FAMILY-BASED TREATMENT OF PEDIATRIC OBESITY IN LOW-INCOME MINORITY YOUTH: STRATEGIES, OUTCOMES, AND NOVEL PREDICTORS OF SUCCESS

Gina Lauren Tripicchio

A dissertation submitted to the faculty at the University of North Carolina at Chapel Hill in partial fulfillment of the requirements for the degree of Doctor of Philosophy in the Department of Nutrition in the Gillings School of Global Public Health.

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Approved by:

Alice S. Ammerman

Dianne S. Ward

Kimberly P. Truesdale

Kyle S. Burger

Ann M. Davis

ABSTRACT

Gina Lauren Tripicchio: Family-based treatment of pediatric obesity in low-income minority youth: Strategies, outcomes, and novel predictors of success.
(Under the direction of Alice S. Ammerman)

Childhood obesity remains a pressing public health issue. Low-income minority children are disproportionately affected by obesity and disparities are potentially widening in these populations. Multicomponent family-based behavioral group (FBBG) treatment programs, which use comprehensive approaches to target multiple health behaviors, currently provide the strongest evidence for childhood obesity treatment. However, low-income minority children are not adequately represented in these studies.

To address this gap, the primary aim of this study was to examine the effect of Healthy Hawks (HH), a standard FBBG treatment program, in low-income minority youth 2-19 years of age who are overweight or obese. Parent-child dyads were recruited from various urban clinics to participate in a standard 12-week FBBG program targeting diet, physical activity, and related weight-change skills. Child body mass index (BMI) percent above the 95^{th} percentile ($\%BMI_{p95}$) was measured as the primary outcome at baseline, post-intervention (12-week), and 1-year follow-up. Findings from this primary aim suggest that HH is effective in improving $\%BMI_{p95}$ at post-intervention (n=201; β=-1.29 (0.37), $p<0.001$), but effects are not maintained at 1-year (n=115; β=-0.51 (1.06), $p=0.64$).

The secondary aims of this study tested two novel strategies to improve child weight outcomes: 1) Technology adjuncts (physical activity app and web-based health coaching sessions) were added subsequently alongside the standard HH program in two cohorts; 2) the

Healthy Hawks Primary Plus (HHP+) program was developed and implemented by recruiting participants from a single pediatric clinic and engaging primary care providers to administer visits between post-intervention and 1-year follow-up. Three cohorts have participated in HHP+.

HHP+ participants (n=34) had significantly higher retention at 1-year follow-up compared to HH (HH: 38.3%, HHP+: 73.9%, $\chi^2 = 20.59$, $p \leq 0.001$) and greater child $\%BMI_{p95}$ reductions at 1-year ($\beta = -3.24(1.48)$, $p = 0.03$). The cohort that received both technology adjuncts had significantly greater $\%BMI_{p95}$ reductions at post-intervention compared to HH, which received no technology (n=18, $\beta = -2.42$ (0.83), $p = 0.004$). This research addresses several important gaps in the existing child obesity treatment literature and provides innovative targets for improving outcomes in high-risk populations. These approaches can be used to bolster future child obesity intervention efforts in populations most in need of efficacious treatment.

I dedicate this dissertation to my family for their unwavering support and encouragement.
Thank you for teaching me the value of pursuing what you love.

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In addition, there are a few others to acknowledge- Thank you to Dr. Myles Faith, for his guidance and encouragement as I started my journey down the PhD path and for continuing to be a wonderful mentor and friend; thank you to Dr. Cathy Zimmer at the Odum Institute for her assistance on many of my projects, including this one; and thank you to all of the teachers and students in the Department of Nutrition (and other departments) at UNC for your inspiration, motivation, support, and friendship.

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LIST OF ABBREVIATIONS AND SYMBOLS

Δ	Change
$\geq$	Greater than or equal to
$>$	Greater than
$<$	Less than
$\leq$	Less than or equal to
ANOVA	Analysis of Variance
B	Beta coefficient
BL	Baseline
BMI	Body Mass Index
BMI%	Body mass index percentile
$\%BMI_{p95}$	Body mass index percent above the 95^{th} percentile
BMI-z	BMI z-score
cm	Centimeters
χ^2	Chi-squared
CI	Confidence interval
FBBG	Family-based behavioral group
FV	Fruit and vegetable
TECH1	Technology cohort 1
TECH2	Technology cohort 2
GB	Gigabyte
HBM	Health Belief Model
HH	Healthy Hawks

HHP+	Healthy Hawks Primary Plus
Kg	Kilograms
M	Mean
MVPA	Moderate-to-vigorous physical activity;
SEM	Social Ecological Model
SCT	Social Cognitive Theory
SD	Standard deviation
SE	Standard error
SSB	Sugar-sweetened beverage
US	United States

CHAPTER 1: INTRODUCTION

Background

Despite evidence that childhood obesity rates have plateaued among some sub-groups, the prevalence of children with overweight and obesity is still high, demonstrating a need for efficacious treatment interventions.[1] Approximately one-third of children in the United States (U.S.) are overweight or obese, and Hispanic and non-Hispanic black youth have significantly higher rates compared with non-Hispanic white youth. Additionally, these populations are more likely to suffer from co-morbidities associated with obesity such as type 2 diabetes and hypertension, and are often underrepresented in treatment studies.[2,3] Multicomponent, family-based treatment programs, or programs that use comprehensive approaches to target multiple health behaviors, have shown promising evidence for improving child weight status.[4] However, less evidence exists for low-income, diverse populations, and more research is needed to guide in the development and testing of effective treatment programs for these at-risk groups. Moreover, identifying strategies that improve outcomes in these hard-to-reach populations is warranted.

Healthy Hawks (HH) is a multicomponent pediatric obesity intervention program designed to change health behaviors and improve weight status in children, 2-18 years of age who are classified as overweight or obese. HH recruits parent-child dyads via health clinics in urban areas serving predominantly low-income, minority populations. HH parent-child dyads participate in a 12-week family-based behavioral group (FBBG) treatment intervention targeting diet, physical activity, and related weight-change skills.[5] The program has been active since 2006, and while preliminary studies indicate promise for improvements in child weight, the effect of this program requires in-depth examination. **Thus, the primary purpose of this study is to determine the impact of HH, a standard FBBG treatment program, on changes in child weight status at post-intervention and 1-year follow-up in low-income minority children.** This study will include the first 25 HH cohorts, which were implemented from April 2006 to February 2015.

Starting in 2014, enhancements were added to the HH program to test strategies to improve retention and increase reductions in child weight status. First, technology adjuncts were added alongside the traditional 12-week FBBG sessions to improve outcomes at post-intervention in two cohorts. These cohorts are referred to as the TECH cohorts. Additionally, HH was embedded in a pediatric clinic and referred to as HH Primary Plus (HHP+). This program was designed to test a community-clinic collaboration; HHP+ is embedded in a single primary care clinic and includes the addition of bi-monthly physician visits for 1-year following the standard 12-week FBBG program. The goal of the TECH and HHP+ cohorts is to test strategies to improve recruitment, engagement, retention, and outcomes in hard-to-reach populations. For all aims, changes in child weight status are assessed using child body mass index (BMI) above the 95th percentile (%BMI_{95}), as this metric is recommended for assessing changes in adiposity in children with severe obesity.[6,7] **Overall, it is intended that the findings from this study can fill existing gaps in the pediatric obesity intervention literature by identifying successful treatment approaches and predictors of success in low income minority children.**

Specific Aims

Aim 1. Determine the effect of Healthy Hawks (HH), a 12-week family-based behavioral group treatment intervention on child %BMI_{95} at post-intervention and 1-year follow-up in racially/ethnically diverse children, 2-18 years of age, who are overweight or obese.

Hypothesis: Children who participate in the HH intervention will show a significant reduction in $\%BMI_{95}$ at post-intervention and at 1-year follow-up.

Aim 2. Examine feasibility and the effect of adding technology components, specifically a physical fitness app and web-based health coaching sessions, alongside the 12-week traditional FBBG program on child $\%BMI_{95}$ at post-intervention and compare effects to the standard HH program.

Hypothesis: Adding technology components to a traditional FBBG treatment program will significantly reduce child $\%BMI_{95}$ at post-intervention and reductions will be significantly greater when compared to the standard HH program only.

Aim 3. Evaluate the impact of a community-clinic collaboration intervention (HHP+) on participant retention and child $\%BMI_{95}$ at 1-year follow up.

Hypothesis: Children in the HHP+ intervention will demonstrate significant improvements in retention and reductions in $\%BMI_{95}$ at 1-year follow-up, and retention and child weight status reductions will be significantly greater when compared to children who participated in the HH intervention only.

CHAPTER 2: LITERATURE REVIEW

Childhood obesity: Development and consequences

The prevalence of childhood obesity in the United States is a major public health concern and successful strategies for addressing this epidemic remain challenging. Over the past 30 years, rates of obesity have tripled among youth and adolescents, and over 30% of children ages 2-19 years are overweight.[8] While the causes of childhood obesity are multidimensional and complex, excessive energy intake, lack of physical activity, genetics, maternal weight status, and environmental influences have been consistently linked to child overweight and obesity.[9,10,11,12] Additional factors such as parent-child interactions,[13,14] media exposure,[15] high sugar-sweetened beverage consumption,[16] breast-feeding occurrence,[17] child temperament,[18] inadequate fruit and vegetable intake, excessive snack and fast food consumption,[19] neighborhood environment, and sleep have been identified as other factors potentially impacting child weight status and adiposity.[20]

Childhood overweight and obesity is associated with adverse health outcomes and increased risk for physiological co-morbidities such as type 2 diabetes, sleep apnea, dyslipidemia, hypertension, and metabolic syndrome.[21] Perhaps even more severe than the medical outcomes are the negative psychosocial consequences that occur including stigma, discrimination, teasing and bullying, including depression,[22] low self-esteem, poor social functioning, low academic achievement, and negative body image.[23,24]

Childhood weight status trajectories track into adulthood[25,26] and these trends are persistently deleterious unless children receive treatment.[27] Children with overweight or obesity are also at greater risk for mortality in adulthood associated with co-morbidities.[28,29] Moreover, the long-term impact of obesity extends beyond personal physical and psychological consequences, having societal and economic implications. Longitudinal studies provide evidence that overweight or obese youth are less likely to be married, and make lower incomes as adults compared to normal weight counterparts,[30] and these trends might be more evident in women.[31] Adult productivity is negatively impacted by obesity, accounting for increased absenteeism in the workplace,[32] and projected rates of overweight and obesity will account for significant increases in health care costs over the next several decades.[33]

Since children are continuously growing and changing, obesity risk is assessed using age- and gender-specific body mass index (BMI) percentiles.[34] Children in the 15^{th} to 85^{th} percentile are considered normal weight; children with BMI greater than the 85^{th} percentile are considered overweight; children with a BMI at or above the 95^{th} percentile are considered obese. From 2011 to 2014, the prevalence of childhood obesity in the United States was 17.0%.[2] Obesity trends increase with age and are consistent across genders; prevalence is 8.9% among children 2 to 5 years, 17.5% among children 6 to 11 years, and 20.5% among adolescents 12 to 19 years.

Racial disparities in childhood obesity

Racial disparities in health research have persisted for decades and the disparities related to childhood obesity are no exception. Despite data indicating that prevalence of obesity among youth has not increased over the past decade, rates are still problematic and disproportionately affect black and Hispanic youth. The prevalence of obesity among Hispanics is 21.9% and 19.5% among non-Hispanic black children, compared to 14.7% among non-Hispanic white children.[35] Combining overweight and obesity, data from 2009-2010 including youth 6-19 years indicate that 41.2% of Hispanic children and 41.8% of non-Hispanic black children are overweight or obese compared to 29.0% of non-Hispanic white children.[36] When examining gender differences, Hispanic males have significantly higher prevalence rates of obesity compared to all other race/ethnic groups (22.4%). Hispanic females also have the highest prevalence (21.4%), though prevalence among black females is similarly high (20.7%).[2]

In addition to higher rates of obesity, increased sedentary behaviors such as excess screen time are observed in these populations, potentially contributing to the link between the environment, lack of physical activity, and obesity.[37,38] Hispanic and black children are also more likely to be living in poverty and experiencing environmental and material hardships related to lower socioeconomic status that have negative consequences on dietary intake.[39,40] Those living in poverty are more likely to receive poorer quality of care, and consequently more likely to have poorer health status.[41]

Contrary to obesity and co-morbidity trends, Hispanic and black children are less likely to be included in treatment studies, thus limiting the applicability of empirically supported approaches in this population. In a meta-analytical review of family-based intervention studies, only 30% of the studies included a racially/ethnically diverse sample.[42] Additionally, most treatment studies including minority populations have been conducted in community settings, such as schools, limiting the application of strategies proven to be effective in treatment, such as parental involvement and lifestyle changes.[43] Despite the lack of adequate obesity treatment programs currently being implemented, children in poverty often receive insurance through public programs, providing an opportunity for plan-based interventions to address health disparities.

Familial contributions to childhood obesity and associated disparities

The socio-ecological model (SEM) provides an important theoretical guide for pediatric obesity intervention, conceptualizing the contexts in which children and families exist, and highlighting the interaction of multi-levels influence the development of childhood obesity.[20] SEM emphasizes that children are directly rooted in the family environment and it is here that factors such as food access, attitudes and beliefs around eating, and dietary habits are developed.[44] The Family Ecological Model, presented in Figure 1, illustrates principles of SEM as they apply to the family unit, including the multiple factors that influence parenting behaviors, and the environments in which families exist and interact.[45] As shown in the model, there is a significant body of evidence supporting the need for childhood obesity programs being conducted in the context of the family, as many maladaptive behaviors and risk factors interact to influence child health outcomes.[46] Interventions targeting the family-at-large could more effectively improve childhood obesity outcomes,[47] as parents of obese children are often overweight or obese.[48]

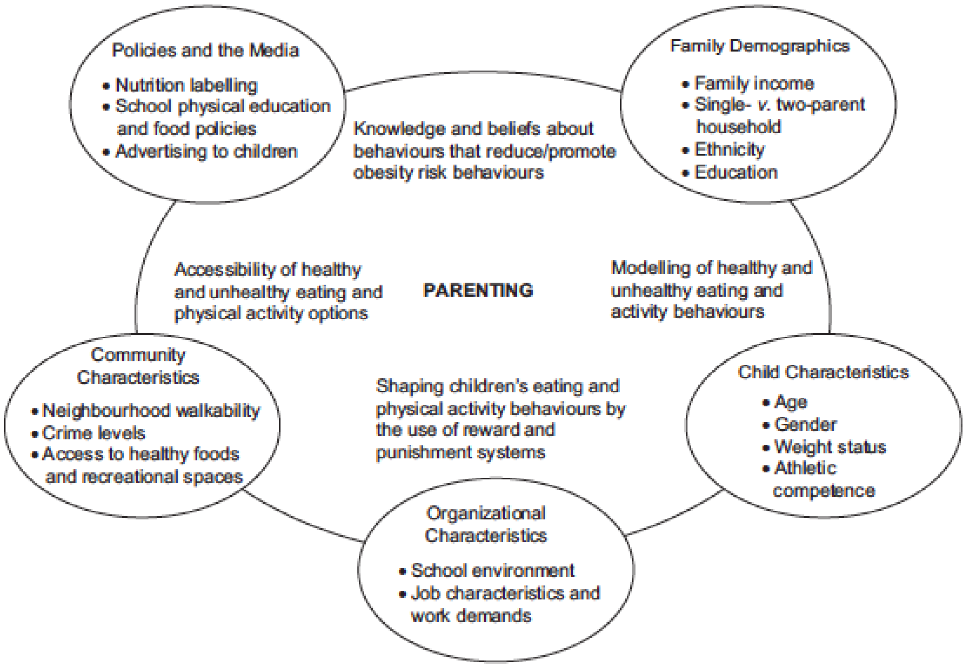

Figure 1. The Family Ecological Model.

Horn and Beal also provide a multi-level framework that conceptualizes child health disparities, and again highlights the driving influence of important familial factors, including race, culture, and socio-economic status.[41] Since obesity prevalence is higher among Hispanic and Black adults compared to white adults, familial transmission of genetic and environmental influences might be fueling racial disparities for childhood obesity.[2] To address these racial disparities in childhood obesity, their framework calls for the development and testing of effective, multi-level interventions in diverse populations.

Using theoretically-driven models to identify predictors of treatment success is essential for evaluating program outcomes and informing future studies. As indicated in models described previously, including the socio-ecological model and family ecological model, parents are critically important for influencing child weight status. The associations between parent weight and child weight are well supported and parents play an important role in influencing child weight changes in treatment.[49] In a study modeling the relationship between childhood obesity and related behaviors, parent's BMI and parent's nutrition and physical activity knowledge had the strongest direct association with child BMI z-score.[50] In another study including children ages 7-12 participating a 5-month family-based behavioral treatment program, parent baseline self-efficacy and parent BMI reductions were associated with greater reductions in child weight status, suggesting that baseline familial factors might also influence treatment outcomes.[51] Programs targeting parenting strategies have also been shown to be effective in improving child weight, specifically in a treatment context.[52]

Since data on racially/ethnically diverse and low-income children are generally lacking, an examination of characteristics associated with treatment success is critical for informing future studies. The role of treatment-specific factors, including child adherence to goal setting/self-monitoring and intervention intensity should be investigated, as they are theoretically driven constructs associated with changes in target health behaviors.[53,54] Previous studies have shown that adherence to targeted behaviors promoted during interventions, such as self-monitoring and goal setting, are associated with improvements in weight change.[55,56] Though these approaches are commonly implemented in treatment programs, few studies actually present data on adherence to these targeted skills or examine if adherence is associated with outcomes. In a study by Theim et al., adherence was assessed via a 4-point self-report questionnaire, completed by both parents and children.[57] Higher adherence to goal setting and self-monitoring was the only behavior associated with a long-term decrease in child percent overweight at 2-years follow-up.

Family-based behavioral group treatment programs

Multicomponent, family-based behavioral group treatment programs are the most empirically supported treatment approach for pediatric obesity to date.[58] Evidence from quantitative reviews of treatment programs in children 2-19 years of age demonstrate that lifestyle interventions resulted in significant treatment effects compared to no-treatment controls and information/education only controls.[59,60] In a review of interventions in early childhood (2-5 years), interventions implementing a multidisciplinary approach, including nutrition, physical activity, and lifestyle targets for behavior change were successful in reducing child weight outcomes.[4] A meta-analysis of randomized controlled trials for the treatment of pediatric obesity found that combined lifestyle programs (e.g., those including diet and physical activity) had a small to moderate effect on BMI, and the largest effects were seen in studies that involved parents.[61] Moreover, Epstein and colleagues have demonstrated long-term maintenance of such approaches including sustained weight changes at 10-year follow-up.[62] Given this body of evidence, intensive, multicomponent, behavioral interventions involving parents are most likely to produce significant improvements in child weight status. It should be noted as a limitation that while empirical evidence suggests the use of a family-based multicomponent treatment program for effectively treating childhood obesity, these studies often include predominately white, middle-income participants. Findings from these samples provide a framework for future studies, but should be adequately tested in diverse populations before they are deemed generalizable.

In 2007, a report from the Expert Committee Recommendations for the Prevention, Assessment, and Treatment of Child and Adolescent Overweight and Obesity[63] attempted to clearly define the interaction between children, parents and care providers to strategically address obesity treatment. A chronic care model for obesity intervention was presented to illustrate the need for the integration of public health efforts (in schools, family, worksites and communities) with health care efforts (in medical offices and health care systems broadly). Then, recommendations for treatment were presented in four stages. The first stage of treatment is identified as “Prevention Plus” and encourages healthier eating habits and increased physical activity. Improved BMI status is measured as the outcome at 3- to 6-months follow-up, with intermittent visits as needed. The second stage is “Structured Weight Management,” which involves the creation of specific eating and activity goals for the child and self-monitoring of those behaviors. Monthly visits are recommended for this stage. Stage 3 is a “Comprehensive Multidisciplinary Intervention” involving a family-based behavior modification program. Frequent visits (every 8 to 12 weeks), home environment consultation and group sessions are recommended to increase the effectiveness of behavior modification programs. This stage often requires a multidisciplinary care team in addition to a primary care provider. Stage 4, “Tertiary Care Intervention,” involves intensive therapies such as medication, bariatric surgery and rigorous interventions that are only appropriate for older and severely obese children.

The primary care setting

Current family-based studies involving primary care providers in low-income, diverse populations are limited to feasibility designs and are aimed at better understanding approaches to care in these populations. For example, in a single, two group feasibility study including 418 mother-child dyads (82% Hispanic, 18% African American; child age 2-4 years; 21% overweight and 21% obese), physicians targeted four weight-related health behaviors (milk consumption, juice and sugar-sweetened beverage consumption, television/screen time, and physical activity), during regularly scheduled visits over 12-months.[64] Motivational interviewing, goal setting, and self-monitoring were fundamental program components and rates of BMI percentile increase were significantly lower in the intervention group with only an average of 1.36 ±0.67 visits. This study demonstrates that physicians can deliver messages about child weight, diverse populations are reachable using this approach, and even modest contact can have an impact.[64]

A two group, 6-week feasibility study in low-income, urban, Latino youth, 9-12 years, and their parents, found that Latino families deem group classes and health coaching acceptable approaches for childhood obesity treatment programs.[65] A larger 16-week intervention implemented group classes with overweight and obese youth 7-17 years and their parents (3% African, 15.2% African American, 3% White, 78.8% Hispanic) yielded pre-post improvements in parent and child diet and physical activity, but did not have an impact on weight.[66] Efforts to implement culturally tailored interventions have also been made to reach children in diverse families. In a study of 54 Latino families with overweight or obese children 8-12, six core sessions were implemented with additional, optional activities. The program included bi-lingual staff, "prevention plus" strategies, goal setting, and a family-focused child-centered approach. Dietary improvements were seen in parents and children, but only modest improvements in child weight.[67] These studies provided evidence for feasible strategies to implement programs in primary care including training for health professionals, tailoring behavior change strategies and intensity, and using empirically supported strategies to support behavior changes such as self-monitoring and motivation.[68] Given the identification of feasibility strategies and acceptable approaches for delivering treatment programs in low-income diverse populations, testing the efficacy of comprehensive behavioral programs on the treatment of overweight and obesity in these populations is warranted.

As mentioned in the previously described Expert Committee recommendations, in order to address the obesity epidemic, involving primary care providers is essential.[69] Primary care providers not only have the ability to reach a large number of children, but have long-term relationships with children and families, making them a trusted authority for parents seeking strategies to improve child health. A review of pediatric treatment interventions in primary care settings indicated that programs are generally effective in improving child outcomes across age ranges (3 to 17 years).[68] Though these outcomes vary, behavior change was possible, even with short, low-intensity programs. Evidence from a single primary care-based intervention showed that these types of interventions can also be successful in reducing parent BMI in addition to child, indicating that the primary care setting can maintain a family-based approach to care.[70] Currently, a majority of the studies providing evidence for treatment in primary care are conducted outside the U.S., representing a need for further investigations in U.S. populations.

Technology in pediatric obesity treatment interventions

Given the ubiquitous nature of technology, integrating technology into obesity treatment is a promising approach for increasing access and disseminating more comprehensive programs. Technology components (e.g., apps, websites, Telemedicine, etc.) may provide easier access to treatment services[71] and could reinforce strategies that support behavior change, such as goal-setting, immediate feedback, and increased intervention contact.[72] Research from other child treatment literature has shown that Telemedicine is an adequate strategy for delivering interventions and therapies to children, and is deemed acceptable by families.[73] Additionally, a study by the American Heart Association identified the inclusion of new technologies into treatment programs as a gap in the current childhood obesity literature.[74] Despite this, few studies have examined the use of technology, specifically in the treatment of pediatric obesity,[75] and the evidence for the use of technology interventions in youth indicates a dearth of rigorous study designs and evaluations.[76]

Pediatric obesity treatment programs that have tested the efficacy of technology have found it to be acceptable and yield improvements in some health behaviors, but have failed to show significant, sustained changes in weight when implemented alone.[77] For example, a study examining a text-messaging component in addition to in-person clinic visits found the approach was acceptable, and associated with modest improvements in parents' knowledge and beliefs.[78] A recent review indicates interventions with mobile and wireless technologies as the primary component do positively impact some health behaviors such as physical activity and fruit and vegetable intake.[79] Additionally, a pilot program using a web-based intervention for overweight children 8-12 years did impact BMI z-score (BMI-z) and found that change was related to usage of the intervention technology; those who were frequent users reduced BMI-z after 4 weeks, whereas infrequent users had an increase in BMI-z.[80] Another review of electronic interventions in obesity treatment and prevention programs indicates these approaches can improve child weight status, but few studies examined technology targeting both parents and children, and findings are constrained by poor study quality and design.[81]

Collectively, these studies suggest that the use of technology in pediatric obesity treatment warrants further investigation. Given the insufficient evidence for interventions delivered via technology platforms only, testing the effect of technology adjuncts might be a more sound strategy for learning about these approaches in children. There is evidence from the adult obesity treatment literature to support this methodology.[82] Therefore, using technology as a means to improve participant contact, intervention dose received, and participant retention, in the context of a larger, more intensive program, seems promising.

CHAPTER 3: METHODS

Study Design

Healthy Hawks (HH)

Data for this study are from the Healthy Hawks (HH) program. Healthy Hawks is an ongoing multi-component, family-based behavioral group (FBBG) treatment program for pediatric obesity offered by a multidisciplinary team at The University of Medical Center in Kansas City, KS. Children who are overweight or obese, and their families, are recruited for the 12-week program. HH participants are recruited using a multi-site, multi-strategy approach. Potential participants are recruited at health fairs, community events, and via physician referral at pediatric clinics in the Kansas City area. Interested families are given a number to call, then eligibility screening is conducted by phone, and if eligible, potential participants are asked to complete an intake form via mail. Recruitment and assessment materials are offered in both English and Spanish. All participants 7 years of age or older complete written assent and parental consent is provided from at least one parent or legal guardian. Recruitment continues until there are enough parent-child dyads to fill a cohort (approximately 16) and cohorts began approximately every 4-5 months, avoiding holidays. The HH intervention program has been active since 2006 and this study includes the first 25 cohorts, conducted from April 2006 to February 2015, with 300 participants.

Healthy Hawks Primary Plus (HHP+)

In order to test strategies to improve recruitment, retention and reductions in child weight status, an enhanced version of HH was developed called Healthy Hawks Primary Plus (HHP+).

HHP+ started in May 2014 and in addition to receiving the traditional FBBG 12-week program, the HHP+ participants were recruited via physician referral at a single pediatric clinic, and received bi-monthly primary care visits between post-intervention and 1-year to test the effect on retention and child weight status at 1-year. A clinic-based recruitment coordinator was assigned (10% full-time effort) to manage participant referrals, enrollment, and program participation. A total of 46 parent-child dyads have participated in HHP+ over 3 cohorts.

Technology Cohorts

Another enhancement strategy was the addition of technology components. Two technology components (a physical activity app and Telemedicine health-coaching sessions) were added alongside the standard 12-week FBBG program to improve participant engagement and reductions in child weight status between baseline and post-intervention. TECH1 (n=20) received the FBBG sessions plus one technology component- digital tablets equipped with an fitness app (Fitnet), to increase physical activity at home; TECH2 (n=23) received the FBBG sessions and two technology components- the digital tablets with the fitness app as well as individual Telemed health-coaching sessions delivered via Skype. Additional information about each of the components is presented below.

These technology components were implemented in both HH and HHP+ cohorts since both programs receive the same 12-week FBBG program and participate in the program together at a community center. TECH1 and TECH2 are compared to NO TECH, the first combined HH and HHP+ cohorts, which did not receive any adjuncts. A total of 64 (18 HH; 46 HHP+) parent-child dyads were enrolled in over 3 cohorts; the NO TECH cohort was implemented in May 2014, followed by the TECH1 cohort in September 2014, and the TECH2 cohort was initiated in February 2015. Participants recruited for HH and HHP+ between February 2014 and May 2014 participated in the NO TECH cohort. HH and HHP+ Participants recruited between June 2014 and September 2014 participated in the TECH1 cohort, and those recruited between October 2014 and February 2015 participated in the TECH2 cohort. **Figure 2**. illustrates the HH and HHP+ programs, **Figure 3** illustrates the timelines and enhancements associated with HH and HHP+ cohorts, and **Figure 4** specifically illustrates the technology adjuncts added alongside the 12-week FBBG sessions in the HH and HHP+ cohorts.

Eligibility Criteria (All Cohorts)

Children ages 2 to 18 years, with a BMI ≥ 85th percentile as defined by age- and sex-specific cutoffs, are eligible for the HH and HHP+ programs. At least one parent or caregiver must agree to attend the program and complete measures, but all family members are encouraged to attend. If referred/enrolled children have siblings who are eligible for the program, they are encouraged to enroll as well. Participants are excluded if the parent or child speaks a language other than English or Spanish, and/or if the child has any health diagnosis that would make participation in a group-based program difficult (e.g., severe Autism Spectrum Disorder, etc.)

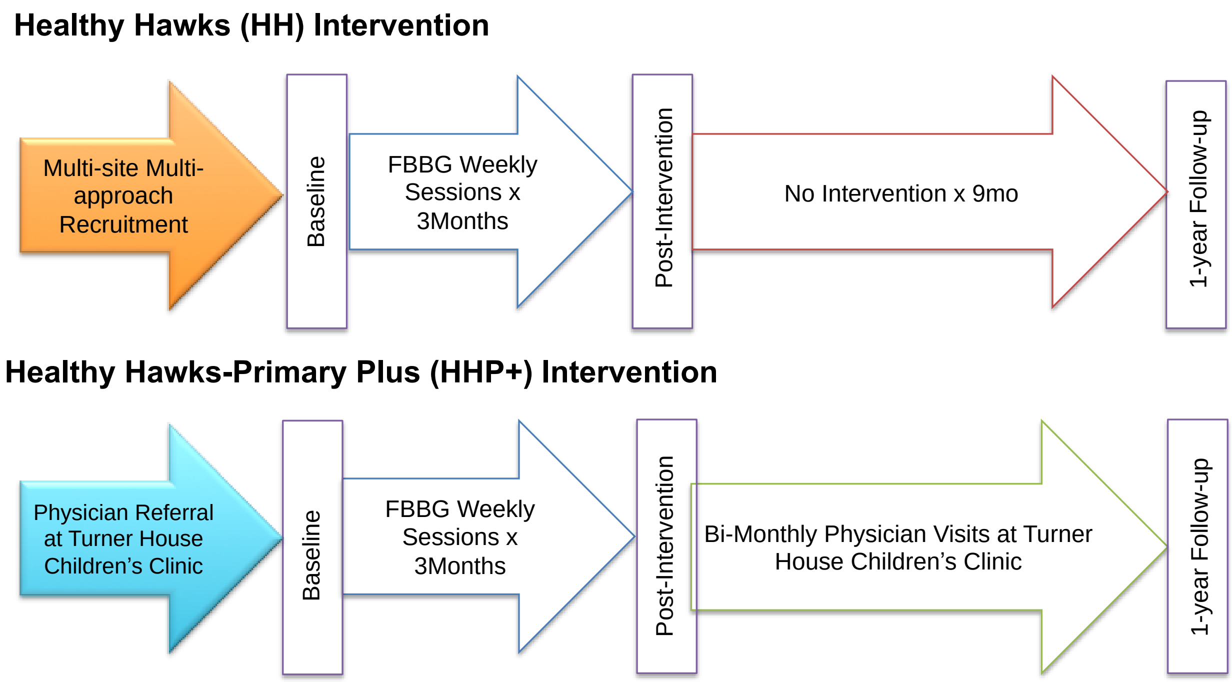

Figure 2. HH and HHP+ intervention components.

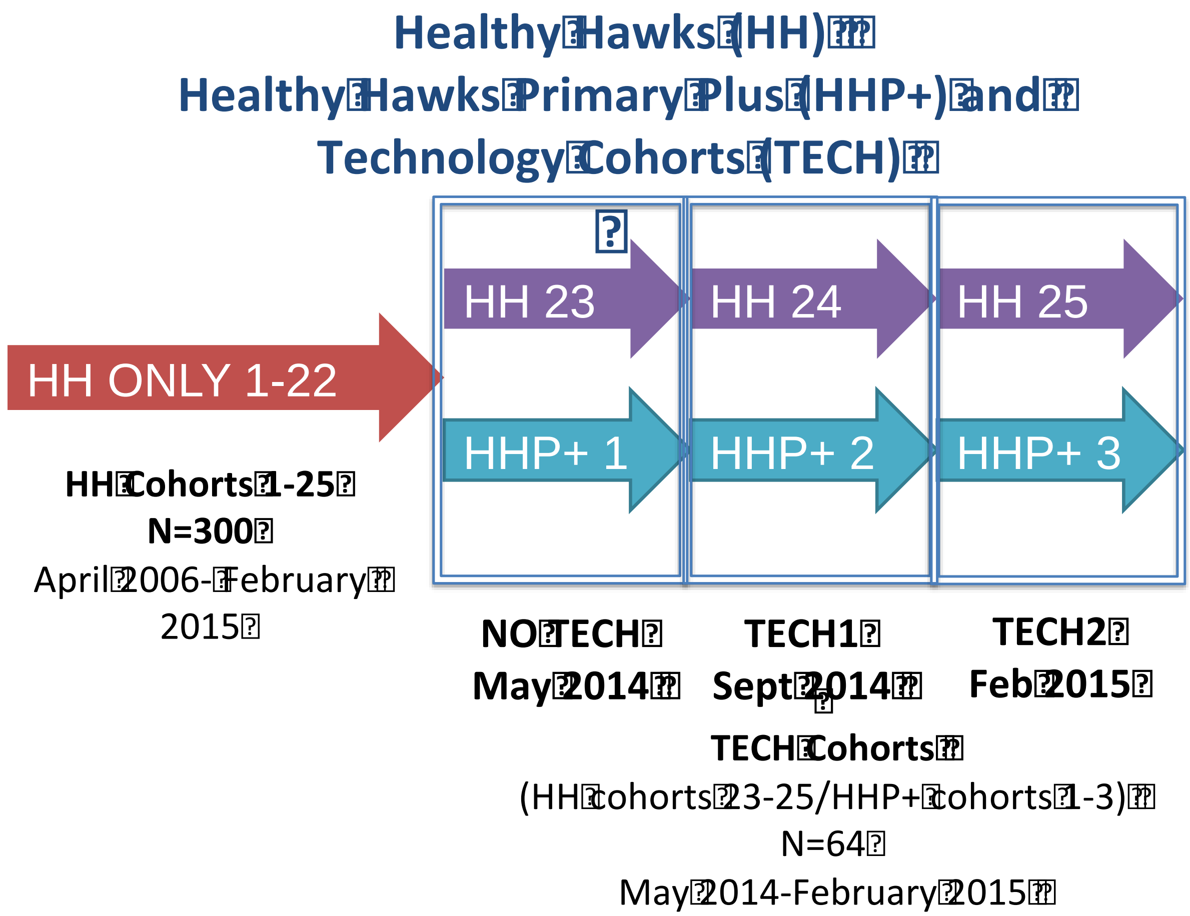

Figure 3. Overview of HH, HHP+, and TECH cohort implementation.

Aim 1 included all HH cohorts (1-25; n=300); Aim 2 examined NO TECH (HH23 and HHP+1, n=21), TECH1 (HH24 and HHP+2, n=20) and TECH2 (HH25 and HHP+3, n=23) and compared TECH to HH only (1-22, n=282); Aim 3 examined the HHP+ cohorts (HHP+ 1-3; n=46) and compared them to all HH only (1-25, n=300).

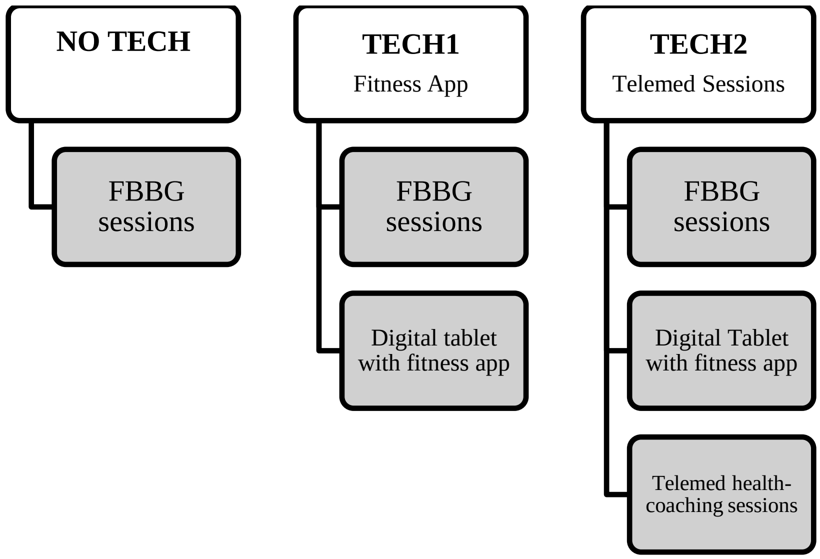

Figure 4. Intervention components for each technology cohort.

NO TECH (n=21) received the standard 12-week FBBG in-person sessions only; TECH1 (n=20) received FBBG sessions and a digital tablet equipped with a fitness app; TECH2 (n=23) received FBBG sessions, a digital tablet with fitness app and web-based health-coaching sessions.

Healthy Hawks (HH) Intervention Components (All Cohorts)

Family-based behavioral group (FBBG) sessions. The FBBG sessions, received by all cohorts, consist of 12 lessons administered over 12-weeks. The program is held on Monday evenings every week and lasts for 2 hours. Parents are separated from children for the first hour; parent groups are organized based on language preference (Spanish or English), and children are placed into groups based on age (under 5, 6-9, 10-12, and 13 and older). All child sessions are conducted in English and all children who attend participate in the group sessions, regardless of enrollment status. Sessions include a one-hour lesson integrating behavior change techniques, nutrition education, and physical activity promotion, followed by a one-hour group exercise activity involving parents and children. The parents and children learn the same intervention concepts, but the parents are taught didactically, and the children are taught through age appropriate activities. The 12-weekly group session topics are listed below in **Table 1**.

To ensure consistent intervention delivery of the FBBG sessions, intervention staff and volunteers receive training and follow a scripted manual. Parents and children also receive copies of the manual for corresponding sessions (available in English and in Spanish). Sessions are sporadically video-recorded to monitor interventionist delivery and observe participant engagement. The number of sessions attended by each participant is recorded and participant satisfaction is measured using a self-report survey.

Table 1. Healthy Hawks Family-based Behavioral Group Session Topics.

FBBG Session	Topic
1	Getting Started (Goal-setting and self-monitoring)
2	Move Those Muscles
3	Healthy Eating the Stop Light Way
4	Portion Control
5	Fruits, Vegetables, and Fiber
6	Eating Away from Home
7	Bring on the Children (Child Health Behaviors)
8	Privileges (Privileges, rules, consequences, and sleep)
9	Exercise for Children
10	Stop Light Diet (Review)
11	Problem Solving, Tempting Situations, and Self-Esteem
12	Graduation!

Goal setting/Self-monitoring. Parents and children were given daily self-monitoring sheets to track servings of "red foods," servings of fruits and vegetables (i.e., "green foods"), and physical activity (APPENDIX 1). Parents were given pedometers to wear to track daily steps. Children received incentive points each week for returning their self-monitoring sheets. Each week new goals were established in the in-person sessions and these were the focus of participant behavior change for the subsequent week.

Program Incentives. Participating families are eligible to receive a free 3-month family membership to the local YMCA upon successful completion of the program. Children are incentivized to attend weekly sessions and bring their goal-setting sheets with the use of a point incentive system. If children return their goal sheet every week, and indicate they did some level of self-monitoring, they receive 1 point. Whether or not they achieve their goals is not necessary to earn a point. Children have the option to trade in the points for incentives weekly; incentives range in point values and children can choose from small incentives every week or save their points for larger incentives at the end of the study. Examples of small incentives include stickers or small toys, and examples of a larger incentive include a $5 Wal-mart gift card or a football.

Technology Cohorts (TECH) Intervention Components

Technology delivery for TECH1 and TECH2 cohorts. Every family in TECH1 and TECH2 received a digital tablet (Apple iPad with Retina Display, 16GB, Wi-Fi+ Verizon LTE, 4th generation) equipped with a data plan for the duration of the 12-week intervention. Participants were assigned a tablet during the first session and provided detailed instructions on how to use the tablet and the programs. Participants were also encouraged to bring their tablets to the sessions weekly to troubleshoot any issues.

Fitnet. Fitnet is a physical activity app that can be downloaded for free from the app store and accessed from digital devices, including phones, tablets and other web-based platforms. Fitnet was the only technology adjunct for TECH1 and was one of two technology adjuncts for TECH2. Fitnet was downloaded on the digital tablet and each family was given a program specific username and password for log-in. The app features both adult- and child-focused workout videos of varying length and difficulty (e.g., yoga, strength conditioning, dance fitness, etc.) and was used to encourage and guide child physical activity at home. Participants set goals around using Fitnet in the weekly sessions and could set individual goals using the app as well. Initially, participants were encouraged by Healthy Hawks staff to use Fitnet for 30 minutes per week with the intention of increasing usage over the course of the intervention, setting new physical activity goals each week, and ultimately achieving the recommended 60 minutes of physical activity per day for children.[83] Fitnet usage data were captured and downloaded directly from the app.

Web-based Health Coaching Sessions. In the TECH2 cohort, the goal was to deliver a total of five web-based health-coaching sessions via Skype to provide individualized support for each family. Each family was scheduled to receive online video calls on their study digital tablets (described above) and coaching sessions were conducted in Spanish or English depending on family preference. Sessions were scheduled bi-weekly and were anticipated to last 30 minutes, but some families opted to alter this schedule based on other activities and calls lasted as long as needed. The purpose of the sessions was to reinforce teachings from the FBBG sessions with an increased focus on goal setting and adherence, physical activity, and nutrition. The sessions provided the opportunity for parents and children to have one-on-one support and ask questions that were not addressed in the weekly FBBG sessions. Each family was given a Skype name and the health coaches also created accounts and usernames specifically for this program to increase personal security. Prior to delivering sessions to families, the health coaches were trained on motivational interviewing and behavior modification techniques. The health coaching team met regularly to discuss common challenges presented by families, review strategy recommendations, and troubleshoot any technology issues.

Healthy Hawks Primary Plus (HHP+) Intervention Components

Physician Visits. For the HHP+ cohorts, bi-monthly physician visits followed the 12-week FBBG program until 1-year follow-up. Physicians at the pediatric clinic received training on Fit-tastic!, a program designed to promote healthy lifestyles and healthy weight. The program has five messages that align with the Expert Committee guidelines for the prevention, assessment and treatment of child overweight and obesity,[63] and these messages and corresponding goals were encouraged during the physician visits. Descriptions of the Fit-tastic! messages are listed below in **Table 2.**

Table 2. Description of pediatrician-delivered messaging for the HHP+ intervention cohorts.

Fit-tastic! Message	
1	1 hour or more of physical activity
2	2 hours maximum screen time
3	3 servings of low- or non-fat milk or yogurt
4	4 servings of water; not sugary drinks
5	5 or more servings of fruits and vegetables

Electronic Medical Records. Another feature of the HHP+ intervention was the use of the Electronic Medical Records (EMR) system to connect physicians to participant progress. The clinic-based coordinator logged participant attendance at the weekly FBBG sessions so physicians would have information on their participation. Additionally, the "1-2-3-4-5-Fit-Tastic!" messages were embedded into the EMR system to prompt physicians during the bi-monthly follow-up visits. The inclusion of the Fit-tastic! program targets was intended to support physicians in their ability to provide counseling during the follow-up visits and assist participants set new goals.

Theoretical guides to intervention development

All the HH programs targeted individual and interpersonal level constructs through the 12-week FBBG sessions, applying principles from the Health Belief Model (HBM) and Social Cognitive Theory (SCT) in a socio-ecological framework. Additionally, some of these strategies were reinforced in the primary care component of the HHP+ program. Designing a program targeting multiple levels of intervention is important, as these types of programs are more effective than targeting a single level of change.[84] On the individual level, the program aims to provide strategies to improve individual knowledge, skills, and beliefs that can positively impact behavior. On the interpersonal level, the inclusion of parents, other family members, and peers of similar age, provides modeling and social support. The HBM provides constructs that map on to intervention targets intended to shift individual behavior change,[85] while SCT provides concepts that operate on an interpersonal level to influence behavior.[86] It should be noted that self-efficacy operates in both theories, on the individual and interpersonal levels. The primary theoretical constructs hypothesized to facilitate behavior change, and their corresponding intervention approaches, are outlined in **Table 3.**

Table 3. Theoretical constructs and corresponding HH intervention components.

HBM concept	**HH Intervention Component**
Perceived Benefits	Educational sessions emphasize positive effects associated with behavior change and provide strategies to define actions to receive benefits.*
Perceived Barriers	Educational and physical activity sessions aimed to reduce perceptions associated with challenges in engaging in these behaviors using information, support, and encouragement.*
Self-efficacy (SCT and HBM)	Provided training, guidance, and strategies such as goal setting to help improve parent and children's confidence in their abilities to improve in targeted health behaviors.*
SCT concept	**HH Intervention Component**
Observational Learning	In physical activity sessions, group facilitators, parents, and other children act as models; Parents are given skills to model behaviors at home.
Incentive Motivation	Weekly incentive structure for children reinforces goal-setting/self-monitoring.
Facilitation	Parents and children are provided with knowledge and tools to shift health behaviors.
Self-regulation	Children and parents engage in weekly goal setting, self-monitoring and feedback to develop regulatory practices for improving health behaviors.

*= Reinforced during primary care visits with pediatricians in the HHP+ cohorts.

Measures

Primary Outcome Measure

Child Weight Status. Trained research assistants measured child height within 0.1 centimeter (cm) on a standard laboratory stadiometer with children wearing light clothing and no shoes. Child weight was measured by digital scale, recorded in pounds to the nearest 0.01, and then converted to kilograms (kg). Height and weight were used to calculate body mass index (BMI: kg/m^2), and BMI scores were converted to age- and sex-specific BMI percentiles and BMI z-scores (BMI-z) using CDC growth charts.[87] Child BMI percent above the 95^{th} percentile

(%BMI_{p95}), measured as baseline, post-intervention, and 1-year follow-up, was used as the primary outcome measure for this study.

Selecting a Primary Outcome Measure. Determining an appropriate metric for assessing change in child adiposity over time is critically important for evaluating intervention outcomes. While BMI-z is typically used as a primary outcome in treatment studies and provides consistency for comparing findings across studies, this measure might not be ideal for capturing changes in child adiposity over time.[88] The current CDC growth charts (from 2000) only include parameters for the 3rd to the 97th percentiles, indicating data being extrapolated above or below these percentiles should be done with caution.[6] The report that accompanies the growth charts acknowledges these precautions and indicates another metric might be better suited for evaluating child weight status in severely obese children.[34]

Various studies have examined other outcomes including body mass index (BMI), percent over BMI, and BMI sympercent (%),[89] but these studies include limited populations and children of varying weight status (i.e., normal weight, overweight, and obese).[90] To find a solution for examining treatment outcomes in severely obese children, a recent study of nationally representative children 2-19 years, including racially diverse children, found child BMI percentage above the 95th percentile (%BMI_{p95}) to be an appropriate metric of longitudinal adiposity change in the severely obese children.[7] Studies examining the approaches for describing values of BMI above the 97th percentile suggest that expressing high BMI values as a percentage of the 95th percentile is the most acceptable approach for describing and tracking children with higher BMIs.[6] Additionally, new growth charts have been developed for tracking severely obese children, representing child BMI as a percentage of the 95th percentile.[91] It should be noted that all BMI metrics are strongly correlated, but measures vary in their correlation with objective measures of adiposity.[92] In a scientific statement from the American Heart Association, endorsed by the Obesity Society, it is recommended that BMI ≥120% of the 95th percentile be used as a measure of severe obesity in children ≥ 2 years of age.[93] Given these considerations, all primary outcome analyses will be conducted using %$BMI_{p95.}$

Secondary Outcomes and Covariates

Demographic variables. Parents reported child age, gender, and race/ethnicity and self-reported age, gender, and language preference. Insurance status was also recorded.

Language. Parent language preferences for group session participation and measure completion were English or Spanish. Families could also select their language preference (English or Spanish) for the web-based health coaching sessions in TECH2.

Insurance Status. Insurance status assessed whether participants had private insurance, Medicaid, or no insurance. Though no data were collected on income, self-reported insurance status was used as a proxy of socio-economic status.

Race/Ethnicity. All cohorts (1-10) implemented prior to May 2009 were asked to self-report race/ethnicity based on the following categories: 1=White/Caucasian; 2= Black/African American; 3= Hispanic/Latino; 4=Other. Beginning in May 2009, race and ethnicity were captured separately, following new U.S. census guidelines. Self-reported race categories included: 1= American Indian or Alaskan Native; 2=Asian; 3=Black or African American; 4=Native Hawaiian or other Pacific Islander; 5=White or Caucasian. Ethnicity was captured separately with a binary response reporting 1= Hispanic or Latino; 2=Non-Hispanic or Latino. Since separate race and ethnicity data were not available for the initial cohorts, race/ethnicity was combined for this study and recoded to include the following categories: 1=White or Caucasian; 2=Black or African American; 3=Hispanic or Latino; 4=other. If participants reported being Hispanic they were categorized as Hispanic, regardless of self-reported race. If participants self-reported being American Indian, Alaskan Native, Asian, Native Hawaiian, Pacific Islander, or being more than two races, they were categorized as "Other." Finally, since only n=3 participants were categorized as "Other," this group was combined with the white sample for analytical purposes, when appropriate. The final three race/ethnicity categories included in this study are: 1=white/Caucasian/other; 2= black/African American; 3=Hispanic/Latino.

Child Diet. Children's dietary intake was assessed using a 3-day food diary. Parents, or children if appropriate, kept a record of all foods and beverages consumed by the child over three consecutive days (2 weekdays, 1 weekend day) using a provided template. Total energy (kcals/day), macronutrient intake, servings of fruits and vegetables and sugar-sweetened beverages, servings of red foods, and servings of green foods will be derived from the recalls. "Red foods" and "Green foods" are based on the Stoplight Diet.[94] "Red foods" are foods high in fat, sugar, and calories and low in nutrients and should be consumed rarely; "Green foods" are foods nutrient-dense foods low in calories, fat, and sugar and should be consumed frequently. Participant diet records were considered valid and included if they completed at least two days (1 weekday and 1 weekend). The records were analyzed using the Nutrition Data System for Research (NDSR; Nutrition Coordinating Center, University of Minnesota, Minneapolis, MN). Dietary data were only available for cohorts 7-24 (n=251).

Child Physical Activity. Physical activity was measured using the ActiGraph accelerometer (GT3X and GT1M models, Actigraph LLC, Pensacol, FL). The ActiGraph objectively records the duration and intensity of activity and is shown to be reliable in children.[95] Participants were instructed to wear the device on their non-dominant hip for all waking hours, for 7 consecutive days. Days that captured more than 6 hours of data were considered valid and participants with at least 3 valid days were included. Activity minutes were combined to provide an estimate of minutes spent in moderate-to-vigorous physical activity (MVPA), adjusted for wear time.

Parent BMI. Trained program staff objectively measured parent height and weight, using the same approach as described above, at baseline, post-intervention (12-weeks), and 1-year follow-up. Height (cm) and weight (kg) were used to calculate BMI. Parents were categorized as normal BMI (18.5-24.9 kg/m^2), overweight (25.0-29.9 kg/m^2), obese (30.0-39.9 kg/m^2), or severely obese ($\geq$40.0 kg/m^2).

Sibling Status. Sibling status was categorized based on whether or not siblings attended the FBBG sessions weekly. If participants had siblings attend sessions who met the eligibility criteria, they were enrolled as well. Sibling status was categorized based on: 0= no siblings attended sessions; 1= siblings attended sessions but were not enrolled; 2= siblings attended sessions and were enrolled.

Analytical Plan

AIM 1

Aim 1. Determine the effect of Healthy Hawks (HH), a 12-week family-based behavioral group treatment intervention, on changes in child weight status, assessed using child body mass index percentage above the 95^{th} percentile ($\%BMI_{p95}$), at post-intervention and 1-year follow-up in a sample of low-income racially/ethnically diverse children, 2-19 years of age, who are overweight or obese.

Hypothesis: Children in the HH intervention will show a reduction in $\%BMI_{p95}$ at post-intervention and at 1-year follow-up.

The primary aim of this study (Aim 1) is to examine the impact of the HH program on change child weight status (%BMI_{p95}) at post-intervention. The impact of the HH program on child %BMI_{p95} at 1-year follow-up was also examined. Due to the lack of understanding of FBBG program effectiveness in low-income ethnic minority groups, differences in effect were also assessed by race/ethnicity. Secondary outcome measures included child diet (total calories, servings of fruits and vegetables (i.e. “green foods”), sugar-sweetened beverage intake, and servings of “red foods,” physical activity (minutes in moderate-to-vigorous physical activity), and change in parent BMI.

HH program impact was assessed using a pre-post test design. Descriptive statistics were used to describe participant characteristics for the entire sample (all cohorts combined) at baseline, post-intervention and 1-year follow-up. Chi^2 (X^2) and t-tests were used to determine differences in completers at each time point.

For the primary outcome, an intent-to-treat analysis was conducted and all participants were included if they completed the follow-up measures for the primary outcome, regardless of treatment session attendance (i.e., all participants who have completed measures for child height and weight at baseline and post-intervention were included in the post-intervention analysis. At 1-year follow-up, all participants who completed measures for child height and weight at baseline and 1-year follow-up were included in the 1-year follow-up analysis.) Linear regression models tested changes in %BMI_{p95} at post-intervention and 1-year follow-up, accounting for clustering by family. To examine differences in %BMI_{p95} by race/ethnicity, within- and between-group analyses were conducted using the three primary race/ethnicity categorizations: White/other; Black; Hispanic. Empirically supported covariates were assessed for inclusion in a second model including child baseline BMI, parent BMI, race/ethnicity, age, gender, language, insurance type, cohort, treatment session attendance, parent baseline BMI, parent BMI change, and sibling status. Appropriate covariates were identified based on sample size, correlations between variables, and variables that influence the primary outcome by +/- 10%.

General linear regression modeling was also used to assess secondary outcomes (dietary intake variables, physical activity, parent BMI) adjusted for clustering within families. To examine the role of parents in family-based treatment, parent BMI change was examined as a predictor of child weight change at each time point. Sensitivity analyses were conducted to compare effects of completers-only to the intent-to-treat sample. All analyses were conducted using STATA 14.

Interpretation of findings. All tests were two-sided and outcomes were considered significant at $p<0.05$. Mean changes in $\%BMI_{p95}$ were used to determine the percentage of participants that significantly changed classification from severely obese ($\%BMI_{p95} \geq 120$) to obese ($\%BMI_{p95} \leq 120$). The percentage of participants who change percentiles from obese to overweight or overweight was also examined. This level of significant weight loss has been previously shown to have a positive impact on psychological changes, including improvement in atherogenic risk factors.[96] Effect sizes were calculated for each outcome to determine the magnitude of change and compare outcomes across aims.

Sample size and power. This study is powered to detect at least a moderate effect size similar to other treatment studies (standardized mean differences of less than 0.2 are considered small, about 0.5 as moderate, and 0.8 or greater as a large effect).[61] In order to have 80% power to detect an effect size of 0.50 at $p<0.05$, a sample size of 34 would be required for a within person design. With a sample size at post-intervention of N=164, this study will have 80% power to detect a within-person single group SD difference as small as 0.22 BMI z-score units. At 1-year follow-up a sample size of N=86 will have 80% power to detect a within person SD difference of at least 0.31 BMI z-score units. These numbers are based on a one-sample mean test using the power analysis function in STATA 14.

Process Evaluation. Process evaluation was necessary for providing context to treatment outcomes. Therefore, factors including attendance and retention were quantified and assessed. The number of sessions was used as a measure of attendance, and attendance was dichotomized into <6 sessions and ≥6 sessions to test the effect on changes in child $\%BMI_{p95}$ at post-intervention and 1-year follow-up.

AIM 2

Aim 2. Examine feasibility and the effect of adding technology components, specifically a physical fitness app and web-based health coaching sessions, alongside the 12-week traditional FBBG program on child $\%BMI_{95}$ at post-intervention and compare effects to the standard HH program.

Hypothesis: Adding technology components to a traditional FBBG treatment program will significantly reduce child $\%BMI_{95}$ at post-intervention and reductions will be significantly greater when compared to the standard HH program only.

HH cohorts 23-25 and HHP+ cohorts 1-3 were included in the analyses for Aim 2. In addition to receiving the standard 12-week FBBG intervention, the last two combined cohorts received technology adjuncts added along side the 12-week HH program (TECH1 and TECH2) and were compared to the first combined cohorts that received no adjuncts (NO TECH). Despite differences in the HH and HHP+ cohorts (i.e., recruitment strategies and post-intervention exposures), both intervention groups received the same 12-week FBBG treatment between baseline and post-intervention. The cohorts were combined for the 12-week FBBG sessions conducted in a community meeting space and a new technology cohort was implemented approximately every 4 months. The NO TECH cohort (n=21) received the standard 12-week FBBG treatment only and no technology components; TECH1 (n=20) received the FBBG sessions plus one technology component- digital tablets equipped with an fitness app (Fitnet), to increase physical activity at home; TECH2 (n=23) received the FBBG sessions and two technology components- the digital tablets with the fitness app as well as individual Telemed health-coaching sessions delivered via Skype. NO TECH was implemented in May 2014, TECH1 in September 2014, and TECH2 in February 2015.

Descriptive statistics were used to assess baseline participant characteristics. In-person weekly session attendance, Fitnet usage, Telemed session participation, acceptability surveys, and open-ended questions were summarized for completers. For the purposes of this study, participants were considered completers if child height and weight measures were collected at baseline and post-intervention. T-tests and chi-squared tests assessed differences at baseline, between cohorts, and between completers and non-completers. Linear regression models were used to examine within-group %BMI_{p95} change for each cohort (NO TECH, TECH1, TECH2). Then, to compare between group effects, linear regression models were conducted to evaluate differences in child weight status between the technology cohorts and the previous HH cohorts that received no technology (cohorts 1-22, n= 282). Model 1 controls for clustering by family only and Model 2 controls for clustering by family, race/ethnicity, age, and gender. Regression models were also used to examine differences in %BMI_{p95} change between the three cohorts and HH only. Finally, linear regression models were used to examine the intervention components (i.e., treatment attendance, Fitnet usage, and Telemed sessions) as predictors of child %BMI_{p95} change in each of the TECH cohorts. Model 3 tested Fitnet usage and treatment attendance on

%BMI_{p95} change in TECH1, while Model 4 tested Fitnet usage, treatment attendance, and Telemed sessions on %BMI_{p95} change in TECH2; both models control for clustering by family. All analyses were conducted using STATA version 14.

AIM 3

Aim 3. Evaluate the impact of a community-clinic collaboration intervention (HHP+) on participant retention and changes in child %BMI_{p95} at 1-year follow up.

Hypothesis: Children in the HHP+ intervention will demonstrate improvements in retention and reductions in %BMI_{p95} at 1-year follow-up, and retention and child weight status reductions will be significantly greater when compared to children who participated in the HH intervention only.

The analysis for Aim 3 will evaluate the HHP+ cohorts to determine the effect of the HHP+ program on child %BMI_{p95} at post-intervention and 1-year follow-up. Baseline descriptive characteristics were assessed for all HH and HHP+ participants and differences between groups were examined. This non-equivalent two-group design was assessed using linear regression models to examine differences between child %BMI_{p95} in HH and HHP+ programs, controlling for clustering within families. Secondary models were adjusted for race/ethnicity, age, and gender in addition to clustering within families, to account for differences between groups. Within- and between-group changes in child %BMI_{p95} were assessed at post-intervention (12-weeks) and 1-year follow-up (one year from baseline). Retention was measured at each time point and differences in retention were compared between HH and HHP+. The total number of physician visits attended between post-intervention and 1-year follow-up was recorded and correlated with participation retention at 1-year follow-up using Pearson's correlations.

SUMMARY

The goal of this study is to test the effectiveness of a Healthy Hawks, a FBBG treatment program on changes in child $\%BMI_{p95}$ at post-intervention and 1-year follow-up, in a sample of low-income, racially/ethnically diverse youth, 2-19 years of age, with overweight or obesity. Aim 2 assesses the impact of adding technology adjuncts alongside the 12-week FBBG program. Aim 3 examines the additional effect of embedding the intervention in a single primary care clinic and engaging clinicians to provide bi-monthly follow-up sessions. These novel approaches are investigated to better understand factors associated with intervention participation and retention, and improvements in child weight status. It is intended that the findings from this study can fill gaps in the current pediatric obesity treatment literature and inform future studies in low-income, diverse populations.

CHAPTER 4: OUTCOMES OF A FAMILY-BASED PEDIATRIC OBESITY TREATMENT INTERVENTION IN LOW-INCOME MINORITY YOUTH

Overview

Racially/ethnically diverse children are disproportionately affected by obesity and related co-morbidities. However, these populations are also less likely to be included in treatment studies and the effectiveness of treatment approaches in this population is not fully understood. The aim of this study is to determine the effect of a family-based behavioral intervention in a population of low-income minority youth.

Healthy Hawks (HH) is a 12-week, family-based behavioral group (FBBG) pediatric obesity intervention program designed to improve health behaviors and weight status in children who are overweight or obese. Child weight status was assessed as the primary outcome at baseline, post-intervention (12-weeks), and 1-year follow-up. Secondary outcomes examined measures of dietary intake, physical activity, and parent BMI. Retention at post-intervention and 1-year follow-up is also examined.

Child %BMI_{p95} was significantly reduced at post-intervention (β=-1.29 (0.36), $p<0.001$), but reductions were not maintained at 1-year follow-up (β=-0.51 (1.06), $p=0.64$). There were no significant between-group differences by race/ethnicity at either time point, but within-group differences indicated this intervention might be effective for white children (β=-2.26 (0.78), $p=0.01$) and Hispanic children (β=-1.00 (0.48), $p=0.04$), but not black children (β=-1.13 (0.80), $p=0.17$). Retention at post-intervention was 67.0% and 38.3% at 1-year follow-up. Significant reductions in total calories (β=-350.6 (6), $p<0.001$), servings of red foods (β=-1.6 (0.3), $p<0.001$), and sugar-sweetened beverage consumption (β=-0.3 (0.1), $p=0.04$) were observed at post-intervention, and only red foods were significantly reduced at 1-year follow-up (β=-1.0 (0.5), p=0.04).

Children in the HH program had significant reductions in %BMI_{p95} at post-intervention, but not at 1-year follow-up. This study addresses gaps in the childhood obesity treatment literature by providing much needed data on ethnic minority children. Future studies are needed to improve child weight status and participant retention in family-based treatment programs involving low-income minority youth.

Introduction

Racial disparities in child health have persisted for decades[97] and the disparities influencing childhood obesity develop early in life.[98] Despite data indicating that prevalence of obesity among youth has stabilized in some subgroups,[1] rates are still problematic and significantly affect black and Hispanic youth.[99] The prevalence of childhood obesity among Hispanics is 21.9% and 19.5% among non-Hispanic blacks, compared to 14.7% among non-Hispanic whites.[35] Combining overweight and obesity, prevalence increases to 41.2% of Hispanic children and 41.8% of non-Hispanic black children compared to 29.0% of non-Hispanic white children.[36] In addition to higher rates of obesity, Hispanic and black children are more likely to be living in poverty and experiencing environmental and material hardships related to lower socioeconomic status that have negative consequences on diet and health. Moreover, obesity trends and corresponding co-morbidities persist into adulthood[100] and those living in poverty are more likely to experience poorer quality of care, and consequently more likely to have poorer health status.[41] Given the challenges associated with overweight and obesity in low-income, racial/ethnic minority children, there is a pressing need for quality intervention designed specifically for this population.

Despite obesity and co-morbidity trends, Hispanic and black children are less likely to be represented in treatment studies, thus limiting the applicability of empirically supported approaches in this population.[101] In a meta-analytical review of family-based intervention studies, only 30% of the studies included racially/ethnically diverse samples.[42] Most treatment studies including minority populations have been conducted in specific organizational settings, such as schools, limiting the application of strategies proven to be effective in treatment, such as parental involvement and lifestyle changes.[43]

The socio-ecological model (SEM) provides an important theoretical guide for pediatric obesity intervention, conceptualizing the contexts in which children and families exist, and highlighting the interaction of multiple levels of influence on the development of childhood obesity.[20] SEM emphasizes that children are directly rooted in the family environment and it is here that factors such as food access, attitudes and beliefs around eating, and dietary habits are developed.[44] Therefore, interventions targeting the family-at-large could more effectively improve childhood obesity outcomes.[47] Horn and Beal provide a multi-level framework that conceptualizes child health disparities highlighting the driving influence of important familial factors, including race, culture, and socio-economic status.[41] To address these racial disparities in childhood obesity their framework calls for the development and testing of multi-level interventions in diverse populations.

Family-based behavioral group (FBBG) treatment programs are the most empirically supported treatment approach for pediatric obesity to date.[58] A meta-analysis of randomized controlled trials for the treatment of pediatric obesity found that combined lifestyle programs (e.g., those including diet and physical activity) improve body mass index (BMI), and the largest effects were seen in studies that involved parents.[61] Epstein and colleagues have demonstrated long-term maintenance of such approaches in children including sustained weight changes at 10-year follow-up.[62] Given this body of evidence, intensive, multicomponent, behavioral interventions involving parents are most likely to produce significant improvements in child weight status. Additional evidence, however, is needed to understand the efficacy of these interventions in racial/ethnically diverse populations.

This study will address current gaps in the literature by testing the translation of effective family-based pediatric obesity treatment interventions for use with a population of low-income minority youth and their families. The primary aim is to examine change in child weight status (assessed using child body mass index [BMI] percentage of the 95% percentile [$\%BMI_{p95}$]) at post-intervention (12-weeks) and 1-year follow-up among children in families participating in a behavioral pediatric obesity treatment intervention. As a secondary aim, changes in dietary intake, physical activity, and parent BMI are assessed. Retention is also examined as treatments studies involving hard-to-reach population often suffer from high attrition.

Methods

Study Design

Healthy Hawks (HH) is an ongoing, multicomponent pediatric obesity intervention program designed to improve health behaviors and weight status in children who are overweight or obese. Children are recruited at health fairs, community events, and two urban pediatric clinics serving predominately low-socioeconomic status children in Kansas City, KS. Interested families are given a number to call, and complete an intake form via mail. In order to be eligible children 1) have to be 2 to 18 years of age, 2) have a BMI ≥85th percentile, 3) have at least one parent agree to attend program sessions and complete measures, and 4) not have a diagnosis that would make participation in a group setting difficult without individualized support (e.g., severe

Autism Spectrum Disorder, etc.) Recruitment and assessment materials are offered in both English and Spanish. Recruitment is ongoing and continues until there are enough parent-child dyads to fill a cohort. A total of 25 HH cohorts, which have been conducted from April 2006 to February 2015, are included in this analysis. A novel component of this program is that in addition to parents, siblings are encouraged to attend group sessions and if eligible, are enrolled. The current study builds on preliminary evidence presented on the Healthy Hawks program, described elsewhere.[102] The Institutional Review Board at The University of Kansas Medical Center approved all procedures.

Theoretical guides to intervention development

Designing a multi-level, multi-component intervention is important since these types of programs are more effective than interventions targeting a single level of change.[84] The HH program targets individual and interpersonal level constructs through the 12-week FBBG sessions, applying principles from the Health Belief Model (HBM) and Social Cognitive Theory (SCT) in a socio-ecological framework.[54] On the individual level, the program aims to provide strategies to improve individual knowledge, skills, and beliefs that can positively impact behavior. On the interpersonal level, the inclusion of parents, other family members, and peers of similar age, provides modeling and social support. The HBM provides constructs that map on to intervention targets intended to shift individual behavior change,[85] while SCT provides concepts that operate on an interpersonal level to influence behavior.[86]

Family-based behavioral group (FBBG) sessions

The FBBG sessions consist of 2-hour lessons administered every week for 12-weeks. Parents and children are separated for the first hour, which focus on educational strategies to promote behavior change. Parent groups are organized based on language preference (Spanish or

English). All children who attend, regardless of enrollment status, are placed into groups based on age (under 5 years, 6-9 years, 10-12 years, and 13 years and older) and all child sessions are conducted in English. Parents and children learn the same concepts each week, but the parents are taught didactically, and the children are taught through age appropriate activities. During the second hour, all family members engage in physical activity together. Examples of activities include Zumba, soccer, neighborhood walks, body weight strength training, relay races, and yoga. To ensure consistent intervention delivery of the FBBG sessions, intervention staff and volunteers receive training and followed a scripted manual. Parents and children also receive copies of the manual (available in English and in Spanish) and sessions are sporadically video-recorded to monitor delivery fidelity and observe participant engagement.

Participating families are eligible to receive a free 3-month family membership to the local YMCA, upon successful completion of the program. Children are incentivized to attend weekly sessions with the use of a point system. Children earn points for attendance and using their goal-setting sheets and then have the option to trade in the points for incentives every week or save their points for larger incentives at the end of the study.

Measures

All baseline measures were administered and collected at the beginning of the first session after parents provided consent and children (≥7 years) provided assent. Parents self-reported race/ethnicity, date of birth, and gender for themselves and their child.

Child anthropometrics. Child height and weight were objectively measured at baseline, post-intervention (12-weeks), and 1-year follow-up (1-year from baseline). Trained program staff completed measures with participants wearing light clothing and no shoes. Height was measured in to the nearest 0.1 centimeters (cm) using a stadiometer (Holtain Ltd., Crymych, Dyfed, UK), and weight was measured to the nearest 0.01 kilograms (kg) using a digital scale (Temp-StikDigitron 8000 digital scale National Medical Corp., Temp-Stikcorp). Height and weight were used to calculate BMI and %BMI_{p95} using CDC SAS program for the growth charts. Child %BMI_{p95} was selected as the primary outcome because this measure is a considered a more acceptable estimate of adiposity change in severely obese children,[87] and is recommended as an outcome for children in obesity treatment programs.[92]

Child diet. Dietary intake was assessed using a 3-day food diary at baseline, post-intervention, and 1-year follow-up. Parents (or children if age appropriate) kept a record of all foods and beverages consumed over 3 consecutive days (2 weekdays, 1 weekend day) using a provided template. Total energy (kcals/day), servings of fruits and vegetables, sugar-sweetened beverages, and servings of “red foods” were derived from the recalls. “Red foods” are based on the Stoplight Diet[94] and include foods high in fat, sugar, and empty calories. Participant recalls were included if they completed at least 2 (1 weekday and 1 weekend). The recalls were analyzed using the Nutrition Data System for Research (NDSR; Nutrition Coordinating Center, University of Minnesota, Minneapolis, MN). Dietary data are only available for cohorts 7-24 (n=251).

Child physical activity. Physical activity was measured using the ActiGraph accelerometer (GT3X and GT1M models, Actigraph LLC, Pensacol, FL). The ActiGraph objectively records the duration and intensity of activity and is shown to be reliable in children.[95] Participants were instructed to wear the device on their non-dominant hip for all waking hours, for seven consecutive days. Days that captured more than 6 hours of data were considered valid and participants with at least three valid days were included. Activity minutes were combined to provide an estimate of minutes spent in moderate-to-vigorous physical activity (MVPA), adjusted for wear time.

Parent BMI. Trained program staff objectively measured parent height and weight, using the same approach as described above at baseline, post-intervention (12-weeks), and 1-year follow-up. Height (cm) and weight (kg) were used to calculate BMI. Parents were categorized as normal BMI (18.5-24.9 kg/m^2), overweight (25.0-29.9 kg/m^2), obese (30.0-39.9 kg/m^2), or severely obese ($\geq$40.0 kg/m^2).

Analysis

Program impact was assessed using a pre-post test design. Descriptive statistics were used to describe participant characteristics for the entire sample (all cohorts combined) at baseline, post-intervention, and 1-year follow-up. Chi^2 (X^2), and t-tests were used to determine differences in completers at each time point. Participants were considered completers and included in the analysis if they had measured child height and weight at either follow-up time point (12-weeks and/or 1-year). For the primary outcome, linear regression models tested changes in $\%BMI_{p95}$ at post-intervention and 1-year follow-up, accounting for clustering by family. General linear regression modeling was also used to assess secondary outcomes (dietary intake, physical activity, parent BMI) adjusted for clustering within families. To examine differences in $\%BMI_{p95}$ by race/ethnicity, within- and between-group analyses were conducted using the three primary race/ethnicity categorizations: White/other; Black; Hispanic. To examine the role of parents in family-based treatment, parent BMI change was examined as a predictor of child weight change at each time point. All analyses were conducted using STATA 14.

Results

Participant descriptive characteristics are presented in **Table 4**. At baseline (N=300), participants were 10.1 ±3.3 years, 55.3% female, mean BMI percentile (BMI%)=97.8±2.7, 18.7% white/other, 22.3% black, and 59.0% Hispanic. A majority of parents were Spanish-speaking (52.7%), female (95.1%), had an average baseline BMI of 33.9 ±7.7 (91.2% overweight or obese), and received Medicaid (70.0%) or had no insurance (9.3%).

Retention and measure completion

Completion rate at post-intervention was 67.0% and 38.3% at 1-year follow-up. There were no differences in any baseline characteristics between completers and non-completers post-intervention. There were only significant differences at 1-year follow-up by language (X^2= 6.3, p=0.01) and by parent BMI at baseline (t281)=-2.0, p=0.04. No other differences in completion were observed for child age, gender, baseline BMI%, race/ethnicity, or insurance status at either time point.

Completion rates for secondary outcome measures were low. Of those who completed post-intervention child weight status measures in cohorts 7-24 (n=195), only 31.8% (n=62) completed dietary intake measures, and 30.8% (n=41) of those who completed 1-year follow-up (n=133) also completed dietary measures. Physical activity measures were collected for all 25 cohorts and completion rate at each time point was slightly higher (54.7% [n=110] at post-intervention; 64.3% [n=74] at 1-year follow-up).

Primary outcome

Relative to baseline, child $\%BMI_{p95}$ was significantly lower at post-intervention (β(SE) = -1.29(0.37), p<0.001), but reductions were not maintained at1-year follow-up (β(SE) =-0.51 (1.06), p=0.64) (**Table 5**). Within group differences in $\%BMI_{p95}$ by race ethnicity indicated significant reductions in white/other children (β=-2.27 (0.78), p=0.01), and Hispanic children (β=-0.99(0.48), p=0.04) but not in black children (β=-1.13 (0.80), p=0.17). However, these between-group differences were not significant, and no groups had significant within-group changes at 1-year follow-up (**Table 6**).

Secondary outcomes

There were no significant differences between completers and non-completers for secondary outcome measures (diet and physical activity) at post-intervention or 1-year follow-up by child age, gender, baseline BMI%, race/ethnicity, insurance type, language or parent baseline BMI. Children with completed measures demonstrated significant reductions in total calorie intake at post-intervention (β=-350.63 (69.19), p<0.001), but not at 1-year follow-up (β=-87.98 (103.15), p=0.40) (**Table 5**). Sugar-sweetened beverage consumption was also reduced at post-intervention (β=-0.29 (0.14), p=0.04), but not at 1-year follow-up (β=-0.07 (0.12), p=0.59). Daily servings of red foods were reduced at post-intervention (β=-1.55 (0.33), p<0.001), and 1-year follow-up (β= -0.97 (0.46), p=0.04), but no increases in fruit and vegetable intake were observed at either time point (post-intervention: β= 0.09 (0.35), p=0.80; 1-year follow-up: β=-0.24 (0.37), p=0.52).

Parent BMI significantly decreased from baseline at post-intervention (β(SE)= -0.4 (0.1), p<0.001) and 1-year follow-up (β(SE)= -0.6 (0.2), p=0.02). However, parent BMI change at post-intervention was not significantly associated with change in child $\%BMI_{p95}$ at post-intervention (β = 0.86 (0.46), p=0.07). Similarly, parent BMI change at 1-year was not associated with change in child $\%BMI_{p95}$ at 1-year follow-up (β= -0.05 (0.88), p=0.95). There was no significant change in minutes of moderate-vigorous physical activity for children at post-intervention (β(SE)= 0.51 (1.92) , p=0.79) or 1-year follow-up (β(SE)= -2.49 (2.31), p=0.29).

Discussion

A 12-week family-based behavioral group intervention reduced child $\%BMI_{p95}$ at post-intervention, but not at 1-year follow-up in a population of low-income, racially/ethnically diverse youth. Some improvements in weight-related dietary behaviors were also observed. While between-group changes by race/ethnicity were not significantly different and subgroups analyses were not powered to detect differences, it is interesting to note that within-group differences did vary by race/ethnicity. White/other and Hispanic children exhibited significant pre-post reductions in $\%BMI_{p95}$, but black children did not. This might reflect the fact that this traditional family-based approach has been shown to be efficacious in white children and was adapted into Spanish for a Spanish-speaking population. There might not have been sufficient cultural tailoring to meet the needs of black children and families.

When examining the role of parents, the relationships and predictors of child treatment success observed in other family-based treatment studies were not observed in this population. Parent BMI change was not associated with change in child weight status at either time point. Previous reports have identified parents as critically important for influencing child weight status[49] and parent weight change has been identified as a predictor of child weight status change in other family-based treatment programs.[103,104] Other studies have suggested that understanding and intervening on the broader family context, including ethnic and cultural factors, might be more important for influencing weight status in racially/ethnically diverse children[105] and a better understanding of family systems and theories might improve outcomes.[106]

This is one of few studies to provide data from a sample of low-income, racially/ethnically diverse, urban youth participating in a family-based pediatric obesity treatment program. However, this study has limitations. First, this is a pre-test, post-test design lacking an experimental control, and thus constraining causal inferences that can be drawn. Next, attrition for this study was relatively high (67.0% at 12-weeks and 38.3% at 1-year), though consistent with previous studies in this population.[107] Also problematic was the missing follow-up data for secondary outcome measures (i.e., diet and physical activity). While baseline measures of secondary outcomes were not different between completers and non-completers at post-intervention or 1-year follow-up, the lack of data limits the interpretation of these outcomes and suggests these measures might have impacted overall attrition. The most common reason for overall study attrition was moving out of the area or having scheduling conflicts, but there is no information regarding why families did not complete dietary or physical activity measures. Future studies should identify strategies for improving measure completion as these are critically for understanding the pathways between treatment, retention, and success, especially in hard-to-reach populations.

Conclusion

Based on a pre-post assessment, Healthy Hawks, a FBBG treatment program, appeared to be effective in reducing $\%BMI_{p95}$ at post-intervention in a population of low-income ethnic minority youth. Short-term dietary improvements in intake of overall calories and sugar-sweetened beverages were observed among those available for follow-up measures, and consumption of “red foods” was reduced at post-intervention and 1-year. Though there was no significant between group differences by race/ethnicity, within-group tests indicate this program might be more effective for white and Hispanic participants and less so for black participants. These findings are important as family-based treatment has been implicated as the gold standard, but this approach might not be the most effective for all groups. Future studies should use more rigorous designs to evaluate the extent to which these programs can be effective in low-income ethnic minority populations, and explore novel strategies to improve retention and long-term outcomes in hard-to-reach populations.

Table 4. Descriptive characteristics for HH sample at baseline, post-intervention, and 1-year follow-up.

		Full Sample	Post-intervention Completers	1-year Follow-up Completers
N		300	201	115
Retention Rate			67.0%	38.3%
Age (years)		10.1 (3.3)	10.1 (3.3)	10.5 (3.4)
$\%BMI_{p95}$		126.0 (24.7)	125.9 (24.0)	127.4 (24.1)
BMI%		97.8 (2.7)	97.4 (4.0)	97.7 (3.1)
Child Gender	Female	55.3%	55.9%	52.9%
Race/Ethnicity	White/other	18.7%	22.3%	24.4%
	Black	22.3%	21.8%	23.4%
	Hispanic	59.0%	55.9%	52.2%
Language	Spanish	52.7%	48.8%	43.5%
Parent Gender	Female	95.1%	93.4%	95.5%
Insurance Type	Medicaid	70.0%	69.2%	69.5%
	Private	20.7%	23.4%	20.9%
	None	9.3%	7.5%	9.6%
Parent BMI		33.9 (7.7)	34.0 (8.0)	35.0 (8.8)
Parent BL BMI classification				
	Normal weight	8.8%	9.2%	10.8%
	Overweight	26.9%	27.7%	21.6%
	Obese	46.6%	43.6%	42.4%
	Severely obese	17.7%	19.5%	25.2%

Continuous variables (age, $\%BMI_{p95}$, %BMI, parent BMI) are presented as Means (Standard Deviation). Categorical variables are presented as percentages (%). $\%BMI_{p95}$= percentage above the 95th percentile; BMI%= body mass index percentile; BL= baseline; Δ= change; BMI= body mass index; BL= baseline

N=300 for baseline measures of age, $\%BMI_{p95}$, BMI%, child gender, race/ethnicity, language, parent gender, insurance type, n=283 for baseline measures of Parent BMI and Parent BL BMI classification; N= 201 for measures of age, $\%BMI_{p95}$, BMI%, child gender, race/ethnicity, language, parent gender, and insurance type at post-intervention; n= 195 for measures of Parent BMI and Parent BL BMI classification at post-intervention; N=115 for measures of age, $\%BMI_{p95}$, BMI%, child gender, race/ethnicity, language, parent gender, and insurance type at 1-year follow-up; n=111 at for measures of Parent BMI and Parent BL BMI classification1-year follow-up

Table 5. Primary and secondary outcome measures at post-intervention and 1-year follow-up in HH cohorts.

	N	β(SE)	CI	p-value
$\%BMI_{p95}$				
Δ12-weeks	201	-1.27 (0.36)	-2.01, -0.57	0.000***
Δ1-year	115	-0.51 (1.06)	-2.62, 1.61	0.64
Parent BMI				
12-weeks	191	-0.37 (0.07)	-0.51, -0.22	0.000***
Δ1-year	94	-0.61 (0.24)	-1.09, -0.12	0.02*
Total Calories				
Δ12-weeks	62	-350.63 (69.19)	-489.59, -211.67	0.000***
Δ1-year	40	-87.98 (103.15)	-297.84, 121.88	0.4
FV intake				
Δ12-weeks	62	0.09 (0.35)	-0.61, 0.78	0.80
Δ1-year	41	-0.24 (0.37)	-1.00, 0.50	0.52
SSB intake				
Δ12-weeks	61	-0.29 (0.14)	-0.57, -0.01	0.04*
Δ1-year	40	-0.07 (0.12)	-0.31, 0.18	0.59
Red foods				
Δ12-weeks	62	-1.55 (0.33)	-2.21, -0.90	0.000***
Δ1-year	40	-0.97 (0.46)	-1.90, -0.04	0.04*
MVPA				
Δ12-weeks	110	0.51 (1.92)	-3.30 4.31	0.79
Δ1-year	74	-2.49 (2.31)	-7.12, 2.14	0.29

All models are adjusted for within-person repeated measures and clustering by family.

B= beta coefficient; SE= standard error; CI= confidence interval; $\%BMI_{p95}$= body mass index percent above the 95^{th} percentile; BMI= body mass index; FV= fruit and vegetable; SSB= sugar-sweetened beverage; MVPA= moderate-to-vigorous physical activity;
*$p \leq 0.05$; *** $p \leq 0.001$

Table 6. Within and between-group differences in child weight status by race/ethnicity in HH cohorts.

			Within-group differences		**Between-group differences**	
	N	**M(SD)**	**β(SE)**	**p-value**	**β(SE)**	**p-value**
12-weeks						
White	43	130.58 (25.31)	-2.27 (0.78)	p=0.01		
Black	43	130.25 (28.56)	-1.13 (0.80)	p=0.17	1.14(1.11)	0.31
Hispanic	115	120.22 (21.02)	-1.00 (0.48)	p=0.04	1.28 (0.92)	0.16
	N	**M(SD)**	**β(SE)**	**p-value**	**β(SE)**	**p-value**
1-year						
White	28	128.88 (25.90)	-0.10 (1.76)	0.96		
Black	27	126.86 (33.65)	-2.70 (3.63)	0.46	-2.60 (4.03)	0.52
Hispanic	60	126.06 (22.15)	0.29 (0.92)	0.76	0.39 (1.98)	0.85

M= mean; SD= standard deviation; β= beta coefficient; SE= standard error

CHAPTER 5: TECHNOLOGY COMPONENTS AS ADJUNCTS TO A FAMILY-BASED PEDIATRIC OBESITY TREATMENT PROGRAM IN LOW-INCOME MINORITY YOUTH

Overview

Strategies to treat pediatric obesity are needed, especially among high-need populations. Technology is an innovative approach; however, data on technology as adjuncts to in-person treatment programs are limited.

A total of 64 children (body mass index (BMI) ≥85th percentile, mean age=9.6±3.1 years, 32.8% female, 84.4% Hispanic) were recruited to participate in one of three cohorts of a family-based behavioral group (FBBG) treatment program: NO TECH, TECH1, and TECH2. The cohorts were implemented using a non-randomized, pre-post design and participants were enrolled in an on-going basis. NO TECH received the standard, in-person 12-week treatment only (n=21); TECH1 received FBBG plus a digital tablet equipped with a fitness app (Fitnet) designed to increase physical activity levels (n=20); TECH2 received FBBG and Fitnet, plus five individually-tailored Telemed health-coaching sessions delivered via Skype (n=23). Child weight status was assessed at baseline and post-intervention. Weekly session attendance was recorded and Fitnet usage data were automatically generated by the app. Secondary aims examined feasibility/acceptability, and the effect of technology engagement on child weight status.

NO TECH and TECH1 participants had no significant change in $\%BMI_{p95}$ at post-intervention (NO TECH: β=-0.79 (1.25), p=0.53; TECH1: β=-0.81 (1.21), p=0.50). TECH2 did have significant pre-post reductions in child $\%BMI_{p95}$ (β=-3.71 (0.74), p<0.001). Overall, participants rated the technology as highly acceptable. This study indicates that technology adjuncts are feasible, used by hard-to-reach participants, and show promise for improving child weight status in obesity treatment programs.

Introduction

The prevalence of children with obesity (body mass index (BMI)-for-age and sex ≥ 95th percentile) remains high; minority populations are disproportionately affected with higher obesity rates observed in Hispanic and Black children.[2] Children with obesity are at greater risk for health complications such as hypertension, type II diabetes, and metabolic syndrome, and are more likely to continue their unhealthy weight trajectory into adulthood.[26,108] Therefore, it is essential that efficacious treatment programs are available. A variety of interventions, including drug therapy, diet-only, or physical activity-only programs have had modest success in addressing pediatric obesity in the short term, while combined lifestyle interventions (diet and physical activity) that include parental involvement show greater impact.[61,109]

Current standards for treatment recommend implementing family-based behavioral group (FBBG) programs to promote healthy lifestyle modification as part of a staged treatment approach.[63,110] These programs typically involve parents as the main agents of change, incorporate behavioral techniques (e.g., self-monitoring, goal-setting), and focus on modifying multiple health behaviors including diet and physical activity.[111] The effectiveness of family-based childhood obesity treatment has been well documented; however, changes in child weight status tend to be small.[58,112] Furthermore, very few programs have targeted low-income minorities, indicating that these programs are not effectively reaching the populations most in need of treatment.[113] Given the modest outcomes and the limited reach of current obesity treatment programs, novel strategies are needed to enhance reach and effectiveness.

Using technology-based approaches (e.g., internet, tablets, or mobile phones) could be one strategy to address these challenges.[114] Technology components (e.g., apps, websites, Telemedicine, etc.) may provide easier access to treatment services[71] and could reinforce strategies that support behavior change, such as goal-setting, immediate feedback, and increased intervention contact.[72] Research from other child treatment literature has shown that Telemedicine is an adequate strategy for delivering interventions and therapies to children, and is deemed acceptable by families.[73] Additionally, a study by the American Heart Association identified the inclusion of new technologies into treatment programs as a gap in the current childhood obesity literature.[74] Despite this, few studies have examined the use of technology, specifically in the treatment of pediatric obesity,[75] and the evidence for the use of technology interventions in youth indicate a dearth of rigorous study designs and evaluations.[76]

Although limited, existing studies show that the use of technology may be a promising avenue for behavior change.[77] A study examining a text-messaging component in addition to in-person clinic visits found the approach was acceptable, and associated with modest improvements in parents' knowledge and beliefs.[78] A recent review indicated interventions with mobile and wireless technologies as the primary component do positively impact some health behaviors such as physical activity and fruit and vegetable intake.[79] Additionally, a pilot program using a web-based intervention for overweight children 8-12 years impacted BMI z-score (BMI-z) and found that change was related to usage of the intervention technology; those who were frequent users reduced BMI-z after 4 weeks, whereas infrequent users increased.[80] Another review of electronic interventions in obesity treatment and prevention programs indicate these approaches can improve child weight status, but few studies examined technology targeting both parents and children, and findings are constrained by poor study quality and design.[81]

Collectively, these studies suggest that the use of technology in pediatric obesity treatment warrants further investigation. Given the insufficient evidence for child treatment interventions delivered via technology platforms only, testing the effect of technology adjuncts might be a more sound strategy for learning about these approaches in children. There is evidence from the adult obesity treatment literature to support this methodology.[82]

The primary purpose of the current study is to examine the effect of three Health Hawks (HH) cohorts, which include the addition of two technology components alongside a 12-week FBBG treatment program, on changes in child weight status at post-intervention. Secondary aims will examine the effect of technology adjuncts on feasibility, engagement, retention, and change in child weight status.

Methods

Intervention Design. The three cohorts in this study were part of Healthy Hawks (HH) and Healthy Hawks Primary Plus (HHP+), two multicomponent primary care-based pediatric obesity interventions designed to change health behaviors and improve weight status in children with overweight and obesity. Specifically, cohorts 23-25 of HH and cohorts 1-3 of HHP+ both received the same standard 12-week FBBG intervention, in a common community meeting space. Parents and children both participated in the 12 weekly 2-hour FBBG sessions, which included 1-hour educational sessions on strategies to promote behavior change (i.e., goal-setting, self-monitoring, parent role modeling, diet/physical activity/lifestyle modification) and 1-hour of physical activity. Parents and children were separated for the first hour; parent groups were organized based on language preference (English/Spanish), children were placed into groups based on age, and all child sessions were conducted in English. The stoplight diet was used as a framework for promoting dietary changes[94] and strategies for increasing physical activity were presented and practiced as a group during the second hour. Parents and children were given daily self-monitoring sheets to track servings of "red foods," servings of fruits and vegetables, and physical activity. Parents were given pedometers to wear to track daily steps. Children received incentive points each week for returning their self-monitoring sheets.

In addition, two of the three cohorts received technology adjuncts added along side the 12-week HH program. The three cohorts were implemented using a non-randomized, pre-post design and participants were enrolled in an ongoing basis. A new cohort was implemented approximately every four months; participants who were recruited from February 2014 to May2014 participated in the NO TECH cohort implemented in May 2014; participants recruited from June 2014 to September 2014 participated in the TECH1 cohort implemented in September 2014; participants recruited between October 2014 and February 2015 participated in the TECH2 cohort implemented in February 2015. The NO TECH cohort (n=21) received the standard 12-week FBBG treatment only and no technology components; TECH1 (n=20) received the FBBG sessions plus one technology component- digital tablets equipped with an fitness app (Fitnet), to increase physical activity at home; TECH2 (n=23) received the FBBG sessions and two technology components- the digital tablets with the fitness app as well as individual Telemed health-coaching sessions delivered via Skype. Additional details of the technology components are presented below. The three HHP+ cohorts were implemented consecutively (NO TECH, TECH1, TECH2) from May 2014 until February 2015 and a description for each cohort is presented in **Figure 4**.

Participant Eligibility. Children and their families were recruited from pediatric clinics in the Kansas City area. Children were referred and eligible to enroll if they had a BMI $\geq 85^{th}$ percentile, were 2-18 years of age, and did not have a diagnosis that would make participation in a group setting difficult without individualized support (e.g., severe Autism Spectrum Disorder, etc.) At least one parent had to agree to attend program sessions and complete measures. However, all family members were invited to attend sessions and participate. If referred children had a sibling that was eligible based on the criteria specified above, they were also enrolled. The parent portion of the program was offered in both English and Spanish, but all children completed program sessions and measures in English. The Institutional Review Board at the University of Kansas Medical Center approved all study procedures.

Technology Delivery for TECH1 and TECH2 Cohorts. Each family in TECH1 and TECH2 received a digital tablet (Apple iPad with Retina Display, 16GB, Wi-Fi + Verizon LTE, 4th Generation) equipped with a data plan for the duration of the 12-week intervention. All participants were guided on how to use the tablets in the first group session and encouraged to bring their tablets to the sessions weekly to troubleshoot any issues. Families had to return the digital tablets at the end of the 12-week program.

Fitnet. Fitnet was implemented in TECH1 and TECH2. Fitnet is a free physical activity app that can be downloaded from the App Store. The app features workout videos of varying lengths and difficulty levels (e.g., yoga, strength conditioning, dance fitness, etc.), and was used to encourage and guide child physical activity at home. The app integrates theoretically supported behavioral change strategies such as goal setting, feedback, and personal tailoring. Fitnet was downloaded on the tablets and each family was given their own program-specific login. While the accounts were open to the entire family, families were instructed to use the app 1) together, or 2) parents could guide child use of Fitnet, or 3) older children could use the app independently. Participating children were initially instructed to use Fitnet for 30 minutes per week and the usage goal increased every week, with the ultimate goal of reaching the recommended 60 minutes of physical activity per day for children.[83] Total Fitnet usage was recorded in minutes per week from the data report automatically generated by Fitnet.

Web-based health coaching sessions. TECH2 participants received tailored videoconferencing health coaching sessions via Skype on the digital tablets. Trained health coaches provided individualized support for each family and sessions were conducted in Spanish or English depending on family preference. Prior to conducting sessions, the health coaches were trained on protocols, motivational interviewing, and behavior modification techniques. Protocols were established for conducting the videoconferencing sessions and materials were created to support participants' use of Skype for the web-based health coaching sessions (Appendix 2). Additionally, an acceptability survey was developed to more comprehensively examine how the web-based health coaching sessions influenced parent and child health behavior change, and the surveys included closed- and open-ended questions (Appendix 3). Five sessions were scheduled for families across the duration of the 12-week intervention (one every other week) and sessions were anticipated to last 30 minutes, but some families opted to alter this schedule based on availability and calls lasted as long as needed. The goal for each family was to receive five sessions and the purpose was to reinforce teachings from the FBBG program. While it was encouraged that the calls be conducted together as a family, the attendance for each call could vary between families. Families and health coaches were given unique, program specific usernames and Skype accounts to ensure personal security. Additionally, the health coaching team met regularly to discuss common challenges presented by families, review recommendations, and troubleshoot any technology issues.

Measures. Participants completed measures at baseline and post-intervention (12-weeks). Parents self-reported race/ethnicity (white/Caucasian, black/African American, Hispanic/Latino, other), date of birth, gender (male/female), and insurance status (private, Medicaid, no insurance) for themselves and their child at baseline. Though no data were collected on the use of government assistance, educational attainment or household income, self-reported insurance status was used as a proxy of socio-economic status. Trained program staff objectively collected anthropometric data. Child height and weight was measured with participants wearing light clothing and no shoes. Height was measured in centimeters using a stadiometer (Holtain Ltd., Crymych, Dyfed, UK), and weight was measured in kilograms using a digital scale (Temp-StikDigitron 8000 digital scale National Medical Corp., Temp-Stikcorp). Height and weight were used to calculate BMI, and age-and-sex adjusted percentiles for height and weight.[87] Child BMI percent above the 95th percentile was used as the primary outcome (%BMI_{p95}).

Process measures included attendance at the 12 in-person treatment sessions, Fitnet usage, and Telemed session participation. Total Fitnet usage was objectively reported in minutes per week and recorded directly from the data report automatically generated by Fitnet. The trained health coaches tracked Telemed session attendance and completed reports to summarize the topics discussed with each family. Acceptability surveys were developed for this study to assess Fitnet use and the Telemed sessions. Participants in TECH1 and TECH2 responded to open-ended question on Fitnet acceptability and usage (e.g., “What could be done to improve Fitnet?”), though wording of the questions varied slightly for each cohort. TECH2 participants completed a post-intervention survey assessing how helpful the Telemed sessions were in achieving parent and child behavior change goals. Questions asked parents to rate their experience separately from their child’s and response options were rated on a 5-point scale

(1=not helpful; 5=extremely helpful). Additional participant feedback was provided via open-ended questions (Appendix 3).

Analysis. Descriptive statistics were used to assess baseline participant characteristics. In-person weekly session attendance, Fitnet usage, Telemed session participation, acceptability surveys, and open-ended questions were summarized for completers. For the purposes of this study, participants were considered completers if child height and weight measures were collected at baseline and post-intervention. T-tests and chi-squared tests assessed baseline differences between cohorts, and differences between completers and non-completers at post-intervention. Linear regression models were used to examine within-group %BMI_{p95} change for each cohort (NO TECH, TECH1, TECH2). Then, to compare between group effects, linear regression models were conducted to evaluate differences in child weight status between the technology cohorts and the previous HH cohorts that received no technology (cohorts 1-22, n= 282). Model 1 controls for clustering by family only and Model 2 controls for clustering by family, race/ethnicity, age, and gender. Regression models were also used to examine differences in %BMI_{p95} change between the three cohorts and HH only. Finally, linear regression models were used to examine the intervention components (i.e., treatment attendance, Fitnet usage, and Telemed sessions) as predictors of child %BMI_{p95} change in each of the TECH cohorts. Model 3 tested Fitnet usage and treatment attendance on %BMI_{p95} change in TECH1, while Model 4 tested Fitnet usage, treatment attendance, and Telemed sessions on %BMI_{p95} change in TECH2; both models control for clustering by family. All analyses were conducted using STATA version 14.

Results

Baseline descriptive characteristics are presented in **Table 7**. A total of 64 children were recruited and participated in one of the three cohorts (NO TECH n=21; TECH1 n=20; TECH2 n=23). On average children were 9.6 ±3.1 years of age, 32.8% female, 84.4% Hispanic, and had a mean BMI% of 98.6(1.6). Parents were predominately Spanish-speaking (68.8%) and all study parents were female (100.0%, n=61). There were no differences between the three cohorts by child age (F=0.06, p=0.90), child gender (χ^2 =5.6, p=0.06), parent language (χ^2 =0.8, p=0.69), or child baseline BMI% (F=1.9, p=0.20), but the cohorts did differ in their racial/ethnic composition (χ^2 =16.6, p=0.01) at baseline.

Retention and engagement data for completers are presented in **Table 8.** and described below. Though not significantly different (χ^2=1.2, p=0.56), post-intervention retention rate was slightly lower in NO TECH with 66.7% (n=14) of children completing BMI follow-up at 12-weeks. TECH1 had 80.0% retention (n=16) and the TECH2 had 78.3% retention (n=18). There were no differences between completers and non-completers by child age (F(1,62)=0.2, p=0.70), child gender (χ^2 = 0.02, p=0.88), race/ethnicity (χ^2 =1.6, p=0.67), parent language (χ^2 =1.6, p=0.21), or child baseline BMI% (F(1,62)= 2.1, p=0.15).

NO TECH participants attended an average of 10.3 ±1.1 in-person treatment sessions out of 12. Participation in TECH1 and TECH2 was slightly lower, with an average of 9.4 ±2.0 and 9.6 ±2.0 sessions, respectively. All but three families in TECH1 (81.3%) and every family in TECH2 (100.0%) used Fitnet at least once. The total number of usage minutes in the TECH1 was 225.2±148.4 compared to 425.4±275.6 minutes in TECH2. Participants in the TECH2 used Fitnet significantly more than participants in TECH1 (F=5.6, p=0.02). Every family in TECH2 received at least one Telemed session and almost half (44.5%) received the goal of five sessions or more (M=3.4 ±1.7). Of the 14 TECH2 families (n=18 child participants), only 3 families requested to participate in the web-based health coaching sessions in English; 2 Spanish-speaking health coaches conducted sessions with the other 11 families. Telemed sessions were intended to be 30 minutes and on average lasted 30 minutes to 1 hour. Health coaches reported requiring significant time and multiple call attempts to reach families, so the total time period to make and complete calls was about 1-2 hours. Typically, parents and children attended sessions together, but on occasion, just parents or just children would participate due to scheduling conflicts for the entire family. The primary topics covered in the sessions as reported by the health coaches included specific goal-setting, reinforcing benefits to physical activity and healthy eating, addressing reported barriers to making lifestyle changes (e.g., lack of time, knowledge), initiating and supporting new routines, and reviewing content from weekly FBBG sessions, especially if families missed a session.

***Child weight status*.** NO TECH and TECH1 participants had no significant change in $\%BMI_{p95}$ at post-intervention (β=-0.79 (0.38), p=0.53, and β=-0.81 (1.21), p=0.50, respectively) (**Table 9, Figure 5.**). TECH2 did have significant pre-post reductions in child $\%BMI_{p95}$ (β=-3.71 (0.74), $p<0.001$). Examining between group differences, when compared to the previous 22 HH cohorts that received no technology TECH2 participants had significantly greater reductions in $\%BMI_{p95}$ (β=-2.42 (0.83), p=0.004). In Model 3 Fitnet and FBBG treatment sessions were not significant predictors of change in child $\%BMI_{p95}$ at post-intervention. In Model 4, Fitnet, FBBG treatment sessions, and Skype were not significant predictors of change in child $\%BMI_{p95}$ at post-intervention.

Treatment Acceptability. Overall, 100% of TECH2 parents reported that the online sessions were "very" or "extremely" helpful in enhancing their ability to reach *their own* health goals

(M=4.4 ±0.5), 90% rated them just as helpful for their *children* (M=4.3 ± 0.7), and 100% said they would be "very" or "extremely" enthusiastic to recommend online sessions to other families (M=4.8±0.5). Parents reported that the online sessions "*helped to keep my daughter active*," "*motivated us*," and "*when I had doubts they helped me find the solution*." Other parents expressed benefits related to health behavior change such as "*learning a lot of things…to eat portions and fruits, vegetables*," and "[my kids] *want to do more and more exercises*."

In response to open-ended Fitnet acceptability surveys, participants reported "*Exercises are very good for my child…"* and "[there are a] *variety of hard and easy exercises*." TECH1 participants who completed a survey said they would use Fitnet if it were available after the program ended and among participants in TECH2 who completed a survey reported Fitnet was very helpful for becoming active, and said it helped them stay active.

Discussion

The purpose of the current study was to assess the addition of technology components to an existing pediatric obesity treatment program. To our knowledge, this is the first study to examine technology adjuncts in a treatment program in low-income, minority youth. Participants in the TECH cohorts successfully used the provided technology components and this engagement did not seem to displace participation in in-person sessions. Additionally, both TECH cohorts had slightly higher retention at post-intervention. There has been a great deal of attention in recent years focused on how to get low-income, minority participants to stay in weight loss programs,[115] and our results suggest that supplementing treatments with Telemed support may be one option to consider.

Interestingly, TECH2 is the only cohort that demonstrated significant reductions in child weight status at post-intervention. TECH1 participants did not see significant changes in child weight status at post-intervention and Fitnet usage was very low overall. On average, TECH1 participants used Fitnet about 20.5 minutes per week and TECH2 participants used Fitnet about 38.7 minutes per week. While this indicates that participants were somewhat successful in reaching the initial goal of 30 minutes per week, they did not increase their goals or their Fitnet usage over the course of the study. This might suggest that participants did not find the technology as supportive in helping them reach their daily 60 minute physical activity goals, or that other strategies and activities presented in the group sessions were more appealing (e.g., outdoor activities, physical activity games, sports, etc.). Additional questions in follow-up surveys could have better probed for this information and should be included in future studies. Telemed session participation in TECH2 was significantly associated with reductions in $\%BMI_{p95}$, and participants in TECH2 used Fitnet significantly more than participants in the TECH1. Therefore, it is possible that the Telemed sessions increased participants' self-efficacy for using other technologies, or participants were able to receive tailored support for the Fitnet app during their Telemed sessions. More rigorous study designs, that include randomization, baseline evaluations of technology use, and well-measured changes in technology-related self-efficacy, would help disentangle these findings.

While implementing the technology components, there were some barriers and challenges. The most common technology issue was weak or inconsistent Internet connection. While we do not fully know the extent to which this impacted Fitnet usage, this was an issue during the web-based health coaching calls. Some calls were dropped or required multiple attempts to establish a good connection. Another barrier for participants was logging out and logging back in. Many participants had issues remembering passwords or using proper tabs (i.e., "login vs. sign up"). Lastly, specific to the web-based health coaching sessions, some families had issues with the cameras on their tablets and would only be able to use voice call instead of video. Despite these barriers, the health coaching sessions were very well received and seem to have positively impacted child weight status. The tailored one-on-one support provided by health coaches could have been very impactful in addressing issues and challenges that families did not have time to discuss in the weekly group sessions, or did not feel comfortable talking about in a group setting.

Although this study provides promising evidence for the use of technology in pediatric obesity treatment, there are limitations. First, this was a treatment-seeking sample from an ongoing clinical program, and families were not randomly assigned to cohorts, limiting experimental control and subsequently, the conclusions that can be drawn. Second, all participants in the TECH cohorts were provided with digital tablets and data plans to use for the duration of the study, limiting external validity. Next, technology malfunctions could have disrupted participants' ability to use the technology as intended, presenting a threat to internal validity. All of participating parents were female, presenting another limitation. While there were no specific efforts to recruit dads, all adults living in the households were encouraged to attend the weekly FBBG sessions. In the future, auxiliary adults who attend should be tracked and measured. Also, child co-morbidities were not assessed, limiting an understanding of the challenges facing children and families in achieving health behavior change and significant decreases in child weight status. Lastly, as a pilot study, all family members in the respective TECH cohorts were invited to use the fitness app and participate in the Telemed health coaching sessions. In order to do so, families were assigned a single digital tablet with one user account for Skype, and one user account for Fitnet. Therefore, we were unable to determine how parents and children varied in their use of the components, or if parents and children found the various technology components differentially acceptable.

While the technology was generally accepted, it is interesting to note that three families refused to accept and use the digital tablets out of concern for them getting lost or broken, even despite being told that they would not be held responsible. At the end of the study, all tablets distributed to study families were returned without any damage. Future studies should examine the willingness of participants to use their own technology devices to better understand the potential for dissemination. Dissemination approaches are likely feasible, even in hard-to-reach populations, given that 68% of adults in the United States have a smartphone, and even among low-income households, more than half (52%) are smartphone owners.[116] More research is also needed to learn how overall technology usage intersects with technology used for obesity treatment, especially given that excessive use of these platforms, including tablets and smartphones, is associated with obesity and related risk factors.[117] Future studies should more carefully examine how participant characteristics influence the usage of technology intervention components. For example, the effect of child age should be examined to better understand if older or younger children and their parents participated differentially. If so, strategies to better capture individual engagement are needed (e.g., weekly reporting via survey of who used the technology in the previous week). Lastly, the version of Skype that was used for this study did not provide tracking data on sessions. Future studies should use an upgraded version of Skype or other web-based communication platform that tracks call attempts, call duration, and session frequency. These data could be very useful for understanding how much time health coaches invested in providing tailored support to each family.

Conclusion

In summary, this study contributes novel information regarding the use of technology components as adjuncts to family-based treatment for pediatric obesity treatment in low-income minority youth. Technology components, specifically digital tablets with a fitness app and Telemed health coaching sessions, are typically used even by hard-to-reach populations, and are deemed highly acceptable when the necessary equipment is provided. The findings from this study support the use of Telemed health coaching as a promising strategy for improving child weight status in treatment programs and suggest that technology additions might improve outcomes by increasing providing tailored treatment support to families. Future studies should examine technology-based enhancements with larger samples, using designs that isolate effects.

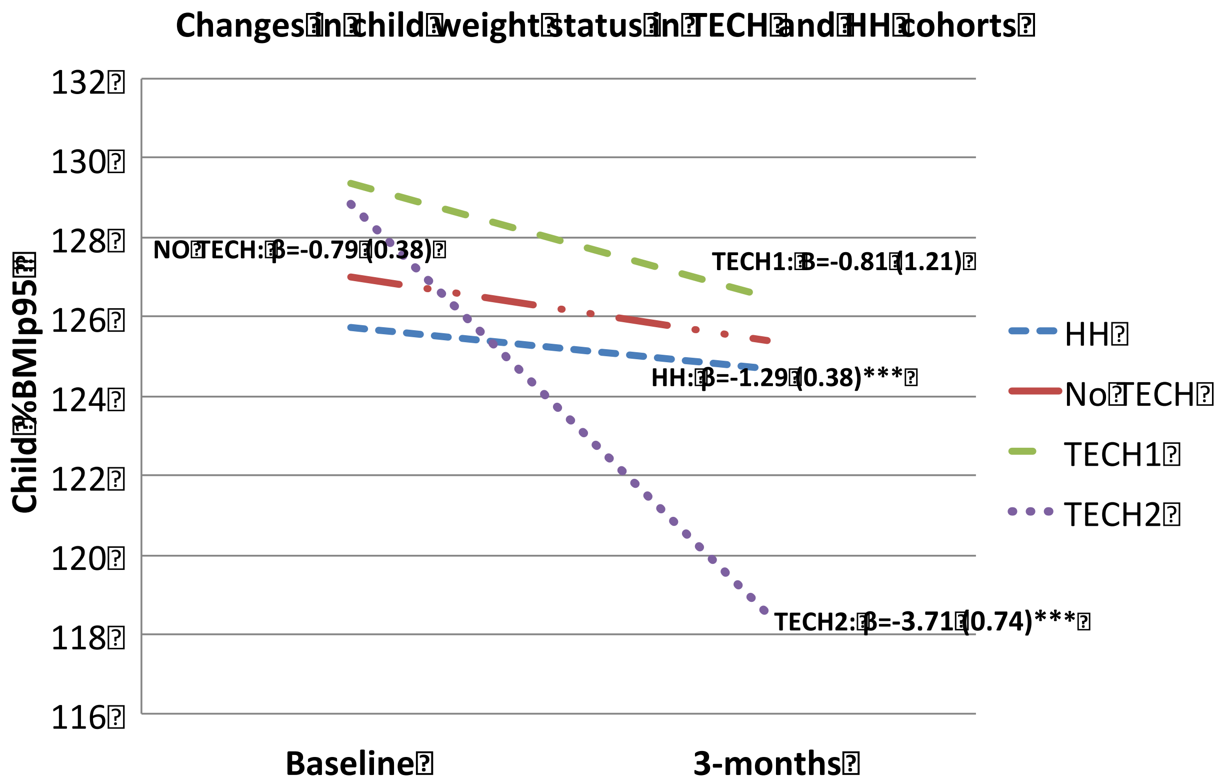

Figure 5. Technology adjuncts and changes in child weight status between baseline and post-intervention.

Data are presented as beta coefficients (standard errors)

%BMI$_{p95}$= body mass index percent above the 95th percentile; TECH= technology cohorts; HH= Healthy Hawks cohort; β= beta coefficient;

HH: n= 300 at baseline; n=201 at 3-months
NO TECH: n= 21 at baseline; n=14 at 3-months
TECH1: n=20 at baseline; n=16 at 3-months
TECH2: n=23 at baseline; n=18 at 3-months
***p<0.001

Table 7. Baseline descriptive characteristics and differences by technology cohorts.

	Total (n=64)	NO TECH (n=21)	TECH1 (n=20)	TECH2 (n=23)	p value
Age (years)	9.6 (3.1)	9.8 (1.4)	9.5 (3.6)	9.5 (3.2)	F(61)=0.06, p=0.90
Gender (%male)	67.2%	47.6%	80.0%	73.9%	χ^2 =5.6, p=0.06
Race/Ethnicity (%)					χ^2 =16.6, p=0.01*
White/other	3.1%	0.0%	10.0%	0.0%	
Black	12.5%	33.3%	0.0%	4.3%	
Hispanic	84.4%	66.7%	90.0%	95.7%	
Language (% Spanish)	68.8%	42.9%	75.0%	72.2%	χ^2 =0.8 p=0.69
BMI percentile	98.6 (1.6)	98.7 (1.4)	99.1 (0.6)	98.2 (2.2)	F(61)=1.9, p=0.20

FBBG= Family-based behavioral group sessions only; TECH1= technology 1 cohort; TECH2= technology 2 cohort; BMI= body mass index
* p<0.05; *** p<0.001

Table 8. Completers' intervention participation by treatment component for each technology cohort.

	NO TECH n=14	TECH1 n=16	TECH2 n=18	p value
Retention at post-intervention	66.7%	80.0%	78.3%	χ^2 =1.2, p=0.56
Treatment Session Attendance	10.3 (1.1)	9.4 (2.0)	9.6 (2.0)	F (2,45)=1.0, p=0.37
Fitnet Usage (minutes)	--	225.2 (148.4)[a]	425.4 (275.6)	F (1, 29)= 5.6, p=0.03*
Skype Session Attendance	--	--	3.4 (1.7)	--

Treatment session range 5-12 sessions; TECH1 Fitnet usage range 41-507 minutes; TECH2 Fitnet usage range 53-873 minutes; TECH2 Skype session range 1-6 sessions
*p<0.05
[a] Three families would not accept the digital tablets at the beginning of the study; n=13 for Fitnet Usage in TECH1

Table 9. Change in child weight status at post-intervention for each technology cohort.

		β (SE)	CI	p-value
FBBG				
Model 1[a]		-0.79 (0.38)	(-3.25, 1.68)	0.53
Model 2[b]		-0.89 (1.31)	(-3.47, 1.69)	0.50
TECH1				
Model 1[a]		-0.81 (1.21)	(-3.19, 1.57)	0.50
Model 2[b]		-1.03 (1.14)	(-3.29, 1.23)	0.37
Model 3[c]	Treatment Sessions	-0.37 (0.28)	(-1.00, 0.26)	0.21
	Fitnet Usage	0.02 (0.01)	(-0.005, 0.05)	0.10
TECH2				
Model 1[a]		-3.71 (0.74)	(-5.16, -2.26)	<0.001***
Model 2[b]		-3.96 (0.75)	(-5.43, -2.49)	<0.001***
Model 4[d]	Treatment Sessions	-0.75 (0.36)	(-1.53, 0.03)	0.06
	Fitnet Usage	0.001 (0.002)	(-0.004, 0.006))	0.67
	Telemed Sessions	-0.26 (0.41)	(-1.16, 0.63)	0.54

[a] Model 1 is adjusted for clustering by family
[b] Model 2 is adjusted for clustering by family, gender, and race/ethnicity
[c] Model 3 is adjusted for clustering by family and includes treatment session attendance and fitnet usage as predictors of $\%BMI_{p95}$ change
[d] Model 4 is adjusted for clustering by family and includes treatment session attendance, Fitnet usage, and Telemed session participation as predictors of $\%BMI_{p95}$ change

$\%BMI_{p95}$= body mass index percent above the 95th percentile; HHP+= Healthy Hawks Primary Plus; β= beta coefficient; SE= standard error; CI= 95% confidence interval; ***p<0.001

CHAPTER 6: EMBEDDING A FAMILY-BASED OBESITY TREATMENT INTERVENTION IN A PEDIATRIC CLINIC IMPROVES RETENTION AND CHILD WEIGHT STATUS IN LOW-INCOME MINORITY YOUTH

Overview

Low-income minority children are disproportionately affected by obesity, yet are underrepresented in treatment studies and have higher rates of attrition when enrolled in treatment programs. Collaborations between family-based treatment programs and primary care providers are an innovative approach to treatment and a way to provide more comprehensive care. The purpose of this study is to determine the effect of embedding a family-based behavioral group (FBBG) treatment program in a pediatric clinic, on participant retention and changes in child weight status, compared to a standard treatment program.

Children (2-18 years of age, body mass index (BMI) $\geq 85^{th}$ percentile) and their parents were recruited from a single pediatric clinic for participation in a 12-week FBBG obesity treatment program (Healthy Hawks Primary Plus [HHP+]). Children were referred by primary care providers (PCPs) and enrolled by a bi-lingual clinic-based recruitment coordinator. Participants also engaged in visits with their PCP between post-intervention and 1-year follow-up to reinforce concepts from the FBBG sessions. Child BMI percentage above the 95^{th} percentile ($\%BMI_{p95}$) was measured as the primary outcome at baseline, post-intervention and 1-year follow-up. The impact of the three HHP+ cohorts were compared to the mean effects of a standard treatment program, Healthy Hawks (HH), conducted in 25 cohorts over the past 10 years.

Both HH and HHP+ participants had significant reductions in $\%BMI_{p95}$ at 12-weeks post-intervention (HH: β=-1.29(0.36), p=0.000; HHP+: β=-2.12(0.93), p=0.03). At 1-year follow-up, only participants in the HHP+ program had significant reductions in child weight status (β= -2.48(1.15), p=0.03) and these between group differences were significant after controlling for race/ethnicity, gender, and age (β=-3.24(1.48), p=0.03). Participation in HHP+ significantly improved retention at 1-year (HH: 38.3%, HHP+: 73.9%, χ^2 =20.59, $p \leq 0.001$) and the frequency of PCP visits was correlated with retention at 1-year (r=0.69, $p<0.001$).

These findings suggest that community-clinic partnerships might improve longer-term retention and greater reduction in child weight status in obesity treatment programs enrolling at-risk children. Future studies should replicate these findings using larger samples and more rigorous designs to elucidate effects.

Introduction

Childhood obesity remains a pressing public health issue. Despite studies indicating rates are stabilizing in some subgroups,[1] low-income minority children are disproportionately affected and disparities might be widening in these populations.[99] Overweight and obesity affect 41.2% of Hispanic children and 41.8% of non-Hispanic black children compared to 29.0% of non-Hispanic white children.[36] A primary concern is that obesity trends track into adulthood and increase risk for associated co-morbidities, however, the reality is that obese children are already experiencing consequences of obesity-related disease.[118] Children with obesity are more likely to develop type 2 diabetes, hypertension, dyslipidemia, sleep apnea, and steatohepatitis,[119] and require immediate intervention.

Currently, multicomponent family-based programs provide the strongest evidence for impact in the treatment of childhood obesity.[59,62] However, low-income minority populations are underrepresented in these studies and more data are needed to inform programs designed for long-term impact.[101,120] One strategy that has been suggested for reaching this population is embedding family-based programs in existing community settings where families currently seek services and support, such as primary care clinics.[121] This type of integration might assist in reaching low-income families by overcoming barriers to receiving care, improving trust, and involving practitioners who already engage with these populations.[122,123] Generally, low-income families are less likely to participate in research,[124] sometimes due to higher levels of stress and lower levels of education.[125] Parents in these populations are less likely to recognize child weight issues, and consequently, are also less likely to participate in treatment programs.[126] These weight loss programs are often time-intensive and costly to operate and attrition rates among at-risk populations are high.[127,128] Therefore, strategies are needed to improve the reach, retention, and impact of these types of programs.

Partnerships between primary care and community programs, including physician program referral, have been suggested as a strategy for more comprehensively addressing pediatric obesity.[65] These types of partnerships can alleviate the barriers and burdens experienced by medical practitioners attempting to address childhood obesity within the scope of their practice, including lack of time, training, and resources.[129] Recent studies have piloted similar treatment approaches in low-income, minority families. In one study testing a physician referred family-based intervention, children (8-12 years, 54% black, BMI ≥85th percentile) showed significant reductions in BMI z-score (BMI-z) at 12-weeks, but sample size was small (n=26) and no long-term follow-up was measured.[130] Another study at a pediatric specialty hospital recruited participants via physician referral and tested a 12-month weight management program in low-income children (7-18 years, BMI ≥85th percentile, 59.7% Medicaid, 67.3%

black).[107] While BMI-z significantly improved, the study suffered from very high attrition (81% loss to follow-up). An additional study recruited low-income Latino children (9-12 years, BMI ≥85th percentile) to participate in a 6-month family-centered, primary care based program.[65] Though retention rates were slightly better in this study (63%), there were no significant changes in child weight status at post-intervention.

Given the promise and challenges associated with testing family-based programs in a clinic setting, the purpose of this study is to examine the efficacy of a community-clinic partnership to deliver a family-based behavioral group (FBBG) treatment program in a pediatric clinic for a low-income, predominately Hispanic population. It is hypothesized that embedding the program in a pediatric clinic setting and engaging physicians to provide intervention support will improve child weight outcomes and retention compared to a standard treatment program. The primary outcome will examine change in child weight status at post-intervention and 1-year follow-up. Secondary outcomes will examine participant recruitment and retention.

Methods

Interventions

Healthy Hawks (HH) is a standard, 12-week family-based behavioral group (FBBG) pediatric obesity treatment program.[102] The HH intervention has been ongoing for over 10 years and uses a multi-site, multi-strategy recruitment approach to enroll participants. HH participants are recruited at health fairs, community events, and via urban pediatric clinics in the Kansas City area, serving predominately low-income children. Interested families are given a number to call to receive an intake form, which is completed via mail. Once enrolled, HH parent-child dyads participate in 12 weekly 2-hour FBBG sessions focused on strategies to improve health behaviors and weight status. The program is offered free of charge for all participants and additional details about the HH program are available elsewhere.[102] The HH program has been active since 2006. Participants are enrolled on an ongoing basis and new cohorts begin approximately every 4-5 months. As a comparison group, this study includes the first 25 HH cohorts (implemented from April 2006 to February 2015) with at total of 300 participants. Though the HH program has been shown to improve child weight status in the short-term, outcomes are modest and attrition has been high. Therefore, an enhanced treatment program was designed to test strategies to improve reach, retention, and outcomes.

Starting in 2014, Healthy Hawks Primary Plus (HHP+) was developed by embedding HH in a single pediatric clinic. Compared to HH, HHP+ has 4 key features: 1) HHP+ is embedded in a pediatric clinic; 2) a bi-lingual clinic-based recruitment coordinator manages referrals from physicians, enrolls participants, and tracks participation; 3) physicians are trained and deliver bi-monthly visits between post-intervention and 1-year follow-up; 4) program tracking and lifestyle goals are integrated into the electronic medical records systems to support physicians in providing ongoing care. The goal of this enhanced treatment program was to test a community-clinic collaboration to provide comprehensive, innovative care to populations most affected by obesity.

The HHP+ program was initiated in May 2014 and to date, 46 participants have been enrolled and participated as a part of 3 different cohorts. A bi-lingual program coordinator was hired and trained to enroll participants at the clinic who were referred directly from their primary care providers (PCPs). Participants were enrolled on a rolling, non-randomized basis and once enrolled, HHP+ parent-child dyads participated in the same 12-week FBBG intervention as HH participants. Then, between post-intervention and 1-year follow-up, HHP+ participants engaged in visits with their PCPs reinforcing the health behaviors emphasized in the FBBG sessions. HH participants did not receive any intervention between post-intervention and 1-year follow-up. The clinics serving the HH participants are distinct from the clinic recruiting HHP+ participants, while the combined FBBG sessions are held in a community meeting space. A diagram showing the intervention components for HH and HHP+ is presented in **Figure 1**.

In order to deliver counseling during the bi-monthly follow-up visits, PCPs at the HHP+ clinic received training on *1-2-3-4-5 Fit-tastic!* a program designed to promote healthy lifestyles and weight.[131] The program has five messages that align with the recommended guidelines for the prevention, assessment and treatment of child overweight and obesity,[63] and these messages and corresponding goals were encouraged during the PCP visits. The five messages include daily diet, physical activity, and lifestyle recommendations: 1 or more hour of physical activity; 2 hours maximum screen time; 3 servings of low- or non-fat milk or yogurt; 4 servings of water, not sugary drinks; 5 or more servings of fruits and vegetables. These messages also align with the American Medical Association Expert Committee recommendations for childhood obesity prevention and treatment strategies delivered via physicians as part of routine care.[132] HHP+ participants were encouraged to visit their PCPs bi-monthly after the FBBG program, but participants could visit as many times as deemed necessary. The clinic-based coordinator scheduled visits and attendance was recorded.

Another feature of the community-clinic collaboration in the HHP+ program was the tracking of program participation and lifestyle goals in the Electronic Medical Records (EMR) system. During the FBBG sessions, the clinic-based program coordinator tracked HHP+ participant attendance and logged participation data into the EMR to keep the PCPs connected to progress being made in the community-based program. The *1-2-3-4-5 Fit-tastic!* goals were also integrated into the EMR system. At the follow-up visits, PCPs could reference the information in the EMR for patients participating in the HHP+ program and be prompted to provide ongoing support and set new goals.

HH and HHP+ eligibility

Inclusion criteria were the same for both HH and HHP+ programs. In order to participate in HH or HHP+ children must have a BMI greater than or equal to the 85^{th} percentile and can not have any other conditions that would prevent them from participating in group-based programs without additional support (e.g., severe Autism Spectrum Disorder). Parents must be able to speak and write in Spanish or English and be willing to attend sessions and complete measures. While other studies working with high-burden populations provide childcare to support parent attendance, in the HH and HHP+ programs all family members were encouraged to attend FBBG sessions and actively participate. If siblings attended sessions and were eligible, they were also enrolled. Regardless of enrollment status, all family members who attended sessions participated in their appropriate groups (parents participated in one of two groups based on language preferences (Spanish/English); children participated in groups based on age).

Measures

In both programs, all baseline measures were administered and collected at the beginning of the first session after parents provided consent and children (≥7 years) provided assent. Parents self-reported race/ethnicity, date of birth, and gender for themselves and their child. Race/ethnicity was combined into a single variable and included the following categories: 1= white, Caucasian, or other; 2= black or African American; 3=Hispanic. Child height and weight were objectively measured at baseline, post-intervention (12-weeks), and 1-year follow-up. Trained program staff completed measures with participants wearing light clothing and no shoes. Height was measured in centimeters (cm) to the nearest 0.1cm using a stadiometer (Holtain Ltd., Crymych, Dyfed, UK), and weight was measured to the nearest 0.01 kilograms (kg) using a digital scale (Temp-StikDigitron 8000 digital scale National Medical Corp., Temp-Stikcorp). Height and weight were used to calculate BMI, and age-and-sex adjusted percentiles for height and weight.[87]

The primary outcome measure was child BMI percentage above the age-and-sex specific 95^{th} BMI percentile (%BMI_{p95}). This variable is derived using the appropriate SAS code for the CDC growth charts,[87] and is recommended as an appropriate metric for capturing change in adiposity in severely obese children enrolled in treatment programs.[6] This measure is strongly correlated with other child BMI assessments, and a score of 100 is equivalent to the 95^{th} BMI percentile.[7] A scientific statement from the American Heart Association recommends that BMI ≥120% of the 95^{th} percentile be used as a measure of severe obesity in children ≥ 2 years of age.[93]

Data Analytic Plan

Baseline descriptive characteristics were assessed for all HH and HHP+ participants and differences between groups were examined. This non-equivalent two-group design was assessed using linear regression models to examine differences between child %BMI_{p95} in HH and HHP+ programs, controlling for clustering within families. Secondary models were adjusted for race/ethnicity, age, and gender in addition to clustering within families. Changes in child %BMI_{p95} were assessed at post-intervention (12-weeks) and 1-year follow-up (one year from baseline). Retention was measured at each time point and differences in retention were compared between HH and HHP+. The total number of physician visits attended between post-intervention and 1-year follow-up was recorded and correlated with participation retention at 1-year follow-up using Pearson's correlations.

Results

Participant Characteristics. Descriptive characteristics for HH and HHP+ are presented in **Table 10**. A total 46 participants were enrolled in the HHP+ program over three cohorts (Mean (*M)*= 15.3 per cohort) and the HH program enrolled 300 participants in 25 cohorts (*M*= 12.0 per cohort). HHP+ participants were 9.6±0.5 years (range 2-16 years), had a baseline BMI of 28.2±0.8, were predominately Hispanic (87.0%), and Spanish-speaking (76.1%), 23.9% female, and 91.1% received Medicaid. HHP+ parents were 100.0% female, had a mean BMI of 31.9±0.8 and 95.4% were classified as overweight or obese. HH participants were on average 10.1±0.2 years (range 2-18 years), had a baseline BMI 28.7±0.4, racial/ethnic breakdown of 18.0% white, 22.3% black, 59.0% Hispanic, 0.7% other, were 55.3% female, 52.7% Spanish-speaking, and 70.0% received Medicaid, 20.7% had private insurance, and 9.3% reported having no insurance.

Baseline group differences. HH participants were not significantly different from HHP+ participants at baseline in age, BMI, parent gender, or parent BMI. However, they did differ significantly in child gender ($p<0.001$), race/ethnicity ($p=0.001$), language ($p=0.003$), and insurance status ($p=0.003$).

Effects of treatment group on Child %BMI$_{p95}$. At post-intervention, HH participants had significant reductions in %BMI$_{p95}$ (β=-1.29(0.36), p=0.36). HHP+ participants also had significant reduction in %BMI$_{p95}$ at post-intervention (β=-2.12(0.93), p=0.03) and between group differences were not significant (β=-0.83 (1.01), p=0.41). At 1-year follow-up, HH participants reductions in%BMI$_{p95}$ were not significant (β=-0.51 (1.07), p=0.64), but HHP+ participants did have significant reductions in %BMI$_{p95}$ (β=-2.48 (1.15), p=0.03). After controlling for race/ethnicity, age, and gender, these between group differences were significant (β=-3.24 (1.48), p=0.03). The changes in $\%BMI_{p95}$ for the HH and HHP+ cohorts are visually presented in **Figure 6** and listed in **Table 11**.

Effect of physician visits**.** On average, HHP+ participants had 4.9±2.3PCP visits between post-intervention and 1-year follow-up. PCP visits were positively and significantly associated with retention at 1-year follow-up (r=0.69, p<0.001).

Retention. At post-intervention, 67.0% of HH participants completed follow-up compared to 76.1% of HHP+ participants, and these differences were not significant (χ^2 =1.52, p=0.22). However, at 1-year follow-up participants in HHP+ were significantly more likely to complete follow-up compared to HH participants (χ^2 =20.59, p≤0.001); only 38.3% of baseline HH participants completed 1-year follow-up compared to 73.9% of HHP+. Of those who completed post-intervention (12-weeks), 57.2% of HH completed measures at 1-year, while 97.1% of HHP+ who completed post-intervention, completed 1-year follow-up. When examining HHP+ only, there were no differences between HHP+ completers and non-completers on any variables (age, gender, race/ethnicity, language, insurance type, parent baseline BMI, parent BMI change, or child baseline BMI) at post-intervention or 1-year follow-up.

Discussion

PCPs have been identified as important stakeholders and collaborative partners for efforts addressing pediatric obesity.[69] The current study examined the impact of embedding a FBBG intervention in a pediatric clinic and found that providing a treatment program in partnership with a pediatric clinic along with providing follow-up visits with the PCPs significantly improved participant retention and child $\%BMI_{p95}$ at 1-year follow-up compared to a standard 12-week program. A similar study, including FBBG approaches and direct support from PCPs also showed significant improvements in weight status in children 2-5 years.[70] The current study extends these findings to include predominately ethnic minority children 2-16 years of age. Another study that did include an ethnically diverse population of children with obesity, involving older children 8-16 years, found that providing lifestyle intervention sessions for12-months sustained treatment effects at 24-months, but the study still experience high rates of attrition.[133]

High attrition rates are common among Hispanic and African American children participating in obesity treatment trials.[115] This not only presents challenges for drawing conclusions about effective strategies and examining long-term impact, but also indicates programs might not be working in these populations. The retention rates observed in HHP+ provide promising evidence for much-needed strategies to improve retention in these groups. There were 46 participants enrolled in the HHP+ group at baseline and 35 (76%) completed follow-up at 12-weeks. Of those, all but one completed measures at 1-year follow-up. This suggests that if participants can be retained at post-intervention, the community-clinic partnership could support participant retention longer-term. Additionally, it is relevant to note that the bi-monthly physician visits were billed by the pediatric clinic to participants' respective insurance provider. This suggests potential for translation and generalizability to other clinic-based settings and offers a strategy for supporting the cost of pediatric obesity treatment programs.

There are various reasons why this approach could have improved participants' retention and 1-year %BMI_{p95} outcomes. First, using a community-clinic collaboration to increase program credibility has been shown to be an effective retention strategy in other childhood obesity programs in at-risk children.[134] Increasing overall intervention contact and providing opportunities for one-on-one tailored assistance from PCPs could have also contributed to improved retention and reductions in child weight status.[135]

The additional self-monitoring that occurred as a result of attending the PCP visits could have influenced retention and child $\%BMI_{p95}$ improvements. Beyond the brief training delivered to PCPs and prompts delivered via EMR, we are not sure what PCPs focused on in each sessions and we do not know the extent to which 1-2-3-4-5 Fit-Tastic! was discussed or delivered. However, we do know that children were weighed at every visit and parents and children set goals for future success based on personal lifestyle modification targets. Self-monitoring is a theoretical construct that is central to behavior change,[136] and is implicated in long-term obesity reduction in children.[62] In a meta-regression of healthy eating and physical activity interventions among adults, interventions that included self-monitoring and one other behavior change technique were significantly more impactful than any other intervention.[137] Despite the ubiquitous inclusion of self-monitoring in adult weight loss programs, behavior change techniques in children, including self-monitoring, warrant more investigation. There are multiple dimensions of self-monitoring to consider in family-based pediatric obesity treatment including parent self-monitoring, parent monitoring of child behavior, and child self-monitoring (based on age-appropriateness).

Despite promising findings to inform future studies, this study has limitations. First, HH and HHP+ programs were implemented using a non-experimental design, making results susceptible to threats to internal validity and limiting the causal inference that can be drawn from the findings. Next, while participants were encouraged to schedule PCP visits bi-monthly following the FBBG intervention, it is not clear from the attendance records that participants scheduled visits on regular intervals. Future studies should more closely monitor PCP visit frequency, content delivered by PCPs, and visit dose required for meaningful impact. Third, the final follow-up for this intervention was 1-year from baseline, but given the likelihood that children will continue to visit their PCP for regular care, longer-term follow-up should be planned to better measure the impact of this approach. It should also be mentioned that children were not assessed for the presence of co-morbidities (e.g., metabolic syndrome, type 2 diabetes, hypertension, etc.). Therefore, we could not evaluate whether or not there were other barriers to improving child weight status, or if PCPs were targeting other health conditions in addition to obesity in the PCP visits. Lastly, the findings from this study are limited by sample size. The HHP+ group has only had 46 participants enrolled to date. Though the preliminary findings are promising, future studies should conduct this study in larger samples to better assess between-group differences.

Conclusion

This study suggests that initiating a community-clinic partnership to deliver a traditional FBBG program in a pediatric clinic can improve participant retention and child %BMI_{p95} at 1-year follow-up. Hiring a clinic-based program coordinator, linking program efforts through EMR, and providing post-intervention PCP visits could be contributing to the improvements observed. These approaches can be used to bolster future child obesity intervention efforts in populations most in need of efficacious treatment.

Table 10. Baseline descriptive characteristics of HH and HHP+ participants.

		HH (n=300)	HHP+ (n=46)	p-value
Age (years)		10.1 (0.2)	9.6 (0.5)	0.31
Child BMI		28.7 (0.4)	28.2 (0.8)	0.64
Child Gender				<0.001***
	Female	55.3%	23.9%%	
Race/Ethnicity				0.001***
	White/other	18.7%	2.2%	
	Black	22.3%	10.9%	
	Hispanic	59.0%	87.0%	
Language				0.003*
	Spanish	52.7%	76.1%	
Parent Gender				0.14
	Female	95.1%	100.0%	
Insurance Type				0.003*
	Medicaid	70.0%	91.1%	
	Private	20.7%	--	
	None	9.3%	8.9%	
Parent BMI		33.9 (0.5)	31.9 (0.8)	0.10
Parent BMI classification				0.08
	Normal weight	8.8%	4.7%	
	Overweight	26.9%	27.9%	
	Obese	46.6%	62.8%	
	Severely obese	17.7%	4.7%	

HH=Healthy Hawks: HHP+= Healthy Hawks Primary Plus; BMI= body mass index

Data are presented as Means (Standard Deviations) for age, child BMI, and parent BMI measures. All other data are categorical and presented as percentages.

HH: n= 300 for measures of age (years), child BMI, child gender, race/ethnicity, language, parent gender, and insurance type; n=283 for parent BMI and parent BMI classification

HHP+: n=46 for measures of age (years), child BMI, child gender, race/ethnicity, language, and parent gender; n=45 for insurance type; n=43 for parent BMI and parent BMI classification

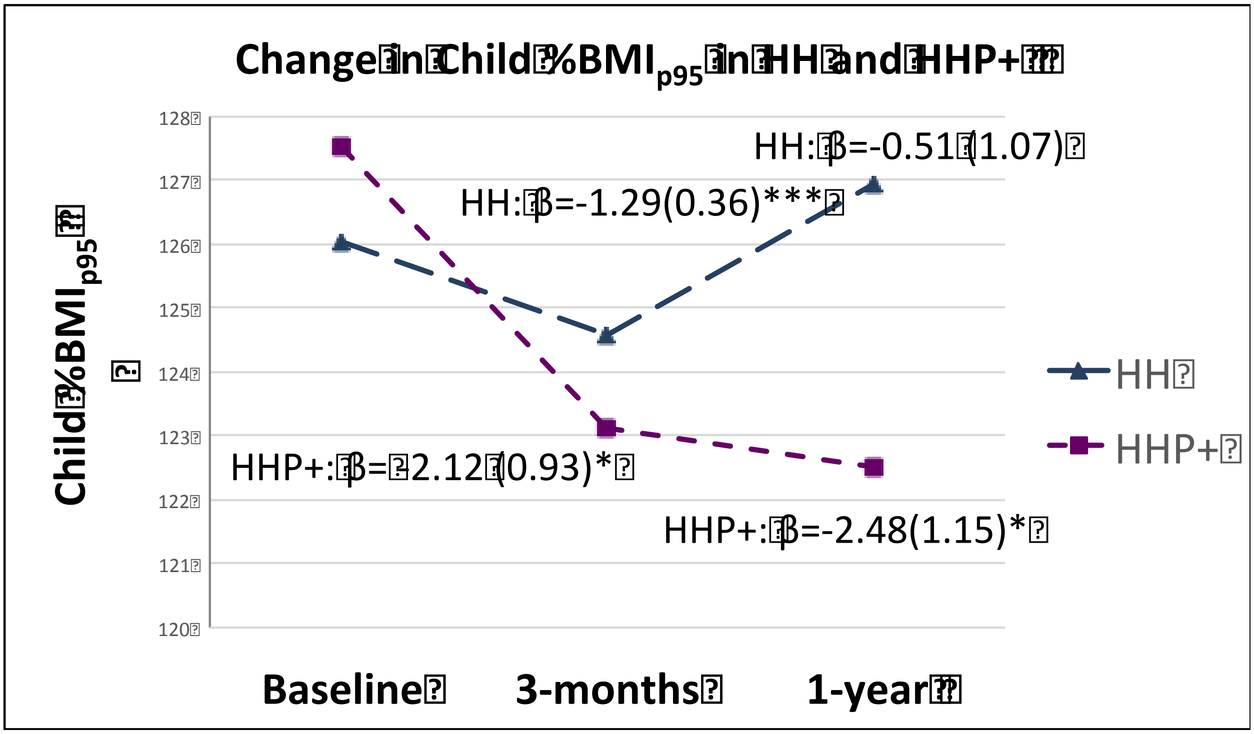

Figure 6. Changes in child %BMIp95 from baseline to post-intervention and 1-year follow-up in HH and HHP+ cohorts.

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Data are presented as beta (standard error); HH=Healthy Hawks: HHP+= Healthy Hawks Primary Plus; $\%BMI_{p95}$= child body mass index above the 95th percentile; β= beta coefficient

HH: n=300 at baseline, n=201 post-intervention and n=115 at 1-year
HHP+: n=46 at baseline, n=35 at post-intervention and n=34 at 1-year

*** $p<0.001$; *$p<0.05$

Table 11. Changes in child weight status in HH and HHP+ cohorts at post-intervention and 1-year follow-up.

Δ %BMI_{p95} [a]				Between-group differences		
	β(SE)	**CI**	**p-value**	**β(SE)**	**CI**	**p-value**
12-weeks						
HH	-1.29 (0.36)	-2.01, -.057	0.000***	-0.83 (1.01)	-2.82, 1.16	0.41
HHP+	-2.12 (0.93)	-3.96, -0.27	0.03*			
1-year						
HH	-0.51 (1.07)	-2.62, 1.61	0.64	-1.97 (1.57)	-5.08, 1.14	0.21
HHP+	-2.48 (1.15)	-4.75, -0.20	0.03*			

Δ %BMI_{p95} [b]				Between-group differences		
	β(SE)	**CI**	**p-value**	**β(SE)**	**CI**	**p-value**
12-weeks						
HH	-1.26 (0.37)	-1.98, -0.53	0.001***	-1.07 (0.99),	-3.03, 0.88	0.28
HHP+	-2.33 (0.91),	-4.12, -0.54	0.01*			
1-year						
HH	-0.22 (1.00)	-2.20, 1.77	0.83	-3.24 (1.48)	-6.17, -0.30	0.03*
HHP+	-3.45 (1.23)	-5.90, -1.01	0.006*			

[a] controlling for clustering by family only
[b] controlling for clustering by family, race/ethnicity, age, and gender

HH= Healthy Hawks; HHP+= Healthy Hawks Primary Plus; β= beta coefficient; SE=standard error; CI= confidence interval; %BMI_{p95}= child body mass index percentage above the 95^{th} percentile; Δ= change

HH post-intervention n=201; HH 1-year n=115
HHP+ post-intervention n=35, HHP+ 1-year n=34

*** $p<0.001$; *$p<0.05$

CHAPTER 7: SYNTHESIS

Overview of Findings

Childhood obesity is an imperative public health problem. Rates in the U.S. are disproportionately higher among groups of children less likely to be reached by current treatment programs (i.e., higher among black and Hispanic youth compared to their counterparts). Therefore, the purpose of this study was to examine the effect of a standard family-based behavioral group (FBBG) treatment program adapted for an at-risk population of youth, and to test innovative strategies (technology enhancements and primary care collaboration) to improve outcomes. Low-income minority children who participated in the 12-week Healthy Hawks (HH) program had significantly lower child weight status (as assessed by child body mass index (BMI) percentage above the 95^{th} percentile ($\%BMI_{p95}$)) at post-intervention, but those reductions were not significant at 1-year follow-up. Children who participated in the standard 12-week FBBG-only intervention demonstrated an average $\%BMI_{p95}$ change at post-intervention of -1.29 (0.36), which is equivalent to an effect size of -0.06. Though statistically significant and similar to effect sizes shown in other behavioral interventions to treat obesity,[138] this effect size is small ($d < 0.20$).

When examining within-group differences by race/ethnicity in the standard HH intervention, significant reductions in child weight status were observed for white/other children and Hispanic children, but not black children. Between-group differences were not significant and the study was not powered to detect these changes, but the trends are interesting to note. Since these types of programs have been developed and validated in white children, it is logical that these groups would see positive outcomes. Additionally, the program was translated into Spanish, providing some level of tailoring for Hispanic families. Since there was no tailoring specifically designed for black children, this could explain the smaller effects observed in that subgroup.

In the HH program, overall attrition was high and completion of secondary outcome measures was poor. However, these rates are not uncommon for family-based interventions or programs inclusive of a high-need population. There were no demographic differences in baseline characteristics between completers and non-completers at post-intervention and only differences in parent baseline BMI and language at 1-year follow-up. Attrition rates might indicate that the intervention is not meeting the needs of these populations, which is problematic given that these groups suffer disproportionately from the burden of obesity compared to higher-income and white counterparts. The findings from Aim 1 indicate that a FBBG program offered in both Spanish and English can reduce child weight status in the short-term, but strategies are needed to boost long-term effects and retention.

In Aim 2, the addition of technology components alongside the 12-week FBBG session was tested as a strategy to improve reductions in child weight status at post-intervention. Specifically, Fitnet, a physical activity app, and five web-based videoconferencing health coaching sessions delivered via Skype were added. TECH1 cohort received Fitnet only and TECH2 cohort received Fitnet and web-based health coaching sessions. Within-group differences were examined and effects were compared to the HH cohorts that did not receive any technology. TECH1 did not demonstrate significant reductions at post-intervention, but TECH2 did demonstrate significant reduction in child weight status at post-intervention and differences were significantly greater when compared to the HH only cohorts. Change in weight status among TECH2 participants was equivalent to an effect size of -0.41. This a moderate effect size (d=0.2-0.5), providing additional evidence that this approach might have greater impacts on child weight status compared to a standard treatment program only.

The addition of technology components, specifically web-based health coaching sessions delivered to individual families alongside a group-based program, might be very helpful for improving outcomes in a family-based intervention. Participants rated the web-based health coaching sessions favorably and indicated that the sessions were very useful in helping them and their children reach their health behavior goals. Evidence has shown that technology can be an effective strategy in rural populations, but this study suggests that the approach might also be helpful for urban populations. In this efficacy study, there is not enough evidence to suggest how many web-based health coaching sessions are needed and future studies should more closely examine dose, and assess the content that was of specific concern to children and families.

Lastly, the goal of Aim 3 was to the test the effect of a community-clinic collaboration by embedding the Healthy Hawks intervention in a primary care setting. This program, referred to as Healthy Hawks Primary Plus (HHP+), was significantly effective in increasing retention at 1-year follow-up and improving child weight at 1-year. Children in HHP+ who completed measures at 1-year follow-up had an average $\%BMI_{p95}$ reduction of -3.24(1.48), $p=0.03$, and this reduction was significantly lower compared to the HH intervention at 1-year when controlling for differences in race/ethnicity, age, and gender. HHP+ had significantly higher retention at 1-year (HH: 38.3%, HHP+: 73.9%, $\chi^2=20.59$, $p<0.001$). Translating outcomes to effect size, the HHP+ intervention had an effective size of -0.28. Again this is a moderate effect size that shows greater impact on child weight status than HH alone.

On average, the HHP+ participants attended 4.9 follow-up visits with physicians, indicating adherence to this intervention component was high (6 bi-monthly follow-up visits were the recommendation). This could have supported improvements in child weight in a variety of ways. First, bi-monthly visits, at which the children were weighed, could have mimicked the self-monitoring strategies that are shown to be very effective in adult weight loss programs. Additionally, children and parents were still receiving content and a trusted medical professional was delivering that content. This might have continued to provide motivation and support for maintaining important health behaviors after the active intervention ended.

Overall, the findings from this study address current gaps in the pediatric obesity treatment literature by evaluating the outcomes of an adapted family-based behavioral group treatment program in low-income minority children. The addition of technology components improved reductions in child weight status at post-intervention, and embedding the program in a primary care setting improved child weight status and retention at 1-year follow-up. These strategies show promise for boosting and extending the modest effects shown in the FBBG standard treatment only.

Strengths and Limitations

Healthy Hawks is one of the first programs to test the effect of a family-based treatment programs in low-income minority children who are overweight or obese. This program has been ongoing since 2006 and provides rich, real-world data about at-risk participants in treatment programs. For this study, 25 cohorts were included, and various strategies to improve treatment outcomes in recent cohorts were assessed. This information can be used to address the gaps in the current pediatric treatment literature, in which high-need populations are often underrepresented.

HH is also novel in that all family members are invited and included in participation, regardless of weight status. This includes extended family (e.g., grandparents, step-parents, etc.) and siblings. Siblings who attend the program participate in treatment sessions regardless of whether or not they are enrolled. Using this approach aligns with family-based models of childhood obesity etiology, and there is evidence to suggest that the family context might be even more important for addressing child weight in racially/ethnically diverse populations.

While this study provides many promising strategies and directions for future study, it is not without limitations. The primary limitation of this study is the use of a rolling, non-randomized, pre-post design. This restricts the ability to infer causal relationships and makes the study susceptible to internal validity threats. While the pre-post study design is a limitation, it is worth discussing the ethical implications of using a randomized design to intervene in low-income, minority children who are severely obese. This vulnerable population is traditionally marginalized in research and given that children are extremely high-need, delaying treatment could produce even greater attrition than typically experienced with this population. Despite this consideration, there are experimental limitations to drawing conclusions from these data, given the study design.

It should be noted that in this study Hispanic and black children were the only at-risk minority groups represented. No other racial/ethnic minority children were adequately represented and this is a limitation of the universal use of the term "minority." There are other known minority groups who are at increased risk for obesity and should be a focus of future studies, including American Indian and Native Hawaiian children.[139,140]

Lastly, child co-morbidities were not assessed. This is a limitation, especially given the severity of obesity in this population. It is unknown if children were seeking support for other health issues, what the focus of the physician visits entailed in HHP+, and if other factors could have been influencing their ability to adopt health behaviors (i.e. diet and physical activity) and improve weight status.

Significance and Public Health Impact

This study provides evidence for approaches to treatment in underserved populations and identifies novel intervention targets that could positively impact other health and behavior outcomes. This is one of the few studies to date to demonstrate significant changes in child weight status reduction at 12-weeks in a sample of low-income minority children and to present results by race/ethnicity to inform future studies.

The use of technology to enhance treatment outcomes has significant public health promise as it could provide participants with access to care from any where at times that are most convenient for them and their schedules Also, the potential for dissemination of technology is high. Today, most families regardless of income- or education-status have smartphones and access to web-based technology. Therefore, once strategies are better tested and refined, the use of technology to deliver treatment can have an extensive reach and impact.

Community-clinic collaborations also hold much promise for public health impact as they embed services in locations where participants are already seeking care and have established trust in providers. The visits with pediatricians are billable by third party payers, and therefore, there is no cost to the participant or the provider for this care strategy. This provides a strategy for program sustainability and a potential mechanism for attenuating the costs of implementing obesity treatment programs.

Future Directions

This study has presented many exciting directions for future research. First, larger sample sizes and more rigorous designs are needed. The use of comparison groups, and if appropriate, randomization, would add strength to the relationships identified here. Additionally, longer-term outcomes should be assessed and if possible, other measures of adiposity and physiological markers should be included to fully examine program impact, given the severity of obesity in this population.

Next, it is important to further examine other "familial" influences in family-based treatment, including siblings, extended family members, and other adults living in the household including dads and grandparents. A majority of target parents included in this study were mothers. However, 4.3% of the target parents were fathers and an additional 11.3% of fathers attended treatment at some point. Also, 80.6% of participants had a sibling attend sessions. Other adults and siblings who were not enrolled in the program were not tracked and this could be a missed opportunity for better understanding family dynamics, changes in health behaviors across the family, and examining potential impacts on treatment. The effect of encouraging all family members to attend treatment, their subsequent attendance and their impact on treatment, should be more closely measured in future studies. Additionally, a measure of household composition (e.g., single-family, same-sex, multi-generational, etc.) would help better understand these dynamic relationships.

When thinking about technology adjuncts, the next step for this research would be to isolate the effects of the technology components and examine the long-term impact. Given the study design constraints, this was not possible in the current study. It will also be important for future studies to more carefully monitor the content delivered in the web-based health coaching sessions, in order to better measure fidelity and improve models for disseminations. Mapping behavioral change techniques on to web-based delivered content could be an exciting next step for refining this approach. Additionally, the implementation of the technology should be more closely monitored. Unfortunately, we do not have number of attempts or duration of calls recorded for the web-based health coaching sessions. This information would have been very useful for evaluating how much effort was required for health coaches to contact families and how long participants were engaged in one-on-one support in each session.

Another exciting direction for future study is to further explore how to leverage primary care clinics for insurance (plan-based) interventions to address health disparities. This study provides evidence for community-clinic collaborations and further refining the physician training, the role of the clinic-based coordinator and the electronic medical record support could provide a stronger model for dissemination.

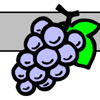
This study provides a collection of evidence for strategies that might help address disparate rates of childhood obesity in the U.S. Given the promising outcomes observed, future studies should seek to replicate these findings in more diverse populations and settings, implement more rigorous designs, and conduct thorough process evaluation to identify the most robust intervention components for treatment programs. This work spans over 10 years, includes racially/ethnically diverse children 2 to 19 years of age, and aims to address the challenges facing children with obesity by using innovative solutions that reach those most in need of treatment. These results have suggested targeted approaches for designing effective pediatric obesity treatment programs for hard-to-reach, underserved populations. The continuation of this research could have meaningful, long-term impact ranging from improvements in individual child health outcomes to the attenuation of the social burdens associated with obesity and obesity-related diseases.

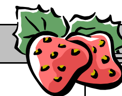
APPENDIX 1: CHILD SELF-MONITORING FORM

CHILD MONITORING FORM

Name:____________________________ Day of Week:__________Wk#: ___

FRUIT AND VEGES





Type of Fruit or Veggie (100% Juice Counts)	Meal	Amount
TOTAL FRUITS AND VEGETABLES EATEN TODAY =		
_____**Did I reach my Fruits and Vegetables Goal today (circle)? Yes No**		

RED FOODS

Food	**Meal**	**Amount**	**Calories**
TOTAL NUMBER OF RED FOOD EATEN TODAY =			
My goal: _______ Did I reach my Red Food Goal today? Yes No			

STEPS

Number of Pedometer Steps Today: _______	**My Step Goal for Today ___________**

Planned Activities

Activity	**Number of Minutes**
Walking for exercise	
TOTAL:	_____________

TV Time (Minutes)	**Leisure Computer Time (Minutes)**	**Other Sedentary Activity (Minutes)**	**TOTAL (Minutes)**

APPENDIX 2: WEB-BASED HEALTH COACHING MANUAL

Prep*:* Health Coaches to review Weeks 1 and 2 of the intervention handbook

****** Verify connection and functioning of technology before the session begins. Troubleshoot any issues.

Healthy Hawks Online Sessions

Tell families about what they can expect from the online sessions.

> "The online sessions are an opportunity for us to discuss the successes and challenges you are experiencing as you go through the Healthy Hawks program. It is your chance to ask questions and it allows us to be able to provide you with feedback that is helpful to you and your family. Each week the sessions will last about 25-30 minutes."

We will review the challenges and successes you are experiencing as you work to meet your weekly goals.

1) **Introductions (2-3 minutes)**
   a) **Greet everyone cheerfully!** and set a positive tone.
   b) **Introduce yourself** and then give families the opportunity to introduce themselves as well. **Have everyone share one fun fact about him or herself to get acquainted.**
   c) Be sure to engage all present family members in conversation
2) **Assess questions regarding weekly session content** (**5-10 minutes)**
   a) Week 1- Goal setting; Introduction to Exercise
   b) Week 2- BMI and Energy Balance
   c) Prompts:
      i) "Do you have any questions about what you discussed during either session?"
   d) FitNet- Using the app for more physical activity
3) **Review Goal Charts (15-20 minutes)**
   a) Emphasize behavior modification: setting and reaching meaningful goals
   b) Sample prompts:
      i) "What goals did you set last week? What goal did you set this week?"
      ii) "What are you doing to make sure you meet your goals?"
      iii) "What challenges are you facing in meeting your goals?"
4) **Closing (2-3 minutes)**
   a) Assess if there are any other issues or questions they would like to discuss
   b) Always thank participant/s for their time "Thank you so much for joining me online today."
   c) Provide a reminder for the next session "As a reminder, we will have our next online session _________ at ___pm."

Health Coach Report- Week 1

Session 1 to be scheduled: Week of February 17th

Day/time of meeting: ____

Please report number of previous contacts, day/time of previous contact and any other communication attempts here:
Family members in attendance:
Main discussion points:
Counseling issues to report:
Technology issues to report:
Additional notes:

Healthy Hawks Online Protocol

- Log in to Skype 15 minutes prior to the scheduled session time
- Send Skype call at assigned time
    - If no one answers, wait 5 minutes, then try again.
    - If no on answers after a second attempt, call the primary phone number.
    - If no one answers, leave a message.
        - "Hi, this is __________ from Healthy Hawks. We are scheduled to have an online session tonight. Please log in to Skype or call me back at ___________. I will wait 10 minutes, and then try you again."
- Continue call attempts via Skype and phone for 24-hours (based on personal availability)
    - If no contact is made within 24-hours, inform Gina.

Gina will make contact attempts for 24-hours. If no contact is made Gina will inform Ann/Myles for additional 24-hours of follow up.

Instructions for translation services:
Proprio: 913-825-6800
For Spanish option select "1"
Account: # 1130
Department: KU Pediatrics

Contacts:
Gina:
Email: gtripicc@live.unc.edu
Cell: 856-430-0643

Ann:
Email: adavis6@kumc.edu
Cell: 913-226-1758

Myles:
Email: mfaith@email.unc.edu
Cell: 919-636-2522

Online Health Coach Information

Names,

We are very excited to begin the Healthy Hawks online sessions! This is an opportunity for your family to- work one-on-one with a health coach to discuss challenges and successes, and ask questions as you go through the program.

Your family's health coach will be Name .

<u>Online Sessions</u>

You will access the online sessions using Skype. Skype is an app available on the iPad.

Your Skype username is: healthyhawksxx
Your Skype password is: 2015healthyhawks

To use Skype:

- Make sure you are connected to the internet
- Open the app; log in with the username and password above
- Your health coach will call you on the assigned day and time listed below
    - **Your health coach's username is**: hh_coach_gt
- If your coach cannot reach you, they will call you at this number: **913-636-5732 or 913-944-9298**
    - If this is not correct, please let the session coordinator know

<u>Online Schedule</u>

Sessions will last approximately 25-30 minutes and all family members are encouraged to attend. Based on your request, you will meet with your online coach during the following days/times:

Session 1: Tuesday February 24th at 5pm
Session 2: Tuesday March 3rd at 5pm
Session 3: Tuesday March 10th at 5pm
Session 4: Tuesday March 24th at 5pm
Session 5: Tuesday April 7th at 5pm

APPENDIX 3: WEB-BASED HEALTH COACHING SATISFACTION SURVEY

The Healthy Hawks Online Skype Health Coaching
Satisfaction Survey

These ratings are based on YOUR experience. Overall, how helpful to you were the online Skype health coaching meetings for:

	1=Not Helpful	2=Little Helpful	3=Moderately Helpful	4= Very Helpful	5=Extremely Helpful
Reaching your HH behavior goals?	1	2	3	4	5
Improving your physical activity?	1	2	3	4	5
Improving your healthy eating behaviors?	1	2	3	4	5
Improving your parenting skills?	1	2	3	4	5
Improving role modeling for your child?	1	2	3	4	5
Learning positive reinforcement of your child's behavior?	1	2	3	4	5

The following ratings are based on your CHILD/CHILDREN'S experience. Overall, how helpful were the online Skype health coach meetings for:

	1=Not Helpful	2=Little Helpful	3=Moderately Helpful	4= Very Helpful	5=Extremely Helpful
Helping your child reach his/her behavior goals?	1	2	3	4	5
Improving your child's physical activity?	1	2	3	4	5
Improving your child's healthy eating behaviors?	1	2	3	4	5
Improving your child's enjoyment of the HH program?	1	2	3	4	5

Do you have another device on which you can use Skype if we did not provide the iPad?	**Yes**	**No**
Do you have internet access at your home?	Yes	No

	1=not enthusiastic	2=Little enthusiastic	3=Moderate enthusiastic	4=Very enthusiastic	5=Extremely enthusiastic
How enthusiastically would you recommend Skype coaching sessions for other families?	1	2	3	4	5

1. How specifically did the use of the iPad and the online Skype health coaching sessions help you reach your goals?
2. Do you wish you had more or fewer calls? Why?
3. What did you like most about the online Skype health coach calls? What did your child like most about the online Skype health coach calls?
4. How would you change the online sessions to make it more beneficial for you and your child?
5. Please provide any other thoughts and comments about the online Skype health coaching sessions here:

Thank you for your time!!!

Encuesta de satisfacción de Healthy Hawks del entrenamiento de salud de Skype en línea

Estas calificaciones están basadas en SU experiencia. En general, qué provechoso eran las reuniones con el entrenador de salud de Skype en línea para:

	1= no fue provechoso	2= Poco provechoso	3= Moderadamente provechoso	4= Muy provechoso	5= Extremadamente provechoso
Alcanzar sus objetivos de comportamiento de HH?	1	2	3	4	5
El mejoramiento de su actividad física?	1	2	3	4	5
El mejoramiento de sus comportamientos de comida sanos?	1	2	3	4	5
El mejoramiento de sus habilidades de la crianza de los hijos?	1	2	3	4	5
El mejoramiento de su modelado a seguir?	1	2	3	4	5
El aprendizaje de refuerzo positivo del comportamiento de su hijo?	1	2	3	4	5

Las siguientes clasificaciones se basan en la experiencia de su(s) hijo(s). En general, qué provechoso eran las reuniones con el entrenador de salud de Skype en línea para:

	1= no fue provechoso	2= Poco provechoso	3= Moderadamente provechoso	4= Muy provechoso	5= Extremadamente provechoso
Ayudar a su hijo para alcanzar sus objetivos de comportamiento de HH?	1	2	3	4	5
Mejorar la actividad física de su hijo?	1	2	3	4	5
Mejorar los comportamientos alimentarios saludables de su hijo?	1	2	3	4	5
El mejoramiento del placer de su hijo en el programa de HH?	1	2	3	4	5

¿Tiene otro dispositivo en el que puede utilizar Skype si no le hubieramos prestado el iPad?	**Si**	**No**
¿Tiene acceso al internet en su casa?	Si	No

	1=no entusiasmo	2= poco entusiasmo	3= Moderado entusiasmo	4=Mucho entusiasmo	5= Extremadamente entusiasmo
El entusiasmo con que recomendaría Skype sesiones de entrenamiento para otras familias?	1	2	3	4	5

1. Cómo específicamente el uso del iPad y las sesiones de entrenamiento de la salud de Skype en línea le ayudarán para alcanzar sus metas?
2. ¿Desea tener más o menos llamadas? ¿Por qué?
3. ¿Qué es lo que más le gustó de las llamadas de Skype? ¿Qué es lo que más le gustó a su hijo de las llamadas de Skype?
4. ¿Cómo cambiaría las sesiones en línea para que sean más beneficiosos para usted y su hijo?
5. Por favor de cualquier otro pensamiento o comentarios sobre las sesiones de entrenamiento de salud en Skype aquí:

<u>Gracias por su tiempo!!!</u>

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