

EVALUATION OF THE SHAPEDOWN WEIGHT LOSS PROGRAM CONDUCTED
THROUGH A HOSPITAL IN NORTH CENTRAL INDIANA:
A FAMILY APPROACH

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ABSTRACT

TITLE: Evaluation of the SHAPEDOWN Weight Loss Program Conducted Through a Hospital in North Central Indiana: A Family Approach

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The purpose of this study was to determine if participation in the ten-week SHAPEDOWN program was associated with a reduction in body mass index and improved measures of physical fitness among obese children and their parent-participants and to determine if a parent's success in the program was correlated with his or her child's success. Subjects included 47 obese children aged 8-18 years and their parent-participants who completed the program during 2009-2011. Results obtained during the first session (e.g., height, weight, BMI, and endurance, stretch, and flexibility tests) were compared to post-test results in a paired analysis. Results indicated participation was associated with a decrease in BMI ($p < 0.01$) and heart rate ($p < 0.01$) and an increase in flexibility ($p < 0.01$) and the number of sit ups completed in one minute ($p < 0.01$) among the children and an increased number of sit ups ($p < 0.01$) and flexibility ($p < 0.01$) among the parents. No reduction in body weight was observed among the children ($p = 0.33$) or their parent-participants ($p = 0.16$) over the ten weeks. A positive correlation was observed between the parent-child for both weight loss ($p < 0.01$) and flexibility ($p < 0.01$). These results indicate SHAPEDOWN positively impacted indices of health and that parental

participation positively impacted a child's weight loss and flexibility. Parents should be encouraged to engage in healthy behaviors with their overweight child.

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CHAPTER 1

INTRODUCTION

Childhood obesity in children and adolescents between the ages of 2-19 years has more than tripled in the past 30 years, with the rate increasing from five percent in the 1960s to the current National Health and Nutrition Examination Survey (NHANES) estimate of 17 percent in 2007-2008 (Ogden & Carroll, 2010). Evidence indicates that the relationship between obesity and disease risk begins early in life as the visceral abdominal fat appears to set off a cascade effect exacerbating hyperlipidemia, hypertension, and insulin resistance, dramatically increasing the risk for cardiovascular and metabolic diseases (Shalitin et al., 2009). *Healthy People 2020* identified overweight and obesity as one of 12 leading health indicators and called for the prevention of obesity and a reduction in the proportion of children and adolescents who are overweight or obese (U.S. Department of Health and Human Services, 2011).

The rise in obesity, and the great health risk it poses for children and adolescents, begs for effective approaches to prevent and treat childhood obesity. Currently a variety of different methods are being used to help children become healthier and maintain a healthy weight, including the SHAPEDOWN program, Committed to Kids Pediatric Weight Management Program, SlimKids program, Trim Kids program, and Sparkteens

(Suskind et al, 2009; Bocco, 2010). Some programs take a multidisciplinary approach which address psychological disturbances and social distress along with weight control, while other programs use a family-centered approach which involves the whole family in the program rather than just the obese child (Kitzman-Ulrich, 2010).

SHAPEDOWN has been the leading family-centered weight management program for children and adolescents ages 6-18 years of age for over 30 years (SHAPEDOWN, 2012). A hospital in north central Indiana uses this program to help promote weight loss among outpatients. SHAPEDOWN is generally taught in a group setting to increase the program's efficiency and effectiveness. Both children and a parent or guardian participate in the 10-week program which involves nutrition education, physical activities, parenting skills, and group discussions. The 10-week program is conducted at this Indiana hospital twice a year with an average of 12 families per session. The sessions are headed by a registered dietitian who is also available to counsel program participants one-on-one. Although this program has been in place for eight years, no empirical evaluation has been conducted to determine the program's ability to improve children's lifestyle choices using this family-based approach.

Problem

National Health and Nutritional Evaluation Survey (NHANES) data from 2007-2008 estimated that 17 percent of children and adolescents between the ages of 2-19 years are obese (Ogden & Carroll, 2010). Evidence indicates that the relation between obesity and disease risk begins early in life, dramatically increasing the risk for cardiovascular and metabolic diseases (Shalitin et al., 2009). The rise in childhood

obesity demands a variety of effective approaches to prevent and treat childhood obesity. The SHAPEDOWN program has been a leading weight management programs for children and adolescents for over 30 years (SHAPEDOWN, 2012). Although it has been implemented at a hospital in north central Indiana for the past eight years, no true evaluation of the program has been conducted to determine its effectiveness in helping families achieve a healthier weight.

Purpose

The purpose of this study was to determine if completion of the SHAPEDOWN program, offered through a hospital in north central Indiana between 2009 and 2011, was associated with a reduction in body weight and improved measures of physical fitness among obese adolescents and their parent-participants. A secondary purpose of the study was to determine if a relationship existed between a parent's success and his or her child's success in reducing body weight and improving measures of physical fitness.

Research Questions

The following research questions were examined in this research study:

RQ#1: Compared to baseline, did obese children who attended all ten SHAPEDOWN sessions:

- a) Lose weight?
- b) Reduce their BMI?
- c) Improve their physical endurance (e.g., heart rate, flexibility, sit ups)?

RQ#2. Compared to baseline, did the parents of the children who attended all ten SHAPEDOWN sessions:

- a) Lose weight?
- b) Reduce their BMI?
- c) Improve their physical endurance (e.g., heart rate, flexibility, sit ups)?

RQ#3. Was there a relationship between a parent's success and his or her child's success in the SHAPEDOWN program (e.g., Family change) as indicated by their:

- a) Weight loss?
- b) Reduced BMI?
- c) Improved physical endurance(e.g., heart rate, flexibility, sit ups)?

Rationale

Results of this evaluation of the SHAPEDOWN program will be valuable to the health care providers at the Indiana hospital as they evaluate the use of SHAPEDOWN in their outpatient weight loss programs. This evaluation will also provide a better understanding of the parent's role in the child's weight loss treatment. The research questions asked will help to evaluate the relationship between parent and child within the weight loss program. If a positive relationship exists between a parent's success and his or her child's success, the information can be shared with future parent-participants to encourage and motivate them to actively participate with their child as they struggle with their weight.

Assumptions

The researcher made the following assumptions in the implementation of the study and in the interpretation of the data:

1. The instruments (e.g., weight, height, step-test heart recovery rate) used to collect the data were calibrated correctly.
2. The same instruments were used for pre and post testing.
3. The data was accurately recorded.

Definitions

For the purpose of this study, the following definitions will be used:

1. Obesity. BMI at or above the 95th percentile for children of the same age and sex (Barlow, 2007).
2. Overweight. BMI at or above the 85th percentile and lower than the 95th percentile for children of the same age and sex (Barlow, 2007).
3. Body Mass Index (BMI). Weight in kilograms divided by height in meters, squared. Although technically not a body composition assessment technique, it correlates well with estimates of body composition derived from skinfold measurements, and underwater weighing, and can easily be calculated from weight and height (Nelms, Sucher, & Long, 2007).

Summary

Childhood obesity causes severe health problems for many individuals.

SHAPEDOWN is a family-based weight loss program that has been implemented at a

hospital in north central Indiana to help fight childhood obesity. There has been no true evaluation of the program to determine its ability to improve children's lifestyle choices and the effects of using a family-based approach. An analysis of the data collected from 2009-2011 has been used to evaluate the program as well as evaluate the parent's effects on his or her child's success of the program.

CHAPTER 2

REVIEW OF LITERATURE

The purpose of this study was to determine if completion of the SHAPEDOWN program, offered through a hospital in north central Indiana between 2009 and 2011, was associated with a reduction in body weight and improved measures of physical fitness among obese adolescents and their parent-participants. A secondary purpose of the study was to determine if a relationship existed between a parent's success and his or her child's success in reducing their body weight and improving measures of their physical fitness. This chapter will present a review of the literature that describes general background information about childhood obesity; an evaluation of current weight loss programs that use nutrition, physical activity, and psychology to help address the childhood obesity epidemic; and an examination of the role of parents and family involvement in weight loss programs.

Childhood Overweight and Obesity

This section of the literature review defines childhood overweight and obesity and describes its prevalence in the United States. In addition, risk factors and co-morbidities related to childhood obesity will be discussed.

Definition

Body mass index (BMI), expressed as weight in kilograms divided by height in meters squared, is a measurement commonly used to classify overweight and obesity. Children with a BMI at or above the 85th percentile for their age and gender as indicated by the Centers for Disease Control (CDC) growth charts are categorized as overweight; children with a BMI at or above the 95th percentile for their age and gender are categorized as obese (Ogden and Carroll, 2010). Prior to 2009, the term “at risk for overweight” was used to describe children who are now referred to as “overweight” while the term “overweight” was used to describe children who are now referred to as “obese.” The change in terminology was made to reflect the terms used by organizations such as the Institute of Medicine and the American Academy of Pediatrics (Ogden & Carroll, 2010). The BMI cutoff point is not diagnostic as it does not take into account certain factors such as muscle mass, however, when assessing populations, an elevated BMI among children does indicate an increased risk for health problems.

Prevalence

The progress toward reducing the national prevalence of obesity is monitored using the data from the National Health and Nutrition Examination Survey (NHANES), a program of studies designed to assess the health and nutritional status of adults and children in the United States that combines interviews and physical examinations. NHANES data indicates childhood obesity and overweight has tripled in the past three decades reaching epidemic portions and is quickly becoming one of the most common chronic diseases among children (U.S. Department of Health and Human Services, 2011).

Changes in obesity prevalence from the 1960s show a rapid increase in the 1980s and 1990s, when the prevalence tripled, from nearly five percent to approximately 15 percent among children and teens. The rate has continued to increase, with results from the 2007-2008 NHANES indicating an estimated 17 percent of children and adolescents aged 2-19 years are obese (Ogden and Carroll, 2010). During the past ten years, the rapid increase in the rate of obesity has slowed and almost leveled off. However, among those classified as obese, a significant increase in BMI has been observed, with the heaviest getting even heavier. Older children and teens are more likely to be obese compared with preschoolers (Ogden and Carroll, 2010).

Risk Factors

A gain in body weight is a consequence of a positive energy balance over time (e.g., eating more calories than one expends). Over time, positive energy balance results in overweight and obesity. Multiple risk factors contribute to childhood obesity, including environmental, genetic, socioeconomic, and psychological risk factors. The relationship between these factors and overweight or obesity in children will be examined in this section of the literature review.

Environmental

Environmental factors associated with the increase in childhood obesity include global shifts in lifestyle and aspects measured on a smaller level, such as family and individual behavioral patterns (Hunter, Steele, & Steele, 2008), including increased

access to calorie dense foods, reduced levels of physical activity, increased sedentary activities and a home environment which promotes these factors (Sobko et al., 2011).

Urbanization-related intake behaviors have also been shown to promote obesity, including frequent consumption of meals at fast-food outlets, consumption of oversized portions at home and at restaurants, consumption of high calorie foods, such as high-fat, low-fiber foods, and intake of sweetened beverages (Raj & Kumar, 2010). Portion sizes have increased over the last three decades just as obesity has increased. The convenience of fast food means children are eating more processed foods and not getting a variety of fruits and vegetables from these meals. These behaviors are nurtured in an environment in which high calorie food is plentiful, affordable, available, and easy to consume with minimal preparation (Raj & Kumar, 2010).

Low levels of physical activity are promoted by an automated and automobile-oriented environment that encourages a sedentary lifestyle (Epstein & Saelens, 2000). Many youth do not engage in the recommended amounts of physical activity and engage in a high rate of sedentary behaviors (Kitzman-Ulrich et al., 2010). Sedentary activities such as television viewing, video games and computer programs not only promote physical inactivity but also increases exposure to high fat foods marketed to children, therefore promoting obesity (Eliakim, et al., 2002; Gutin et al., 2002). The lack of physical activity and increase intake of high calorie food increases an imbalance between energy intake and energy expenditure which ultimately leads to weight gain (Eliakim et al., 2002).

The home environment appears to have a significant impact on a child's weight. Parental food choices, for better or worse, significantly influence the child's food

preferences (Strauss & Knight, 1999). A parent's education level also seems to be a risk factor, with a lower level of parental education correlating with childhood obesity. It is not known if this correlation is a consequence of a person not having the skills needed to get an education, the education itself, or the lack of mental stimulation in the home environment (Gronbaek, Madsen, & Michaelsen, 2009). Obesity is more prevalent in families of low socioeconomic status; however the association between socioeconomic status and obesity is not well defined as it is unclear which specific factors affect childhood obesity (Gronbaek et al., 2009). Nonetheless, parents appear to play a very important role in promoting a healthy diet, increasing physical activity and decreasing sedentary activity in the home for their children.

Genetic Risk Factors

Parents are not only involved creating the home environment that can promote risk factors for obesity, but they also supply the genetics that may promote obesity. Several researchers indicate that the single greatest risk factor for overweight is a family history of a weight problem (Strauss & Knight, 1999; Whitaker et al., 1997). The Avon longitudinal Study demonstrated that the odds of children age seven becoming obese if the father, mother or both had obesity were 2.93, 4.66 and 11.75, respectively, clearly demonstrating the dominant influence of parental obesity (Reilly et al., 2005). Long-term follow-up indicates that obese children and adolescents tend to become obese adults, therefore promoting a family history of obesity (Eliakim et al., 2002). Several genetic conditions are known to be associated with obesity, including Prader-Willi syndrome, Bardet-Biedl syndrome, and Cohen syndrome (Raj & Kumar, 2010).

Impact of Childhood Obesity

Childhood obesity is a serious chronic disease which has both short term and long term consequences that impacts many different parts on an individual's life (CDC Grand Rounds: Childhood Obesity in the United States, 2011). While the most profound impact of obesity is on the child's health, there can also be severe psychological affects as a result of being obese (Suskind et al., 2000). Another costly effect that some people overlook is the economic impact of obesity. The impact of obesity touches not only every part of an obese individual's life and can also impact non-obese individuals (Finkelstein, Trogdon, Cohen, and Dietz, 2009)

Health Impact

Obesity is also linked to an increased risk of morbidity and mortality as well as reduced life expectancy (Raj & Kumar, 2010). Evidence indicates the relationship between obesity and disease risk begins early in life, as the visceral abdominal fat appears to set off a cascade exacerbating hyperlipidemia, hypertension, and insulin resistance, dramatically increasing the risk for cardiovascular and metabolic diseases (Shalitin et al., 2009). Metabolic syndrome has a number of risk factors that include obesity, dyslipidemia, impaired glucose metabolism and high blood pressure, which are all major predictors for cardiovascular disease (De Ferranti & Osganian, 2007). Type 2 diabetes mellitus --once thought of as occurring only in adults, but now being diagnosed in overweight adolescents – is another co-morbidity of obesity (Sinha et al., 2002).

Psychological Impact

Other immediate health consequences are psychological in nature rather than physical. Overweight children often report social discrimination, poor self-esteem, and depression (Davison & Birch, 2006). Obese children are often stigmatized socially and develop psychosocial problems (Shaltin et al., 2009). The degree of social discrimination or teasing is associated with higher weight concerns, more loneliness, poor self-perception of body image, a higher preference for sedentary or isolated activities and lower preference for social activities (Raj & Kumar, 2010). Overeating in adolescents is associated with adverse behaviors and negative psychological experiences including suicidal tendencies (Ackard, Neumark-Sztainer, Story, & Perry, 2003). It is important when treating an obese child not to neglect their mental health by solely focusing on their physical health.

Economic Impact

Over the last two decades there has been a dramatic increase in health care costs due to obesity and related issues among children and adolescents (Wang & Dietz, 2002). There is a huge financial burden associated with the short and long term consequences of childhood obesity. Finkelstein, Trogon, Cohen, and Dietz (2009), estimate that approximately nine percent of all medical costs in 2008 were related to obesity, amounting to \$147 billion compared to \$78.5 billion ten years prior. Given the increased prevalence of overweight children, it can be assumed that the billions in health care cost will continue to rise unless there is prevention and reduction in the number of adolescents and children suffering from obesity (Finkelstein et al, 2009).

Weight Loss Programs

There are many challenges to combating childhood obesity, one of which is finding an effective intervention program. Since surgical procedures and drugs are generally not recommended in obese children, preventive and therapeutic activities must focus on lifestyle modification (Shalitin et al., 2009). Traditional treatment of obesity includes changes in lifestyle through nutrition, education, an increase in physical activity, and adjustments of behavior (Suskind, 2000). More programs are now taking on a more holistic or combination approach to help reduce obesity. Some programs focus on family involvement as the key to the child's success in of the treatment. There is a limited amount of quality data on the components of programs to treat childhood obesity that favor one program over another (Shalitin et al., 2009). This section of the literature review discusses the different program approaches involving nutrition, physical activity and psychological components, including combination approaches and family-centered weight loss programs.

Nutrition Component

While nutrition is a key component of most childhood obesity weight loss programs, weight loss programs take varying approaches on how diets are implemented in their treatment protocol. Many programs focus on the prevention of weight gain, rather than weight loss, allowing the child to grow into their weight by becoming thinner over time as they grow taller (Cole, Faith, Pietrobelli, & Heo, 2005). The Pediatric Task Force on the Prevention and Treatment of Obesity noted that very low-calorie diets are generally safe when used under proper medical supervision in moderately and severely

obese patients (Suskind et al., 2000). The use of very low calorie diets are usually effective in promoting significant short-term weight loss, however, long-term maintenance of weight loss with this diet alone is not adequate, and is no better than other forms of obesity treatment (Suskind et al., 2000). It is important to remember that dietary management should aim at weight maintenance or weight loss without compromising adequate calorie intake and healthy nutrition (Raj & Kumar, 2010).

Physical Activity Component

Although extensive research in the development of obesity has focused on the role of energy intake, far less evidence-based data is available on the role of exercise in weight loss, especially in children (Shalitin et al., 2009). Several studies indicate that lower physical activity levels and sedentary behaviors are associated with a higher prevalence of obesity and that exercise can modify obesity associated risk factors (Shalitin et al., 2009). In addition to weight reduction, exercise training is linked to changes in fat and lean body mass, cardiovascular fitness, muscular strength and glucose metabolism, all of which reduce the co-morbidities associated with obesity (Watts, Jones, Davis, & Green, 2005). Ideally children should be prescribed physical activity that is safe, developmentally appropriate, interesting, practical, and provides a social element (Raj & Kumar, 2010). As Shalitin et al. (2009) observed, there is some degree of weight loss with exercise of moderate intensity alone in the short-term, however a reduction in BMI is better achieved with diet combined with exercise.

Psychological Component

While many weight loss programs focus on exercise and/or nutrition, it is important to note that obesity is also linked with an individual's attitude and overall lifestyle (Yin, Wu, Liu, & Yu, 2005). Psychosocial factors seem to be more important for the child than the functional limitations of obesity itself (Shalitin et al., 2009). Addressing only the physical components of obesity at the expense of the psychological components can increase the number of individuals who do not complete weight loss programs. For children who need psychological help, the motivation to start and remain in a treatment program depends largely on others, such as parents and teachers, to provide the needed emotional support (Braet, Jeannin, Mels, Moens & Van Winckel, 2009).

Combination Approach

Research has demonstrated that a multicomponent pediatric obesity treatment is very effective at treating obesity (Braet et al., 2010). The treatment of childhood obesity must function in a multidisciplinary setting and must take into account both the physiological and psychological maturation of the growing child (Gronbaek, Madsen, & Michaelsen, 2009). A multidisciplinary team may include a pediatric physician, nurse practitioner, dietitian, physical instructor, behavioral therapist and a social worker in addition to parents and teachers (Raj & Kumar, 2010). The team works to treat all aspects of obesity that affect children to help promote a healthy weight and lifestyle.

Family Involvement

Besides behavioral therapy in dietary and physical exercise courses, which have been regarded as significant components of weight-loss interventions, treatment of

obesity in childhood should involve the family environment (Pott et al., 2009). Most authors agree that the treatment of childhood obesity should be family-based and should use methods to motivate families to join and stay in the treatment program (Gronbaek, Madsen, & Michaelsen, 2009). Programs vary in the type of parental involvement incorporated in the treatment program including those that have parents as facilitators of their child's treatment, the target of treatment themselves, or a combination of both (Hunter et al., 2008). Numerous program treatment models have been based on the premises that parents may positively or negatively affect child's lifestyle choices through a number of mechanisms, including modeling behaviors related to nutrition and exercise, managing the foods provided and activities available to members of the household, formulating rules about how resources and time will be used, and reinforcing the choices made by family members (Hunter, Steele, & Steele, 2008). The prevention of adult obesity, by targeting children and their parents, may provide the best solution to the decreasing prevalence of obesity overall (Suskind et al., 2000).

Programs to treat obesity in childhood are not commonly available, and when offered, are usually unsuccessful in maintaining weight loss, often due to the fact that the lifestyle factors that contribute to the development of obesity were not effectively altered (Suskind et al., 2000). Changing a child's eating habits alone, for example, is not as effective as changing the whole family's eating habits. Despite a broad consensus on the significance of family involvement in weight loss interventions for children, the question of whether family characteristics are associated with success to control the weight loss has seldom been analyzed (Pott, Albayrak, Hebebrand & Pauli-Pott, 2009).

Shalitin et al. (2009) observed a positive correlation between a higher pre-intervention BMI and the subsequent reduction achieved, with no correlation found between reduction in BMI and parental BMI. In contrast, Eliakim et al. (2004) observed that parental obesity and a high pre-intervention BMI reduce the likelihood for success of a childhood obesity program. These conflicting findings show the need for more research on the effects of parent's impact on the child's successful treatment in a weight loss program.

Summary

Childhood obesity and overweight has tripled in the past three decades reaching epidemic portions and is quickly becoming one of the most common chronic diseases among children. Multiple risk factors contribute to childhood obesity, including environmental factors, genetic factors, socioeconomic factors and psychological factors. Childhood obesity is a serious chronic disease which has both short term and long term impacts on health, mental health and the economy. Traditional treatment of obesity includes changes in lifestyle through nutrition, education, an increase in physical activity, and adjustments of behavior. More programs are now taking on a more holistic or combination approach and including family involvement to help reduce obesity.

CHAPTER THREE

METHODOLOGY

The purpose of this study was to determine if completion of the SHAPEDOWN program, offered through a hospital in north central Indiana between 2009 and 2011, was associated with a reduction in body weight and improved measures of physical fitness among obese adolescents and their parent-participants. A secondary purpose of the study was to determine if a relationship existed between a parent's success and his or her child's success in reducing their body weight and improving measures of their physical fitness. This chapter describes the methods used to conduct the study.

Institutional Review Board

Permission to analyze the previously collected data used in this study was obtained from the Institutional Review Boards of the north central Indiana hospital (Appendix A-1) and Ball State University (Appendix A-2). This researcher completed the Collaborative Institutional Training Initiative (CITI) training (Appendix A-3).

Subjects

Subjects in the study include all of the participants who completed the SHAPEDOWN program at a north central Indiana hospital between 2009-2011. The

subjects include obese children between the ages of 8-18 years and their parent/guardian participant who attended the first and last sessions when the data was collected.

Methods

SHAPEDOWN was developed by faculty members of the University of California, San Francisco, School of Medicine and includes contributions from nutrition, exercise physiology, endocrinology, psychology, family therapy, adolescent medicine, family medicine and behavioral and developmental pediatrics (SHAPEDOWN, 2012). Children and teens in SHAPEDOWN enhance their self-esteem, improve peer relationships, adopt healthier habits and begin to normalize their weight within their genetic potential (SHAPEDOWN, 2012).

The SHAPEDOWN program is held for ten weeks, with one session per week lasting two to two and half hours per session. The children must attend each session with their parent or guardian participant. The first session is for orientation when participants are supplied with workbooks, anthropometrics are taken, fitness testing is conducted and participants are introduced to one another as well as the instructors and given a schedule for the next nine weeks. The sessions are led by a registered dietitian following the SHAPEDOWN instructor's guide. The sessions are broken down into family time, separate child and adult session, and physical activity. Sessions are fun, supportive and stimulating.

Each week the session starts with all the participants turning their food record from the prior week for the dietitian to look over and make recommendations for improvement. While there is no set diet, participants discuss SHAPEDOWN's dietary

recommendations which are consistent with the Institute of Medicine's Dietary Reference Intake and the National Cholesterol Education Project Guidelines. Parent and child participants show the dietitian the exercises in their workbooks that they have completed each day throughout the week. The group then shares the struggles or the celebrations that they have had for the week. Then the topic of discussion is guided to discuss different elements each week such as understanding your health, assertive and emotionally expressive communication, problem solving, stress management, active and enriching lifestyles and body image therapies.

Once the discussions and activities are done, the children are separated from their parents. The children are further separated by age group where they participate in an age-appropriate physical activity. While the children are exercising, the parents participate in educational sessions that focus on parenting skills such as understanding their child's weight issues, how to be a good role model, how to set limits and how to be a more nurturing parent. The parents later join the children in an activity before the session is closed.

SHAPEDOWN at this north central Indiana hospital has the following six program requirements: 1) the participant must come to all sessions, 2) the participants must come to sessions prepared, 3) the entire family must attempt to improve their nutrition and activity, 4) the family must take 15 minutes per day for recording/family time to praise one another, 5) the participants must take one to two hours per week for the self-study course, and 6) overweight parents should attempt to gradually lose weight to be a good role model for their child. The program goals are the same for both the parents and their overweight children. The goals include: 1) to spend at least five minutes daily in

family time to review records and praise each other's progress; 2) to watch eight or fewer hours of television per week; 3) to exercise daily; 4) to eat in a healthy way; and 5) if overweight, lose one half to one pound per week.

The data used in this study was collected by dietitians and dietetic interns who conducted the SHAPEDOWN program during 2009-2011 under the oversight of a hospital in north central Indiana. On the first day of the SHAPEDOWN program, each member completes a basic assessment which includes a brief questionnaire and the completion of anthropometric (e.g., height and weight) and fitness assessments (e.g., sit/reach test for flexibility, sit ups in 60 seconds to measure strength, and the step test to measure endurance). These anthropometric and physical measurements were taken on both the child and his or her parent/guardian; these same measurements were repeated ten weeks later during the last session. All data was recorded on the SHAPEDOWN Evaluation Summary Form (Appendix B).

Weight and height were measured to calculate the participant's Body Mass Index (BMI) using the standard formula. Both weight and height were taken shoeless and with light street clothes. Subjects' weight was measured using a model BWB-800S digital scale (TANITA, 2011) and was recorded to the nearest pound, with values of 0.5 and above rounded to the next whole number. Subjects' height was measured using a model IP0955 stadiometer (Invicta Plastics Limited, 2011).

The fitness tests involve assessing the three dimensions of fitness: strength, flexibility and endurance. The tests selected have been identified in the National Children and Youth Fitness Study and the President's Council on Physical Fitness and Sports. Bent-knee sit-ups are used as an indicator of strength. In this test the participant lies face

up with knees bent and feet flat on the floor, with his or her heels between 12 and 18 inches from one's buttocks and with one's hands interlocked behind the neck. Subjects' feet are held down by another individual. Once positioned correctly, the participant performs as many sit-ups as possible in a 60-second period. Correct form requires that the elbows touch the knees and that a full lying position is attained. Through increased activity, one's strength is projected to increase.

Subjects' flexibility was measured using the sit-and-reach test using a sit and reach box. In this test, a participant's feet contacted the box while sitting with one's legs extended directly in front and knees pressed against the floor. The participant puts his or her index fingers of both hands together and reaches forward as far as possible. Subjects' knees were kept on the floor and movement slow. The distance reached is then recorded. In addition to flexibility, the sit-and-reach test is influenced by the length of the individual's arms and legs and central adiposity in the severely obese. Through increased activity, one's flexibility is projected to increase.

Subjects' endurance was measured using the step test. The step test is based on the nearly linear relationship between heart rate and oxygen consumption during light and moderate exercise. The test is used to predict VO_2 max, by taking post-exercise heart rate after a standardized regimen of submaximal exercise performed on a step test. Participants step up and down on a bench 12 inches high. A cycle consists of stepping first with the right foot onto the bench, then with the left foot onto the bench. Then return the right foot to the floor, followed by the left foot to the floor. The participant then does 24 step-cycles per minute. After stepping for three minutes, the participant stops and heart rate monitor is immediately conducted. Through increased activity, one's

endurance is projected to increase as indicated by a reduction in one's step test heart rate reading.

Data Entry and Analysis

The previously collected data used for this study was extracted from the SHAPEDOWN Evaluation Summary Form (Appendix B) and entered into an Excel spreadsheet by the primary investigator. The data was then uploaded from Excel into SPSS v.19.0 for Windows (SPSS, 2011) for analysis. Descriptive statistics and frequency counts were run on all variables. A paired t-test was run to compare the pre and post data from height, weight, BMI, flexibility test, endurance test, and strength test. Pearson's correlation coefficient was used to compare the relationship between parent and child as a family unit (e.g., if a parent had more than one child enrolled in SHAPEDOWN, the data for both children was averaged and compared to the data from the parent). Statistical significance was set at $p \leq 0.05$.

Summary

Subjects in the study include all participants in the SHAPEDOWN program hosted at a north central Indiana hospital from 2009-2011. The data measurements analyzed in this study included the anthropometric measures of height and weight and fitness tests to measures flexibility (sit and reach test), strength (sit-ups), and endurance (step test). The results obtained during the first visit for each individual participant were compared to his or her post-test using a paired t-test analysis. Pearson's correlation

coefficient was used to determine if there is a correlation between the changes in the child and parent pairs.

CHAPTER IV

RESULTS

The purpose of this study was to determine if completion of the SHAPEDOWN program, offered through a hospital in north central Indiana between 2009 and 2011, was associated with a reduction in body weight and improved measures of physical fitness among obese adolescents and their parent-participants. A secondary purpose of the study was to determine if a relationship existed between a parent's success and his or her child's success in reducing their body weight and improving measures of their physical fitness. The results of this study will be presented in this chapter.

Subject

Participants in this study included 47 children and 34 parent participants for a total of 81 participants in the study. These 81 participants belonged to 33 unique "family units" which consist of a parent and his or her child or children participants. The participants include obese (e.g., BMI greater than the 95th percentile for age and gender) children between the ages of 8-18 years and their parent/guardian participant who attended the first and last SHAPEDOWN sessions during which the data was collected.

RQ#1: Child Participants SHAPEDOWN Program Results

The first research question in this study examined the effectiveness of SHAPEDOWN in helping the obese children who attended all ten SHAPEDOWN sessions lose weight, reduce their BMI, and improve their physical endurance.

The initial weight of the 47 subjects was 182.4 ± 59.2 pounds. At the end of the 10th week, the mean weight of the participants was 181.7 ± 58.6 pounds. Paired t-test indicated a mean weight loss of 0.7 ± 4.9 pounds ($t= 0.987$; $p=0.329$; NS) (Table 1). The initial height of the 47 subjects was 60.9 ± 5.3 inches. At the end of the 10th week, the mean height of the participants was 61.1 ± 5.1 inches. Paired t-test indicated a significant increase in height of 0.2 ± 0.4 inches ($t= -3.93$; $p<0.001$) (Table 1). Subjects' initial mean BMI was 33.8 ± 7.5 . At the end of the 10th week, the mean BMI of the 47 participants was 33.4 ± 7.4 , resulting in a statistically significant reduction of 0.4 ± 0.9 ($t= 2.71$; $p=0.010$) (Table 1).

Subjects' physical fitness was measured by three aspects: strength (number of sit ups completed in 60 seconds), flexibility (sit and reach test), and endurance (heart rate post step test). The mean number of sit ups completed by participants at the beginning of SHAPEDOWN was 23.2 ± 11.6 . At the end of the 10th week, the mean number of sit ups had increased to 26.2 ± 11.8 . Paired t-test indicated a significant increase in the number of sit ups by 3.0 ± 5.2 ($t= -3.94$; $p<0.001$) (Table 1).

After completing a 60 second step test, participants' mean heart rate at the beginning of SHAPEDOWN was 162.1 ± 18.6 beats per minute. At the end of the 10th week and upon completion of the step test, participants' mean heart rate had decreased to 155.33 ± 18.5 . Paired t-test indicated a significant decrease in the resting heart rate of 6.8

± 14.8 beats per minute, indicating a greater level of fitness among participants upon completion of the ten week program ($t=3.03$; $p=0.004$) (Table 1)

The mean number of inches a participant could reach and stretch at the beginning of SHAPEDOWN was 8.5 ± 3.8 inches. At the end of the 10th week, the subjects' mean reach had increased to 10.3 ± 3.5 inches. Paired t-test indicated a significant increase in the flexibility of the participants by 1.8 ± 2.3 inches ($t= -5.36$; $p<0.001$) (Table 1).

Table 1. Children's Pre and Post Data from SHAPEDOWN (n=47)

Measure	N	Pre-Measure	Post Measure	Difference	t	p
Weight, pounds	47	182.4 ± 59.2	181.7 ± 58.6	0.7 ± 4.9	0.99	.329
Height, inches	47	60.9 ± 5.3	61.1 ± 5.1	0.2 ± 0.4	3.93	<.001
BMI	47	33.8 ± 7.5	33.4 ± 7.4	0.4 ± 0.9	2.71	.010
Sit Ups/60 seconds	46	23.2 ± 11.6	26.2 ± 11.8	3.0 ± 5.2	3.94	<.001
Heart Rate, beats/minute	44	162.1 ± 18.6	155.3 ± 18.5	6.8 ± 14.8	3.03	.004
Flexibility, inches	47	8.5 ± 3.8	10.3 ± 3.5	1.8 ± 2.3	5.36	<.001

RQ#2: Parent Participants SHAPEDOWN Program Results

The second research question in this study examined the effectiveness of SHAPEDOWN in helping the parents of the obese children who attended all ten SHAPEDOWN sessions lose weight, reduce their BMI, and improve their physical endurance.

The initial weight of the 34 parents was 195.0 ± 50.4 pounds. At the end of the 10th week, the mean weight of the parent-participants was 193.7 ± 50.4 pounds. Paired t-test indicated a mean weight loss of 1.3 ± 5.1 pounds ($t= 1.43$; $p=0.161$; NS) (Table 2). The initial height of the 34 parent-participants was 63.9 ± 2.5 inches. At the end of the 10th week, the mean height of the participants remained identical at 63.9 ± 2.5 inches. Paired t-test indicated no difference in the height of the parents after ten weeks ($t= 0.65$; $p=0.521$; NS) (Table 2). Subjects initial mean BMI was 33.6 ± 8.4 . At the end of the 10th week, the mean BMI of the 34 parent-participants was 33.4 ± 8.5 , resulting in a reduction of 0.2 ± 1.0 ($t= 1.42$; $p=0.165$; NS) (Table 2).

The parents' physical fitness was measured by three aspects: strength (number of sit ups completed in 60 seconds), flexibility (sit and reach test), and endurance (heart rate post step test). The mean number of sit ups completed by the parent-participants at the beginning of SHAPEDOWN was 20.3 ± 11.9 . At the end of the 10th week, the mean number of sit ups had increased to 23.4 ± 13.7 . Paired t-test indicated a significant increase in the number of sit ups by 3.1 ± 7.0 ($t=2.35$; $p=0.026$) (Table 2).

After completing a 60 second step test, the parent-participants' mean heart rate at the beginning of SHAPEDOWN was 140.4 ± 19.9 beats per minute. At the end of the 10th week and upon completion of the step test, the parent-participants' mean heart rate had decreased to 136.4 ± 14.5 . Paired t-test indicated a non-significant decrease in the resting heart rate of 4.0 ± 15.5 beats per minute upon completion of the ten week program ($t=1.32$; $p=0.199$; NS) (Table 2)

The mean number of inches a parent-participant could reach and stretch at the beginning of SHAPEDOWN was 9.2 ± 3.9 inches. At the end of the 10th week, the

parent-participants' mean reach had increased significantly to 10.5 ± 3.5 inches. Paired t-test indicated a significant increase in the flexibility of the participants by 1.3 ± 2.1 inches ($t=-3.46$; $p=0.002$) (Table 2).

Table 2. Parent Pre and Post SHAPEDOWN (n=34)

Measure	N	Pre	Post	Difference	T	p
Weight, pounds	34	195.0 ± 50.4	193.7 ± 50.4	1.3 ± 5.1	1.43	.161
Height, inches	34	63.9 ± 2.5	63.9 ± 2.5	0.0 ± 0.2	0.65	.521
BMI	34	33.6 ± 8.4	33.4 ± 8.5	0.2 ± 1.0	1.42	.165
Sit Ups/60 seconds	29	20.3 ± 11.9	23.4 ± 13.7	3.1 ± 7.0	2.35	.026
Heart Rate	26	140.4 ± 19.9	136.4 ± 14.5	4.0 ± 15.5	1.32	.199
Flexibility	30	9.2 ± 3.9	10.5 ± 3.5	1.3 ± 2.1	3.46	.002

RQ#3: Correlation between the Parent:Child Success in SHAPEDOWN

The third research question examined the relationship between a parent's success in the SHAPEDOWN program and his or her child's success in the SHAPEDOWN program.

A "family unit" for this study was defined as the parent participant and his or her child or children who completed the ten-week SHAPEDOWN program. Of the 37 families, 30 had one child participate in SHAPEDOWN, four families had two children participants, and three families had three children participating in SHAPEDOWN at the same time. In addition, one family had two parents participate. There were a total of 33 unique family units. To compare the results of a parent with the results of his or her

child/children, the average parent change was matched to the average child change within each family.

The mean child weight difference was 0.5 ± 4.6 pounds, while the mean parent weight difference was 1.1 ± 5.0 pounds ($t=0.643$; $df = 32$; $p=0.525$; NS). The Pearson correlation for child and parent weight difference was $r=0.467$ ($p=0.006$), indicating that if a parent lost weight during SHAPEDOWN, his or her child was likely to lose weight as well (Table 3).

The mean BMI difference for children was 0.4 ± 0.8 , while the mean BMI difference for parents was 0.2 ± 0.9 ($t=-0.836$; $df = 32$; $p=0.409$; NS). The Pearson correlation for child and parent BMI difference was $r=0.316$ which is not significant ($p=0.073$) (Table 3).

The measures of physical fitness were also compared for the family units. The mean difference for sit ups in children was 3.7 ± 4.6 , while the mean difference for sit ups in parents was 2.8 ± 6.9 sit ups per minute ($t=0.550$; $df = 27$; $p=0.587$; NS). The Pearson correlation for the child and parent sit up difference was $r=-0.091$ which is not significant ($p=0.645$) (Table 3).

The mean difference for flex test in children was 1.4 ± 2.3 while the mean difference for flex test in parents was 1.4 ± 2.1 ($t=0.222$; $df = 28$; $p=0.826$). The Pearson correlation for child and parent flex test difference was $r=0.583$ ($p=0.001$), which indicated if the parent was able to increase their reach, so too did his or her child.

The mean difference for heart rate test in children was 7.5 ± 13.5 while the mean difference for heart rate test in parents was 3.7 ± 15.4 ($t=-0.739$; $df = 24$; $p=0.467$). The

Pearson correlation between child and parent heart rate difference was $r=-0.226$ which is not significant ($p=0.278$) (Table 3).

Table 3. Correlation between Parent and Child “Family Unit” (n=33).

	N	Correlation	p
Child Wt. Difference	33	0.467	0.006
Parent Wt. Difference			
Child BMI Difference	33	0.316	0.073
Parent BMI Difference			
Child Sit ups Difference	28	-0.091	0.645
Parent Sit ups Difference			
Child HR Difference	25	-0.226	0.278
Parent HR Difference			
Child Flex Difference	29	0.583	0.001
Parent Flex Difference			

Summary

A total of 47 children and 34 parents participated in the ten week SHAPEDOWN program. There were 33 family units which consisted of parent participants and his or her child or children participants. The difference in weight and BMI pre to post were evaluated for both the parent group and the children group. While there was no significant difference in the children’s post weight difference, there was significance in the children’s post height and BMI.

The participant's physical endurance was measured using three aspects: strength (sit ups), flexibility (sit and reach test) and endurance (heart rate post step test). The children's post data showed significance for all three categories.

The parent analysis indicated no significance between the pre and post weight, height, or BMI. There was a significant difference between the number of sit ups a parent was able to complete between pre- and post-testing, as well as an increased flexibility as measured by the reach test, among the parent participants. However, no difference was detected in the parent's recovery heart rate after completing the one-minute step test.

The comparison between parent and child units showed a significant correlation between the child's weight difference and the parent's weight difference and between the child's flexibility test difference and the parent's flexibility test difference. No significant correlation was observed between BMI, number of sit ups and recovery heart rate.

CHAPTER V

DISCUSSION

The purpose of this study was to determine if completion of the SHAPEDOWN program, offered through a hospital in north central Indiana between 2009 and 2011, was associated with a reduction in body weight and improved measures of physical fitness among obese adolescents and their parent-participant. A secondary purpose of the study was to determine if a relationship existed between a parent's success and his or her child's success in reducing their body weight and improving measures of their physical fitness. A discussion of the results will be presented in this chapter.

RQ#1: Child Participants SHAPEDOWN Program Results

Although no significant reduction in post weight among the children ($p=0.329$) was observed at the end of the ten week SHAPEDOWN program, a significant reduction in the children's post BMI ($p=0.010$) was observed, indicating the children were "growing into" their weight, as an increase in height without weight gain mathematically results in a decrease in one's BMI. A child's weight by itself does not determine if the child is overweight, obese or of normal weight; rather, BMI is the preferred tool used to classify overweight and obesity because it takes into consideration the height as well as the weight of the child.

The results observed in this study are similar to the observation of Cole et al., (2005) who emphasized the importance of weight gain prevention rather than weight loss, allowing the child to become thinner over time as they grow taller (Cole, Faith, Pietrobelli, & Heo, 2005). A reduction in a BMI standard deviation score of >0.5 over a one year in obese children is associated with improvements in the lipid profile (lower triglycerides, higher HDL, cholesterol), blood pressure and measures of insulin sensitivity (Sabin, et al., 2007).

The physical endurance of the SHAPEDOWN subjects was measured by three aspects strength (sit ups), flexibility (sit and reach test) and endurance (heart rate post step test). The children's post data showed significance for all three categories ($p=0.000$; $p=0.000$; $p=0.004$ respectively). Several studies indicate that lower physical activity levels and sedentary behaviors are associated with a higher prevalence of obesity and that exercise can modify obesity associated risk factors (Shalitin et al., 2009). SHAPEDOWN embraced this style of thought by incorporating physical activity into the program. The results showed that the children improved their physical activity level which was measured by three aspects, strength (sit ups), flexibility (sit and reach test) and endurance (heart rate post step test). The children's post data showed a significant improvement for all three categories. This has similar results to a larger study conducted over a six month period, compared to baseline the children in the study showed a significantly reduced BMI ($P<0.05$) and endurance time significantly increased ($P<0.0005$). In contrast, obese children who did not participate in the structured program gained weight, increased their BMI, and improved fitness less significantly (Eliakim, et al., 2002).

RQ#2: Parent Participants SHAPEDOWN Program Results

The parent analysis indicated no significance between the pre and post weight ($p=0.161$), BMI ($p=0.165$) or heart rate ($p=0.199$). There was, however, a significant difference between the pre and post number of sit ups ($p=0.026$) and flexibility of the parents ($p=0.002$).

One of the main risk factors for the development of childhood obesity is parental overweight (Eliakim, et al., 2002). The study showed that the parents had no statistically significant difference in weight or BMI at the end of the 10 week session. It is important to note that not all parents of the child participants were overweight at the start of the program. Unlike the growing children there was no growth in height that would lead to a lower BMI in the parent participants. A study done on a ten week treatment program that included nutrition education and exercise instruction delivered by a licensed nutritionist with a focus on healthy-lifestyle changes and activities of daily living, much like the current study, found different results. Their results showed the parents to have a significant decrease in weight from pre- to post treatment ($p<.001$) (Hunter, Steele, & Steele, 2008).

A key component to the intervention used in a study by Suskind, et al., (2000) was family intervention, both during weekly sessions and home-based exercise. Parents were encouraged to participate in the many varied activities offered during the exercise portion of the weekly meetings. Likewise, parents' participation at home with their children during exercise sessions improved compliance and overall success. A similar result was found in this study as parents did show a statistically significant difference in two of the three measures of physical activity.

RQ#3: Correlation between the Parent:Child Success in SHAPEDOWN

The comparison between parent and child units showed a statistically significant positive correlation between the child's weight difference and the parent's weight difference ($r=0.47$; $p=0.006$), indicating that the children of parents who lost weight were more likely themselves to lose weight. In addition, a significant correlation between the child's flexibility test difference and the parent's flexibility test difference ($r=0.583$; $p=0.001$) was observed, indicating that the children of parents who became more flexible were more likely themselves to become more flexible. There was no significant correlation between the parents and children with regard to BMI ($r= 0.316$; $p=0.073$), sit ups ($r=-0.031$; $p=0.645$) or heart rate difference ($r= -0.226$; $p=0.226$).

Hunter, Steele, & Steele (2008) conducted a similar study over a ten week period. Their results indicated a 4 percent reduction in the BMI of the children, with the single greatest predictor of change in the children's BMI found to be the parental weight loss. Similarly, Davis, et al., (2011) found a significant positive relationship between parental and child body mass index and between the child's weight loss and the parent's weight loss. No correlation between pre- and post-treatment BMI scores was observed, suggesting that the parent's role in the weight loss program may impact the child's weight loss or lack of weight loss in the program, although the findings are not as strong as the results of Hunter et al. (2008) and in the present study.

The results of a study done by Eliakim, et al. (2002) indicated that parental overweight had no effect on body weight and BMI changes during the first three months of the program. However, during the second three months of the six month intervention, subjects with both obese parents had less favorable BMI responses compared to obese

children without parental overweight. This suggests that parental involvement and support is probably less effective in obese families and results in a greater risk of obesity for the entire family. The current study was conducted in less than three month period and also found no indication that parental BMI changes impacted child BMI changes.

Family involvement in weight loss programs that incorporate the family in the treatment process, which includes decreasing caloric intake and improving diet, increasing calorie expenditure through physical activity, and includes training in behavioral skills such as self-monitoring and goal-setting was more effective than control groups (Kitzman-Ulrich, et al., 2010). The current study found similar results when comparing the family units; there is a correlation between the child's weight difference and the parent's weight difference. There was also a significant correlation between the child's flexibility test difference and the parent's flexibility test difference. However for this study there was no control group to use for comparison.

Conclusions

The results of the child's statistically significant BMI scores in the present study is similar to the results of other child weight loss programs that focus on weight gain prevention rather than weight loss (Cole, Faith, Pietrobelli, & Heo, 2005). Shalitin et al. (2009) observed that the reduction in BMI is better achieved with diet combined with exercise just as it was done in this study with the SHAPEDOWN program. The results showed that the children improved their physical activity level by all three of the measured aspects. This has similar results to a larger study conducted over a six-month

period; compared to baseline the children in the study showed a significantly reduced BMI and endurance time significantly increased (Eliakim, et al., 2002).

One of the main risk factors for the development of childhood obesity is parental overweight (Eliakim, et al., 2002). The study showed that the parent's had no statistically significant difference in weight or BMI at the end of the 10 week session. A study done on a ten week treatment program that included nutrition education and exercise instruction delivered by a licensed nutritionist with a focus on healthy-lifestyle changes and activities of daily living, much like the current study, found different results. Their results showed the parents to have a significant decrease in weight from pre- to post treatment (Hunter, Steele, & Steele, 2008). A key component to the intervention used in a study by Suskind, et al., (2000) was family intervention, such as parents' participation at home with their children during exercise sessions improved compliance and overall success. A similar result was found in this study as parents did show a statistically significant difference in two of the three measures of physical activity.

Family involvement in weight loss programs that incorporate the family in the treatment process, which includes decreasing caloric intake and improving diet, increasing calorie expenditure through physical activity, and includes training in behavioral skills such as self-monitoring and goal-setting was more effective than control groups (Kitzman-Ulrich, et al., 2010). The current study found similar results when comparing the family units there is a correlation between the child's weight difference and the parent's weight difference. There was also a significant correlation between the child's flexibility test difference and the parent's flexibility test difference. However for this study there was no control group to use for comparison.

CHAPTER VI

CONCLUSIONS AND RECOMMENDATIONS

In conclusion, an analysis of the SHAPEDOWN program offered through a hospital in north central Indiana between 2009 and 2011 indicated participation over the ten-week program period was associated with a reduction in body mass index and improved measures of physical fitness among obese adolescents. Although their parent-participants did not show a reduction in body mass index or weight reduction, an improvement in two of the three measures of physical fitness was observed. In addition, the study demonstrated a positive relationship between the weight difference and flexibility difference from pre- to post-treatment. The level of change was similar for parents and child, meaning that both child and parent participants changed in relatively similar ways, indicating parents can be positive role models for their children who are trying to become healthier.

Limitations

The limitation for the study included:

1. The participants were not randomly selected but were taken from previously collected data.

2. The population in this study only included one geographic area in the state of Indiana which warrants caution when applying these findings at a national level.
3. The results only show short term effects of the program.
4. There is no control group since all the obese participants referred to the program were interested in participating in the intervention.

Recommendations for Future Research

Based on the results of this study, the following recommendations for future research are made:

1. Increase the sample size by examining other sites that are using the same SHAPEDOWN program.
2. Conduct a longitudinal study to fully evaluate whether the newly learned behaviors during the ten week program were assimilated as permanent changes to the participants eating and lifestyle patterns.
3. Assess if follow up sessions following the ten week program would have an impact on continued weight loss and weight maintenance.
4. Examine other parent behaviors such as nurturing styles, role-modeling of healthful behavior as this study was limited to one type of parental involvement (e.g., parent weight loss and physical fitness).

Recommendations for Practice

The results of this and other studies suggest:

1. A family approach to weight loss can impact the child's outcomes as such it is important to have a family participation.

2. Using a combined diet and physical activity in the program can increase weight loss for the participants.

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APPENDIX A

INSTITUTIONAL REVIEW BOARD MATERIALS

- A-1 IRB Approval from the Hospital
- A-2 IRB Approval from Ball State University
- A-3 CITI Certificate of Competition

A-1 IRB Approval from the North Central Indiana Hospital



INSTITUTIONAL REVIEW BOARD

REVIEW CERTIFICATE (Version 04-11)

Keyword/Protocol Title: Family Weight Loss / A Family Weight Loss Approach to Reduce Childhood Obesity

Principal Investigator: Mary Harter, RD

- | | |
|---------------------------------------------------------|---------------------------------------------------------|
| <input checked="" type="checkbox"/> Protocol Submission | <input type="checkbox"/> Deviation |
| <input type="checkbox"/> Continuing Review | <input type="checkbox"/> Serious Adverse Event |
| <input type="checkbox"/> Amendment | <input type="checkbox"/> IND Safety Report/MedWatch |
| <input type="checkbox"/> Study Closure | <input checked="" type="checkbox"/> Other <u>EXEMPT</u> |
| <input type="checkbox"/> Non-Compliance | |

Additional Information: Full Board Notification

- Study found to be Exempt per [45 CFR 46.101 \(b\) \(4\)](#)
- Protocol, dated 03-05-12
- Data Collection Form, dated 02-11-12
- Request for Waiver or Alteration of Consent and HIPAA Authorization, dated 02-15-12
- Expedited Review by Dennis Dykhuizen

Date of Original Expedited IRB Approval of Waiver: 03-26-12

Date of Full Board Notification IRB Meeting: 04-20-12

Expiration Date: Exempt

Approval Status:

- Approved
- Re-approved
- Study Closed
- Acknowledged
- Deferred
- Suspension of Approval
- Other

COMMENTS:

As with all investigational protocols, serious, related or possibly related, unanticipated Adverse Events are to be reported to the [] IRB within 10 working days; changes to the research may not be initiated without prior [] IRB approval of the change; and a Continuing Review of study activity by [] IRB must occur at least annually for re-approval of the study.

Dennis F. Dykhuizen / CDH

Dennis F. Dykhuizen, J.D.

[] IRB Chairman

A-2 IRB Approval from Ball State University



Institutional Review Board

DATE: June 28, 2012
TO: Mary Harter
FROM: Ball State University IRB
RE: IRB protocol # 301264-1
TITLE: Childhood Obesity A Family Weight Loss Approach
SUBMISSION TYPE: New Project
ACTION: DETERMINATION OF EXEMPT STATUS
DECISION DATE: June 28, 2012

The Institutional Review Board reviewed your protocol on June 28, 2012 and has determined the procedures you have proposed are appropriate for exemption under the federal regulations. As such, there will be no further review of your protocol, and you are cleared to proceed with the procedures outlined in your protocol. As an exempt study, there is no requirement for continuing review. Your protocol will remain on file with the IRB as a matter of record.

Editorial notes:

1. Approved

While your project does not require continuing review, it is the responsibility of the P.I. (and, if applicable, faculty supervisor) to inform the IRB if the procedures presented in this protocol are to be modified or if problems related to human research participants arise in connection with this project. **Any procedural modifications must be evaluated by the IRB before being implemented, as some modifications may change the review status of this project.** Please contact please contact John Mulcahy at (765) 285-5106 or jmulcahy@bsu.edu if you are unsure whether your proposed modification requires review or have any questions. Proposed modifications should be addressed in writing and submitted electronically to the IRB (<http://www.bsu.edu/irb>) for review. Please reference the above IRB protocol number in any communication to the IRB regarding this project.

Reminder: Even though your study is exempt from the relevant federal regulations of the Common Rule (45 CFR 46, subpart A), you and your research team are not exempt from ethical research practices and should therefore employ all protections for your participants and their data which are appropriate to your project.

CITI Collaborative Institutional Training Initiative

**Social & Behavioral Research - Basic/Refresher Curriculum Completion Report
Printed on 11/16/2011**

Learner: Mary Harter (username: ttpmannr)

Institution: Ball State University

Contact

Department: Ball State University

Information

Email: mrtippmann@bsu.edu

Social & Behavioral Research - Basic/Refresher: Choose this group to satisfy CITI training requirements for investigators and staff involved primarily in Social/Behavioral Research with human subjects.

Stage 1. Basic Course Passed on 11/16/11 (Ref # 6546000)

Required Modules	Date Completed	Score
Belmont Report and CITI Course Introduction	09/06/11	3/3 (100%)
Students In Research	09/06/11	9/10 (90%)
History and Ethical Principles - SBR	09/06/11	4/4 (100%)
Defining Research with Human Subjects - SBR	09/06/11	4/5 (80%)
The Regulations and The Social and Behavioral Sciences - SBR	09/06/11	4/5 (80%)
Assessing Risk In Social and Behavioral Sciences - SBR	11/16/11	5/5 (100%)
Informed Consent - SBR	11/16/11	5/5 (100%)
Privacy and Confidentiality - SBR	11/16/11	4/5 (80%)
Research with Prisoners - SBR	11/16/11	4/4 (100%)
Research with Children - SBR	11/16/11	4/4 (100%)
Research in Public Elementary and Secondary Schools - SBR	11/16/11	4/4 (100%)
International Research - SBR	11/16/11	3/3 (100%)
Internet Research - SBR	11/16/11	4/4 (100%)
Research and HIPAA Privacy Protections	11/16/11	5/5 (100%)
Vulnerable Subjects - Research Involving Workers/Employees	11/16/11	4/4 (100%)
Conflicts of Interest in Research Involving Human Subjects	11/16/11	4/5 (80%)
Ball State University	11/16/11	no quiz

For this Completion Report to be valid, the learner listed above must be affiliated with a CITI participating institution. Falsified information and unauthorized use of the CITI course site is unethical, and may be considered scientific misconduct by your institution.

Paul Braunschweiler Ph.D.
Professor, University of Miami
Director Office of Research Education
CITI Course Coordinator

[Return](#)

APPENDIX B
SHAPEDOWN DATA COLLECTION SHEET

APPENDIX B

SHAPEDOWN DATA COLLECTION SHEET



SHAPEDOWN Evaluation Summary

Child/Teen Name _____

Parent/guardian _____

Week 1	Week 10	Change	
<u>Weight (lbs.)</u>			
_____	_____	_____	_____
<u>Height</u>			
_____	_____	_____	_____
<u>Body Mass Index</u> (BMI = weight (kg)/height (m ²):)			
_____	_____	_____	_____
<u>Waist (inches)</u>			
_____	_____	_____	_____
<u>Hip (inches)</u>			
_____	_____	_____	_____
<u>Fitness Testing</u>			
<u>Strength</u> (Number of sit-ups in 60 seconds):			
_____	_____	_____	_____
<u>Endurance - Cardiovascular Function</u> (Heart rate after walking up a step for 3 minutes):			
_____	_____	_____	_____
<u>Flexibility</u> (distance in inches that the child can reach past a certain point):			
_____	_____	_____	_____
<u>Blood Pressure</u>			
_____	_____	_____	_____