Weight Loss for Prediabetes Using Episodic Future Thinking (MINDD4)

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Protocol and Statistical Analysis Plan

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PROTOCOL TITLE:

MINDD 4: Prediabetes, Delay Discounting and Weight Control

1.0 Objectives

Assess the effectiveness of adding episodic future thinking (EFT) to our standard behavioral weight control program to improve weight loss, DD, working memory, glycemic control (HbA1c) and behavioral and/or medication adherence over a 6 month period in persons with prediabetes.

2.0 Hypotheses

Specific Aim 1: To determine whether change in weight loss is superior for those with prediabetes randomized to behavioral treatment for obesity + EFT (BT-EFT) versus behavioral obesity treatment (BT. We hypothesize that weight loss for BT-EFT will be superior to BT after 6 months of treatment.

Specific Aim 2: To determine whether change in HbA1c is superior for those with prediabetes randomized to behavioral treatment for obesity + EFT (BT-EFT) versus behavioral treatment (BT). We hypothesize that reductions in HbA1c for BT-EFT will be superior to BT after 6 months of treatment.

Specific Aim 3: To determine whether change in DD is superior for those with prediabetes randomized to behavioral treatment for obesity + EFT (BT-EFT) versus behavioral treatment (BT). We hypothesize that reductions in DD for BT-EFT will be superior to BT after 6 months of treatment.

Secondary Aim 1: To determine whether change in medication and behavioral adherence for hypertension and/or hyperlipidemia medications is superior for those with prediabetes randomized to behavioral treatment for obesity + EFT (BT-EFT) versus behavioral treatment (BT). We hypothesize that medication and behavioral adherence for BT-EFT will be superior to BT after 6 months of treatment.

Secondary Aim 2: To determine whether improvements in working memory are superior for those with prediabetes randomized to behavioral treatment for obesity + EFT (BT-EFT) versus behavioral treatment (BT). We hypothesize that working memory improvements for BT-EFT will be superior to BT after 6 months of treatment.

Exploratory Aim 1: To examine the relationship between baseline DD and DD change with weight loss, improvements in HbA1c and medication adherence. We hypothesize that baseline DD and DD change will predict weight loss, improvements in HbA1c and medication adherence.

3.0 Scientific Endpoints

The primary endpoint is the reduction of discounting of the future, weight loss, and improved glycemic control.

4.0 Background & Significance

DD has been related to several adverse health behaviors including smoking (Bickel et al., 1999) and obesity (Rollins et al., 2010). Our laboratories have extensive experience collecting information about DD and these various health outcome behaviors.

Initial research on Type 2 diabetes (T2D) using a brief monetary choice questionnaire showed T2D individuals who discount the future have worse metabolic control than those who delay gratification (Reach et al., 2011). To our knowledge, there has been no research on the effects of EFT on DD among patients with prediabetes.

Adults with greater DD is associated with obesity (Appelhans et al., 2012), and low activation of brain sites critical for self-control in DD predicts longitudinal weight gain in adults (Kishinevsky et al., 2012). Likewise, inability to delay gratification predicts greater subsequent weight gain in young children (Francis and Susman, 2009) and poorer response to evidence-based pediatric weight control programs (Seeyave et al., 2009).

In turn, the prevalence of T2D is associated with obesity (Kahn et al., 2006). Moreover, T2D (Vanhanen et al., 1997, Kanaya et al., 2004, Yaffe et al., 2004) and risk for T2D (Vanhanen et al., 1997) are associated with increased risk of executive dysfunction. This association suggests one of two possibilities: (1) diabetes causes a decline in executive function, or (2) inadequate executive function contributes to obesity and then diabetes. In either case, the relationship between executive function and both obesity and diabetes can present challenges in adhering to behavioral and medical therapies (Smith et al., 2011, Primožič et al., 2012). Poor planning, low working memory, cognitive inflexibility, poor attention to detail in combination with excessive DD can lead to weight gain and poor metabolic outcomes.

Research supports Episodic Future Thinking (EFT), self-projection into the future to pre-experience an event (Atance & O'Neill, 2001), as an effective approach to reduce bias towards immediate gratification (Daniel & Epstein, 2013; Daniel, Stanton, & Epstein, 2013). However, little is known about EFT's effect in individuals at risk for Type 2 Diabetes. Understanding the effect of EFT in prediabetics can be efficacious in translating this technique into an efficacious health intervention.

5.0 Study Design

This study is an experimental between-subjects design; subjects will be randomized to Behavioral Treatment for obesity + Episodic Future Thinking (BT-EFT) or control group Behavioral Treatment for obesity (BT).

6.0 Local Number of Subjects

Up to 200 subjects will be enrolled at the University at Buffalo (up to 400 nationally). The second site is located at Virginia Tech Carillon Instutite, local PI, Warren Bickel, PhD. We expect about 25% of participants to meet our in-lab screening criteria, 20% of those participants subjects to drop out and about 80 subjects will complete the study. In addition, a small sample (approximately 4-6

subjects) will be assigned to be pilot participants to help with quality assurance and data validity procedures. Participants will be informed if they are a pilot participant at the time of consent.

7.0 Inclusion and Exclusion Criteria

Inclusion:

Participants must be 18 years of age or older to participate.

Prediabetes: Participants must have a diagnosis of prediabetes within the last 2 years or meet criteria for prediabetes. The American Diabetes Association guidelines (Group, 2003) defines prediabetes as Fasting Plasma Glucose (FPG) 100-125 mg/dl, 2h glucose 140-199 mg/dl after Oral Glucose Tolerance Test (OGTT), or hemoglobin A1c (HbA1c) approximately 5.4-6.7%.

Exclusion:

Type 2 Diabetes: Individuals will be excluded if they have Type 2 Diabetes.

Pregnancy: Women who are pregnant or lactating will be excluded from participation.

Substance use, abuse, or dependence: Individuals that currently have problems with substance dependence, addiction, or problematic substance use that would limit participation (e.g., binge drinkers, alcoholics, daily stimulant/opiate users) will be excluded.

Conditions that affect adherence: Participants should not have a condition that would limit participation which include medical conditions that would affect individuals' ability to use the computer for prolonged period of time; leave the individual unable to ambulate; or current diagnoses of an eating disorder other than binge-eating disorder (anorexia, bulimia), unmanaged psychiatric disorder (depression, anxiety, attention deficit hyperactivity disorder (ADHD), schizophrenia), or an intellectual impairment that would impact study adherence. Additionally, participants should be able to attend to all or most group and individual sessions. If a participant is not able to make most sessions (e.g. participant is out of town for several days or weeks during the study (e.g. work or vacation travel)) they may be excluded from the study

Abnormal glucose related to medications: Participants should not be taking medications that would limit participation and cause abnormal glucose levels (e.g. atypical antipsychotic medications or glucocorticoids) including diabetic drugs such as Metformin.

Prior participation in similar studies: Individuals who have recently participated in a laboratory study using similar methods may also be excluded.

Recent changes in weight: Individuals should not have had any significant changes in weight (e.g. 10% change) prior to starting this study.

8.0 Vulnerable Populations

☒ **N/A**: This research does not involve pregnant women.

☒ **N/A:** This research does not involve non-viable neonates or neonates of uncertain viability.

☒ **N/A:** This research does not involve prisoners.

☒ **N/A:** This research does not involve persons who have not attained the legal age for consent to treatments or procedures ("children").

☒ **N/A:** This research does not involve cognitively impaired adults.

9.0 Eligibility Screening

Interested participants will have the opportunity to complete an initial screening by phone, online, or paper upon their preference to determine if they meet the inclusion criteria as previously described. Information about the study will be provided and consent will be obtained to prescreen for eligibility purposes. Additionally, we may send the person a link to a video that explains what the purpose of the study is and what can be expected.

During the prescreen, along with other screening questionnaires participants will also complete the PHQ-2, a shorter version of the PHQ-9, which measures current (within the past two weeks) feelings of depression or loss of interest in activities. Those that score a 3 or above on the PHQ-2, will be contacted for follow-up via phone or in person at the screening session by a trained research staff member and be given the remainder of the PHQ-9. The PHQ-9 is a validated measure that looks not only at feelings of depression and associated symptoms, but also assesses for thoughts of self-harm. Given the concern for having a participant indicate thoughts of self-harm, this procedure would allow for a real-time conversation with that participant to monitor responses and also provide them with appropriate resources. Additionally, if the participant appears to be extremely upset and/or emotional, we may ask them to fill out the Beck Depression Inventory (BDI), a reliable measure of assessing depression (Sprinkle et. al. 2002).

As part of the prescreen survey, prospective participants will also complete the Three Factor Eating Questionnaire (TFEQ) (Stunkard & Messick, 1985), a validated instrument to detect dietary restraint (Allison, Kalinsky, & Gorman, 1992) with three subscales that assess dietary restraint, hunger, and disinhibition. A short revised version, the Three factor eating questionnaire-R18 (TFEQ-R18), measures 3 aspects of eating behavior: cognitive restraint, uncontrolled eating, and emotional eating (Karlsson, Persson, Sjöström, & Sullivan, 2000). After completing the prescreen survey, responses will be reviewed by research staff to assess eligibility. Participants will be called, emailed, or mailed a letter (depending on their preferred method of contact provided in the prescreen survey) regarding their eligibility. Those who are eligible will be scheduled to come into our lab for an in person screening visit (session 1).

At the in person session 1 screening appointment, all participants will be given the Eating Disorder Examination (EDE) Questionnaire which is a well-established

and valid measure for eating disorders (J.M Mond et. al. 2004). If it is determined that they may have an eating disorder other than binge-eating disorder, the participant will not be eligible to continue with the study, and their physician may be notified. Binge-eating disorder or binge-eating disorder symptomology will not be considered exclusionary as behavioral weight loss treatment is both safe and effective for individuals with binge-eating disorder and binge-eating disorder symptomology (Grilo et al., 2011; Munsch et al., 2007). All participants who complete the EDE will be provided with a list of resources.

At the in person screening visit (session 1) documented consent will be obtained from potential participants. During the screening procedure, participants will be asked to sign a medical release form allowing the primary care physician to provide us with the information regarding eligibility and also allow us to send any pertinent medical information to their primary care physician (i.e. diagnoses of obesity, prediabetes, hypertension, dyslipidemia, depression score assessed by the BDI). If we do not receive the form within about 5 business days we will call to follow up with the primary care physician. Participants will also be asked to sign a release form for relevant pharmaceutical records (e.g. refill history of medications used to treat pre-diabetes, diabetes, and/or hyperlipidemia and hypertension) from their current pharmacy. Release of pharmaceutical records may be attained through the end of study participation if not attained at screening and will cover the period from about 90 days prior to screening to about the end of study participation. At the screening visit, participants will have their HbA1c levels measured by finger stick to obtain a drop of blood. If subjects meet eligibility criterion based on HbA1c levels (approximately 5.4% - 6.7%) at the initial screening visit, they may be eligible to participate regardless of confirmatory PCP diagnosis. Additionally, participants will be assessed for hyperlipidemia by finger stick and blood testing as well as for hypertension using an automated blood pressure machine.

Additionally at the first visit, participants may provide us with a urine sample to check for recent substance use and for pregnancy status for females. If the pregnancy results are positive the participant will be informed and they will not be eligible to continue with study. If throughout the study there is reason to believe a participant has become pregnant (i.e. the participant expresses that is their belief), we will provide pregnancy testing. If the pregnancy results are positive, the participant will be informed and they will not be eligible to continue with the study.

Finally, at the in person screening visit (session 1), participants will have their responses to the prescreen eligibility survey reviewed with a research team member to follow up on any items or any new discoveries that may affect adherence to the study program. At the completion of the screening visit, participants will not know if they are eligible to continue, and all of the information gathered from the participant will be reviewed with all study team members to make a mutual decision if the participant will likely be able to successfully adhere to all study procedures (e.g. attend all study sessions). After that decision is made by the research team, the participant will be followed up

with by phone or email (or participant's preferred method of contact) within one week regarding their eligibility. If eligible to continue, participants will then be scheduled for the baseline assessment session.

Study personnel will inform participants that this information will be used to communicate with them about study eligibility and that this information will be kept confidential and not shared with anyone outside of the study team.

The information assessed during screening is recorded in a secure database that requires a password to enter. The database is used by all members of the Division of Behavioral Medicine and has been approved for use by previous IRB committees. Information is retained in the database only if the subject gives consent.

10.0 Recruitment Methods

The Project Coordinator will oversee all study recruitment and enrollment activities. Participants will be recruited through recruitment materials (e.g., flyers, letters, and handouts/postcards), the Buffalo Research Registry, and web-based recruitment (e.g., departmental website, Facebook, Twitter, Craigslist, ResearchMatch, ClinicalTrials) disseminated through the local community, university campuses, and medical clinics including UB-MD, the university physician network, Urban Family Practice, and the Upstate New York Practice Based Research Network which is engaged in multiple research projects to improve patient care in Western New York.

We may also use the i2b2 database through UB's Institute for Healthcare Informatics (IHI) to recruit participants from the UBMD medical data base

The study team may also utilize the University at Buffalo's Clinical and Translational Science Institute (CTSI) for recruitment assistance and consultation. The CTSI's Recruitment Team provides resources, guidance on appropriate recruitment strategies, and assistance in linking out study team with partners to effectively reach recruitment goals and target populations. We may also work with CTSI Community Engagement Team (CET) to create awareness of the study through their professional and community contacts. The tools they have available may include the Buffalo Research Registry (BRR), the Patients Voices Network (PVN), the Conventus CTSI/PVN Research Table, and conducting outreach at various community events. The BRR is a voluntary registry which can connect us to community members who have completed a health profile and are interested in participating in research. These community members have agreed to be contacted about potential research opportunities based on their self-reported information. These tools are method by which the CET distributes IRB-approved recruitment information to community members.

The CET also tables at many events in the community throughout the year and may display the IRB approved flyer for this project at their table at community events. Examples of events the CET attends include Good for the Neighborhood hosted by Independent Health Foundation, UB on the Green, Juneteenth, Elmwood Arts Festival and many others.

The CET also hosts a standing table at the Conventus Building on the 4th floor of UBMD where the IRB approved flyer can be made available to community members and patients. This will occur only after agreement between the CRL and UBMD Conventus partners that the study is appropriate for the Conventus space.

Additionally, a database of participants that have been involved in previous studies at the University at Buffalo Behavioral Medicine laboratory that expressed interest in future studies will be used. Participants who have indicated interest in contact for future studies will be contacted by email or phone with the study advertisement and survey link.

In addition, several other IRB-approved projects in our lab are recruiting participants who are also pre-diabetic. To minimize the likelihood participants screen for multiple projects in our lab, and in order to efficiently direct participants to the study that might suit them, a shared online (Qualtrics) questionnaire will be used that asks participants questions about their height and weight, diabetes/prediabetes status, if they are taking medications for blood glucose management, hypertension, or high cholesterol, if they are interested in weight loss, if they shop at local grocery stores, and if they are on public assistance.

11.0 Procedures Involved

Upon arrival to the Division of Behavioral Medicine (G56 Farber Hall), participants will be greeted and escorted to a private interview room where they will be given a verbal explanation about the study and provide documented consent. After signing the consent forms, participants will have their blood HbA1c, blood pressure, cholesterol, height and weight measured to calculate BMI, complete measures of delay discounting and study questionnaires including demographics, consumption, alcohol, tobacco, substance use, and executive function such as time perspective and memory. In addition, participants may sign forms for release of their relevant medical records to confirm their eligibility (e.g., diagnosis with prediabetes). Participants will be given a choice as to whether they would like their screening results shared with them and/or with their physician. If participants have values at a certain critical level (e.g. critically high blood pressure) they may be automatically notified. Participants may also complete a urine drug screen to confirm non-substance abuse and female participants may complete a urine pregnancy test to ensure eligibility. If throughout the study there is reason to believe a participant has become pregnant (i.e. the participant expresses that is their belief), we will provide pregnancy testing. If the pregnancy results are positive, the participant will be informed and they will not be eligible to continue with the study. Following the screening session, participants will be reviewed by members of the study team to make a decision if the participant is eligible.

Participants will also be given a choice as to whether they would like to be re-contacted after the conclusion of their 6-month involvement in study treatment in order to complete in a longer-term follow-up assessment that would occur at about 6 months after study completion, or at about 12 months after their initial

baseline session and would be conducted virtually via video conference. Participants will be informed that their decision about being re-contacted for the longer-term follow-up will in no way preclude them from being involved in the study over the initial 6-month period.

If participants are determined to be eligible (e.g., have an HbA1c measurement in the prediabetes range, are not pregnant, do not report alcohol or substance misuse, are able to adhere to all study procedures, etc.) they will be followed up by phone call or email (or preferred method of contact) within one week and scheduled for a baseline appointment. They will also be given a detailed orientation of what will be expected of them during the study, including tasks they need to complete, recording food consumption and activity levels, and frequency of visits to our lab. At the baseline assessment session, eligible participants may also be provided with an Actigraph WGT3X-BT accelerometer to measure physical activity. They will be instructed how to properly wear the accelerometer and asked to record a diary of its wear-time. After wearing the accelerometer for about 7 days, participants may be asked to visit the lab to return it. At the baseline session participants will also be instructed on how to complete a food recall, complete measures of delay discounting, behavioral economic demand, demographics, working memory, medication adherence, and physiological measures (e.g. HbA1c, cholesterol, weight, etc).

After the first several weeks of treatment (about 6 weeks), eligible participants will be randomized to one of two groups, BT-EFT or BT. Participants in both groups will first attend weekly group meetings followed by bi-weekly group meetings, and then monthly group meetings for up to 6 months. Group sessions may be audio or video recorded so that if a participant misses the meeting, they are able to receive the information and learn the materials on their own time. They will be provided general information on healthy diet, physical activity and medication adherence. During the in lab appointments participants will be taught a number of behavioral treatment techniques. The treatment includes: 1) The Traffic Light Diet, which utilizes RED, YELLOW, and GREEN labels for food to guide participants toward the goal of consuming low energy dense, low glycemic, high nutrient dense foods; 2) the Traffic Light Activity Program, which also utilizes RED, YELLOW and GREEN labels for different levels of caloric expenditure, and 3) a variety of behavioral techniques, including stimulus control, self-monitoring, goal setting, problem solving, resetting rewarding mechanisms by reducing need for immediate gratification, finding behavioral substitutes for highly reinforcing food, and EFT (for the intervention group).

During each treatment meeting, participants will be weighed and then have a group session that lasts up to 60 minutes either preceded or followed by a session with a case manager that may last up to 30 minutes. The group sessions review information about weight loss and maintenance and engage in group problem solving for participants who are struggling with behavior change. During the individual meeting with their case manager, participants are taught behavior change techniques and review and address diet and activity self-monitoring and any barriers to adherence with the weight-loss behaviors.

After participants are randomized, participants in the EFT group will be asked to generate episodic cues similar to the tasks used in our previous studies on EFT's effect (Daniel et al., 2013). Each group will list and describe events for different time periods. The episodic component of the thinking task will occur while the participants are asked to describe what they are imagining about each event (e.g., vacations, weddings, parties, and so forth). EFT participants will list positive future events they are looking forward to and list events that could happen at different general future time points (e.g., 1 month, 2-6 months, 7-12 months). In contrast, the BT group will not generate any cues. All EFT participants may rate the salience, valence, arousal, feasibility and vividness of each event and events with the highest ratings for vividness will be used in the generation of episodic cues. An "imagery" score may be calculated by averaging the frequency/vividness scores for each event. Reductions in rate of discounting occur at higher levels of episodic imagery (Peters & Buchel, 2010). Additionally, participants may record their highest rated events into audio cues.

Experimenters will train participants in the EFT group on how to retrieve cues from their cell phone or alternative internet accessible device (e.g. laptop, tablet, desktop computer), to pay attention to and think about the cues, and how to adhere to the study's expectations for utilizing the cues. If participants do not have an internet accessible device one may be provided to them (e.g. smartphone) for the duration of the study at no cost to them. Participants may be prompted several times a day to use their cues and instructed to use their cues any time that need to, especially around eating episodes, using the thought training website – Mobile Audio Management and Response Tracker (MAMRT) (Sze, Daniel, Kilanowski, Collins, Epstein, 2015).

Ecological momentary intervention (EMI) uses mobile technology to deliver interventions to individuals during their everyday lives (i.e. in real time) and in their natural settings (i.e. real world). EMIs enhance the ability to influence behavior in real-world contexts as participants often experience tempting food situations in their natural environments. In this study, the EMI will involve daily prompts to use EFT cues and answer questions about their cues using the thought training (MAMRT) (Sze, Daniel, Kilanowski, Collins, Epstein, 2015). MAMRT will deliver cues/prompts daily to participants. Participants will also be able to access MAMRT and their EFT cues as many times a day as they desire.

During individual sessions case managers may review progress, habit changes, medication adherence, and use of EFT. In the control group participants will not use cues but will still be prompted to log into the MAMRT website and answer questions about their eating behaviors. Participants in the control group will otherwise engage in the same tasks. During weeks when participants do not visit the lab and do not meet with their case manager, they may be contacted by phone, email, or text by their case manager to check in and review progress, similar to an in-person case management meeting.

In response to the coronavirus pandemic, we are enacting preventative measures to ensure both participants and employees limit exposure. For group sessions and case management sessions, this may entail conducting group sessions by sending

participants a recorded video or using a password-protected video conference (Such as via Webex or Zoom Meeting) on a secured network. In this event, a link with a password to access the secured meeting room would be sent to participants and necessary staff. Case management sessions intended to occur in-person may also be carried out via secured video conference or by phone. As is the case for in-person group sessions, video-conference group sessions may be audio or video recorded so that if a participant misses the meeting, they are able to receive the information and learn the materials on their own time.

The impact of the coronavirus on participants will be monitored via a questionnaire to be administered about once a month. The questionnaire may ask about any major changes participants have experienced, a measure of delay discounting, questions about food demand, perceived stress, loneliness as well as perceived risk of testing positive for coronavirus. This may be administered via phone/video conference interview or via survey link sent to participants. The MAMRT website will be used to provide information about the intervention, downloadable manuals for the Traffic Light Diet and Activity Program, provide tools for cooking and getting more physical activity, and managing the EFT component of the intervention where participants may be able to read and listen to recordings of their self-generated EFT cues. Quizzes to assess mastery of educational materials will be implemented on the study website, with multiple versions of quizzes on each module available to account for those participants who will acquire the information more slowly than others. . Participants may have access to traditional paper and pencil self-monitoring. After self-monitoring skill is acquired, participants can choose to use traditional or technology-based recording. The website will also contain password protected sections that are for internal use by study personnel. The website will not contain protected health information.

Participants will also be taught how to record food and drink, exercise, and at home weight measurements in MyFitnessPal. MyFitnessPal is a smartphone and web based app that tracks diet and exercise and can record the number of calories, macro and micronutrients consumed. These recordings may be shared with their case manager and other study team members to review progress and behavior change.

Measurements for blood HbA1c, blood pressure, cholesterol, height and weight measured to calculate BMI, measures of delay discounting, food demand, other executive functions (e.g. working memory), energy intake, physical activity, and medication adherence will be collected at baseline, 3 months, and 6 months. In response to the coronavirus mandatory closures, these assessment measures may also be recorded remotely. In the event that a participant must have assessment measures performed remotely, a staff member may conduct a conference call or video conference with the participant to instruct them on how to complete questionnaires and complete executive function tasks online via online survey (For example, on Qualtrics). The staff member may also instruct the participant on how to weigh themselves and observe the participant taking their weight at home via video conference. In order to collect A1c measures for remote

assessment sessions, participants may be sent an A1CNow test kit (PTS Diagnostics, *Sunnyvale, CA*), a commonly used self-administered A1c test that is available over-the-counter and that provides a valid measure of A1c (Chang et al., 2010), and may also be observed conducting the at-home A1c test by a staff member. In addition, participants may be sent an Actigraph with instructions on its use in order to assess physical activity for remote assessments. At the 3 and 6 month assessment sessions, an adverse event questionnaire will also be administered. After completion of the final assessment session, study staff will request records of participants' prescription refills from their current pharmacies and will be debriefed about the study. Participants may also be asked if they would be willing to anonymously complete a study evaluation on which participants can check a box to indicate whether or not they would allow their anonymous responses to be shared with others as testimonials. Research staff will be able to answer any questions the participant may have about the group they were assigned to at that time. For those consenting to be recontacted for a longer-term follow up, there may be an additional assessment at the 12-month time point that will entail follow-up measures of A1c, delay discounting and weight and could be conducted via video conferencing in the same manner as assessments done during the coronavirus mandatory closures. In addition, participants electing to complete the 12-month assessment will also complete the coronavirus and AE questionnaires.

			Month 1				Month 2				Month 3		Month 4	Month 5	Month 6	Month 12***
Week #	Screening	0 (baseline)	1	2	3	4	5	6	7	8	9-10	11-12	13-16	17-20	21-25	~52 weeks
Group Meeting Topic*		Orientation	TLD	TLD	Meal Planning	Physical Activity	Portion Control	EFT/Control	High Risk Situations	Stimulus Control	Review, Portion Control	Shopping Healthy **	Self-monitoring weight	EFT/RT in high risk situations	Maintaining Healthy Habits**	
Review with Case Manager			X	X	X	X	X	X	X	X	X	X	X	X	X	
Primary Assessment Session		X										X			X	X
DD Assessment with EFT Cues									X			X			X	X
Wearing Actigraph		X										X			X	
Use Cues On MAMRT							Starts around week 7									
Compensation		x										x			x	X

*Group meeting topics are subject to change and may be presented in a different order.
**Group meeting content may be shared via video in lieu of in-lab group session.
*TLD = Traffic Light Diet
*** 12-month session only for those consenting for re-contact following 6-month assessment – to be conducted via video conferencing

12.0 Measurements

Recordings: Sessions where treatment is delivered may be audio or video recorded for Clinical Supervisor to review treatment fidelity and provide feedback to Interventionists/Case Managers.

Demographics and Health Behavior: Race/ethnicity, household income, and educational level will be assessed using a survey-based questionnaire. Participants will also be asked about their health behavior, including substance use, mental health, medical history, and food consumption.

Food Consumption Questionnaire. Food consumption, including any food or beverages ingested in the last 24 hours will be measured using the ASA24 (Automated Self-Administered Recall System).

Major Life Events: Individuals will be asked to complete the major life events questionnaire which measures major life events that may have been experienced during their involvement in the study. Individuals who are undergoing major life events such as a move, new baby or a new job may influence their performance on study measures and tasks.

Financial Planning and Longevity. Individual differences in time period of financial planning will be assessed with the question, "In planning your, or your family's, saving and spending, which of the time periods is more important to you and your partner, if you have one?" (Picone, Sloan, & Taylor, 2004). Answer choices provided will range from not planning, to planning longer than ten years. Financial planning will be reported categorically, and will be converted to a continuous variable for analysis using midpoints of the categories. Subjective probability of living to age 75 will be measured by asking "What do you think are the chances you will live to be 75 or more (where 0 means there is no chance you will live to 75 or more, and 100 means you will definitely live to 75 or more)?" (Picone et al., 2004). Higher values on either question will indicate greater future orientation.

Time Perspective: Individual differences in temporal perspective will be assessed using measures that assess temporal orientation. Consideration of Future Consequences Scale (CFCS). CFCS assesses the extent to which individuals consider the potential future outcomes of their current behavior and the extent to which they are influenced by the imagined outcomes (Strathman et al., 1994).

Positive and Negative Affect Schedule (PANAS): The PANAS comprises two mood scales, one that measures positive affect and the other which measures negative affect (Watson et. al., 1988).

Medication Adherence (pill counts): Participants will be asked to bring their prescription bottles to both baseline and follow-up visits. Remaining pills will be counted and medication adherence will be calculated as: (quantity dispensed – remaining)/(quantity prescribed per day * days since last refill))*100, yielding a measure of percent adherence. In addition, we will utilize participant refill history from their pharmacies to estimate prescription adherence from baseline to final assessment.

Medication Adherence (self-report): Participants will complete a self-report medication adherence questionnaire validated for use with patients with type 2 diabetes, yielding a measure of percent adherence.

Height, Weight, BMI: Participants' height will be assessed using a digital stadiometer. Participants' weight will be assessed using a digital scale. Based on the height and weight data, Body Mass Index (BMI) will be calculated according to the following formula: BMI = kg/m^2. These are the current standards set forth by the Centers for Disease Control and Prevention (Kuczmarski et al., 2002).

Blood pressure: Blood pressure will be measured 3 times using an OMRON automated blood pressure device by trained personnel. The latter two readings will be averaged.

Hemoglobin A1c (HbA1c): HbA1c will be measured using the A1CNow+® or A1CNow® self-check systems (PTS Diagnostics, Sunnyvale, CA) or the Alere Afinion^{TM} AS100 Analyzer System (Abbott, Abbott Park, IL).

Blood Glucose: Blood glucose may be measured using the FreeStyle Lite Glucose Monitor or the FreeStyle Libre Pro (Abbott, Abbott Park, IL).

Cholesterol: Blood for lipid profile (e.g., total cholesterol, HDL, LDL, triglycerides, HDL/LDL ratio, etc.) will be measured using the Alere Cholestech LDX® system (Alere Inc., Coral Springs, FL).

Physical Activity. Physical activity may be measured using the Actigraph WGT3X-BT accelerometer. Participants will be shown how to properly wear the monitors and will be asked to wear their monitors for about a week. Data will be collected at a rate of 30 Hz and converted to one minute epochs for data analysis. Total activity counts and activity in the moderate to vigorous (MVPA) and vigorous (VPA) ranges will be estimated. Physical activity may be measured using a Fitbit (San Francisco, CA) or other activity monitor.

Subjective Hunger: Participants will be asked to provide subjective ratings of their hunger. Hunger will be assessed using a 5-point Likert scale (anchored by 1-Extremely Full and 5-Extremely Hungry).

Subjective Preferences: Participants may be asked to provide subjective ratings of their food/activity preferences by ranking, rating their liking using a 5-point Likert scale (anchored by 1-Do not like and 5-Like very much), and making choices between their food/activity.

Cue Attention: A Likert-style scale assessing attentiveness to the episodic cues and vividness cues during tasks will be assessed on a scale from 1 to 5, where 1 indicates "not at all" and 5 indicates "very much".

Delay Discounting: An operational definition of impulsivity is delay discounting, the degree to which a person will discount the value of a larger delayed reward in favor of a smaller immediate reward. Computerized/ experimenter administered assessments will provide participants with choices between a smaller amount of a hypothetical commodity available immediately or a larger amount available later. Participants will make choices between rewards such as money, food, physical activity, and health gains. Two methods may be used to measure discounting, Adjusting Amount and Adjusting Delay.

Adjusting Amount Discounting. The magnitude of the immediate commodity is adjusted until it is subjectively equivalent to the later larger amount. Subjective equivalence will be obtained at delays such as; 1 day, 1 week, 1 month, 3 months, 6 months, and 1 year. To ensure comparison between money and non-monetary rewards, prior to running the discounting programs for food, physical activity and health, participants will indicate the amount of the commodity whose receipt "right now" would be equally valuable to the participants as receiving a set amount of money, for example $100. Participants may be presented with their EFT cues before making decisions at each delay period.

Adjusting Delay Discounting. The adjusting delay discounting task is a five trial task in which participants are asked how much money they would prefer (e.g. $500) immediately or a larger reward after a delay (e.g. $1000). This task is presented on a computer screen and is designed to measure the amount of monetary discounting that occurs when rewards are presented at a delay. This task adjusts the delay to the larger reward and allows for the calculation of k-values. This task will be completed matching each of the traditional tasks parameters (i.e. type and magnitude of the reinforcer).

Executive Function: Cognitive processes, such as planning, cognitive flexibility, working memory, prospective memory, retrospective memory and attention may be measured by using computerized tasks or paper and pencil that involves solving problems, remembering a set of letters or spatial locations while alternating with a distracter tasks (e.g., Backwards CORSI).

Relative Reinforcing Efficacy Food Purchasing Task: The food purchasing task is modified off of the cigarette purchasing task (CPT) that has been used by Jacobs and Bickel (1999) and assesses a number of different metrics of relative reinforcing efficacy. The procedure we will use is a modified version of this procedure and will assess the relative reinforcing efficacy of a range of foods via an online survey or computerized task. The chosen food will be displayed during the task so that participants have a frame of reference when completing the questionnaire.

Coronavirus Questionnaire: A questionnaire developed to monitor the effects of the coronavirus pandemic on participants will include a modified Major Life Events questionnaire similar to that described above but asking about a longer time frame (about a month), the five-trial Adjusting Delay Discounting task described above, food purchasing questions asking the maximum amount a participant would spend on preferred snack foods, a question asking if participants know someone diagnosed with coronavirus, a question asking their perceived risk of being diagnosed with coronavirus (measured on a 0-100 scale), two self-report questionnaires the 10-item Perceived Stress Scale (PSS; Cohen, 1994), and the 5-item Loneliness Scale from the NIH toolbox for assessment of neurological and behavioral function (Gerson et al., 2013). The PSS asks that participants rate on a 5-point scale (0 = never; 1 = almost never; 2 = sometimes; 3 = fairly often; 4 = very often) how often over the last month they have thought or felt different situations were stressful. Example questions include, "In the last month, how

often have you been upset because of something that happened unexpectedly?" and, "In the last month, how often have you felt that things were going your way?" The 5-item longlines scale asks participants to select how often over the past month they feel lonely as described by 5 different statements. Answers are given on a 5-point Likert scale (1 = Never; 2 = Rarely; 3 = Sometimes; 4 = Usually; 5 = Always). Example statements include, "I feel alone and apart from others" and "I feel that I am no longer close to anyone".

13.0 Setting

This research will be conducted at the University at Buffalo (UB) and Virginia Tech University (VT). All facilities are locked and require key or badge access to enter in relevant research areas.

The UB team will conduct research at the Division of Behavioral Medicine Research Labs, University at Buffalo South Campus.

The VT research team will conduct research at the Addiction Recovery Research Center at the Virginia Tech Carilion Research Institute. Recruitment and screening will be in collaboration with Carilion Clinic Department of Family and Community Medicine in Roanoke and surrounding areas.

Virginia Tech Carilion Research Institute will follow the same scientific and ethical review structure as the University at Buffalo. All research staff working on the project will need to complete Human Subjects Training as per the University requirements. Staff will be trained across sites to follow the same procedures and weekly/monthly meetings will be organized to ensure this.

14.0 Statistical Analysis Plan

Analytic plan is to use factorial ANCOVA to compare between group differences in different measures of DD, executive function, weight loss, changes in metabolic control, dietary composition, and physical activity for subjects randomly assigned BT-EFT/BT. Covariates will be used if significant differences between groups are observed in subject characteristics. We predict a main effect of EFT such that EFT will reduce the discounting, improve metabolic control, and increase weight loss compared to BTsubjects.

The estimated sample size for this study is based on an ESd for reducing DD of 0.72 in obese/overweight subjects. In our pilot study of EFT vs control in a weight control program we observed even larger ESd of 1.64 for weight and 1.04 for energy intake. Based on ESd = 0.72 for DD, using power of 0.80 and alpha of 0.05, we can detect differences between groups in DD with 32 subjects per group, 64 total. Since we are anticipating 20% attrition for the field study, we will recruit 78 persons with prediabetes to start.

15.0 Provisions to Monitor the Data to Ensure the Safety of Subjects

Data will be reviewed weekly and secured in Division of Behavioral Medicine Research Lab. The Principal Investigator, Leonard H. Epstein, PhD, will be responsible for ensuring data integrity and safety monitoring for human subjects

who are involved in the research and may work with a Data Safety Officer consistent with our NIH DSMP.

Study questionnaires and measurements that are collected by study personnel will be reviewed and monitored.

This study poses no greater than minimal risk; therefore, there are no safety endpoints.

Participants will be encouraged to contact study personnel if they experience any problems or difficulties, and if any adverse events (AE) are reported, the study personnel contacted will record the AE. AE will be recorded as soon as they are reported, and the PI and study coordinator will be made aware. The study coordinator will summarize the AE in a memo; the participant will be called and the summary will be read to them to ensure that the information is accurate. The memo will then be submitted to the University at Buffalo IRB and the PI. If the PI, or the IRB decide that further action is warranted, the PI and study coordinator will then formulate and carry out a plan to respond to the AE. The study coordinator will write a memo summarizing such actions; this memo will then be forwarded to the IRB. Safety information will be collected and reported to both the UBIRB and the Safety Officer in the time frames outlined by the UBIRB.

Serious Events and Problems (SEP) will be monitored by the Principal Investigator and project coordinator as well as reported to both the IRB and the Safety Officer in the timeframes outlined by the IRB.

16.0 Withdrawal of Subjects

Subjects who do not adhere to the protocol procedures and study instructions may be withdrawn from research analyses, as determined by the Principal Investigator and/or NIH Data Safety Committee. In addition to not adhering to study instructions, possible reasons for removal may include nonsystematic responding to questionnaires and HbA1c (blood sugar) levels that are not in the study prediabetes range. If a participant is withdrawn from the study without their consent, they will be debriefed about the nature of the study and be compensated for the amount of time spent in the study. We may also stop an ongoing session, or end participation in the study because we have collected all the information we need.

Participants will be debriefed about the nature of the study and the reason for their removal. No additional follow-up is needed.

Participants can withdraw from the research at any time. If participants withdraw, no further data will be collected, but any information that had been provided may be retained by the researcher and analyzed.

17.0 Risks to Subjects

There may be some sensitivity associated from certain questions asked when filling out questionnaires or having body measurements taken and subjects might feel uncomfortable disclosing some personal information such as medical history. Subjects can refuse to answer any questions that they are not comfortable

answering. Subjects will be free to withdraw from the study at any time, and their refusal to continue will not affect other medical care provided at any healthcare facility.

Participants may experience hunger due to refraining from eating before the session. Feelings of hunger will subside when the participant is able to eat after the. In addition, only personnel certified in CPR, first aid, and AED will conduct study sessions and these individuals are trained to contact appropriate medical personnel in the event of an emergency.

Breach of confidentiality is another potential risk. The studies will occur in our facilities at the University at Buffalo and the Virginia Tech Carilion Research Institute. To protect confidentiality, we will use only ID numbers and keep all data in locked cabinets or in locked offices and password protected electronic files in password protected computers. Any data shared between sites will involve de-identified data only and files will be encrypted or password protected. These screening, monitoring, and confidentiality procedures have been in effect for more than 10 years and for more than 2,000 subjects across the various protocols employed by our group.

Participants may have a small bruised area on the finger from the pinprick site. The bruise should fade over time without treatment. If during the course of the study, a subject's blood glucose exceeds the range for prediabetes (Fasting Plasma Glucose (FPG) 100-125 mg/dl, or 2h glucose 140-199 mg/dl after Oral Glucose Tolerance Test (OGTT) or hemoglobin A1c (HbA1c) 5.4-6.7%), that subject may be directed to his or her physician or other medical care provider for further evaluation.

Participants may have their blood pressure measured. If during the course of the study, a subject's blood pressure reaches hypertensive crisis (180/110 mmHg), that subject may be directed to his or her physician or other medical care provider for further evaluation.

There are no other risks anticipated. All personnel on the study will be CITI course certified and have completed the good research practices certification. All identifiable data will be password protected and only the research team will have access to that information. Subjects will be informed of the risks associated with the study.

We have several provisions in place to ensure participants' privacy and safety is protected while the data is being collected. The lab facilities of the Division of Behavioral Medicine research laboratory consist of private interview rooms that will be used. Only the interviewer and participant will be present in the room during interviews. Data is recorded such that not even the person putting it in the file would ever be able to associate the data with the identity of the person providing it. Data and files that have been de-identified and encrypted will be shared between sites. Therefore, there is no reasonable risk of a breach of confidentiality. Only personnel certified in CPR, first aid, and AED will conduct study sessions and these individuals are trained to contact appropriate medical personnel in the case of a serious event.

Subjects will be allowed to refuse to answer any questions they are not comfortable with.

We may offer urine pregnancy test for females at the beginning and throughout the study. We will notify females of positive pregnancy test results and discontinue them from the study.

18.0 Potential Benefits to Subjects

Participants may benefit from improved health such as weight loss, improvements in blood sugar regulation, HbA1c, and blood cholesterol levels. Participants may also learn about the experimental research process and their health.

19.0 Compensation for Participation

Participants may earn up to $250 in the form of a personal check, cash, gift card (e.g., Target, Wegmans, Amazon), or reloadable debit card, based on preference. Participants will be compensated $10 for completing the screening session and if eligible to continue, will be compensated $10 for completing the baseline assessment session. Participants will also be compensated $20 for wearing the Actigraph for 7 days and completing the food recall for 3 days. Participants will be compensated $30 at the 3-month assessment session, $20 for wearing the Actigraph for 7 days and completing the food recall for 3 days. Finally, participants will be compensated $40 at the 6-month assessment session, $20 for wearing the Actigraph for 7 days and completing the food recall for 3 days. Incomplete sessions will be paid on a prorated basis. In response to the novel coronavirus outbreak participants may be asked to complete an additional questionnaire battery on a monthly basis. Each time they complete this battery they can earn an additional $10 ($60 for completion during each month of the study). Participants electing to complete the longer-term (12 month) follow-up will be compensated $30 for the 12-month assessment session, and an additional $10 for the completion of the coronavirus questionnaire.

20.0 Consent Process

Interested participants will be screened over the phone or have an opportunity to complete the survey online. Consent to screen for eligibility will be obtained verbally over the phone or through an action (e.g. clicking an “I agree” button) online. Screening consent will be obtained prior to asking any contact or eligibility questions. Documented informed consent will be obtained in a private room at the Division of Behavioral Medicine Research Lab during the scheduled laboratory appointment.

There will not be a significant interval of time between obtaining and documenting consent and the actual participation in the initial research procedures (i.e. shortly after the person signs the document they will begin research procedures at their scheduled convenience). However, if a subject requests more time to review the consent form, they are able to take the consent home to review and discuss with family members, then schedule a visit at a later date.

Subjects will be seen weekly or monthly; therefore, have the ability to discontinue the study at any time. Future revisions or modifications will be reviewed with the participants to insure continued consent if necessary.

21.0 Multi-Site Research (Multisite/Multicenter Only)

Principal Investigators. Leonard H. Epstein, PhD, at the University at Buffalo will be responsible for the oversight of subject issues and coordination of experimental behavioral medicine approaches. Warren K. Bickel, PhD, at Virginia Tech will be responsible for management related to behavioral task data collection and analyses. Each PI will be responsible for recruitment at their site, communication with each other and their team, and for his own fiscal and research administration.

Communication Process. Project coordinator, study staff and/or the PIs will have a local weekly meeting to discuss any current issues with the study, including, but not limited to; IRB approvals, procedures, staff training, data safety, and interim analyses. PI and/or project coordinator will schedule monthly conference calls to discuss study information. Monthly reports/meetings will be used to track recruitment, data, data quality control, interim analyses and any IRB concerns. The agendas and reports will be saved and filed at both locations. The PIs will communicate as needed, either by phone, e-mail, or in person, to discuss experimental design, data analysis, and all administrative responsibilities. Each PI will share their respective research results with the other PI, key personnel, and collaborators.

IRB approval records. UB's IRB will be the IRB of record for both sites. UB will have records of IRB approval for both sites. This will include copies of consents, protocols, questionnaires, and any other IRB-related document. Amendments and modifications will be discussed in weekly conference call meetings and implemented through UB's IRB as required.

Data Safety & Sharing/Transfer. Any and all potential safety concerns will be reported both to the IRB and additional site in a timely manner. We will follow the outlined procedures based on UB's IRB New Information Reporting form. Any adverse event will be communicated to both sites within 24 hours to inform. UB will report new information to the IRB.

Procedures. The two research groups will work collaboratively to implement research methods across the sites, and will develop common training procedures for the delay discounting, episodic future thinking, dietary protocol, exercise and activity protocol, and prediabetes components of the study. Members of each research team will be responsible for development of relevant manuals of operation for study methods. These will be communicated in regular email and phone meetings, as well as face-to-face meetings where investigators will travel to the other University for training and quality control issues. Team members are used to this approach since they have been involved in multi- center basic science and clinical projects. Each site will be responsible for data quality control, based on a common protocol, and quality control will be implemented after data sets are built prior to analysis.

Problems. Problems will be reported within 24 hours for adverse events and within 1 week for any methodological problems to both study coordinators. Study coordinators and PI's will be responsible for reporting adverse events to the IRB within the UB IRB Reporting form time frame (i.e. 5 days for new information that impacts participant risk). Study coordinators and PI's will be responsible for determining amendments required for changes to study protocol.

Interim results. Data will be shared between sites and all data will be de-identified prior to sending a password-protected/encrypted file. Study coordinators and PI's will be responsible for communicating any interim results that are analyzed.

Closure. All continuing review and closure forms will be shared between sites in an IRB related file.

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