AN INTERVENTION FOR FAMILIES WITH OVERWEIGHT OR OBESE CHILDREN DELIVERED BY EXTENSION: ASSESSMENT OF FEASIBILITY, IMPLEMENTATION, AND PARTICIPANT EXPERIENCES

By

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ABSTRACT

AN INTERVENTION FOR FAMILIES WITH OVERWEIGHT OR OBESE CHILDREN DELIVERED BY EXTENSION: ASSESSMENT OF FEASIBILITY, IMPLEMENTATION, AND PARTICIPANT EXPERIENCES

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While family-based behavioral intervention programs have demonstrated effectiveness in treating childhood obesity and overweight, there is a lack of affordable, accessible, and scalable community-based programming to meet the growing needs of families. The specific aims of the current study were to: 1) assess the feasibility, implementation challenges, and preliminary effectiveness of a weight management program for low-income families delivered by Extension; 2) assess participant experiences in the weight management program; and 3) describe protocol for a trial to evaluate program effectiveness. A two-phase study was conducted using clinical, behavioral, and quality of life evaluations as well as focus group discussions.

Researchers from Michigan State University Departments of Food Science & Human Nutrition (FSHN) and Human Development & Family Studies (HDFS) designed a curriculum, *Healthy Kids, Healthy Families* (*HKHF*), for delivery through Michigan State University Extension (MSUE). Trained community health workers from MSUE delivered the program to low-income families with children aged 6 to 14 years who were overweight (BMI-for-age and gender between the 85th and 94th percentile) or obese (BMI-for-age and gender \geq 95th percentile). Research assistants at partnering clinics identified eligible children; introduced the program; and recorded baseline clinical and available biochemical data. The families were then referred to the local Extension office. *Healthy Kids, Healthy Families* started with a one-on-one session with MSUE staff to complete baseline behavioral and quality of life assessments with children. Following the one-on-one session, families began a series of six multi-family group sessions. Focus groups with families assessed participant experiences in the program.

A total of 72 children enrolled in the program. The majority (mean age 9.3 years) were African American (68%), female (57%), obese (71%), and Medicaid recipients (73%). Less than 20% of obese children received the recommended screening for comorbidities and most were not meeting dietary recommendations. After enrolling in the program, 33 children (46%) completed the initial one-on-one session. However, only 12 of these 33 children completed the entire program. Results indicated significant changes (p < .05) in physical activity, health-related quality of life, and emotional health of children who completed, with large effect sizes. Participants and caregivers reported positive experiences with MSUE staff and the intervention.

Together, results from Aims 1 and 2 indicated that although the program was effective for and well-received by program completers, attrition rates were high and engagement was low. When designing a trial to test program effectiveness, researchers made modifications to address challenges during the feasibility study. Modifications included more flexible programming options with referrals through numerous organizations; program expansion using various sites and times throughout the targeted city; family selection of program delivery method (one-on-one or group); text/e-mail check-in between sessions; and inclusion of a process evaluation to monitor program implementation. Future research should investigate different methods of referral and delivery as well as formative research focused on barriers and facilitators to participation in an effort to improve program feasibility among low-income populations.

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CHAPTER 1 - Introduction

Background

It is well-established that childhood obesity is a significant problem in the United States (US) and globally, with serious health and social consequences for millions of children [1, 2]. Approximately 12.5 million children 6 to 19 years of age are identified as obese, which is double the prevalence from 20 years ago [3, 4]. Even worse, the prevalence of extreme obesity in children is continuing to rise [5-7]. Obese children are more likely to remain obese through adulthood [8, 9], placing them at increased risk for diabetes [10-13], cardiovascular disease [14-18], and certain types of cancer [19-23]. While family-based behavioral intervention programs have demonstrated effectiveness in treating childhood obesity and overweight, there is a lack of affordable, accessible, and scalable community-based programming to meet the growing needs of families.

Obesity results from a sustained energy imbalance in conjunction with various genetic, behavioral, cultural, environmental, and economic factors [24]. The condition is disproportionately higher among children from poorer families [25], as well as Mexican American, Native American, and African American children [26]. Children who are successful in reducing weight status may experience health benefits [27-29], but it is difficult to reverse obesity through interventions [30].

Evidence from systematic reviews has determined that the most effective treatment for childhood obesity is through family-based behavioral weight management programs [31, 32]. However,

the research in this area generally includes a small number of participants treated in carefully controlled clinical trials or obesity specialty clinics [27-29, 31-41]. Programs that are currently available often require a team of highly-skilled health professionals and specialized facilities, making their implementation costly and limiting their availability [37, 38]. Programs are not easily accessible, particularly in low-income communities, and are often inconvenient for families to attend [37, 42]. In addition, demand for treatment at these centers exceeds current capacity – many have long waiting lists [43] and high attrition rates [6, 44, 45].

Screening for childhood obesity is another important issue. Recent recommendations indicate that primary care providers should screen for overweight and obesity and provide anticipatory guidance [46, 47], but many fail to do so [48, 49]. Research has consistently demonstrated under-diagnoses of pediatric obesity during regular preventive visits, and the use of body mass index (BMI)-percentile screening in primary pediatric practices is underused [48, 49]. Furthermore, after diagnosis, most obese children and adolescents are not receiving the recommended laboratory screening [50]. Physicians specifically indicate a lack of available referral sources among the reasons for failing to screen for obesity [48].

Literature investigating the feasibility and effectiveness of community-based interventions as treatment options for overweight and obese youth is limited [51-55], particularly with regard to programs administered through land-grant outreach systems, specifically Extension [52]. The current study explored the feasibility, implementation challenges, and participant experiences in a community-based intervention, administered through Michigan State University Extension (MSUE), targeting low-income families with overweight or obese children. Trained MSUE

Program Associates delivered a theory-driven curriculum to children and families recruited from partnering pediatric clinics. Research assistants at the pediatric clinics identified and recruited children and families into the program and recorded clinical and available biochemical measures. Bandura's Social Cognitive Theory best describes the approach, which suggests that behavior change is explained by a three-stage, dynamic model between personal factors, environmental factors, and behavior [56, 57].

The **long-term goal** of the current study is to create a model for collaboration between Extension, primary care physicians, and families to effectively manage childhood overweight and obesity. Important objectives were to examine whether this collaboration between pediatricians and Extension was feasible and to identify challenges with program implementation in low-income communities. From qualitative findings, researchers examined parent and child experiences in *Healthy Kids, Healthy Families* as well as changes that resulted from program participation. The study was accomplished by the following three specific aims.

Specific Aims

Aim 1: To assess the feasibility, implementation challenges, and preliminary effectiveness of *Healthy Kids, Healthy Families*, a community-based weight management program for low-income families

Hypothesis for Aim 1: Healthy Kids, Healthy Families is a feasible intervention for low-income families with overweight or obese children.

Research Questions:

- Was a collaboration between pediatricians (responsible for screening and referral) and Extension (responsible for programming) an effective strategy to identify and recruit families with overweight or obese children into a weight management program?
- 2) What challenges and opportunities were evident when low-income families with overweight or obese children were invited to participate in *Healthy Kids, Healthy Families*?

Aim 2: To assess participant experiences in a weight management program for families with overweight or obese children delivered through Extension

Hypothesis for Aim 2: The model for collaboration to address childhood overweight will be positively viewed by participating children and families.

Research Questions:

- 3) How did families that participated in *Healthy Kids, Healthy Families* describe their experiences in the program?
- 4) Following participation in *Healthy Kids, Healthy Families*, how did children perceive their own ability to achieve a healthier lifestyle?
- 5) To what extent did *Healthy Kids, Healthy Families* influence parent/caregiver behavior related to support of their children and modeling of appropriate health-related behaviors?

Aim 3: To describe the protocol to evaluate the effectiveness of *Healthy Kids, Healthy Families*, a weight management program for families with overweight or obese children delivered through Extension

Applied Significance of Research

Primary care providers are not adequately trained nor do they have the time to counsel all overweight or obese pediatric patients. Additionally, widespread programming that addresses childhood obesity treatment is not available or accessible in most communities. There is a growing need for innovative solutions to the epidemic of childhood obesity.

The proposed project offers a practical and scalable solution to a complicated and costly condition. Because the intervention is delivered through an Extension system, it is reproducible on a nationwide scale. Additionally, the research results provide new information regarding program feasibility in high-risk areas as well as participant experiences with Extension staff who deliver a weight management program to children and their families.

Organization of the Dissertation

This dissertation is organized into seven chapters. Chapter one presents the general introduction of the problem and rationale for the study. Chapter two provides a review of the literature on the prevalence of overweight and obesity in children, causes and consequences of childhood obesity, screening recommendations and practices, and current community-based resources available to manage the condition. Chapter three presents the methods used to achieve the objectives of the study. The dissertation is organized into two phases: Phase 1 involves implementation of *Healthy Kids, Healthy Families* and collection and analysis of baseline and exit data; and phase 2 encompasses a focus group study with families that completed the program. Chapter four presents manuscript number one which addresses the first aim of the study. Chapter five presents manuscript number two, the qualitative findings of the study, by examining family

experiences with *Healthy Kids, Healthy Families*. Chapter six presents manuscript number three, which is the third aim of the study, and describes a protocol for a trial which we hope to implement in the future as a result of this dissertation. Chapter seven provides an overall summary of the three studies with conclusions. This chapter also provides recommendations for future research studies in this area. This dissertation is primarily targeted toward nutrition and health professionals and others concerned with nutrition, health, and quality of life of US children.

Working Definition of Terms

- Multidisciplinary Pediatric Weight Management An approach to pediatric weight management that involves more than one discipline and a team of different health professionals, such as physicians, registered dietitians, nurses, exercise physiologists, and behavioral psychologists.
- 2) Community-Based Pediatric Weight Management An approach to pediatric weight management that is designed to reach children and families outside of the traditional healthcare setting using existing social structures, such as schools, faith-based organizations, or communities.
- 3) Family-Based Behavioral Weight Management An approach to pediatric weight management that includes one or both parents; nutrition and physical activity; and a behavioral change process that is goal-directed, process oriented, incorporates behavioral approaches advocating small changes, and utilizes self-monitoring and problem-solving skills.
- 4) Extension A nationwide, noncredit educational network designed to help people use research-based knowledge to improve their lives. The service is provided by land-grant universities throughout the country and includes a network of local offices throughout each state.
- 5) Michigan State University Extension (MSUE) An organization that has successfully taught nutrition education statewide since 1914 using trained community health workers, supervised by professional staff and supported by MSUE campus staff. The organization also provides Michigan residents with research-based information and programming in

the areas of agriculture, business and community, family, food and health, lawn and garden, natural resources, and youth.

6) Community Health Worker – A frontline public health worker who is a trusted member of and/or has an unusually close understanding of the community served. The worker serves as a liaison between health services and the community to facilitate access to services.

CHAPTER 2 – Review of the Literature

The literature reviewed includes a description of childhood obesity, associated health risks, causes, and consequences. A general explanation of current screening practices by primary care providers and available community-based treatment options for families with overweight and obese children is also provided.

Childhood Obesity and Overweight

Definition

Overweight and obesity in children can be easily assessed through the calculation of body mass index (BMI) which is obtained by dividing measured weight (kilograms) by measured height (square meters). BMI is then plotted on age- and gender-specific CDC growth charts. In the US, weight status in children, aged 2 to 19 years, is determined using these age and gender normreferenced values derived from previous national surveys [58]. Overweight is defined as BMIfor-age and gender at or above the 85th percentile but less than the 95th percentile, and obesity is defined as BMI-for-age and gender greater than or equal to the 95th percentile [59]. The BMI classification shows the association between excess adiposity and serious health risks [58].

Prevalence

In the US, 31.8% of youth between the ages of 2 and 19 years are overweight and 16.9% are obese [3]. Consistent evidence indicates that children from lower socioeconomic background are at elevated risk for overweight and obesity [25, 60-64]. Additionally, obesity is disproportionately higher among Mexican American, Native American, and African American

children [26]. **Table 1** summarizes recent data published by Ogden and colleagues describing prevalence of child overweight and obesity [3].

 Table 1. Prevalence of High Body Mass Index by Selected Cut Points for Youth Aged 2 to

 19 Years, United States, 2011-2012*

	% (95% CI)			
	2-19 years	6-11 years	12-19 years	
Overweight or Obese	$(BMI \text{ for } Age \ge 85^{\text{th}})$	Percentile of CDC Gro	owth Charts)	
All race/Hispanic origin groups**	31.8 (29.1-34.7)	34.2 (30.1-38.5)	34.5 (30.1-39.2)	
Boys	32.0 (29.2-35.0)	33.2 (27.7-39.1)	35.1 (29.7-40.9)	
Girls	31.6 (27.2-36.5)	35.2 (29.2-41.8)	33.8 (27.9-40.4)	
Obese (BMI for Age	≥ 95 th Percentile of th	e CDC Growth Charts	3)	
All race/Hispanic origin groups**	16.9 (14-9-19.2)	17.7 (14.5-21.4)	20.5 (17.1-24.4)	
Boys	16.7 (13.9-19.8)	16.4 (12.9-20.6)	20.3 (15.7-25.9)	
Girls	17.2 (14.8-19.9)	19.1 (15.8-22.8)	20.7 (16.8-25.1)	

^{*}Data are from the National Health and Examination Survey; estimates are weighted; **Includes race/Hispanic origin groups not shown separately. Adapted from Ogden, et al., 2014.

Although no significant change in obesity prevalence by age group was observed between 1999-2000 and 2009-2010 (suggesting a plateau or leveling of obesity), the prevalence of childhood obesity and overweight are well above national goals [65]. Healthy People 2020 objectives are to decrease the proportion of children considered obese by 10% (or 15.7% of children aged 6 to 11 years) by 2020 [65].

Persistent obesity (obesity that maintains over time and throughout life) appears to be established before the age of eleven [66]. A recent study followed 3,961 children from fifth through tenth grade, and authors determined that 83 percent of children who were obese at 16 years of age had been obese at age 11, while only 12 percent of children who were obese at 11 years of age transitioned to a healthy weight by age 16 [67]. Earlier research in US children found that overweight kindergarteners were more likely than their normal weight peers to become obese in middle school [68].

Additionally, the prevalence of extreme obesity in children is rising in the US [5-7]. Using nationally representative data, Skinner and colleagues demonstrated an upward trend in more severe forms of obesity in children, described as class 2 and class 3 obesity [7]. Class 2 obesity is defined as a BMI \geq 120% of the 95th percentile or BMI \geq 35, whichever is lower [5]. Class 3 obesity is defined as 140% of the 95th percentile or BMI \geq 40, whichever is lower [5]. In 2011-2012, 5.9% of children met criteria for class 2 obesity (up from 3.8% in 1999-2000) and 2.1% met criteria for class 3 obesity (up from 0.9% in 1999-2000) [7].

Childhood obesity, both moderate and severe, is a significant public health issue. There is a growing need for programming that successfully reaches those at highest risk before persistent obesity develops.

<u>Consequences</u>

Some consider childhood overweight to be the most serious and prevalent nutrition disorder in the US – the consequences of which are both acute and chronic [69]. Obese children and

adolescents are at increased risk for cardiovascular disease, hypertension, pseudotumor cerebi, orthopedic problems, sleep apnea, steatohepatitis, cholethiasis, polycystic ovary disease, type 2 diabetes, and early onset of puberty [33, 70]. In addition to the physical implications, there are psychosocial consequences of childhood obesity, which include increased risk for peer group discrimination; low self-esteem; impaired quality of life; increased psychological stress; poor body image; and depression [71-78].

The Centers for Disease Control and Prevention (CDC) recently reported dramatic increases in the prevalence of diagnosed diabetes in the US [79], while rates of chronic disease are increasing across the globe [80]. As indicated in an editorial by David Katz, Founding Director of Yale University Prevention Research Center, these reports are about adults but "portend the future that awaits today's children" [81]. Obese children are, in fact, more likely to remain obese through adulthood [8, 9], and there is an increased morbidity rate associated with adult obesity, particularly with regard to diabetes [10-13], cardiovascular disease (CVD) [14-18], and certain types of cancer [19-23].

There are numerous potential comorbidities linked with obesity in children, many of which track into adulthood [82]. Consistent evidence demonstrates that childhood overweight is significantly and independently associated with increased risk of type 2 diabetes in adulthood [10-13]. It is yet unknown whether the dramatic increases in childhood overweight during the past 30 years will bring about soaring rates of type 2 diabetes diagnoses in young adults. Additionally, obesity in youth is associated with an increased risk of CVD in adulthood [14-18] as well as elevated risk of liver [20], thyroid [21], breast [22], and endometrial [23] cancers.

Metabolic syndrome in adults is described as a clustering of risk factors including hypertension, insulin resistance/elevated glucose, dyslipidemia, and abdominal obesity [83]. In adults, the condition increases risk for cardiovascular disease and type 2 diabetes [84]. Metabolic syndrome has recently been identified in children and adolescents, and the clustering of risk factors is similar to adults [85, 86]. A systematic review indicated that the prevalence of metabolic syndrome in population based studies was 3.3% in normal weight children, 11.9% in overweight children, and 29.2% in obese children [83].

In addition to metabolic syndrome, children and adolescents who are obese are more likely than their normal weight peers to have risk factors for cardiovascular disease, such as high cholesterol or high blood pressure [87]. In a large population-based study, the overall prevalence of dyslipidemia among US children and adolescents was 20.3% and increased to 42.9% in obese children and adolescents [88]. In addition, childhood obesity can be considered an early manifestation of cardiovascular disease [4, 89], with higher BMI percentile in childhood associated with an increased risk of heart disease in adulthood [90]. Obesity in adulthood is associated with elevated total cholesterol, triglycerides, and LDL-cholesterol, which are major risk factors for heart disease and stroke [4]. The evidence of an association between increased BMI percentile in children and cardiometabolic risk factors is compelling [91, 92], but there is little information from diverse communities in the US [92].

Similarly, high blood pressure in childhood often tracks into adulthood [93]. As hypertension is the leading cause of premature death [94], early detection in children may be necessary to improve long-term outcomes [95]. Obesity is considered the primary risk factor for high blood

pressure in children, but few studies have investigated the association between changes in BMI percentile and improvements in blood pressure in children [96]. A recent review indicated that childhood obesity programs demonstrate a moderate effect on reducing blood pressure, with programs targeting diet and physical activity showing greater effectiveness [97].

The current epidemic of childhood obesity has led to subsequent increases in prediabetes and type 2 diabetes in older children and adults [4, 87]. Type 2 diabetes is a growing public health concern that is more common among children of color and very often undiagnosed [98]. In addition, children living in poverty have high levels of diabetes risk factors [99]. There is, therefore, an increased need for early detection and intervention programs, particularly in these vulnerable populations [99, 100].

There are also psychosocial consequences of childhood obesity, which include increased risk for peer group discrimination; increased anxiety; low self-esteem; impaired quality of life; increased psychological stress; poor body image; and depression [71-78, 82]. Severely obese children and adolescents have similar health-related quality of life as youth diagnosed with cancer [74]. Recent studies have also demonstrated a direct association between obesity and school absenteeism [101] as well as an inverse association between obesity and academic performance [102-104]. Obese adolescents are four times more likely to have difficulty with concentration, homework completion, and missed school days than their normal weight peers [74]. Overweight and obese adolescents also have higher lifetime rates of eating disorders, particularly bulimia nervosa, when compared with normal weight adolescents [105].

Management of obesity during childhood is essential to prevent long-term consequences of the condition. Once established, 77-92% of teenagers will remain obese into adulthood [106]. Obesity is not only a significant cause of disability and excess mortality, but it is also responsible for lower productivity and higher medical costs in adults [107]. Without effective interventions, it has been predicted that at least half of adults will be obese by 2030 [108].

Causes

Obesity results from a sustained energy imbalance in conjunction with various genetic, behavioral, cultural, environmental, and economic factors [24]. It is generally accepted that this imbalance is between energy intake and expenditure [109]. Child risk factors for obesity include poor dietary habits, lack of physical activity, and increased sedentary behaviors [110]. Dietary habits specifically associated with obesity in children include increased consumption of sugarsweetened beverages [111-114], increased intake of calorie-dense snack foods [111, 115], consumption of large portions [111, 116], and increased intake of fast foods [117]. Family characteristics, such as parenting styles, as well as environmental factors, such as demographics and parents' work-related demands, influence eating and activity behaviors of children [60, 61, 109, 118-120].

Consistent research indicates that children from lower socioeconomic background are at higher risk for overweight and obesity [60-62]. Previous research has largely focused on factors such as access to healthy and unhealthy foods, safe places to play and engage in physical activity, and the physical home environment [61, 121, 122]. Larson and colleagues recently determined that those with better access to supermarkets and limited access to convenience stores have healthier

diets and lower levels of obesity [122]. On the other hand, a previous review found that the availability of healthy versus unhealthy foods was inconsistently related to obesity while neighborhood features that discourage physical activity were consistently associated with increased BMI [121].

Family socioeconomic status (SES) is further related to perceptions of obesity and the home food environment [123]. Similar to earlier studies, Anderson and colleagues found that low-income Black and Hispanic parents underestimated the weight of their overweight children [124]. Previous literature has also demonstrated numerous differences between families of low SES and those of higher SES when addressing the home food environment [123-127]. Vereecken and colleagues examined differences in mothers' food parenting practices by educational level and determined that mothers at the lowest educational level tended to have less authoritative feeding practices -- authoritative parenting style (demonstrating sensitivity to children's needs) is associated with a lower risk of childhood obesity when compared with other parenting styles [126]. Additionally, children of mothers at the lowest educational levels received less discouragement from eating sweets and ate fewer fruits and vegetables when compared with children of mothers at the highest educational levels [126]. Previous studies have also found that the frequency of family meals is positively associated with SES [125, 127] and with intakes of fruits, vegetables, grains, and calcium-rich foods, and negatively associated with intake of soft drinks [125].

Parental and familial factors influence child eating behaviors. Food preferences in children as young as two years of age have been shown to reflect mothers' food preferences [128]. Studies

have further demonstrated that mealtime structure, including families eating together, television viewing while eating, and sources of meals (restaurants, schools, home), are important factors related to children's eating patterns [129]. Finally, parents directly influence eating behaviors through their own behaviors, attitudes, and feeding styles [129].

Childhood obesity is influenced by many other factors not specifically addressed in the current study. For example, intrauterine and postnatal factors, such as prenatal exposure to smoking and gestational diabetes as well as breastfeeding duration, are also associated with obesity later in life [130]. Additionally, and in rare cases, pathologic causes (genetic or endocrine) may lead to rapid weight gain [82].

The current study sought to engage families in the management of childhood obesity in those 6 to 14 years of age. The focus was on examining the feasibility of and participant experiences in a weight management program delivered by Extension that was specifically designed for low-income families with overweight or obese children. With Bandura's Social Cognitive Theory as the framework [56], particular attention was placed on improving personal factors related to the child (knowledge, skills, self-efficacy, outcome expectancies) and environmental factors surrounding the child (parental support, parental modeling, and access to healthy foods and safe places to play).

Childhood Obesity and Overweight Screening by Primary Care Physicians

Weight status of obese children who are referred for treatment has often not been addressed by primary care providers until well after obesity onset [43]. Current recommendations include

assessing and monitoring BMI in all children during every health visit [39, 46, 47, 131, 132], and screening obese pediatric patients for comorbid conditions, such as hyperlipidemia and diabetes [49, 50].

The Institute of Medicine, American Academy of Pediatrics, and American Heart Association have each addressed assessment and monitoring of BMI [39, 46, 131-133]. The American Academy of Pediatrics recently published a clinical report delineating the role of the pediatrician in the primary prevention of obesity in children [47]. In this report, pediatricians are instructed to identify children at risk of developing obesity using the new World Health Organization normative growth charts from birth to 23 months of age [134]. For children aged 2 years and older, pediatricians should monitor BMI changes by calculating and plotting BMI on the CDC growth charts at every health care visit [47]. Pediatricians should address an upward trend in BMI percentiles even before reaching the 85th or 95th percentile [46, 47, 135].

After appropriately identifying children as overweight or obese, primary care physicians should follow screening guidelines to test for comorbid conditions [49, 50, 136]. For current screening guidelines, see **Figure 1**. Screening guidelines for obesity-related conditions in children who are overweight or obese has changed throughout the years. Screening recommendations prior to 2005 were considered vague and unclear [50], but in 2005 and 2007 more complete guidelines were published [137, 138]. An expert committee convened in 2007 by the American Medical Association, CDC, and the Health Resources and Services Administration made a recommendation that all obese pediatric patients be tested for comorbid conditions, such as hyperlipidemia and diabetes [49, 50, 137].

In spite of the clarity of the recommendations in 2005 and 2007, screening for obesity and comorbid conditions has not shown any visible improvements [48-50]. There is a consistent problem with underdiagnoses of pediatric obesity during regular preventive visits, and the use of BMI-percentile screening in primary pediatric practices is underused [48, 49]. Additionally, even after an obesity diagnosis, most obese children and adolescents are not receiving the recommended laboratory screening [50]. A survey from a nationally representative sample of pediatricians and family practice physicians found that less than half of all primary care physicians assessed BMI percentiles regularly in children, and only 18 percent reported referring for treatment [136]. Using NHANES data from 1999-2008, only 22% of the parents with children who had a BMI at or above the 85th percentile reported having been told by their primary care provider that their child was overweight [139].

Screening may not occur because of lack of physician comfort with weight status screening, diagnosis, or management as well as limited time with patients [48, 140]. Additionally, many primary care providers hesitate to screen for excess weight gain without confidence in their ability to provide obesity-treatment options [141]. Few physicians believe there are good treatment programs for obese children, and many feel they do not have the training or resources to provide the necessary services [48]. Therefore, increasing the accessibility and availability of evidence-based programming to address childhood obesity may improve screening and referral practices of primary care providers.



Figure 1. Universal Assessment of Obesity Risk and Steps to Prevention and Treatment Figure Credit: Barlow S E Pediatrics 2007;120:S164-S192

Multidisciplinary Programs as Treatment Options for Childhood Obesity and Overweight Determination of program effectiveness has relied almost entirely upon clinic- or hospital-based multidisciplinary programs that are led by highly trained professional staff and behavioral psychologists [27-29, 31-36, 38-41], the most effective of which are family-based behavioral weight management programs [31, 32]. Although not clearly defined, family-based behavioral weight management tends to include one or both parents, and the behavior change process is goal directed; process oriented; incorporates behavioral approaches advocating small changes; and utilizes self-monitoring and problem-solving tools [142-144]. Research examining the effectiveness of these programs has generally included only a small number of participants treated in carefully controlled clinical trials or obesity specialty clinics [27-29, 31-41]. Additionally, most of the studies have been conducted in motivated, middle-class, Caucasian populations, limiting their generalizability [33, 42].

Tertiary referral centers (or specialty clinics) are currently the primary sites for child obesity treatment [6]. These centers are staffed with a team of highly-skilled health professionals, such as behavioral psychologists, exercise physiologists, registered dietitians, and physicians and often require specialized facilities. This team works together to address obesity in a multidisciplinary manner.

The programs that have been studied tend not to adequately consider practical application on a broad scale. Multidisciplinary programs have demonstrated moderate success in treating childhood obesity [32], but the programs are not widely available or accessible in most communities [37, 42]. Where the programs are available, the demand for treatment exceeds capacity, with many having long waiting lists of families requesting treatment [43]. In addition, the interventions are costly, and expenses are unlikely to be reimbursed by insurance [6]. Finally, program attrition is high at these centers, with over half of participating families dropping from hospital-based programs [6, 44, 45, 145]. Participants often point to scheduling difficulties as well as programming failing to meet family needs or expectations as reasons for program attrition [6, 45, 145]. Drop-out rates from multidisciplinary programs are higher among families receiving public health insurance [45]. Whatever the rationale for dropping from the

programs or missing appointments, the costs incurred, in terms of finances and overall health, are immense.

There is limited research that examines the effectiveness of collaborations between medical and community-based organizations in the management of childhood obesity, particularly among low-income families [54]. The results of the current study add to the body of knowledge investigating the feasibility of such collaborations. Research results also provide new information regarding the effectiveness of trained community health workers in delivering a weight management program to low-income children and their families through an Extension system.

Community-Based Programs for Families with Obese and Overweight Children

The literature investigating community-based interventions as treatment options for overweight and obese youth is scarce [31, 146]. There is a growing need for studies that examine the feasibility and effectiveness of accessible and scalable weight management programs delivered to families with overweight or obese children [147].

Results of two separate single-arm studies performed at YMCA facilities in North Carolina and Rhode Island have been reported [148, 149]. Foster and colleagues examined a program delivered at eight YMCA facilities in Rhode Island to overweight and obese children aged 6-17 years (n=155) and their caregivers [148]. The program included 24 sessions over six months, with half of treatment sessions delivered by YMCA staff and half delivered by parents/caregivers at home [148]. Children experienced a reduction in percentage overweight (p=.001) as well as significant improvements in health-related quality of life [148]. Schwartz and colleagues tested the design and feasibility of a YMCA program for obese and overweight children aged 6-11 years (n=59) in North Carolina [149]. Children participated in physical activity sessions three times a week for three months, and parents received once-weekly nutrition education classes conducted by a registered dietitian using the 10-session *NC Eat Smart, Move More* curriculum [149]. Significant reductions in BMI percentile were observed at 3, 6, and 12 months (p<.001) [149]. Authors further reported improvements in dietary and physical activity behaviors [149]. Both programs, delivered through the YMCA, used existing staff with college degrees, most with advanced degrees [148, 149].

Robertson and colleagues investigated a program in the United Kingdom with 27 overweight or obese children aged 7-13 years and their parents [150]. *Families for Health* was a 12-week program with parallel groups for parents and children [150]. Authors reported a statistically significant reduction in BMI z-score at 3 (p=.008) and 9 months (p=.007) as well as improvements in children's quality of life and health-related behaviors [150].

Two randomized controlled trials examining community-based programs in the treatment of childhood overweight and obesity have been reported [52, 151]. Janicke and colleagues assessed the effectiveness of parent-only versus family-based interventions for overweight and obese children aged 8-12 years (n=93) in underserved rural settings [52]. All sessions were held for eight weeks, then bi-weekly for another eight weeks and were conducted in Florida by Cooperative Extension Agents with graduate degrees. Families were randomized into behavioral family, behavioral parent-only, or control [52]. At 10-month follow-up, children in both parent-

only and family-based interventions demonstrated greater decreases in BMI z-score than controls (p<.05) [52]. There was no significant difference between intervention groups [52]. Sacher and colleagues evaluated the effectiveness of the *Mind*, *Exercise*, *Nutrition*, *Do it* (*MEND*) program in the United Kingdom [151]. Obese children aged 8-12 years (n=116) were randomly assigned to intervention or wait list control, and parents and children attended 18 group sessions held twice each week. Children in the intervention group had reduced waist circumference (p<.0001) and BMI z-score (p<.0001) at 6-months when compared to controls [151].

Previous literature, although limited, has provided evidence to support community-based programming in the management of childhood overweight and obesity. However, many of the programs used staff with specialized training or advanced degrees, limiting reproducibility. Utilizing trained community health workers, supervised by health professionals, to disseminate evidence-based weight management programs is a feasible alternative. Community health workers are defined as individuals who serve as bridges between their ethnic, cultural, or geographic communities and health care providers [152]. Community health workers may or may not have a college degree and are specifically trained to facilitate access to health education programs as well as provide on-going support and guidance. Growing evidence demonstrates their effectiveness in improving health behaviors, health outcomes, and knowledge related to chronic disease [153-158].

Trained community health workers are effective in improving health behaviors related to chronic diseases, such as type 2 diabetes. Custack and colleagues examined the impact of a 10-week lifestyle management program delivered by trained community health workers in improving
clinical markers and behaviors related to diabetes control in 156 low-income adults with type 2 diabetes [158]. Results indicated significant changes between baseline and follow-up measures of Hemoglobin A1c (a measure of long-term blood glucose control) (p<.001), BMI (p<.05) smoking tobacco (p<.05), fruit and vegetable intake (p<.01), and appraisal of diabetes (p<.001) [158]. Spencer and colleagues tested the effectiveness of a community health worker-led intervention on improving glycemic control in 164 African American and Latino adults with type 2 diabetes [155]. Authors reported a significant improvement in Hemoglobin A1c values of the intervention group (p<.01) with no improvement in the control group [155]. Similarly, systematic reviews have indicated that community health workers play an important role in the management of diabetes [154], hypertension [153], heart disease and stroke [159] in the adults.

Furthermore, studies using community health workers as agents of change for children with chronic conditions, such as asthma, have consistently identified positive outcomes [157, 160-162]. A recent systematic review examining the role of community health workers in the treatment of chronic conditions in children indicated that these interventions were cost-effective and may lead to improvements in urgent care use, symptoms, and parental psychosocial outcomes [163]. Unfortunately, this review only included one intervention focused on obesity in children, which was a pilot parent-directed trial that resulted in only modest reductions in BMI percentile of children [55].

There is, therefore, increasing awareness and agreement surrounding the effectiveness of trained community health workers in the management of chronic conditions in both adults and children. However, only a limited number of studies have examined the feasibility and effectiveness of

community health workers in the management of overweight and obesity in children, and the results are inconsistent. One study examined the effectiveness of community health workers in the treatment of childhood obesity using a family-based weight management program in lowincome populations (Smart Choices for Healthy Families) [54]. Obese children aged 8-12 years (n=26) and their parents were referred to lay health workers from Cooperative Extension by their pediatrician [54]. The program included six bi-weekly group sessions and six automated telephone calls over three months [54]. Authors reported that children experienced significant decreases in BMI z-score (p < .05) as well as increases in lean muscle mass (p < .001) and improved quality of life (p < .0001) [54]. Resnick and colleagues reported the effectiveness of a pilot parentdirected trial with 46 parents of overweight or obese elementary school children. Parents were randomly assigned to either a group that received educational materials through the mail or a group that received educational materials through interactions with community health workers [55]. The mean BMI percentile for all children dropped from 94.1 to 90.6 (p=.005), but authors found no differences in the reduction of the children's BMI between the group that received educational materials through the mail and the group that received education through interactions with community health workers [55].

Few studies have examined community health workers as agents of change for families with obese or overweight children. Furthermore, research specifically evaluating their effectiveness in delivering a weight management program through an Extension system is lacking.

Weight Management Programs for Families through Michigan State University Extension

The Extension service is a nationwide, noncredit educational network designed to help people use research-based knowledge to improve their lives. The service is provided by land-grant universities throughout the country and includes a network of local offices throughout each state. In addition to programming focused on nutrition and health, Extension features programming in agriculture, business and community, family, lawn and garden, natural resources, 4-H and youth. Families are referred to programs within Extension based on need and interest.

Michigan State University Extension (MSUE), an organization that has successfully taught nutrition education statewide since 1914, uses trained community health workers, hereafter referred to as Program Associates, supervised by professional staff and supported by MSUE campus staff, to deliver basic nutrition education. MSUE is uniquely positioned to address the growing issue of childhood overweight and obesity in Michigan by providing education and behavior change strategies at the community level. Approximately 160 trained MSUE Program Associates provide group teaching to limited income families throughout Michigan. MSUE has the capacity to build a network of community health workers to support families in managing overweight and obesity.

A pilot study for the current research project was implemented in Grand Rapids in 2008 through a partnership between MSUE and Spectrum Health [164]. Families with overweight or obese children between the ages of 8 and 12 years who were receiving Medicaid were eligible to participate in the program. Research assistants at the partnering pediatric clinic identified eligible children and recruited families into the program. Families were then referred to the local

MSUE office in Grand Rapids. The program, *Healthy Kids, Healthy Families*, was taught by a trained MSUE Program Associate, who was supervised by professional staff trained in nutrition. Thirteen families enrolled in the program, with seven children in the intervention group and six in the control group. Baseline results indicated that average age of the participants was 8.75 years and the BMI of each of the children in the intervention group was above the 95th percentile [164]. Mean LDL-cholesterol level of program participants was 133.5 mg/dL, which is borderline risk for coronary heart disease [164]. Unfortunately, funding constraints prevented researchers from collecting follow-up data to examine program effectiveness.

In addition to the lack of studies examining feasibility and effectiveness of community health workers in the treatment of childhood obesity, there is a dearth of literature assessing feasibility and effectiveness of collaborations between medical and community-based organizations in the management of childhood obesity [54]. The current study provides new information about whether a collaboration between pediatricians and Extension is feasible in areas with high rates of poverty, violence, and unemployment. In addition, the results provide evidence for the feasibility, preliminary effectiveness and participant satisfaction with the intervention as well as the trained MSUE Program Associates who deliver the program.

Theoretical Foundation for Conducting Focus Groups Related to Program Intervention Family-based weight management programs, whether through community-based interventions or multidisciplinary treatment centers, are not successful for all children who participate [165]. There is a growing need for studies to examine why programs are more (or less successful) for the children and families that participate [31]. More in-depth information is needed from

children about their own objectives, priorities and interests with regard to achieving a healthy weight; barriers to healthy eating and regular physical activity; feelings of self-efficacy related to changing unhealthy behaviors; personal experiences with their own families with regard to achieving a healthy weight; and views of the environmental support that surrounds them. Similarly, more information is needed from parents about their own objectives, priorities and interests with regard to their child's weight; barriers and facilitators to healthy eating and physical activity for themselves and their families; and confidence in modeling and supporting healthy behaviors for their children.

The current study targets low-income families in two post-industrial cities in Michigan. The experiences of participating families may not be representative of all, but certainly provide a better understanding of the experiences and challenges of those families that are hardest to reach.

Social Cognitive Theory

Social Cognitive Theory (SCT) suggests that behavior is explained by a three-stage, dynamic model between personal factors, environmental factors and behavior [56, 57]. These factors operate in a reciprocal manner, with each influencing the other [56]. *Personal factors* within SCT for understanding behavior change include, but are not limited to, knowledge, skills, self-efficacy and outcome expectancies [166]. The primary *environmental factors* within SCT for understanding behavior change are modeling, rewarding/reinforcement (from parents and others), support, and availability (such as provision of healthy foods) [166]. Personal factors, environmental factors, and behaviors (responses or choices made) influence each other in a reciprocal fashion [56].

According to SCT, knowledge of health risks and benefits creates the precondition for change [56], but beliefs of self-efficacy are needed for most people to overcome the barriers to adopting and maintaining healthy lifestyles [56]. Improving self-efficacy, which refers to one's judgment about their capability to perform particular tasks [56], is important for behavior change. Since children are generally guided by parents in their dietary intake and levels of physical activity, environmental factors, such as parental modeling and support as well as access to healthy foods/physical activity, offer promise when working with children [166]. Modeling, for instance, is an important environmental factor as children often learn behaviors from observing their parents and imitating that behavior [120, 167, 168]. Parents, then, have an important responsibility to ensure that the environment surrounding their overweight child is one that promotes a healthy lifestyle.

Social Cognitive Theory provides a framework from which multiple contextual factors affecting the achievement of healthy weight in children can be viewed. The intent of the qualitative portion of the current study was to elicit the unique experiences and voices of the families struggling with childhood obesity. The focus groups provided a better understanding of not only participant experiences in the program, but also changes in environmental variables, such as parental modeling and support behaviors, which resulted from program participation. Additionally, researchers examined whether changes in knowledge, skills, self-efficacy, and outcome expectancies of participating children resulted from program participation. Families had the opportunity to share what specifics aspects of the program led to improvements in health behaviors and overall weight management.



Figure 2. Application of Social Cognitive Theory

Conceptual Model

By employing the SCT, the factors influencing the development and maintenance of obesity and overweight in children (personal, environmental, and behavioral) were characterized as the inputs. How these inputs were modified as a result of the throughput (participation in the intervention) and thus facilitated the outcome (improved quality of life, eating and physical activity behaviors, and weight) were of particular importance. This model proposes that personal factors (knowledge, skills, self-efficacy, outcome expectancies), environmental factors (parental modeling, parental support, availability of healthy foods), and reciprocal behavioral responses are all inputs that influence a child's ability to maintain a healthy weight. Based on the conceptual map and the literature, research questions were derived.



Figure 3. Conceptual Framework

The Academy of Nutrition and Dietetics (AND) recommends comprehensive, multi-component interventions that include diet, physical activity, and behavior as well as parent or caregiver engagement in the management of overweight and obesity in children [58]. A well-designed community-based and theory-driven intervention to help children and families manage childhood overweight and obesity could have meaningful impacts. Additionally, the use of trained community health workers from an organization with offices in nearly every county in Michigan allows for widespread program dissemination. The current study sought to evaluate the feasibility and participant experiences of such a program in two post-industrial cities with high rates of poverty, violence, and unemployment.

CHAPTER 3 - Methods

This chapter is organized into two phases. Phase 1 involves an examination of program feasibility and includes collection and analysis of quantitative data from a single-arm study (Aim 1); and Phase 2 encompasses a focus group study and analysis using qualitative methods (Aim 2). The third aim synthesizes results from the first two aims to describe a protocol for a trial to evaluate program effectiveness.

Approach for Aim 1

The first aim of the current study was to assess the feasibility, implementation challenges, and preliminary effectiveness of *Healthy Kids, Healthy Families*, a weight management program for families with overweight or obese children delivered by Extension. A secondary aim was to describe baseline characteristics and degree of overweight of children who enrolled in the program to better understand the need, in targeted areas, for an obesity management program.

Study Design

This was a feasibility study to evaluate challenges and opportunities when implementing a weight management program designed for families and delivered by Extension community health workers, hereafter referred to as MSUE Program Associates. Researchers assessed whether, and to what degree, families agreed to participate and engage in the program as well as preliminary effectiveness. An examination of physician monitoring of BMI percentile and screening for comorbid conditions is also included. Descriptive data of children's degree of overweight and risk for comorbidities at baseline provides important information regarding the need, in targeted areas, for a weight management program for children.

Research assistants at partnering pediatric clinics identified children who were overweight or obese and recruited families into the program. The families were then referred to the local Extension office. *Healthy Kids, Healthy Families* began with a one-on-one session between the MSUE Program Associate and the participating family. At the first visit, the program was initiated and children completed a series of baseline behavioral and quality of life assessments. Following the home visit, the trained MSUE Program Associate began a series of six multifamily group sessions. Follow-up behavioral and quality of life data were collected at program exit.

Sample and Recruitment

The current study identified a sample of low-income overweight and obese children living in Flint and Saginaw, Michigan. Both are post-industrial cities with similar demographics. Families self-selected into the program after children were identified by their pediatrician, and the research assistants provided a detailed description of the program. Participants were recruited from two partnering pediatric clinics (Hurley Hospital Pediatric Clinic in Flint and Healthy Futures Private Practice Clinic in Saginaw). For a more detailed description of the partnering clinics as recruitment sites, please see **Appendix A**.

The lead researcher trained four research assistants (three at Hurley Pediatric Clinic in Flint and one at Healthy Futures Clinic in Saginaw) to recruit participants into the program. Families were eligible for participation if their child was an active patient at the identified clinic; was between 6 and 14 years of age; and was mentally competent to provide assent. Research assistants targeted children with a BMI percentile $\geq 85^{\text{th}}$ percentile for age and sex.

Procedures

Following approval from the Institutional Review Boards (IRB) of Michigan State University and Hurley Medical Center and ensured compliance with the Health Insurance Portability and Accountability Act (HIPAA) guidelines, trained research assistants began to recruit families with overweight or obese children at partnering clinics in Saginaw (January 2015) and Flint (May 2015). During scheduled office visits at partnering pediatric clinics, a health professional collected baseline height and weight (for BMI percentile calculation) and blood pressure. Physicians then notified research assistants of eligible families following the determination of BMI percentile. The research assistants visited families in patient rooms and provided a description of the program. Following the program description, the research assistants obtained parental consent, child assent, and HIPAA authorization from families interested in participating in the program. At that time, all parents and guardians also agreed to participate in home visits and group sessions with their child/children.

Next, research assistants recorded demographic information, including the gender, age, and ethnicity of the child as well as the type of health insurance. The research assistants also recorded baseline clinical data which included height, weight, systolic blood pressure, and diastolic blood pressure. Baseline biochemical data, including Hemoglobin A1c, total cholesterol, LDL-cholesterol, HDL-cholesterol, and triglycerides, was recorded when available in patient charts.

Following the collection of all baseline clinical and biochemical data, the research assistants contacted the Extension office in Flint or Saginaw and provided contact information for families.

The trained MSUE Program Associate collected baseline behavioral and quality of life evaluations with children during a scheduled home visit. These assessments, selected because of their direct association with the development and maintenance of obesity in children, included the collection of one 24-hour dietary recall, and completion of the following questionnaires: Physical Activity Questionnaire for Children [169] and Health-Related Quality of Life (Pediatric Form) [170]. After completing all baseline assessments (clinical, biochemical, behavioral, and quality of life), the MSUE Program Associate began a series of six multi-family group sessions.

At the conclusion of the final session of the program, the MSUE Program Associate collected follow-up behavioral and quality of life evaluations. Small incentives, such as water bottles, reusable lunch bags, and children's books, were given for program participation and completion of assessments. Given the focus on feasibility and implementation; short timeframe of exit data collection; behavioral approach being one of small measurable changes; and the expectation that clinical values would not be significantly changed [143, 144, 171], researchers did not require children to have height and weight (for calculation of BMI percentile) and blood pressure measured at program exit.

Intervention

Researchers from MSU Departments of Food Science & Human Nutrition and Human Development & Family Studies developed a theory-driven curriculum via funding from Michigan Department of Community Health (MDCH). The curriculum centered around a wellrecognized theory of behavior change. Social Cognitive Theory (SCT) describes behavior change as an interaction between personal, behavioral and environmental factors [57]. The

factors operate in a reciprocal manner with each influencing the other and can be translated into specific constructs that shape the components of an intervention [172]. Specific curriculum components that incorporated SCT included the following: providing opportunities for food preparation and physical activity in sessions; providing opportunities to practice positive role-modeling; self-monitoring of behavior; behavior contracting (weekly behavior goals); and praise and reinforcement.

Healthy Kids, Healthy Families was intended for delivery by trained MSUE Program Associates to support families in dealing with the physical, psychological, and emotional barriers to a healthy lifestyle. The project team developed a single one-on-one session followed by a series of six multi-family group sessions that focus on family development and communication and provide basic nutrition and health information. See **Appendix B** for an overview of the group curriculum. Each of the sessions included a number of interactive activities designed to engage families. Sessions contained information about family dynamics, behavior change, body image, nutrition, meal planning, physical activity, and community resources. **Table 2** provides a list of topics, objectives, and focus of sessions.

Each of the seven sessions followed a similar template. Beginning in the first one-on-one session, participants are asked to set one specific and measurable goal for themselves for the upcoming week (**Appendix R**) and to work with their family to set one family goal for the upcoming week (**Appendix S**). Those goals were recorded on weekly tracking sheets, and children were given stickers to place on the sheets when goals were met. At the start of each group session, participants and families reported back to the entire group on weekly goal

progress and explained any barriers or facilitators to goal achievement (**Appendix T**). New goals were set and monitored every week. Participants were also asked to report how they were feeling in the "How Ya' Doing" segment and whether and how the group could offer support to those who needed it.

Following the goal tracking and setting activity, families engaged in at least 20 minutes of physical activity. These activities varied from site to site but included aerobic, muscle strengthening, and bone strengthening activities. Families were taught a variety of different activities that could be done indoors or outdoors. Exercising as a family was an important focus as was exercising within the family's current environment.

A learning activity, lasting approximately 20-30 minutes, followed the physical activity. The *Healthy Kids, Healthy Families* manual included a script for the sessions and learning activities specific to each session topic. Learning activities were interactive and included topics focused on nutrition, physical activity, body image, behavior change, and maintaining a healthy lifestyle. The focus was on the importance of change as a family and parental modeling of appropriate health behaviors (such as preparing and eating a variety of foods, shopping skills, making time for family meals, and engaging in physical activity).

Sessions ended with a 20-30-minute cooking activity. Families were given the choice of several different recipes to prepare and taste during the session. Children participated in food preparation with the MSUE Program Associate and were given the recipes to take home.

	Home	Group	Group	Group	Group Service 4	Group	Group
~ •	VISIT I	Session 1	Session 2	Session 3	Session 4	Session 5	Session 6
Session	Getting	We Can Do	Eat Smart, Eat	Be Strong, Be	Jump and Groove!	There's No	Wrappin It
Title	Started!	It!	Healthy!	Healthy!		One Like	Up!
						Me!	
Learning	Describe	Identify six	Identify	Identify three	Identify two	Recognize	Identify
Obj	roles of	skills that lead	different food	factors that	strategies for	the	strategies to
-	family	to successful	groups.	impact overall	achieving more	importance	manage
	members	behavior	0	health and well-	daily physical	ofa	overall health
	in food	change.	Identify foods	being.	activity.	positive	after program.
	preparation	U	that fit into	0	5	body	1 0
	and meal		various food	Describe	Describe the three	image.	Describe
	selection		groups	behaviors to	types of physical	8	problem
			Stoups.	promote and	activity	Appreciate	solving
	Indicate		List healthy	maintain a	uoti vity.	differences	techniques
	readiness		snack options	healthy lifestyle		in various	teeninques.
	to change		snack options.	meaning mestyle.		hody types	
	to change.					body types.	
Key	Change to	Parenting	Importance of	Caring for your	Promotion of	Self-	Summary and
Concents	improve	roles	eating a variety	body and	nhysical activity	esteem and	reinforcement
Concepts	health	providing a	of foods in	lifestyle choices	physical activity	positive	of program
	hehaviora	providing a	or roous in moderation for	mestyle choices	Introduction to	body	
	Dellaviors	fomily	moderation for		turnes of physical	imaga	points
			good health		types of physical	innage	Duchland
		environment,	and weight				Problem
		and initiating	maintenance		guidelines and		solving
		behavior			recommendations		techniques for
		change	Introduction to				maintaining
			MyPlate				healthy family
							lifestyles

Table 2. Healthy Kids, Healthy Families Topics, Objectives, and Key Concepts

Training of Program Associates

Trained MSUE Program Associates, who were supervised by county-based registered dietitians, delivered each of the seven *Healthy Kids, Healthy Families* sessions. Each had previous experience facilitating nutrition programs through Extension. Although not necessary for their positions with Extension, the selected Program Associates had completed college. Their Extension supervisor was a Master's level registered dietitian.

Ms. Custack, a registered dietitian and lead researcher, trained the MSUE Program Associates and their supervisors to deliver the program during a one-day training. This training also delineated research procedures; introduced Extension staff to behavior change theories; and provided opportunities to practice sessions with one another.

In addition, the lead researcher provided a journal in which to record program experiences – challenges and successes. MSUE Program Associates were instructed to spend time at the end of each session recording information specific to that session, such as date, time, and number of participants. They were asked to record activities that did/did not work with the families; recipes and activities that were popular; struggles they had while teaching the session; and elements of the session that participants particularly enjoyed.

Ms. Custack visited Extension staff and partnering pediatric offices regularly (approximately twice a month). Weekly conference calls between researchers and Extension staff were held in an effort to address concerns, update program materials, educate staff, and allow staff to share experiences and challenges. MSUE Program Associates were also provided with educational

handouts to distribute, exercise equipment, teaching aides, and a list of local and national resources.

Instruments and Variables

Demographic Data. Demographic data included the gender, age, and race-ethnicity of participating children. In addition, parents/caregivers reported their current health insurance provider.

Clinical Data. A health professional collected baseline height and weight (for BMI percentile calculation) and blood pressure during a scheduled office visit, and a research assistant recorded the information (**Appendix O**).

Body Mass Index (BMI) - BMI is calculated from a child's weight and height and, when categorized into percentiles by sex and age, serves as an indicator of risk for overweight and obesity [173]. The BMI number can then be plotted on the CDC BMI-for-age growth charts to obtain a percentile ranking. The percentile indicates the position of the child's BMI number among children of the same sex and age. The growth charts show the weight status categories used with children (underweight, healthy weight, overweight, and obese). Researchers categorized children as follows: overweight (BMI \ge 85th percentile for age and sex), obese (BMI \ge 95th percentile for age and sex). Degree of obesity in children who fell above the 95th percentile was characterized according to the following formula: (child's BMI/BMI at 95th percentile) x 100%; with moderate or class 1 obesity (BMI > 100-120% of the 95th percentile), class 2 obesity (BMI > 120-140% of the 95th percentile), and class 3 obesity (>140%) [7, 174].

Blood Pressure - Researchers determined high blood pressure ($\geq 90^{\text{th}}$ percentile based on sex, age, and height) using the National Heart, Lung, and Blood Institute (NHLBI) series of age

and gender specific measurement tables for children 3 through 17 years [94].

Biochemical Data. HbA1c and lipid profile (total cholesterol, LDL-cholesterol, HDLcholesterol, triglycerides) were recorded at baseline, when available, from patient charts (**Appendix O**). Researchers examined whether, and to what degree, partnering pediatric practices were screening obese children for comorbidities in accordance with current recommendations [137, 138].

Hemoglobin A1c (HbA1c) - The American Diabetes Association (ADA), the International Diabetes Federation (IDF), and the European Association for the study of Diabetes (EASD) jointly recommend the use of HbA1c assay for the diagnosis of diabetes [175]. Evidence supports HbA1c as a good predictor of type 2 diabetes in obese children and an excellent predictor of type 2 diabetes in insulin-resistant children [176]. For the purposes of the current study, children with HgA1c less than 5.7% were considered normal; those with HbA1c values between 5.7 and 6.4% at-risk; and those with HbA1c equal to or above 6.5% were considered to have diabetes [177].

Lipid Profile - Researchers followed 2011 guidelines set by an expert panel on integrated guidelines for cardiovascular health in children and adolescents [178]. The high range for triglyceride concentrations was defined as 90-129 mg/dL; the high range for LDL-cholesterol as 110-129; and the low range for HDL-cholesterol as 40-45 mg/dL [178]. Participants with total cholesterol above 170 mg/dL were considered borderline risk while those children with total cholesterol above 200 mg/dL were considered high risk for early cardiovascular disease [178].

Behavioral and Quality of Life Data. The MSUE Program Associate collected baseline behavioral and quality of life evaluations with children during the initial one-on-one session. These assessments included the collection of one 24-hour dietary recall, and completion of the following questionnaires: Physical Activity Questionnaire for Children [169] and Health-Related Quality of Life (Pediatric Form) [170]. At the conclusion of the final session, the MSUE Program Associate collected exit behavioral and quality of life evaluations.

Dietary Behaviors - Eating behaviors were measured using one 24-hour dietary recall following the United States Department of Agriculture (USDA) multiple pass method [179, 180]. Results from the Child and Adolescent Trial for Cardiovascular Health (CATCH) study determined that 24-hour recall is a valid measure for assessing the dietary intake of children as young as eight years old [181]. When assessing the diets of children under the age of ten, one or both parents were asked to give combined responses with the child. This approach has been shown to give more accurate information than a recall from either parent alone [182]. Dietary data were analyzed using Nutritionist Pro Diet Analysis Software (Axxya Systems).

Physical Activity - Physical activity was assessed using the Physical Activity Questionnaire (PAQ-C), which is a self-administered questionnaire that has been validated for use in children [169, 183, 184]. It was used to determine the amount of physical activity performed in the seven days preceding the evaluation. Parents were allowed to assist younger children complete the PAQ-C. Evidence supports the PAQ-C as a reliable and valid measure of general physical activity levels in children [169, 183, 184]. When administered to elementary school children, the measures demonstrated acceptable scale reliability for both females ($\alpha =$ 0.83) and males ($\alpha = 0.80$) [169]. Two additional studies by Kowalski, Crocker, and Faulkner supported the PAQ-C as a valid measure of general physical activity levels [183, 184]. *Health-Related Quality of Life* – Health related quality of life was measured using the Pediatric Quality of Life Inventory (PedsQL). PedsQL measures health-related quality of life in healthy children, and those with acute and chronic conditions, aged 2 to 18 years [170]. It is a child self-report consisting of 23 items. The scale has summary, physical, social, emotional and school scores that show adequate reliability and validity [185].

Statistical Analysis

Baseline descriptive characteristics are reported for demographic as well as clinical, biochemical, and behavioral variables. In order to explore whether certain behavioral variables (health-related quality of life, physical activity, and dietary behaviors) explained an inherent grouping within the participants with respect to their BMI percentile, hierarchical cluster analysis was performed [186]. This resulted in a strong grouping of the participants similar in terms of their BMI percentile and dietary behaviors. To quantify the strength of the relationships between the groupings of participants and all behavioral variables, researchers used independent samples *t*-tests with overweight/normal weight children representing Group 1 and obese/severely obese children representing Group 2. Differences in health-related behaviors at baseline were considered statistically significant based on a p-value of less than 0.05 using two-tailed tests.

In order to determine preliminary program effectiveness, baseline and exit scores on behavioral and quality of life outcomes were compared using Wilcoxon signed rank test [187] and effect size calculations [188]. Differences in baseline and exit data were considered statistically significant based on a p-value of less than 0.05 using two-tailed tests. Effect sizes were

interpreted using Cohens thresholds for interpreting effect size (small = .10; medium = .30; large = .50) [189]. All analyses were conducted using SPSS version 23 (IBM Analytics, 2015).

Approach for Aim 2

The second aim of the study was to examine parent and child perceptions of and experiences with *Healthy Kids, Healthy Families* as well as changes in environmental and personal variables that resulted from program participation.

Study Design

This was a triangulated qualitative study that included demographic surveys and focus groups or in-depth interviews to assess family perceptions of and experiences in *Healthy Kids, Healthy Families* as well as personal and environmental variables that changed following program participation. Triangulation of data from focus groups or interviews and demographic surveys was completed to identify themes related to participant experiences and changes in personal and environmental variables (**Figure 4**). Triangulation integrated these different data sources to enhance understanding of participants and their experiences and create a more complete picture [190].

The research strategy used for the current study, which included focus groups or interviews and a survey of demographic characteristics of caregivers, was the most efficient way to accomplish the goals for this phase of the study [191, 192]. More specifically, information relating to program experiences, changes in children's personal factors, and changes in environmental factors surrounding the children was sought. Focus groups or interviews at the conclusion of the

program facilitated in-depth discussion of parental and child perspectives within the context of the larger group. With Bandura's Social Cognitive Theory [56] as the theoretical framework, questions were developed for the focus group guide that were guided by literature, research questions, and the primary investigator's experience with this topic and population (**Appendix K**).



Figure 4. Triangulation of Data

Rationale for a Qualitative Study

Given the exploratory nature of the research questions and specific interest in understanding participant experiences with *Healthy Kids, Healthy Families*, a qualitative approach was deemed the best fit for the study. Qualitative research seeks to understand and interpret personal experiences; give voices to those who are rarely heard; conduct initial explorations to develop theories; and provide rich descriptions of complex phenomena (including those related to health) [191, 193, 194]. Particularly important to the current study is that qualitative research is able to address questions that quantitative research cannot, such as why certain health care interventions are more (or less) successful [193].

Participants who drop from pediatric weight management programs often indicate that they were not satisfied with the program [45, 165]. Families point specifically to unmet expectations; programs failing to meet family needs; and disliking specific program components as reasons for dropping from programs [45, 165, 195]. An examination of family perceptions of and experiences in weight management programs is essential to understanding participant satisfaction and potential reasons for attrition, but these factors have not been well-studied [31, 196, 197].

This qualitative assessment of participant experiences in a weight management program for families with obese or overweight children delivered by Extension helps elucidate not only the feasibility of such a program, but also the effectiveness of the intervention in improving healthrelated behaviors of parents and children. The model was intentionally different from traditional multidisciplinary weight management programs as it utilized a community health worker model of delivery. Researchers were interested in how the families connected with these program instructors, given the body of literature documenting their success in working with children and vulnerable populations [152-163].

Procedures

After completion of the last session, families participated in either focus groups or interviews (families were given the option to participate with their class or alone). Focus groups were scheduled as the final class in the series and lasted approximately 45 minutes. Families were asked to come together to share their thoughts about the program and celebrate their graduation from *Healthy Kids, Healthy Families*. When possible, parents and children were separated into two groups, allowing both parents and children to report their experiences openly and honestly.

Table 3 describes the relationship between Social Cognitive Theory, concepts, research questions and select focus group questions. In addition to the questions in **Table 3**, the focus group guide in **Appendix K** also includes questions about program content, goals and expectations, new information learned, the feelings about group leader, and suggestions for improving the program. The demographic survey (MSUE Enrollment Form) and extraction form are included as **Appendices L and M**. Researchers examined the results from these data sources to inform the intervention as well as future recruitment methods.

Qualitative Analysis

Focus Groups and Interviews. The data were organized and analyzed in the following manner:

1) After each interview or focus group, the recordings were transcribed verbatim by the researcher who was present at the interviews. Whenever there was obscurity during the

data collection, the researcher had a formal verification with participants by repeating both question and answer to ensure the data collected were accurate. All transcripts were read again while listening to the recordings to ensure accuracy. Two researchers (both graduate students in Human Nutrition trained in qualitative studies) reviewed and discussed the transcripts.

- 2) The transcripts were individually coded by these two researchers utilizing qualitative methodology with a thematic analysis approach [198-200]. The use of thematic analysis, which is a method for identifying, analyzing, and reporting patterns or themes within data [200], provides a framework for further research in the area of participant experiences and behavioral outcomes in weight management programs for children and families. Researchers used purposive sampling because there was a limited pool of participants, given that families had to agree to participate in and complete the program.
- Researchers independently developed initial codes. Initial codes were checked and discussed until consensus was reached. Initial codes were then grouped into categories, agreed upon by both researchers, and assigned themes.
- All steps and changes throughout the study were documented as on-going memos by Ms. Custack.

Social	Contents	Descent Orestin		
Theory	Concepts	Research Question	Interview Question	
Person	Skills	How do children perceive their own ability to achieve a healthier lifestyle?	How do you (children) feel about your ability to exercise more and make healthier foods choices? <i>Prompts:</i> Do you think you can exercise and eat healthier?	
	Self-efficacy		How do you (children) feel about your own ability to reach the goals you set for yourself? <i>Prompts:</i> Do you think goals are reachable? Why? How?	
	Outcome Expectancies		What do you (children) believe will be the result/outcome if you follow the program suggestions? <i>Prompts</i> : Do you think you can be healthier if you eat better and exercise?	
Environment	Support from Others	To what extent did <i>HKHF</i> influence parent/caregiver behavior related to support of their children and modeling of appropriate health-related behaviors?	<i>Parents</i> : What changes did you make to help support your children during the program? <i>Kids</i> : What did your mom/dad do to support you during the program that they didn't do in the past?	
	Modeling Behavior		<i>Parents</i> : How would you describe the changes in your own eating and exercise habits as a result of <i>HKHF</i> ? <i>Kids</i> : What differences did you notice in your parents' eating and activity since starting <i>HKHF</i> ?	

 Table 3. Relationship with Social Cognitive Theory, concepts, and questions

Approach for Aim 3

The third aim of the study was to describe, using information gathered from the feasibility study (Aim 1) and participant experiences (Aim 2), a protocol for a trial to evaluate the effectiveness of *Healthy Kids, Healthy Families*. Together, results from Aims 1 and 2 indicated that although the program was effective for and well-received by program completers, attrition rates were high, and program engagement was low. The tested model of referral and delivery was, therefore, not feasible in its current design. Modifications were made to include more flexible programming options with referrals through primary care providers as well as through other Extension programs, schools, community centers, faith-based organizations, and the like. The proposed trial to examine program efficacy includes referrals from numerous sources; expands programming to include various sites and times convenient for families; and incorporates a process evaluation to monitor and document program implementation.

Study Design

In an effort to examine effectiveness of the program, researchers compare changes in behavioral, quality of life, and clinical data in the intervention versus control groups. Data is collected at three time points (baseline, 12-weeks, and 25-weeks).

Healthy Kids, Healthy Families begins with a one-on-one home visit with the MSUE Program Associate who introduces the program, measures height and weight of child and primary caregivers, and completes a series of baseline behavioral and quality of life assessments with children in both the intervention and control groups. Following the home visit, the trained MSUE Program Associate begins a series of six multi-family group sessions with families in the intervention group. These sessions take place in a variety of locations (pediatric offices, schools, community centers, faith-based organizations and Extension offices) at times that are convenient for families. Follow-up data is collected at 12-weeks and again at 25-weeks. See **Table 4** for study design and group comparisons.

Week	Intervention Group	Control Group	
1-3	Baseline Data Collection	Baseline Data Collection	
4-11	Intervention Period	Standard Care	
12-13	Behavioral Post Test	Behavioral Post Test	
25-26	Follow-Up	Follow-up	

Table 4. A Randomized Controlled Trial Study Design and Group Comparisons

Sample and Recruitment

The randomized controlled trial is conducted with a sample of children living in Saginaw, with recruitment from primary care pediatric and family practice offices in Saginaw, newspaper advertisements, schools, other Extension programs, Parks and Recreation, and community organizations. Interested families call the local Extension office for eligibility screening based on child's age and caregiver-reported weight status. Participating children must be between 8 and 14 years of age - researchers modified age requirements for the program based on feedback from parents and MSUE Program Associates (Aim 2). Children are randomly assigned to either the intervention or control group. All children in the control group and their families are invited to participate in the program after their 25-week follow-up data are complete. Children in the

control group who choose to attend the program after follow-up data collection do so as a participant with no requirement for continued participation in the research study. Extension staff assign a number to the children based on the order/time families call and express interest in the study. Children assigned an even number are placed into the control group and children assigned an odd number are placed into the intervention group. In an effort to keep families together, children in the same family are assigned consecutive even or odd numbers.

Procedures

Approval for a randomized controlled trial has been issued by the Institutional Review Board (IRB) of Michigan State University. Advertisements and information regarding *Healthy Kids*, *Healthy Families* are shared at pediatric and family practice clinics, local elementary schools, other Extension programs, Saginaw County Parks and Recreation, faith-based organizations, and newspapers. Parents contact Extension directly (via telephone or email) to enroll in the program. The MSUE Program Associate screens for eligibility based on child's age and parent-reported weight status of the child.

The MSUE Program Associate completes the informed consent process for parental consent, and child assent from families at a scheduled one-on-one session in the home or another convenient location. At that time, the Program Associate also collects baseline child and primary caregiver's height and weight (for BMI/BMI percentile calculations), behavioral and quality of life evaluations including one 24-hour food recall, Physical Activity Questionnaire for Children, and Health-Related Quality of Life. After completing all baseline assessments, the MSUE Program Associate delivers *Healthy Kids, Healthy Families* (curriculum described in Aim 1) in

multi-family group or individual family sessions with those in the intervention group. Families in the control group continue to receive standard care and are offered program participation following collection of follow-up data.

Approximately 12-weeks after data collection, the MSUE Program Associates collects follow-up behavioral and quality of life evaluations as well as child and primary caregiver's height and weight (for BMI/BMI percentile calculations). The Program Associates schedules home visits with control children to coincide with these dates and collect behavioral and quality of life evaluations as well as child and primary caregiver's height and weight. The MSUE Program Associates collects follow-up data a second time during a scheduled home visit with intervention and control children at 25-weeks. Small incentives, such as backpacks, water bottles, kitchen utensils, reusable lunch and grocery bags, and sports balls, are given for program participation and completion of assessments. See **Figure 5** for a flow chart of the data collection and intervention delivery.



Figure 5. Flow Chart of Data Collection and Study Schedule

Statistical Analysis

A comparative analysis of intervention and control groups by age, gender, race/ethnicity, and socioeconomic status (using insurance carrier) is accomplished, with degree of similarity between groups tested using ANOVA–F-tests, nonparametric and chi-square tests, as appropriate. Substantive differences are controlled for in subsequent analyses of outcomes by regression techniques.

Regression models examine differences from baseline, program exit, and 3-month follow-up between the intervention and control groups. The primary outcome is the child's BMI-percentile, which is an age and gender adjusted measure of BMI using the US CDC 2000 growth reference. The outcome for analysis is a continuous measure on a bounded range, for example, BMI-percentile (0,100). For this continuous measure and other continuous measures, researchers use linear regression. Researchers use multivariable logistic regression to analyze for categorical outcomes. All quantitative data is analyzed using SPSS version 23.

PASS version 11 was used to accomplish advance repeated measures ANOVA power analysis to determine the detectable change in BMI percentile with each subject measured two times. A repeated measures design with 1 between factor and 1 within factor has 2 groups with 19 subjects each for a total of 38 subjects [201]. This design achieves 91% power to test for a difference in BMI percentile between subjects if a Geisser-Greenhouse Corrected F-Test is used with a 5% significance level and the actual effect standard deviation is 0.45 (an effect size of 0.55). This design achieves 100% power to test for a difference in BMI percentile within

actual effect standard deviation is 0.39 (an effect size of 0.95). This design achieves 100% power to test the between and within subjects differences in BMI percentile if a Geisser-Greenhouse Corrected F-Test is used with a 5% significance level and the actual effect standard deviation is 0.39 (and effect size of 0.95).

Because intake of sugar and sugar-sweetened beverages was significantly different between overweight and normal weight children as compared to obese/severely obese children (Aim 1 results), researchers specifically examine changes in this dietary factor from baseline to followup. PASS version 11 was used to accomplish advance repeated measures ANOVA power analysis to determine the detectable change in sugar-sweetened beverage intake with each subject measured three times. A repeated measures design with 1 between factor and 1 within factor has 2 groups with 22 subjects each for a total of 44 subjects [201]. This design achieves 91% power to test for a difference in one cup sugar-sweetened beverage between subjects if a Geisser-Greenhouse Corrected F-Test is used with a 5% significance level and the actual effect standard deviation is 0.42 (an effect size of 0.51). This design achieves 100% power to test for a difference in one cup sugar-sweetened beverage within subjects if a Geisser-Greenhouse Corrected F-Test is used with a 5% significance level and the actual effect standard deviation is 0.42 (an effect size of 1.04). This design achieves 100% power to test the between and within subjects differences in one cup sugar-sweetened beverage if a Geisser-Greenhouse Corrected F-Test is used with a 5% significance level and the actual effect standard deviation is 0.42 (and effect size of 1.04).

Since sugar-sweetened beverage intake is the limiting outcome variable (requiring a larger sample size), researchers determined sample size using this variable. Assuming a 20% drop-out rate, a total of 54 children are to be recruited as subjects for the current study (27 in the intervention group and 27 in the control group).

Process Evaluation

Results from Aims 1 and 2 indicated a need for a process evaluation. Therefore, a process evaluation to assess program fidelity, dose (delivered and received), recruitment, retention, and reach is also accomplished in Aim 3 [202]. Process evaluation is used for both formative and summative purposes in an effort to understand the extent to which *Healthy Kids, Healthy Families* is delivered as designed (fidelity); incorporates the suggested number of lessons (dose); successfully recruits participants and families (recruitment); maintains low attrition rates (retention); and influences positive behavior change not only on intended participants but also family members (reach).

Program fidelity is assessed during weekly conference calls and monthly meetings between MSUE Program Associates and researchers. Effort logs are used for MSUE Program Associates to document that all components of each session were successfully covered. Additionally, at least two unannounced site observations occur throughout the program intervention period. Dosedelivered is documented using MSUE attendance sheets and time-logs that indicate length of each session. Researchers assess recruitment and retention by intervention or control group and by recruitment sites. Those families dropping out of the program are compared with those who remain in the program in terms of demographic characteristics. Researchers request and record reasons for attrition.

A key method for further assessing fidelity, dose, and reach is accomplished through focus group discussions at the conclusion of the program. With Bandura's Social Cognitive Theory as the theoretical framework, questions developed for the focus group guide, were guided by literature, research questions, and researchers' experience with this topic and population (**Appendix L**). Focus groups specifically examine changes in environmental and personal variables that resulted from program participation. The focus group guide also includes questions about program content, program goals and expectations, likes and dislikes, feelings about group leader, and suggestions for improving the program.

In addition to the focus group evaluation, participants and their caregivers also complete goal sheets each week. The purpose of these sheets is to monitor progress toward individual and family behavioral goals. Participants and their caregivers are asked to set measurable goals each week. The following week, families report barriers and facilitators to goal achievement. Researchers collect and record this information in an effort to better understand the unique struggles of low-income families with overweight and obese children.

Qualitative Analysis

After each focus group, the recordings are transcribed verbatim by the researcher who was present at the interviews. The transcripts are individually coded by three researchers, checked, and discussed by those researchers until consensus was reached. Thematic analysis best
describes the approach [198-200]. Using thematic analysis, researchers independently develop the initial codes, and any discrepancies are reconciled. Initial codes are grouped into categories and assigned themes. Qualitative data is managed with NVivo version 8.

CHAPTER 4 - *Healthy Kids, Healthy Families*: Feasibility and implementation of a weight management program for low-income families delivered by Extension

Abstract

Background: Trials examining the effectiveness of obesity management programs for children have largely consisted of efficacy studies conducted in controlled settings, such as academic research or tertiary care centers. There are limited studies examining feasibility and effectiveness of scalable, affordable, and accessible community-based interventions as treatment options for obese or overweight youth, particularly those that utilize community health workers. **Objective:** The objective of the current study was to evaluate the feasibility, implementation challenges, and preliminary effectiveness of a weight management program for low-income children and their families administered through Michigan State University Extension (MSUE). A secondary objective was to describe baseline characteristics and degree of overweight of children who enrolled in the program to better understand the magnitude of the problem in targeted areas.

Methods/Design: *Healthy Kids, Healthy Families* was a program offered to families of overweight or obese children aged 6 to 14 years who were patients at partnering pediatric clinics in Michigan. Two clinics in Flint and Saginaw, Michigan, both serving vulnerable communities, were selected to recruit overweight or obese children. After enrollment, trained community health workers (MSUE Program Associates) scheduled a one-on-one visit to initiate the program. Supervised by registered dietitians, MSUE Program Associates delivered a seven-week intervention (one home visit followed by six multi-family group sessions) that included information about nutrition, physical activity, family communication and cohesion, goal setting,

and problem solving. Baseline clinical, biochemical, behavioral, and quality of life data were collected to determine need, in targeted areas, for a weight management program for children. Behavioral and quality of life data were collected at baseline and program exit, and results were analyzed using Wilcoxon signed rank test and effect size calculations.

Results: A total of 72 children enrolled in *Healthy Kids, Healthy Families*. The majority of participants (mean age 9.3 years) were African American (68%), female (57%), obese (71%), and Medicaid recipients (73%). Less than 20% of obese children received the recommended screening for comorbidities, and most were not meeting dietary recommendations. Although 33 children (46%) participated in the initial one-on-one session, only 12 of these 33 children completed the program. Results indicated significant changes (p < .05) in physical activity, health-related quality of life, and emotional health of children who completed the program, with large effect sizes for each of these measures. Participants and caregivers who completed the program reported positive experiences with MSUE Program Associates and the intervention. **Conclusions:** The disproportionately large number of participants who were obese or severely obese; had not been screened for comorbidities; and were not meeting dietary recommendations warrants concern in these vulnerable communities. Participants who completed the program experienced significant improvements in physical activity and health related-quality of life and expressed positive experiences with regard to the program and MSUE Program Associates. However, program completion was reported to be a personal challenge for many, and the current model of referral and delivery appeared not to be feasible on a large scale. The model should be modified to include more flexible programming options with referrals through primary care providers as well as other programs and organizations. Additionally, and keeping in mind the numerous barriers to participation, families should be given the choice to participate in a group

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or one-on-one setting. Future studies should include formative research focused on barriers and facilitators to participation in an effort to improve program feasibility among low-income populations.

Background

In the United States (US), 31.8% of youth between the ages of 2 and 19 years are overweight and 16.9% are obese [3], with disproportionately higher rates among children from poorer families [25], as well as Mexican American, Native American, and African American children [26]. There are immediate and long-term consequences of obesity in children affecting both physical and emotional health [33, 69-76, 78, 203]. Even worse, the prevalence of extreme obesity in children is now recognized as the fastest growing subcategory of obesity in children and adolescents in the US [5-7]. Extreme obesity in children is described as class 2 obesity (BMI \geq 120% of the 95th percentile or BMI \geq 35) and class 3 obesity (BMI \geq 140% of the 95th percentile or BMI \geq 40) [5, 7].

Low-income ethnic minority children are at increased risk for obesity [3, 25, 204]. Their families often encounter substantial challenges related to living a healthy lifestyle, particularly in areas where access to supermarkets and physical activity resources is limited [204-207]. These and other underserved populations frequently experience additional barriers, not faced by their higher income counterparts, such as insufficient health insurance to care for their families, transportation issues, long work hours, limited ability to purchase healthy foods, and perceived discrimination [208-210]. Programming to address childhood obesity in these high-risk

populations has, therefore, been met with extensive challenges in recruitment, retention, and demonstrated effectiveness.

Clinic or hospital-based multidisciplinary programs are currently the primary sites of obesity treatment for children. These programs demonstrate only limited effectiveness and are seldom available in low-income communities [5, 211, 212]. Often requiring a team of highly-skilled health professionals and specialized facilities, multidisciplinary programs are costly to implement and difficult to access [37, 38]. These programs also tend to have high attrition rates [6, 45, 195], particularly among low-income families receiving public health insurance [45]. Transportation issues, scheduling conflicts, unmet expectations, time commitment, clinic hours, and disliking specific program components are frequently cited as reasons for dropping from treatment programs [45, 165].

Innovative approaches designed to reach and engage obese children and their families in weight management programs are urgently needed, particularly among low-income populations [38]. Community health workers, described as individuals who share the same ethnicity, language, or geographic community of the persons they serve as well as similar life experiences [213], could play an important role in reaching and educating families in need. Extensive evidence supports the effectiveness of trained community health workers in promoting healthy behaviors among adults with chronic disease [153-156, 158, 159, 213]. Research further demonstrates their success in improving symptoms and urgent care use in children with chronic conditions, such as asthma and type 1 diabetes [157, 160-163]. However, literature examining feasibility and

outcomes of weight management programs for children and families that are delivered by community health workers is limited [55].

The Extension service is a nationwide, noncredit educational network designed to help people use research-based knowledge to improve their lives. The service is provided by land-grant universities throughout the country and includes a network of local offices throughout each state. Michigan State University Extension (MSUE), an organization that has successfully taught nutrition education statewide since 1914, currently uses trained community health workers, supervised by professional staff and supported by MSUE campus staff, to deliver basic nutrition education. MSUE is uniquely positioned to address the growing issue of childhood overweight and obesity in Michigan by providing education and behavior change strategies at the community level. Approximately 160 trained community health workers, hereafter referred to as MSUE Program Associates, currently provide group teaching to limited income families throughout Michigan. MSUE has the unique capacity to build a network of Program Associates across Michigan to support families in managing overweight and obesity.

We, therefore, developed an intervention for families with overweight or obese children using trained MSUE Program Associates. Researchers partnered with pediatric offices in two post-industrial cities in Michigan to identify and recruit eligible children and families into the program. The intervention is unique in design as it specifically targets low-income areas and uses MSUE Program Associates, supervised by registered dietitians, to deliver a theory-driven curriculum focused on health and nutrition; behavior change; personal and family goal setting and monitoring; cooking; and physical activity. The aim of the current study is to examine the

feasibility, implementation challenges, and preliminary effectiveness of this weight management program. Researchers also describe baseline characteristics and severity of overweight among children who enrolled in the program to justify the need for this, and similar programs, in the targeted population.

Methods

Sample and Recruitment

Low-income overweight or obese children living in Flint and Saginaw (two cities in Michigan with high rates of poverty, crime and unemployment) were the focus of the current study. Four research assistants (three at Hurley Children's Hospital Pediatric Clinic in Flint and one at Healthy Futures Private Practice in Saginaw) were trained to recruit participants into the program. Families were invited to enroll in the program after children were identified by their pediatrician and a trained clinic-based research assistant provided a detailed description of the program.

Families were eligible for participation through one of the partnering clinics if their child was an active patient at the identified clinic; between 6 and 14 years of age; and mentally competent to provide assent. Research assistants targeted overweight and obese children, but normal weight children who were interested in the program were also allowed to participate. Researchers received approval from the Institutional Review Boards (IRB) of Michigan State University and Hurley Medical Center and ensured compliance with the Health Insurance Portability and Accountability Act (HIPAA) guidelines.

Healthy Kids, Healthy Families Curriculum Development and Delivery

Healthy Kids, Healthy Families was a theory-driven curriculum developed by a team of researchers with expertise in nutrition and family therapy, including three PhD- or Masters-level registered dietitians, one certified diabetes educator, and three marriage and family therapists. The curriculum was based on Social Cognitive Theory (SCT), a widely used theory for developing interventions focused on improving health behaviors in children [214]. *Healthy Kids, Healthy Families* was intended for delivery by trained MSUE Program Associates to support families in dealing with the physical, psychological, and emotional barriers to a healthy lifestyle. The research team together developed a single one-on-one session followed by a series of six multi-family group sessions (**Table 5**). The sessions focused on family development and communication and provided important nutrition and health information. Each of the sessions included a number of interactive activities designed to engage families and contained information about family dynamics and communication, behavior change, body image, nutrition, meal planning, physical activity, and accessing community resources.

	Home Visit 1	Group Session 1	Group Session 2	Group Session 3	Group Session 4	Group Session 5	Group Session 6
Session	Getting Started!	We Can Do It!	Eat Smart, Eat	Be Strong, Be	Jump and Groove!	There's No One	Wrappin It Up!
Title			Healthy!	Healthy!		Like Me!	
Learning	Describe roles of	Identify six	Identify different	Identify three	Identify two	Recognize the	Identify
Obj	family members	skills that lead	food groups.	factors that impact	strategies for	importance of a	strategies to
	in food	to successful		overall health and	achieving more	positive body	manage overall
	preparation and	behavior	Identify foods that	well-being.	daily physical	image.	health after
	meal selection.	change.	fit into various food		activity.		program.
			groups.	Describe behaviors		Appreciate	
	Indicate			to promote and	Describe the three	differences	Describe
	readiness to		List healthy snack	maintain a healthy	types of physical	between different	problem solving
	change.		options.	lifestyle.	activity.	body types.	techniques.
Key	Concept of	Parenting	Importance of eating	Caring for your	Promotion of	Self-esteem and	Summary and
Concepts	change to	roles,	a variety of foods in	body and lifestyle	physical activity	positive body	reinforcement of
	improve health	providing a	moderation for good	choices		image	program points
	behaviors	supportive	health and weight		Introduction to		
		family	maintenance		types of physical		Problem solving
		environment,			activity,		techniques for
		and initiating	Introduction to		guidelines and		maintaining
		behavior	MyPlate		recommendations		healthy family
		change					lifestyles

 Table 5. Healthy Kids, Healthy Families Topics, Objectives, and Key Concepts

Training of MSUE Program Associates

Key roles and responsibilities of all project staff are described in **Figure 6**. Trained MSUE Program Associates (one in Flint and one in Saginaw), who were supervised by registered dietitians, delivered each of the seven *Healthy Kids, Healthy Families* sessions. Each Program Associate had previous experience facilitating nutrition programs through Extension. Although not necessary for their positions with Extension, the selected Program Associates had completed college. Their Extension supervisors were Master's level registered dietitians.

MSUE Program Associates and their supervisors participated in a one-day training prior to program initiation and were given a scripted manual to follow when leading each of the seven sessions. The training also described research procedures; introduced staff to behavior change theories; and provided opportunities to practice sessions. MSUE Program Associates and their supervisors were also required to participate in additional trainings, conference calls, and meetings during the year with the lead researcher to address concerns with recruitment and retention, update program materials, educate staff, and share experiences. Educational handouts, exercise equipment, teaching aides, and a list of local and national resources were also provided.

Physician

Identify Eligible Children and Families Refer Eligible Families to Research Assistant Promote Program to Patients and Families Work with Lead Researcher to Identify and Address Challenges with Recruitment



Research Assistant

Explain Program to Eligible Families Complete Consent Process Record Baseline Clinical and Biochemical Data Contact MSUE with Family Contact Information



MSUE Program Associate Contact Enrolled Families Schedule Sessions In-Program Evaluations Deliver Program Participate in Weekly Conf Calls

MSUE Supervisor

Supervise all Program Associate Activities Contact Lead Researcher with Concerns Participate in Weekly Conference Calls



Lead Researcher

Train all Staff Provide Leadership, Coordination, and Support of the Project Complete all Necessary IRB Approvals and Revisions Record, Maintain, and Analyze Project Data Disseminate Findings through Publications and Presentations

Figure 6. Project Team Key Roles and Responsibilities

Recruitment and Data Collection

During scheduled office visits at partnering pediatric clinics, a health professional collected baseline height and weight (for BMI percentile calculation) and blood pressure. Physicians then notified the research assistant of eligible families following the determination of child's BMI percentile. The research assistant visited families in patient rooms and provided a description of the program followed by signed parental consent, child assent, and HIPAA authorization from families interested in participating in the program. At that time, all parents and guardians agreed to participate in one-on-one and group sessions with their child/children.

The research assistant recorded demographic information, including the gender, age, and ethnicity of the child as well as the type of health insurance. The research assistant also recorded baseline clinical data which included height, weight, and systolic and diastolic blood pressure. Baseline biochemical data, including Hemoglobin A1c, total cholesterol, LDL-cholesterol, HDLcholesterol, and triglycerides, were recorded when available in patient charts to document the extent to which comorbidities were also present.

Following the collection of all baseline clinical and available biochemical data, the research assistant contacted the MSUE office in Flint or Saginaw to provide contact information for families. The MSUE Program Associates contacted families directly to schedule the first one-on-one session. In addition to a program introduction, baseline behavioral and quality of life evaluations were collected during the initial one-on-one visit. These assessments included the collection of one 24-hour dietary recall, and completion of the following questionnaires: Physical Activity Questionnaire for Children [169] and Health-Related Quality of Life [185].

After completing all baseline assessments, the MSUE Program Associates began a series of six multi-family group sessions.

At the conclusion of the final session of the program, the MSUE Program Associates completed exit behavioral and quality of life evaluations. Given the focus on feasibility and implementation; short timeframe of exit data collection; behavioral approach being one of small measurable changes; and the expectation that clinical values would not be significantly changed [143, 144, 171], researchers did not require children to have height, weight, and blood pressure measured at program exit.

Instruments and Variables

The research assistants recorded measured height and weight (for BMI percentile calculation) and blood pressure as well as available lipid profiles and Hemoglobin A1c values from participating children at baseline.

Body Mass Index (BMI) - A health professional weighed and measured children individually in a private screened area, without shoes or heavy garments. Children were categorized, using age and gender specific CDC growth charts, as follows: normal weight (BMI between the 5th percentile to the 85th percentile); overweight (BMI between the 85th percentile to the 95th percentile); moderate obesity or class 1 (BMI 100-119% of the 95th percentile); class 2 obesity (BMI \geq 120% of the 95th percentile); class 3 obesity (BMI \geq 140% of the 95th percentile) [5, 7].

Blood Pressure. Systolic and diastolic blood pressure were taken while children were seated and at rest. Researchers determined high blood pressure ($\geq 90^{\text{th}}$ percentile based on sex,

age, and height) using the National Heart, Lung, and Blood Institute (NHLBI) series of age and gender specific measurement tables for children 3 through 17 years [94].

Glycosylated Hemoglobin (HbA1c). HbA1c assay is recommended for the diagnosis of diabetes [175] and was recorded by the research assistants when available in patient charts. Children with HbA1c less than 5.7% were considered normal; those with HbA1c values between 5.7 and 6.4% at-risk for diabetes; and those with HbA1c equal to or above 6.5% were considered to have diabetes [177].

Lipid Profile. Research assistants recorded lipid profile values when available in patient charts. The 2011 guidelines, set by an expert panel on integrated guidelines for cardiovascular health in children and adolescents, were followed in the current study [178]. The high range for triglyceride concentrations was defined as 90-129 mg/dL; the high range for LDL-cholesterol as 110-129; and the low range for HDL-cholesterol as 40-45 mg/dL [178]. Participants with total cholesterol above 170 mg/dL were considered borderline risk while those children with total cholesterol above 200 mg/dL were considered high risk for early cardiovascular disease [178].

The MSUE Program Associates collected dietary, physical activity, and quality of life questionnaires from children at baseline and program exit.

Dietary Behaviors. Eating behaviors were measured using a single 24-hour dietary recall following the United Stated Department of Agriculture (USDA) multiple pass method [179, 180]. Parents gave combined responses when children were under the age of ten [182]. Researchers were particularly interested in percentage of total calories from carbohydrates, fat, and protein as well as intake of sugar and sugar-sweetened beverages, sodium, fruits, vegetables,

and fiber. Dietary data was analyzed using Nutritionist Pro Diet Analysis Software (Axxya Systems).

Physical Activity. Physical activity was assessed using the Physical Activity Questionnaire (PAQ-C), a self-administered assessment that has been validated for use with children [169, 183, 184]. It was used to determine the amount of physical activity performed in the seven days preceding the evaluation. PAQ-C provides activity scores between 1 and 5, with 1 indicating low physical activity and 5 indicating high physical activity. PAQ-C is a reliable and valid measure of general physical activity levels in children [169, 183, 184].

Health-Related Quality of Life. The Pediatric Quality of Life Inventory (PedsQL) was used to measure health-related quality of life in children [170]. This was a child self-report consisting of 23 items that use a scale with five Likert response options, 'never', 'almost never', 'sometimes', 'often', and always' corresponding to scores of 100, 75, 50, 25, and 0, respectively. This evaluation tool is reverse-scored and linearly transformed, with a higher score (scale of 0 to 100) indicating a better HRQoL. The scale has summary, physical, social, emotional and school scores that show adequate reliability and validity [185].

Statistical Analysis

Baseline descriptive characteristics are reported for demographic as well as clinical and biochemical variables. Researchers also provide baseline behavioral (dietary and physical activity) and health-related quality of life data for all children who participated in the initial oneon-one session. In order to explore whether certain behavioral variables collected during the first visit explained an inherent grouping within participants with respect to their BMI percentile, hierarchical cluster analysis was performed. This resulted in a strong grouping of participants similar in terms of their BMI percentile and dietary behaviors. To quantify the strength of the relationships between the groupings of participants and all baseline behavioral variables, researchers used independent samples *t*-tests with overweight/normal weight children representing Group 1 and obese/severely obese children representing Group 2. Differences in health-related behaviors and quality of life at baseline were considered statistically significant based on a *p*-value of less than 0.05 using two-tailed tests.

In order to determine preliminary program effectiveness, baseline and exit scores on behavioral and quality of life outcomes were compared using Wilcoxon signed rank test [187] and effect size calculations [188]. Differences in baseline and exit data were considered statistically significant based on a *p*-value of less than 0.05 using two-tailed tests. Effect sizes were interpreted using Cohens thresholds for interpreting effect size (small = .10; medium = .30; large = .50) [189]. All analyses were conducted using SPSS version 23.

Results

A total of 72 children (33 from Hurley Hospital Pediatric Clinic in Flint and 39 from Healthy Futures Private Practice Clinic in Saginaw) enrolled in *Healthy Kids, Healthy Families*. The majority of children who enrolled in the program were African American (68%) and receiving Medicaid (73%). Mean age was 9.3 years and 57% were female (**Table 6**). Of the total sample recruited into the program, 14% (10 children) were normal weight, 15% (11 children) overweight, and 71% (51 children) obese. Nearly half of obese children enrolled in *Healthy Kids, Healthy Families* met criteria for severe obesity (**Table 6**).

Table 6: Characteristics of Sample

Participants	Total Sample (n=72)	Program Initiators (n=33)	Program Non-Initiators (n=39)	Program Completers (n=12)	Program Non- Completers (n=60)
Age Mean ± Standard Deviation	9.31 ± 2.11	9.48 ± 2.18	9.13 ± 2.07	9.42 ± 2.46	9.25 ± 2.05
Gender	Male – 31	Male – 13	Male – 18	Male – 4	Male – 27
Frequency	Female – 41	Female – 20	Female – 21	Female – 8	Female - 33
Race/Ethnicity	Afric Am – 47	Afric Am – 17	Afric Am – 30	Afric Am – 5	Afric Am – 42
Frequency	Caucasian – 13 Hispanic/Latino – 6 Other - 6	Caucasian – 10 Hispanic/Latino – 1 Other - 5	Caucasian – 3 Hispanic/Latino – 5 Other - 1	Caucasian – 7	Caucasian – 6 Hispanic/Latino – 6 Other - 6
Health Insurance	Medicaid – 43	Medicaid – 15	Medicaid – 28	Medicaid – 8	Medicaid – 35
Provider	Private Health	Private Health	Private Health	Private Health	Private Health
Frequency	Insurance – 16 Other/No Resp – 13	Insurance – 8 Other/No Resp – 10	Insurance – 8 Other/No Res - 3	Insurance – 3 Other/No Resp – 1	Insurance – 13 Other/No Resp – 12
Normal Weight Frequency (Percent)	10 (14%)	9 (27%)	1(3%)	3 (25%)	7 (12%)
Overweight Frequency (Percent)	11 (15%)	4 (12%)	7 (18%)	2 (17%)	9 (15%)
Obese	51 (71%)	20 (61%)	31 (80%)	7 (58%)	44 (73%)
Moderate Obesity*	28 (39%)	11 (34%)	17 (44%)	2 (17%)	26 (43%)
Severe Obesity** Frequency (Percent)	23 (32%)	9 (27%)	14 (36%)	5 (42%)	18 (30%)

*Moderate obesity is defined as BMI 100-119% of the 95th percentile **Severe obesity is defined as BMI greater than or equal to 120% of the 95th percentile (class 2 obesity) and BMI greater than or equal to 140% of the 95th percentile (class 3 obesity)

Clinical and Biochemical

Table 7 provides baseline results of clinical data (BMI percentile and blood pressure) for all overweight and obese children enrolled in *Healthy Kids, Healthy Families*. The table further categorizes children by degree of overweight (overweight, obese, class 2 obesity, class 3 obesity). Mean BMI percentile of the entire sample of overweight and obese children was 96.15 \pm 3.54, indicating obesity. Of the 51 obese children who enrolled in the program, 55% met criteria for moderate obesity (BMI 100-119% of the 95th percentile), 27% met criteria for class 2 obesity (BMI \geq 120% of the 95th percentile), and 18% met criteria for class 3 obesity (BMI \geq 140% of the 95th percentile).

Mean systolic blood pressure for the total sample of overweight and obese children was 107.26 ± 9.54 , and mean diastolic blood pressure was 67.11 ± 8.32 . **Table 7** shows that blood pressure increased with degree of overweight, with readings highest for those children with class 3 obesity. When comparing systolic blood pressure in overweight children versus obese/severely obese children, there was a significant effect for degree of overweight (p=0.01), with overweight children having significantly lower mean systolic blood pressure (100.91 ± 7.23) than obese/severely children (108.78 ± 9.45). Additionally, a significant effect for degree of overweight (p=0.02) was apparent with lower mean diastolic blood pressure in the overweight group (62.18 ± 6.95) versus the obese/severely obese group (68.21 ± 8.24).

Measurement BMI Percentile	Total Sample (Mean ± SD) (n=62) 96.15±3.54 (86-99.89)	Overweight (Mean ± SD) (n=11) 89.62±2.90	Moderately Obese* (Mean ± SD) (n=28) 96.58±1.10	Class 2 Obesity** (Mean ± SD) (n=14) 98.49±0.51	Class 3 Obesity*** (Mean ± SD) (n=9) 99.18±0.35
Measurement Systolic Blood Pressure (mmHg)	Total Sample (Mean ± SD) (n=57) 107.26±9.54 (82 – 130)	Overweight (Mean ± SD) (n=11) 100.91±7.23	Obese (Mean ± SD) (n=25) 107.04±7.98	Class 2 Obesity (Mean ± SD) (n=12) 110.33±11.72	Class 3 Obesity (Mean ± SD) (n=9) 111.56±10.04
Diastolic Blood Pressure (mmHg)	67.11±8.32 (50- 90)	62.18±6.95	67.12±7.57	67.50±7.44	72.56±10.41

Table 7. Baseline Clinical Data for Overweight and Obese Children

*Moderate obesity is defined as BMI 100-119% of the 95th percentile **Class 2 obesity is defined as a BMI \geq 120% of the 95th percentile ***Class 3 obesity is defined as BMI \geq 140% of the 95th percentile

Although current recommendations indicate that all obese pediatric patients be tested for comorbid conditions, such as hyperlipidemia and diabetes [49, 50, 137], only eight of the 51 obese children enrolled in *Healthy Kids, Healthy Families* (16%) had results from a lipid profile recorded in their medical chart, and six (12%) had a Hemoglobin A1c value recorded (**Table 8**). Mean biochemical values for our sample of eight obese children were within an acceptable range for most measurements (**Table 8**); however, the mean triglyceride level (126.13 \pm 94.14) indicated elevated risk for cardiovascular disease. It is important to mention that many of the families that enrolled in the program were experiencing multiple stressors, and partnering pediatricians needed to prioritize patient needs during visits. Additionally, failure to screen for comorbidities was the result of *both* a lack of screening by health care professionals as well as patient/caregiver failure to follow physician orders (some children had orders for laboratory screening in their charts but had not completed the bloodwork).

Measurement	Sample (Mean ± SD)	Normal Values*
Hemoglobin A1c (n=6)	5.53 ± 0.49 (4.9-6.3)	< 5.7%
Total Cholesterol (n=8)	160.63 ± 28.12 (124-199)	< 170
HDL Cholesterol (n=8)	46.63 ± 9.29 (33-61)	> 45
LDL Cholesterol (n=8)	86.75 ± 18.41 (54-110)	< 110
Triglycerides (n=8)	126.13 ± 94.14 (18-323)	< 75 (0-9 years of age) < 90 (10-19 years of age)

 Table 8. Available Biochemical Data for Obese Children

*Normal values for Hemoglobin A1c are based on American Diabetes Association thresholds[177] and normal values for lipid levels follow 2011 expert panel integrated guidelines for cardiovascular health and risk reduction in children and adolescents [178]

Physical Activity, Health Related Quality of Life and Dietary Behaviors

All behavioral data was collected during the one-on-one session with MSUE Program Associates. **Table 6** shows that 33 of the 72 participants who enrolled in the program (46%) completed the initial one-on-one session at their home or another convenient location. MSUE Program Associates reported difficulties with scheduling and attendance at the first one-on-one session -- caregivers failed to respond to calls to schedule the one-on-one session; phones were disconnected or unable to take messages; caregivers/children were not home at the scheduled time; caregivers/children were no longer interested in the program; or families relocated. Although most families were home for the initial scheduled visit, some asked the Program Associates upon arrival to reschedule the meeting. Baseline behavioral results are reported for those children who enrolled in the program and successfully completed the first one-on-one session.

Thirty-three participants completed the health-related quality of life (HRQoL) form. The mean HRQoL score for the entire sample at baseline was 81.69 ± 9.24 (**Table 9**). Although the mean HRQoL score was higher in the normal/overweight group (86.58 ± 12.78) compared to the obese/severely obese group (81.43 ± 10.15), there was not a significant effect for obesity category (p=0.24) (**Table 9**).

Physical activity was assessed using the Physical Activity Questionnaire (PAQ-C) [169, 183, 184]. Activity scores are between 1 and 5, with 1 indicating low physical activity and 5 indicating high physical activity. Twenty-nine of 33 participants completed this form during the initial home visit. The mean physical activity score for the entire sample was 2.71 ± 0.66 (**Table**

9). Although the mean physical activity score was higher in the normal/overweight group (2.82 \pm 0.61) compared to the obese/severely obese group (2.62 \pm 0.70), there was not a significant effect for obesity category (*p*=0.43) (**Table 9**).

Measurement	Total Sample	Normal/Overweight	Obese/Severely	Significance
	Mean ± SD	Mean ± SD	Obese	of Effect of
	(n=33)	(n=13)	Mean ± SD	Degree of
			(n=20)	Overweight
Health Related	81.69 ± 9.24	86.58 ± 12.78	81.43 ± 10.15	<i>p</i> = 0.24
Quality of Life				
Physical	87.56 ± 10.45	86.06 ± 13.95	88.54 ± 7.64	p = 0.57
Emotional	79.06 ± 17.75	84.23 ± 17.66	75.70 ± 17.42	p = 0.19
Social	85.38 ± 16.61	90.38 ± 11.81	82.13 ± 18.66	p = 0.13
School	80.34 ± 16.10	85.00 ± 19.26	77.31 ± 13.34	p = 0.23
Measurement	Total Sample	Normal/Overweight	Obese/Severely	Significance
	Mean ± SD	Mean ± SD	Obese	of Effect of
	(n=29)	(n=13)	Mean ± SD	Degree of
			(n=16)	Overweight
Physical	2.71 ± 0.66	2.82 ± 0.61	2.62 ± 0.70	<i>p</i> = 0.43
Activity**				_

Table 9. Baseline Behavioral Data

*HRQoL was reverse scored and linearly transformed. Higher scores indicate better HRQoL. **Activity scores are between 1 and 5 with 1 indicating low physical activity and 5 indicating high physical activity. Eating behaviors were measured at baseline using one 24-hour food recall following the United States Department of Agriculture (USDA) multiple pass method [179, 180]. Twenty-four of 33 participants completed one 24-hour food recall. **Table 10** shows that mean baseline values from children who completed the 24-hour food recall indicated that children were not meeting dietary recommendations, with reported high intake of total calories, percent of calories from sugar, and total sodium intake; and low intake of fiber, fruits, and vegetables. **Table 11** shows a significant effect for obesity category, with the obese/severely obese group having significantly lower percent of total calories from protein (p=0.04), higher percent of calories from sugar (p=0.03), and higher sugar-sweetened beverage intake (p=0.04). Total sugar intake (in grams of sugar) was also significantly higher (p=0.01) in the obese/severely group (132.03 ±55.43) when compared to the normal/overweight group (75.64 ± 39.93), suggesting an association between weight status and intake of sugar. Additionally, empty calories (from added fats and sugars) made up an average 35% of the total caloric intake of participating children.

Overall, a need for programming to address childhood obesity, both moderate and severe, was clearly demonstrated with baseline clinical and behavioral results. In spite of the lower intensity of the current program (compared to multidisciplinary programs), the majority of children who enrolled were obese and had not previously participated in a weight management program. Obese children were unlikely to receive the recommended screenings for comorbidities, making it difficult to assess risk. Obese children also demonstrated significant differences in certain dietary behaviors when compared to overweight and normal weight children, indicating a need for dietary interventions in this high-risk group.

Table 10. Baseline Dietary Data

Measurement (n=24)	Dietary Data (Mean + SD)	Range	Recommendations*
Total Kilocalories	1914 ± 717	823 - 3944	1600 (females) 1800 (males)
Carbohydrate, % kcal	51.84 ± 6.85	39.00 - 63.30	45-65
Protein, % kcal	14.51 ± 3.71	7.70-24.50	10-30
Fat, % kcal	33.65 ± 6.46	19.10 - 48.80	25-35
Total Sugars, % kcal	21.96 ± 9.79	5.12 - 40.60	< 10 (added sugar)
Sodium (mg)	3146.75 ± 1529.13	789.29 - 6382.23	2200
Fiber (g)	14.93 ± 6.32	7.93 – 28.36	22.4 (females) 25.2 (males)
Fruit (cups)	0.88 ± 1.06	0.00 - 4.30	1.5
Vegetables (cups)	0.92 ± 1.15	0.00 - 3.00	2 (females) 2.5 (males)

*Daily nutritional goals for 9- to 13-year-old female and male children based on Dietary Reference Intakes, Dietary Guidelines Recommendations, and MyPlate [215]

Measurement	Normal/Overweight	Obese	Significance
	Mean ± SD	Mean ± SD	_
	(n=12)	(n=12)	
Total	1750 ± 612	2092 ± 807	<i>p</i> =.273
Kilocalories			-
Carbohydrate, %	51.85 ± 6.09	51.82 ± 7.81	<i>p</i> =.993
kcal			
Protein, % kcal	16.06 ± 3.67	12.96 ± 3.16	<i>p</i> =.037*
Fat, % kcal	32.01 ± 6.14	35.21 ± 6.66	<i>p</i> =.246
Sugars, % kcal	17.65 ± 9.00	26.27 ± 8.87	<i>p</i> =.027*
-			
Sodium, mg	2888.71 ± 1362.32	3404.78 ± 1699.37	<i>p</i> =.421
			_
Fiber, g	15.66 ± 7.10	14.21 ± 5.65	<i>p</i> =.584
Total Sugar, g	75.64 ± 39.93	132.03 ± 55.43	<i>p</i> =.010*
Sugar Sweetened	0.46 ± 0.72	1.45 ± 1.29	<i>p</i> =.039*
Beverages, cups			

Table 11. Differences in Baseline Dietary Data by Degree of Overweight

**p* < .05

Preliminary Effectiveness

Of the 32 children who completed the initial home visit, 12 completed (attending \geq 5 sessions). Table 2 illustrates that eight of the children were female, mean age was 9.4 years, and 5 children were African American. Seven of the children who completed the program were obese and 2 were overweight. Exit data were collected approximately 3 months after baseline data collection was completed. Although the intervention was designed to run weekly for seven weeks, individual sessions were frequently rescheduled because of inclement weather, instructor or participant illness, transportation issues, or school activities (such as parent-teacher conferences or sporting events).

Changes in health-related quality of life and physical activity are reported in **Table 12** along with effect size. Significant improvements are reported for physical activity (z=2.29; p=0.022), with a large effect size (r=0.513). The mean score on the PAQ increased from baseline (2.71) to program exit (3.05). Overall health-related quality of life improved significantly following participation in *Healthy Kids, Healthy Families* (z=2.31; p=0.021), with a large effect size (r=0.493). The mean HRQoL score increased from baseline (83.46) to program exit (89.03). When addressing sub-scores of health-related quality of life, children's emotional health improved significantly from baseline to program exit (z=2.38; p=0.017) with a large effect size (r=0.507). Mean scores for emotional health increased from baseline (79.06) to exit (87.73).

Measurement	Baseline Mean ± SD	Exit Mean ± SD	Significance	Effect Size
	(n=11)	(n =11)		
Health Related	81.69 ± 9.24	86.58 ± 12.78	<i>p</i> = 0.021*	<i>r</i> = 0.493
Quality of Life				
Physical	90.06 ± 7.76	92.62 ± 2.71	p = 0.475	
Emotional	70.36 ± 15.70	87.73 ± 16.94	p = 0.017*	r = 0.517
Social	84.10 ± 13.00	90.00 ± 15.81	p = 0.227	
School	79.92 ± 13.52	83.64 ± 9.77	p = 0.227	
Measurement	Baseline	Exit	Significance	Effect Size
	Mean ± SD	Mean ± SD		
	(n=10)	(n=10)		
Physical	2.65 ± 0.47	3.05 ± 0.44	p = 0.022*	r = 0.513
Activity				

Table 12. Preliminary Program Effectiveness

**p* < .05

Children who completed the program experienced significant improvements in health-related quality of life and physical activity at program exit. Unfortunately, only seven children agreed to complete the 24-hour food recall upon program exit, and changes in dietary patterns were not significant. Attrition rate was high, but similar to traditional multidisciplinary weight management program for children [45, 196]. **Table 13** demonstrates that program completers had strong positive feelings about both the MSUE Program Associates and the overall program.

Table 13. Participant Feedback from Focus Group Discussions Community-Based Health Workers

"She was awesome! She could cook good and gave us really good tips on how to eat well and cook good." *14-year old girl*

"She was really nice and had good advice for being healthier." *11-year old boy*

"She was wonderful. Very knowledgeable, friendly, and warm... warm to talk to." *Mother of 10-year old girl*

"She was really nice. She was very friendly with the kids." *Mother of 11- year old boy and 6-year old girl*

Program Satisfaction

"She (granddaughter) looked forward to coming here every week. It was a big to-do. She would count-down from Saturday. She really enjoyed it." *Grandmother of 6-year old girl*

"It (the program) went really, really well. I think it's a great program. I don't think it should be for one type of kid. I think everybody can get something out of it. I don't think it needs to be just for overweight kids." *Mother of 11-year old boy and 6-year old girl*

"It (the program) overexceeded my expectations.. it really, really did. You know what, they should always have family do it together." *Mother of 14-year old girl*

"I know it (the program) is like an hour, but I wish it were two. And more weeks. More weeks for me to come." *10-year old girl*

"I liked that we could eat a new snack every Tuesday and we would ask questions to help accomplish our goals." *9-year old boy*

Discussion

The current study examined the feasibility, implementation challenges, and preliminary effectiveness of *Healthy Kids, Healthy Families*, a community-based program for low-income families with overweight or obese children. This collaborative effort between MSUE, pediatricians, and families targeted children living in two post-industrial cities in Michigan with high rates of poverty, violence and unemployment. Researchers were particularly interested, given the documented high rates of attrition in multidisciplinary clinic-based programs, in better understanding the specific struggles encountered when using trained Extension staff to implement a weight management program in vulnerable communities.

Recruitment was challenging at the beginning of the study because research assistants were often scheduled to recruit during times when few eligible patients were scheduled. This issue was resolved within the first two months of recruitment at each clinic as research assistants worked with researchers to determine the most effective strategy to identify eligible children prior to scheduled appointments. Because no-show rates were as high as 50% at both clinics, recruitment was a consistent struggle throughout the project. Oftentimes, research assistants would identify a number of eligible patients with scheduled visits, but few of those children actually arrived at their appointments. Similar to previous studies, regular reminders from the partnering pediatric clinics were largely unsuccessful [216, 217]. Although few studies specifically examine "no-show" rates in urban primary pediatric practices, rates appear to be higher for well-visits (versus sick visits) and among African American children [218], with caregivers primarily reporting personal issues as reasons for missing appointments [218-220]. Interventions that recruit directly

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from primary care clinics should be aware of "no-show" rates and work with partnering practices to identify and improve personal issues that prevent families from attending scheduled visits.

Because the program was considered less intensive than multidisciplinary hospital-based programs, researchers and pediatricians anticipated that the majority of patients referred to the program would be mildly overweight without associated comorbidities. However, the fact that 71% of the children referred to the program were obese, with nearly half meeting criteria for extreme obesity, is concerning. This overrepresentation of obese and severely obese children may have been the result of limited programming options in the targeted communities.

Less than 20% of obese children were screened for related comorbidities. As a result, researchers were unable to document risk for the majority of obese children. Earlier research indicates that, even after an obesity diagnosis, most obese children and adolescents are not receiving the recommended laboratory screening [50, 221]. Some children, however, did have orders in their charts to receive the recommended screening, but physician orders were not followed. Future efforts should focus on educating not only health care professionals, but also parents on the health implications of excess weight, importance of screening, and interpretation of those measurements. The failure of parents to have laboratory work completed for their child justifies the need for education of parents regarding the importance of following physician orders.

In spite of recruitment difficulties, initial enrollment was adequate (n=72 children). However, there was difficulty with passive refusal at the one-on-one visits throughout the program. Although home visiting removed the transportation barrier, many families indicated that they

were uncomfortable with staff coming into their homes. Some families that completed the program further indicated, during focus group discussions, that they viewed home visiting as an intrusion. This finding is different from previous research demonstrating that home visiting in child obesity management programs increases accessibility and dosage [222, 223], and specifically, home visitation by paraprofessionals holds promise for high-risk families [224]. Future studies should evaluate, prior to recruitment, whether families prefer sessions in the home or away from the home, and, if possible, offer both methods of delivery.

The poor dietary quality exhibited by the subsample that completed the 24-dietary food recalls is of concern. When researchers compared baseline dietary data from overweight/normal weight children to obese/severely obese children, the obese/severely obese group demonstrated a significantly higher intake of total sugar and sugar-sweetened beverages. Results of the current study are consistent with research showing an association between these important modifiable risk factors and obesity severity in children [111, 112]. Previous studies have indicated that intake of dietary sugars or sugar-sweetened beverages is a determinant of body weight [225-229], and evidence supports that reducing sugar-sweetened beverage intake will significantly reduce childhood obesity [113, 230, 231]. Future interventions targeting families with obese and overweight children should include dietary information and activities specific to sugar and sugar-sweetened beverage intake.

After enrolling at partnering pediatric offices, less than half of participants (45%) completed the first home visit, and only 12 of the 33 children who initiated the program completed at least five sessions. The high attrition was compounded in Flint, Michigan (half as many children

completed the program in Flint when compared to Saginaw) because many families, living in a city that experienced an unprecedented water crisis during the study period, relocated with their families, and contact information was lost. Additionally, most families who remained in the city shifted their focus to the safety of their drinking water when the crisis occurred. Other reported reasons for attrition in Flint and Saginaw included lack of childcare, transportation issues, scheduling difficulties, parental custody issues, lack of interest, and competing extracurricular activities for children. In the current study, the average number of children in the household was four, but some families reported as many as ten children living in the home. In future programs, accommodations for all children in the household should be made in an effort to reduce childcare stressors for the parents. Although this increases costs, it was shown to be an important and consistent barrier to program initiation after enrollment.

There are several strengths to the current study. This is one of the first to examine a theorydriven program for low-income overweight or obese children delivered through an Extension system. MSUE has offices in nearly every county in Michigan, and the potential for building a network of Program Associates to disseminate *Healthy Kids, Healthy Families* statewide is great. The partnership with pediatricians built capacity with regard to the management of childhood obesity though MSUE programs. However, several limitations of the study, in addition to those related to attrition, should be noted. Our sample was small and did not include a control group, but researchers were interested in maximizing program reach and examining feasibility with lowincome families. Because researchers chose two communities that were difficult to reach and included primarily low-income families using public insurance, high attrition rates were expected [45, 232-235]. The current study may not be generalizable to all but does provide information regarding families in vulnerable communities.

Conclusions

The current study provides preliminary results of an intervention delivered through an Extension system. With increasing awareness and agreement surrounding the effectiveness of trained community health workers in the management of chronic conditions in both adults and children, the results of this intervention are important to efforts surrounding the treatment of childhood obesity, particularly in low-income communities. Children who completed the program demonstrated short-term improvements in physical activity and health-related quality of life.

However, program engagement was limited and attrition was high. The current model of referral and delivery appears not to be feasible on a population-wide basis and should be modified to include more flexible programming options with referrals through primary care providers as well as other Extension programs, schools, community centers, faith-based organizations, and the like. Additionally, and keeping in mind the numerous barriers to participation, families should be given the choice to participate in a group or one-on-one setting. Future research should provide additional information regarding long-term effectiveness as well as how to effectively reduce barriers and enhance facilitators to program participation in high-risk communities.

CHAPTER 5 - Participant experience in a weight management program for families delivered by Extension

Abstract

Background: A weight management program targeting families with overweight and obese children 6-14 years of age was delivered by trained community health workers through Extension. The program, *Healthy Kids, Healthy Families*, was offered to low-income families in two post-industrial cities in Michigan. The objective of the current study was to examine parent and child experiences with the program as well as changes in environmental and individual-level variables that resulted from program participation.

Methods: Following participation in *Healthy Kids, Healthy Families*, 13 participants (5 mothers, 1 grandmother, and 7 children) completed either an interview or focus group. Focus groups and interviews at the conclusion of the program facilitated in-depth discussion of parental and child perspectives within the context of the larger group and specifically addressed family perceptions of and experiences in the program. Researchers also examined changes in personal and environmental variables, from the perspective of both parents and children that resulted from program participation.

Results: Families reported only positive feedback with regard to the overall program and the instructors who delivered the program. Parents and children particularly enjoyed the interaction as well as the nutrition and cooking activities. Most parents indicated that shopping and eating habits changed since initiating the program. Families suggested that the program include more families during weekly sessions, add text or email check-ins between sessions, and increase time spent on physical activity. Children learned goal setting techniques in the program that helped build confidence in their ability to reach behavior goals. Environmental factors, particularly

parental support of children and modeling of appropriate health behaviors improved as a result of participation in *Healthy Kids, Healthy Families*. Furthermore, family involvement proved critical to improving the eating and exercise behaviors of participating children.

Conclusions: The current model of delivery was acceptable, from the perspective of parents and children who completed the program, to address obesity and overweight in children. However, only 12 of the 72 children who enrolled in the program completed, and seven participated in a focus group or interview. Program attrition was high (with most children dropping from the program prior to initiation) and should be addressed. Future research is needed to examine different models of referral and delivery with a more diverse population as well as barriers to participation.

Background

Pediatric obesity is among the most serious and prevalent nutrition disorders in the United States [69]. Obese children and adolescents are at increased risk for cardiovascular disease, hypertension, pseudotumor cerebi, orthopedic problems, sleep apnea, steatohepatitis, cholethiasis, polycystic ovary disease, type 2 diabetes, and early onset of puberty [33, 70]. In addition to the physical implications, there are psychosocial consequences of childhood obesity, which include increased risk for peer group discrimination; low self-esteem; impaired quality of life; increased psychological stress; poor body image; and depression [71-78]. Consistent evidence indicates that children from lower socioeconomic backgrounds are disproportionately affected by obesity and overweight [60-62], but interventions to address childhood obesity are often not accessible or available in low-income communities [5].

Current programming to manage childhood obesity is primarily through multidisciplinary treatment centers [6]. These programs are often administered by a team of highly skilled-health professionals and available only in select hospitals, clinics, or, more recently, community settings [196]. Attrition rates at these treatment facilities are high, particularly among families receiving public health insurance [6, 45, 195]. Hospital-based weight management clinics generally report attrition rates ranging from 27-73% [196], with some reporting rates as high as 91% [236]. In addition to logistical barriers to participation, such as transportation issues and scheduling conflicts [45, 145], participants frequently indicate that they were not satisfied with the program [45, 165]. Families point specifically to unmet expectations; programs failing to meet family needs; and disliking specific program components as reasons for dropping from weight management programs [45, 165, 195]. An examination of family perceptions of and

experiences in obesity-treatment programs is essential to understanding participant satisfaction and attrition rates, but these factors have not been well-studied [31, 196, 197].

In an effort to provide more affordable, accessible, and scalable programming options, researchers in the current study developed an intervention for families with overweight or obese children using trained community health workers from a statewide organization. *Healthy Kids, Healthy Families* focused on health and nutrition; behavior change; personal and family goal setting and monitoring; cooking; and physical activity. Uniquely different from traditional multidisciplinary programs, *Healthy Kids, Healthy Families* specifically targeted low-income families and was delivered by trained community health workers, supervised by registered dietitians. The community health workers, hereafter referred to as Program Associates, were employed by Michigan State University Extension (MSUE), an organization with offices in nearly every county in Michigan. In addition to the dearth of literature examining participant satisfaction with obesity management programs for children, there are no qualitative studies that assess perceived effectiveness of trained community health workers delivering a weight management program to families with overweight or obese children through an Extension system.

In cooperation with Hurley Hospital Pediatric Clinic (Flint, Michigan) and Healthy Futures Clinic (Saginaw, Michigan), MSUE implemented *Healthy Kids, Healthy Families* between February of 2015 and March of 2016. The purpose of the current study was to explore family perceptions of and experiences in *Healthy Kids, Healthy Families* to determine overall program
satisfaction. With the conceptual framework based on Social Cognitive Theory [56], researchers further examined changes in personal and environmental variables, from the perspective of both parents and children, that resulted from program participation. Factors influencing the development and maintenance of obesity and overweight in children (personal, environmental, and behavioral) were characterized as the inputs. How these inputs were modified or improved as a result of the throughput (participation in *Healthy Kids, Healthy Families*) and thus facilitated the outcome (improved quality of life, diet and physical activity behaviors, and weight) were of particular importance. This model proposed that personal factors (*skills, self-efficacy, and outcome expectancies*), environmental factors (*parental support and modeling*), and reciprocal behavioral responses are all inputs that influence a child's ability to maintain a healthy weight. Based on the conceptual map and the literature, researchers specifically examined how children perceived their own ability to achieve a healthier lifestyle after participation in *Healthy Kids, Healthy Families* as well as the extent to which the program influenced parental support and modeling of appropriate health-related behaviors.

Methods

Sample and Recruitment

Families that completed *Healthy Kids, Healthy Families* between August of 2015 and January of 2016 were invited to participate in focus group discussions. Families were eligible for participation in *Healthy Kids, Healthy Families* if their child was an active patient at either Hurley Hospital Pediatric Clinic or Healthy Futures Private Practice Clinic; between 6 and 14 years of age; and mentally competent to provide assent. Families agreed to participate in the

program after children were identified by their pediatrician and given a description of the program. Overweight and obese children were targeted for the study, but normal weight children who expressed interest were allowed to participate. One focus group with five participants (2 mothers and 3 children), and three in-depth interviews with eight participants (3 mothers, 1 grandmother, and 4 children) were conducted with a total of five families.

Program Overview

Healthy Kids, Healthy Families was intended for delivery by trained MSUE Program Associates to support families in dealing with the physical, psychological, and emotional barriers to a healthy lifestyle. The project team, which included experts in the field of nutrition and family therapy, developed a single one-on-one session followed by a series of six multi-family group sessions that focused on family development and communication and provided basic nutrition and health information. Each of the sessions followed a similar template and included a number of interactive activities.

Beginning in the first session, participants were asked to set one specific and measurable goal for themselves for the upcoming week and to work with their family to set one family goal. Goals were recorded on weekly tracking sheets, and children were given stickers to place on the sheets when goals were met. Participants and families reported back to the entire group on weekly goal progress, and new goals were set and monitored every week. Following the goal setting activity, families engaged in at least 20 minutes of physical activity that was done indoors or outdoors. A variety of different learning activities (specific to each session), focused on nutrition, physical

activity, body image, behavior change, and maintaining a healthy lifestyle, followed the physical activity. Sessions concluded with a cooking activity that lasts approximately 20 minutes.

Procedures

After completion of the final session, participants and their families were invited to participate in focus groups or interviews. Focus groups and interviews were scheduled as the final class in the series and ranged in length from 25 to 45 minutes. When possible, parents and children were separated into two groups, allowing both to report their experiences openly and honestly.

An interview guide was developed by researchers prior to the study and was guided by literature, research questions, and the researchers' experiences with the topic and population. Focus groups or in-depth interviews were conducted between August of 2015 and January of 2016. Focus groups and interviews assessed parent and child goals and expectations prior to program initiation; general enjoyment of the program; new information learned in the program; feelings about program content and length; impressions of MSUE Program Associates; and suggestions for improvement. Additionally, with Bandura's SCT [56] as the theoretical framework, questions examined changes in personal factors, environmental factors, and reciprocal behavioral responses that influence a child's ability to maintain a healthy weight. Families provided written consent and assent prior to participating in the focus groups or interviews and were provided \$5 vouchers from the local farmer's market for their participation. Institutional Review Board (IRB) approval was obtained from Michigan State University and Hurley Medical Center.

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Qualitative Analysis

After each interview or focus group, the recordings were transcribed verbatim by the researcher who was present at the interviews. All transcripts were read again while listening to the recordings to ensure accuracy. The current study utilized qualitative methodology with thematic analysis approach [198-200]. The use of thematic analysis, which is a method for identifying, analyzing, and reporting patterns or themes within data [200], provides a framework for further research in the area of participant experiences and behavioral outcomes in weight management programs for children and families. Using thematic analysis, two researchers independently developed the initial codes, and any discrepancies were reconciled when the researchers met. Initial codes were then grouped into categories and assigned themes.

Trustworthiness

Researchers ensured trustworthiness using several methods. Two researchers, trained in qualitative analysis, reviewed and discussed the transcripts. The transcripts were then individually coded by these researchers, checked, and discussed until consensus was reached. Analysis was an iterative process through discussion and refining of the major themes. There was peer debriefing for all questions developed. Whenever there was obscurity during the data collection, the researcher had a formal verification with participants by repeating both question and answer to ensure the data collected were accurate. All steps and changes throughout the study were documented as on-going memos by the lead researcher, and all data coded manually.

Results

Attrition rates for the current program were high, but similar to traditional multidisciplinary weight management programs [45, 196]. A total of 71 children enrolled in *Healthy Kids, Healthy Families*, with 33 attending the first one-on-one session (45%). Twelve of the 33 children who participated in the first one-on-one session completed the program. Seven children, who completed the program, agreed to participate in either a focus group or interview with their parents. Based on similar qualitative studies that have been published, researchers originally aimed to conduct focus groups or interviews with a sample of 20 subjects, up to the point of data saturation. After 13 subjects (5 mothers, 1 grandmother, and 7 children) completed either an interview or focus group, it was noted that no new information was forthcoming. Therefore, based on data saturation, 13 subjects were determined as an adequate sample size for analyses. Characteristics of focus group and interview participants are presented in **Table 14**. The majority of children were female and obese, and all of the caregivers were women.

The results of the current study were driven by the research questions and resulting themes. The first set of results, "Participant Experiences with *Healthy Kids, Healthy Families,*" are descriptive of participant experiences in the program. The second set of results, "Participant Changes Following Participation in *Healthy Kids, Healthy Families,*" are guided by Bandura's Social Cognitive Theory [56].

Children (n=7)	
Age in Years (Mean ±SD)	9.1 ± 2.8
Gender: Female (n=4)	57%
Male (n=3)	43%
Ethnicity: Caucasian (n=5)	71%
African American (n=2)	29%
Weight Status: Normal (n=2)	29%
Overweight (n=1)	14%
Obese (n=4)	57%
Caregivers (n=6)	
Maternal Age in Years (Mean ± SD)	37.3 ± 8.2
Gender: Female (n=6)	100%
Male (n=0)	0%
Ethnicity: Caucasian (n=3)	50%
African American (n=3)	50%

 Table 14. Descriptive Characteristics of the Total Sample (N=13)

Participant Experiences with Healthy Kids, Healthy Families

An examination of parent and child experiences in *Healthy Kids, Healthy Families* was critical to understanding whether the current model, which includes delivery of a theory-driven curriculum by trained MSUE Program Associates, was a feasible option for families with obese or overweight children. Researchers developed a series of questions to address family perceptions of and experiences in *Healthy Kids, Healthy Families* in an effort to investigate how the current model was viewed by participating families. The main themes that evolved from this analysis were: program uncertainty upon enrollment; parental need for outside nutrition guidance; desired focus on interaction and activity; importance of positive change as a family; and positive program experiences. A description of participants' views of each of these themes and associated quotes from parents and children is provided below.

Expectations at Enrollment: Uncertainty

Families were introduced to the program at partnering pediatric offices by a trained research assistant, who explained the program and obtained parental consent and child assent. Researchers were interested in clarity of the program description and overall program expectations, from the perspective of parents and children, upon recruitment at pediatric offices. Most parents reported that, when enrolling in *Healthy Kids, Healthy Families*, they were uncertain of specific program components but expected a nutrition and exercise program focused on helping their child. Similarly, participating children reported that they did not know what to expect when they agreed to participate, but most understood the program to be about eating and exercise. Overall, there seemed to be relative uncertainty with regard to the program and what it entailed. Mother of obese female, age 10: I had no idea, really. I was told she is in the higher percentile for weight, and we would learn about food and nutrition.

Mother of obese female, age 14: I thought automatically we were going to talk about nutrition. I thought, okay, she is going to teach us the way to eat, but I wasn't exactly sure.

<u>Grandmother of obese female, age 6</u>: I thought it was going to be something where they did activities for weight loss, like exercise and healthy eating. I knew it was supposed to be something to help her.

<u>Obese female, age 10:</u> *I thought you would get to cook and learn about healthy food.* <u>Normal weight male, age 11:</u> *I didn't know. Mom just took us.*

Overweight male, age 11: I thought it was going to be like a gym room, and they would tell you what to eat.

<u>Obese female, age 14:</u> *I thought it was going to be this lady telling you what to do and what to eat.*

Program Goals: Guidance

Parents and children were asked about their goals when they enrolled in the program. The most frequently reported goal for parents was to have someone outside of the home provide guidance with regard to healthy eating, particularly for their children. Parents struggled with finding healthy foods that their children would find acceptable and needed assistance with recipes and ideas from someone outside of the family. Children indicated that they either had no goals prior to program participation or came simply because the program seemed fun. From the perspective of parents, the primary goal was to have guidance with regard to nutrition and healthy eating for their family.

Mother of overweight male, age 11 and obese male, age 9: I was really looking for someone outside of me to let them know there are other ways to eat cause I do it all day long. I give them the food they should eat, but they would rather have some pizza. Grandmother of obese female, age 6: Just to get some ideas. It's hard to find out what's missing from what you eat. Sometimes it's better for somebody on the outside to see. Mother of one normal weight male, age 11 and one normal weight female, age 6: Good behavior, you know. That's kind of what I wanted to reinforce. I didn't realize that they didn't know what MyPlate was.

Mother of obese daughter, age 10: I wanted my daughter to learn positive things, so she won't be as big as I am when she gets older.

Normal weight male, age 11: No goals. Before knowing and going in, I didn't. Obese female, age 10: To have fun and learn more about healthy eating. I want to go on a cooking show!

Program Enjoyment: Interaction and Activity

When asked whether they enjoyed the program, all parents and children gave positive responses. Parents most enjoyed the interaction and watching their children participate in program activities. Parents specifically mentioned that cooking and weekly goal setting activities were the most enjoyable parts of the program. The children most enjoyed cooking activities and fitness activities during the program. Overall, families enjoyed the program, specifically the interaction with each other and the MSUE Program Associates as well as the hands-on activities.

Mother of obese female, age 14: I liked the interaction and working together. I really loved it for my daughter. She seen the struggle the other parents and children have and how you work together and can actually meet... just that interaction, I thought was great. Mother of obese female, age 10: I enjoyed watching her have fun and enjoy cooking and stuff. She got to be more hands-on.

Mother of one normal weight male, age 11 and one normal weight female, age 6: The kids loved the goal setting. That was something they could do on their own. We wrote the goal out, and at the end of the night, they got to put a sticker on it.

Obese female, age 6: Cooking! My mama loves to cook.

Obese female, age 10: Yes... I got to cook!

Overweight male, age 11: I liked that we got to try a new healthy snack each week. Normal weight male, age 11: The exercise stuff... especially the pedometer.

Learning Components: Importance of Change as a Family

Most parents reported that they learned the importance of making positive changes with their child. Children reported learning how to eat healthy and prepare nutritious foods as well as how to exercise differently and track activity. Parents and children agreed that the incentives enhanced learning and helped families work together to make positive changes. Together, parents and children seemed to recognize the importance of the entire family working together to make positive changes, rather than the child doing so on their own.

<u>Mother of obese female, age 14:</u> When you have a partner, it helps tremendously. Families should do this because it helped mom as well. Now, I have someone to work right along with me. We have the determination and consistency there... once we leave the program, it's already in place.

Mother of obese female, age 10: I try to cut out time for me and her. For me to focus on her to make sure she is doing good and we learn (together). I am learning what she is supposed to be learning.

Mother of obese male, age 9 and overweight male, age 11: She gave us measuring cups and a brush to wash fruit and stuff. Those things were helpful cause I can tell them to measure, and we can do it together. So, it was more hands-on. I felt like those things worked and helped.

Overweight male, age 11: I learned the different foods that we could eat that are healthier for you than other foods.

<u>Obese female, age 10:</u> *I learned how to cook. I learned how to stay healthy and keep active.*

Normal weight female, age 6: I learned about eating MyPlate. Obese female, age 10: I learned about the pedometer. I go really high. I passed 1,000

Length of the Program: Competing Views

and one time I got to 5,000!

Most parents felt that length of the weekly sessions as well as the overall program were acceptable, but some suggested that the MSUE Program Associates contact families between meetings to offer support and encouragement. Most children seemed to enjoy the program but felt strongly that it should be longer (both number and length of sessions). Parents seemed to have competing views with their children regarding the appropriate length of the program, with most children reporting that they had fun and wished that the program was longer.

<u>Mother of obese female, age 10:</u> *I think it's a good amount. Cause it's an easier goal to set rather than telling your kids that you have to be there so many different times. Seven is a pretty good number. We only missed one.*

Mother of obese male, age 9 and overweight male, age 11: I think seven weeks is appropriate. But I thought, because we only meet once a week, it would have been good to have an email check-in or a text check-in. Like in the middle of the week, just do a check-in... How are you doing? Is there anything else we can work on this week? Mother of obese female, age 14: Six weeks of group sessions was fine. Obese female, age 6: The program is not long enough! Obese female, age 14: We should meet twice a week. Obese female, age 10: Too short... I know it's like an hour, but I wish it was two. And more weeks. More weeks for me to come!

Feelings About MSUE Program Associates and Overall Program: Positive Experiences

All parents had strong positive feelings about the MSUE Program Associates, who led the sessions. Most parents shared that their instructors connected with the children and made the program both educational and enjoyable. Parents indicated that children frequently talked about the instructors away from class. Similarly, children expressed only positive reactions to the MSUE Program Associates. All parents who participated in *Healthy Kids, Healthy Families*

reported that the program met or exceeded their expectations, with most parents indicating that the program specifically helped with goal setting and improved dietary behaviors. All parents and children had positive experiences in the program and with the MSUE Program Associates.

MSUE Program Associate:

Mother of normal weight male, age 11 and normal weight female, age 6: She was really nice. She was friendly with the kids. She didn't just give them the (exercise) tools, she showed them different ways to use them. Like, here's a jump rope, now you don't just use it as a jump rope, we can use it to jump back-and-forth or do relay races. She got up and showed them and did it with them.

Mother of obese female, age 14: I think she was very personable. Not only that, she could relate very well to them. My daughter loved her and talked about her all the time. Mother of obese female, age 10: She is wonderful... very knowledgeable and friendly and warm, warm to talk to.

<u>Obese female, age 14:</u> She was pretty awesome. She cooked good, and she gave us really good tips on how to eat well.

Overweight male, age 11: She was really nice, and she had good advice for being healthier.

<u>Obese female, age 6:</u> *I feel happy about her.*

Program Satisfaction:

Mother of obese female, age 14: It over-exceeded my expectations. It really, really did.

<u>Grandmother of obese female, age 6:</u> She (granddaughter) looked forward to coming every week. I mean, it was a big to-do. She would count-down from Saturday. So, she really enjoyed it. I don't know what we are going to do next week.

Mother of obese male, age 9 and overweight male, age 11: We went to the store and bought stuff we tried here. They actually liked the food they tried here... I don't think they would have even tried it at home. Being here and everybody watching them, they tried the food.

Mother of normal weight male, age 11 and normal weight female, age 6: It was a great program. The kids really liked the goal setting. It was a good summer activity, and we are still doing it.

Suggestions at Completion: More Interaction and Activity

Parents were also asked about suggestions that might improve the program. Half of parents indicated that the classes could be improved if more families attended and some parents indicated that the program could be improved with more activity for younger children. Children suggested adding more activity and increasing program length.

Mother of obese female, age 10: The reason she (daughter) wanted to do this was because other people were supposed to be here, and she likes hanging out with other kids. But it turned out just to be us. I wish there were more people. If there was a way you could make sure everybody showed up, that would be cool.

Mother of obese male, age 9 and overweight male, age 11: For my kids, because they are younger and boys, they needed more activity.

<u>Obese male, age 9:</u> Maybe we could go outside and play.

Obese female, age 14: The only thing I didn't like is that we couldn't meet more because I thought it was pretty fun.

Feedback from parents and children indicated that the overall program was acceptable to those who completed. From the perspective of participating families, *Healthy Kids, Healthy Families* appeared also to be effective, at least in the short-term, in teaching families how to improve lifestyle factors associated with obesity. Parents specifically mentioned that, during the program, they learned the importance of changing physical activity and dietary behaviors as a family and worked closely with their children to modify these behaviors. In addition, families reported only positive feedback with regard to the overall program as well as the MSUE Program Associates who delivered the program. Parents and children particularly enjoyed nutrition and cooking activities, and most parents indicated that shopping and eating habits had changed since initiating the program. Suggestions from families regarding program improvements included having more families participate in sessions and increasing physical activity.

Participant Changes Following Participation in Healthy Kids, Healthy Families

With the conceptual framework based on Social Cognitive Theory [56], researchers examined changes in personal and environmental factors, from the perspective of both parents and children, that resulted from program participation. Children's personal factors (*self-efficacy, skills, and outcome expectancies*) and parental environmental factors (*modeling and support*) that influence a child's ability to maintain a healthy weight were assessed following participation in *Healthy Kids, Healthy Families*. Researchers were specifically interested in understanding how children perceive their own ability to achieve a healthier lifestyle after participation in *Healthy*

Kids, Healthy Families as well as the extent to which the program influenced parental behaviors related to support and modeling of appropriate health-related behaviors.

Personal Factors Following Participation in Healthy Kids, Healthy Families: Improvements

In order to understand whether children's skills, self-efficacy, and outcome expectancies changed as a result of program participation, children were asked a series of questions with probing techniques to help elicit responses (Table 15). Most children reported that skills and self-efficacy were improved as a result of participation in Healthy Kids, Healthy Families. Children specifically reported that exercise or cooking improved after participation in the program (skills). Some children mentioned that, because they were able to taste new foods and cook in class, they improved eating habits at home. Others indicated that they increased physical activity or experimented with new ways to be physically active as a result of program participation. Since they reached their individual weekly goals throughout the program (most children set goals related to physical activity and healthy eating), all children felt better able to set and reach goals in the future (self-efficacy). All of the children were proud to report that they reached their individual goals throughout the program but some indicated that family goals were more difficult to accomplish. Most children said it was easier to reach goals with the advice they learned in the program. When asked what they believed would happen if they continued to follow the program (outcome expectancies), some children reported that they would be healthier while others mentioned improvements in physical appearance if they continued to follow the program. Collectively, children reported improvements in personal factors following participation in Healthy Kids, Healthy Families.

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Social Cognitive Theory	Concepts	Theory-Driven Research Questions	Interview Question
Person	Skills	How do children perceive their own ability to achieve a healthier lifestyle following participation in <i>HKHF</i> ?	How do you (children) feel about your ability to exercise more and make healthier foods choices? <i>Prompts:</i> Do you think you can exercise and eat healthier?
	Self-efficacy		How do you (children) feel about your own ability to reach the goals you set for yourself? <i>Prompts:</i> Do you think goals are reachable? Why? How?
	Outcome Expectancies		What do you (children) believe will be the result/outcome if you follow the program suggestions?<i>Prompts</i>: Do you think you can be healthier if you eat better and exercise?
Environment	Support from Others	To what extent did <i>HKHF</i> influence parent/caregiver behavior related to support of their children and modeling of appropriate health-related behaviors?	<i>Parents</i>: What changes did you make to help support your children during the program?<i>Children</i>: What did your mom/dad do to support you during the program that they didn't do in the past?
	Modeling Behavior		<i>Parents</i> : How would you describe the changes in your own eating and exercise habits as a result of <i>HKHF</i> ? <i>Children</i> : What differences did you notice in your parents' eating and activity since starting <i>HKHF</i> ?

 Table 15. Relationship Between Social Cognitive Theory, Concepts, and Questions

Skills

Obese female, age 10: I don't feel the same as I did before. I can cook more if my mom would let me.

Obese female, age 14: I feel like I am more able to do it, and it will be on my conscience if I don't eat right.

Obese male, age 9: I feel like I can do it more now (exercise and healthy eating).

Self-efficacy

Obese female, age 10: I reached my goals every time!

Normal weight boy, age 11: I always reached my goals, but not all the time with family goals.

<u>Obese female, age 14:</u> It's easier to reach goals especially when you have the right advice.

Outcome Expectancies

Obese female, age 10: We would be a lot healthier.

Obese female, age 14: I'm gonna be party!

Overweight male, age 11: I'll lose weight and be healthy.

Parental Support and Modeling After Participation in Healthy Kids, Healthy Families: Increased Family Involvement

To determine whether families felt that parental support and modeling of healthy behaviors changed while participating in *Healthy Kids, Healthy Families*, parents and children were asked a series of questions with probing techniques to help elicit responses (**Table 15**). From the perspective of parents, support was accomplished by making changes in nutrition and physical activity as a family. Most parents reported that all family members were included in the changes that were made to improve lifestyle, even those who did not attend the program. Similarly, most children recognized that their entire family, those who attended the class as well as those who did not, improved eating and exercise habits while participating in the program and began to model healthier eating and exercise behaviors. Children recognized improvements in parental eating behaviors while participating in the program.

Support

Mother of normal weight male, age 11 and normal weight female, age 6: Our goal may have been to eat from three food groups at every meal. And the entire six weeks, he (husband/father) would be like, "Did we actually eat from the three food groups? I did, how about you." So, we really did it as a family thing.

Mother of obese female, age 10: I just reminded her that she is not doing this alone. I made sure that I put on her brothers' plates whatever we tried. And I would eat it with her.

Mother of obese female, age 14: My husband is way past 250 pounds. He is the major cook in the house and was reared with a lot of greasy foods. So, we had to eat what he cooked. Since the class, he has a membership at the YMCA, started drinking water more, and listening to her (MSUE Program Associate). He never came (to class), but we talk about it so much when we are home that its beginning to slowly rub-off on him. Mother of obese male, age 9 and overweight male, age 11: With the little pedometer thing, we went for more walks together. Cause usually, I just take the baby with me, and the boys sit home. We were able to do a few more things together because my younger son wanted to see his numbers go up.

<u>Obese female, age 10:</u> *They* (mom and dad) *would make me do my goal... especially my mom. We dance all the time!*

<u>Obese female, age 14:</u> *My mom has been eating with me, and my mom and my dad and me have signed up for the YMCA.*

Modeling

Mother of normal weight male, age 11 and normal weight female, age 6: *I was better about eating and making choices from multiple* (food) *groups. Sometimes I would be like, wow, everybody else is but me. At breakfast time, you are getting everybody else ready, and you only have time to grab coffee on the way out the door. So, they* (children) *were really concerned that I wasn't eating from the food groups.*

Mother of obese male, age 9 and overweight male, age 11: As a family, we made some of the recipes. I mean, I make new things, and they really don't have interest in it. But

since we had it in class, we went to the grocery store and we got like peas and hummus and stuff.

Mother of obese female, age 14: I went to the store, got a lot of tomatoes, and a lot of lettuce and everything. I used to drown my salad in with a lot of salad dressing, and I don't do that anymore. Our eating habits started changing.

<u>Obese female, age 14:</u> *They* (mom and dad) *became more conscience, and they decided to start eating out less and start buying more organic food.*

<u>Obese male, age 9:</u> *They* (mom and dad) *started not getting unhealthy food.*

Overweight male, age 11: *My mom started exercising more than before and eating healthier foods.*

<u>Obese female, age10:</u> *Mom's behavior changed. She would try a lot of food with me.*

Social Cognitive Theory suggests that behavior is explained by a three-stage, dynamic model between personal factors, environmental factors and behavior, with each of these factors operating in a reciprocal manner [56, 57]. The major themes identified in the current study were: learning to cook and exercise were important for change (skills); experience with goal setting improved children's feelings of confidence in improving behaviors (self-efficacy); parental modifications in diet and physical activity were important for children's success (parental support and modeling); and the new emerging theme was family involvement (**Figure 7**). Children reported improvements in personal factors (*skills and self-efficacy*) that may influence their ability to maintain a healthy weight. Of particular importance was improvement in self-efficacy as most children learned goal setting techniques in the program and felt confident that they could continue to reach behavior goals after the program ended. Focus on environmental

factors (modeling, support, and access to healthy foods/physical activity) has demonstrated success when working with younger children [166]. In the current study, parental support of children and modeling of appropriate health behaviors improved as a result of participation in *Healthy Kids, Healthy Families*. Furthermore, family involvement, including family members who attended the class as well as those who did not, proved critical to improving the behaviors of the participating children.



Discussion

The current study is one of the first to specifically gain insights from low-income families participating in a weight management program delivered through an Extension system. As part of a larger examination of the feasibility, implementation challenges, and preliminary effectiveness of an obesity management program for low-income families, this phase of the study is a qualitative report that includes focus groups and interviews with parents and children who completed the program. The intervention specifically targeted low-income families in two cities in Michigan with high rates of unemployment, crime, and poverty. The feedback from participating families may not be representative of all, but certainly provides important information about program experiences of families that are hard to reach.

The major theme surrounding parental goals at enrollment was nutritional guidance to support healthy eating. This finding is similar to previous studies indicating that parents perceive gaps in nutrition knowledge as an impediment to healthy eating [237, 238]. Parents in the current study indicated that they were unaware of what was "missing" from their diets and needed someone outside of the home to guide their families. Parents also wanted someone outside of the home to educate and guide their children toward healthier eating behaviors. In the current study, nutritional guidance was provided through direct education as well as hands-on cooking and shopping activities, with a primary focus on changing eating behaviors as a family.

Parents and children reported different program goals when initiating the program. As previously mentioned, parents wanted someone outside of the home to provide guidance with

regard to healthy eating, particularly for their children; while children either had no goals or came simply to have fun. This finding is similar to earlier research indicating that parents and children often have conflicting goals with regard to participation in weight management programs [197, 239]. Most children indicated that they wanted the program to be entertaining and fun, with female participants particularly interested in cooking and male participants interested in physical activity. Although empirical evidence demonstrates that parent-child dyads as a unit of intervention is a more effective than focusing only on the child [240], it is important to understand that parents and children likely have very different goals and reasons for attending weight management programs.

Previous research has indicated that continued family support is essential to children's weight control [241, 242]. Although many parents in the current study enrolled in *Healthy Kids, Healthy Families* specifically to help their overweight or obese child, parents learned, during the course of the program, the importance of working with their children to change behaviors as a family. Additionally, most parents believed the lessons they learned in class would help their entire family in the future. Parents specifically appreciated learning and practicing goal setting techniques, and most indicated that they would continue to prepare program recipes and practice the exercises after the program ended.

Healthy Kids, Healthy Families met or exceeded parent and child expectations. However, participants did have suggestions for improving the program. Half of parents indicated that more families should attend for increased interaction, and some suggested MSUE Program Associates should check-in with families between weekly sessions. Attrition rates were similar to

multidisciplinary pediatric weight management programs [6, 45], and some sessions were completed with only one or two families attending the sessions regularly.

Researchers applied Social Cognitive Theory to assess the effectiveness of Healthy Kids, Healthy Families in helping parents and children modify factors related to maintenance of healthy weight in children. Personal factors, such as child's self-efficacy and skills, are necessary to perform behaviors that children feel will help them to achieve the desired outcome [56, 57]. Environmental factors, such as parental modeling and support, influence eating and activity behaviors of children [109]. Parental modeling is a strong predictor of dietary intake in children, suggesting these behaviors are learned from observing parents and imitating behavior [243]. Children learned to cook and exercise (skills), and their experience with goal setting improved feelings of confidence in improving health-related behaviors (self-efficacy). Parents modified their own diet and physical activity behaviors, which was important for children's success in the program (parental support and modeling). Parents and children shared that the changes made during the program were made as a family. It was clear that all members of the family, those who attended the classes as well as those who did not, participated in program activities at home. Similar to earlier studies with children and adolescents that indicated a desire for significant family involvement in weight loss efforts [120, 244, 245], family involvement was critical to children's success in the program.

Limitations of the current study should be acknowledged. This study specifically examined parent and child experiences in one MSUE program designed for families with overweight and obese children. The sample size was small and the results may not be generalizable to a broader population. In addition, not all participants who completed *Healthy Kids, Healthy Families* agreed to participate in the focus group or interview discussions. Feedback from families who chose not to participate may differ from those who agreed to share their experiences. A larger sample of participating children and families may be necessary to provide a better understanding of program experiences and feasibility in diverse populations.

Conclusion

This is one of the first studies to examine participant experiences in a weight management program led by trained community health workers who were employed through an Extension system. The focus groups provided a better understanding of changes in environmental variables, specifically parental modeling behaviors and support, which resulted from program participation. Additionally, children reported that changes in skills and self-efficacy resulted from goal-setting activities. Important to the results of the current study are the positive feedback, from children and parents, regarding the overall program and the Extension staff. However, attrition rates in the current program were high, and program engagement was low, together indicating that the current model of referral and delivery is not feasible on a populationwide basis. Most of the participants dropped from the program before the first one-on-one session, suggesting that disappointment with the program/program instructor was not the primary reason for attrition. Many of the families that enrolled in the program were experiencing multiple stressors which likely impacted program participation. Keeping in mind the numerous barriers to participation, future programs should recruit from various sources and identify potential barriers to participation upon enrollment.

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CHAPTER 6 - Protocol for a randomized controlled trial to evaluate *Healthy Kids, Healthy Families*, a weight management program for families with overweight or obese children delivered by Extension

Abstract

Background: Childhood obesity is a significant public health issue in the United States. While family-based behavioral intervention programs have demonstrated moderate effectiveness in treating childhood obesity, there is a lack of affordable, accessible, and scalable community-based programming to meet the growing needs of families. The aim of the current paper is to describe a randomized controlled trial to test the effectiveness of a weight management program for low-income families with overweight or obese children. The program uses community health workers (Program Associates) who are trained and employed by Michigan State University Extension (MSUE), a statewide organization.

Methods/Design: Researchers from Michigan State University Departments of Food Science & Human Nutrition and Human Development & Family Studies designed *Healthy Kids, Healthy Families* for delivery through MSUE. The curriculum is grounded in Social Cognitive Theory and includes seven modules with information about nutrition and overall health, physical activity, self-esteem, parenting roles, family support and communication, goal setting, and problem solving. This is a randomized controlled trial with intervention and control children – all children in the control group are invited to participate in the program after their follow-up data collection is complete. Trained MSUE Program Associates deliver *Healthy Kids, Healthy Families* to low-income families with children aged 8 to 14 years who are overweight (BMI-forage and gender between the 85th and 94th percentile) or obese (BMI-for-age and gender \geq 95th percentile). Participants are recruited through primary care pediatric and family practice offices in Saginaw as well as through other organizations and programs. Interested families contact the

local MSUE office for eligibility screening based on child's age and caregiver-reported weight status. Children are randomly assigned to either the intervention or control group. *Healthy Kids, Healthy Families* begins with a one-on-one session with the MSUE Program Associate, who explains the program, measures baseline height and weight, and completes behavioral and quality of life assessments. The MSUE Program Associate then begins a series of six multi-family group or individual family sessions with children in the intervention group. Control children continue to receive standard care. Height, weight, behavioral, and quality of life data is collected from intervention and control children at 12- and 25-week follow-up. Regression models are used to examine differences from baseline and follow-up between intervention and control groups. A process evaluation is also conducted.

Discussion: Widespread programming to treat childhood obesity is not available or accessible in most communities, and there is a growing need for innovative solutions. If the proposed intervention is successful, a new community-based program for families with overweight and obese children will be available through Extension. Because the intervention is delivered through an Extension system, it is reproducible on a nationwide scale. Additionally, the research results provide new information regarding the effectiveness of trained MSUE Program Associates in delivering a weight management program to children and their families.

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Background

It is well-established that childhood obesity is a significant problem in the United States (US), with serious health and social consequences for millions of children [1, 2]. Additionally, it has been demonstrated that obesity in children tracks into adulthood, with high body mass index (BMI) in childhood increasing risk of cardiovascular disease, type 2 diabetes, and premature death [5, 9, 19]. The condition is disproportionately higher among children from poorer families [25], as well as Mexican American, Native American, and African American children [26].

Approximately 32% of US youth between the ages of 2 and 19 years are overweight and 16.9% are obese [3]. Although no significant change in obesity prevalence by age group was observed between 1999-2000 and 2009-2010 (suggesting a plateau or leveling of obesity), the prevalence of childhood obesity and overweight are well above national goals [65]. Additionally, extreme obesity in children is now recognized as the fastest growing subcategory of obesity in children and adolescents in the US [5-7].

Current treatments for childhood obesity, both moderate and severe, have shown only limited effectiveness and are not widely available [5, 211, 212]. Trials focused on pediatric weight management have largely consisted of efficacy studies conducted in controlled settings, such as academic research or tertiary care centers [52]. These programs require a team of highly-skilled health professionals, making their implementation costly and their availability limited [37, 38]. There is a growing need for research that examines the effectiveness of low-cost, accessible, and scalable weight management programs that can be delivered to families with obese children.

Programs utilizing community health workers, trained and supervised by professional staff, provide an alternative for families with obese children. Community health workers serve as bridges between their ethnic, cultural, or geographic communities and health care providers [152]. In the US, community health workers have consistently demonstrated success in facilitating access to health education programs, providing patient-centered care, improving adherence, reducing health care costs, reducing health inequalities, and providing on-going support [154, 155, 157-159, 246-248].

The Extension Service is a nationwide, non-credit educational network designed to help people use research-based knowledge to improve their lives. The service is provided by land grant universities throughout the country and includes a network of local offices throughout each state. Michigan State University Extension (MSUE) has been using trained health workers, hereafter referred to as Program Associates, supervised by county-based professional staff and supported by university staff, to deliver basic nutrition education statewide since 1914. With nearly 160 trained MSUE Program Associates who provide home visits and group teaching to limited income families throughout Michigan, MSUE has the unique capacity to build a network of staff to provide education to families with overweight and obese children. In addition to programming focused on nutrition and health, MSUE also features programming in agriculture, business and community, family, lawn and garden, natural resources, 4-H and youth. Individuals and families are frequently referred to programs within MSUE based on need and interest.

The proposed project evaluates the effectiveness of an obesity management program for families living in one urban city in Michigan with high rates of poverty, violence and

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unemployment. This innovative approach includes the use of trained Program Associates from MSUE – allowing for widespread program dissemination. The current paper presents an overview of the program as well as a description of the study design.

Methods

Preliminary Work

A feasibility study for the current project was completed between February of 2015 and March of 2016. Seventy-two children, from two pediatric clinics in Michigan, enrolled in the program. Qualitative data from in-depth interviews and focus groups indicated that participants and their families learned new skills, improved health-related behaviors, and positively viewed both the overall program as well as the MSUE Program Associates who delivered the program. At program exit, participating children demonstrated significant improvements in health-related quality of life (z=2.31; p<0.05), emotional health (z=2.38; p<0.05), and physical activity (z=2.29; p<0.05). Although the program was well-received by participating families and successful in improving health-related behaviors and quality of life of participating children, only 12 of 72 children who enrolled at partnering pediatric offices completed (with most dropping prior to program initiation). Together, results indicated that although the program was effective for and well-received by program completers, attrition rates were high, and program engagement was low. The tested model of referral and delivery was, therefore, not feasible as designed.

Researchers made modifications to address challenges with recruitment and retention during the feasibility study as well as to incorporate participant suggestions with regard to program delivery (**Figure 8**). Changes include more flexible programming options with referrals through

numerous agencies and organizations; family initiation of program enrollment; program expansion using various sites and times throughout the targeted city; family selection of program delivery method (one-on-one or group); text or e-mail check-in between sessions; and inclusion of a process evaluation to monitor and document program implementation.

<u>Aim 1 Findings</u>

- *Healthy Kids, Healthy Families* demonstrated short-term effectiveness
- Barriers to participation included childcare, transportation, scheduling difficulties, and competing activities
- Most families dropped from program prior to initiation

Aim 2 Findings

- *Healthy Kids, Healthy Families* was positively viewed by program completers
- Participants expressed disappointment with small class sizes
- Participants indicated discomfort with home visits
- Paricipants suggested email or text check-in between sessions

Modifications for Randomized Controlled Trial

Referral from numerous agencies/organizations Families contact MSUE directly to enroll/initiate program Barriers to particiation identified and addressed prior to initiation

Families choose method of delivery (group or one-on-one) Email or text check-in between sessions

Flexible program options at various sites in the community

Figure 8. Synthesis of Previous Findings and Related Modifications

Study Design

Approval for a randomized controlled trial has been issued by the Institutional Review Board (IRB) of Michigan State University. Advertisements and information regarding *Healthy Kids, Healthy Families* are shared with pediatric and family practice clinics, local elementary schools, Saginaw County Parks and Recreation, faith-based organizations, local newspapers, and other MSUE programs. Parents are asked to contact MSUE directly (via telephone or email) to enroll in the program. The MSUE Program Associate screens for eligibility based on child's age and parent-reported weight status of the child. At that time, all parents/caregivers must also agree to participate in home visits and group sessions with their child/children and are asked to identify and share any barriers to participation (transportation, childcare, extracurricular activities, work schedule, etc.). These barriers are then recorded and addressed in an effort to identify and reduce attrition rates.

Participating children must be between 8 and 14 years of age and reported as overweight or obese by parent/caregiver. Children are randomly assigned to either the intervention or control group. All children in the control group and their families are invited to participate in the program after follow-up data are complete. Children in the control group who choose to attend the program after follow-up data collection do so as participants with no requirement for continued participation in the research study. MSUE Program Associates assign a number to the children based on the order/time families call and express interest in the study. Children assigned an even number are placed into the control group, and children assigned an odd number are placed into the intervention group. In an effort to keep families together, children in the same family are assigned consecutive even or odd numbers.

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Focus groups with families who participate in the program are held exactly one week after families have completed the program. Focus groups are included as part of a process evaluation to assess fidelity, dose, and reach and help researchers gain insight from families about program satisfaction as well as health-related behavior changes that resulted from program participation.

Data Collection

The MSUE Program Associate completes the informed consent process for parental consent and child assent at a scheduled one-on-one session in the home or another convenient location. At that time, the Program Associate also collects demographic information, baseline child and parent/caregiver height and weight (for BMI/BMI percentile calculations), and behavioral and quality of life evaluations. These assessments include the collection of one 24-hour dietary recall (children), and completion of the following questionnaires: Physical Activity Questionnaire for Children [169] (children) and Health-Related Quality of Life [185] (parents and children). After completing all baseline assessments, the MSUE Program Associate asks families whether they prefer to participate in *Healthy Kids, Healthy Families* (curriculum described in Aim 1) through one-on-one or multi-family group sessions. Families in the intervention group begin the program approximately one week after baseline data collection, while families in the control group continue to receive standard care and are offered program participation following collection of all follow-up data.

At approximately 12-weeks, the MSUE Program Associate collects follow-up behavioral and quality of life evaluations as well as child and parent/caregiver height and weight (for BMI/BMI percentile calculations). The Program Associate schedules home visits with control children to

coincide with these dates and collects behavioral and quality of life evaluations as well as child and caregiver height and weight (for BMI/BMI percentile calculations). The MSUE Program Associate collects follow-up data a second time during a scheduled home visit with intervention and control children at 25-weeks. Small incentives, such as backpacks, water bottles, kitchen utensils, reusable lunch and grocery bags, and sports balls are given for program participation and completion of assessments. See **Table 16** for study schedule.

Table 16. A Randomized Controlled Trial Study Design and Group Comparisons

Week	Intervention Group	Control Group
1-3	Baseline Data Collection	Baseline Data Collection
4-11	Intervention Period	Standard Care
12-13	Behavioral Post Test	Behavioral Post Test
25-26	Follow-Up	Follow-up

Sample Size and Power

PASS version 11 was used to accomplish advance repeated measures ANOVA power analysis to determine the detectable change in children's BMI percentile with each subject measured three times. A repeated measures design with 1 between factor and 1 within factor has 2 groups with 19 subjects each for a total of 38 subjects [201]. This design achieves 91% power to test for a difference in BMI percentile between subjects if a Geisser-Greenhouse Corrected F-Test is used with a 5% significance level and the actual effect standard deviation is 0.45 (an effect size of 0.55).
Because intake of sugar and sugar-sweetened beverages was significantly different between overweight and normal weight children as compared to obese/severely obese children in the feasibility study, researchers specifically examine changes in sugar-sweetened beverage intake from baseline to follow-up. PASS version 11 was used to accomplish advance repeated measures ANOVA power analysis to determine the detectable change in sugar-sweetened beverage intake with each subject measured three times. A repeated measures design with 1 between factor and 1 within factor has 2 groups with 22 subjects each for a total of 44 subjects [201]. This design achieves 91% power to test for a difference in one cup sugar-sweetened beverage between subjects if a Geisser-Greenhouse Corrected F-Test is used with a 5% significance level and the actual effect standard deviation is 0.42 (an effect size of 0.51). This design achieves 100% power to test for a difference in one cup sugar-sweetened beverage within subjects if a Geisser-Greenhouse Corrected F-Test is used with a 5% significance level and the actual effect standard deviation is 0.42 (an effect size of 1.04). This design achieves 100% power to test the between and within subjects differences in one cup sugar-sweetened beverage if a Geisser-Greenhouse Corrected F-Test is used with a 5% significance level and the actual effect standard deviation is 0.42 (and effect size of 1.04).

Since sugar-sweetened beverage intake is the limiting outcome variable (requiring a larger sample size), researchers determined sample size using this variable. Assuming a 30% drop-out rate, a total of 58 children will be recruited as subjects for the current study (29 in the intervention group and 29 in the control group).

Healthy Kids, Healthy Families Curriculum Development and Delivery

A theory-driven curriculum, *Healthy Kids, Healthy Families*, was developed by researchers from MSU Departments of Food Science & Human Nutrition and Human Development & Family Studies. The research team that developed the curriculum included four registered dietitians, one certified diabetes educator, and three marriage and family therapists. The curriculum was intended for delivery by trained MSUE Program Associates to support families in dealing with the physical, psychological, and emotional barriers to a healthy lifestyle. The project team developed a single one-on-one session followed by a series of six individual or multi-family group sessions. Each of the sessions is interactive and includes information about family dynamics and communication, behavior change, body image, nutrition, meal planning, physical activity, and community resources. An important focus of the curriculum is improving the environment that surrounds the children to promote healthy eating and regular physical activity.

Each of the six group sessions of *Healthy Kids, Healthy Families* follows a similar template. Beginning in the first group session, participants are asked to set one behavioral goal for themselves for the upcoming week and to work with their family to set one family goal for the upcoming week. Those goals are recorded on weekly tracking sheets, and children are given stickers to place on the sheets when goals are met. At the start of each group session, participants and families report back on weekly goal progress and explain any barriers or facilitators to goal achievement. New goals are set and monitored every week. Participants are also asked to report how they are feeling about goal progress each week and whether help is needed.

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Following the goal setting and tracking activity, families engage in at least 20 minutes of physical activity. Exercises vary from site to site but include aerobic, muscle strengthening, and bone strengthening activities. Families are taught a variety of different physical activities that may be done indoors or outdoors, placing particular focus on exercise as a family.

A learning activity, lasting approximately 20-30 minutes, follows the physical activity. The *Healthy Kids, Healthy Families* manual includes a script for the sessions and learning activities specific to each session topic. Learning activities are interactive and include topics focused on nutrition, physical activity, body image, behavior change, and maintaining a healthy lifestyle. The focus is on the importance of change as a family and parental modeling of appropriate health behaviors (such as preparing and eating a variety of foods, making time for family meals, and engaging in physical activity).

Sessions end with a 20-30-minute cooking activity. Families are given the choice of several different recipes to prepare and taste during the session. Families participate in food preparation with the MSUE Program Associate and are given the recipes to take home.

Theoretical Framework

Healthy Kids, Healthy Families is based on social cognitive theory (SCT), which is widely used when developing interventions focused on improving health behaviors in children [214]. SCT suggests that behavior is explained by a three-stage, dynamic model between personal factors, environmental factors and behavior [56, 57]. According to SCT, knowledge of health risks and benefits creates the precondition for change, but beliefs of self-efficacy are needed to overcome

the barriers to adopting and maintaining healthy lifestyles [56]. Improving self-efficacy, which refers to one's judgment about their capability to perform particular tasks [56], is important for behavior change. *Healthy Kids, Healthy Families* includes activities to improve self-efficacy of both children and parents, such as cooking/food preparation and practicing various indoor and outdoor exercises. Because children are often guided by parents in their dietary intake and levels of physical activity [166], the curriculum also focuses on improving environmental factors related to the family, such as parental modeling, parental reinforcements, and access to healthy foods/physical activity.

Training of MSUE Program Associates

Healthy Kids, Healthy Families is delivered by a trained MSUE Program Associate, supervised by county-based professionals with nutrition experience. The MSUE Program Associate and supervisors participate in a two-day training led by MSUE campus-based staff and researchers. At the training, the Program Associate is given a manual to follow when leading each of the seven sessions. The manual includes a script for the sessions and learning activities specific to each session topic. The training also delineates research procedures; introduces staff to behavior change theories; and provides opportunities to practice sessions.

The MSUE Program Associate and supervisors are also required to participate in additional trainings during the year and visited regularly (at least twice each month) by researchers. Weekly conference calls between researchers and MSUE staff are required. The purpose of the additional trainings and conference calls is to address concerns, update program materials, educate staff, and share experiences. The MSUE Program Associate receives educational

handouts to distribute, exercise equipment to use during the intervention, teaching aides, and a list of local and national resources.

Instruments and Variables

Figure 9 describes the study schedule and data collection points.

Demographic Data

Demographic data include the gender, age, and race/ethnicity of all children. In addition, caregivers report their current health insurance carrier.

Weight Status

The MSUE Program Associate collects baseline height and weight from parents/caregivers and children (for BMI/BMI percentile calculations). The Program Associate measures the weight and height individually, without shoes or heavy outer garments. On each occasion (baseline, 12-and 25-weeks), two measures are made and the averages recorded. Height is measured to the closest 0.1 cm and weight is measured to the closest 0.2 kg. To assess any changes in parental weight status, BMI is also calculated for adults. Children's BMI is calculated from a child's weight and height and, categorized into percentiles by gender and age, serving as an indicator of risk for overweight and obesity [173]. Children are categorized, using age and gender specific CDC growth charts, as follows: normal (BMI between the 5th percentile to the 85th percentile); overweight (BMI between the 85th percentile to the 95th percentile); class 3 obesity (BMI \geq 120% of the 95th percentile); class 3 obesity (BMI \geq 140% of the 95th percentile).

Behavioral and Quality of Life Data

The trained MSUE Program Associate collects behavioral and quality of life evaluations at three separate times (baseline, 12-, and 25-weeks). These assessments include the collection of one 24-hour dietary recall (child), and completion of the following questionnaires: Physical Activity Questionnaire for Children [169] (child) and Health-Related Quality of Life [185] (parent and child).

Eating behaviors are measured using one 24-hour dietary recall following the United States Department of Agriculture (USDA) multiple pass method [179, 180]. When assessing the diets of children under the age of ten, one or both parents give combined responses with the child. This approach has been shown to provide more accurate information than a recall from either parent alone [182]. Children complete one 24-hour food recall on each occasion (baseline, 12and 25-weeks).

Physical activity is assessed using the Physical Activity Questionnaire (PAQ-C), a selfadministered questionnaire that has been validated for use with children [169, 183, 184]. It is used to determine the amount of physical activity performed in the seven days preceding the evaluation. Activity scores are between 1 and 5, with 1 indicating low physical activity and 5 indicating high physical activity. Evidence supports the PAQ-C as a reliable and valid measure of general physical activity levels in children [169, 183, 184]. When administered to elementary school children, the measures demonstrated acceptable scale reliability for both females ($\alpha =$ 0.83) and males ($\alpha = 0.80$) [169]. Children complete this form on each occasion (baseline, 12and 25-weeks). The Pediatric Quality of Life Inventory (PedsQL) measures health-related quality of life in healthy children, and those with acute and chronic conditions, aged 2 to 18 years [170]. It is a child self-report and parent proxy-report consisting of 23 items using a scale with five Likert response options, 'never', 'almost never', 'sometimes', 'often', and always' corresponding to scores of 100, 75, 50, 25, and 0, respectively. A higher score indicates better health-related quality of life and a lower score indicates poor health-related quality of life. The scale has summary, physical, social, emotional and school scores that show adequate reliability and validity [185]. Children and parent/caregiver complete this form independent of one another on each occasion (baseline, 12- and 25-weeks).



Figure 9. Flow Chart of Data Collection and Study Schedule

Statistical Analysis

A comparative analysis of intervention and control groups by age, gender, race/ethnicity, and socioeconomic status (using insurance carrier) is accomplished, with degree of similarity between groups will be tested using ANOVA–F-tests, nonparametric and chi-square tests, as appropriate. Substantive differences exist are controlled for in subsequent analyses of outcomes by regression techniques.

Researchers use regression models to examine differences from baseline and follow-up between the intervention and control groups. The primary outcome is the child's BMI-percentile, which is an age and gender adjusted measure of BMI using the US CDC 2000 growth reference. The outcome for analysis is a continuous measure on a bounded range, for example, BMI-percentile (0,100). For this continuous measure and other continuous measures, researchers use linear regression. Significance is set at p = 0.05. All quantitative data is analyzed using SPSS version 23.

Process Evaluation

In an effort to monitor and document program implementation, a process evaluation that assesses program fidelity, dose (delivered and received), recruitment, retention, and reach is included as part of the study [202]. Process evaluation is particularly important to the current study because researchers are interested in how or why *Healthy Kids, Healthy Families* is more (or less) successful [249]. Researchers in the current study use process evaluation for both formative and summative purposes in an effort to understand the extent to which *Healthy Kids, Healthy Families* is delivered as designed (fidelity); incorporates the suggested number of lessons (dose);

successfully recruits participants and families (recruitment); maintains low attrition rates (retention); and has an impact not only on intended participants but also family members (reach).

Program fidelity is assessed during weekly conference calls and monthly meetings between MSUE Program Associates and researchers. MSUE Program Associates to document/record that all components of each session are successfully covered. Additionally, at least two unannounced site observations occur throughout the program intervention period. Dose-delivered is documented using MSUE attendance sheets and length of each session. Researchers assess recruitment and retention by intervention or control group and by different recruitment methods. Those families dropping out of the program are compared with those that remained in the program in terms of demographic characteristics. Researchers request and record reasons for attrition.

A key method for further assessing fidelity, dose, and reach is accomplished through focus group discussions at the conclusion of the program. With Bandura's Social Cognitive Theory as the theoretical framework [56], questions developed for the focus group guide, were guided by literature, research questions, and researchers' experience with this topic and population. Focus groups specifically examine changes in environmental and individual-level variables that resulted from program participation. The focus group guide also includes questions about program content, program goals and expectations, likes and dislikes, feelings about group leader, and suggestions for improving the program.

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In addition to the focus group evaluation, participants and their caregivers also complete goal sheets each week. The purpose of these sheets is to monitor progress toward individual and family behavioral goals. Participants and their caregivers are asked to set measurable goals each week. The following week, families report barriers and facilitators to goal achievement. Researchers collect and record this information in an effort to better understand the unique struggles of low-income families with overweight and obese children.

Qualitative Analysis

After each focus group, the recordings are transcribed verbatim by the researcher who was present at the interviews. The transcripts are individually coded by three researchers, checked, and discussed by those researchers until consensus is reached. The current study utilizes qualitative methodology with thematic analysis approach [198-200]. Three researchers independently develop the initial codes, and any discrepancies are reconciled. Initial codes are then grouped into categories and assigned themes. All steps and changes throughout the study are documented as on-going memos by the lead researcher. Qualitative data is managed with NVivo version 8.

Discussion

Although it has been suggested that solutions to childhood obesity will require substantial collaboration between medical and community-based organizations [33], literature investigating the feasibility and effectiveness of community-based interventions as treatment options for obese youth is limited [51-55]. Even fewer studies examine the effectiveness of theory-driven programs for families with overweight and obese children delivered through an Extension

system. With increasing awareness surrounding the effectiveness of trained community health workers in the management of chronic conditions in both adults and children and the capacity of Extension to build a network of Program Associates across Michigan, an examination of the effectiveness of the current program is warranted.

There have been dramatic increases in the prevalence of diagnosed diabetes in the United States [79], and rates of chronic disease are increasing across the globe [80]. As indicated in an editorial by David Katz, Director of Yale University Prevention Research Center, these reports are about adults but "portend the future that awaits today's children" [81]. Widespread programming for the treatment of childhood obesity is not available or accessible in most communities. The proposed project offers a practical, accessible, and scalable solution.

CHAPTER 7 – Summary and Conclusions

Childhood obesity is clearly recognized as one of the most serious public health challenges in the United States [250]. In addition to the physical, psychological, and social consequences of obesity during childhood and adolescence, obese children are likely to remain obese into adulthood, increasing rates of morbidity and mortality [9, 19]. While family-based behavioral intervention programs have demonstrated moderate effectiveness in treating childhood obesity and overweight, there is a lack of affordable, accessible, and scalable community-based programming to meet the growing needs of families.

Although systematic reviews have determined that family-based behavioral treatment programs are moderately effective for obese children [31, 32], research on this topic has largely focused on results from controlled clinical trials or academic research [27-29, 31-41]. In addition, the programs that are currently available to treat childhood obesity often require a team of highly-skilled health professionals and specialized facilities, making their implementation costly and their availability limited [37, 38]. These programs are not easily accessible, particularly in low-income communities, and are often inconvenient for families to attend [37, 42]. Furthermore, the demand for treatment at these centers exceeds current capacity, with most reporting long waiting lists [43] as well as high attrition rates [6, 44, 45]. Weight management programs adapted for community-based setting are severely limited, which presents a significant barrier to reducing obesity prevalence in children, particularly among those at highest risk [52].

Screening for childhood obesity is another important issue. Recent recommendations clearly indicate that primary care providers should screen for overweight and obesity and provide

anticipatory guidance [46, 47], but many fail to do so [48, 49]. Research has consistently demonstrated underdiagnoses of pediatric obesity during regular preventive visits, and the use of BMI-percentile screening in primary pediatric practices is underused [48, 49]. Furthermore, and after diagnosis, most obese children and adolescents are not receiving the recommended laboratory screening [50]. Physicians specifically indicate a lack of available referral sources among the reasons for their failure to screen for obesity [48].

The current study, therefore, explored the feasibility, implementation challenges, and participant experiences in an intervention, administered through Michigan State University Extension (MSUE), that specifically targets low-income families with overweight and obese children. MSUE is a statewide organization with offices in nearly every county in Michigan, allowing for widespread program dissemination. Uniquely different from traditional multidisciplinary weight management programs, *Healthy Kids, Healthy Families* was delivered by trained community-based health workers (Program Associates) who were supervised by registered dietitians. The curriculum used in the current study was written by a team of experts in the field of nutrition and family therapy and was driven by Bandura's Social Cognitive Theory [56, 57]. Partnering hospital-based and private practice pediatric clinics worked with researchers and MSUE to identify and recruit children and families into the program and provide clinical and biochemical measures.

A two-phase study was conducted using clinical, biochemical, behavioral, and quality of life evaluations as well as focus groups or in-depth interviews. In Phase 1 of the current study, researchers assessed the feasibility, implementation challenges, and preliminary effectiveness of a weight management program for families with overweight or obese children delivered through MSUE. A secondary aim of this phase of the study was to describe baseline characteristics and degree of overweight of children who enrolled in the program to better understand the magnitude of the problem in targeted areas. Phase 2 of the study examined participant perceptions of and experiences in *Healthy Kids, Healthy Families* through focus group discussions and in-depth interviews with families that completed the program. The main aim of this phase of the study was to determine whether participants were satisfied with the program and identify health-related changes in personal and environmental factors that resulted from program participation. Information gathered from these two phases of the study was used to develop a protocol to test the effectiveness of a revised model through a randomized controlled trial.

The primary finding of the current study demonstrated that, although attrition rates were similar to those reported in multidisciplinary weight management programs [45, 251], there was a need for programming to address childhood obesity in the targeted communities. Preliminary results indicated that participants who completed the program experienced significant changes (p < .05) in physical activity, health-related quality of life, and emotional health, with large effect sizes for each of these measures. Although program completion was a personal challenge for many, all participants and caregivers reported positive experiences with MSUE Program Associates and the intervention.

A total of 72 children enrolled in the program, and the majority were African American, female, Medicaid recipients, and obese. Overall, disproportionately large number of participants were obese or severely obese; had not been screened for comorbidities; and were not meeting dietary recommendations. Concerns regarding the dietary habits of children enrolled in the program were further emphasized by 24 participants who completed one 24-hour dietary recall during a one-on-one session with the MSUE Program Associate. When researchers compared baseline dietary data from overweight/normal weight children to obese/severely obese children, the obese/severely obese group demonstrated a significantly higher intake of total sugar and sugar-sweetened beverages. These results are consistent with research showing an association between intake of sugar and sugar-sweetened beverages and obesity severity in children [111, 112] as well as those demonstrating that intake of dietary sugars or sugar-sweetened beverages is, in fact, a determinant of body weight [225-229].

From qualitative findings, researchers sought a better understanding of parent and child experiences in *Healthy Kids, Healthy Families* as well as changes in personal and environmental factors that resulted from program participation. Although the sample of program completers was small, all children and families reported only positive feedback with regard to the overall program as well as the MSUE Program Associates who delivered the program. Interaction with MSUE Program Associates and other families as well as hands-on activities, such as cooking, exercise, and goal setting were mentioned as the most enjoyable parts of the program. Parents and children suggested that the program include more families during weekly sessions, add text or email check-ins between sessions, and spend more time focused on physical activity. Children reported improvements in personal factors and indicated that they learned goal setting techniques in the program that helped build confidence in their ability to reach behavior goals. Environmental factors, particularly parental support of children and modeling of appropriate health behaviors improved as a result of program participation. Family involvement emerged as a critical component when trying to improve the eating and exercise behaviors of the children. The long-term goal of the current study is to create a model for collaboration between MSUE, primary care physicians, and families to effectively manage childhood overweight and obesity through accessible, scalable programming that reaches the most vulnerable families.

Researchers, therefore, used the information learned in the first two phases of the study to develop a protocol study to test the effectiveness of the program through a randomized controlled trial. Modifications were made to address challenges with recruitment and retention during the feasibility study as well as to incorporate participant suggestions with regard to program delivery. Additionally, a process evaluation is included in the protocol for both formative and summative purposes in an effort to understand the extent to which *Healthy Kids, Healthy Families* is delivered as designed (fidelity); incorporates the suggested number of lessons (dose); successfully recruits participants and families (recruitment); maintains low attrition rates (retention); and has an impact not only on intended participants but also family members (reach) [202].

Strengths

There are several strengths to the current study. This is among the first studies to examine a theory-driven program for low-income overweight or obese children delivered through an Extension system. MSUE has offices in nearly every county in Michigan, and the potential for building a network of Program Associates to disseminate *Healthy Kids, Healthy Families* statewide is great. Furthermore, the partnership with pediatricians built capacity with regard to

the management of childhood obesity though MSUE programs. Another key strength of *Healthy Kids, Healthy Families* is its acceptability to families that completed the program. The qualitative analysis provided important information from voices of families who are often not heard. Parents and children shared their experiences with the program, and all participants provided strong positive feelings about the program as well as the MSUE Program Associates. It bares mentioning, however, that the majority of children who enrolled did not complete the program. Feedback from those who dropped from the program may have been different from those who completed.

Limitations

Several limitations of the study should be noted. The attrition rates in the current program were high, but not unlike those of more expensive multidisciplinary weight management programs [45, 145]. Most families either dropped from the program immediately after enrollment or demonstrated passive refusal when Program Associates attempted to schedule one-on-one sessions. Our sample was small and did not include a control group, but researchers were interested in maximizing program reach and examining feasibility with low-income families. Because researchers chose two communities that were difficult to reach and included primarily low-income families using public insurance, high attrition rates were expected [45, 232-235]. The results of the current study may not be generalizable to all; however, program results do provide important information regarding families in vulnerable communities. Finally, the lead researcher was involved in both the implementation and the evaluation of the current study which may have introduced bias.

Future Directions

Future research is ongoing for the current study and will measure the effectiveness of a revised model when delivered on a larger scale through a randomized controlled trial. Protocol for a randomized controlled trial also includes a process evaluation to address issues that were recognized during the feasibility study. Following the determination of program effectiveness, a cost analysis of the current study may be warranted. Given the high cost of multidisciplinary programs and the high attrition rates, the current model may be a more cost-effective method of reaching growing numbers of families with overweight and obese children.

After enrolling in the current program, 33 children of the 72 children who enrolled in the program (46%) completed the initial one-on-one session to initiate the program. Only 12 of those 33 children completed the program. Future research should focus on how to better address barriers to participation and decrease attrition. In the current study, MSUE Program Associates reported passive refusal when scheduling one-on-one visits as families refused to answer the door; were not home (or at the agreed upon location) at scheduled time; did not have eligible children with them; or asked to reschedule when MSUE Program Associates arrived. Additionally, many families indicated that they were uncomfortable with staff coming into their homes. This finding is not consistent with previous research demonstrating that home visiting in child obesity management programs increases accessibility and dosage [222, 223]. Aside from the Flint water crisis, other reported reasons for attrition in the current study included transportation issues, scheduling difficulties, lack of childcare, parental custody issues, lack of interest, and competing extracurricular activities for children.

Another important issue to consider is whether the current program would have been more successful, in terms of retention rates, had it targeted a more socioeconomically advantaged population. It is well-recognized that certain public health interventions may increase inequalities in health by disproportionately benefiting less disadvantaged groups (intervention generated inequalities) [252]. It is unclear whether community-based interventions targeting families with obese and overweight children generate these inequalities. Researchers in the current study were interested in examining the feasibility of the program in highly disadvantaged groups in an effort to first examine whether the program is successful in reaching those in greatest need. It would be interesting, however, to compare program results with a differing demographic audiences.

In summary, childhood obesity is a pressing public health issue in the United States and worldwide. Current programming to address the condition is currently unable to meet the needs of all families, particularly those in greatest need. The current study examined the feasibility of an innovative model to address childhood obesity that is accessible in communities and scalable on a statewide level. Results indicated that the program was successful in improving healthrelated behaviors and quality of life and was positively viewed by those families that completed the program. However, attrition rates were high, and program engagement was low. The current model of referral and delivery appeared not to be feasible on a population-wide basis. Modifications to the model include more flexible programming options with referrals through numerous agencies and organizations; family initiation of program enrollment; program expansion using various sites and times throughout the targeted city; family selection of program delivery method (one-on-one or group); text or e-mail check-in between sessions; and inclusion of a process evaluation to monitor and document program implementation. With increasing awareness and agreement surrounding the effectiveness of trained community health workers in the management of chronic conditions in both adults and children, the results of this intervention are important to efforts surrounding the treatment of childhood obesity, particularly in lowincome communities. **APPENDICES**

APPENDIX A: Description of Partnerships with Pediatricians

Each of the partnerships with pediatricians in Flint and Saginaw was unique, but each was strong and sustainable. In Saginaw, Dr. Ramani is a private practice pediatrician with a small staff. Dr. Ramani was willing to partner and serve as a primary recruitment site in Saginaw but asked that staff from MSUE and Ms. Custack serve as research assistants and recruit patients directly from her clinic. Dr. Ramani was present when recruitment occurred and frequently explained benefits of the program to potential participants. She called patients to encourage their participation and referred patients to the program when research assistants were not present. Dr. Ramani presented the program to colleagues in Saginaw and was extremely supportive.

Dr. Hanna-Attisha is the Director of the Pediatric Residency Program at Hurley Medical Center and was integral to program initiation in Flint. Dr. Hanna-Attisha recruited medical students and residents to serve as research assistants for the project and invited Ms. Custack to participate in several meetings to introduce the current study to her colleagues at Hurley Medical Center. Each of the students and residents participated not only in recruitment, but also in the preparation of abstracts for professional presentations. Dr. Gwen Reyes, the chief pediatric resident, presented the current study to residents and staff on several occasions and continually offered her assistance with recruitment. In Ms. Custack's absence, Dr. Onyinye Nweke presented an abstract describing the current project at the 2015 American Academy of Pediatrics Conference.

As a result of partnerships in Flint, Ms. Custack was invited to present the current study during grand rounds at McLaren Flint. Family practice physicians were interested in sharing information about *Healthy Kids, Healthy Families* with their patients as well as involving

medical students and residents in the research project. Strong partnerships with the pediatricians, medical students, and residents have been established in Flint and Saginaw.

APPENDIX B: Overview of Group Curriculum

Group Session One:

Overview: This session introduces **Healthy Kids, Healthy Families**. Participants will assess their own health behaviors and behavior change skills. Participants will be introduced to six behavior skills that the program will help them develop. Participants will also discuss the role of the family, and the importance of a supportive environment to encourage behavior change. **Objectives:** By the end of the first session, participants should be able to:

- 1. Get excited about HKHF
- 2. Discuss the role of the family in promoting behavior changes in children/teenagers
- 3. Identify six skills that can lead to behavior change.
- 4. Develop goals using the "KISS'M" ("Keep it short, simple, and measurable") concept.

Group Session Two:

Overview: This session will focus on the importance of eating a variety of foods in moderation for good health and maintenance of a healthy weight.

Objectives: By the end of session three, the participants will be able to:

- 1. Recognize MyPlate.
- 2. Identify the different food groups.
- 3. Identify several foods that fit into each of the different food groups.
- 4. List healthy snack options.
- 5. Identify individual eating patterns using a 24-hour recall.

Group Session Three:

Overview: The focus of this session is caring for your body. Participants and their families will be able to identify factors and lifestyle choices that impact their health.

Objectives: At the closing of this session, participants should be able to:

- 1. Identify three factors that impact overall health and well-being.
- 2. Identify and discuss the five behaviors to help promote and maintain a healthy lifestyle.
- 3. Discuss goal setting and set one individual and one family goal for the upcoming week.

Group Session Four:

Overview: The focus of this session is promoting physical activity and helping participants to think positively about making changes in their lifestyle.

Objectives: By the end of session four, the participant should be able to:

- 1. Identify at least two strategies for getting more physical activity.
- 2. Describe why physical activity is beneficial for health.

Group Session Five:

Overview: This session will focus on self-esteem and positive body image.

- *Objectives:* By the end of session four, the participants will be able to:
 - 1. Recognize their own self-worth
 - 2. Appreciate the differences between different body types.

Group Session Six:

Overview: The focus of session six is to wrap up **HKHF** by summarizing the points made in the program and reinforcing these concepts. Participants also will be encouraged to problem-solve how they will continue to stick with it in the weeks and months ahead. Participants will also discuss other support programs available to help maintain healthy lifestyles.

Objectives: By the end of this session, the participant should be able to:

- 1. Identify strategies for successfully managing overall health in the weeks and months ahead.
- 2. Identify the current status of their Healthy Lifestyle behaviors.
- 3. Describe how *HKHF* was/was not helpful to them in making self-directed behavior changes and building skills for positive lifestyle changes.
- 4. Identify community resources for healthy lifestyle changes and support.



Initial IRB Application Approval

August 4, 2014

- Lorraine Weatherspoon To: 334 Trout FSHN Bldg MSU
- IRB# 14-469 Category: EXPEDITED 6, 7 Re: Approval Date: June 9, 2014 Expiration Date: June 8, 2015

Title: Healthy Kids, Healthy Families (CGA136800)

The Institutional Review Board has completed their review of your project. I am pleased to advise you that your project has been approved.

This IRB approval letter is being re-issued from the previously released approval letter dated 06/09/2014 due to a grammatical error.

This approval includes all tasks under Phase I of the IRB application.

The committee has found that your research project is appropriate in design, protects the rights and welfare of human subjects, and meets the requirements of MSU's Federal Wide Assurance and the Federal Guidelines (45 CFR 46 and 21 CFR Part 50). The protection of human subjects in research is a partnership between the IRB and the investigators. We look forward to working with you as we both fulfill our responsibilities.

Renewals: IRB approval is valid until the expiration date listed above. If you are continuing your project, you must submit an Application for Renewal application at least one month before expiration. If the project is completed, please submit an Application for Permanent Closure.

Revisions: The IRB must review any changes in the project, prior to initiation of the change. Please submit an Application for Revision to have your changes reviewed. If changes are made at the time of renewal, please include an Application for Revision with the renewal application.



Office of Regulatory Affairs Human Research **Protection Programs**

Biomedical & Health Institutional Review Board (BIRB)

Community Research Institutional Review Board (CRIRB)

Social Science Behavioral/Education Institutional Review Board (SIRB)

Olds Hall

Olds Hall 408 West Circle Drive, #207 East Lansing, MI 48824 (517) 355-2180 Fax: (517) 432-4503 Email: irb@msu.edu www.humanresearch.msu.edu

MSU is an affirmative-action, equal-opportunity employer.

Problems: If issues should arise during the conduct of the research, such as unanticipated problems, adverse events, or any problem that may increase the risk to the human subjects, notify the IRB office promptly. Forms are available to report these issues.

Please use the IRB number listed above on any forms submitted which relate to this project, or on any correspondence with the IRB office.

Good luck in your research. If we can be of further assistance, please contact us at 517-355-2180 or via email at IRB@msu.edu. Thank you for your cooperation.

Sincerely,

ashirKuman.

Ashir Kumar, M.D. BIRB Chair

c: Amy Custack, TIARRA WRIGHT, Betsy Schumacher, Erin Powell

APPENDIX D: Michigan State University Institutional Review Board Approved Informed Consent for use at Healthy Futures Clinic (Saginaw)

Research Participant Information and Consent Form

Researchers are required to provide a consent form to inform you about the research study, to convey that participation is voluntary, to explain risks and benefits of participation, and to empower you to make an informed decision. You should feel free to ask the researchers any questions you may have.

<u>Study Title</u>: Healthy Kids, Healthy Families

Researcher and Title: Lorraine Weatherspoon, PhD, RD, Associate Professor

Department and Institution: Dept. of Food Science and Human Nutrition, Michigan State University

Address and Contact Information: Lorraine Weatherspoon, PhD, RD Michigan State University Trout Building East Lansing, MI 48824-1224 (517)355-8474 (ext. 136) Weathe43@msu.edu

<u>Sponso</u>r: Michigan State University

1. PURPOSE OF RESEARCH

- Healthy Kids, Healthy Families is a seven-week program for you and your child to improve eating habits and increase physical activity. The program is part of a research study.
- You and your child have been selected because you have expressed interest in learning more about nutrition
 and physical activity.
- You and your child will be asked to participate in this study one day a week for seven weeks. Each class lasts about an hour and a half (90 minutes).

2. WHAT YOU WILL DO

- You and your child will help researchers determine whether *Healthy Kids, Healthy Families* can help improve eating behaviors, physical activity, and quality of life.
- Your child will be given a random number. Every form you and your child complete will have only that number on it. The forms that you complete will be sent to researchers at Michigan State University.
- Healthy Kids, Healthy Families sessions will be at the Genesee or Saginaw County Extension offices.
- Healthy Kids, Healthy Families will begin with a visit from an employee of MSU-Extension. After the first visit, you and your child will join other families for six group sessions.
- At the end of the program, researchers will ask you and your child to provide feedback about your experiences. This will help researchers to modify and improve the program. During this final session, researchers would like to hold a meeting with you, your child, and other participants and audiotape the discussion. This discussion will be about the program, your experiences, and what you liked/did not like about the program.

This consent form was approved by a Michigan State University Institutional Review Board. Approved 09/26/2014 - valid through - 06/08/2015. This version supersedes all previous versions. IRB #14-469 Parents and caregivers will be asked to:

- > Allow researchers access to information from routine physical exam records of your child.
- > Participate in seven educational sessions with your child.
- > Complete a weekly goal sheet with your child.
- > Participate in a focus group to provide feedback on the program.

Children will be asked to:

- > Allow researchers access to information from your routine physical exams.
- Participate in seven educational sessions.
- Complete surveys at the beginning of the program; at the end of the program; and 6-months after finishing the program.
- > Complete a weekly goal sheet.
- > Participate in a focus group to provide feedback on the program.

3. POTENTIAL BENEFITS

• Because this is a research study, researchers do not know whether there will be a benefit. Researchers hope you and your child will learn how to make better food choices and increase physical activity.

4. POTENTIAL RISKS

- You and your child will be asked to participate in group sessions that include some light physical activity, such as walking or using stretch bands. If you or your child experience discomfort, you and/or your child do not have to complete the activity.
- You and your child may decline participation in physical activity at any point during the sessions.

5. PRIVACY AND CONFIDENTIALITY

- The data for this project will be kept confidential.
- All data will be sent to Dr. Weatherspoon and her study staff at Michigan State University. Data will have only
 randomized numbers and will not include any identifying names. Signed consent forms will be sent to the
 study investigator is separate sealed envelopes.
- Data will be stored in Dr. Weatherspoon's laboratory in locked file cabinets. Consent forms will be kept in separate locked files from all data. All data used in this study will be identified only by an ID number.
- Access to this data will be limited to Dr. Weatherspoon and her research staff, and Human Research Protection Program (HRPP) of Michigan State University. Research records will be kept for at least three (3) years after the close of the study.
- The results of this study may be published or presented at professional meetings, but the identities of all research subjects will remain anonymous.

6. YOUR RIGHTS TO PARTICIPATE, SAY NO, OR WITHDRAW

- Participation is voluntary. Refusal to participate will involve no penalty or loss of benefits to which you are
 otherwise entitled. You and your child may discontinue participation at any time without penalty or loss of
 benefits to which you are otherwise entitled.
- You and your child may choose not to answer specific questions or to stop participating at any time.

7. COSTS AND COMPENSATION FOR BEING IN THE STUDY

• There is no cost for participation in this study.

8. THE RIGHT TO GET HELP IF INJURED

 If you are injured as a result of your participation in this research project, Michigan State University will assist you in obtaining emergency care, if necessary, for your research related injuries. If you have insurance for medical care, your insurance carrier will be billed in the ordinary manner. As with any medical insurance, any costs that are not covered or in excess of what are paid by your insurance, including deductibles, will be your responsibility. The University's policy is not to provide financial compensation for lost wages, disability, pain or discomfort, unless required by law to do so. This does not mean that you are giving up any legal rights you may have. You may contact *Dr. Weatherspoon (517- 355-8474 ext.136)* with any questions or to report an injury.

9. OBLIGATION TO REPORT

 Due to a recent addition in University policy, researchers at MSU are obligated to report any suspected child abuse or neglect to the MSU Police Department. If, in my position at MSU, I suspect a child may be abused or neglected, I must contact the MSU Police Department (MSUPD) immediately. MSUPD will determine whether or not I am obligated to report the suspected incident to Child Protective Services.

10. CONTACT INFORMATION

If you have concerns or questions about this study, such as scientific issues, how to do any part of it, or to report an injury, please contact the researcher at:

Lorraine Weatherspoon, PhD, RD Trout Bldg. 469 Wilson Rd., Room 140 East Lansing, MI 48824 (517) 355-8474 (ext.136) weathe43@msu.edu

If you have questions or concerns about your role and rights as a research participant, would like to obtain information or offer input, or would like to register a complaint about this study, you may contact, anonymously if you wish, the Michigan State University's Human Research Protection Program at 517-355-2180, Fax 517-432-4503, or e-mail <u>irb@msu.edu</u> or regular mail at Olds Hall, 408 West Circle Drive #207, MSU, East Lansing, MI 48824.

11. DOCUMENTATION OF INFORMED CONSENT

Your signature below means that you voluntarily agree to participate in this research study.

Parent/Caregiver Signature

Date

I voluntarily agree to allow my child to participate in this research study.

Child's Name

Parent/Caregiver Signature

Date

This consent form was approved by a Michigan State University Institutional Review Board. Approved 09/26/2014 - valid through - 06/08/2015. This version supersedes all previous versions. IRB #14-469

I agree to allow audio taping of the focus group.	No	
Parent/Caregiver Signature	-	Date

Date

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Parent/Caregiver Signature

You will be given a copy of this form to keep.

APPENDIX E: Approval from Hurley Scientific Review Committee

Hurley Scientific Review Committee (SRC)

Date:	12/01/2014
To:	Amy Saxe Custack & Lorraine Weatherspoon
From:	Hurley Scientific Review Committee
Study Title:	A Paraprofessional-Led Intervention for Families with Overweight and Obese Children: Assessment of Behavioral, Biochemical, Clinical, and Psychosocial Outcomes
SRC Suggested Submission Type:	Full Board Review

Dear Principal Investigator:

Thank you for submitting your protocol to the Hurley Scientific Review Committee. The committee has completed its final reviewed your protocol. There are still changes that need to be made before submitting to the Hurley Institutional Review Board (IRB) but you are not required to resubmit to the SRC.

Sincerely,

Hurley Scientific Review Committee

Hurley Scientific Review Committee

APPENDIX F: Hurley Medical Center Institutional Review Board Approval

HERLEY MEDICAL CENTER	
One Hurley Plaza Flint, Michigan 48503	
DATE:	April 30, 2015
TO:	Lorraine Weatherspoon, PhD, RD
FROM:	Hurley Medical Center Institutional Review Board
STUDY TITLE:	[708700-2] Healthy Kids, Healthy Families
SUBMISSION TYPE:	Revision
ACTION:	MODIFICATIONS REQUIRED
APPROVAL DATE:	March 31, 2015
EXPIRATION DATE:	March 30, 2016
REVIEW TYPE:	Full Committee Review

Dear Dr. Weatherspoon:

On March 31, 2015, the Institutional Review Board at Hurley Medical Center convened to consider the following documents for the above-referenced research project:

Consent Form - Revised Consent Form 03.20.2015 (UPDATED: 03/20/2015)

The HMCIRB voted its unanimous approval of this study, pending the following changes:

- · In the consent document on page 2, add an explanation for randomization assignment.
- Under section 11, add the statement: "I have had the opportunity to ask questions and have those questions answered to my satisfaction."

Your revised informed consent/authorization should be uploaded in the IRBNet system as a subsequent package (see instructions in the Forms and Templates library for submitting subsequent packages). Once it is received and deemed satisfactory, based on our recommendations, it will be stamped "Approved by the Hurley Institutional Review Board" and made available to you in IRBNet for issuance to potential research participants.

This IRB's approval will expire on March 30, 2016. Should you require an extension beyond the approval period, you must submit a Study Status Report and Request for Renewal of Research to the IRB no less than 45 days before the expiration date. If approval expires, research activities must stop, and no new subjects may be enrolled in the study. Study Status Report forms can be obtained in IRBNet via the Forms and Templates library.

Any variance(s) in the procedures described in your originally IRB-approved protocol or consent document, no matter how minor, require IRB approval. Federal Regulations require the Hurley IRB to approve all proposed changes in research activity prior to its implementation. You may contact the IRB Office at (810) 262-9974, if you require additional information.

Additionally, intentional or accidental protocol deviations should be reported, in writing, to this IRB immediately or upon its discovery. Your report should include a description of the deviation, the justification

- 1 -

Generated on IRBNet

or reason(s) for the alteration, whether the deviation caused harm to subject(s), how the deviation was/will be corrected or addressed, and how it will be avoided in the future.

Thank you for submitting your protocol to the HMCIRB. The Board wishes you well in your investigative research endeavors.

Sincerely,

Scott Kaatz, DO and Amy Benko, PharmD Co-Chairs, Institutional Review Board

This letter has been electronically signed in accordance with all applicable regulations, and a copy is retained within Hurley Medical Center's records.

APPENDIX G: Hurley and Michigan State University Approved Informed Consent for use at Hurley Medical Center (Flint)

Page 1 of 5

Research Participant Information and Consent Form

Researchers are required to provide a consent form to inform you about the research study, to convey that participation is voluntary, to explain risks and benefits of participation, and to empower you to make an informed decision. You should feel free to ask the researchers any questions you may have.

Study Title: Healthy Kids, Healthy Families

<u>Researchers and Title</u>: Lorraine Weatherspoon, PhD, RD, Professor, Michigan State University Amy Saxe Custack, MPH, RD, Doctoral Candidate in Human Nutrition, Michigan State University Mona Hanna-Attisha, MD, Director of Pediatric Residency Program, Hurley Medical Center

Department and Institution: Dept. of Food Science and Human Nutrition, Michigan State University Hurley Medical Center

Address and Contact Information: Lorraine Weatherspoon, PhD, RD Michigan State University Trout Building East Lansing, MI 48824-1224 (517)355-8474 (ext. 136) Weathe43@msu.edu

Mona Hanna-Attisha, MD Hurley Medical Center 806 Tuuri Pl Flint, MI 48503 (810) 262-7042 MHanna1@hurleymc.com

Sponsors: Michigan State University Hurley Medical Center

1. PURPOSE OF RESEARCH

- Healthy Kids, Healthy Families is a seven-week program for you and your child to improve eating habits and increase physical activity. The program is part of a research study.
- You and your child have been selected because your doctor has identified your child as either overweight or obese.
- You and your child have also been selected because you have expressed interest in learning more about nutrition and physical activity.
- You and your child will be asked to participate in this study one day a week for seven weeks. Each class lasts about an hour and a half (90 minutes).
- Researchers will select approximately 84 children to participate in the program. Some families will start the
 program immediately, while others may wait six months before starting the program.

This consent form was approved by a Michigan State University Institutional Review Board. Approved 09/26/2014 - valid through - 06/08/2015. This version supersedes all previous APPROVED BY THE HURLEY MEDICAL CENTER INSTITUTIONAL REVIEW BOARD OK ______S///2015 Page 2 of 5

You and your child will be randomly chosen to join either the "intervention" or "control" group. Randomization
is just like flipping a coin to determine the group assignment. The "intervention" group will begin the program
immediately and the "control" group will begin the program in approximately six months. If chosen to be in the
"control" group, children will be asked to complete surveys a total of six separate times.

2. WHAT YOU WILL DO

- You and your child will help researchers determine whether *Healthy Kids, Healthy Families* can help improve eating behaviors, physical activity, and quality of life.
- Your child will be given a random number. Every form you and your child complete will have only that number on it. The forms that you complete will be sent to researchers at Michigan State University.
- Healthy Kids, Healthy Families sessions will be at the Genesee or Saginaw County Extension offices.
- Should you have difficulty with transportation, MSU-Extension may be able to assist with bus passes.
- Healthy Kids, Healthy Families will begin with a visit from an employee of MSU-Extension. After the first
 visit, you and your child will join other families for six group sessions.
- At the end of the program, researchers will ask you and your child to provide feedback about your experiences. This will help researchers to modify and improve the program. During this final session, researchers would like to hold a meeting with you, your child, and other participants and audiotape the discussion. This discussion will be about the program, your experiences, and what you liked/did not like about the program.

Parents and caregivers will be asked to:

- > Allow researchers access to information from routine physical exam records of your child.
- Participate in seven educational sessions with your child.
- Complete a weekly goal sheet with your child.
- Participate in a focus group to provide feedback on the program.

Children will be asked to:

- > Allow researchers access to information from your routine physical exams.
- > Participate in seven educational sessions.
- Complete surveys at the beginning of the program; 3-months after beginning the program; and 6-months after beginning the program. At each of these three points, your child will be asked to complete two 24-hour recalls (to examine eating behaviors); one Physical Activity Questionnaire (to examine exercise behaviors); and one Pediatric Quality of Life Inventory (to measure health-related quality of life).
- Complete a weekly goal sheet.
- > Participate in a focus group to provide feedback on the program.

3. POTENTIAL BENEFITS

Because this is a research study, researchers do not know whether there will be a benefit. Researchers hope
you and your child will learn how to make better food choices and increase physical activity.

4. POTENTIAL RISKS

- You and your child will be asked to participate in group sessions that include some light physical activity, such as walking or using stretch bands. If you or your child experience discomfort, you and/or your child do not have to complete the activity.
- You and your child may decline participation in physical activity at any point during the sessions.

5. PRIVACY AND CONFIDENTIALITY

The data for this project will be kept confidential.

This consent form was approved by a Michigan State University Institutional Review Board. Approved 09/26/2014 - valid through - 06/08/2015. This version supersedes all previous versions. IRB #14-469

APPROVED BY THE HURLEY MEDICAL CENTER INSTITUTIONAL REVIEW BOARD OK ______S/1/2015
Page 3 of 5

- All data will be sent to Dr. Weatherspoon and her study staff at Michigan State University. Data will have only
 randomized numbers and will not include any identifying names. Signed consent forms will be sent to the
 study investigator is separate sealed envelopes.
- Data will be stored in Dr. Weatherspoon's laboratory in locked file cabinets. Consent forms will be kept in separate locked files from all data. All data used in this study will be identified only by an ID number.
- Access to this data will be limited to Dr. Weatherspoon and her research staff, and Human Research Protection Program (HRPP) of Michigan State University. Research records will be kept for at least three (3) years after the close of the study.
- The results of this study may be published or presented at professional meetings, but the identities of all
 research subjects will remain anonymous.

6. YOUR RIGHTS TO PARTICIPATE, SAY NO, OR WITHDRAW

- Participation is voluntary. Refusal to participate will involve no penalty or loss of benefits to which you are
 otherwise entitled. You and your child may discontinue participation at any time without penalty or loss of
 benefits to which you are otherwise entitled.
- You and your child may choose not to answer specific questions or to stop participating at any time.

7. COSTS AND COMPENSATION FOR BEING IN THE STUDY

- There is no cost for participation in this study.
- Participants will be given the following items: Home Visit Potholders with Completion of Baseline Data; Session 1 – Magnetic Tracking Sheet to Track Goal Progress; Session 2 – MyPlate Magnet, MyPlate Plastic Plate, MyPlate Bookmark; Session 3 – Measuring Cups; Session 4 - Pedometer; Session 5 – Picture Frame; Session 6 – Graduation Certificate and Recipe Book.
- Small items (potholders at baseline, MSU book bags at 3-month follow-up, and water bottles at 6-month follow-up) will be given to children and families as they complete the surveys.

8. THE RIGHT TO GET HELP IF INJURED

If you are injured as a result of your participation in this research project, Michigan State University will assist
you in obtaining emergency care, if necessary, for your research related injuries. If you have insurance for
medical care, your insurance carrier will be billed in the ordinary manner. As with any medical insurance, any
costs that are not covered or in excess of what are paid by your insurance, including deductibles, will be your
responsibility. The University's policy is not to provide financial compensation for lost wages, disability, pain
or discomfort, unless required by law to do so. This does not mean that you are giving up any legal rights you
may have. You may contact *Dr. Weatherspoon (517- 355-8474 ext.136)* with any questions or to report an
injury.

9. OBLIGATION TO REPORT

 Due to a recent addition in University policy, researchers at MSU are obligated to report any suspected child abuse or neglect to the MSU Police Department. If, in my position at MSU, I suspect a child may be abused or neglected, I must contact the MSU Police Department (MSUPD) immediately. MSUPD will determine whether or not I am obligated to report the suspected incident to Child Protective Services.

10. CONTACT INFORMATION

If you have concerns or questions about this study, such as scientific issues, how to do any part of it, or to report an injury, please contact the researcher at:

Lorraine Weatherspoon, PhD, RD Trout Bldg. 469 Wilson Rd., Room 140 East Lansing, MI 48824

> This consent form was approved by a Michigan State University Institutional Review Board. Approved 09/26/2014 - valid through - 06/08/2015. This version supersedes all previous versions APPROVED BY THE HURLEY MEDICAL CENTER INSTITUTIONAL REVIEW BOARD OK 5/1/2015

Page 4 of 5

(517) 355-8474 (ext.136) weathe43@msu.edu

Mona Hanna-Attisha, MD 806 Tuuri PI Flint, MI 48503 (810) 262-7042 MHanna1@hurleymc.com

If you have questions or concerns about your role and rights as a research participant, would like to obtain information or offer input, or would like to register a complaint about this study, you may contact, anonymously if you wish, the Michigan State University's Human Research Protection Program at 517-355-2180, Fax 517-432-4503, or e-mail <u>irb@msu.edu</u> or regular mail at Olds Hall, 408 West Circle Drive #207, MSU, East Lansing, MI 48824. You may also contact Hurley Medical Center's Institutional Review Board at 810-262-9974, Fax 810-262-9587, or e-mail <u>cadams2@hurleymc.com</u> or regular mail at 1 Hurley Plaza, Flint, MI 48503.

11. DOCUMENTATION OF INFORMED CONSENT

I have had the opportunity to ask questions and have those questions answered to my satisfaction. Your signature below means that you voluntarily agree to participate in this research study.

Date

Date

Parent/Caregiver Signature

I voluntarily agree to allow my child to participate in this research study.

Child's Name

Parent/Caregiver Signature

I agree to allow audio taping of the focus group. Yes No If you do not agree to the audio taping of the focus group (during the final session of the program), you will be asked not to come to the final session. Researchers will be audio taping this session to understand participant views of the program and their overall experiences.

Parent/Caregiver Signature	Date
I agree to allow my child to be audio taped during the focus gro	oup. Yes No
Parent/Caregiver Signature	Date
This consent form was approved by a Michigan State U Approved 09/26/2014 - valid through - 06/08/2015. This version	Jniversity Institutional Review Board. I supersedes all previous versions. IRB #14-469 APPROVED BY THE HURLEY MEDICAL CENTER INSTITUTIONAL REVIEW COARD OK 5/1/2015

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You will be given a copy of this form to keep.

APPROVED BY THE HURLEY MEDICAL CENTER INSTITUTIONAL REVIEW BOARD OK 5/1/2015

This consent form was approved by a Michigan State University Institutional Review Board. Approved 09/26/2014 - valid through - 06/08/2015. This version supersedes all previous versions. IRB #14-469

APPENDIX H: Hurley and MSU IRB-Approved Statement of Assent (Hurley-Flint) Statement of Assent

Children ages 8 and older: You are invited to participate in the Healthy Kids, Healthy Families program. Researchers would like to determine whether this program helps kids eat healthier, exercise more, and improve their weight. You will be asked to come to 7 sessions with your parents or caregivers for about an hour and a half. You will be asked to complete surveys about your eating and exercise habits. You will also be asked to participate in cooking demonstrations, exercises, and games about health. If you would like to participate in this 7-week program by Hurley, Michigan State University and Michigan State University Extension, please sign your names below.

Name:	Date:
Name:	Date:
Name:	Date:

Children ages 6 to 7: You are invited to participate in the Healthy Kids, Healthy Families program. Researchers would like to determine whether this program helps kids eat healthier, exercise more, and improve their weight. You will be asked to come to 7 sessions with your parents or caregivers for about an hour and a half. You will be asked to complete surveys about your eating and exercise habits. You will also be asked to participate in cooking demonstrations, exercises, and games about health. If you would like to participate in this 7-week program by Hurley, Michigan State University and Michigan State University Extension, please tell us you would like to do so.

APPENDIX I: Hurley and MSU-IRB Approved Authorization for Release of Protected Health Information

PATIENT AUTHORIZATION FOR DISCLOSURE OF HEALTH INFORMATION FOR RESEARCH

Patient Name:

Address:

Date of Birth: ____

I AUTHORIZE THE DISCLOSURE OF MY HEALTH INFORMATION

FROM: Hurley Medical Center

TO: Michigan State University

DESCRIPTION OF INFORMATION TO BE DISCLOSED:

Only disclose the following information: Hemoglobin A1c, Blood Pressure, Height, Weight, Total Cholesterol, HDL, LDL, Triglycerides, Age, Gender, Ethnicity

RESEARCH STUDY FOR THIS DISCLOSURE:

Title of Study: Healthy Kids, Healthy Families

Name of Research Leader: Lorraine Weatherspoon, PhD, RD

Affiliation of Researcher: Professor, Michigan State University

IRB#: 14-469

Name of IRB: Michigan State University Institutional Review Board

EXPIRATION: 06/08/2015

REVOCATION, REFUSAL, REDISCLOSURE:

You may revoke this Authorization in writing at any time by contacting _

(e.g., the healthcare system or provider or hospital named above), but it will not affect any information already released to the researcher(s).

You may refuse to sign this authorization and your refusal will not affect your ability to obtain treatment, however, it may affect your ability to participate in this research study.

Your information that is disclosed to the researcher(s) may no longer be protected by Federal privacy regulations if the researcher(s) is not a health care provider covered by the regulations, however the researcher(s) agrees to protect your information as required by law.

Signature of Patient or Personal Representative

Date

Name of Personal Representative and Relationship to Patient (or description of authority to act on behalf of the patient)

PROVIDE COPY TO PATIENT

APPENDIX J: Michigan State University IRB-Approved Statement of Assent for use at Healthy Futures Clinic (Saginaw)

Statement of Assent

Children ages 8 and older: You are invited to participate in the Healthy Kids, Healthy Families program. If you would like to participate in this 7-week research program nutrition, physical activity, and health by Michigan State University and Michigan State University Extension, please sign your names below.

Name:	Date:
Name:	Date:
Name:	Date:

Children ages 6 to 7: You are invited to participate in the Healthy Kids, Healthy Families program. If you would like to participate in this 7-week research program about nutrition, physical activity, and health by Michigan State University and Michigan State University Extension, please tell us you would like to do so.

This assent form was approved by a Michigan State University Institutional Review Board. Approved 06/09/2014 - valid through - 06/08/2015. This version supersedes all previous versions. IRB #14-469

APPENDIX K: Focus Group Guide

HEALTHY KIDS, HEALTHY FAMILIES FOCUS GROUP GUIDE

Program Evaluation

- 1.) PARENTS: What were your expectations when you signed up for the program?
- 2.) PARENTS: Did the program meet your expectations? IF yes, how? IF no, why not?
- 3.) PARENTS: What were your goals for the program? What did you want to accomplish? What did you want your child to accomplish?
- 4.) PARENTS: Did you enjoy the program? What did you like most? What did you like least?
- 5.) CHILDREN: What was your impression of the program when you signed up for it? What did you think you would do while you were here?
- 6.) CHILDREN: What were your goals for the program? What did you want to accomplish?
- 7.) CHILDREN: Did you enjoy the program? What did you like most? What did you like least?
- 8.) PARENTS AND CHILDREN: What did you learn while you were in the program?
- 9.) PARENTS AND CHILDREN: How did you feel about the length of the program (both individual sessions and total program)? Was the program too long or not long enough?
- 10.) PARENTS AND CHILDREN: If you could change something about the program, what would it be?
- 11.) PARENTS AND CHILDREN: How did you feel about your instructor?

12.) PARENTS AND CHILDREN: Is there anything else you would like to share about the program – your experiences and overall thoughts?

Relationship Between Social Cognitive Theory, Concepts, and Research Questions

Research Questions: How do children perceive their own ability to achieve a healthier lifestyle?

- 1.) CHILDREN: Since you finished the program, how do you now feel about your ability to exercise more and make healthier food choices? (SKILLS)
- 2.) CHILDREN: Since you finished the program, how do you now feel about your own ability to reach the goals you set for yourself? Are these goals reachable: Why? How? (SELF-EFFICACY)
- 3.) CHILDREN: What do you believe will be the result if you follow what you learned in the program? What will happen if you eat better and exercise? (OUTCOME EXPECTANCIES)

<u>Research Questions: To what extent did HKHF influence parent/careqiver behavior related to</u> <u>support of their children and modeling of appropriate health-related behaviors?</u>

- 4.) PARENTS: What changes did you make to help support your children during *HKHF*? (SUPPORT FROM OTHERS)
- 5.) CHILDREN: What did your parents do to support you during the *HKHF* program that they did not do before participating in the program? (SUPPORT FROM OTHERS)
- 6.) PARENTS: How would you describe the changes in your own eating and exercise habits as a result of participating in *HKHF*? (MODELING BEHAVIOR)
- 7.) CHILDREN: What differences did you notice in your parents' eating and exercise habits since you started *HKHF*? (MODELING BEHAVIOR)

APPENDIX L: Michigan State University Extension Data Adult Nutrition Education **Enrollment Form**

MICHIGAN STATE	Adult Nutrition Education Enrollment Form
Name:	
Address: C	ity: ZIP:
Phone: () E	mail:
Have you enrolled in this program before?]Yes □No on? □Yes □No
Age:	Monthly Household Income: \$
Highest grade completed:	Include the total monthly income for all persons in your household.
□ Male □ Female	Ages of Children in Household:
Pregnant Breastfeeding	household:
Race and Ethnicity: Please identify both.	-051015
Ethnicity, Salast and	161116
	271217
□ Non-Hispanic or Latino	3 8 13 18
□ I do not wish to provide this information.	4 9 14 19
Race: Select all that apply.	Number of other adults in household: Do not include yourself.
□ Asian	Public Assistance: Select all that apply.
Black or African American Netice Lloweiian or Other Desifie Islander	SNAP/Bridge Card (Food Assistance Program)
	Child Nutrition (School lunch program)
□ Other:	
\Box I do not wish to provide this information.	□ Head Start
Residence: <i>Select one.</i>	TANF/FIP (Temporary Food Assistance to Needy Families/Family Independence Program)
□ Town under 10,000 and rural, non-farm	□ TEFAP (The Emergency Food Assistance Program)
 Town and city 10,000 – 50,000 Suburb and city over 50,000 Central city over 50,000 	WIC/CSFP (Women, Infant and Children/Commodity Supplemental Food Program) Other:

Items below to be completed by nutrition educator only:

Educator:	County:		
Subgroup:	Group Name:		
Entry Date:	Program:	□ SNAP-ED	

FY 2014

APPENDIX M: Healthy Kids, Healthy Families Data Extraction Form (Data extracted from MSUE Adult Nutrition Education Enrollment Form)

Healthy Kids, Healthy Families Data Extraction Form (MSUE Enrollment)

ID Number:_____

Parental Age: _____

Highest Grade Completed: _____

Gender: _____

Race and Ethnicity: _____

Residence: _____

Monthly Household Income: _____

Ages of Children in Household: _____

Public Assistance: _____

APPENDIX N: Pediatric Quality of Life Inventory

ID#	
Date:	

TM

PedsQL Pediatric Quality of Life Inventory

Version 4.0

CHILD REPORT (ages 8-12)

DIRECTIONS

On the following page is a list of things that might be a problem for you. Please tell us **how much of a problem** each one has been for you during the **past ONE month** by circling:

- 0 if it is never a problem
- 1 if it is almost never a problem
- 2 if it is sometimes a problem
- 3 if it is often a problem

4 if it is almost always a problem

There are no right or wrong answers. If you do not understand a question, please ask for help.

PedsQL 4.0 - (8-12) 01/00

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PedsQL 2

ABOUT MY HEALTH AND ACTIVITIES (problems with)	Never	Almost Never	Some- times	Often	Almost
 It is hard for me to walk more than one block 	0	1	2	3	4
2. It is hard for me to run	0	1	2	3	4
It is hard for me to do sports activity or exercise	0	1	2	3	4
It is hard for me to lift something heavy	0	1	2	3	4
5. It is hard for me to take a bath or shower by myself	0	1	2	3	4
It is hard for me to do chores around the house	0	1	2	3	4
7. I hurt or ache	0	1	2	3	4
8. I have low energy	0	1	2	3	4

In the past ONE month, how much of a problem has this been for you ...

ABOUT MY FEELINGS (problems with)	Never	Almost Never	Some- times	Often	Almost
 I feel afraid or scared 	0	1	2	3	4
2. I feel sad or blue	0	1	2	3	4
3. I feel angry	0	1	2	3	4
4. I have trouble sleeping	0	1	2	3	4
5. I worry about what will happen to me	0	1	2	3	4

How I GET ALONG WITH OTHERS (problems with)		Almost Never	Some- times	Often	Almost
 I have trouble getting along with other kids 	0	1	2	3	4
2. Other kids do not want to be my friend	0	1	2	3	4
3. Other kids tease me	0	1	2	3	4
4. I cannot do things that other kids my age can do	0	1	2	3	4
5. It is hard to keep up when I play with other kids	0	1	2	3	4

ABOUT SCHOOL (problems with)	Never	Almost Never	Some- times	Often	Almost
 It is hard to pay attention in class 	0	1	2	3	4
2. I forget things	0	1	2	3	4
3. I have trouble keeping up with my schoolwork	0	1	2	3	4
I miss school because of not feeling well	0	1	2	3	4
5. I miss school to go to the doctor or hospital	0	1	2	3	4

APPENDIX O: 24-Hour Recall Form

Time of Day	Food Items	Amount/Portion	What were you doing?	Where were you eating?

APPENDIX P: Physical Activity Questionnaire

12 Physical Activity Questionnaire (Elementary School) ID Age: We are trying to find out about your level of physical activity from the last 7 days (in the last week). This includes sports or dance that make you sweat or make your legs feel tired, or games that make you breathe hard, like tag, skipping, running, climbing, and others. Remember: There are no right and wrong answers — this is not a test. 1. 2. Please answer all the questions as honestly and accurately as you can - this is very important. 1. Physical activity in your spare time: Have you done any of the following activities in the past 7 days (last week)? If yes, how many times? (Mark only one circle per row.) 7 times No 1-2 3-4 5-6 or more SkippingO 0 0 0 0 -0 Rowing/canoeingO 00000 In-line skating O Walking for exercise O Bicycling O Jogging or runningO 0 AerobicsO Swimming O DanceO FootballO Badminton O SkateboardingO SoccerO Street hockey O Volleyball O Floor hockeyO Basketball O Cross-country skiing 0 0 Ice hockey/ringette O 0 0 Other: 0 0 00 00 0 0 õ _.....O 8

In the last 7 days, during your physical education (PE) classes, how often were you very active (playing hard, running, jumping, throwing)? (Check one only.)

I don't do PE	O
Hardly ever	O
Sometimes	o
Quite often	O
Always	o

3. In the last 7 days, what did you do most of the time at recess? (Check one only.)

Sat down (talking, reading, doing schoolwork)	O
Stood around or walked around	0
Ran or played a little bit	
Ran around and played quite a bit	0
Ran and played hard most of the time	

 In the last 7 days, what did you normally do at hunch (besides eating lunch)? (Check one only.)

Sat down (talking, reading, doing schoolwork)	<u></u> O
Stood around or walked around	O
Ran or played a little bit	0
Ran around and played quite a bit	.0
Ran and played hard most of the time	_0

In the last 7 days, on how many days right after school, did you do sports, dance, or play games in which you were very active? (Check one only.)

None	O
l time last week	o
2 or 3 times last week	o
4 times last week	
5 times last week	o

6. In the last 7 days, on how many ewnings did you do sports, dance, or play games in which you were very active? (Check one only.)

None	\circ
l time last week	0
2 or 3 times last week	0
4 or 5 last week	0
δ or 7 times last week	0

On the last weekend, how many times did you do sports, dance, or play games in which you were very active? (Check one only.)

None	0
l time	0
2 — 3 times	
4 — 5 times	
6 or more times	

8. Which one of the following describes you best for the last 7 days? Read all five statements before deciding on the one answer that describes you.

A. All or most of my free time was spent doing things that involve little physical effort	
B. I sometimes (1 — 2 times last week) did physical things in my free time (e.g. played sports, went running, swimming, bike riding, did aerobics)	
C. I often (3 — 4 times last week) did physical things in my free timeO	
D. I quite often (5 — 6 times last week) did physical things in my free time O	
E. I very often (7 or more times last week) did physical things in my free time O	

9. Mark how often you did physical activity (like playing sports, games, doing dance, or any other physical activity) for each day last week.

		Little			Very
	None	bit	Medium	Often	often
Monday		0	0	0	0
Tuesday	O	0	0	0	0
Wednesday	o	0	0	0	0
Thursday	o	0	0	0	0
Friday	O	0	0	0	0
Saturday	o	0	0	0	0
Sunday	O	0	0	0	0

10. Were you sick last week, or did anything prevent you from doing your normal physical activities? (Check one.)

Yes)
NoC)

If Yes, what prevented you? _____

APPENDIX Q: Chart Review Data Collection Form

CHART REVIEW DATA COLLECTION FORM

Patient ID#_____

Date ______
Insurance Carrier _____

-

APPENDIX R: My Weekly Goal Sheet



REMEMBER TO KEEP IT SHORT, SIMPLE, AND MEASURABLE My goal for next week is to:

This is what I can do to accomplish my goal:

Put a sticker on each day that you were able to meet your goal!

Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday

ID Number: _____

APPENDIX S: Our Family Goal Sheet



REMEMBER TO KEEP IT SHORT, SIMPLE, AND MEASURABLE Our family goal for next week is to:

We can accomplish this TOGETHER by:

Put a sticker on each day that you were able to meet your family goal!

Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday

ID Number: _____

APPENDIX T: My Goal Progress Sheet



My Goal Progress

<u>I did my goal:</u> All of the time		ome of 1	the time		□ None of t	he tim
Did anything get in your w What were the problems?	ay?		Yes		No	
Did anything help you to re	each	your go	al? 🗆 .	Yes	□ No	

ID Number _____

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