Study Title: iAmHealthy: A Home-based Rural Pediatric Obesity Treatment

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I. Purpose

The purpose of this study our primary aim is to assess the effectiveness of rural pediatric obesity treatment delivered virtually to family homes (iAmHealthy) compared to an active attention control group (control).

A. Background and Significance

The prevalence and incidence of pediatric obesity in the United States remains a critical public health concern. Data from the National Health and Nutrition Examination Survey (NHANES) from 2009 to 2010 indicate that 16.9% of US children and adolescents are classified as obese (BMI $\geq$ 95th percentile) and 31.8% of youth are either overweight or obese (BMI $\geq$ 85th percentile).[1]Childhood obesity continues to be associated with significant short-term health consequences and severe long-term risk for obesity and health problems.[1,2]

Children in rural areas are disproportionately affected by pediatric obesity.[2]They experience higher rates of overweight and obesity than their urban counterparts (50% higher odds of being obese for rural over urban children[4]). Although prevention efforts can be helpful, experts agree that treatment programs are necessary to combat the pediatric obesity epidemic. There are few treatments available to meet the needs of these individuals. Rural children are also exposed to unique barriers such as lack of nutrition education, poor access to healthcare providers, lower socioeconomic status, and fewer opportunities for physical exercise.[2]Our own research[3] indicates that there are differences in the health behaviors of rural and urban children, with rural children more likely to eat junk food and urban children more likely to skip breakfast, for example. Rural children also engage in lower levels of moderate to vigorous physical activity (MVPA) and engage in lower rates of sedentary activity than their urban counterparts. It is likely that these differences in health behavior are due to their rural status.

B. Aim and Hypotheses

The primary aim of this study is to assess the effectiveness of rural pediatric obesity treatment delivered virtually to family homes (iAmHealthy) compared to an active attention control group (control). This is a cluster randomized design, with schools being assigned to condition (iAmHealthy or control) and the 8 parent/child pairs at each school being assigned to the same condition. Having children and families from the same school participate in the same mHealth group allows us to target the unique environmental characteristics that are both barriers to and facilitators of success in iAmHealthy.

II. Research Plan and Design

A. Design and Intervention.

The intervention is a cluster randomized design as groups will be randomized by school. Schools will be contacted via a flyer sent to all 550 rural elementary schools in the state of Kansas. Schools will contact researchers via a toll-free number and given detailed instructions on how to complete the required human subjects training and earn Institutional Review Board approval. Recruited schools will be stratified by two key variables (school size, percent free/reduced lunch) and then assigned to one of the intervention groups, such that all children/families who sign up at each elementary school will be assigned by school as a single group to either iAmHealthy or control (i.e., randomization occurs at the school level, not at the individual level). Any subsequent schools will be waitlisted for participation the next year.

Once 6 schools are randomized, they will be sent research grade scales and stadiometers and trained by research staff in all measurement and intervention procedures. At this time school representativeness will be analyzed each year, and if schools are not representative on either of the key metrics, schools recruited the following year will be oversampled in order that schools reach a representative sample by the end of the 5-year study.

The iAmHealthy family-based intervention provides behavioral, nutrition, and physical activity topics (see Table 4 and Appendix A). The intervention has an 8-week intensive weekly intervention phase followed by a 6-month period of monthly intervention sessions, for a total intervention period of 8 months (to coincide with the length of the typical school year).

Table 4. iAmHealthy Standard Intervention Topics.		Rurally Tailored Topics
Goal Setting & Sticker Charts	Reading Food Labels	Decreased focus on fast food
Stop Light Diet	Energy Balance	Increased focus on eating at social gatherings
Parent Health Behavior Changes	Use of Privileges	Increased information on exercise activities for children that can be done alone (due to poor proximity to neighbors, etc.)
Decreasing Sedentary/Increasing Physical Activity for Parents and Children	Family Exercise Ideas and Cooking with a Limited Budget	
Praising & Ignoring/ Making Healthy Choices	Parties, Bar-B-Qs, and Eating Out	
Monitoring Screen Time	Nutrient Density	Increased attention to self-esteem
Portion Sizes/Healthy Foods in the Home	Self-Esteem	Tips for dressing appropriately for larger body types

Intervention groups will be delivered weekly to family homes at times that are convenient for participating families (typically evenings and weekends). If a participating family misses one group session, they will receive a makeup phone call. The 8 parent/child pairs from each school will meet together via technology in a single cohort from their homes with intervention staff and meetings will last about one hour. The intervention focuses on behavioral, nutrition, and exercise topics, and contains both activities and didactic lessons. These topics are discussed at the individual, family and school/community level, allowing families to discuss barriers as well as facilitators unique to their rural schools and communities. The sessions begin with a review of progress since the last meeting, and end with parents and children setting goals. Parents and children will work together throughout each session, and both will be required to attend for the entire meeting.

Families will also be asked to complete their homework assignments with intervention staff via the iPad interactive televideo technology. This work will focus on goal setting, problem solving of barriers, reinforcement for tracking, and on completion of assigned homework assignments that are part of the manual. We will provide 11 hours of remote homework assistance to each family using the iPad interactive technology. We determined the 11 hour time period because 14 hours of regular sessions plus 11 hours of homework assistance puts our intervention at the 25 hour threshold of contact hours set by the USPSTF (we will also have homework for each session, which will ensure that participants get the 25 hours recommended). The USPSTF suggests that in the area of pediatric obesity treatment, children who receive at least 25 contact hours over a 6-8 month period are significantly more likely to be successful than children who receive fewer hours.[22]

Table 5. Intervention Timeline (25 contact hours total per USPSTF guidelines).

	Weeks 1-8	Weeks 9-12	Weeks 13-16	Weeks 17-20	Weeks 21-24	Weeks 25-28	Weeks 29-32
iAmHealthy Intervention	8 weekly sessions	1 session	1 session	1 session	1 session	1 session	1 session
	11 hours of homework help via remote technology						

B. Sample Criteria

1. Sample Size:
    a. About 144 parent/child pairs (8 or more parent/child pairs at 18 schools). Approximately 175 parent/child pairs will be consented to have 144 children go on to enrollment.

1. Inclusion/Exclusion Criteria:
    a. Inclusion Criteria:
        i. Family lives in a rural area (city and/or county population <20,000)
        ii. Child BMI >85th and <99th percentile
        iii. Child in 2nd thru 4th grade
        iv. Both child and parent speak English
        v. Family is available at times intervention is offered
    b. Exclusion Criteria
        i. Child has physical limitation or receives and injury which significantly limits physical activity
        ii. Child has significant medical issue known to the school (i.e. cancer)
        iii. Child and/or parents have a significant developmental delay or cognitive impairment that is known to the school

iv. Child has a sibling already enrolled in the program
v. Family moves to a non-participating school

C. Enrollment, Consent, and Procedures.

Schools will send home letters to parents and families explaining the study and interested parents will be invited to call the researchers via a toll-free number with any questions. Parents will then come in for an orientation visit at the school and meet with the onsite school representative. In the event of school closure (ie. COVID-19 outbreak), these consenting sessions will take place remotely over the Zoom teleconferencing app instead of in person. At this meeting, the onsite school representative will go over the e-consent form with the parent and child. The e-consent will be housed in REDCap, and school study personnel will pull up the consent form on an iPad or a computer for the parent to review. The parent, child, and the onsite school representative will e-sign the consent form either with their finger or a mouse, depending on if they are using an iPad or a non-touch screen desktop computer. The consent form reads that a copy of the signed consent form will be mailed to them. KUMC study staff will print the signed consent form in REDCap and mail this form to the family once all the families in the school cohort have consented (which will be approximately a 1–2-week window). We will also have paper consent forms available in case of technology difficulties. Onsite school representative will only be permitted to use a paper consent process in the rare occurrence of internet or REDCap outage. If a paper consent is signed, a signed copy may be given to the parent at the time of consent. Paper consent forms would then be securely shipped to KUMC via FedEx express mail.

After parents and children are consented, the onsite school representative will measure height and weight and calculate BMI percentile for each child to assure that they qualify for the study. Schools will each recruit 8 target parent/child pairs. If they cannot recruit 8 parent/child pairs, the school will be waitlisted until such a time as they can. If more than 8 families express interest and complete enrollment procedures, if the school is assigned to iAmHealthy, those beyond the initial 8 will be offered a paper copy of the intervention manual to complete on their own and will not be enrolled as subjects (for the newsletter group, they will be sent the newsletter but will not be enrolled as subjects).

Following completion of all baseline measures (which will take one hour; see Measures below), iAmHealthy families will receive their technology devices via postal service and will be scheduled for a 30-minute phone orientation session to all technology. Intervention components will then be implemented for iAmHealthy or newsletter. Weight and height measurements will be taken at each child's school at the start of the intervention and monthly throughout the intervention period for both parents and children by onsite trained staff. Parents or children may have their weight taken at a local hospital or clinic if a medical specialty scale is needed, such as a wheelchair scale or a high-capacity scale. In the event schools are closed (ie. COVID-19 outbreak), parents will be trained on how to obtain height and weight at home. Digital scales and tape measures will be sent to the families, and each family will measure the height and weight during a video call via Zoom app with an iAmHealthy team member to ensure measurement accuracy. At the completion of the intervention (8 months later), the second one-hour measures collection will take place. Sixteen months following the end of the intervention, the third one-hour measures collection will take place (20-month follow-up).

Families from the intervention/control study will be paid proportionally for completion of measures as is required by our local IRB ($80 at baseline, 8 months, and 20 months, plus $100 for monthly heights and weights over 10 time points). Participants who wear the activity monitors for at least 7 days will receive an extra $20 at baseline, 8 months, and 20 months. Altogether, families may receive up to $400. A payment timeline for participants is attached below:

	Start of Study	1 Month	2 Month	3 Month	4 Month	5 Month	6 Month	7 Month	8 Month	20 Month	**Total for Study Completion**
Online Surveys	*$80*								*$80*	*$80*	

Height & Weight	*$10*	*$10*	*$10*	*$10*	*$10*	*$10*	*$10*	*$10*	*$10*	*$10*	
Activity Monitors	*$20*								*$20*	*$20*	
Total	**$110**	**$10**	**$10**	**$10**	**$10**	**$10**	**$10**	**$10**	**$110**	**$110**	**$400**

In case of activity monitor malfunction, we would like to be able to offer an additional $20 for the participant to wear the device again. Thus, a participant could earn over $400 if they are asked to wear the monitor a 2nd time.

In case parents or children need to be weighed on a medical specialty scale at another location (local hospital or clinic), we would like to be able to offer an additional $10 each timepoint for the participant's time in collecting the measurement at another location. If this is the case, a participant could earn over $400.

In the event schools are closed (ie. COVID-19 outbreak), participants will receive an additional $10 for each completed study measure, up to an additional $100. If this is the case, a participant could earn over $400. Participants will be informed of this change over the phone, and not asked to come into the school to be reconsented.

The onsite school representative will be paid for their services to the study outside of normal school hours/duties ($30/hr, up to $2000 per completed site). If the onsite school representative leaves employment with the school, they will be replaced by another suitable school employee selected by the principal. Schools will also be allowed to retain the scales and stadiometers provided by the study, although participants will be required to return all technology equipment, including the iPads.

D. Data Collection

Measures will be completed through REDCap, a secure, web-based application designed exclusively to support data capture for research studies, just prior to the start of the intervention (**baseline**), immediately following the 8-month intervention (**8 months**), and 16 months after the end of the intervention (**20 months**), with the exception of parent and child weight, which will be taken at these time points as well as monthly throughout the 8 month intervention time period. See Table 6 for the Measures Timeline.

Primary Measures

Photo-assisted 24 hour food recall (24hr FR). The photo assisted 24hr FR is a standardized five-pass method, developed by the US Department of Agriculture for use in national dietary surveillance. We will collect two weekdays and one weekend day at each assessment point, as is recommended. The data will be collected using highly standardized probes by trained research staff and parents will be sent paper food models and measuring devices prior to phone interviews to reference during the call. Participants will be encouraged to take photos of their food to assist in the diet recall process. During the initial call, participants will receive instructions on how to take photos that do not include PHI (ie. photos should not include individuals' faces or other identifiers). Photos will be emailed to the KUMC study email address (iamhealthy@kumc.edu) and photos will be retained for diet analysis. The current study will specifically focus on servings of sugar sweetened beverages per day, number of "red" food items per day (foods with >7 grams of fat and/or 12 grams of sugar), and number of servings of fruits and vegetables per day, as calculated by the computer software.

Table 6. Measures timeline.

Primary Outcome Measures		Baseline	8 months	24 months
	24 hour food recall (child)	X	X	X
	Physical Activity Monitors (child)	X	X	X
	Child BMIz/ Parent BMI [1]	X	X	X
Reach				
	Participation	X	X	
	Structured Interviews with Non-participants		X	
Efficacy				
	HRQOL (parent, child)	X	X	X
	Parent Distress (parent)	X	X	X
	Peer Victimization (child)	X	X	X
	Child Depression (child)	X	X	X
	Satisfaction (parent, child)		X	
	Stigma (parent, child)		X	
Adoption				
	Assess Representativeness of Participating Schools	X		
Implementation				
	Attendance/Participation		X	
	Cost		X	
	Group Process		X	
Maintenance				
	Structured Interviews With Participating Schools		X	
Other Measures				
	Demographics (parent)	X		
	Food Insecurity	X		
	Post Questionnaire (parent)		X	
	Technology Feasibility (parent)	X	X	

[1] Child BMIZ/Parent BMI will be taken monthly throughout the 8 month intervention period.

1. ***ActiGraph Physical Activity Monitors.*** The ActiGraph (ActiGraph LLC, Pensacola, FL) is a small, lightweight activity monitor worn on an adjustable belt over the non-dominant hip allowing objective measurement of physical activity. Participants will wear their monitor for at least 7 consecutive days and receive detailed instructions on wearing and caring for the monitor. For analyses, at least 6 hours of wear time in a 24 hour period will be considered a "valid" day (consistent with previous research);[37] and children will be required to have a minimum of 4 of 7 days at each assessment period in order to be included in analyses. All data will be processed with ActiLife software, which accounts for age and gender cut-offs[38]; these data are then normalized for wear time. The primary outcome will be: average (across valid wear days) time spent per day in MVPA as well as % time spent in MVPA.

2. ***Child Body Mass Index z score (BMIz) and Parent Body Mass Index (BMI).*** To calculate child BMIzand parent BMI we will use standard formulas/equations. Height and weight will be assessed by fully trained onsite school representatives on standardized, calibrated equipment provided by the study. All staff will be trained in standard research anthropometric measurement protocol, including calibration techniques. Standing height will be assessed in triplicate via a Harpenden Holtain stadiometer, Model 603 (Holtain, Crymych, UK). Weight will be measured in triplicate on a portable SECA digital scale (SECA, Hamburg, Germany) after the participant has been asked to void. Parents and children will be measured with light clothing and no shoes.

Other Measures

1. ***Demographics***. This questionnaire will ask about age, race, ethnicity, income, free/reduced lunch status, and parental education. We will also assess for the availability of home computers, high-speed internet access, tablets, smartphones, or other technology already present in the home that could be utilized for secure videoconference

connections in future studies.

2. ***Food Insecurity.*** Food insecurity will be measured using the 5 survey questions from the Centers for Disease Control and Prevention instrument to measure food insecurity,[54] including whether they had enough money to buy meals, had balanced meals, skipped meals due to money, ate less than they felt they should, or went hungry because they could not afford more food. All questions will be asked of adult participants (as is typical) and previous research has indicated this measure is reliable and valid for US populations.
3. ***Post Questionnaire.*** In order to assess for possible contamination effects, participants will complete a short questionnaire asking about any contact they had with their primary care physician during the intervention period, as well as other weight loss efforts or health behavior change efforts in which they engaged.
4. ***Technology Feasibility.*** Technology problem logs will be kept by group leaders to record difficulties they have 1) connecting to the participant homes, or 2) with technology interruptions during sessions. Our previous research indicates these problems are rare, but the degree of these types of problems when delivering groups to the home is unknown.
5. ***Health Related Quality of Life (HRQOL).*** Health related quality of life will be assessed via child self-report (Sizing Me Up) and parent-proxy report (Sizing Them Up). *Sizing Me Up (SMU).* SMU is a 22-item obesity-specific self-report measure designed to evaluate HRQOL in children between 5 and 13 years of age. Questions are worded in a manner, so that children respond to questions in the context of their size (e.g., "teased by other kids because of your size"). All response items are ordered on a 4-point Likert scale ranging from "none of the time" (1) to "all of the time" (4). The measure is comprised of five core scales: Emotional Functioning, Physical Functioning, Social Avoidance, Positive Social Attributes, and Teasing/Marginalization. A Total Quality of Life score combines all 5 subscales. Higher scores represented better HRQOL. This scale has demonstrated acceptable psychometric properties in previous studies.[39] Sizing Them Up (STU*).* STU is a 22-item parent-proxy, obesity-specific measure that evaluates HRQOL in children between 5 and 18 years of age. Questions are worded in a manner so that parents respond to questions in the context of their child's weight or size. All response items are ordered on a 4-point Likert scale ranging from "none of the time" (1) to "all of the time" (4). The measure consists of six core scales: Emotional Functioning, Physical Functioning, Social Avoidance, Positive Social Attributes, Mealtime Challenges, and School Functioning. A Total Quality of Life score combines all 6 subscales. Higher scores represent higher HRQOL. The English-version of this scale has demonstrated acceptable psychometric properties. Overall, Sizing Them Up is a reliable and valid parent-proxy measure of obesity-specific HRQOL that can be used in both clinical and research settings.[40]
6. ***Parent Distress.*** Parent distress will be assessed via the Brief Symptom Inventory (BSI)[41] which assesses symptomatic distress in adults. The Global Severity Index score summarizes an individual's overall level of psychological distress and will be used as a measure of parent distress, as was done in previous work in this area.
7. ***Peer Victimization.*** Peer victimization will be assessed via the Schwartz Peer Victimization Scale which assesses the frequency of overt and relational forms of peer victimization among children.[42] For each item, children are asked to rate how often they experience a specific form of peer victimization (e.g., gossip, hitting/pushing). Higher scores suggest higher levels of victimization.
8. ***Child Depression***. Child depressive symptoms will be assessed via the Children's Depression Inventory–Short Form (CDI-SF). The CDI-SF[43] screens for the presence of depressive symptomatology over the past 2 weeks. Higher scores indicate higher symptom severity. This measure asks about a child's thoughts of suicide. Study staff will view the responses to this measure within 3 days of the measure being completed. If a child indicates they want to commit suicide on the measure, the PI who is a licensed child psychologist will be notified. The PI then review the child's other relevant measures and contact the parent to decide if a referral to local support centers is necessary.
9. ***Parent and Child Satisfaction***. Our existing parent measure is 18 items and will be slightly modified for the current study to add two questions focused on the delivery method of the intervention (iPad, newsletter). The child satisfaction measure was developed specifically for the current study and will shadow the parent satisfaction items. The questions will be read to the child by a research staff member without the parent present in order that parents do not influence child responses. Specific to technology, we will also administer the 12-item Parent-Reported Satisfaction Measure which previous research has shown to be reliable and valid,[45] assessing three technology-related satisfaction domains: technical, comfort with technology and perceived privacy, and access. We will also randomly select a subset of participants to do a structured phone interview about parent satisfaction.

Stigma. Stigma specific to participation will be measured by asking the parent: "Has your child been the victim of any stigma as a result of participation in this intervention program?" or the child: "Have people made fun of you because you were in iAmHealthy?" as is common in treatment related stigma measurement.

10. ***Qstarz GPS Monitors.*** The Qstarz GPS monitor (Qstarz International Co., Ltd, Taipei, Taiwan) is a small, lightweight activity monitor worn on an adjustable belt over the non-dominant hip allowing measurement of GPS location. Participants will wear their monitor for at least 7 consecutive days and receive detailed instructions on wearing and caring for the monitor. Participant's GPS location will be geotagged using the Qstarz software, and matched with their physical activity data, which will allow for identification of where physical activity is occurring (ie. school, home, parks, etc.)
11. ***COVID-19 Family Impact.*** Participants will complete a 37-item COVID-19 Exposure and Family Impact Survey (CEFIS), which was developed using a rapid iterative process in late March/early April 2020. At that time the COVID-19 pandemic was impacting most, if not all, American families to some extent. Communities were coming under "stay at home" orders, schools were closing, and health and financial implications of the COVID-19 pandemic were unfolding. Various aspects of the COVID epidemic are likely to impact families and may influence the findings of research in pediatric health. CEFIS was designed to be used in ongoing and new studies where COVID-19 may influence study outcomes. It conceptualizes exposure to potentially traumatic aspects of COVID-19 and assesses the impact of the pandemic on the family. CEFIS should be completed by caregivers. We will also randomly select a subset of participants to do a structured phone interview about how the COVID-19 pandemic has impacted their family's health behaviors. Families will be paid $20 for completing the CEFIS Questionnaire, and $30 for completing the structured interview over the phone. De-identified structured interview audio recordings will be transcribed by a professional transcription service.
12. ***Perceived Stress Scale.*** To gauge the impact of COVID-9 pandemic on parental stress, participants will complete 10-item Perceived Stress Scale (PSS). The PSS is a measure of the degree to which situations in one's life are appraised as stressful. Items were designed to tap how unpredictable, uncontrollable, and overloaded respondents find their lives. The scale also includes a number of direct queries about current levels of experienced stress.

Other Variables Assessed

1. ***%Expressed Interest/ %Enrolled.*** As a marker of reach, participation rates will be calculated as the total number of children who express interest in the program divided by the total number of children eligible. Percent enrolled will be calculated as the total number of children who complete enrollment procedures divided by the total number of children who expressed interest.
2. ***Adoption.*** Adoption will be measured by calculating the representativeness of the participating schools. Specifically, participating schools will be measured on their student body size and their percent free/reduced lunch and will be compared as a group to the overall data that is available for all elementary schools in the state of Kansas on these key variables to assess for the representativeness of participating schools.
3. ***Attendance and Participation.*** Percent attendance will be calculated for each parent/child pair as the percent of sessions attended divided by the total number of sessions offered. Participation will be assessed for both groups by asking the parents and children about additional health related information they sought to supplement the content of the program, such as health websites, apps, books, programs, etc. For both groups participation will also include the amount of homework that was completed from the sessions (as a percent) self-reported as part of the Post Questionnaire at the 8-month time point.
4. ***Cost.*** Cost will be analyzed in terms of cost effectiveness, defined as cost per unit change in BMIz, by our experienced health economist (Lee). The cost perspective will be societal, meaning that both provider and client costs will be measured.[50]
5. ***Group Process Factors.*** In order to assess factors related to the group process for the iAmHealthy intervention, as well as to assess for engagement in the group sessions, we will use the Living in Familial Environments Coding System. [55,56] Per proper procedures, only initial sessions will be coded for the 15 content codes (facilitative, solicitous, self-positive, problem statement, proposed solution, complaint, oppositional, command unaccountable, self-complaint) which fall into 3 categories (positive, negative, neutral). This coding will be completed for each parent and child separately and allow for a calculation of child engagement and parent engagement uniquely.
6. ***Pedometer Steps.*** Both parents and children in the intervention group will be asked to track their steps throughout the study. We will provide Garmin Vivofit devices to parents and children, or the family may choose to use a device

they already own (such as a FitBit). We will ask them to share their data with the iAmHealthy FitBit or Garmin accounts. The health coach will then be able to see the parent and child's daily steps and give them feedback during their 1-on-1 health coaching calls. The data will be retained as part of the study database and used for analysis. Parents and children may keep the pedometer after the study ends.

7. ***Maintenance.*** The study team will conduct structured interviews with participating schools to assess their ability to sustain key components of the iAmHealthy intervention over time. This will include reflections on key factors associated with long-term maintenance of behavior change by participating families, but also key factors at the school/organizational level in regard to their ability to implement and maintain iAmHealthy, focusing in detail on which aspects of the program were maintained and how these specific factors were maintained.

E. Statistical analyses.

Quantitative Analysis. In order to address the Aims, both Intent-to-Treat (ITT) analyses and analyses of completers are proposed. The ITT analysis is necessary as we predict that at least some participants will withdraw prior to the completion and compares those randomized to each of the treatment conditions. Any participant who consents to participate, completes all baseline measures, and has at least one measurement after baseline will be included in the intent-to-treat analyses. Since monthly assessments are done on weight and height for intervention purposes, we will have parent and child outcome data available for use in the intent-to-treat analysis for the secondary hypothesis variable of BMIz and several of the other variables to address questions of intervention effectiveness through the 8-month intervention period. The second is an efficacy analysis for those who are identified as completers of the intervention. A completer will be defined as a participant who receives at least 80% of their assigned intervention. For those in the comparison group, the criteria will be 80% of their data collection time points. The analysis approach will be the same for both efficacy and intent-to-treat analyses; only the participants and scores included will vary.

Some outcomes will be analyzed using the multilevel model described above with a baseline covariate. These outcomes include Efficacy outcomes for parent and child reports of HRQOL, parent distress, child depression, and child peer victimization. A second set of outcomes involve tests of treatment condition differences where a baseline covariate is not available. These outcomes will be analyzed similarly with a multilevel model, however there will not be a level-1 covariate for the outcome at baseline. Outcomes to be analyzed in this manner include: parent and child satisfaction within Efficacy as well as attendance, participation, and cost from Implementation. The stigma outcome within Efficacy will be analyzed by comparing the proportions reporting child stigmatization between treatment conditions. This will be done for both child and parent report. A third set of outcomes will be examined descriptively. These outcomes include participation from Reach as well as descriptions of the barriers obtained in the qualitative analysis, school-level demographics from Adoption, engagement from Implementation, the number of schools retaining intervention components and summaries of factors related to maintenance from Maintenance. Participant demographics, reported food insecurities, and technological feasibility will also be examined descriptively.

Missing Data. While attrition and incomplete data may be unavoidable, the deleterious effects missing data may have on our results can be mitigated through a combination of careful data collection and thoughtful analysis. Full information maximum likelihood estimation which uses all available data to build a multidimensional likelihood function for each highest-level unit (schools) will be used for the multilevel models. For variables brought into the likelihood function, any missing cases are assumed missing at random, which means random only after conditioning on model predictors and the observed outcomes. Reasons for student departure (e.g., dropout versus changing schools) can be tracked and included as model predictors to help reduce the bias that might otherwise be created.

Qualitative Analyses. Research indicates qualitative methods can be highly effective in studying interventions in health behavior change.[58]Families who participate in the qualitative portions of the current study will be verbally consented over the phone and will be asked a series of structured questions regarding why they elected not to enroll. Questions will focus on hypothesized barriers such as not seeing their child's weight as a problem, and/or not having time to participate; as well as hypothesized solutions such as offering the intervention via the web 24 hours a day or removing the group component and allowing families to proceed at their own pace. These interviews will be transcribed and analyzed using the accepted

qualitative analysis techniques of Morgan and Krueger.[59]Any discrepancies on themes will be resolved prior to dissemination. The PI and Co-I Nelson have the necessary training/experience to conduct focus group studies, and have been published in this area.[9,60,61-64]

IV. References

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