Weight, Eating, Exercise, and Weighing Behaviors					
Body Mass Index (kg/m ²)	33.0 (3.6)	25.4-40.8	33.4 (3.6)	32.7 (3.6)	33.0 (4.2)
Bathroom Scales at Home	0.9 (0.5)	0-3	1.0 (0.5)	0.9 (0.5)	0.9 (0.5)
Self-Weighing Frequency					
Never	5.9%		6.1%	6.4%	5.2%
Once a year or less	9.7%		8.8%	8.3%	12.1%
Every other month	23.9%		24.6%	23.9%	23.3%
Monthly	16.2%		18.4%	18.4%	12.1%
Weekly	33.0%		36.0%	32.1%	31.0%
Daily	11.2%		6.1%	11.0%	16.4%
Weight Tracking Barriers score	34.1 (12.0)	18-71	34.5 (12.3)	33.8 (11.5)	34.0 (12.1)
Self-Efficacy, Eating and Exercise	51.5 (13.1)	12-80	52.6 (11.6)	51.9 (13.5)	50.0 (14.1)
Self-Efficacy, Weight Tracking	30.9 (6.7)	10-40	32.0 (5.7)	30.7 (6.4)	29.9 (7.6)
Total Energy Intake (kilocalories/day), DHQ	1781 (613)	864-3101	1725 (564)	1857 (640)	1765 (630)
Blocks Walked (per day)	9.2 (12.2)	0-96	8.4 (11.3)	10.1 (12.1)	9.0 (13.1)
Stair Flights Climbed (per day)	7.7 (10.6)	0-99	7.2 (9.6)	7.0 (9.9)	8.7 (12.0)
Light Activity (minutes/week)	14.9 (44.0)	0-280	18.0 (49.3)	16.6 (41.4)	10.3 (40.9)
Moderate Activity (minutes/week)	44.3 (85.9)	0-540	40.8 (85.9)	47.4 (87.4)	44.7 (85.1)
Vigorous Activity (minutes/week)	17.8 (53.2)	0-450	23.0 (62.2)	18.3 (57.8)	12.2 (36.4)
Psychosocial Measures					
Body Image	17.3 (6.7)	0-38	17.3 (6.7)	17.5 (6.9)	17.0 (6.7)

	Total Sample (n = 339)		Daily Weighing (n = 114)	Weekly Weighing (n = 109)	No Weighing (n = 116)
Variable	M (SD) or %	Range	M (SD) or %	M (SD) or %	M (SD) or %
Sample Demographics					
Self-Esteem	49.4 (7.6)	26-60	49.3 (8.0)	50.6 (7.4)	48.5 (7.2)
Negative Affect	15.0 (4.3)	10-34	14.8 (4.3)	14.7 (4.5)	15.4 (4.2)
Positive Affect	34.1 (6.3)	17-50	35.0 (6.3)	34.6 (6.1)	32.6 (6.1)
Number of Life Events (past year)	2.0 (2.0)	0-10	2.2 (1.9)	2.2 (2.2)	2.2 (2.0)
Beck Depression Inventory score	4.1 (3.7)	0-19	4.0 (3.6)	4.0 (3.7)	4.2 (3.7)
Beck Anxiety Inventory score	2.6 (3.3)	0-17	2.3 (3.1)	2.6 (3.6)	2.8 (3.3)
Binge Eating Episodes (yes/no, past 3 months)	3.9%		4.4%	2.8%	4.3%

Note. DHQ = Diet History Questionnaire.