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Research Protocol

Weight Loss Intervention for Mothers with Young Children

I. Objectives

1. Assess intervention fidelity (dose, delivery, receipt) and acceptability by the study participants
2. Investigate potential intervention impact on the primary (body weight) and secondary outcomes (pants size)
3. Explore potential intervention impact on lifestyle behaviors (diet and physical activity)
4. Explore potential intervention impact on motivation (autonomous motivation, self-efficacy, social support), emotion (emotion control, stress), and cognition (impulsivity).
5. Assess cost of different recruitment approaches

II. Background and Rationale

Low-Income Overweight or Obese Mothers of Young Children: Our Priority Population. In the U.S., nearly 50% of low-income women aged 20-40 years are at high risk for type 2 diabetes, because they live in poverty and are overweight or obese (body mass index [BMI] ≥ 25.0 kg/m^2).[1-4] One-year postpartum, low-income women have over twice the risk (68-75%) for significant weight retention (≥ 10 lbs) compared to higher-income women (32%).[5] Significant postpartum weight retention is a strong predictor for lifelong obesity[6] and adverse maternal and birth outcomes, such as gestational diabetes and macrosomia[7-13] during subsequent pregnancies. Weight gain of ≥ 11 lbs during young adulthood increases risk for obesity-related conditions including type 2 diabetes,[14] which can be delayed and reduced by weight loss.[15]

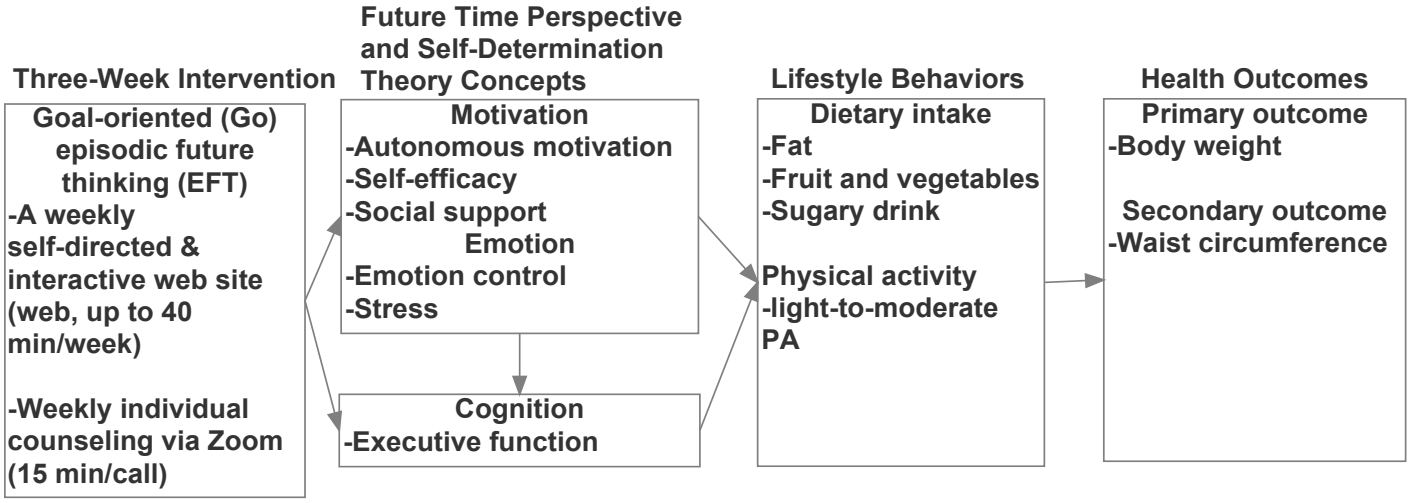
Current Lifestyle Weight Loss Intervention Studies. Two recent meta-analyses[16,17] and an individual effectiveness intervention study[18] have shown that healthy lifestyle behaviors (healthy eating, PA) promote postpartum weight loss, including for low-income, overweight or obese women.[18] Despite the promise of the existing research, most prior studies have had relatively *small sample sizes,* mainly due to limitations for enrolling women within one year postpartum[16,17] -- high infant care demands prevent women from participating in intervention studies.[16] This is a missed opportunity to have broader impact on the obesity epidemic[19] and pregnancy-related maternal outcomes, because 40-50% of obese women gain ≥ 2 BMI units between pregnancies.[20] Also, prior studies *paid little or no attention to mechanisms* of motivation (autonomous motivation, self-efficacy, social support), emotion (emotion control, stress), and cognition (executive function), all of which play important roles in healthy lifestyle behaviors and resulting positive health outcomes.[21-30] Finally, previous lifestyle interventions have involved costly staff involvement that would be *difficult or impossible to scale up and maintain in clinical practice*.[31] The previous research suggests that progress is possible but fails to provide clinically-feasible and scalable options. *Thus, there is an urgent need to test scientifically rigorous, novel intervention programs, like the one that we proposed, for achieving weight loss in the priority population that could also potentially address feasibility limitations of prior work*.

Scientific Premise. **Previous research strength**. Lifestyle interventions can promote weight loss. **Previous research limitations**. (1) The proposed priority population has been significantly underrepresented in prior lifestyle weight loss intervention studies. (2) Prior lifestyle interventions in overweight or obese mothers have suffered from threats to internal validity and have not specifically addressed motivation, emotion, and cognition (especially executive function), all of which are critical for promoting and maintaining healthy lifestyle behaviors and health outcomes. (3) *There has been little evidence that any of the potentially efficacious strategies researched previously were even possible under real-world conditions.* The proposed small pilot study builds on strength and effectively addresses limitations of prior research. *The ultimate goal of the proposed study is to create a more feasible and scalable intervention that can be easily implemented and sustained in real-world settings. We propose to assess intervention fidelity and acceptability; we also investigate the potential utility of a web-based intervention in which participants identify their motivation for making positive behavior change, weekly goals, and means of attaining those goals, supplemented by periodic individual phone calls*. Moreover, we will assess cost of different recruitment approaches. **Significance**. The

proposed study will *add scientific knowledge on intervention implementation in a hard-to-reach population at high risk for type 2 diabetes*.

Conceptual Framework

Figure 1. Study Conceptual Framework



The proposed lifestyle weight loss intervention study will be *the first to jointly apply future* time perspective *and Self-Determination* Theory concepts (motivation [autonomous motivation, self-efficacy, social support], emotion (emotion control, stress), and cognition (executive function). **Conceptual Framework** (Figure 1). We use Future Time Perspective Theory (anticipation of future goals or personal experience across the past, present, and future[32]) as a guiding conceptual framework. Future time perspective drives motivation and behavior in everyday life.[33] Future Time Perspective Theory concepts include motivation,[34] emotion,[33] and cognition.[35] Implementation of future time perspective has focused on episodic future thinking.[35] We also apply key concepts from Self-Determination Theory**:** Autonomous motivation, competence (self-efficacy)**,** and relatedness (social support), all of which foster motivation and activity engagement.[36] Self-Determination Theory -based interventions have effectively promoted and maintained healthy eating,[22,37] physical activity,[38] weight loss,[23,39-41] goal progress,[42] and intervention adherence.[39] Our **preliminary work** with the proposed priority population supports the study conceptual framework. A lifestyle intervention including stress management can effectively reduce stress[43] and fat intake.[44] Stress was positively associated with fat intake.[45] Self-efficacy and social support buffer stress[46] and dietary intake[47,48] Autonomous motivation and self-efficacy mediated the association between a lifestyle intervention and fat intake.[49] Self-efficacy mediated the association between a lifestyle intervention and stress.[47] Using an ActiGraph accelerometer (ActiGraph) to measure physical activity in the proposed population,[50] we found that 33.3% met physical actviity recommendations (≥ 150 min/week moderate physical activity), 23.9% had some but were below the recommendations, and 42.8% had no physical activity. The proposed **Goal-oriented EFT (GoEFT)** intervention has two unique components that differentiate it from our own and other previous research: weekly self-directed and interactive web site (**web**) and individual counseling via Zoom. The vivid imagination (visualization, episodic future thinking) of goal-relevant future events in the individual's life[51] is specifically designed to improve motivation (autonomous motivation, self-efficacy, social support), emotion (emotion control, stress), and cognition (executive function), all of which promote success in achieving goals for healthy lifestyle behaviors. Key lifestyle behaviors include dietary intake (fewer calories, less fat and sugary drinks, and more fruit and vegetables) and physical activity (increase light-to-moderate physical activity). The proposed light-to-moderate physical activity is a realistic goal for the priority population and is consistent with public health recommendations that even modest increases in daily physical activity can yield measurable health benefits.[52-56] The primary outcome is weight loss (body weight) and the secondary outcome is waist circumference -- stronger predictors of obesity-related chronic conditions than BMI.[57-62]

Connecting Episodic Future Thinking to the Proposed Mechanisms. Goal-oriented episodic future thinking[29] is a promising approach to improve motivation, emotion, and cognition (the proposed mechanisms connecting the intervention to the targeted lifestyle behaviors and health outcomes). Neuroimaging[63-66] and fMRI[67-69] studies have shown that episodic future thinking activates the common core network of brain regions associated with executive function during daily activity and brain regions associated with emotion regulation, decision-making, and memory. **Influences on motivation: autonomous motivation, self-efficacy, and social support.** Autonomous motivation -- will to engage in a behavior because of personal value, interest, or choice -- is important for achieving one's goals.[36] Self-efficacy refers to beliefs that one can successfully undertake an action.[70] Social support means receipt of various types of support, such as help from friends, family members, or others.[71] Episodic future thinking increases motivation by facilitating the link between goals and actions and by enhancing the subjective likelihood and/or value of a goal.[72] **Influences on emotion: emotion control and stress.** Emotion control, one's ability to manage emotional reactions using appropriate strategies, is associated with ability to cope with stress.[73] Episodic future thinking improves emotion,[67,74-76] because it activates brain regions associated with emotion regulation.[67-69] **Influences on cognition (executive function).** Executive function enables individuals to coordinate thoughts, actions, and emotions[77] to achieve healthy lifestyle behaviors[30,78] and positive health outcomes.[30,77] Executive function includes inhibitory control (important for EC and resisting temptation to overeat and over-react[77]), memory, reasoning, problem-solving, and planning.[77] Executive function enables individuals to take goal-directed action.[78] Episodic future thinking, especially goal-oriented episodic future thinking,[29] effectively increases inhibitory control including in overweight or obese women.[28,79-81] Such episodic future thinking consequences enable reduced energy intake[28,29,80,82] promoting weight loss[83] by shifting the time perspective of decision making[84] and activating brain areas associated with prospection.[85] Also, episodic future thinking fosters more relevant steps in problem solving,[86] detailed steps to attain a goal,[72] and prospective memory.[87] Finally, episodic future thinking increases reasoning, problem-solving, and planning.[67,72,86,88,89] Thus, there are many reasons to expect goal-oriented episodic future thinking to impact the proposed mechanisms.

Connecting Proposed Mechanisms to Each Other and to Lifestyle Behaviors and Health Outcomes. Motivation and emotion are inter-related components of self-regulation that enable individuals to adhere to a healthy lifestyle and achieve positive health outcomes.[90] **Motivation**. Increased autonomous motivation, self-efficacy, and social support are strongly associated with reducing stress in overweight or obese women[46,47,91] and with promoting cognitive performance[92] (e.g., problem solving[93]) and a healthy lifestyle.[21-25,47,48,94] Also, autonomous motivation predicts successful goal pursuit[32,95] and promotes weight management.[24,40,96,97] **Emotion** influences cognition.[98] Stress negatively affects diet (increased intake of high-fat, sugary, energy-dense foods, leading to weight gain[27]) and physical activity.[26] Higher levels of stress are associated with lower levels of inhibitory control[27] and interfere with cognitive performance,[99] but reducing stress improves executive function.[100] **Cognition (executive function)**. Low levels of inhibitory control have been associated with increased energy intake in overweight or obese women,[79] but high levels of inhibitory control have been associated with reduced consumption of total calories, percent calories from fat,[28,29] and snacking and food intake[80,82] in women. Executive function also predicts moderate-to-vigorous PA,[30] maintenance of PA,[101] and weight loss.[30] Executive function deficits are more likely in overweight or obese than normal-weight women[102-105] and can be improved through training and practice.[100] Thus, previous research supports associations among the key mechanisms and connects those mechanisms to healthy lifestyle behaviors and to health outcomes.

The study would also be *the first to apply episodic future thinking outside the lab with no in-person component (emphasizing clinical feasibility). The use of episodic future thinking is more effective for long-term motivation and planning than self-generated thought without episodic future thinking. Episodic future thinking enables individuals to generate detailed goal-relevant scene construction*,[64,88,106,107] whereas *self-generated thought without episodic future thinking focuses on behaviors with minimum or no scene construction.*[108] With the exception of one "internet plus in-person" four-week intervention,[83] all prior *episodic future thinking* studies have been conducted in lab settings where participants followed intensive and specific scripts directing them through vivid imagination of future events. Thus, the relevance and scalability of *episodic future thinking* for clinical practice remains speculative. Moreover, prior *episodic future thinking* studies have only focused on one

form of *episodic future thinking*: episodic simulation (mental representation of the future).[67] The proposed intervention includes episodic simulation, prediction (benefits for achieving goals), intention (identifying when and where the activity will take place), and planning (generating specific steps rather than general plans for achieving the goal done by prior research), all of which come together to support prospective cognition.[109] Furthermore, the study would be *the first to ask participants to vividly imagine their personal plans followed by enabling them to weekly customize the plans*. This approach supports the sense of volition and choice and fulfilling the psychological needs of the participants, which in turn promotes quality of intervention engagement and outcomes.[110] Finally, the study would innovate in *use of participant-generated short reminders to promote cohort retention and intervention dosage.*[111]

A. Research Design

This pilot quasi experimental design study aims to (1) assess intervention fidelity (dose, delivery, receipt) and acceptability by the study participants, (2) investigate potential intervention impact on the primary (body weight) and secondary outcomes (waist circumference), (3) explore potential intervention impact on lifestyle behaviors (diet and physical activity), (4) explore potential intervention impact on motivation (autonomous motivation, self-efficacy, social support), emotion (emotion control, stress), and cognition (impulsivity), and (5) assess cost of different recruitment approaches. We will enroll 30 overweight or obese women with diverse racial and ethnic backgrounds. All measures will be assessed at baseline (T1) and immediately after the three-week intervention (T2).

B. Sample

Inclusion Criteria. Self-reported
■ BMI of 25.0-45.0 kg/m^2 (calculated using height and weight) ■ Current enrollment in government assistant programs (for example, WIC, food stamp (SNAP), or Madicaid) ■ 6 weeks - 5 years postpartum ■ 18-45 years old ■ Fluency in speaking, reading, and writing English ■ Ownership of a smart phone with unlimited text messages and internet access ■ Committed to a three-week intervention study

Exclusion Criteria. Self-reported
■ Current pregnancy or lactation ■ Plan to become pregnant during the trial ■ Type 1 or 2 diabetes ■ Untreated thyroid disease ■ Drug or alcohol abuse or dependence within last six months ■ Major psychiatric disorder (e.g., schizophrenia, bipolar) ■ History of bulimia or anorexia ■ Current taking of appetite suppressant or (antipsychotic) medications known to affect body weight ■ Current participation in a weight control or drug study ■ Current or planned participation in a commercial weight loss program ■ Previous weight loss surgery ■ Contraindications to physical activity.

Sample size/power. We did not perform a formal sample size calculation but based on our available funding and resources. Because of budget constraint, we think a sample size of 30 women is appropriate for this pilot, which will provide preliminary data for us to apply future NIH R01.

C. Measurement/ Instrumentation

All participants will be assessed at baseline (T1) and immediately after the three-week intervention (T2). Survey data will be collected online using password-protected security-ensured Research Electronic Data Capture (REDCap), a secure web application for building and managing online surveys and databases. Participants will receive up to $10 for completing T1 data collection and $20 for T2 data collection. We will contact participants to verify or clarify survey data, e.g., body weight is entered as 90 (most unlikely because we will enroll overweight or obese women) instead of 190.

Feasibility. We will use our tracking records to assess recruitment and retention. To assess intervention implementation, we will extract data from our study web site that will track and capture details about all activities (e.g., amount of and type of activities completed and percent of participants used type in box). We will record the attendance of individual coaching session. Participants will report their motivation and barriers preventing them from engaging in the intervention activities and evaluate the usefulness of with each episodic

future thinking intervention component. We will also use semi-structure interview questions (up to 20 minutes/an individual interview via zoom) to ask participants to evaluate the intervention. We will use website tracking data, individual coaching session, and results of zoom interview to revise the intervention contents for a future large scale intervention study (R01).

Primary outcome: body weight. We will collect self-reported body weight.

Secondary outcome: waist circumference. We will collect self-reported pants size, which is a good indicator of waist circumference.

Lifestyle behaviors.

Dietary fat. The NCI brief dietary fat intake survey (16 items)[112] will be used to measure dietary fat intake. Participants will be asked about frequency of consuming a list of foods. ***Fruit and vegetable intake***. NCI five factor screener (9 items) [113] will be used to measure fruit and vegetable intake. Participants will be asked about the frequency of eating fruit and vegetables. ***Sugar intake***. NCI five-factor screener (4 items)[114] will be used to measure sugar intake. Participants will be asked about the frequency of eating foods and sweeten beverage. ***Physical activity***. The International Physical Activity Questionnaire Short Form (7 items)[115] will be used to measure physical activity. Participants will be asked amount of time spent on physical activities.

Concepts.

Motivation. *Autonomous motivation* will be measured using Treatment Self-Regulation Questionnaire (18 items) that asks why the respondent does a behavior.[116] *Self-efficacy* will be measured using a 10-item survey for general self-efficacy,[117] an 8-item survey for healthy eating self-efficacy,[118] and a 10-item survey for physical activity self-efficacy[119] that ask participants' confidence in performing the specific activity. Social support measures ask mothers to report social support from their family members, friends, or other people to manage stress (6 items), eat healthier (6 items), and engage in PA (4 items).[119] ***Emotion***. *Emotion control* will be measured using the Emotion Regulation Questionnaire (10 items) that assess emotion regulatory process using reappraisal, suppression and regulating negative emotion.[120] *Stress* will be measured using The Perceived Stress Scale (10 items)[121] that measures the degree to which situations in one's life are appraised as stressful. ***Cognition***. To measure executive function (impulsivity), we will use Barratt Impulsiveness Scale (30 items) to measure impulsivity.[122]

Process evaluation.

All participants will report receipt of lifestyle behavior counseling from their clinicians, midwifes and dietitians and joining other programs.

Recruitment cost

We will track time and effort spend on each recruitment method.

Sent messages to participants

We will email and text participants to complete study activates. Please note the sequence listed below corresponding to the sequence listed on the file called "All Email and Text Messages."

Activities	Email	Text	Notes
A. Enrollment Phase			
A1. Attend information session (first zoom meeting)	Yes	Yes	Up to 3 times
A2. Full consent to participation	Yes	No	Up to 3 times
A3. Attend second zoom meeting	Yes	Yes	Up to 3 times
B. Intervention Phase			
B1: Complete Part I intervention: becoming a better me	Yes	Yes	Need to send both email and text (at the same time) because of including web link—participants can

			complete via smart phone or computer internet access. Up to 3 times for each
B2. Complete Part II intervention: safe care booster	Yes	Yes	Need to send both email and text (at the same time) because of including web link. Up to 3 times for each
B3. Join the weekly individual coaching via zoom	Yes	Yes	Up to 3 times
C. Throughout the project			
C1. Fill out online survey	Yes	Yes	Need to send both email and text (at the same time) because of including web link. Up to 3 times for each
D. Notify Incentives	Yes	Yes	Up to 3 times for each

E. Detailed study procedures

Recruitment and enrollment. Participants will be recruited via four approaches: (1) FaceBook, (2) Study Search, (3) Research Match, (4) MyChart, and (5) study flyer

FaceBook, We will post the study flyer at FaceBook (File name: Flyer_FaceBook Add). Potential participants who are interested in the study will contact the study office for screening.

Study Search. We will post the study flyer at Study Search via OSU Medical Center website (File name:Flyer_study search). Potential participants who are interested in the study will contact the study office for screening.

Research Match. We will post the study flyer at Research Match website (File name: Flyer_Research Match, which describe how participants will be identified in details). The study office will contact the potential participants who are interested in the study.

MyChart. We will post the study flyer at MyChart (via 'OSU BMI', File name: Flyer_MyChart). Upon IRB approval, we will submit an "honest broker data request form" followed by working with 'OSU BMI' to identify potential participants. Once potential participants who are interested in the study are identified, 'OSU BMI' will refer these potential participants to IHIS box. The trained research staff will log into IHIS to contact the potential participants.

Study Flyer. We will post the study flyer in, for example, clinics, website (e.g., Craig's list, google). We will also ask organizations that agree to collaborate with us to send the study flyer via email or other social media to their clients or customers. Potential participants who are interested in the study will contact the study office for screening.

Initial Contact of Potential Participants regardless methods of recruitment. We will obtain verbal consent prior to screening and obtaining demographic information. Collecting demographic data will help us revise or plan for recruitment strategies for a future R01. If eligible, participants will provide up to three working telephone numbers (at least one capable of receiving text messages), email address, and physical address as contact information. We will ask if we can leave a message via phone (Yes/No). Next, the Research Staff will schedule a zoom meeting (individual information session, described below) within the five business days with the qualified participants (we will allow extension if participants indicate the time line does not work for them). Then, the trained research staff will send the full consent form to the participants for review (via email) prior to the first scheduled zoom meeting. Participants will be informed the zoom meeting will be either audio or video recorded per their preferences.

First zoom meeting (information session lead by research staff). Participants will use their personal devise, for example, computer or smartphone to join the zoom meeting, which will take up to 40 minutes. *First*, the trained research staff will ask participants if they have questions and answer questions accordingly. Next, they will review key summary of incentive and intervention requirements (using Zoom "share") with the participants and answer questions that they may have. Also, research staff will ask the potential participants to think through their current and anticipated responsibilities and life situations before providing electronic signature (via REDCap) for participation. After that, the research staff will obtain consent (participants providing electronic signature via REDCap) followed by showing them how to complete the online survey and requirements. Then, participants will be asked to self-generate reminders to complete data

collection activities. Finally, participants will be informed about the purpose of the second zoom meeting. They will also be informed that they must complete the online survey within three weeks of the first Zoom meeting in order to be invited to attend the second zoom meeting.

Second zoom meeting (either audio or video recorded per participant preferences. Participants will be enrolled. First, they will be asked to self-generate 3-5 text messages to remind them to complete the intervention activities and join brief individual coaching via Zoom. Next, they will receive a link to complete part I intervention activities, which will take up to 35 minutes to complete. Participants will use their first and last name, and birthday and own device (e.g., smart phone) to log into the intervention website and complete activities, while the research staff still on Zoom to answer women's questions if they have. After completion of the Part I intervention activities, the research staff will schedule an individual coaching session via zoom with the trained interventionist within the next two days. Participants will be informed that each coaching session will be recorded (either audio or video per their preferences). The recording will be transcribed and be analyzed to help us revise the individual coaching sessions for future studies. We will send a zoom link to participants to join the individual coaching session.

Cohort retention. We will apply our previously successful retention strategies. We will allow temporary lapses as needed (e.g., partial data collection at T2) or extend the time window for data collection. We will monitor the retention rate monthly and keep retention logs by asking participants over the phone about their reasons for dropout and any adjustments that could keep them in the study.

Intervention: A self-directed, web-based lifestyle behavior intervention (tailored to participants' needs). ***Intervention mode.*** All intervention participants will receive the weekly web-based intervention for three weeks. The intervention includes *three topics*: stress management, healthy eating, and physical activity (Figure 2). ***Intervention (long-term) goals****. P*articipants are strongly encouraged to (1) daily manage stress and emotional reactions using positive strategies, (2) daily eat a diet low in fat and consume less sugary drinks, (3) daily eat a diet high in fruits and vegetables, and (4) walk at a brisk pace for 30 min most days a week.[56]

Figure 2. Topics for the three-week intervention. *Stress management* includes three subtopics (e.g., better ways to handle everyday life) and 13 short-term goals (e.g., have a better relationship with family). *Healthy eating* includes four subtopics (e.g., effective ways to reduce junk food intake) and 11 short-term goals (e.g., daily eat less junk food and be mindful what I eat). *Physical activity* has one subtopic and three short-term goals (e.g., being more physically active outdoors).

	Week 1	Week 2	Week 3
Weekly web (up to 40 min/week)	Stress management	Healthy eating	Physical activity
Weekly individual coaching via zoom (15 min/call, 10 calls)	x	x	x

Intervention development based on preliminary work. ***Informal interviews with stakeholders.*** We informally met with several clinicians who provided prenatal care to the target audience to inform our mode of intervention delivery. They suggested a self-directed, web-based intervention because of its easy implementation and future scalability to overcome clinicians' time constraints to providing additional information on stress management, healthy eating and physical activity to help women manage their weight. ***Study one.*** We conducted seven focus group discussions with overweight or obese pregnant women (N = 96) to identify their critical needs in stress management, healthy eating, and physical activity. Women reported, for example, poor relationships with significant others, feeling emotional, eating foods for comfort, and lack of motivation to be physically active.[123] Results of this study were used to develop the pre-written short-term goals for the participants (Figure 2) because most women had challenges in goal setting. ***Study two****.* Below, we present lessons learned from our prior NIH-NIDDK R18 intervention study of overweight or obese women of child-bearing age[124] to develop the two parts of the GOEFT intervention (Figure 3). Part I. *Motivation.* Lesson learned: Personal values and interest (autonomous motivation) motivated women to make positive lifestyle

behavior changes. Many women had low commitment and confidence (self-efficacy) to implement plans/steps to achieve personal values and make positive changes. *Emotion and cognition.* Lesson learned: Realizing the importance (i.e., the potential benefits) of accomplishing personal goals and responding to open-ended questions (e.g., WHAT and WHY) helped women aware of current life situations/challenges and motived them to make positive changes. Yet, most women faced challenges in setting goals and identifying specific steps to accomplish the goals. Also, many challenges (e.g., lack of willpower, time, or energy) prevented them from implementing their plans. Including explicit planning and (HOW) material for how to overcome challenges should buttress the effectiveness of the current intervention. Part II: *Evaluation of goal progress with feedback*. Lesson learned: women were often unaware what strategies helped them accomplish their goals. They often gave up when unaware of the progress toward their goals or the benefits received from making positive changes. *Based on the conceptual framework (Figure 1) and results of the preliminary work, Drs. Chang (an expert in healthy lifestyle behavior interventions including stress management) and Wegener (Co-I, an expert in psychological emotion and cognition research) worked with five peers of the target audience to develop the proposed self-directed, web-based goal-oriented episodic future thinking intervention (Figure 3)*. After developing the draft intervention, we used feedback from several additional peers of the target audience to review and finalize the intervention.

Figure 3. A three-week self-directed, web-based intervention (35-40 min/week)
Part 1 (Weekly Days 1-4: 30-35 min)
Motivation (Autonomous motivation, self-efficacy)
-Three most important personal values, ways to commit to personal values followed by ways to boost confidence in achieving personal values
Emotion (emotion control, stress) and Cognition (Executive function)
-The first short-term goal, WHAT (the week's goal),WHY(importance of the goal), WHEN and WHERE (the goal taking place), WHO (persons involved in the goal) and HOW (generating three steps to achieve the goal) followed by selecting the second short-term goal and repeating five Ws and H
Motivation (self-efficacy)
-Three daily challenges to implement the steps, three solutions to each of the chosen challenge, and benefits of overcoming chosen challenges.
Summary of part I
Part II (Weekly Days 5-7: 5 min)
Evaluation of Goal Process with Feedback
-Two short-term goals, helpful tips used to achieve the goals, benefits of achieving the goals, four long-term goals followed by personal values
Summary of part II

Intervention implementation *(Figure 3).* Research staff will provide the intervention web link (via text, email) and instructions on completing the weekly intervention activities online. Intervention participants will use their smart phone, first and last name, and birthday to log into the website to complete the Part I intervention activities for week one. Week one Part I activity will be completed during the second zoom meeting to increase participants interest in participation. Also, research staff will answer any questions that participants may have. The day of the week that the participants complete the Part I intervention activities will count as their weekly day one. All participants will be given the study office number to call for questions and technical problems. Participants will use their own device to complete Part II intervention activities for week one and the additional two weeks of the intervention at convenient times and locations. We will send the web link to participants weekly via email and text with an “intervention adherence” text message reminder (generated by the participants) to log in and complete the intervention activities.

Part I (weekly days 1-4, 30-35 min/week): **Motivation, emotion and cognition**. ***Motivation***. Participants will first be asked to visualize, then use a dropdown menu to select their responses (or type in a box) for the following: their personal values and ways to help them commit to and increase confidence in achieving their personal values. ***Emotion and cognition*.** First, participants will select a subtopic from the week’s designated topic (Figure 2) followed by selecting a pre-written short-term goal (or typing in a box) under the chosen subtopic that meets their need for that week’s focus.Then, they will visualize and describe WHAT the week’s goal is, WHY it is important, WHEN, WHERE, and with WHOM it will take place, and HOW it can be

accomplished, all of which enhance prospective memory, thus enabling individuals to carry out the plan to reach the goal.[125] Related to HOW, they will be asked to view an example with three specific detailed steps to achieve their chosen goal. *Step I. Use open-ended questions* to ask themselves, thus to raise awareness of their current life situations/challenges (e.g., How often do I eat junk foods?). *Step II*. *Take specific steps to overcome the challenges to achieve the chosen goal* (e.g., pay attention to foods I eat and how much I eat). S*tep III*. *Record ways to reward themselves without using foods* (e.g., smile and tell myself, "Wow, I am proud of myself of eating less junk food and being mindful what I eat, each time I follow through my plans"). *After that*, participants will visualize and describe their three steps (by typing) to accomplish the chosen goal. Next, they will repeat the same process for a second short-term goal for the week. ***Motivation.*** they will visualize and use the dropdown menus to select (or type in a box) (1) their three most important challenges (e.g., I don't have the willpower) in implementing their steps to accomplish each of chosen goal for the week, (2) three potential solutions to overcome each chosen challenge and (3) benefits of overcoming the challenges. Phase I concludes with a summary of the participant's motivation, emotion and cognition. *Participants will be encouraged* to accomplish their chosen goal within the next few days and mentally rehearse their "identified steps" two times daily because rehearsal increases effectiveness of goal-oriented episodic future thinking on the chosen goals.[126]

Part II (weekly days 5-7, 5 min/week): Evaluation of goal progress with feedback. After implementing steps to achieve both chosen goals, they will log into the intervention website and use the dropdown menus to evaluate their progress on accomplishing their short-term goals, identify tips that proved helpful, recognize short- and long-term benefits of accomplishing the chosen goals, and rate progress on the four long-term intervention goals and three chosen personal values. They will receive feedback to their response for each evaluation component (e.g., short-term goal). Part II concludes with a summary of goal progress with feedback.

Individual coaching session via Zoom (15 min/call, 10 calls). Participants will receive a call within 1-2 days after they complete the Part I intervention activities. All coaching session will be either video or audio recorded (per participants' preference) with participants' permission. Participants will be informed that the recording will be transcribed and be used to refine the individual coaching session for future studies. During each call, the research will listen empathetically and use open-ended questions asking participants to visualize and describe how the week's goals fit with their personal values, thereby supporting their motivation (autonomous motivation).[36] Next, participants will be asked to visualize and describe how they will accomplish the goal(s) – what specific steps they will take. Then, the research staff will assess the specificity of the steps and reinforce or help modify the plans (emotion and cognition). Finally, participants will be asked to visualize and describe barriers to implement plans and strategies to overcome barriers. The research staff will assist with problem solving as needed (self-efficacy). We will keep IPC attendance records. Fidelity. Dr. Chang and each research will listen to a random 25% of the audio recordings monthly and use the fidelity checklist to assess protocol adherence, strengths, and reasons for deviations.

Intervention adherence. Each week, participants will receive up to three prescheduled text reminders via their smart phone to engage in the week's intervention activities (until they complete). If women have not completed all activities after seven days, the research staff will call and ask them to complete the activities that they have missed and ask reasons for nonadherence. When a woman expresses interest in quitting some aspects of the intervention activities, we will assess barriers to adherence, brainstorm strategies to overcome barriers, and offer options to reduce intervention adherence burden. We will keep intervention adherence log.

F. Internal Validity

Feasibility of recruitment, retention, intervention adherence and acceptability (Aim 1). We already plan to track *recruitment and retention* activities. *Intervention adherence.* The web will track and capture details about all activities (e.g., number of logins and amount of and type of contents used). We will also ask intervention participants about motivation and barriers preventing them from using the web. *Acceptability*. We will assess acceptability by asking participants to evaluate the usefulness of with each intervention component,

e.g., personal values, using 5 Ws and H, and rehearsal. Lessons learned and results of this aim will be used to refine our future R01, e.g., recruitment and intervention.

Measures (See above and File Name: Study Survey. shown above). Self-reported data will be collected online using password-protected security-ensured Research Electronic Data Capture (REDCAP).

G. Statistical analysis

Statistical analysis. We will use descriptive statistics to examine variable distributions, check for outliers, and summarize sample characteristics. **Aim 1.** We will (1) conduct content analysis to analyze recruitment, enrollment, retention and intervention adherence logs to identify successful strategies used, (2) review quality of steps generated to achieve goals (using a scoring system), and (3) perform descriptive statistics. We will also perform content analysis (for semi-structure interview questions). ***Aims 2, 3, and 4*. Aim 5.** We will perform descriptive analysis. We will first preform descriptive statistics. Next, we will preform mixed-effects linear modeling. ***Missing data****.* We will carefully examine the pattern of missing data and conduct appropriate multiple imputation if missing at random is indicated. The mixed-effects modeling allows for missing at random. If missing not at random exists, pattern mixture modeling will be used. Sensitivity analysis will evaluate the robustness of study findings without multiple imputation vs. those with imputation or from pattern-mixture modeling.

Zoom IRB Boilerplate:

Zoom is a secure, user-friendly, cloud-based enterprise videoconferencing service that Ohio State University implemented in 2018. Zoom is accessible to faculty and staff at all Ohio State campuses via https://carmenzoom.osu.edu .

This multifaceted video and audio conferencing system supports video and audio conferencing across multiple platforms, including room systems, mobile devices, desktops and telephones.

The Zoom platform at Ohio State University has two main features: Zoom meetings and Zoom webinars.

Designed to support collaboration, Zoom meetings support up to 300 video participants. By default, any participant in a meeting can share their video and audio and utilize the chat feature to exchange messages with participants. The meeting host controls all meeting features, which include mute/unmute participants, screen sharing, recording options, video sharing, remote screen control and participant annotation. Annotation allows participants to draw and highlight on the screen share. Zoom webinar provides access for up to 300 view-only attendees and features live question-and-answer, polling, registration and post-webinar reporting.

Ohio State University Zoom offers both local recording and cloud recording and has a storage capacity of 270 days for recordings. Cloud recording includes an option to produce an audio transcript for a meeting or webinar. The transcript is saved to the cloud as a separate .vtt text file, and the host can elect to display the transcript text within the video itself, similar to a closed-caption display.

Zoom is accessed via Ohio State's single sign-on solution, which provides an environment in which users can authenticate/log in at one time to a central server and connect with web-based services. Meeting security best practices such as waiting lobby, inability to join before host, disabling of sharing for participants, and disabling annotation by participants by default have been implemented.

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