Testing Digital Technologies to Help Families Build Healthy Habits

Study 2

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A. List of Abbreviations

FBT	Family-based Behavioral Treatment
VR	Virtual Reality
REC	Recruitment Enhancement Core
REACH	Community Based Recruitment and Retention
WUSM	Washington University in St. Louis School of Medicine
NIH	National Institutes of Health
NIDDK	National Institute of Diabetes and Digestive and Kidney Diseases
PI	Principal Investigator
SUS	System Usability Scale
USE	Usefulness, Satisfaction, and Ease of Use Questionnaire
HIPAA	Health Insurance Portability and Accountability Act
PHI	Protected Health Information
T3 Research	Translation to practice, including comparative effectiveness research, post-marketing studies, clinical outcomes research, as well as health services, and dissemination & implementation research
WU PAARC	Washington University Pediatric Adolescent Ambulatory Research Consortium

ChEDE-Q	Child Eating Disorder Examination-Questionnaire
CDTR	Center for Diabetes Translation Research (at Washington University in St. Louis)

B. Introduction

B1. Study Abstract

One in five children in the U.S. now has obesity.[1] A child with obesity faces a life-threatening cascade of cardiovascular and metabolic disease and suffers from severe teasing and bullying that contribute to poor quality of life.[2,3] Although evidence-based treatments exist, such as FBT,[4,5] they are not widely available.[6-11] Even when available, these treatments are costly and time-intensive, limiting reach, scalability, and adoption. More scalable approaches are needed for addressing childhood obesity. We propose to develop and build a 10-minute, prototype VR experience for children with overweight/obesity and their parents, based on a key tenet of FBT, in order to foster commitment to behavior changes in a format that would be engaging for children and scalable. This pilot study occurs after we have conducted usability testing with children with overweight/obesity and their parents over two cycles to inform refinements.

B2. Primary Hypothesis

Piloting the VR experience through a small-scale randomized trial will allow for analysis of feasibility for a larger-scale NIH grant and provide initial impressions on whether VR may be able to magnify the effects of consideration of future consequences on cognitions and behavior.

C. Background

C1. Rationale for this Study

VR has been described as "the most psychologically powerful medium" in history.[12] A fundamental characteristic of VR is that it provides users with a sense of "being there" (i.e., psychological presence), which results in VR environments producing emotional, behavioral, and physiological responses similar to those in real life, particularly in children.[13-15] VR has shown promise for addressing obesity, eating disorders, and other psychiatric concerns in adults,[16-19] yet to date, there is a dearth of research on VR for childhood obesity. For this prototype, we plan to translate the FBT strategy of episodic future thinking to VR, which involves mentally projecting oneself into the future and pre-experiencing" a future event through visualization.[20] This increases the value of future events and hence motivation.[21] Given VR's ability to create psychological presence, this strategy is ripe for translation. If successful, this approach has potential for widespread dissemination and is in line with T3 research, as the ultimate goal is to translate key tenets from an evidence-based treatment into everyday settings by using a more scalable format. This work is highly aligned with the Strategic Plan for NIH Obesity Research,[22] which highlights key research opportunities, including "design[ing] and test[ing] novel weight-control interventions that incorporate existing or emerging technologies (e.g., …virtual reality

mediums)" and investigating "how electronic applications…can expand reach… and rapid dissemination."

C2. Prior Literature and Studies

Research has shown that VR is a promising tool for augmenting treatment approaches,[23] including for obesity and eating disorders.[24,25] Preliminary work also shows VR as effective for delivering behavioral interventions in children.[26,27] Embodiment experiences in immersive virtual environments, which allow individuals to see, hear, and feel digital stimuli as if they were in the physical world, have been shown to impact adults' prosocial behavior and social anxiety;[28] however, less is known about VR's effects in children. VR research in children has focused on treatment of ADHD, autism spectrum disorder, anxiety, pain, and rehabilitation,[27, 29] and research with children undergoing physical rehabilitation suggests VR increases children's self-efficacy and adherence to their exercises by having their virtual bodies appear to move more fluidly than their physical bodies.[30] Embodiment in VR may be particularly compelling compared to less immersive mediums, because children can control their avatar with their body movements, and the view of their physical body is replaced with their virtual body.[31] Thus, embodiment in VR may be particularly promising for health interventions, and especially so for children.[14,32] Despite burgeoning research on VR for health promotion, there is no work yet that leverages a VR experience as an intervention tool for childhood obesity.[17]

FBT for childhood obesity is an evidence-based behavioral intervention that has been evaluated over the past 30 years by Co-Investigator Dr. Denise Wilfley and colleagues.[5,33] One key tenet involves consideration of future consequences (i.e., episodic future thinking) to promote behavior change and is ripe for translation to VR, whereby the cognitive exercise of considering how present behavior impacts future health can be enhanced through embodiment. *Specifically, a VR experience could amplify the impact of this strategy by allowing a child to experience what it might be like to live in various bodies in the future and see the long-term effects of dietary and activity behaviors in the immediate*. Leveraging the flexibility of VR allows for the creation of avatars whose movements can differ from that of the participants' own, increasing the potential impact of consideration of the "future self" on motivation and behavior.[34,35] Much work demonstrates the impact of consideration of one's future or "possible" self on motivation and behavior across domains,[36,37] including health behavior in early adolescents.[38] VR has been used to connect individuals with a future self to promote behavior change;[35] however, this has not been applied to health behaviors in children. This project (studies 1 and 2) would translate a key tenet of FBT into a burgeoning technology and examine the usability, acceptability, and efficacy of the intervention on motivation and behavior among children aged 6-12 with overweight/obesity and their parents.

D. Study Objectives

D1. Study Aim

Study 2 aims to evaluate the efficacy of the VR experience vs video in terms of (2a) acceptability, (2b) motivation for behavior change, (2c) behavioral beliefs and intentions, and (2d) behavior (i.e., physical activity and dietary behavior two weeks later). Outcomes will be assessed at both the child and parent levels. Finally, we will compare the indirect effects of the two conditions on behavior through behavioral cognitions (2e; exploratory).

With this study, we will generate data to set the stage for and inform subsequent NIH R-series grants, thus launching a research program to establish a scalable solution to increase access to care for childhood obesity.

D2. Rationale for the Selection of Outcome Measures

All participants will provide demographic information at baseline and will have height and weight measured. To determine acceptability (Aim 2a), we will use the SUS and USE. Those randomly assigned to VR will also complete the PQ. To examine motivation to make behavior change (Aim 2b), participants will complete measures assessing self efficacy[39] and readiness to change behavior.[40] Specifically, they will complete the 16-item Self-Efficacy for Healthy Eating and Physical Activity measure[41] and self-efficacy to lose weight will be assessed with the 8-item Weight Efficacy Lifestyle Questionnaire.[42,43] Readiness to change behavior will be measured by the 6-item Readiness to Change Diet and Physical Activity Scale.[44] To examine behavioral beliefs and intentions (Aim 2c), participants will complete measures of behavioral cognitions from the Theory of Planned Behavior, including behavioral beliefs, attitudes, and intentions related to eating an activity behaviors.[45,46] Finally, to examine behavior (Aim 2d), participants will complete self-report measures of activity and eating behavior over the past week, adapted from the Health Behavior in School-aged Children survey[47] at baseline and 2-week follow-up. The 10-item Positive and Negative Affect Schedule for Child and Parent[48] will be administered to control for mood and the child emotional eating scale serves as a measure of emotion regulation. Body esteem will be measured with several items from the Body Esteem Scale.[49, 50]

E. Study Design

E1. Overview or Design Summary

Study 2 will use a randomized pilot trial design to compare the VR experience to a video (created by team at WUSM) that provides child-friendly education on what types of foods are most nutritious and which are less healthy, and how the food they eat and activity they engage in now affects their health and future. The video will also encourage consideration of future consequences.

E2. Subject Selection and Withdrawal

E2.A. Inclusion Criteria

1. Parent is biological or legal guardian and can therefore consent on behalf of the child
2. Parent BMI is greater than or equal to 25 (overweight or obese)
2. Parent is under 80 years old and child is between 6 and 12 years old
3. Child BMI is at or above the 85th percentile for age and sex.[51]
4. Child is not in behavioral weight-loss treatment (behavior weight-loss treatment will not include if their pediatrician is counseling them on their weight, but instead refers to intensive outpatient behavioral treatment for overweight/obesity only)
5. Child and parent do not have a history of seizures, a history of severe psychiatric conditions such as Schizophrenia or Paranoia, or use any medical devices such as pacemakers
6. Child is not exhibiting any disordered eating behavior (i.e. purging, laxative or diuretic use).

E2.B. Exclusion Criteria

1. Parent is not biological or legal guardian and therefore cannot consent on behalf of the child
2. Parent BMI is less than 25 (not overweight or obese)
2. Parent is over 80 years old and/or child is younger than 6 or older than 12
3. Child BMI is below the 85th percentile for age and sex.[51]
4. Child is in behavioral weight-loss treatment (behavior weight-loss treatment will not include if their pediatrician is counseling them on their weight, but instead refers to intensive outpatient behavioral treatment for overweight/obesity only)
5. Child and parent have a history of seizures, a history of severe psychiatric conditions such as Schizophrenia or Paranoia, or use any medical device such as a pacemaker
6. Child has a history of disordered eating behavior (i.e. purging, laxative or diuretic use).

E2.C. Ethical Considerations

All key personnel involved in the design or conduct of research involving human subjects will receive the required education on the protection of human research participants prior to the start of the study. Participants will be informed that they do not have to answer any questions that make them uncomfortable. There are minimal risks for participating in pilot testing. Testing and assessments will occur in private rooms to protect the anonymity of the participant.

Participants will be provided with the contact information of the research staff. As a clinical psychologist, the PI is trained in how to address safety issues. The PI, a licensed psychologist, will be available for in-person crisis assessment. Any participants that indicate they are engaging in disordered eating behaviors during screening or participation in the study will be offered referral information for in-person treatment. Any adverse event will be reported promptly to the IRB.

Confidentiality: Participant confidentiality will be maintained in compliance with HIPAA privacy protected servers. Study IDs will be linked with participant names and email addresses in a separate password-protected file stored on a secure, password-protected server that only key study personnel have access to. All hard copy PHI will be stored in locked cabinets within locked doors in our laboratory at WUSM. All employees of the study with access to PHI are required to complete HIPAA training and comply with the privacy procedures in place at Washington University.

BehaVR (https://behavr.com) is a HIPAA-compliant company focused on building VR products for behavior change and has a dedicated and talented team of software engineers. BehaVR will host the proposed VR experience and all data collected within the VR experience. Prior to beginning this study, BehaVR and Washington University will enter into a collaboration agreement.

Adverse Events: For the purpose of this study, adverse events will be defined as unanticipated problems involving risks to the study participant. A serious adverse event will be defined as any untoward occurrence that results in death, is life-threatening, or creates persistent and significant disability. The study team will work together to identify serious adverse events. Any potentially adverse events will be evaluated by the study team within 72

hours. All serious adverse events will be immediately reported to the IRB. All adverse events and study withdrawals, together with a detailed explanation of the event and withdrawal, will be recorded.

It is important to note that in previous studies of digital health interventions, the procedures outlined above have been used to protect against and minimize potential risks to participants, and they have proved effective in preventing emotional and physical complaints as well as adverse events.

E2.D. Participant Recruitment Plans and Consent Process

We plan to enroll 60 English-speaking children between the ages of 6 and 12 and one of their biological or legal adult guardians.

Participants will be recruited from the community using methods such as social media, flyers and word of mouth. Flyers will be posted in local (i.e., primarily St. Louis, MO) kid-friendly public spaces. Social media recruitment will occur over family-friendly social media and webpages. The social media advertisement will be posted on relevant WUSM accounts and to relevant web pages (i.e. family-based and health related pages and groups). We may also utilize participant recruitment services available through REC and REACH. Additionally, we may seek permission from WU PAARC to ask pediatric practices that are familiar with our lab through another study we are conducting (PLAN with families) if they would be willing to advertise for this study via postcards made available to give to patient families.

Interested individuals may call or email our research team whose contact information will be provided on flyers and social media posts and we may also reach out directly to some potential participants. If individuals are still interested after discussing the study directly with a research team member over phone and/or email, a research team member will conduct a brief phone screen to determine eligibility. If eligible, an appointment will be made for the parent and child to come into our lab at WUSM to review and sign consent and assent documents and then complete the study. Consent and assent information will be emailed to them so that they may have plenty of time to review these documents at their leisure. Upon arrival to our lab the informed consent process will take place, and subsequently the study. The informed consent process will occur in a private room in the Center for Healthy Weight and Wellness at Washington University School of Medicine in St. Louis. Participants will be consented according to the policies and procedures of the WUSM IRB, the IRB of Record for the study.

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We will also use snowball sampling by reaching out to completed participants via email to ask if they would be willing to share recruitment materials with friends or family who may be interested in participating.

E2.E. Randomization Method

Using a random number generator, families will be randomly assigned to the experimental or control condition after baseline measures are taken. Those assigned to the experimental

condition will undergo the 10-minute VR experience (both children and parents) while those assigned to the control condition will view the educational video and play the educational game for a total of 10 minutes.

E2.F. Risks and Benefits

Risks: All key personnel involved in the design or conduct of research involving human subjects will receive the required education on the protection of human research participants prior to the start of the study. Participants will be informed that they do not have to answer any questions that make them uncomfortable. There are minimal risks for participating in pliot testing. Testing and assessments will occur in private rooms to protect the anonymity of the participant.

Participants will be provided with the contact information of the study staff. As a clinical psychologist, the PI is trained in how to address safety issues. If any participant appears to be in crisis during the experiment, appropriate action will be taken based on established crisis assessment protocol. All participants completing the experiment will be offered referral information for in-person treatment. Any serious adverse event will be reported promptly to the IRB.

Physical Risks: Participants will be engaging with the virtual environment through physical movement (e.g., stepping), and will be unable to see their surroundings (because they will be wearing a device over their eyes to engage with the VR experience), so the area in which individuals use the VR equipment will be open and clear of objects. Users will be monitored by trained staff to ensure they are safe when using the VR equipment. Finally, some individuals can feel motion sickness or nausea during a VR experience. Although this is not likely, participants will be told that if they do not feel well, they do not have to continue with the VR experience and that they can discontinue participation in this aspect of the study without penalty. Trained staff will assist in the event that participants need further care.

Psychological Risks: There are minimal psychological risks of participating in the pilot study for our proposed VR experience, although we recognize that programs designed to address weight may promote increased focus on weight in some individuals, more than which may exist before starting the program. It is also possible that participants may feel uncomfortable disclosing information or related thoughts about their weight. However, we have asked questions of a similar nature in several studies in the past and have not had participants report major discomfort. Because children may also be more likely to perceive the virtual environment as real, special consideration will be given to children after the VR experience to ensure they understood that the VR environment was not real if necessary (we did not find this to be an issue in study 1). Finally, participants may experience negative affect when experiencing the future embodiment part of the time machine game that is reflective of continued engagement in unhealthy behaviors with decreased agility. In order to decrease the likelihood of negative affect in the VR experience, all participants in the VR condition will experience the healthy and unhealthy future self, and the first future they go to will be determined by a food choice game in the present. This gives the participant the autonomy of choice, and presents two different futures, so that it is clear that they are not being told one way or another how they may feel in

the future, just how it may feel if they were to engage in healthy vs. unhealthy behavior. Participants will be told that if they feel too uncomfortable in the VR experience, they can stop using it at any time without penalty.

Social Risks: There may be some embarrassment related to completing questions related to weight and intentions to lose weight.

Financial Risks: N/A

Legal Risks: N/A

Risks to Privacy: There are minimal to no risks to participant privacy. We will go to great lengths to keep participant information private and confidential.

Other Risks: N/A

*Alternative Treatment*s: N/A – Participants in the current study will be participating in a pilot trial to test a VR experience to address childhood obesity. There are few widely available digital tools designed for this purpose. All participants who participate will be offered referral information for in-person treatment.

Benefits

For individuals participating in the pilot study, there may be no direct benefits in terms of addressing overweight or obesity. However, individuals participating may benefit from knowing that their feedback is helping to design a digital tool that may ultimately address childhood obesity.

E2.G. Early Withdrawal of Subjects

Informed consent will make clear that participants may withdraw at any time with no penalty.

E2.H. When and How to Withdraw Participants

Taking part in this research study is voluntary. Participants may choose not to take part in this research study or may withdraw their consent at any time. They may withdraw by telling the research team they are no longer interested in participating in the study. If participants do not respond to phone calls or emails after 6 attempts to contact, they will be withdrawn from the study. Additionally, there will be 6 attempts to contact participants for the 2 week follow-up surveys via email or phone. There will be no penalty or loss of benefits to which they were otherwise entitled.

E2.I. Data Collection and Follow-up for Withdrawn Subjects

When a participant withdraws from the study, the research team will stop collecting data from them.

F. Study Procedures

F1. Screening for Eligibility

Eligibility will be assessed using the phone eligibility screen.

F2. Schedule of Measurements

Construct	Measure(s)	Participant(s) Taking	Time point
Eligibility			
Screen for disordered eating behaviors	Selected and Adapted Questions from ChEDE-Q	Parent self and proxy-report	Phone screen
Screen for overweight and conditions that could make it unsafe to participate in VR condition	Other Eligibility Questions In-lab height & weight	Parent self and proxy-report Parent & Child	Phone screen Pre
1. Acceptability (Aim 2a)			
Usability	System Usability Scale	Parent proxy-report	post
	Selected Child Interview Questions	Child self-report	
Ease of Use	Usefulness, Satisfaction and Ease of Use	Parent proxy-report	
	Selected Child Interview Questions	Child self-report	
Degree of immersion (for those in VR condition)	Presence Questionnaire	Parent self-report	
	Selected Child Interview Questions	Child self-report	
1. Motivation to Change behavior (Aim 2b)			
Self-Efficacy	Self-Efficacy for Healthy Eating and Physical Activity (SE-HEPA)	Child self-report,	Pre & post
Readiness to Change Behavior	Readiness to Change Diet and Physical Activity Scale	Parent self-report	Pre and post or 2-weeks depending on each question
1. Behavioral Beliefs and Intentions (Aim 2d)			
Attitudes, Beliefs, and Intentions	Theory of Planned Behavior Items	Parent and child self-report	Pre and post
1. Behavior (Aim 2d)			
Eating and Physical Activity Behavior	Weekly intake of fruits and vegetables; fast food; foods away from home; consumption of breakfast	Parent proxy-report	Pre and 2-week

	Screen time and minutes of mild, moderate, and vigorous activity over the past week		
1. Other Measures			
Body Mass Index (BMI)	In-lab height and weight	Parent & Child	pre
Demographics	Demographic Questionnaire	Parent report	pre
Hunger	1 item 7 point likert scale	Child report	pre
Affect	Positive and Negative Affect Schedule (PANAS)	Child	Pre and post
	Child Emotional Eating Scale Short Form (EES-C SF)	Child self-report	Pre and post
	Body Esteem Scale (adapted)	Child self-report	Pre and post

F3. Data Collection and Reporting Procedures for Adverse Events

For the purpose of this study, adverse events will be defined as unanticipated problems involving risks to the study participant. A serious adverse event will be defined as any untoward occurrence that results in death, is life-threatening, or creates persistent and significant disability. The study team will work together to identify serious adverse events. Any potentially adverse events will be evaluated by the study team within 72 hours. All serious adverse events will be immediately reported to the IRB. All adverse events and study withdrawals, together with a detailed explanation of the event and withdrawal, will be recorded.

It is important to note that in previous similar clinical trials of digital health interventions, the procedures outlined above have been used to protect against and minimize potential risks to participants, and they have proved effective in preventing emotional and physical complaints as well as adverse events.

G. Data Handling and Record Keeping

G1. Confidentiality and Security

Participant confidentiality will be maintained in compliance with HIPAA regulations. Data will be stored in locked file cabinets and on HIPAA privacy protected servers. Study IDs will be linked with participant names and email addresses in a separate password-protected file stored on a secure, password-protected server that only key study personnel have access to. All employees of the study with access to protected health information are required to complete HIPAA training and comply with the privacy procedures in place at Washington University.

BehaVR (https://behavr.com) is a HIPAA-compliant company focused on building VR products for behavior change and has a dedicated and talented team of software engineers. BehaVR will host the proposed VR experience and all data collected within the VR experience. Prior to beginning this study, BehaVR and Washington University will enter into a Business Associate and Qualified Service Organization agreement. BehaVR will comply with the rules on handling of Protected Health Information under HIPAA**.**

Training: All staff personnel are trained and comply with HIPAA regulations. All study team members will complete the CITI training and Good Clinical Practice training.

Performance Monitoring: The Data and Safety Monitoring Plan for this trial includes close monitoring by the PI. Any adverse event will be reported promptly to the IRB.

H. Study Administration

H.1. Funding Source and Conflicts of Interest

This study is funded by the Washington University Center for Diabetes Translation Research, which is funded by the NIDDK. Any potential financial conflicts of interest for individual research team members are reported according to the IRB requirements and procedures.

H.2. Participant Payment

Participants will each receive a $25.00 gift card for completing the in-lab visit and a $25.00 gift card for completing the two week follow-up survey as well as a chance to win one of two $250 gift cards via a raffle.

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J. Statistical Analysis Plan

Univariate analyses of variance (ANOVA) models evaluated pre- to post-test changes in positive and negative affect by condition. T-tests evaluated the difference in acceptability measures between conditions. Repeated-measures general linear models, with time as the within-subjects factor, tested the effect of the VR intervention on eating and activity behaviors (pre to two-weeks) and cognitions (pre to post). Child age was included as a covariate in all analyses. Tests of normality were conducted on dependent variables across and within conditions using histograms, normality plots, skewness, and kurtosis metrics, and relevant dependent variables were transformed (e.g., cubed) when necessary. Assumptions of linearity and homogeneity of regression slopes were examined with scatterplots and interaction terms of condition and the relevant pre-test variable.