Research Protocol

Using mental imagination to prevent excessive gestational weight gain in overweight and obese pregnant women

I. Objectives

1. To determine feasibility of the goal-oriented intervention: recruitment, randomization, retention, and intervention implementation.

2. To investigate the potential efficacy of the intervention on gestational weight gain (primary outcome) and maternal and birth outcomes (secondary outcomes: gestational diabetes, gestational hypertension, mode of delivery, length of labor, apgar score, new born body weight, and premature baby).

   Primary hypothesis. A higher proportion of intervention participants will have healthy gestational weight gain than the usual prenatal care participants

   Secondary hypothesis. A lower proportion of intervention participants will have gestational diabetes, gestational hypertension, cesarean delivery, premature birth, longer duration of labor, unhealthy birth weight (>4000 or < 2500 grams), premature birth, and APPGAR score ≤ 3 than the usual prenatal care participants.

3. To investigate the potential impact of the intervention on lifestyle behaviors: diet (caloric, fat, sugary drink, fruit and vegetable intakes) and physical activity (walking steps and energy expenditure).

   Hypothesis 1. A higher proportion of intervention participants will eat healthier than the usual prenatal care participants.

   Hypothesis 2. A higher proportion of intervention participants will have more walking steps and higher energy expenditure than the usual prenatal care participants.

4. To investigate the potential intervention effects on motivation (autonomous motivation, self-efficacy, consideration of future, happiness, and hope), emotion (emotion control, stress, and depressive symptoms), cognition (executive function and impulsiveness) and psychological eating (cognitive restraint eating, emotional eating, overeating and eating out of boredom)

   Hypothesis 1. A higher proportion of intervention participants will have higher motivation and self-efficacy, better emotion, higher cognition, and lower psychological eating than the usual prenatal care participants.

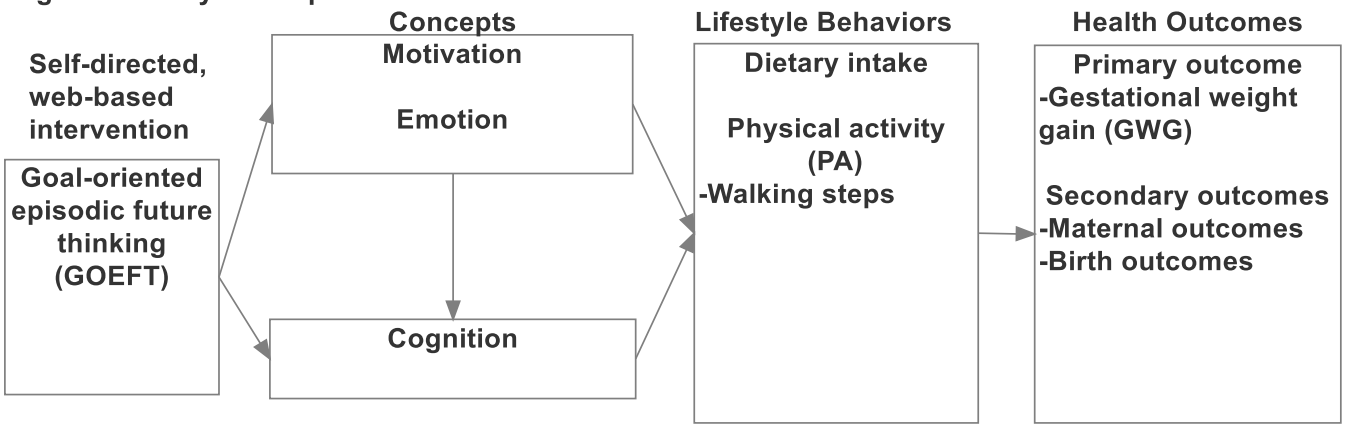
II. Background and Rationale

A.1. Overweight or obese pregnant women. Nearly 56% of American women aged 20-39 are overweight or obese.[1] These women are at least two times more likely than normal weight women (65-85% for overweight or obese vs. 34% for normal weight) to experience excessive gestational weight gain (EGWG),[2-8] exceeding Institute of Medicine (IOM) pregnancy weight gain guidelines.[9] EGWG is a serious public health problem because it negatively influences maternal and birth outcomes: gestational diabetes,[10] gestational hypertension,[11] cesarean delivery,[12] and fetal macrosomia (birth weight > 4000 gm).[12,13] EGWG is also a strong predictor of significant postpartum weight retention (retaining ≥ 10 lbs), which is associated with lifelong obesity in mothers[14] and childhood obesity.[15,16] Pregnancy is a teachable movement for weight management and obesity prevention.[17] Therefore, it is imperative to help overweight or obese pregnant women prevent EGWG.

A.2. Previous lifestyle behavior intervention studies. Healthy lifestyle behaviors (healthy eating and physical activity, **PA**) can prevent EGWG in overweight or obese pregnant women.[18-28] Efficacious strategies identified in prior studies involve personalized caloric restriction,[21-25] frequent in-person meeting attendance[22-24] or phone counseling[25,26] and frequent text messages requiring responses.[26] Such interventions have limited practicality, scalability, and sustainability due to high participant burden and excessive cost for clinical practice. Also, adherence was problematic,[22,26,29-31] perhaps because of educational materials and counseling that were prescriptive and not sufficiently flexible or tailored to individuals.[32] Moreover, the prior studies paid little or no attention to motivation, emotion and executive function, all of which are crucial for healthy lifestyle behaviors.

A.3. Conceptual framework (Figure 1). We use future time perspective **(FTP**) theory (the present anticipation of future goals or personal experience in the past, present and future[33]) as a guiding conceptual framework. FTP drives human motivation and behavior in everyday life[34] and is crucial to motivate individuals to perform an activity.[35] FTP concepts include motivation,[36] emotion,[34] and cognition.[37] Implementation of FTP has focused on episodic future thinking **(EFT**).[37] Our goal-oriented (**GO**)EFT intervention -- vivid imagination (visualization) of goal-relevant future events in the individual's life[38] -- is designed to improve motivation (autonomous motivation, **AuM** and self-efficacy, **SE**), emotion (emotion control, **EC** and stress), and cognition (executive function, **ExF**), all of which promote success in achieving goals for lifestyle behaviors. Key behaviors include healthy dietary intake (less caloric, fat and sugary drink intake and more fruit and vegetable intake) and **PA** (more walking steps and energy expenditure). Key health outcomes are gestational weight gain (**GWG**, *primary outcome*), gestational diabetes (**GDM**), gestational hypertension (**GHT**), cesarean delivery and fetal macrosomia (*secondary outcomes*).

Figure 1. Study Conceptual Framework



Connecting EFT to proposed mechanisms. GOEFT[39] is a promising approach to improving motivation, emotion and cognition (the key proposed mechanisms connecting the intervention to the targeted lifestyle behaviors and health outcomes). Neuroimaging[40-43] and fMRI[44-46] studies have shown that EFT activates the common core network of brain regions associated with ExF during daily activity and brain regions associated with emotion regulation, decision-making and memory. **Influences on motivation: AuM** and **SE.** *AuM*, will to engage in a behavior because of personal value, interest or choice, is important for achieving one's goals.[47] *SE* refers to beliefs that one can successfully undertake an action.[48] EFT increases motivation by facilitating the link between goals and actions and by enhancing the subjective likelihood and/or value of a goal.[49] **Influences on emotion: EC and stress.** EC, one's ability to manage emotional reactions using appropriate strategies, is associated with ability to cope with stress.[50] EFT improves emotion[44,51-53] because EFT is emotionally positive and effectively influences emotion.[54] **Influences on cognition: ExF.** ExF enables individuals to coordinate thoughts, actions, and emotions to achieve healthy lifestyle behaviors[55,56]and positive health outcomes.[56,57] ExF includes inhibitory control (important for controlling one's emotions, staying focused and resisting temptation to overeat and over react[57]), memory, reasoning, problem-solving and planning.[57] ExF enables individuals to take goal-directed action.[55] EFT, especially GOEFT,[39] effectively increases inhibitory control (including in overweight or obese women[58-61]), thus reducing energy intake[39,59,61,62] and promoting weight management[63] by shifting the time perspective of intertemporal decision making[64] and activating brain areas associated with prospection.[65] Also, EFT fosters detailed generation in memory, more relevant steps in

problem solving[66] and detailed steps to attain a goal[49] and increases prospective memory.[67] Finally, EFT increases reasoning, problem-solving and planning.[44,49,66,68,69] Thus, there are substantial reasons to expect EFT to influence the key proposed mechanisms. Yet, there are limitations of prior EFT health behavior studies. With the exception of one "web plus in-person" four-week intervention,[63] all prior EFT studies have been conducted in lab settings where participants followed intensive and specific scripts to vividly imagine future events. Thus, the relevance and scalability of EFT for clinical practice remains speculative. Also prior EFT interventions have only focused on one form of EFT: episodic simulation (specific mental representation of the future).[44]

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 healthy lifestyle behaviors and achieve positive health outcomes.[70] **Motivation**. Increased AuM and SE are strongly associated with reducing stress in overweight or obese women[71,72] and promoting cognitive performance[73] (e.g., future thinking and problem solving[74]), and healthy lifestyle behaviors.[71,75-80] Also, AuM predicts success in reaching goals[33,35] and promotes weight management.[79,81-83] **Emotion** influences cognition.[84] Stress, which is highly prevalent in pregnant women,[85,86] negatively affects diet (increased intake of energy-dense foods that are high in fat and added sugar, leading to weight gain[87]) and PA.[88] Higher levels of stress are associated with lower levels of inhibitory control[87] and interfere with cognitive performance,[89] but reducing stress improves ExF.[90] **Cognition (ExF)**. Whereas low levels of inhibitory control have been associated with increased energy intake in overweight or obese women,[58] high levels of inhibitory control have been associated with reduced consumption of total calories, percent calories from fat,[39,61] snacking and food intake[59,62] in women. ExF also predicts moderate-to-vigorous PA[56] and maintenance of PA[91] and weight loss.[56] ExF deficits are more likely to occur in overweight or obese than normal weight women[92-95] and can be improved through training and practice.[90] Thus, previous research supports the assumed associations among the key mechanisms and connects those mechanisms to lifestyle behaviors and health outcomes.

A.4. Scientific premise. The proposed R21 builds on the strengths and addresses limitations of prior studies. *Strengths*. Lifestyle behavior interventions can prevent EGWG, and EFT improves motivation, emotion, ExF, lifestyle behaviors, and weight management. *Limitations.* Prior lifestyle interventions did not apply FTP, which focuses on motivation, emotion and ExF (critical concepts for promoting healthy lifestyle behaviors and health outcomes). Also, they were too prescriptive and time-consuming for participants (difficult to scale and sustain in practice). Prior EFT studies were mainly conducted in lab and only applied episodic simulation. We propose a 20-week self-directed, web-based intervention (35-40 min/week) and include three forms of EFT: episodic simulation, intention (goal setting), and planning (organization of steps for accomplishing a goal).[96] Our intervention will efficiently apply GOEFT to address motivation, emotion, ExF, lifestyle behaviors and health outcomes (C.3.6). This proposed study will add scientific knowledge in design and delivery of lifestyle interventions aimed to prevent EGWG in overweight or obese pregnant women.

A. Research Design

This proposed pilot randomized controlled trial (RCT) aims to (1) determine feasibility of the GOEFT intervention and investigate the potential efficacy of the intervention on (2) GWG and maternal and birth outcomes, (3) lifestyle behaviors, and (4) motivation, emotion, and cognition. We will enroll 90 overweight or obese pregnant women (50% White, 50% minority). All measures will be assessed at baseline (T1, ≤15 week-gestation), at 24-27 week-gestation (T2) and at 35-37 week-gestation (T3)

B. Sample

Inclusion criteria. Participants must be pregnant women ≤ 13 week-gestation with a single fetus as assessed by ultrasound (Research staff or Dr. Schaffir, Co-I, a board-certified Ob/Gyn at a collaborating clinic will verify eligibility from the patient's Electronic Health Record, EHR). Participants must also have self-reported (1) pre-pregnancy body mass index (BMI) of 25.0-45.0 kg/m^2 and height (we will use height and weight to compute body mass index). (2) ability to read and speak English, (3) age of 18-45 years, (4) access to a working smart phone with unlimited text messaging (89 to 94% of American adults aged 18 to 49 years own a smart phone)[97] and access to internet and (5) receipt of prenatal care and from our collaborating clinics and plan to deliver the baby at The Ohio State University (OSU) Wexner Medical Center, 6) a resident of Franklin Count, and (7) committed to the 20-week intervention.

Exclusion criteria. Self-reported (1) history of ≥ 3 miscarriages, (2) planned termination of the pregnancy, (3) diagnosed hypertension and type 1 or 2 diabetes, (4) history of or current diagnosis of an eating disorder, (5) serious current physical disease (e.g., renal disease or cancer), (6) past bariatric surgery, (7) current or history of substance abuse in the past 6 months, (8) current treatment for a serious psychological disorder (e.g., schizophrenia and bipolar disorder) or (9) contraindications to walking. Consented women will become not eligible to participate in the study if they are not randomized by 16-week 6 days gestation (see D. Detailed Study Procedure: Recruitment and enrollment)—this is because the study intervention starts ≤ 17 weeks gestation. Also, women will become not ineligible for participation if they did not complete the baseline data (T1): online survey via REDCap, two 24-hour dietary recall and wear the Actigraph monitor for at least 4 consecutive days with 6 hours per day.

Sample size/power. Our primary outcome variable is weekly gestational weight gain (GWG). A final sample size of 72 women (36 per group, after accounting for 20% attrition from the 90 enrolled) will have 80% power to detect a time-averaged between-group difference in weekly GWG with a medium effect size (standardized between-group difference of 0.6). This effect size is translated to a between-group difference of 0.33 lb in weekly GWG, assuming a common standard deviation of 0.55 lb (or 0.25 kg) based on previous research.[27] The power analysis was conducted using mixed-effect linear modeling with a two-sided significance level of 0.05, assuming a correlation of 0.7 between the two weekly GWG measures. Due to the pilot nature of the study, our sample size is not powered to detect smaller effect sizes (<0.6). Nevertheless, we will report point estimates, effect sizes, and 95% confidence intervals. These estimates along with clinical significance will guide the results interpretation and sample size determination for a future full-scale RCT (R01).

C. Measurement/ Instrumentation

All participants will be assessed at ≤ 16 week-gestation (T1), 24-27 week-gestation (T2) and 35-37 week-gestation (T3). 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. Primary and secondary outcomes will be extracted from electronic health record. An incentive of $40 will be provided for participation in each point of data collection for all measurements.

Feasibility. We will use our tracking records to assess recruitment, randomization 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 % of participants used type in box). We will record the attendance of individual coaching session. Intervention participants will report their motivation and barriers preventing them from engaging in the intervention activities and evaluate the usefulness of with each EFT 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 phone interview to revise the intervention contents for a future large scale intervention study.

Primary outcome: GWG (in lbs). Body weight or gestational weight gain will be extracted from participants' electronic health record.
To compute weekly GWG, we will subtract the measured weights between two adjacent time points (T2 vs. T1; T3 vs. T2) then divide by the number of weeks between the two time points. The IOM recommends that overweight women (BMI 25.0-29.9) be limited to total GWG of 15-25 lbs and obese women (BMI ≥ 30.0) to 11-20 lbs.[9] To compute the total GWG, we will subtract the self-reported pre-pregnancy weight from weight measured at T3. A woman will be identified as having excessive gestational weight gain if her total gestational weight gain exceeds the Institute of Medicine's criteria.

Secondary outcomes: gestational diabetes, gestational hypertension, mode of delivery, length of labor, apgar score, new born body weight, and premature baby will be accessed by Dr. Schaffir (Co-I) or research staff from the participants' electronic health record.

Lifestyle behaviors. Dietary intake will be assessed using the NCI Automated Self-Administered 24-hour recall (ASA24). Participants will complete 24-hour recalls on two random days over a week.[99,100] The variables of interest include calories, fat, sugary drinks, fruit and vegetable intakes. Physical activity will be assessed using Actigraph (GT3x), an objective measurement of walking steps and energy expenditure. We will distribute the Actigraph in person (T1, C.3.2) and mail it to participants' home (T2 and T3) to wear at the waist for ≥ five consecutive days (≥ 10 hours/per day) except showers/baths and water activities. Then, they will return the Actigraph with steps recorded when we measure their weight at T1, T2 and T3. Psychological eating. We will use the Modified Three-Factor Eating Survey (18 items) to assess emotional eating (3 items), overeating (9 items) and restrained eating (6 items)[101] to measure psychological eating. *Eating out of boredom*. We will use the modified emotional eating scale (8 items).[102]

Concepts. Motivation. *Autonomous motivation* will be measured using Treatment Self-Regulation Questionnaire (18 items) that asks why the respondent does a behavior.[103] *Self-efficacy* will be measured using a 10-item survey for coping self-efficacy,[104] an 8-item survey for healthy eating self-efficacy,[105] and a 10-item survey for physical activity self-efficacy[104] that ask participants' confidence in performing the specific activity. *Consideration of future* will be measured using consideration of future consequences 14 scale (14 items: 7 items measuring future consequences and 7 items measuring immediate consequences).[106] *Happiness* will be measured using the subjective happiness survey (4 items).[107] *Hope* will be measured using Snyder Hope Survey (12 items).[108] Prenatal anxiety will be measured using the revised prenatal distress questionnaire (17 items).[109] Food insecurity will be measured using USDA Food Insecurity Survey (18 items).[110]

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.[111] *Stress* will be measured using The Perceived Stress Scale (10 items)[112] that measures the degree to which situations in one's life are appraised as stressful. Depressive symptoms will be measured using the 10-item Edinburgh Postnatal Depression Scale[113]

Cognition. Executive function will be measured using The Behavior Rating Inventory of Executive Function-Adults (BRIEF-A,75 items).[114] This survey measures an adult's executive function in her everyday environment: for example, inhibitory control, self-monitoring, plan/organization, and organization of materials. BRIEF-A has been used in prior RCTs and is sensitive to detect changes in executive function over time.[115-117] Impulsiveness will be measured using Barratt Impulsiveness Scale (30 items).[118]

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

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
#1 Attend information session (first zoom meeting)	Yes	Yes	Up to 3 times
#2 Consent to full participation (Consent and HIPAA Authorization)	Yes	NO	One time
#2-A. REDCap for electronic signature	Yes	Yes	One time
#3. Delivery and pick up Actigraph	Yes	Yes	Up to 3 times
#4 Attend second zoom meeting	Yes	Yes	Up to 3 times

Intervention Phase			
1A: 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
2A. 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
3A. Join the individual coaching via zoom	Yes	Yes	Up to 3 times
Throughout the project			
1A. 24-hour dietary recall	Yes	Yes	Need to send both email and text (at the same time) because of including web link. Up to 6 times (3 times/dietary recall)
2A. Wear Actigraph	No	Yes	Up to 7 times (1/day) when participants wear the Actigraph
3A. 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
4A. Cohort retention	Yes	Yes	Monthly
5A. Notify Incentives in Email	No	Yes	Up to 3 times

D. Detailed study procedures

Recruitment and enrollment. We will use our previously successful strategies[119] to get clinical care providers (e.g., Ob/Gyn and Midwives, hereafter providers) at five collaborating OSU prenatal care clinics to refer first trimester pregnant women to the study. Drs. Chang (PI) and Schaffir (Co-I) will meet with them to present the study purposes and requirements and demonstrate the web-based intervention. Study flyers will be posted in high-traffic and waiting areas at the clinics and in other locations near our study sites, e.g., pediatric clinics. The medical assistants and/or receptionists at each clinic will distribute the study flyer to participants. Potential participants who are interested in the study will ask their providers about the study or the providers will initiate the conversation about the study with the potential participants. Providers will put the potential participants' chart into IHIS Inbox of trained study staff for screening if the potential participants expressed interest in learning more about the study. Next, the trained research staff will log into IHIS to make an initial screening (for example, gestational age based on ultrasound record and body mass index [if available]). If they are potentially qualified to participate, we will perform "an initial contact of potential participants "(Described below).

Initial Contact of Potential Participants - Research staff will contact potential participants by phone to further determine eligibility. 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 3 telephone numbers (at least 1 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. 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 60 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 "share" function in zoom) 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 verbal consent for participation. After that, the research assistant will electronic consent via REDCap follow by showing them how to complete data collection activities (online survey, 24 hour-dietary recall and Actigraph) 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 participants who complete all data collection activities must join the second zoom meeting by 16 weeks and 6 days gestation. Otherwise, they will become not eligible to participate in the study. This is because our intervention must start at or prior to 17 weeks gestation.

Second zoom meeting (either audio or video recorded per participant preferences)**: Randomization.** Participants will be randomly assigned to an intervention or usual care group (1:1 ratio).

Usual care group. We will thank women in the usual care group and end the zoom meeting.

Intervention group. Intervention participants 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 30 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. The RA will make a monthly retention call to maintain relationships and ask for updated contact information and pregnancy status.. We will allow temporary lapses as needed (e.g., partial data collection) 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.

Randomization. Dr. Tan (Co-I, biostatistician) will generate a randomization schedule. The Project Director will use the randomization schedule to randomize participants to an intervention or usual care group. Our randomization protocol will utilize a stratified permuted-block algorithm.[121,122] Specifically, women in each race stratum (White vs. minority) will be randomly allocated 1:1 to intervention or usual care using permuted block randomization with varying block sizes of 2 or 4.

Usual care. All study participants will receive usual prenatal care from their obstetrician or midwife. The usual prenatal care visit occurs monthly until 28 week-gestation, every other week from 28-36 week-gestation and weekly from 36-week until delivery. At our collaborating clinics, pregnant women are weighed at each prenatal visit and will receive additional healthy eating counseling, e.g., if they have GDM. To improve retention of women randomly assigned to the usual care group, we will email study newsletters every other month with general information about pregnancy-related health (e.g., over-the-counter medication).

Intervention: A self-directed, web-based GOEFT lifestyle behavior intervention (tailored to participants' needs). ***Intervention mode.*** Intervention participants will receive all aspects of usual care plus a self-directed, web-based GOEFT lifestyle behavior intervention. Previous self-directed, web-based interventions have effectively promoted weight management in overweight or obese adults.[123-125] Also, EFT has been delivered on the web and shown promise for promoting weight management.[63,126] ***Intervention duration, dosage and topics***. The intervention will last 20 weeks (start ≤17 weeks gestation), a duration effectively preventing EGWG in overweight or obese women.[20-28] Intervention participants will complete weekly online activities (35-40 min/week) via their smart phone or internet access from any location. The intervention includes *three topics*: stress management, healthy eating, and PA (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.[127]

Figure 2. Topics for the 20-week intervention. SM = stress management, HE = healthy eating. *SM* includes three subtopics (e.g., better ways to handle everyday life) and 13 short-term goals (e.g., have a better relationship with family). *HE* 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). *PA* has one subtopic and three short-term goals (e.g., being more physically active outdoors). Our intervention has greater emphasis on SM and HE than PA, because stress impairs ExF[57] and affects dietary intake,[88,128] which is a strong predictor of EGWG.[27]

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
Weekly web (30-35 min/week)	S	H	PA	S	H	PA	H	S	H	H	S	H	PA	S	H	PA	H	S	H	H
Individual coaching via zoom (15 min/call, 10 calls)	x	x	x	x		x		x		x		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 PA 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 PA. Women reported, for example, poor relationships with significant others, feeling emotional, eating foods for comfort, and lack of motivation to be physically active.[129] 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 **(LL**) from our prior NIH-NIDDK R18 intervention study of overweight or obese women of child-bearing age[130] to develop the two parts of the GOEFT intervention (Figure 3). Part I. *Motivation.* LL: Personal values and interest (AuM) motivated women to make positive lifestyle behavior changes. Many women had low commitment and confidence (SE) to implement plans/steps to achieve personal values and make positive changes. *Emotion and cognition.* LL: 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*. LL: 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 GOEFT 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.

Intervention implementation *(Figure 3).* After randomization and while intervention participants are still at the central study clinic (Visit 2), the Project Director will be present and provide the intervention web link and instructions on completing the weekly intervention activities online. Intervention participants will then 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. The day of the week that the participants complete the Part I intervention activities at WIC/HS will count as their weekly day one. The Project Director will answer questions and provide technical support as needed. S/he will observe and record the extent to which participants need assistance from the study office to complete the EFT intervention activity throughout the 20-week intervention. Participants who need substantial assistance will provide the best time to call so a research assistant can help them complete the intervention activities (e.g., read the responses to them over the phone). 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 19 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. We will lend hotspot connections to intervention participants who lose their internet connection and are unable to access the intervention website outside their home.

Figure 3. GOEFT: A 20-week self-directed, web-based intervention (35-40 min/week)
Part 1 (Weekly Days 1-4: 30-35 min)
Motivation (AuM, SE)
-Three most important personal values, ways to commit to personal values followed by ways to boost confidence in achieving personal values
Emotion (EC, Stress) and Cognition (ExF)
-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 (SE)
-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

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 (Women can select the same short-term goal up to two times during weeks 1-10 and two times during weeks 11-20.) 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.[131] 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). *Step 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 the two chosen goals 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 two chosen goals within the next few days and mentally rehearse their "identified steps" two times daily because rehearsal increases effectiveness of GOEFT on the chosen goals.[132]

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**).[133] 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 RA 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.

E. 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). Dr. Chang will use the NHANES anthropometric manual[134] to train the data collectors (unaware of participants' group assignment) on measuring BW until we reach inter-rater reliability of $\geq$ 95%. Self-reported data will be collected online using password-protected security-ensured Research Electronic Data Capture (REDCAP).

F. Statistical analysis

Statistical analysis-need to consistent with hypothesis. We will use descriptive statistics to examine variable distributions, check for outliers, and summarize sample characteristics. Bivariate tests (T-test and Chi-square) will be used to compare sample characteristics between the two study groups. Congruent with the RCT nature of the design, we will conduct intent-to-treat analysis. **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 use the following criteria to determine feasibility: 30% of women screened will meet the study criteria and 8-9 women enroll monthly (recruitment); 75% of consented women will enroll (randomization); 80% women will have measured body weight at T3 (retention). Also, 85% of women will

complete ≥ 12 weekly intervention activity with ≥ 80% weekly activities completed; 75% of women will be able to generate good quality of steps to achieve their chosen goals; 80% will use the pre-written goals instead of type in (intervention implementation). ***Aim 2,*** we will first use descriptive statistics and trend plots to summarize and visually compare the weekly gestation weight gain over time. Mixed-effects linear modeling will be used to model the weekly GWG as a linear function of treatment (intervention vs. usual prenatal care care), time, and treatment by time interaction. From the model, we can derive estimates of the time-averaged weekly gestational weight gain for each group, the between-group difference in weekly gestational weight gain at each time point and adjust for within-subject clustering from repeated measures and covariates (e.g., race). We will use logistic regression to estimate the between-group (intervention vs. usual care) difference in the probability of having a binary outcome (for example, excessive gestational weight gain, gestational hypertension, new born body weight), adjusting for covariates (e.g., race). ***Aims 3 and 4***, mixed-effects linear modeling will be used to model each continuous outcome (dietary intakes, PA, and psychological eating for Aim 3; motivation, emotion and cognition for Aim 4) as a linear function of treatment, time, and the treatment by time interaction. The intervention effects will be estimated by between-group comparisons of change in the outcome (e.g., healthy lifestyle behaviors) from baseline. Again, we will adjust for within-subject clustering from repeated measures and covariates (e.g., race) in the mixed-effects regression models. ***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.

III. Bibliography

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