Cover Page for Protocol, Statistical Plan and ICF

Official Title:	The Effect of Episodic Future Thinking on Weight-Loss
NCT number:	NCT03731325
Document Type:	Study Protocol and Statistical Analysis Plan
Date of the Document:	6/15/2020

Thought Training and Weight-Loss

PI: Denise Wilfley
IRB ID #: 201807151

Project Details

1. Demographics

1.1 Project Title:
The Effect of a Monetary Incentive and Positive Thought Training Program on Weight-Loss.

1.2 Short Title (required):
Thought Training and Weight-Loss

1.3 Project is primarily:
Social Science/Behavioral (includes History/Anthropology)

1.4 Type of Study:
Other Interventional

1.4.a Is your research study one in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes (NIH clinical trial definition).
Yes

1.5 Select how you plan to obtain consent:
- Sign a consent document or a consent letter
- Script for use either in person or over the phone with no signature

2. Source(s) of Support

2.1 Source(s) of Support

Type/Source	Grant Title	Name of PI on Grant
No Support		

Attachment Name	Category	Version	Date Attached
FULL SUBMISSION HD080292(1).pdf	Grant from funding source or private foundation/association	1	07/24/18

3. Research Team

3.1 Principal Investigator

Name	E-mail	Title	Sc
Denise Wilfley	wilfleyd@wustl.edu	Prof of Psychiatry	Sc

3.2 Team Members

Research Team Members

Role	Name	Role Desc	Student	Email	Title	School	De
PI	Denise Wilfley, PHD		No	wilfleyd@wustl.edu	Prof of Psychiatry	School of Medicine	Psy
	Kirsten Cash, BS, BHS		No	kecash@wustl.edu	Clinical Research Coord I	School of Medicine	Psy
	Genevieve Davison, MPH		No	genevieve.davison@wustl.edu	A&S Graduate Fellowship	School of Arts & Sciences	A&S Psy & B Sci
	Alexis Engel, High School		No	alexis.engel@email.wustl.edu	•Security Access Only		
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	Sula Frausto, High School		No	null	WU Student		
	Elizabeth Goblirsch, High School Diploma		No	egoblirsch@wustl.edu		SCHOOL OF LAW	LAW
	Anne Claire Grammer, MA		No	agrammer@wustl.edu	A&S Graduate Fellowship	School of Arts & Sciences	A&S Psy & B Sci
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	Abhishek Janardan, BA		No	ajanardan@email.wustl.edu	Professional Rater II		
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	Alysandria Wayne, BA		No	alywayne@wustl.edu	Faculty Assistant	School of Arts & Sciences	A&S Che
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Team Member Financial Interest

Name	Financial Interests
Denise Wilfley, PHD	none
Kirsten Cash, BS, BHS	none
Genevieve Davison, MPH	none
Alexis Engel, High School	none
Lauren Fowler, BS, PHD, MPhil	none
Sula Frausto, High School	none
Elizabeth Goblirsch, High School Diploma	none
Anne Claire Grammer, MA	none
Matthew Ho, High School	none
Abhishek Janardan, BA	none
Olivia Laing, MSW	none
Grace Monterubio, BA	none
Nasreen Moursi, BA	none
Melissa Ramel, PHD	none
Mary Katherine Ray, PHD	none
Sophia Rotman, BA	none
Rebecca Steins, MA	none
Donna Van Meer, High School	none
Melissa Vazquez, BA	none
Alysandria Wayne, BA	none
Reuben Welch, PHD	none

4. Other Institutional Reviews/Requirements

4.1 Do any of the objectives of this study involve the diagnosis, prevention, screening, evaluation, treatment or support of cancer patients?
No

4.2 Are more than 30% of the patients involved in this study likely to have an active cancer diagnosis?
No

4.12 Will a Certificate of confidentiality be used for this research?
No

4.13 Does this project need to be registered on ClinicalTrials.gov?
Yes

4.13.a Who is the Responsible Party for registering this study in ClinicalTrials.gov?
Principal Investigator

4.21 Mark all that apply to your study:

Mark any service(s) you'd like to use:

- Participant Recruitment Services available through Recruitment Enhancement Core (REC)
- Participant Recruitment Services available through Community Based Recruitment and Retention (REACH)

1. Protocol

1.1 Is there a separate, written protocol that will be submitted in addition to this form? (Note: a grant application is not considered to be a protocol)
No

1.2 Select up to three key words below that best describe this research study:
- Nutrition
- Psychology
- Clinical

1.3 Provide a short summary/abstract of the purpose and procedures of the study proposed in this IRB application.

- DO NOT include information on studies not proposed in this application.
- Use LAY terminology only. This must be easily understandable by IRB community members and nonscientists.
- DO NOT cut and paste technical abstracts from source of support applications that may not be understood by a general audience.

Purpose: To assess whether episodic future thinking (EFT), thought training that teaches individuals to think prospectively about future events as if they were happening now, promotes weight-loss maintenance in parent and child dyads with overweight/obesity after termination of a monetary incentive program.

Procedures Cohort 1:

Procedures: N=40 parent/child dyads will receive a weekly monetary incentive for losing weight during an initial 12 week weight-loss program. During this time, half of the families will receive EFT training (N=20) and the other half will receive a control thought training program (N=20). After 12 weeks, the monetary incentives program will be terminated, but the parent/child dyads will continue their respective EFT or control thought training programs for an additional 12 weeks. At the end of the additional 12 weeks, weight-loss maintenance will be examined between dyads that received EFT and dyads that received control thought training.

Procedures Cohort 2:

Procedures: N=20 parent/child dyads will receive a weekly monetary incentive for losing weight during an initial 8 week weight-loss program. During this time, half of the families will receive EFT training (N=10) and the other half will receive a control thought training program (N=10). After 8 weeks, the monetary incentives program will be terminated, but the parent/child dyads will continue their respective EFT or control thought training programs for an additional 8 weeks. There will then be an 8 week no intervention follow-up period. At the end of the follow-up period, weight-loss maintenance will be examined between dyads that received EFT and dyads that received control thought training.

Purpose (Cohort 3): To assess whether episodic future thinking (EFT), thought training that teaches individuals to think prospectively about future events as if they were happening now, promotes healthier grocery shopping behaviors in parent and child dyads in which the child is obese/overweight, and to assess subsequent weight loss.

Procedures Cohort 3:

N=6-12 parent/child dyads will receive the full family-based therapy program with a specialized EFT component focused on grocery shopping during this 15 week weight-loss program. This study is a nonconcurrent multiple baseline design; participants will be randomized to a 4 week, 7 week, or 10 week group with staggered baseline periods followed by 4-8 weeks of the intervention consisting of FBT and EFT.

1.4 Specify your research question(s), study aims or hypotheses:
We hypothesize that:

1) Parent/child dyads in both the EFT and the CONTROL thought training conditions will lose weight with the monetary incentive program.

2) Parent/child dyads in the EFT condition will have greater weight-loss maintenance than parent/child dyads in the CONTROL thought training program when the monetary incentive program is terminated.

Cohort 3:
Aim 1: To examine whether EFT will lead to healthier grocery shopping behavior.
Aim 2: To test the influence of EFT on Delay Discounting (DD).

H1: We hypothesize that EFT will improve healthy grocery shopping behaviors.
H2: We hypothesize that EFT will reduce DD.

1.5 Background and significance and/or Preliminary studies related to this project:
Monetary incentive programs have been shown to be effective at reducing weight in the short-term [Leahey, John, Volpp, Ries]; however, numerous studies have demonstrated that individuals often regain weight when incentive programs are terminated [John, Volpp, Reis]. This behavioral change relapse is unsurprising; it is well-established that a specific behavior is often extinguished when reinforcement for that behavior is removed. It is unlikely, then, given the expense, that monetary incentive programs could be implemented long-term for chronic diseases like obesity where lasting behavioral changes are essential. Thus, programs are needed to bridge the gap between the successful short-term weight-loss effects of a monetary incentive program and long-term weight-loss maintenance after the incentives are removed.

A program that could be effective at bridging this gap is thought training, specifically episodic future thinking (EFT). EFT teaches individuals to pre-experience events, or think prospectively, about future events as if they were happening now [Atance]. EFT has been shown to reduce delay discounting (DD) which is defined as discounting larger rewards in the future for smaller rewards now [Daniel, 2013a; 2013b]. For example, individuals with high levels of delay discounting may place more value on eating a highly palatable, unhealthy food now than on the future health benefits of forgoing the unhealthy food. It has been suggested that pre-experiencing future events with EFT increases the value of the future reward and helps individuals make choices that have lasting benefits [Benoit, Gilbert, & Burgess, 2011; Boyer, 2008; Daniel, Said, Stanton, Epstein 2015]. For example, vividly imagining a beach trip one has planned for the summer as happening now might make one more likely to place a higher value on a thinner body for swimsuit comfort than the immediate gratification of eating an ice cream cone.

Given the power of EFT to reduce discounting of future rewards, it is plausible that EFT training during an incentive program could help shift one's thought processes towards the long-term consequences of behavior, promoting behavioral change even after termination of the incentive program. Thus, the primary purpose of this study is to assess whether EFT promotes weight-loss maintenance after termination of a monetary incentive program vs. a CONTROL thought training program.

Cohort 3:

Family-based treatments (FBT) for obesity have been shown to be effective in achieving significant weight reduction in overweight or obese children and parents [Altman & Wilfley, 2015]. One component of the current FBT program used in this study that has received little attention is thought training, specifically episodic future thinking (EFT). EFT teaches individuals to pre-experience events, or think prospectively, about future events as if they were happening now and has been shown to reduce delay discounting (DD) which is defined as discounting smaller rewards now for a larger reward in the [Daniel, Said, Stanton, & Epstein]. Furthermore, EFT has been shown to help people purchase fewer calories when they are grocery shopping [Hollis-Hansen et al., 2019], thereby displaying potential to be an effective measure in modulating the food environment in homes and may play a role in changing eating behaviors related to weight loss [Appelhaus et al.,2019].

Given the power of EFT in promoting the purchase of fewer calories, it is plausible that EFT training focused around grocery shopping during FBT could help shift one’s thought processes towards healthier food choices, promoting behavioral change that has lasting impact on the home environment. Thus, the primary purpose of this study is to assess whether EFT training promotes active behavioral change pertaining to grocery shopping during FBT. In turn, this resulting behavior change could lead to healthier eating behavior and may promote weight loss for the whole family.

1.6 Literature cited/references (if attaching a grant enter N/A):
Leahey et al. (2016). A randomized controlled trial testing an internet delivered cost-benefit approach to weight loss mantenance. Preventative Medicine, 92, 51-57.

John et al. (2010). Financial incentives for extended weight loss: a randomized, controlled trial. Journal of General Internal Medicine, 26, 621-626.

Volpp et al. (2008). A randomized controlled trial of financial incentives for weight loss. JAMA, 22, 2631-2637.

Ries. (2012). Financial incentives for weight loss and healthy behaviors. Healthcare Policy, 7, 23-28.

Atance, & O'Neill. (2001). Episodic future thinking. Trends in Cognitive Sciences, 5, 533-539.

Daniel et al. (2013). The future is now: Comparing the effect of episodic future thinking on impulsivity in lean and

obese individuals. Appetite,71, 120–125.

Daniel et al. (2013). The future is now: Reducing impulsivity and energy intake using episodic future thinking. Psychological Science, 24, 2339-2342.

Benoit et al. (2011). A neural mechanism mediating the impact of episodic prospection on farsighted decisions. The Journal of Neuroscience, 31, 6771-6779.

Boyer. (2008). Evolutionary economics of mental time travel. Trends in Cognitive Sciences, 12, 219-224.

Daniel et al. (2015). Episodic future thinking reduces delay discounting and energy intake in children. Eating Behaviors, 18, 20-24.

Additional Cohort 3 Literature:

Altman, M., & Wilfley, D. E. (2015). Evidence update on the treatment of overweight and obesity in children and adolescents. Journal of Clinical Child & Adolescent Psychology, 44(4), 521-537.

Appelhans, B. M., Tangney, C. C., French, S. A., Crane, M. M., & Wang, Y. M. (2019). Delay Discounting and Household Food Purchasing Decisions: The SHoPPER Study. Health Psychology, 38(4), 334-342. doi:10.1037/hea000072

Hollis-Hansen, K., Seidman, J., O'Donnell, S., & Epstein, L. H. (2019). Episodic future thinking and grocery shopping online. Appetite, 133, 1-9. doi:10.1016/j.appet.2018.10.019

Campbell, K. J., Crawford, D. A., Salmon, J., Carver, A., Garnett, S. P., & Baur, L. A. (2007). Associations between the home food environment and obesity-promoting eating behaviors in adolescence. Obesity, 15(3), 719-730.

1.7 Describe EACH of your participant populations

- Include description of any control group(s)
- Specify the Inclusion/Exclusion criteria for EACH group

Cohort 1:

Experimental Group- Episodic Future Thinking (EFT) Group; Control Group- CONTROL

Both groups will include parent/child dyads with overweight or obesity and inclusion/Exclusion criteria will be the same for both groups:

Inclusion:
1- Child age between 10-14
2- Child height and weight that calculates to a BMI above the 85th percentile (BMI in overweight/obesity range)
3- Parent height and weight that calculates to a BMI above 24.9 (BMI in overweight/obesity range)
4- Possession of at least one electronic device (per family) with WiFi capabilities (e.g. smartphone, tablet, computer)
5- Home internet access
6- Motivation to lose weight

Exclusion:
1- Disordered eating patterns (e.g. binge-eating disorder, extreme weight-loss behaviors)
2- A family history of eating disorders (siblings, children, parents, or grandparents)
3- Medical conditions that are known to interfere with weight-loss (e.g. type 1 diabetes, thyroid disease)
4- Medical conditions that may affect their ability to use the computer for a prolonged period of time or follow study protocol
5- Psychopathology or disabilities that would limit adherence to protocol (e.g. depression, suicidality, ADHD). Participant will only be excluded if the disability would not allow them to adhere to protocol. Just having the disability does not exclude them. Suicidality would be automatically be exclusionary)
6- Substance use, abuse, or dependence (e.g. binge drinkers, illicit substance users, alcoholics)
7- Plans to start or stop a medication that may affect appetite/weight-loss during the intervention period
8- Have started a medication within 6 months that is affecting appetite/weight-loss
9- Plans to move out of the area during the treatment period
10- Pregnancy/breastfeeding or plans of becoming pregnant during the study period
11- Is participating in another weight-loss program
12- Can not successfully record eating behavior in the MyFitnessPal app
13- A) Had bariatric surgery less than one year ago
B) If the potential participant had bariatric surgery over a year ago, their weight has not been stable for at least 6 months

Cohort 2:
The same as Cohort 1 with an additional exclusionary criterion:
- Can not successfully record eating behavior in the MyFitnessPal app

Cohort 3:

Experimental Group- Episodic Future Thinking (EFT) Group with Staggered Baselines (4 week, 7 week, 10 week) Unlike Cohort 1 and 2, there will be no CONTROL (HT) group – all families will receive EFT, however the time at which it is

introduced will differ between groups.

Both groups will include parent/child dyads, with the child with overweight or obesity
Inclusion:
1- Child age between 10 -14
2- Child height and weight that calculates to a BMI above the 85th percentile (BMI in overweight/obesity range – normal is okay, as parent BMI is no longer a primary outcome)
3- Parent height and weight that calculates to a BMI above 18 (Cannot be within the underweight category)
4- Possession of at least one electronic device (per family) with WiFi capabilities (e.g. smartphone, tablet, computer)
5- Home internet access
6- Motivation to learn healthy behaviors

Exclusion:
1- Disordered eating patterns (e.g. binge-eating disorder, extreme weight-loss behaviors)
2- A family history of eating disorders (siblings, children, parents, or grandparents)
3- Medical conditions that are known to interfere with weight-loss (e.g. type 1 diabetes, thyroid disease)
4- Medical conditions that may affect their ability to use the computer for a prolonged period of time or follow study protocol
5- Psychopathology or disabilities that would limit adherence to protocol (e.g. depression, suicidality, ADHD). Participant will only be excluded if the disability would not allow them to adhere to protocol. Just having the disability does not exclude them. Suicidality would be automatically be exclusionary)
6- Substance use, abuse, or dependence (e.g. binge drinkers, illicit substance users, alcoholics)
7- Plans to start or stop a medication that may affect appetite/weight-loss during the intervention period
8- Have started a medication within 6 months that is affecting appetite/weight-loss
9- Plans to move out of the area during the treatment period
10- Pregnancy/breastfeeding or plans of becoming pregnant during the study period
11- Is participating in another weight-loss program
12- Can not successfully record eating behavior in the MyFitnessPal app
13- A) Had bariatric surgery less than one year ago
B) If the potential participant had bariatric surgery over a year ago, their weight has not been stable for at least 6 months

1.8 Check all materials/methods that will be used in recruiting participants:

- Telephone script
- Ads/Brochures/Posters/News Release/Fliers
- Email or letters
- Website or Social Media (printed pages)
- Existing Registry/database - We will be utilizing the Recruitment Enhancement Core (REC) at Washington University which uses a Research Participant Registry.
- Word of Mouth/Snowball sampling
- Referral

Attachment Name	Category	Version	Date Attached
Rip Off Flyer_11.18.19.rtf	Recruitment Materials: Ads/Brochures/Posters/News Release/Fliers	8	11/18/19
FLYER_RS_11.22.19.rtf	Recruitment Materials: Ads/Brochures/Posters/News Release/Fliers	14	11/22/19
Recruitment Flyer_RS(email).rtf	Recruitment: Email or letters	7	08/30/19
RADIO AD-6.10.2019.rtf	Recruitment Materials: Ads/Brochures/Posters/News Release/Fliers	5	06/11/19
NEW FLYER_RS (Website).rtf	Recruitment: Website	8	08/30/19
Postcard_RS.rtf	Recruitment Materials: Ads/Brochures/Posters/News Release/Fliers	1	08/27/19
Recruitment Flyer_RS.rtf	Recruitment Materials: Ads/Brochures/Posters/News Release/Fliers	6	08/30/19
Recruitment Ad Metro Windscreen.Final.rtf	Recruitment Materials: Ads/Brochures/Posters/News Release/Fliers	5	07/03/19
NEWSPAPER AD_RS.rtf	Recruitment Materials: Ads/Brochures/Posters/News Release/Fliers	5	08/30/19

1.10 Describe where the consent discussion will occur (check all that apply):

- Private room or area
- By phone
- Online

1.11 Participants and/or their legally authorized representative will have (check all that apply to the consent process and explain process in Question 1.12 below):

- As much time as they desire to consider enrolling in the study, including:
    - An opportunity to thoroughly review the consent materials with knowledgeable members of the research team, and with family and/or friends as appropriate
    - Sufficient time to have all of their questions answered

1.12 Provide a description of the enrollment and consent process in sequential order and address EACH of the bulleted points below:

- Describe each study population separately including control population
- Describe when recruitment and consent materials are used
- Indicate how much time individuals will have to consider participation
- If eConsent will be used to obtain an electronic signature, describe how the eConsent will be presented to participants, how their questions will be answered and how the participant will receive a copy of the final, signed consent
- Describe the steps that will be taken by the research team to minimize the possibility of coercion or undue influence during the consent process

The Experimental (EFT) and Control (CONTROL) groups will complete the same enrollment and consent processes.

Recruitment: The research team will recruit individuals using the Wash U Recruitment Enhancement Core (REC). The REC recruits participants via a research participant registry, a local volunteer for health site, a Facebook fanpage, flyers/posters, and email blast distribution. Additionally, the researchers may recruit subjects via flyers and advertisements posted and made available around the Wash U campus and community. Specifically within the community, we intend on utilizing local elementary and middle schools, as well as local churches as part of our recruitment strategy. Our project, intended participants and expected outcomes will be explained to an administrator within the school or church. All necessary concerns and questions will be addressed by the study team. Pending approval and cooperation, we will post our IRB-approved flyers in the building or include in weekly bulletins. Researchers may actively recruit participants, and postcards may be used to collect contact information from those interested in participating. Materials such as postcards may be used in pediatric practices with the permission of the practice. Newspaper ads and radio ads may be used. Social media posts and internet recruitment ads on sites like Facebook, Twitter, Craigslist, Researchmatch.org, newspaper ads, and other community websites will also be used to reach interested participants. All recruitment materials will contain the researcher's contact information (email and office phone). When participants reach out with interest in the study, the researcher will complete a short phone screening survey to determine initial eligibility.

Initial Phone Screening Survey: All interested participants will complete the initial eligibility survey with the researcher. The initial survey will collect basic demographic information and asked questions that ensure participants meet all of the inclusion criteria described above. If initially eligible, participants will be scheduled for an individual in-lab screening session at the laboratory to further determine eligibility. Participants will also be emailed a copy of the consent to allow them plenty of time to consider participation before they visit the lab.

In-Lab Eligibility Screening ~ 1 Hour 30 Minutes
Upon arrival to the lab space (Wash U Center for Healthy Weight and Wellness in the Mid Campus Center), the parent and child dyad will be greeted and escorted to a private room where they will be given a brief overview of the study, asked if they have any questions about the study, and consented. Two copies of the consent, parent permission, and assent forms will be signed by the participant and researcher. One copy will be obtained by study personnel and one copy will be given to participants for their records. The copy obtained by study personnel will be kept in a locked cabinet. PHI (Name, SSN, Phone number, Address, DOB, email address) will be kept in the research study record.

Cohort 3 – All new participants will undergo the same enrollment and consent process as Cohorts 1 and 2. As of 2/3, recruitment and enrollment are complete.

RECONSENTING - Only Cohort 3 will be reconsented on the new changes to the study put in place due to COVID-19 pandemic. Cohort 1 and 2 will not be informed of the changes.

The consent process may take place by phone for participants who have barriers to in-person participation. For potential participants who have computer access and capability, the formal study consent process will be conducted using a REDCap-based electronic consent form. The consent form has been developed in REDCap, a secure, web-based, HIPAA-compliant, data collection platform with a user management system allowing the principal investigator to grant and control varying levels of access to study staff. Potential participants would receive an email with a unique link to review the informed consent form online. After the research team explains the study and answers any question, the potential participants can electronically fill in an “Agree” button, followed by their electronic signature. Upon completion of the consent, participants are presented with the option to download a copy of the executed form. The research team will also e-mail a copy of the executed form to the participant. E- consent versioning will be managed using the e-consent Framework in Redcap. Within the e-consent survey options, we have designated the e-consent version number in this application as e-consent version 1. The PDF's of completed responses will have the timestamp, participant name, and e-consent version number inserted in the footer. Future versions of the e-consent will be created by making a copy of the Redcap form and revising it. The old version would be de-activated upon receiving IRB approval for the new version.

If a participant does not have access to a computer at the time of consent potential participants will be provided with a copy of the informed consent form (via mail or email). Once the potential participant has had time to look over the consent form, a study team member will talk with the participant by phone to review the study information and answer any questions. If they choose to continue their participation, they will be asked to sign the consent and return to us

either by mail or scanned and emailed or faxed. We will instruct participants to keep a copy for themselves.

In the event participants who consented using the REDCap e-consent would need to be re-consented, we will send the participant a link to the new version to discuss, sign electronically, download, and receive via e-mail as described above.

NOTIFICATION OF STUDY PROCEDURE CHANGE - Participants will receive a letter describing why the home-visits are cancelled and the Cupboard Inventory is replaced by the Home Food Inventory. Due to the immediate nature of this change, in order to protect the health of the participants, they will not be re-consented, rather they will just be notified of the change.

1.13 Provide a detailed description in sequential order of the study procedures following the consent process - DO NOT cut and paste from the Consent Document.

Describe study populations separately if they will be participating in different procedures

DESCRIBE:

- Control populations, if applicable
- Any randomization, if applicable
- What participants will be asked to do/what happens in the study (in sequential order)
- The time period over which procedures will occur
- Long-term follow-up and how it occurs

Cohort 1:
Session 1- In-Lab Screening- After a brief overview of the study and signing the consent documents, objective measures of height and weight will be collected to ensure participants meet the BMI eligibility criteria. The parent and child will then undergo the remainder of the screening session visit in separate rooms. Participants may also complete: 1) disordered eating behavior via the Eating Disorders Examination Questionnaire (EDE) for parents & Kid's Eating Disorders Survey (KEDS) for kids, 2) a sociodemographic questionnaire,3) a clinical interview to ensure they do not meet any of the exclusion criteria, 4)The Patient Health Questionnaire (PHQ) to assess depressive symptoms, and 5)K-SADS. Children will not be asked question number 9 on the PHQ which asks, "over the past 2 weeks, how often have you been bothered by any of the following problems...thoughts that you would be better off dead, or of hurting yourself." Additionally, if the Patient Health Questionnaire is not completed during the visit, it may be completed over the phone. If a participant's score on any of the questionnaires is out of the normal range, a follow-up visit or phone call may be required. During the follow-up, a trained research team member will administer the K-SADS, or a supplement of the K-SADS, to further assess questionnaire results. The follow-up may also be conducted to probe ambiguous participant responses on the eating disorder questionnaires. This will allow research team members to follow-up on any concerns with participant psychopathology. If participants are still eligible after the in-lab screening, they will be randomized to either the EFT or CONTROL thought training group and a baseline visit will be scheduled.

If any potential participants are ineligible because they show signs of baseline disordered eating patterns or major psychopathology/distress, research assistants will report it to the study contact person and PI of the study, Denise Wilfley, who will help the families find the appropriate resources for help. Participants who are ineligible for other reasons (e.g. do not meet the BMI overweight/obesity criterion) will be given basic information about healthy living to use as a personal resource.
Randomization: After eligible participants complete the in-lab screening session, parent/child dyads will be randomized to receive either EFT training or the CONTROL thought training program and a baseline session will be scheduled.

Session 2- Baseline: ~ 1 Hour 30 Minutes:
During the baseline session, participants will complete the following:

1- Surveys: Consideration of Future Consequences Scale (CFCS), Palatable Eating Motives Scale (PEMS), and Living to 75 assessment.
2- Delay Discounting Task
3- Relative Reinforcing Value Task (will assess level of hunger before the task- hunger scale attached).
4- EFT or CONTROL cue generation needed for thought training.

EFT Cues: A brief cue will be generated in which participants talk about a specific future positive event where they imagine themselves in vivid detail. To generate the cues, participants in the EFT group will be given standardized instructions asking them to think about and list specific events that they are looking forward to in the future (ex: parties, holidays, etc.). Participants will be instructed to generate the EFT cue by describing their events, including a detailed description of themselves at the specific event. After the cue is created, participants will rate this cue for valence, salience, arousal, and the frequency and vividness of episodic associations. Participants who do not rate the cue at least 3 out of 5 for vividness will be asked to generate a new cue using a different event. After the participant has created their cues, they will save their cue for later use in the intervention.

Control Cues: To control for the timing and attention of the EFT cue, participants in the CONTROL group will generate cues that include a specific nutrition statements, selecting cues that they feel will be of personal benefit. To generate the cues, participants in the CONTROL group will select from a list of nutrition statements that they feel will be personally useful in making healthy decisions. After the cue is created, participants will rate this cue for salience. After the participant has created their cues, the participant will save their cue for later use in the intervention.

5- Technology Tutorial: Participants will be learning to use 3 major technologies for this study including:

EFT or CONTROL Cue Retrieval: The experimenter will then train participants in both groups on how to retrieve cues from their cell phone or alternative WiFi device, to pay attention to and think about the cues, and how to adhere to the study's expectations for utilizing to the cues. Participants will be told to use their cues any time they need to, especially

around eating episodes, using the prompt response website - Mobile Audio Management and Response Tracker (MAMRT) (Sze, Daniel, Kilanowski, Collins, Epstein, 2015).

At-home weighing: Participants will send their weights to the researchers once per week (when they aren't visiting the lab outlined in the "Intervention Sessions" section below) from a wireless scale provided to them by the researchers. During this baseline session, participants will be given a tutorial on how to use the wireless scale and associated application to send their weekly weights. Participants are also going to be asked to send a video of themselves weighing to ensure a valid weight result. The researchers will instruct participants on how to record and send these videos. The families will email their weight videos directly to the contact person of the study, Rebecca Steins (rsteins@wustl.edu). Rebecca will store the weight videos on the secured lab drive in a password protected folder. Rebecca is the only person who will have access to the weight videos.

FamZoo: Participants will be receiving their monetary incentives through the FamZoo platform. FamZoo is a prepaid debit card system that will allow the researchers to immediately transfer money to the separate parent or child debit card if the parent/child meet their weight loss goals. Participants will be instructed on how to use the FamZoo platform during the baseline session and will sign up for the account during session.

Intervention Sessions: There will be 24 weekly sessions following the screening and baseline sessions. Participants will only receive monetary incentives during the first 12 weeks. The incentive program is outlined below:

Incentives for individual weight loss (per person)
Parent receives this amount if he/she loses 1 lb that week
Child receives this amount if he/she loses 1/2 lb that week

Session 3 $0.50
Session 4 $1.00
Session 5 $2.50
Session 6 $5.00
Session 7 $5.00
Session 8 $5.00
Session 9 $5.00
Session 10 $5.00
Session 11 $5.00
Session 12 $5.00
Session 13 $5.00
Session 14 $5.00

If the parent or child fails to meet his/her weekly weight-loss goal, the potential earning potential of the participant drops back down to the amount of Session 3 ($0.50). The earning potential will go back up to the expected pay rate after 2 weeks of successive losses. For example, if during the week of Session 6, a parent does not meet his/her weight-loss goal, he/she will not receive a monetary incentive for the week and the earning potential of the week of Session 7 will drop down to $0.50. If the parent meets his/her weight loss goal during the week of Session 7 and the week of Session 8, the earning potential will be back at $5.00.

If both the parent and child meet their weight-loss goals (parent loses 1 lb and child loses 1/2 lb), the parent/child dyad will receive the amount below in addition to the separate parent/child incentive amount. The amount will be split evenly between the parent and child each session.

Session 3 $4.20 (or $2.10 each)
Session 4 $4.20
Session 5 $4.20
Session 6 $4.20
Session 7 $4.20
Session 8 $4.20
Session 9 $4.20
Session 10 $4.20
Session 11 $4.20
Session 12 $4.20
Session 13 $4.20
Session 14 $4.20

Families will also receive $20 in compensation for measurement sessions (sessions 2, 7, 10, 14, 18, 26). The $20 will be split evenly between parent and child ($10 each).

Sessions 3-6 ~ 1 Hour 30 Minutes Each
In-Lab Group Sessions: One researcher will lead a session for the parents and one researcher will lead a session for the children. During these sessions, families will be given information about the Traffic Light Eating Plan which lays out healthy vs. unhealthy foods, reducing serving sizes, eating less, recording their diets, shopping, meal planning, and keeping up healthy behaviors. Participants will have their heights (session 3), weights, and waist circumferences measured during the session. Families will also have a short case management session with the researcher during this session so the researcher can help them best succeed in the Healthy Habits Program.

Session 7 ~ 1 Hour
In-Lab Individual Family Session: Each family will come to the lab for measurements, case management, and payment. Height, weight, waist circumference, and DD will be measured during this session. Participants will also generate new EFT or CONTROL cues.

Sessions 8-9 ~ 20 Minutes Each
Out-of-Lab Individual Family Sessions: Each family will complete a weekly phone session with a researcher. The phone call will act as a case management call asking participants about the progress of the study and offering support. Since participants will not be in the lab during these weeks, they will send their weekly weights wirelessly.

Session 10 ~ 1 Hour
In-Lab Individual Family Session: Each family will come to the lab for measurements, case management, and payment. Height, weight, waist circumference, and DD will be measured during this session. Participants will also generate new EFT or CONTROL cues.

Sessions 11-13 ~ 20 Minutes
Out-of-Lab Individual Family Sessions: Each family will complete a weekly phone session with a researcher. The phone call will act as a case management call asking participants about the progress of the study and offering support. Since participants will not be in the lab during these weeks, they will send their weekly weights wirelessly.

Session 14 ~ 1 Hour
In-Lab Individual Family Session: Each family will come to the lab for measurements, case management, and payment. Height, weight, waist circumference, and DD will be measured during this session. Participants will also generate new EFT or CONTROL cues.

Sessions 15-17 ~ 20 Minutes Each
Out-of-lab Individual Family Sessions: Each family will complete a weekly phone session with a researcher. The phone call will act as a case management call asking participants about the progress of the study and offering support. Since participants will not be in the lab during these weeks, they will send their weekly weights wirelessly.

Session 18 ~ 1 Hour
In-lab Individual Family Session: Each family will come to the lab for measurements, case management, and payment. Height, weight, waist circumference, and DD will be measured during this session. Participants will also generate new EFT or CONTROL cues.

Sessions 19-25 ~ 20 Minutes Each
Out-of-lab Individual Family Sessions: Each family will complete a weekly phone session with a researcher. The phone call will act as a case management call asking participants about the progress of the study and offering support. Since participants will not be in the lab during these weeks, they will send their weekly weights wirelessly.

Session 26 ~ 1 Hour
In-lab Individual Family Session: Each family will come to the lab for measurements, case management, and payment. Height, weight, waist circumference, and DD will be measured during this session.

Total Time after Screenings: ~ 19 Hours
Total Potential Amount Earned Per Family: Incentives: $148.40 + Measurements: $120 = $268.40

If at any point during the study a child dips below the 85th percentile or the parent dips below a BMI of 25.0, the researcher will have a conversation with the family to inform them that they have moved from the overweight range to a healthy weight range. Participants will no longer have the 0.5 lb (child) or 1lb (parent) weight-loss goal. If participants change BMI categories during the monetary incentive portion of the study, the incentives will be contingent on weight-loss maintenance. Therefore, participants will receive the monetary incentive as long as they do not gain weight during that week. Some participants may wish to continue their weight-loss efforts to move further away from the overweight BMI category. The PI will check weights weekly to ensure participants are not losing too much weight.

The following surveys from the full protocol will be in hard copy form and will be stored in a locked cabinet in a locked office at the Center for Healthy Weight and Wellness:
Parent: Clinical interview, Eating Disorders Examination Questionnaire, Sociodemographic Questionnaire
Child: Clinical interview, Kids Eating Disorders Survey

The following surveys from the full protocol will be collected via Qualtrics and will not contain any PHI:
Parent: Consideration or Future Consequences Scale, Delay Discounting Task, Living to 75 Assessment, Palatable Eating Motives Scale
Child: Consideration or Future Consequences Scale, Delay Discounting Task, Living to 75 Assessment, Palatable Eating Motives Scale

Cohort 2:
Session 1- Eligibility Screening: ~1 Hour 30 Minutes; In Lab Session

After a brief overview of the study and signing the consent documents, objective measures of height and weight will be collected to ensure participants meet the BMI eligibility criteria. The parent and child will then undergo the remainder of the screening session visit in separate rooms. Participants may also complete: 1) disordered eating behavior via the Eating Disorders Examination Questionnaire (EDE) for parents & Kid’s Eating Disorders Survey (KEDS) for kids, 2) a sociodemographic questionnaire,3) a clinical interview to ensure they do not meet any of the exclusion criteria, 4)The Patient Health Questionnaire (PHQ) to assess depressive symptoms, and 5)K-SADS. Children will not be asked question number 9 on the PHQ which asks, "over the past 2 weeks, how often have you been bothered by any of the following problems...thoughts that you would be better off dead, or of hurting yourself." Additionally, if the Patient Health Questionnaire is not completed during the visit, it may be completed over the phone. If a participant's score on any of the questionnaires is out of the normal range, a follow-up visit or phone call may be required. During the follow-up, a trained research team member will administer the K-SADS, or a supplement of the K-SADS, to further assess questionnaire results. The follow-up may also be conducted to probe ambiguous participant responses on the eating

disorder questionnaires. This will allow research team members to follow-up on any concerns with participant psychopathology.

If any potential participants are ineligible because they show signs of baseline disordered eating patterns or major psychopathology/distress, research assistants will report it to the study contact and the PI, Denise Wilfley, who will help the families find the appropriate resources for help. Participants who are ineligible for other reasons (e.g. do not meet the BMI overweight/obesity criterion) will be given basic information about healthy living to use as a personal resource.

If participants are still eligible after the in-lab screening, they will be scheduled for a group workshop and told to keep record of their eating behavior/physical activity in the MyFitnessPal app.

Session 2- Group Workshop: ~ 2 Hours 30 Minutes; In Lab Session
Participants will have weights measured in private rooms. Families will also learn the core components of the program in presentations by the research staff. The workshop will also include activities to keep the families engaged and a meal will be provided. If the participants attend the workshop, successfully logged in MyFitnessPal, and still want to participate, they will be randomized to a treatment group and scheduled for a baseline session.

Session 3- Baseline: ~ 1 Hour 30 Minutes; In Lab Session
Participants will complete the following:

1- Have height and weight measured.
2- Complete surveys: Consideration of Future Consequences Scale (CFCS), Palatable Eating Motives Scale (PEMS), and Living to 75 assessment.
3- Complete the Delay Discounting Task
4- Complete EFT or CONTROL cue generation needed for thought training.

EFT Cues: A brief cue will be generated in which participants talk about a specific future positive event where they imagine themselves in vivid detail. To generate the cues, participants in the EFT group will be given standardized instructions asking them to think about and list specific events that they are looking forward to in the future (ex: parties, holidays, etc.). Participants will be instructed to generate the EFT cue by describing their events, including a detailed description of themselves at the specific event. After the cue is created, participants will rate this cue for valence, salience, arousal, and the frequency and vividness of episodic associations. Participants who do not rate the cue at least 3 out of 5 for vividness will be asked to generate a new cue using a different event. After the participant has created their cues, they will save their cue for later use in the intervention.

Control Cues: To control for the timing and attention of the EFT cue, participants in the CONTROL group will generate cues that include a specific nutrition statements, selecting cues that they feel will be of personal benefit. To generate the cues, participants in the CONTROL group will select from a list of nutrition statements that they feel will be personally useful in making healthy decisions. After the cue is created, participants will rate this cue for salience. After the participant has created their cues, the participant will save their cue for later use in the intervention.

5- Go through a technology tutorial: Participants will be learning to use 2 major technologies for this study including:

EFT or CONTROL Cue Retrieval: The experimenter will then train participants in both groups on how to retrieve cues from their cell phone or alternative WiFi device, to pay attention to and think about the cues, and how to adhere to the study's expectations for utilizing to the cues. Participants will be told to use their cues any time they need to, especially around eating episodes, using the prompt response website - Mobile Audio Management and Response Tracker (MAMRT) (Sze, Daniel, Kilanowski, Collins, Epstein, 2015).

At-home weighing: Participants will send their weights to the researchers from a wireless scale provided to them by the researchers. During this baseline session, participants will be given a tutorial on how to use the wireless scale and associated application to send their weekly weights.

Sessions 4-19-Intervention Sessions
The intervention sessions will be separated into 2 phases.

PHASE 1: Sessions 4-10; ~ 30 minutes; In Lab Sessions
Participants will have weight measured, do the thought training program, talk to staff about progress in the program, and receive money from the monetary incentives program. For the monetary incentives program, each participant can earn $20 for meeting their weight loss goals (parent=1 pound, child= 1/2 pound) each week. If both the parent and child meet their weight loss goals, they will earn an additional $5 a piece each week.

The monetary incentive is based on the lowest weight in the study. For example: Let's say the participant's starting weight at Session 3 is 250 and she has a weekly weight loss goal of 1 pound. At Session 4, she meets her weight loss goal (weight=249) and earns $20. If she gains 2 pounds, for Session 5 (weight=251), she will not earn the $20 incentive. Then, for Session 6, she would have to lose 3 pounds (weight=248) to earn the incentive because her weight loss goal of 1 pound is based on her lowest weight in the study so far which was 249. This is to ensure participants aren't reinforced for losing the same pound over and over again.

Families will also receive compensation for attendance. If families attend 6 out of 8 sessions or 8 out of 8 sessions, they will each receive $25 and $50, respectively.

Session 11 ~ 1 Hour; In Lab Session
Participants will have height/weight measured, do the thought training program, talk to staff about progress in the program, and receive money from the monetary incentives program. Participants will also complete surveys during this session.

PHASE 2: Sessions 12-19; Phone Sessions ~ 30 minutes
Participants will talk to staff about progress in the program and do the thought training program.

During both phases of intervention, participants will be encouraged to send weekly weights from the provided scale. Participants will also be asked to log their activity related to the program in the MyFitnessPal app. Researchers will access the information and send feedback to the participants (via text, phone, and/or email) to help them succeed in the program.

Session 19 ~ 1 Hour; In Lab Session
Participants will have height/weight measured, do the thought training program, talk to staff about progress in the program, and complete surveys.

Session 20~ 1 Hour; In Lab Session

Participants will have height/weight measured and complete surveys. This session will take place after an 8 week no intervention follow up that follows Session 19.

If at any point during the study a child dips below the 85th percentile or the parent dips below a BMI of 25.0, the researcher will have a conversation with the family to inform them that they have moved from the overweight range to a healthy weight range. Participants will no longer have the 0.5 lb (child) or 1lb (parent) weight-loss goal. If participants change BMI categories during the monetary incentive portion of the study, the incentives will be contingent on weight-loss maintenance. Therefore, participants will receive the monetary incentive as long as they do not gain weight during that week. Some participants may wish to continue their weight-loss efforts to move further away from the overweight BMI category. The PI will check weights weekly to ensure participants are not losing too much weight.

The following surveys from the full protocol will be in hard copy form and will be stored in a locked cabinet in a locked office at the Center for Healthy Weight and Wellness:
Parent: Clinical interview, Eating Disorders Examination Questionnaire, Sociodemographic Questionnaire
Child: Clinical interview, Kids Eating Disorders Survey

The following surveys from the full protocol will be collected via Qualtrics and will not contain any PHI:
Parent: Consideration or Future Consequences Scale, Delay Discounting Task, Living to 75 Assessment, Palatable Eating Motives Scale
Child: Consideration or Future Consequences Scale, Delay Discounting Task, Living to 75 Assessment, Palatable Eating Motives Scale

Cohort 3 - Due to the COVID 19 outbreak, in-person assessments and interventions are no longer feasible. Therefore, the researchers will carry out these study components remotely. The programs that will be used are phone, Zoom, and Qualtrics.

WEEK 0 - Baseline Session: ~ 2 hours; In-Lab Group Session - All Baseline sessions were completed as planned in lab.

First, upon arriving to the lab, each dyad will be escorted to a private room and will complete the following:
1- Have height and weight measured.
2- Complete surveys: Consideration of Future Consequences Scale (CFCS), EDE-Q (Parent), KEDS (Child)
3- Complete the Delay Discounting Task, the Virtual Shopping Task, and Home Food Inventory. A letter was sent to each family explaining the change from in-home visits with the Cupboard inventory to the self-completed Home Food Inventory, due to growing concern over COVID-19.
4- Receive first assessment payment ($40 dollars)

Following steps 1-4, the families will take part in a group session to learn the core components of the program in presentations by the research staff.

Weeks 1-14 ~ 2 hours; Weekly In-Lab Group Sessions - Due to the COVID 19 outbreak, in-person assessments and interventions are no longer feasible. Therefore, the researchers will carry out these study components remotely. The programs that will be used are phone, Zoom, and Qualtrics.

1. The day of their assigned parent group session, each family will email the study coordinator a photocopy of their food receipts, receipt forms, and food log. They will self-report weights via email as well. Payment will be completed via check request, Amazon Pay, or Forte.

2. Children will join a child-only Zoom group video session, and parents will join a parent-only Zoom video session. Each group will be led by a study team member. In these sessions, participants will do the thought training program, and talk to staff and other group members about progress in the program. Each parent-child dyad will meet via Zoom or phone at a separate time with a study team member to complete the case management portion of the program.
a. During the 15-week intervention, participants will be asked to log their activity related to the program in food logs.
b. Researchers will access the information and send feedback to the participants (via text, phone, and/or email) to help them succeed in the program.

Throughout the baseline period, the study team will assess all participants' adherence levels through looking at data from the food logs and the collected receipts.
Once a family has been determined to be adhering to the study protocol, the participant will then be randomly assigned to either the 4-week, 7- week or 10-week baseline group. Participants who were assigned 4- week baseline, will now be eligible to start the intervention, those in the 7-week will complete three more weeks of baseline prior to the intervention, and those in the 10-week will complete three more weeks of baseline prior to the intervention.

An assessment session will take place the week the group starts the intervention, which will consist of

1- Self-reported weights via email
2- Complete surveys: EDE-Q (Parent), KEDS (Child) on Qualtrics
3- Complete EFT cue generation needed for thought training – See cohort 2 for description – this will be remotely done via Qualtrics.
4- Complete the Delay Discounting Task on Qualtrics and the Virtual Shopping Task via emailed instructions.
5- Review weekly receipts and receive receipt payment if applicable ($25 dollars) via check request, Amazon Pay or Forte.
6- Receive assessment session payment ($40 dollars) via check request, Amazon Pay or Forte.
7. Receive a EFT Cue Retrieval technology tutorial via emailed instructions, or a Zoom or phone session as requested – See cohort 2 for description.

Assessment measures must be completed the day of their assigned group sessions. Child and Parent Zoom-based group sessions will be conducted at their scheduled times, as well as scheduled case management.

Week 15 ~ Final Assessment - All assessment measures for week 15 will be conducted remotely, unless COVID-19 related restrictions are lifted, in which an in-lab visit for final measurements may be conducted.
1- Self-reported heights and weights
2- Complete surveys on Qualtrics: Consideration of Future Consequences Scale (CFCS), EDE-Q (Parent), KEDS (Child), Formative Questionnaire, TT Frequency of Use
3- Complete the Delay Discounting Task, Shelf Life Inventory, and Home Food Inventory on Qualtrics, and the Virtual Shopping Task via emailed instructions.
4- Review weekly receipts and receive payment if applicable ($25 dollars) via check request, Amazon Pay or Forte.
5- Receive final assessment session payment ($45 dollars) via check request, Amazon Pay or Forte.

Assessment measures must be completed the day of their assigned group sessions. Child and Parent Zoom-based group sessions will be conducted at their scheduled times, as well as scheduled case management.

Cohort 3 Compensation Breakdown
- Weekly Payment for Food Purchase Receipts (W1-W15) - $25 per week = 375 total
- Baseline, Assessment 1 and Assessment 2 Payment = 125
- Total Payment per family = $500 via check request, Amazon Pay or Forte.

All surveys and data will be collected remotely by study team members without PHI during sessions. All collected data will be securely stored in Box. All surveys will be done via Qualtrics.

1.14 Will participants be randomized?
Yes

1.15 Will any of the following be used to collect information from the participant or others?

- Screening questions or screening/eligibility questionnaires
- Surveys
- Questionnaires
- Stimuli
- Any other written assessments

Yes

Attachment Name	Category	Version	Date Attached
KSADS_DSM_5_SCREEN_edited.pdf	Subject Data Collection Instruments	1	06/24/19
Formative Questionnaire.docx	Subject Data Collection Instruments	1	11/06/19
Patient Health Questionnaire.pdf	Subject Data Collection Instruments	2	12/27/18
Testimonial Questionnaire.docx	Subject Data Collection Instruments	1	11/06/19
Eating Disorders Examination Questionnaire (EDE-Q) Parent.docx	Subject Data Collection Instruments	2	08/14/18
Consideration of Future Consequences Scale-Parent.docx	Subject Data Collection Instruments	2	08/14/18
Parent_Clinical Interview_12.5.docx	Subject Data Collection Instruments	6	12/12/19
Receipt Collection Instructions.pdf	Subject Data Collection Instruments	1	01/22/20
Grocery Shopping Task.docx	Subject Data Collection Instruments	1	01/22/20

Delay Discounting Task- Parent&Child.docx	Subject Data Collection Instruments	2	08/14/18
Kids Eating Disorders Survey- Child.docx	Subject Data Collection Instruments	2	08/14/18
Child_Clinical Interview_12.5.docx	Subject Data Collection Instruments	4	12/12/19
Home Food Inventory.docx	Subject Data Collection Instruments	1	03/12/20
PHQ Probes.docx	Subject Data Collection Instruments	1	12/11/19
Sociodemographic Questionnaire- Parent.docx	Subject Data Collection Instruments	1	11/09/18
Consideration of Future Consequences Scale-Child.docx	Subject Data Collection Instruments	2	08/14/18
Shelf Life Survey.xlsx	Subject Data Collection Instruments	1	06/15/20
KSADS_DSM_5_Supp1_DepressiveDO_edited.pdf	Subject Data Collection Instruments	1	06/21/19
TT Frequency of Use Question.docx	Subject Data Collection Instruments	1	10/02/19

1.16 Does this project involve creating any audio, video, or photographs?
Yes

1.17 Does the study include any form of deception (e.g., providing participants with false information, misleading information, or withholding information about certain study procedures)?
Examples:

- Procedure includes a cover story that provides a plausible but inaccurate account of the purposes of the research.
- Participants will be provided with false information regarding the particular behaviors of interest in the research.
- Procedures include a confederate pretending to be another participant in the study.
- Participants will be told that the research includes completion of a particular task, when in fact, that task will not be administered.
- Study is designed to introduce a new procedure (or task) that participants are not initially told about.

No

1.18 Indicate any payments or reimbursements to participants (check all that apply)
- Cash
- Gift or Debit Card

1.19 Does this study have a plan to have an individual or committee review combined data from all participants on a periodic basis (such as summary or aggregate safety and/or efficacy data)?
No

1.20 What have you done to minimize any risks?
- No foreseeable risks
- Psychological consultation and/or referrals readily available

1.21 What are the potential benefits related to this project for:

- the participant (if any)
- benefits to society (if any)

There are many potential benefits of the proposed research. Participants in the study could gain new knowledge on how episodic future thinking influences inter-temporal decision making. All participants in all groups are taught methods for healthier grocery shopping, eating and living; therefore, depending on the behavior changes of the participants, it could result in a healthier eating behaviors and a healthier home environment. This in turn could result in potential weight loss for the entire family in the home. If participants do lose weight in the study, it could decrease their risk of weight-related disease such as type 2 diabetes and heart disease.

1.22 Provide a summary of the analysis methods you will use, including, if applicable, the data points or outcomes you will analyze.

Cohort 1:
Preliminary analyses:
Preliminary analyses will be conducted to ensure groups are similar based on demographic characteristics (age, BMI, race/ethnicity, SES).

Primary analyses:
Between group ANOVAs will be performed to make sure the two groups have similar continuous characteristics (age, BMI for adults/percent over BMI for children) and chi-square analyses will be performed to ensure the groups have similar categorical characteristics (race/ethnicity, SES). If a group difference is found, the variable will be entered as a covariate in subsequent analyses.

Two-way repeated measures ANOVAs will then be conducted to determine differences in BMI/percent over BMI, weight, and waist circumference, between the EFT and HT groups over time. Data points will be collected at weeks 2 (baseline), 7, 10, 14 (incentive program ends), 18, and 26 of the program. We hypothesize:
1- The EFT and HT group will both have a reduction in BMI/percent over BMI, weight, and waist circumference from baseline throughout the monetary incentives program (week 7, 10, 14).
2- The EFT group will have a greater reduction in BMI/percent over BMI, weight, and waist circumference from baseline throughout the monetary incentives program (week 7, 10, 14) than the HT group.
3- The EFT group will maintain the reduction in BMI/percent over BMI, weight, and waist circumference from baseline after the termination of the monetary incentives program (week 18, 26).
4- The HT group will not maintain the reduction in BMI/percent over BMI, weight, and waist circumference from baseline after the termination of the monetary incentives program (week 18, 26).

Secondary analyses:
A two-way repeated measures ANOVA will be conducted to determine differences in delay discounting between the EFT and HT groups over time. Data points will be collected at weeks 2 (baseline), 7, 10, 14 (incentive program ends), 18, and 26 of the program. We hypothesize:
1- The EFT group will have a reduction in delay discounting over time (7, 10, 14, 18, 26) compared to baseline.
2- The HT group will not have a reduction in delay discounting over time (7, 10, 14, 18, 26) compared to baseline.
3- The EFT vs. the HT group will have a reduction in delay discounting over time (7, 10, 14, 18, 26).

Regression analyses will also be conducted to determine whether baseline characteristics predict outcome variables (BMI for adults/percent over BMI for children, weight, waist circumference, and DD). These characteristics will be collected from baseline surveys including the Consideration of Future Consequences Scale, Living to 75 Assessment, and Palatable Eating Motives Scale. First, zero order correlations between each predictor and the outcome variables will be established, and then significant predictors will be entered in a multiple regression model that includes demographic characteristics and the significant predictors. This will provide the opportunity to assess what individual characteristics predict child and adult success. In addition, we will assess the influence of parental success on child success in a multiple regression model, again controlling for demographic characteristics.

Cohort 2:
Preliminary analyses will be conducted to ensure groups are similar based on demographic characteristics (age, BMI, race/ethnicity, SES).

Primary analyses: Between group ANOVAs will be performed to make sure the two groups have similar continuous characteristics (age, BMI for adults/percent over BMI for children) and chi-square analyses will be performed to ensure the groups have similar categorical characteristics (race/ethnicity, SES). If a group difference is found, the variable will be entered as a covariate in subsequent analyses.

Two-way repeated measures ANOVAs will then be conducted to determine differences in BMI/percent over BMI and weight between the EFT and HT groups over time. Data points will be collected at sessions 3 (baseline), 11 (monetary incentives end), 19, 20. We hypothesize:
1- The EFT and HT group will both have a reduction in BMI/percent over BMI and weight, and waist circumference from baseline throughout the monetary incentives program (session 11).
2- The EFT group will have a greater reduction in BMI/percent over BMI and weight throughout the monetary incentives program (session 11) than the HT group.
3- The EFT group will maintain the reduction in BMI/percent over BMI and weight from baseline after the termination of the monetary incentives program (session 19, 20).
4- The HT group will not maintain the reduction in BMI/percent over BMI and weight from baseline after the termination of the monetary incentives program (session 19, 20).

Secondary analyses: A two-way repeated measures ANOVA will be conducted to determine differences in delay discounting between the EFT and HT groups over time. Data points will be collected at sessions 2 (baseline), 11 (incentive program ends), 19, and 20. We hypothesize:
1- The EFT group will have a reduction in delay discounting over time (11, 19, 20) compared to baseline.
2- The HT group will not have a reduction in delay discounting over time (11, 19, 20) compared to baseline.
3- The EFT vs. the HT group will have a reduction in delay discounting over time (11, 19, 20).

Regression analyses will also be conducted to determine whether baseline characteristics predict outcome variables (BMI for adults/percent over BMI for children, weight, and DD). These characteristics will be collected from baseline surveys including the Consideration of Future Consequences Scale, Living to 75 Assessment, and Palatable Eating Motives Scale. First, zero order correlations between each predictor and the outcome variables will be established, and then significant predictors will be entered in a multiple regression model that includes demographic characteristics and the significant predictors. This will provide the opportunity to assess what individual characteristics predict child and adult success. In addition, we will assess the influence of parental success on child success in a multiple regression model, again controlling for demographic characteristics.

Cohort 3 -

The results of this study will be analyzed graphically as well as assessing the degree of change from baseline to treatment across the three replications.

1.23 Provide the rationale or power analysis to support the number of participants proposed to complete this study.
This is the first study of this kind, therefore, we were unable to conduct a power analysis. Additionally, a power analysis is not applicable to this multiple baseline design. We are collecting weekly data from participants and will have enough data points to ensure we will be able to achieve the study objectives. The results of this study will be analyzed graphically as well as assessing the degree of change from baseline to treatment across the three replications. For an example of a study that utilized a multiple baseline design, see:

Spaulding, S., Devine, K., Duncan, C., Wilson, N., & Hogan, M. (2012). Electronic Monitoring and Feedback to Improve Adherence in Pediatric Asthma. Journal Of Pediatric Psychology, 37(1), 64–74. https://doi.org/10.1093/jpepsy/jsr059

1.25 Will any data from this project be stored for use in future research studies?
No

1.26 Does this project involve the collection or use of biological samples or genetic data?
No

1.27 Are you requesting institutional certification to contribute human data or samples to a repository or database for broad sharing (public or restricted access)?
No

2. Participants

2.1 Will there be any adult participants?
Yes

2.1.a How many adult participants do you expect to consent or enroll under a waiver for this project?
85

2.1.b What is the age of the youngest adult participant?
18.0

2.1.c What is the age of the oldest adult participant?
No age limit

2.2 Will there be any minor participants?
Yes

2.2.a How many minor participants do you expect to consent or enroll under a waiver for this project?
85

2.2.b What is the age of the youngest minor participant?
10.0

2.2.c What is the age of the oldest minor participant?
14.0

2.3 Will there be any emancipated minor participants?
No

2.4 You may indicate in the table below either a single, or multiple approaches for obtaining assent from minors in your study.

- If you will use the same method for all minors, you only need to enter one row.
- If you will use different assent methods depending on age, add multiple rows, breaking the minors into different age range(s)
- Indicate in each row the appropriate assent method(s) for each age range. Be sure to include the entire age range of your minor population.

Youngest	Oldest	Obtain Assent?	Assent Method(s)	Rationale
10.0	14.0	Yes	• Sign an assent document	Participants who are minors will be between ages 10 and 14 and therefore, unable to provide legal consent to participate in the study.

2.5 Will any minors reach the age of majority during their participation in this study?

No

2.6 Will any of the participants enrolled be in foster care or Wards of the state?
No

2.7 Do you plan to recruit/enroll non-English speaking people?
No

2.8 Do you propose to enroll any of the following in this study as participants?

- Employee of the PI or employee of a research team member
- Individual supervised by PI or supervised by member of research team
- Individual subordinate to the PI or subordinate to any member of the research team
- Student or trainee under the direction of the PI or under the direction of a member of the research team

No

2.9 Is this project about pregnant women?
No

2.10 Will this project involve fetuses?
No

2.11 Does this project involve the use of fetal tissue from any source?
No

2.12 Does this project recruit adult participants who may be incompetent or have limited decision-making capacity on initial enrollment into the study?
No

2.13 Does this project involve prisoners as participants?
No

3. Performance Sites

3.1 Indicate type of site(s) where research will occur (check all that apply):

- Academic Institution

3.2 Where will project procedures take place (check all that apply)?

- School of Medicine

3.3 Is this project also being conducted by other researchers at their own sites (e.g. a multi-site collaborative project)?
Yes

3.3.a What is your site's role(s) for this project (check all that apply)?

- Clinical/participating site
- Central laboratory or laboratory analysis
- Data analysis, statistical analysis or data management

3.3.g What are participating site roles for this project?

- Data analysis, statistical analysis or data management - Leonard Epstein,PhD and Alexis O'Brien- University of Buffalo (UB)
- Other - Dr. Epstein and Alexis will monitor case management phone calls to ensure each researcher provides quality support for each family.

5. Privacy & Confidentiality

5.1 Indicate your plans to protect the privacy interests of the participants during the conduct of the study (check all that apply):

- Only the minimum necessary private information is collected for the purposes of the study
- Any procedures or interventions conducted as part of the study will be conducted in private setting to the extent possible
- Recruitment/consent will occur in a private setting
- Participants will be able to ask questions in a private setting

5.2 Are you collecting or using the Social Security Number of any participants for any purpose?
Yes

5.2.a Provide the intended usage of SSN:
- To provide compensation to participants

5.3 Project uses paper or hard copy consents, surveys, data collection forms, research subject binders, or other hard copy materials (check all that apply):
Yes
- All materials are stored in secured environment
- Access is limited to research team members only

5.4 Project collects, stores and/or transmits electronic data on mobile devices, desktop computers, servers including cloud servers, email, or any other information in electronic form (check all that apply):
Yes
- Password protected
- Access is limited to research team only
- Data are encrypted
- Data in Qualtrics for General Use
- Other - Data sent to the participants from the researchers and between researchers on the team will be sent via Washington University's secured network using a secured email address. Data sent between researchers on the team will also be password protected. However, we cannot be sure the participants are using equally secured means of communicating with the researchers. They are encouraged in the consent form to use secured means of sending personal information.

5.5 Project collects or uses biologic specimens (check all that apply):
No

5.6 Identify any additional protections in place for data and or samples (check all that apply):
- No additional protections