Study Protocol cover page

Official study name: Sharing Digital Self-Monitoring Data with Others to Enhance Long-Term Weight Loss: A Randomized Trial Using a Factorial Design
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Most recent protocol IRB approval: December 5, 2022
Approval letter included in this document.

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Approval of Modifications

Date: December 5, 2022

Protocol Number:	2103008421A017
Principal Investigator:	Meghan Butryn, PhD
Review Type:	Expedited
Review Date:	December 5, 2022
Approved On:	December 5, 2022
Committee:	IRB 3
Sponsor:	National Institute of Health
Project Title:	Sharing Digital Self-Monitoring Data with Others to Enhance Long-Term Weight Loss: A Randomized Trial using a Factorial Design

On December 5, 2022, the IRB approved the following modifications:

- 3 month assessment - clarifying language in protocol and index consent form about the 3 month assessment point.

- addition of radio language for recruitment

- Fengqing Zhang - co-investigator personnel, FCOI and HRP-201

If you modified the consent form, you can access your IRB-approved, stamped consent document or consent script through Coeus. Open the Attachments tab to find the approval letter or approval packet. The stamped documents are labeled as such. **Copies of the IRB approved stamped consent document or consent script must be used in obtaining consent.**

Please contact the IRB at (267) 359-2471 or HRPP@drexel.edu if you have any questions.

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1) Abstract of the study

Adults attempting weight loss through lifestyle modification (LM) typically find maintenance of behavior change difficult. Outcomes might be improved if participants are provided with sustained sources of accountability and support and ongoing opportunities to reflect with others on goal progress. This study proposes that sharing digital data with other parties has the potential to improve long-term weight loss. The proposed study will enroll adults ("index participants") (N = 320) with overweight/obesity in a 24-month LM program and instruct them to use digital tools for self-monitoring of weight, physical activity, and eating on a daily basis. Groups will meet remotely each week in months 1-3 to initiate weight loss. In months 4-24, intervention contact will be remote and will include the following: quarterly group meetings held via videoconference; brief phone calls with the coach held twice per quarter; and monthly text messages with the coach, with a small group of fellow group participants, and with a friend or family member outside of the program. Text message content will vary according to treatment condition, i.e. three types of data sharing partnerships: Coach Share, Group Share, and Friend/Family Share. Outcomes will be measured at months 0, 3, 6, 12, and 24. Primary aims include determining if Coach Share, Group Share, and Friend/ Family Share each improve long-term weight loss, PA, and calorie intake, and examining if effects are additive when participants are assigned to engage in more than one type of data sharing partnership. The secondary aim is to explore mediators and moderators of intervention effects. The tertiary aim is to determine how the quality of relationship with coach, group members, and friends/family member over time may differentially moderate treatment effects and predict data sharing efficacy. As digital technology makes data sharing increasingly feasible, it is critical to determine how to optimize these partnerships to improve long-term outcomes in LM.

2) Protocol Title

Sharing Digital Self-Monitoring Data with Others to Enhance Long-Term Weight Loss: A Randomized Trial using a Factorial Design

3) Sponsor / Funding

National Institutes of Health

4) IRB Review History

This is an original IRB submission for this project.

5) Investigator

Meghan Butryn, Principal Investigator
Drexel University

Evan Forman, Co-Investigator
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Danielle Arigo, Co-Investigator
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Fengqing Zoe Zhang, Co-Investigator
Drexel University

Bonnie Spring, Co-Investigator
Northwestern University

Brandy-Jo Milliron, Co-Investigator
Drexel University

6) Objectives

This study is designed to test new approaches to supporting long-term behavior change. Specifically, this study will test whether using coaches, program peers, or family/friends as sources of support and accountability can improve long-term weight loss.

Aim 1: Test the hypotheses that Coach Share, Group Share, and Friend/Family Share will each improve long-term weight loss (primary outcome) and PA and calorie intake (secondary outcomes) (i.e., outcomes will be compared for participants who are randomized to engage in that type of data sharing partnership, versus those who are not). Exploratory analyses also will determine if effects are partially or fully additive, antagonistic, or synergistic when participants are assigned to more than one type of data sharing partnership.

Aim 2: Test the following mediators of intervention effects: perceived supportive accountability, motivation, self-regulation, self-monitoring engagement, coaching quality, social comparison, and social support.

Aim 3: Determine how quality of the relationship with the coach, group members, and friend/family member over time may differentially moderate treatment effects and predict data sharing efficacy.

7) Background

In the proposed study, adults with overweight/obesity (i.e., "index participants") will enroll in a 24-month LM program and use digital self-monitoring tools on a daily basis (wireless body weight scale, wearable PA sensor, and app to record dietary intake). In months 1-3, groups will meet remotely every week through videoconferencing to initiate weight loss. Contact in months 4-24 will continue remotely, with group meetings continuing to be held via videoconferencing (once per quarter) and brief, individual phone calls with the coach (twice per quarter). Participants also will exchange monthly text messages with the coach; monthly text messages with a small group of fellow participants; and monthly text messages with a friend or family member outside of the program who will be trained to provide support. A factorial design will be used to efficiently test the independent effects of three types of data sharing partnerships:

1) Coach Share: The behavioral coach will view digital self-monitoring data throughout the program and will directly address data observations during intervention contacts.
2) Group Share: Participants in a given LM group will view each other's self-monitoring data in their small-group text messages.
3) Friend/Family Share: A friend or family member will view the participant's data via automated text message.

Coaches, group members, and friends/family in Share conditions will be trained to respond to shared data in ways that support motivation and self-regulation, without judgment or a critical tone. With the 2 x 2 x 2 factorial design, index participants will be randomly assigned such that half receive Coach Share and half do not; half receive Group Share and half do not; and half receive Friend/Family Share and half do not. Amount of intervention contact between the participant and each party is comparable in all conditions, isolating the effects of data sharing. Outcomes will be measured at months 0, 3, 6, 12, and 24.

8) Setting of the Human Research

Group treatment for all months will be held over Zoom videoconferencing software. All study visits will be held remotely and copies of physical data will be held at Drexel's University City Campus.

9) Resources Available to Conduct the Human Research

Center for Weight, Eating and Lifestyle Science (WELL Center)
Drexel University's WELL Center is actively engaged in vibrant research initiatives to advance the science and practice of weight control. The WELL Center currently houses 26 faculty, staff, and trainees and has a portfolio of $15M in research funding. Adequate space in the WELL Center will be devoted to this project. Project staff will have offices available for conducting project management tasks, conducting phone screening of participants, conducting assessments, and storing data and project supplies. The WELL Center is primarily a research center, but there is also an arm with a clinic that serves the community. There is no involvement of the clinic in this study.

Dr. Butryn and Dr. Forman, principal and co-investigator on the project respectively, are experts in the area of the development of treatments for health-related behavior change. Their lab has several NIH-funded research grants related to eating behavior and lifestyle modification, many of which Dr. Zhang (co-investigator) similarly has the primary responsibility of data analyses. Dr. Milliron (co-investigator) is an expert in the areas of community nutrition science and cancer prevention. Dr. Arigo (co-investigator) specializes in understanding social influences on health and health behavior (e.g., social comparison, social support) and harnessing social influences to improve outcomes in health behavior interventions (e.g., for weight loss and physical activity promotion). Dr. Spring (co-investigator) has more than 30 years of experience leading interdisciplinary science teams funded by NIH, VA, and foundation grants to develop and evaluate technology-supported interventions that promote healthy change in multiple chronic

disease risk behaviors, particularly poor quality diet, physical inactivity, obesity, and smoking.

Collective research expertise from the team and past success recruiting for studies ensure that this study will likewise be successful in its recruitment goals. As described in Recruitment Methods below, 320 index participants will be recruited in five cohorts (n = 64 per cohort) through digital media, radio stations, and public transportation, and publicizing the program in primary care practices and community centers. These methods have yielded large samples in previous NIH-funded clinical trials conducted at the WELL Center by this research team. Also, to enhance retention, study staff will send newsletters and birthday/holiday cards to participants. All study staff are well-qualified and well-trained in conducting weight and eating-related research, as well as general best practices for research with human subjects. All persons assisting with research will be trained and monitored by the Principal Investigator.

Department of Psychology

The Department of Psychology is actively engaged in research initiatives to advance the science and practice of psychology. The faculty is highly collaborative, frequently cooperating on research projects, co-mentoring doctoral students, and providing consultation to one another as needed. The department currently houses several prominent research laboratories that focus on research similar to the proposed study.

Computing Facilities

At present, all relevant personnel at Drexel have desktop computers equipped with broadband Internet connections and all necessary word processing and statistical software. The system is protected by firewalls and password protection to ensure security for sensitive data.

10) Prior Approvals

Does not apply

11) Study Design

a) Recruitment Methods

Recruitment will be conducted in five waves using methods that have yielded a high rate of recruitment in recent NIH-funded obesity trials conducted by this research team. Broad study details (including the study purpose and time commitment) and contact information will be provided via digital media, WELL Center mailing list, radio stations, and public transportation, and publicizing the program in primary care practices and community centers via flyers.

The WELL Center Screening and Registry Study is a screening and enrollment tool that collects information of interested participants to determine preliminary eligibility for WELL Center research studies and matches participants with the study that best fits their needs. There are 4 phases within the WELL Center Screening and Registry Study tool, consisting of (1) General Interest Survey, (2) WELL Center Informed Screening

Consent, (3) Universal Eligibility Screener, and (4) Weight Loss Phone Screen. Prior to their scheduled phone screen, participants will be sent the Fitlink Screening Informed Consent Form. The Fitlink Screening Informed Consent is required for Participation in the Project FitLink screening process. At the beginning of the phone screen, the assessor will review the Fitlink Screening Informed Consent Form with the participant. The participant will then be prompted to ask any questions they have. If the participant chooses not to sign the Fitlink Screening Informed Consent Form, the phone screen will not continue. Fitlink Phone Screen acts as a preliminary eligibility check specific to Fitlink study, including participants' interest, friends/family nomination, and availability for meetings.

Participants who are interested and preliminarily appear eligible for this study will be invited to sign up for an information session (specific to this study), at which prospective participants learn more detailed information about the study and the enrollment process (including risks, benefits, and alternatives to participation) and have the opportunity to ask additional questions. Finally, participants who remain interested are scheduled for a remote study visit, when research staff will complete assessment of other aspects of eligibility that were not well suited for the phone screen (e.g., measurement of weight, psychiatric conditions). Participants that completed all materials at the time of the study visit will be sent a copy of the study consent to review. After the clinic visit, index participants will be randomized to treatment condition, stratifying by biological sex and baseline BMI category. During Session 0, participants will review the study consent form with a member of the research team present, able to answer any questions the participant may have. After eligibility is determined and all enrollment requirements are complete, the participant will digitally sign the consent form.

During enrollment, all index participants will nominate one friend or family member to provide support for their LM efforts. After a friend/family member has been selected, the friend/family member will be sent an email from study staff. The email will give a description of the study and provide the friend/family member a link to complete an online consent form and complete self-report measures. The friend/family member will be given the opportunity to sign up for a visit with study staff if they have additional questions. After providing consent, the friend or family member will be asked to participate in one webinar at the start of the program and three booster zoom meetings (at Months 6, 12, and 18) to learn how to provide support for the participant's LM efforts.

b) Inclusion and Exclusion Criteria

Overweight/obese index participants (N = 320) will be recruited and screened by website to assess initial eligibility.

Inclusion criteria for index participants*:*

- Individuals must be of overweight or obese BMI (27-50 kg/m^2)
- Individuals must be adults (aged 18-70)
- Able to engage in physical activity (defined as walking two city blocks without stopping)

- Access and willingness to use a smartphone and internet
- Has one adult friend or family member who indicates willingness to serve in a support role
- Satisfactory completion of all enrollment procedures
- English fluency

Exclusion criteria for index participants:

- Medical or psychiatric condition (e.g., cancer, type I diabetes, psychosis, full-threshold eating disorder) that may pose a risk to the participant during intervention or cause a change in weight, or limit ability to comply with the program or participate appropriately in group-based treatment
- Currently pregnant or breastfeeding, or planning to become pregnant in the next 24 months
- Use of insulin or a medication that can cause significant change in weight
- History of bariatric surgery
- Weight loss of > 5% in the previous 3 months
- Weight loss of ≥ 10% within the past 3 years

No adults unable to consent, children, pregnant women, or prisoners will be enrolled as index participants.

Data for those who fail screenings and do not meet inclusion criteria will be destroyed or, with consent from the participant, participants may be screened for another study or added to the WELL Center database to be contacted for future studies.

Friends and family members (N = 320) have the following eligibility criteria: Age 18 or older; access and willingness to use a smartphone and internet; willingness to serve in a support role. No adults unable to consent, children, or prisoners will be enrolled in the friend/family member role.

c) Local Number of Subjects

We expect to enroll 320 index participants in total (64 per wave). To reach this, we expect to screen 2844 participants over the phone (568 per wave), conduct 525 study visits (105 per wave), and consent 400 participants (80 per wave). Based on previous obesity trials run in the WELL Center, these projections will yield 320 index participants in total enrolled in the study.

In addition to the 320 index participants, we expect to enroll 320 friends/family members of the index participants.

Thus, the total sample size will be 640 participants.

d) Study-Wide Number of Subjects

This is not a multicenter study. Recruitment will be restricted to participants enrolling at Drexel. Please see the recruitment methods specified above for more information on participant recruitment.

e) Study Timelines

Recruitment and enrollment of all participants is expected to take twenty-seven months from the start date, and each participant will be enrolled in the study for duration of twenty-four months. Index participants will complete assessments at 0 months (baseline), 3 months, 6 months, 12 months (mid-treatment), and 24 months (post-treatment). Friend/family members will not be required to attend any assessments. Primary and secondary analyses will be completed within five years of the start date.

f) Study Endpoints

The study is expected to begin in June 2021 and complete data collection by September 2025. Data analyses and write-up will be completed by the summer of 2026.

g) Procedures Involved in the Human Research

Study Design

In the proposed study, 320 index participants will be recruited via digital media, radio stations, and public transportation, and publicizing the program in primary care practices and community centers. These index participants will each select one friend/family member to serve in a support role (N = 320).

Screening and Enrollment Tools

The screening process for this study will utilize the following tools to screen participants for preliminary eligibility:

- WELL Screening and Registry Study (#2112008968)
- Project FitLink Screening Consent Form
- Project FitLink Phone Screen

After attending an information session, participants must complete a total of five self-report surveys before their clinic visit appointment. This information will be used to make determinations about a participant's study eligibility and will not be used for data analyses.

- WALI-A: Weight And Lifestyle Inventory-Abbreviated
- Beck Depression Inventory-II
- PARQ: Physical Activity Readiness Questionnaire
- Technology Use Survey
- Pre-Clinic Visit Food Records

If participants are unable to attend the scheduled clinic visit, they may reschedule one time before they are deemed ineligible.

Participants must do the following to continue in the enrollment process after the Clinic Visit:

- Sign up for Session 0
- Complete Pre-Session 0 instructions
- Attend Session 0
- Successfully set up all study devices and sign the Informed Consent Form
- Complete all baseline assessment requirements
- Attend Session 1

Intervention: Index Participants

Uniform Components

All index participants will receive a 24-month lifestyle modification (LM) intervention. They will receive 20 sessions of group-based behavioral treatment for weight loss. Groups will meet weekly in months 1-3 over the Zoom videoconferencing platform. In months 4-24, one group meeting held over Zoom will take place every 3 months, and two brief (15-minute) individual coach phone calls will occur twice per quarter (14 calls in total over 21 months). During phone calls, coaches will check in about progress towards goals, review core behavioral skills that are most relevant, and collaboratively set goals for the next month. All index participants also will regularly exchange program text messages with the LM coach; with fellow LM participants; and with a designated friend/family member. All index participants will be instructed to use digital self-monitoring devices daily (PA sensor, food record app, smart scale) throughout the program.

Treatment Conditions

The content of the text messages (in particular, whether or not the message includes the participant's digital device data) delivered during months 4-24 will vary according to treatment condition. These three treatment conditions will be provided to 50% of participants, with an equal number of participants randomized to have each of the below three treatment conditions ON or OFF. For example, 160 index participants will have their self-monitoring digital data accessible to their friend/family member, and 160 participants will not have this feature as part of their intervention. Random assignment will be conducted using minimization procedures, which results in better condition balance than simple randomization. Baseline covariates used for randomization will include biological sex and BMI.

1. Coach Share: If an index participant is randomized to have Coach Share ON, the coach will have continuous access to objective, real-time, detailed device data, and address data directly in all individual interactions with index participants (groups, individual weigh-ins, phone calls, texts), conveying that they are closely monitoring progress. Among index participants who are randomized to have Coach Share OFF, the coach will have no access to their device data. Index participants will be explicitly told their coach does not have data access. During groups and phone calls, the participant will self-report progress, and goal setting will be based on that self-report. Text messages from the coach will be personalized in the OFF condition, as they are when coach data sharing is ON, though these messages will not be informed by

device data. Instead, text messages will provide a reminder of key goals and strategies discussed in the previous phone call and provide encouragement for participant efforts in that area.

2. Group Share: If Group Share is ON, participants in a given LM group will view and respond to aspects of each other's self-monitoring device data in their small-group text messages. The project 'bot' will begin each text exchange by highlighting one participant's data. Over the course of 3 or 4 days, one participant's data will be highlighted each day, in order to maximize engagement. Among index participants randomized to have Group Share OFF, supportive accountability will not be the target of participant interactions and no data will be shared with LM program peers. Instead, prompts for the once monthly small group text exchanges will encourage index participants to provide social support (primarily of the informational type) to each other. Index participants will be explicitly told that they should not include information on goal progress such as weight change or minutes of PA. Similar to Group Share ON, prompts to continue the conversation will continue for several days in a row.
3. Friend/Family Share: Index participants who are randomized to have Friend/Family Share ON will give their friend or family member access to their self-monitoring data. Text messages sent by the program bot, which includes the index participant and friend/family member, will use a similar format as described in Group Share ON. The friend or family member will be trained to respond to data in ways that enhance the participant's motivation and self-regulation. If an index participant is randomized to Friend/Family Share OFF, the text messages from the bot will prompt the participant and friend/family member to communicate about the LM program; those messages will be standardized, except for names, and will not be tailored to index participant progress. Index participants will be instructed to refrain from sharing any device data with friends or family members.

Assessments: Index Participants

Research assistants who are blind to study condition will administer assessments remotely at months 0, 3, 6, 12, and 24. These staff members will have no involvement with the intervention. Index participants will be instructed not to disclose information about their treatment condition to assessment staff. Assessment staff will receive training in adherence to the data collection protocol, and their skills will be periodically reassessed for quality control. As compensation for time, index participants will be paid for assessment visits 6, 12, and 24. To enhance retention, study staff will send newsletters and birthday/holiday cards to index participants. Self-report data will be electronically captured and managed through REDCap, a secure web-based research database application.

Primary and secondary outcomes

Weight will be measured using a wireless scale, which is accurate to 0.2 kg. In order to maximize accuracy, we will (1) provide instructions (e.g., place scale on flat, hard surface; weigh upon waking, without clothes, after using the bathroom), (2) require

participants to confirm that they are following instructions at each assessment point, (3) use an average of 4 consecutive daily weights for each timepoint, (4) remove errant weights (e.g., 3%+0.1%*daysbtwnweights *)*.(Height also will be measured at baseline using a tape measure or yard stick to calculate BMI.) Minutes per week of moderate-to-vigorous PA will be measured by using FitBit, a consumer-grade wrist-worn activity tracker utilized in several other studies. The wearable FitBit has superior compliance and close-to-equivalent accuracy as a research-grade accelerometer. The Fitbit is sufficiently well-validated for steps and minutes of PA to support its role in this study and has demonstrated high inter-device reliability (crucial for obtaining accurate within-person change in PA). Seven days of calorie intake as derived from a digital food log will be used as a secondary outcome.

Participants will already be tracking their consumption using the app as part of standard treatment. .

Mediators

Perceived supportive accountability for weight control will be measured with the Supportive Accountability Measure. Self-regulation will be measured with the Helpfulness of Program Components measure. Self-monitoring will be objectively measured as the number of days in which digital devices were used to measure weight, record eating (with a minimum threshold of 5 foods/beverages recorded), or PA (minimum threshold of 500 steps). Coaching quality will be assessed by rating 15% of each coach's group sessions, text messages, and phone calls with a rubric adapted from the ASPIRE-VA checklist. The tendency for participants to engage in social comparison with fellow LM group members will be measured with the Iowa-Netherlands Comparison Orientation Measure, with items modified to be focused on the LM group, and with the FitLink Social Comparison Measure. Perceived social support will be assessed with the Social Support for Healthy Behaviors measure. Index participants will report the frequency with which friends and family members engaged in behaviors that support or undermine healthy eating and physical activity in the past month. Quality of group and friend/family interactions will be assessed with the Quality of Interactions measure. Weight stigma will be assessed using the Weight Self-stigma Measure. A demographic questionnaire will also be administered to participants at the baseline assessment. The Power of Food Scale will be used to assess individual reactions to food in their environment. The food environment will be assessed with Grocery Shopping and Home Food Environment Items. Food Addiction will be assessed using the Modified Yale Food Addiction Scale 2.0 (mYFAS 2.0). Utilization of stimulus control strategies will be assessed with the Measure of Stimulus Control. Satisfaction with the FitLink program will be assessed with the Treatment Acceptability Questionnaire.

Moderators

Relationship quality will be measured with items adapted from the client version of the Working Alliance Inventory-Bond Subscale. Ratings will be completed separately for the relationship with the coach, the LM group, and the designated friend/family support

person, with adaptation in wording as needed, yielding scores for each party. Most mediators and the moderator are only measurable once treatment has begun (e.g., coaching quality, social comparison with the LM group, and quality of the relationship with the group cannot be rated at pretreatment). Therefore, the "baseline" administration of such variables will occur at month 3 of treatment, with analyses controlling for weight loss achieved from months 0-3 as appropriate.

Qualitative data

Semi-structured interviews (n = 30) will be conducted at post-treatment to gather qualitative information about index participant experiences. 30 of the 320 index participants will be randomly selected with representation across conditions, age, sex, and race/ethnicity; additional interviews will be conducted if saturation is not reached. Interviews will last 45-60 minutes and will be digitally recorded and transcribed verbatim.

Optional Ecological Momentary Assessment- Wave 1 Only

Wave 1 participants *only* will have the opportunity to take part in a five-day ecological momentary assessment (EMA) to learn more about participants' thoughts and feelings about self-monitoring their weight, their weight loss trajectory in the program so far, and whether these responses differ by treatment condition (i.e., based on which sources of support they have been sharing their self-monitoring data with). Participants will be paid an additional $75 for completing this optional assessment and will lose $3 for every survey they do not complete.

Wave 1 participants will be verbally informed about the opportunity to complete the optional additional assessment by their coaches. All Wave 1 participants will be emailed a revised informed consent through RedCap that includes the information on this additional assessment. All participants will digitally read and submit and revised informed consent. After, they will indicate whether or not they would like to opt-in to the study. Those who do not want to participate will exit the RedCap survey. Those who do want to participate will be asked to complete a 5-minute survey that asks about their overall satisfaction with weight loss so far, their lowest weight during the program, and their current weight loss goals (maintain, lose a little more, lose a lot).

EMA assessment will last five days. Participants will complete three assessments per day: 1) immediately upon waking, 2) immediately after self-weighing (or if they do not self-weigh, at 10:00 am), and 3) at the end of the day (9:00 pm). The **morning survey** will ask participants to respond to report their state self-compassion (3 items), state distress tolerance (1 item), affect (5 items), motivation for weight control (1 item), body-related shame (1 item), and guilt about weight control behaviors (1 item). The **post-weighing survey** will ask participants to respond to the same questions as the morning survey, as well as a qualitative question (1 item). Participants will be asked to type a couple sentences in response to the question "Please explain your immediate thoughts and feelings about your weigh-in today." Participants who did not weigh in will instead be asked to "Please

explain your thoughts and feelings about your weight loss progress right now." On the final day of the surveys, the post-weighing survey will include an additional open-ended question (1 item) asking participants who skipped any weigh-ins during the period to explain why they chose not to weigh those days. At the **end of-day survey,** participants will be asked to report their expectations for their weight control trajectory based on their behavior that day (1 item), their expectations for whether the following day's weigh-in would show weight gain, maintenance, or loss (1 item), and how they expect to feel about the next day's weigh-in (1 item). They will also report their perceived calorie intake at the end of the day (1 item). Finally, participants will also be asked to respond an open-ended item: "Please explain your thoughts and feelings about your weight loss progress right now." (1 item).

Training and Supervision

Coaches will have a minimum of masters-level training in psychology or a related field and will have experience conducting LM. We anticipate that many of the coaches will be existing members of the research staff who provide intervention for other research studies within the WELL Center. If needed, we will hire additional coaches for this study by advertising the position. Coaches are not participants. Coaches will be balanced across conditions. Initial training, as well as quarterly retraining to prevent drift, will include role plays of session content. Weekly supervision will be conducted. Using a structured rubric, 15% of each coach's group sessions, phone calls, and text messages will be rated for fidelity to the treatment protocol. The rubric will take into account treatment integrity (delivering treatment as intended) and differentiation (the intended separation of study arms). Any coach deviations from the protocol (i.e., fidelity rated at <90%) will be tagged during review and addressed in supervision and retraining sessions.

Intervention and Assessment: Friends/Family Members

Friends/family members are asked to attend a webinar (held in Month 1 of the program, over Zoom), where they will learn how to provide support for the index participant's lifestyle modification. Following the workshop, they will receive monthly text messages for a period of 2 years (24 message exchanges in total) that will prompt them to provide support to the index participant. Depending on which condition the index participant is assigned to, the messages may include information about the index participant's food intake, exercise, and weight data. Friends/family member also will be asked to participate in three booster zoom meetings(one at month 6, one at month 12, and one at month 18) to receive additional guidance and tips about how to provide support.

Friends/family members are not asked to complete any assessment tasks or measures.

a) Data and Specimen Banking

Does not apply.

b) Data Management

Data Collection, Storage, and Quality Control

This study will use methods that have been effective in previous studies in this lab to ensure data security and quality control. Dr. Butryn will administer a data collection and storage training to all project staff, who must demonstrate competence in all tasks (e.g., phone screening, informed consent, etc.) before commencing their responsibilities. Staff will be assigned to review assessment data for accuracy and completion, and to pursue missing data by re-contacting participants. Specialized validity tools (e.g., customized spreadsheets and data entry software) will be used to maximize data accuracy. Double-entry will be utilized where appropriate. To maximize efficiency, data will be electronically captured and managed through REDCap, a secure application that has been successfully used by this team on several projects. For the optional ecological momentary assessment for Wave 1 participants, data will be collected and managed through Ethica, a secure experience sampling platform. Study messages will be sent through a secure, web-based portal to an app on your phone. Index Participants and friends/family members will be assigned a username and password to receive these messages. Their first name, user name, phone number, and email address will be stored on the web-based portal. Information from the participant's scale, Fitbit, and food record will be collected through the Fitbit API, and also stored on the study web-based portal. The study portal will be accessed only by authorized study staff. The development team for the web portal has been approved by Drexel's Information Security Office. The development team has agreed to abide by Drexel's Application Development Standards under the Security of Information and Networked Systems policy, encrypt at rest and in motion, and abide by privacy by design, security by design, and responsible computing principles. As part of participation, participants will be provided with informational handouts that correspond to the skills taught in that week's session. Participants will access these handouts in Google Classroom There will be no personal, identifying, or health information shared in any of these documents. Other features of Google Classroom, such as discussion boards, will not be used; participants will simply be using Google Classroom as a user-friendly place to locate these handouts. All paper-based data will be stored in a locked filing cabinet, and all electronic data will be password protected and stored on secure computer servers. On-site and off-site backup storage will be utilized to protect against loss. All data and informed consent forms will be stored for three years following completion of the study, in accordance with Drexel policy. After this time, the data will be destroyed.

Statistical Analysis

Descriptive statistics and exploratory graphing will be generated for all variables. Data summaries will be produced for the full sample and by condition. Continuous variables will be transformed if necessary. Baseline characteristics will be compared for each ON versus OFF contrast, as well as for each of the 8 study arms, using ANOVAs for continuous variables and a chi-square tests for categorical variables. Key baseline variables that differ by condition will be considered for use as covariates in the analyses described below. Likelihood-based estimation methods and multiple imputation models

will be used to handle missing data.

Aim 1

This study will evaluate the hypotheses that long-term weight loss (primary outcome) and PA and calorie intake (secondary outcomes) will be superior in Coach Share ON vs. OFF; in Group Share ON vs. OFF; and in Friend/Family Share ON vs. OFF. We will model the pattern of change in weight over time using multilevel models. The first level will model individual weight loss over time with baseline as time 0. At the second level, the individual intercept and slope will be entered as outcomes with each of the three types of data sharing examined separately as a predictor. The cross-level interaction between time and type of data sharing (e.g., Coach Share ON vs. OFF) will be used to determine the effect of the partnership factor on the pattern of change in weight. Restricted maximum likelihood will be used to estimate model parameters and to test the significance of random effects. Both linear and higher-order time effects will be examined. Similar multilevel models will separately examine the effect of each of the three partnerships on PA and calorie intake. As an exploratory aim, we also will test the interaction effects of the three data sharing partnerships by adding higher-order interaction terms to the aforementioned multilevel models.

Aim 2

Analyses will determine if change in potential mediators from baseline to 12 months predict weight loss at 24 months. Analyses will determine whether temporally precedent changes in hypothesized mediators explain the effect of condition on weight loss, with the expectation that the Share ON participants will maintain a high level of the proposed mediator from baseline to 12 months, while decreases in that variable will be observed in Share OFF. Coach Share, Group Share, and Friend/Family Share will each be examined separately, with possible mediators including perceived supportive accountability, motivation, self-regulation, and self-monitoring. In addition, coaching quality will be examined as a mediator for Coach Share ON vs. OFF, social comparison will be examined as a mediator for Group Share ON vs. OFF, and perceived social support will be examined as a mediator for Friend/Family Share ON vs. OFF. We will use the mediation model outlined by Preacher and Hayes to estimate the indirect effect of each hypothesized mediator individually. The bias-corrected bootstrap test will be applied to test the significance of the indirect effect, which allows for the most robust and accurate interpretation of the mediating effects. Should these mediation analyses prove promising, we will explore how the entire pattern of changes in the mediators from baseline to later time periods influences the corresponding pattern of weight loss over time using parallel process growth models.

Aim 3

To test if intervention effects depend on quality of the relationship with the coach, group members, or friend/family member, relationship quality will be examined as a potential moderator by adding it to the multilevel model described in Aim 1 and determining whether the effect of condition on change in weight depends on this variable. Relationship quality will be examined at baseline, and also will be examined separately at 6 and 12 months (controlling for weight loss up to that point). Statistically significant interactions will be interpreted by plotting simple regression lines for high and low values of this variable. To analyze qualitative data, transcribed interviews will be coded for thematic analysis. Coding steps will include the development of preliminary themes,

additional codes based on themes that arise, non-substantive codes, and detailed codes for analysis of specific topics. We will create a coding dictionary based on analysis of the first five transcripts, and every fifth subsequent transcript will be double-coded in order to assess interrater reliability. If there is <90% agreement in coding, we will re-assess domains to identify areas in which different labeling may have been used for similar ideas.

Power analyses suggest that a sample size of 238 is required for 80% power with the significant level of 0.05 and four assessment points, assuming the ratio of the variability of level-1 coefficient to the variability of level-1 residual is at least one. The study is adequately powered with the proposed sample size of 320 with up to 25% attrition.

c) Withdrawal of Subjects

Participants will be withdrawn from the research without their consent if there is a change in the subject's medical condition, if all or part of the study is discontinued for any reason by the sponsor, investigator, university authorities, or government agencies, new information is available to the investigator, or there are harmful unforeseen reactions experienced by the participant or other participants in the study. Participants will be notified about any new information that may affect their health, welfare, or choice to stay in the research.

If the friend/family member identified by the index participant does not consent to participate in the study, the index participant will be asked to identify another friend/family member. If they cannot find another friend/family member who would be willing to consent to the study (which is an inclusion criteria), then the index participant will be deemed ineligible and provided with relevant weight loss referrals.

Index participants and friends/family members may withdraw from the study at any time, and it will not be held against them. If an index participant or friend/family member stops being involved in the research, already collected data may not be removed from the study database. Any fee the index participant or friend/family member may be paid will be determined by the amount of time they spend in the trial and, if they do not complete the study, the reason for leaving the study early.

If termination is necessary, the project coordinator will contact the index participant or friend/family member immediately to discuss the grounds for their termination.

2) Risks to Subjects

Potential risks to participants are considered minimal. Participants will be informed of all potential risks when providing consent and assent before study participation. However, key personnel will address any discomfort or concerns expressed by the participant in regard to any aspect of the study if they do occur. If participants indicate any substantial distress, then risk assessment will occur and appropriate referrals for treatment will be provided as necessary.

One risk of the program is that as index participants lose weight, they may need to take less of any medications they are on, or they may develop gallstones. Index participants taking any medication will be instructed to carefully coordinate the oversight of these

medications with their primary care physicians to make any necessary adjustments of dosage necessary if weight loss occurs. Gallstones can result if weight is lost too quickly, but our study is designed to help individuals lose weight at only approximately 1-2 pounds per week. When using exercise equipment, however briefly, there is always a risk for injury if adequate precautions are not taken. In addition, PA may be uncomfortable to those index participants who are inactive or overweight, or may cause exacerbation of certain medical conditions. However, this is unlikely given the moderate recommendation (walking). An Adverse Event Questionnaire will be administered to all participants at 6, 12, and 24 months. This questionnaire will collect information about any medical events that have occurred during the course of the program. If an adverse event is reported and more information is necessary, an interview will be conducted with the participant to collect the additional information. This information will then be reported to NIH.

Psychological risks include reduced self-esteem in persons who fail to lose weight or regain weight, a sense of shame if not meeting program goals, or fellow program members or friends/family making critical remarks about an individual's weight or LM habits. However, several precautions will be taken to guard against psychological risks to participants. A methodical process of treatment development will be carried out to ensure that participant needs are met in a sensitive, caring, and culturally competent way. All clinicians will have had prior training and experience delivering LM programs. In addition, clinicians will receive specialized training in the delivery of the intervention programs, in particular how to monitor, respond to, and prevent participant feelings of shame or embarrassment. Dr. Butryn will take responsibility for ensuring that adequate training and supervision are provided, with assistance from the study co-investigators.

There also is a risk that group members or the designated friend/family member could share information about that index participant outside of the program. For both index participants and friends/family members, there is the risk that having the friend/family member serve in a support role could introduce a strain in the relationship. In all conditions in which any form of data sharing occurs, the coach will regularly discuss with participants any concerns they have about data sharing, so that problem can be addressed (e.g., if a data sharing friend/family member is making critical remarks, the index participant can be coached how to address this with that party, or that party can be replaced with a different friend/family member for data sharing). Coaches will be given training in how to assess any possible iatrogenic effects of data sharing that are disclosed by index participants (e.g., relationship strain with the data sharing partner), and coaches will log all such reports in a REDCap field to allow for trial monitoring and reporting.

Several steps will be taken to protect index participant confidentiality in the context of group-based treatment. At the first group meeting the importance of confidentiality will be discussed and concrete guidelines will be provided regarding permissible versus inappropriate disclosure of information about group-based treatment to others, including via social media (e.g., when discussing this LM program with other parties, the focus should be limited to one's one experience, not what is shared by others in group; names and identifying details of other index participants should never be disclosed to others; etc.). To maximize adherence to these guidelines, they will be presented in a way that elicits feedback from the group (so that group members have a sense of ownership

regarding these norms) and index participants will be encouraged to publicly commit in group to upholding these standards of confidentiality. Index participants will be notified that failure to respect the confidentiality of other group members is grounds for dismissal from the program. Similar training about confidentiality will be conducted with designated friends/family members who participate in the program to support an index participant's LM efforts.

3) Potential Benefits to Subjects

Participants may or may not benefit directly from this study. It is possible that the intervention may promote healthy behaviors, such as increasing physical activity and reducing caloric consumption, which may benefit index participants psychologically and medically. Also, the prescribed behavioral changes for index participants are known to promote improved quality of life and positive health outcomes. Participants in LM programs typically report that mood and quality of life also improve during the course of the program.

4) Privacy and Confidentiality

This study will not use nor disclose Protected Health Information (PHI).

As per policy of the IRB, all participant data, including the fact of their participation, will be treated as confidential and will be safeguarded according to the practices described above. All study staff will be trained regarding the importance of confidentiality, and all possible efforts to protect participant privacy will be observed. Participant materials will be labeled with a study identification number rather than personally-identifiable information (e.g., name). All data will be stored in password-protected files on secure servers that are only accessible to identified study staff. After being stripped of identifiable information, written materials from participants will be stored in locked filing cabinets. Drexel University Institutional Review Board and HIPAA guidelines will be observed.

Privacy and confidentiality will be explained to participants during the consent process, and questions about privacy will be answered as needed throughout the study. Participants will be reminded that they can decline to answer person questions as appropriate (e.g., during assessments). They also will be provided with contact information for the principal investigator and community mental health resources, to be used in the event of unforeseen distress.

Dr. Butryn will administer a data collection and storage training to all project staff, who must demonstrate competence in all tasks (e.g., phone screening, informed consent, etc.) before commencing their responsibilities. Staff will be assigned to review assessment data for accuracy and completion, and to pursue missing data by re-contacting participants. Specialized validity tools (e.g., customized spreadsheets and data entry software) will be used to maximize data accuracy. Double-entry will be utilized where appropriate. To maximize efficiency, data will be electronically managed through REDCap, a secure application that has been successfully used by this team on several projects. All paper-based data will be stored in a locked filing

cabinet, and all electronic data will be password protected and stored on secure computer servers. On-site and off-site backup storage will be utilized to protect against loss.

All data given to the statistician, as well as given to the DSMP-identified security officer, will be masked and, therefore, will contain no identifying information, except as required when reporting adverse events. No identifying information will be contained within study databases. All research data will be kept separate from identifiers and linked with a participant number. Only Dr. Butryn and her research coordinator will have access to the file linking names and participant numbers, and this file will be stored in their locked offices.

5) Economic Burden to Subjects

This research includes free assistance with developing healthy eating and physical activity and use of a commonly used digital self-monitoring device and wireless scale. Index participants will be financially compensated for their time spent in assessments.

Index participants and friend/family members are required to have access to a smartphone and data plan for using the study app. Financial assistance will be provided as needed for this technology or for text message costs.

6) Subject Compensation

Index participants can earn up to $140 for participating in this study, contingent upon the completion of all assessment assignments.

Index participants will be paid $40 for completing the 6-month assessment, $50 for completing the 12-month assessment (mid-treatment), and $50 for completing the 24-month (post-treatment) assessment. Compensation is contingent upon participants completing assigned study tasks.

Wave 1 participants who volunteer to complete the optional ecological momentary assessment study will receive an additional $75, making their total compensation $215.

The selected friend/family member involved in the study intervention will be compensated $50 upon completion of their webinar attendance.

Payment will be provided for index participants and friend/family members as an e-gift card from Amazon or through direct ACH payments to the participant's bank account. ACH is a very common, secure and fast electronic payment method used by all major banks. The use of ACH as a payment option allows for remote payment and helps us protect the privacy and safety of the participants and the research staff. To use this form of payment, we will provide JPMorgan Chase Bank the participant's study ID, name, and email or phone number. Chase will then send the participant an invitation to receive payment either as an email or a text message. Once the participant accepts the invitation, the funds will be deposited to their bank

account. Drexel University and the research team do not have any access to the participant's account information and are not directly involved in the disbursement of the funds.

If participants cannot or do not want to receive a direct, electronic payment nor an e-gift card, they will have the option of receiving a check from Drexel University. This option takes several weeks to process, requires the participant to complete a federal W9 form and requires disclosing their name and social security number to Drexel's Accounts Payable department. They will also need to disclose their name and address to JPMorgan Chase Bank, who would be the distributor of the check.

7) Consent Process

The consent process will follow the IRB recommended "Investigator Guidance: Informed Consent (HRP-802)" document. Index participants will be told that the purpose of the study is to test new approaches to supporting long-term behavior change, specifically, that this study will test whether using coaches, program peers, or family/friends as sources of support and accountability can improve long-term weight loss. They will be told participation is voluntary and they can withdraw from the study at any time. Participants will be sent a copy of the screening consent before the phone screen. They will be prompted to ask any questions and will be assessed for comprehension. After reviewing the form and clarifying any confusion, signatures will be collected. If the participant chooses not to sign the screening consent, the phone screen will not continue.

At the end of the clinic visit, each index participant will be given a copy of the full study consent form. Participants will then review the consent form ahead of their Session 0. At Session 0, a staff member will review the consent in detail and the index participant will digitally sign and return it if.

Full eligibility will not be determined until following the study visit. Index participants will be explicitly informed that their eligibility is still not final at the conclusion of the study visit. There may be some occasions on which it is more subjective whether a prospective participant meets the inclusion or exclusion criteria (e.g., psychiatric condition) and so eligibility cannot be confirmed immediately during the study visit. Throughout the enrollment process, we will hold consensus meetings where these types of enrollment decisions and questions will be reviewed by staff and investigators. We cannot inform index participants of their final eligibility until after these meetings are held and criteria are discussed. Index participants will be contacted after the visit to confirm whether they are enrolled. We do expect that a small number of index participants will be deemed ineligible after the consensus meeting. We will make a phone call to these participants and provide relevant weight loss referrals.

Wave 1 participants who are invited to participate in the optional ecological momentary assessment will be sent an electronic version of the informed consent form to digitally sign and return. Changes to the original informed consent will be clearly highlighted.

Dr. Butryn will provide several hours of training to familiarize study staff with the process of properly obtaining informed consent. Before signatures are collected, participants will be asked the following questions to assess their understanding of the risks and benefits of participation:

- What are we going to ask you to do as part of this study?
- What time commitment will the study require?
- What are the main risks and benefits of participating?

Friend/family members who have been selected by index participants will be sent an email from the research team with study details and a link to provide consent digitally and to complete self-report measures. The friend/family member will be given the opportunity to sign up for a study visit with study staff if they have additional questions. This session will give adequate time for friends/family members to understand the study and ask any questions.

8) Process to Document Consent in Writing

We will be following "INVESTIGATOR GUIDANCE: Informed Consent (HRP-802)." Fitlink Informed Screening Consent Form will be sent out to index participants prior to scheduled phone screen with Fitlink screeners. If participants do not complete the Informed Screening Consent Form before scheduled phone screen, screeners will guide participants to read the consent form. They will then be asked to sign the screening consent via a REDCap survey and encouraged to contact the PI at any time if they have any questions or concerns.

The Index Participant Informed Consent Form will be provided to participants after the clinic visit is complete. The participant will review it ahead of their Session 0. At Session 0 participants will have time to ask any questions that they may have. They will then sign the form via an online REDCap survey and submit. Participants will be encouraged to contact the PI at any time if they have any questions or concerns.

Friends/family members will be provided with a digital consent form before they begin any self-report measures. After friends/family read the consent, they will be asked if they have any questions regarding the research and a member of the research team will be available to read through the consent and answer questions. They will then be asked to sign the consent and encouraged to contact the PI at any time if they have any questions or concerns.

9) Vulnerable Populations

Does not apply.

10) Multi-Site Human Research

Does not apply.

11) Sharing of Results or Incidental Findings with Subjects

Findings will be disseminated to the research and practice communities through presentations at professional conferences and publication of results in peer-reviewed journals. We will register our clinical trial at ClinicalTrials.gov before subject recruitment and ensure that summary results data are submitted there in a timely fashion (e.g., participant flow, baseline characteristics, outcome measures, statistical analyses, data on adverse events). Our informed consent documents will include specific statements related to posting information and results at ClinicalTrials.gov.

Consent forms will also explain that all data will be de-identified prior to the registration of results in order to protect participant privacy and confidentiality. Drexel University has an internal policy in place to ensure that clinical trial registration and results reporting occur in compliance with NIH policy requirements. We will assume full responsibility for following the appropriate requirements and timelines.

12) Research Conducted in a Foreign Country

Does not apply

13) Community-Based Participatory Research

Does not apply

Title: Sharing Digital Self-Monitoring Data with Others to Enhance Long Term Weight Loss: A Randomized Trial using a Factorial Design

Protocol Number.: 2103008421

Sponsor: National Institutes of Health

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Consent to Take Part in a Research Study

You are being invited to take part in a research study. A person who takes part in a research study is called a research subject, or research participant.

Concise Summary of Key Information:

- This research is being done to test new approaches to supporting long-term behavior change. Specifically, this study will test whether using coaches, program peers, or family/friends as sources of support and accountability can improve long-term weight loss.
- Your consent and participation in this study is completely voluntary.
- Participants will be enrolled in the study for a total of 2 years (24 months), with assessments at baseline (0 months), 3 months, 6 months, mid-treatment (12 months), and post treatment (24 months).
- Every day for the full two years, you will use a smart scale to weigh yourself, wear a physical activity tracker, and track your meals on a food record smartphone application.
- For the first 3 months of your participation in the study, you will attend weekly remote group-based behavioral weight loss sessions.
- For months 4-24, you will:
  - Attend a group-based behavioral weight loss session online via Zoom videoconferencing software once every 3 months, and
  - Participate in a brief, individual phone call with a coach once a month.
- Every month, you will exchange text messages concerning your progress in the program with a coach, with fellow group members, and with a friend/family member.
- Depending on your random condition assignment your coach, fellow group members, and/or your friend/family member may have real-time access to the data gathered by your smart scale, physical activity tracker, and food record app to inform their text messages.

- Study messages will be sent through a secure, web-based portal to an app on your phone. You will be assigned a username and password to receive these messages. Information from your scale, Fitbit, and food record will be collected through the Fitbit API, and also stored on the study web-based portal. The study portal will be accessed only by authorized study staff.
- We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include weight loss as the behavioral weight loss treatment employed in this study has much scientific support.
- Participation in the study may involve unforeseen risks. If unforeseen risks are seen, they will be reported to the Drexel Office of Human Protection Office. If any events occur that might be related to the treatment, you should bring them to the attention of your personal physician.
- If you do not wish to take part in this research, we can provide you with a list of referrals for other weight loss programs in the area or you can talk to your doctor.
- You will only be responsible for any smartphone data use incurred from using the

program app.
You can receive a total compensation of $140 for completion of all assessments. Contingent upon completing all assignments, you will receive $40 for 6- months, $50 mid-treatment (12 months), and $50 for post-treatment (24 months). Payment will be in the form of e-gift cards (Target or Amazon), direct ACH payments, or by check.

What should I know about this research?

- Someone will explain this research to you.
- This form sums up that explanation.
- Taking part in this research is voluntary. Whether you take part is up to you.
- You can choose not to take part. There will be no penalty or loss of benefits to which you are otherwise entitled.
- You can agree to take part and later change your mind. There will be no penalty or loss of benefits to which you are otherwise entitled.
- If you don't understand, ask questions.
- Ask all the questions you want before you decide.

Why is this research being done?

The purpose of this research is to test new approaches to supporting long-term behavior change. Specifically, this study will test whether using coaches, program peers, or family/friends as sources of support and accountability can improve long-term weight loss.

320 participants and 320 friends and/or family members of the participants will take part in this research.

How long will I be in this research?

We expect that your taking part in this research will last 2 years (24 months).

What happens to me if I agree to take part in this research?

If you choose to participate in this research study, you will be given a smart scale, physical activity tracker, and access to a food recording smartphone app. You will use these digital data trackers to weigh yourself, track your physical activity, and record all of your meals and snacks daily for the duration of the study (24 months). Due to study requirements, you may only be eligible if you own a smartphone.

For the first three months, you will attend and participate in weekly, remote group-based behavioral weight loss treatment sessions (90 minutes) through the Zoom videoconferencing

platform. Each group will be led by a Masters-level coach, who will teach you skills related to losing weight and maintaining that weight loss in the long term. For the rest of the study, groups will continue to be held online via Zoom videoconferencing, and will take place once every three months. You also will participate in brief (15 minutes), individual phone calls with your coach once per month. During these phone calls, your coach will check in about your progress towards your goals, review core behavioral skills that are most relevant to you, and collaboratively set goals with you for the next month. Lastly, you will exchange text messages monthly with your coach; with 3-4 fellow members of your group; and with a designated friend/family member.

You will be randomly placed in 1 of 8 conditions. Your study condition determines which components of the intervention you will receive. There are 3 components, and they differ by the party with whom your weight, physical activity, and food record data will be shared with: your coach, a small group of your fellow group members, and your friend/family member. Neither you nor the study investigator will choose which components you receive or your study condition.

Every participant will take part in 20 group sessions, 14 coach calls, and monthly text exchanges with a coach, with a small group of fellow group members, and with a friend/family member. Depending on your study condition, your coach, small group of fellow group members, and/or your friend/family member will have access to the data collected by your scale, physical activity tracker, and food record app (i.e. your weight, minutes of physical activity, and caloric intake). They will use this information to inform the text exchanges you have monthly. If they do not have access to your digital data, you will still engage in the text exchanges with each of them. Study messages will be sent through a secure, web-based portal to an app on your phone. You will be assigned a username and password to receive these messages. Your first name, user name, phone number, and email address will be stored on the web-based portal. Information from your scale, Fitbit, and food record will be collected through the Fitbit API, and also stored on the study web-based portal. The study portal will be accessed only by authorized study staff. The development team for the web portal has been approved by Drexel's Information Security Office. The development team has agreed to abide by Drexel's Application Development Standards under the Security of Information and Networked Systems policy, encrypt at rest and in motion, and abide by privacy by design, security by design, and responsible computing principles. As part of participation, participants will be provided with informational handouts that correspond to the skills taught in that week's session. Participants will access these handouts in Google Classroom. There will be no personal, identifying, or health information shared in any of these documents. Other features of Google Classroom such as discussion boards will not be used; participants will simply be using Google Classroom as a user-friendly place to locate these handouts.

Assessments will be completed at the beginning of treatment (0 months), 3 months after treatment begins, 6 months after treatment begins, at the mid-point of treatment (12 months), and at the end of treatment (24 months). At this time, you will be asked to complete a set of surveys and to track weight, physical activity, and food intake for 7 days.

The exception is month 3 assessment, where you will only be asked to complete a limited battery of self-report measures and 7 days of self-weighing. During your final assessment, you may be randomly chosen to participate in a 45-60 minute semi- structured interview to provide feedback about the study.

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible to:

- Attend all required study visits and assessments.
- Every day, you will:
  - Weigh yourself using the smart scale you were given,
  - Wear the physical activity tracker
  - Record your food intake using the designated program smartphone application.
- Attend and participate in all group behavioral weight loss sessions
- Participate in all phone calls with your coach.
- Read and participate in all text message exchanges between you and your coach, you and your small group of fellow group members, and you and your friend/family member.
- Contact the investigator if any complications arise

Could being in this research hurt me?

Participation in this research study includes minimal risk. During this study, you will be undergoing behavioral weight loss treatment with prescriptions of gradual exercise increase and decreased caloric intake with the goal of losing approximately 1-2 pounds per week. If you lose a large amount of weight too quickly, you are at risk of developing gallstones. You also may injure yourself when engaging in physical activity. Both of these risks are unlikely given the prescribed physical activity of brisk walking. If you are taking any medication, you should carefully coordinate the oversight of these medications with your primary care physicians to make any necessary adjustments of dosage necessary if weight loss occurs.

There may also be psychological risks to you such as feelings of shame or embarrassment related to eating habits and/or weight, which may be amplified if you are randomly assigned to share your digital data with a coach, small group of group members, and/or a friend/family member. However, your coach will be trained to deliver the program in a way that feels positive to you and will be able to address your concerns if they arise. Lastly, there is always

a risk for loss of privacy and confidentiality, though the research team will take many precautions to protect against this.

Participation in the study may involve unforeseen risks. If unforeseen risks are seen, they will be reported to the Drexel Office of Regulatory Research Compliance. In addition to these risks, taking part in this research may harm you in unknown ways.

Will it cost me money to take part in this research?

This research includes free assistance with developing healthy eating and physical activity and use of a commonly used physical activity tracker and Fitbit Aria Air smart scale. You will be financially compensated for your time spent in assessments.

You will only be responsible for any smartphone data use incurred from using the program app. Financial assistance will be provided as needed for this technology or for text message costs.

Will being in this research benefit me?

We cannot promise any direct benefits to you or others from your taking part in this research. However, it is possible that the intervention may promote healthy behaviors, such as increasing physical activity and reducing caloric consumption, which may benefit you psychologically and medically. Also, the prescribed behavioral changes are known to promote improved quality of life and positive health outcomes. Participants in LM programs such as this one typically report that mood and quality of life also improve during the course of the program.

What other choices do I have besides taking part in this research?

Instead of being in this research, your choices may include:

- Other programs in the area, for which we can provide you with a list of referrals.
- Talking to your doctor about other weight loss options that may be a better fit for you.

What happens to the information collected for this research?

Your private information will be shared with individuals and organizations that conduct or watch over this research, including:

- The research sponsor: National Institutes of Health (NIH)
- People who work with the research sponsor(s)
- Government agencies, such as the Food and Drug Administration or the Department of Health and Human Services
- The Institutional Review Board (IRB) that reviewed this research
- Drexel University and its affiliates

We may publish the results of this research. However, we will keep your name and other identifying information confidential.

We protect your information from disclosure to others to the extent required by law. We cannot promise complete secrecy.

Data collected in this research might be de-identified and used for future research or distributed to another investigator for future research without your consent.

A description of this clinical trial will be available on http://www.clinicaltrials.gov/, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

What is a Certificate of Confidentiality?

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. A Certificate of Confidentiality helps protect your identifiable information and biological samples. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by The National Institutes of Health which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law, such as child abuse and neglect, or harm to self or others.

Who can answer my questions about this research?

If you have questions, concerns, or complaints, or think this research has hurt you or made you sick, talk to the research team at the phone number listed above on the first page.

This research is being overseen by an Institutional Review Board ("IRB"). An IRB is a group of people who perform independent review of research studies. You may talk to them at (267) 3592471 or HRPP@drexel.edu if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.

Can I be removed from this research without my approval?

The person in charge of this research can remove you from this research without your approval. Possible reasons for removal include:

- If there is a change in your medical condition.
- If the study is discontinued for any reason by the sponsor, investigator, university authorities, or government agencies.
- If new information is available to the investigator.
- If there are harmful unforeseen reactions experienced by you or other participants in the study.

We will tell you about any new information that may affect your health, welfare, or choice to stay in this research.

What happens if I agree to be in this research, but I change my mind later?

You can agree to take part in the research now and stop at any time.

Participation in this study is voluntary, and you can refuse to be in the study or stop at any time. Any fee you may be paid will be determined by the amount of participation you completed and, if you do not complete the study, the reason for leaving the study early.

If you stop being in the research, already collected data may not be removed from the study database.

Will I be paid for taking part in this research?

For taking part in this research, you may be paid up to a total of $140 in the form of e-gift cards (Target or Amazon, your choice) or direct ACH payments to your bank account. ACH is a very common, secure and fast electronic payment method used by all major banks. The use of ACH as a payment option allows for remote payment and helps us protect the privacy and safety of the participants and the research staff. To use this form of payment, we will provide JPMorgan Chase Bank your study ID, name, and email or phone number. Chase will then send you an invitation to receive payment either as an email or a text message. Once you accept the

invitation the funds will be deposited to your bank account. Drexel University and the research team do not have any access to your account information, and they are not directly involved in the disbursement of the funds.

The payment is contingent upon completion of all assessment materials and procedures at each time point, such as surveys and dietary recalls, and is broken down as follows:

- $40 for completing the 6-months assessment
- $50 for completing the mid-treatment (12 months) assessment
- $50 for completing the post-treatment (24 months) assessment

If you cannot, or do not want to, receive a direct, electronic payment, you have the option of receiving a check from Drexel University. This option takes several weeks to process, requires you to complete a federal W9 form and requires you to disclose your social security number to Drexel's Accounts Payable department. You will also be required to disclose your name and address to JPMorgan Chase Bank, who would be the distributor of the check.

Federal tax law requires to you to report this payment as income to the Internal Revenue Service if you are compensated more than $599.00 (in total) this year for participating in research. You may be asked to tell us your social security number or other identifying information (e.g., full name). If payments for this study are more than $599.00, we will report them to the Internal Revenue Service and send you a Form 1099-MISC. This information will not be associated with the information or data you provide for this research. It will be stored separately from your data, it will not be linked in any way, and your identifying information will be destroyed within 1 year of study completion.

What else should I know about this research?

If in your initial assessment, we determine that you do not meet the eligibility for this particular study, you have the option to elect to be screened for other studies at Drexel University's WELL Center as well as to remain in the WELL Center database for future studies. Please initial below if you are interested in one or both of these options:

_____*I elect to be screened for other studies at Drexel University WELL Center if I am not eligible for this study.*

_____*I would like to be added to the WELL Center database to be contacted for future studies that I might be eligible for.*

Signature Block

Your signature documents your consent to take part in this research.

Printed Name and Signature of adult subject capable of consent Date

Printed name and Signature of person obtaining consent Date