

Official study title: Preventing Weight Gain Among Those Who Decline Behavioral Weight Loss Treatment

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## **University of Florida IRB-01**

**1. Title:** Understanding health behaviors and interest in interventions

**2. Investigators:**

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### **3. Abstract:**

Obesity treatment guidelines recommend comprehensive behavioral weight loss treatments as the first line approach for adults with either obesity or overweight with a weight-related comorbidity. However, the vast majority of adults who are eligible for these weight loss treatments do not initiate them, even when offered at no cost. For individuals who decline weight loss treatment, obesity guidelines suggest a focus on weight gain prevention. Unfortunately, existing interventions to prevent weight gain have the same characteristics that cause many individuals to reject weight-loss treatments in the first place, such as didactic-focused meetings and prescriptions for dietary and physical activity change. To prevent weight gain while overcoming these common barriers to engaging in weight management interventions, we propose an intervention that prescribes self-weighing but does not prescribe changes in diet or physical activity behaviors or require attendance at didactic-focused meetings. The potential of self-weighing to promote weight management is supported both by self-regulatory theory and empirical research. Promoting self-weighing may activate participants' self-regulatory skills, leading to spontaneous decisions to reduce calorie intake or increase physical activity, thus preventing further weight gain. The proposed intervention will also provide individuals with text message-based feedback to promote continued self-weighing and to motivate engagement with evidence-based resources for weight management at a time when they may be more open to using these resources—e.g., after experiencing a small weight gain. The current proposal will investigate the feasibility and acceptability of this low burden self-weighing intervention in order to prepare for a fully-powered, pragmatic randomized controlled trial. We will enroll 40 patients with either obesity or overweight with a weight-related comorbidity and who have declined to participate in a comprehensive behavioral weight management program. Participants will be asked to weigh themselves daily via a "smart" scale that transmits weight data directly to the study team via the cellular network. Every-other week, participants will be sent text messages providing brief feedback encouraging continued self-weighing. Moreover, if a small weight gain is observed, participants will be sent text messages aiming to engage them in commercial or community-based evidence-based weight management resources. In a single-arm design, all enrolled participants will receive the intervention for 12 months and will complete assessments at 3 and 12 months to assess feasibility and acceptability of the intervention and trial design, while weight will be obtained from participants' Electronic Health Records (EHR). We will evaluate our success in meeting pre-specified metrics for trial feasibility and intervention acceptability outcomes, including intervention enrollment, intervention satisfaction, and obtainment of weight data abstracted from participants' EHRs. We will also evaluate the success of the intervention in promoting regular self-weighing and use of evidence-based weight management resources.

#### **4. Background:**

Obesity and overweight affect two out of three American adults, and increase the risk for numerous diseases and premature mortality.<sup>1–3</sup> These risks can be minimized by use of comprehensive behavioral weight-loss treatments,<sup>4–6</sup> which are the recommended first-line treatment for adults with obesity or overweight with a weight-related comorbidity.<sup>6</sup> However, 80–93% of affected adults reject these treatments,<sup>7</sup> even when offered for at no cost.<sup>8–10</sup> Research by our team and others indicates that treatment is declined because individuals see no benefit in didactic treatment, dislike in-person and/or group meetings, and have numerous barriers to changing their diet and physical activity.<sup>11–13</sup> For individuals who decline weight-loss treatment, preventing weight gain is the recommended approach.<sup>6</sup> Unfortunately, existing evidence-based interventions to prevent weight gain have the same characteristics that cause individuals to reject weight-loss treatments in the first place: many provide didactic group meetings and focus on changes in diet and physical activity.<sup>14–16</sup> Thus, an alternative approach is needed to prevent weight gain in individuals who decline comprehensive weight-loss treatments. One such approach is to offer a lower-burden intervention. For example, an intervention could prescribe self-weighing but not require changes in diet or physical activity or attendance at didactic meetings.

The efficacy of self-weighing interventions to prevent weight gain has been supported both by self-regulatory theory and existing empirical research.<sup>17–19</sup> However, what has not yet been investigated is the effect of a low-burden self-weighing intervention on preventing weight gain in adults with obesity or overweight, and particularly among those who decline behavioral weight-loss treatments. Thus, the current application proposes a pilot study to investigate the feasibility and acceptability of a self-weighing + text messaging intervention. In the proposed intervention, participants will be asked to weigh themselves daily using a “smart” scale that transmits weight measurements directly to the study team via a cellular network. In addition to receiving text messages every other week which provide feedback and encourage continued self-weighing, participants whose weight gain passes a specific threshold will receive an additional, tailored text message. This text message will encourage the use of low-cost evidence-based weight-management resources (e.g., online dietary trackers). Messages encouraging use of resources may be particularly impactful given that they will come at a time when participants may be more willing to consider using resources to manage their weight (i.e., due to recent weight gain).<sup>20</sup> Further, evidence supports the importance of responding quickly to small weight gains in order to prevent larger gains over time.<sup>21</sup> Participants in this intervention who self-weigh infrequently will receive tailored messages aiming to engage them in more frequent self-weighing or in using weight management resources. This intervention approach has high potential for implementation within health care systems given its low complexity and potential for low cost.<sup>22,23</sup> Further, our preliminary data demonstrate that many adults who decline traditional weight-loss treatments are willing to enroll in this sort of low-burden intervention.

A large clinical trial is needed to test the effectiveness of the proposed intervention. However, prior to that, we need data on feasibility and acceptability of the intervention and trial design, particularly given that individuals declining weight loss treatments have rarely been studied.

## 5. Specific Aims:

**Aim 1:** Identify predictors of willingness to engage in a weight loss intervention and a weight gain prevention intervention.

**Aim 2:** Determine the feasibility of the trial and acceptability of the intervention. We will examine the following feasibility/acceptability outcomes: intervention enrollment, intervention satisfaction, and whether adequate weight data can be extracted from participants' EHR.

**Aim 3:** Evaluate whether the intervention can promote regular self-weighing and use of evidence-based weight-management resources.

**Overview:** This study has two parts. Part 1 is a 15–20-minute survey, which participants are paid \$10 for completing. Some participants will be offered a second survey one month later, which also pays \$10. Part 2 is a 12-month intervention that involves participants being sent a smart scale, asked to weigh themselves daily, and being sent text messages every other week with feedback on their weight and suggestions for weight management. Part 2 also involves obtaining weight from EHR for 3 years after enrollment. Part 2 participants are paid \$10 for each of two online assessments and \$20 for a qualitative interview, for a total possibility of \$40. Only a portion of participants who complete the first (survey) part of this study will be invited to the second (intervention) part. Participants from Part 1 will be asked if they agree to allow us to obtain weight data from their EHR for a period of four years and will be given an option to complete REDCap e-consent for this.

**Participants, recruitment, and enrollment.** We will recruit UF medical patients aged 18–70 years whose EHR records indicate either obesity ( $BMI \geq 30 \text{ kg/m}^2$ ) or overweight ( $BMI \geq 25 \text{ kg/m}^2$ ) accompanied by a weight-related comorbidity.

We aim to obtain a sample size of 40 participants for part 2 of this study (intervention). We will cease recruiting for part 1 (survey) when we reach that goal. Thus, we are not able to know our total sample size for the entire study in advance, though we estimate that it will be 200.

We will recruit via two approaches:

(1) Emails and letters sent to patients identified by an IDR query for patients who meet criteria related to weight/comorbidity and age, have BMI recorded in the past month, and who have consented to be contacted by researchers through consent2share. IDR will provide patients' names, emails address and mailing address so we can send them the Consent2Share recruitment letter, as well as their race and gender so that we can over-recruit minority individuals to ensure representativeness.

(2) Emails and letters to patients who have had an appointment in the prior month with a primary care provider (PCP) who has agreed to allow us to send emails to his/her patients. We will obtain the list of patients by conducting an IDR pull to identify patients with appointments in the prior month who meet weight/comorbidity and age criteria. IDR will provide patients' names, emails address and mailing address so we can send them the letter from their provider, as well as their race and gender so that we can over-recruit minority individuals to ensure representativeness of our sample. We will send a signed letter from the PCPs from the study email address.

Patient identified through Consent2Share or the IDR query who have email addresses will be sent one email and up to one letter; patients who do not have email addresses will be sent one mailed letter. The email or letter sent to participants will inform them about the study and inviting them to complete a survey, with a link provided to a REDCap survey in the email/letter. Once on the REDCap site, all interested participants will read a consent document (see waiver to documentation of informed consent for Part I) and indicate consent by clicking a button, which will then lead to the eligibility portion of the survey.

### Eligibility criteria (Part I)

#### *Inclusion criteria*

- Weight record in EHR from year prior to recruitment email with last BMI in EHR  $\geq 25.0 \text{ kg/m}^2$ .
- Age 18-70.
- Self-report of BMI 24.0-29.9  $\text{kg/m}^2$  with comorbidity ((hypertension, type 2 diabetes, pre-diabetes, dyslipidemia, sleep apnea) or self-report BMI  $\geq 30.0$ .
- Self-report weight  $\leq 375$  lbs (the maximum weight that BodyTrace scales can accurately detect is 397 lbs, thus 375 lbs provides a buffer to allow detection of at least 20 lbs weight gain).
- Self-reported of sending at least one text message per month for past 6 months.
- Able to read and understand English without help.

#### *Exclusion criteria*

- Currently enrolled in comprehensive behavioral weight loss treatment or lifestyle-focused research study.
- Has engaged in self-weighing  $\geq 5$  times per week over prior month.
- Pregnant, breastfeeding, or planning to become pregnant in next 6 months.
- Currently undergoing radiation or chemotherapy for cancer.
- History of Congestive Heart Failure or heart attack in past 6 months.

- History of eating disorder.
- Planning to move out of the region in the following 12 months.
- Answer incorrectly on an attention check/ validation survey item.
- Report unwillingness to use data plan for this study.

Participants will be identified as eligible or ineligible for the intervention component (Part 2) based on responses of the survey study (Part 1, including one-month follow-up). The criteria for eligibility (in addition to being eligible to complete the survey) are:

- Respond “No” to question asking if they would like to enroll in a comprehensive weight loss program in the next month. AND
- Respond “yes” to question asking about interest in a self-weighing weight gain prevention intervention.

OR

- On the one-month follow-up Part 1 survey, respond that they have not enrolled in a weight loss program in the prior month, and that they are interested in a self-weighing weight gain prevention program

## Procedures

Participants who are eligible for the survey study (Part 1) will be directed to the main survey on REDCap. Survey instruments include: Center for Epidemiological Studies-Depression (CES-D), Yale Food Addiction Scale, Social Phobia Scale (SPS-6), Weight Bias Internalization-Modified (WBIS-M), Perceived Treatment Efficacy, Barriers to Help Seeking Scale (BHSS), Financial Stress Measure, Experience of Racism, Stanford Leisure-Time Activity Categorical Item (L-CAT), as well as individual questionnaire items regarding weight loss history, and effects of COVID-19 on health.

Participants who are eligible for the intervention (Part 2) will be immediately linked to a brief introduction to part 2 of this study at the end of the survey and asked to share their contact information (phone number and email address) if they are interested. Research staff will call participants who are eligible and will review the consent form and answer any questions they have about the study and confirm their interest. The participants will be presented with the full informed consent document and consent to participate via signature provided through a REDCap e-consent. After completing this consent, they will be considered enrolled in the intervention.

Participants who indicate interest in the weight loss program will be informed that they will be sent a second survey in one month. They will be asked if it is ok to use the email address they provide for human subject payment to send them this second survey. This survey will ask them if they have joined a weight loss program in the past month, perceived barriers to joining weight loss programs, and if they are interested in the self-weighing program at that time. If they have not joined a weight loss program

and are interested in the self-weighing program, they will be linked to a brief introduction to part 2 (self-weighing intervention) of this study at the end of the survey and asked to share their contact information. Procedures to consent and enroll them in part 2 will be as described above.

After a participant consents to part 2, they will be sent a standalone questionnaire, called the eating disorder examination questionnaire (EDE-Q). This will be sent to the participant's email address via the REDCap platform.

After Part 1 (first survey) all participants will be directed in REDCap to an invitation to share their weight data from their EHR beginning one year prior to the study until 3 years after the study (Part 2b). Interested participants will be presented with an informed consent document and consent to participate via signature provided through a REDCap e-consent.

## **Intervention**

All intervention elements are delivered remotely. Participants who enroll in the intervention (Part 2) will be mailed a cellular-connected "smart" scale (BodyTrace, Inc). Participants will also receive a study handout with instructions on obtaining an accurate weight (e.g., weigh themselves daily, first thing in the morning, after voiding), suggestions for remembering to self-weigh (e.g., placing the scale in a prominent location), and assistance in interpreting changes in weight (e.g., how to spot trends and noting that day-to-day weight fluctuations are normal). Participants will be informed in the consent process that BodyTrace is a third party and data stored there are not regulated by UF.

Every other week, text messages will be sent to the participant's personal cell phones. Messages will be delivered via REDCap/Twilio integration. Messages will differ based on weight change observed and the frequency of scale use over the preceding 2-4 weeks. A library of messages is provided with this submission.

Participants who regularly self-weigh and are not gaining weight will receive messages encouraging them to continue weighing themselves. A message encouraging use of weight management resources will be sent to participants who gain  $\geq 1.5\%$  of their baseline body weight over a 2 or 4 week period, or if a 3% weight gain from baseline is detected. In particular, the first message sent to those with weight gain will ask if they are willing to receive suggestions for weight management. Participants who respond "yes" will be asked to text back how much time per week are they able to spend managing their weight from the choices of <30 minutes or 30 minutes–2 hours. Participants who select <30 minutes will be given information about a popular, freely available online tool for tracking dietary and physical activity (MyFitnessPal). Participants who select 0.5-2 hours will be asked a few additional questions (e.g., preference for in-person vs remote approaches; barriers to weight

loss), then they will be sent information on selected free/low-cost, evidence-based community-based and commercial weight-loss options.

If participants weigh themselves  $\leq 5$  times per week, we will send them tips to increase self-weighing. If this is followed by a period of very infrequent self-weighing (one time per week or less), they will be sent a message suggesting that they may have gained weight and offering weight management resources.

### **Assessments and measures.**

All assessments will be conducted remotely via REDCap. In addition to the Part 1 survey, and the one-month follow-up Part 1 survey (for those who qualify), participants who enroll in the intervention will complete survey assessments at 3 and 12 months, and a portion of participants will be invited to a qualitative interview at 12 months.

#### **Part 1 one-month follow-up survey**

- Study-specific questions about their interest in weight loss programs, and their barriers to joining weight loss programs.

#### **Supplemental Survey/ Part 1**

- **Eating Disorder Examination Questionnaire EDE-Q.**

#### **3- and 12-month surveys**

- **Weight management behaviors.** At 3- and 12-month assessments, we will ask participants if they have engaged in 19 common strategies for weight management since prior assessment using items from the National Health and Nutrition Examination Survey (NHANES). These strategies include eating less food, eating more or less of certain foods, joining a weight-loss program, or using weight-loss medications. We will also ask: (a) for additional details about some of the strategies used (e.g., which weight-loss program) and (b) about the timing of strategy use. This will tell us whether the messages we sent were related to strategy use. We will also ask about their use of food intake tracking apps.
- **Weight management motivation and readiness.** The same questions from baseline/part 1 survey will be asked.
- **Intervention satisfaction.** At 3- and 12-month surveys, participants will rate specific components of the intervention on a seven-point Likert scale, and will be asked to explain their responses. These components will include: (1) helpfulness of self-weighing instructions provided at study onset, (2) ease-of-use of the scale and reasons for any difficulties, (3) helpfulness of message content, (4) frequency of text messages, (5) overall satisfaction with the program, including the things they did or did not like, (6) likelihood of

recommending the program to others and the reasons why, (7) satisfaction with text messages that offered weight-management resources.

- EDEQ
- CESD
- WBIS-M
- COVID-19 health questions

**Self-weighing data from BodyTrace scale.** Self-weighing frequency and weights from self-weighing throughout the 12 month study will be obtained from BodyTrace via an API.

**Qualitative interviews.** At 12 months, we will conduct interviews with 20 participants to better understand their experience of the intervention. Interviews will be conducted over HIPAA-compliant Zoom, with video if participants are willing and able, or otherwise with audio only. The interviews will cover the survey topics (e.g., message content) in greater depth. See interview guide in myIRB.

**Body weight from EHR.** We will extract all clinical body weight data from the EHR of participants from a period beginning one year prior to the study until 3 years after the study.

### **Sample size.**

The primary goal of this study is to evaluate feasibility and acceptability of the self-weighing intervention, and the sample size was determined based on standards for achieving that goal. We aim to obtain a sample size of 40 participants for part 2 of this study (intervention). We will cease recruiting for part 1 (survey) when we reach that goal. Thus, we are not able to know our total sample size for the entire study, though we estimate that it will be 200.

### **Data analyses.**

We will conduct logistic regression analyses to examine predictors of willingness to engage in the weight management interventions, among the variables measured in the survey.

For those who enroll in Part II, we will describe quantitative ratings of intervention satisfaction (mean and standard deviation of satisfaction items) and will conduct qualitative content analyses of the qualitative questions about intervention satisfaction.

To evaluate the potential for intervention effectiveness, we will calculate a sample mean and standard deviation for number of days per week that self-weighing occurs across the 12 month intervention and in each quarter of the intervention (to evaluate sustainability of self-weighing). We will evaluate participants' willingness to learn about weight management resources offered by the research team, initiation of use of resources, and sustain use of resources among those participants offered resources. Finally, we will characterize weight change by reporting means, standard deviations, and the portion who gain  $\geq 3\%$  of baseline weight in order to inform planning for our subsequent trial.

### **Data Safety Monitoring Plan**

The safety of all study participants will be monitored by the study PI, Dr. McVay. Adverse event reporting will occur in accordance with UF IRB guidelines. In particular, we will submit an adverse via myIRB within 5 days of discovery if it is serious and unexpected and related to the study; otherwise, any adverse events discovered will be reported at next continuing review or study closure on the cumulative adverse event table. Unanticipated problems will be reported at the time they are learned of by study investigators. Given the minimal risk of this study, a safety officer or data safety monitoring board is considered unnecessary.

## **6. Possible Discomforts and Risks:**

One area of risk of this study is loss of privacy. There are two ways that privacy is at risk: (a) through data collected and stored by the study team at UF, and (b) by data collected and stored by BodyTrace.

With regard to study team collected data, we cannot guarantee that data will not be unlawfully obtained. To minimize risk of loss of confidentiality, all data obtained directly by the study team will be held on a secure server accessed only by authorized study staff via password. Data will be obtained through REDCap. Written materials will be stored in a locked location within Yon Hall at UF. Prior to access to any study-related information, personnel will be required to sign statements agreeing to protect the security and confidentiality of identifiable information. Whenever feasible, identifiers will be removed from study-related information. At the end of data collection, all identifying information will be removed from all data files.

With regard to BodyTrace data, any data the patients share with Bodytrace (via self-weighing) is subject to the privacy terms of BodyTrace,. Patients will be informed during the consent process that the data they share with BodyTrace is not protected by the University. Participants will be notified in the informed consent document that their name and address will be provided to BodyTrace, Inc. for scale shipping purposes.

Participants will be informed that use of resources suggested to them, such as MyFitnessPal and Noom, are optional. Patients will be informed during the consent process that the data they share with these companies is not protected by the University and is subject to the terms outlined in the privacy policy of these companies.

Data obtained during video- or audio-recorded interviews may be used in future publications but will not be linked with names or identifying information. The audio file will be downloaded from Zoom, saved on a password protected computer in our University office, and transcribed for responses to the questions. No names will be included on the typed files. If any personal information comes up during the interview, the information will be redacted from the transcript. Quotes from the interview may be used in future publications, but will not be linked with names or identifying information. All audio recordings will be deleted from the network drive where it will be stored, with assistance from the IT department once they have been de-identified and transcribed, no later than 12 months after they are recorded.

Another area of risk for this study is the potential for patients to engage in unhealthy or risky health behaviors while pursuing weight loss. Because this study does not provide close supervision by trained professionals and patients may encounter suggestions from the support network that are not consistent with guidelines. This risk is not dissimilar, and is likely lesser, from what individuals encounter when they

attempt weight loss on their own, which over 50% of adults with obesity report attempting in a given year.

Further, it is generally unsafe for women who are pregnant to engage in weight loss efforts, and it is an exclusion criteria in our study. As such, participants will be withdrawn from the study if they become pregnant.

Some participants may find self-weighing to be aversive. However, those participants will have the chance to decline enrolling in the intervention or to withdrawal from the intervention. Although it is possible that regular self-weighing may be aversive to some individuals who enroll, past research clearly demonstrates that there is no increase in eating disorder symptomatology among individuals assigned to daily self-weighing.

**7. Possible Benefits:**

Participants who complete only the survey are not expected to experience any direct benefits. Participants who engage in the intervention may experience improvements in weight management.

**8. Conflict of Interest:**

The investigators have no conflicts of interest to report.

## 9. References

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