The Effectiveness of a Multi-Disciplinary, Family-Centered Pediatric Weight Management Clinic: A Program Evaluation

Keri Montgomery

The University of Alabama

Capstone College of Nursing

Dr. Staci Simmons

Dr. Rebecca Carey

March 7, 2023

PART I: DNP PROJECT PROPOSAL

Table of Contents

Abstract

Introduction/Purpose: Pediatric obesity is a growing problem in the United States, significantly increasing healthcare costs. Though pediatric guidelines remain inconsistent on specific program recommendations, family-centered care stands as a common theme of treatment. The purpose of this DNP project was to evaluate a multi-disciplinary, family-centered pediatric weight management program called "All IN Wellness" to determine its effectiveness.

Methods: A chart review was performed on patients that completed the first eight weeks of All IN Wellness from June 13, 2022, through October 1, 2022. Anthropometric data, behavioral assessments, and quality of life assessments were collected at week one and week eight of the program. Descriptive statistics were used to analyze results of these measures.

Results: Statistically significant positive behavioral changes occurred in patients over the eight-week period. Quality of life assessment results were limited due to small sample size and missing data but did show limited improvement in of quality of life scores. There were no significant changes in BMI.

Discussion: This program evaluation suggests that a multi-disciplinary, family-centered pediatric weight management program is effective at increasing healthy behaviors and improving quality of life. Though no statistically significant changes in BMI were noted, BMI levels remained consistent throughout the first eight weeks of the program, a finding that may be as important as a decrease in BMI in the early stages of treatment. Future investigation of program length, sustainability, and long-term follow up of pediatric weight management programs is essential for improving treatment programs and decreasing pediatric obesity rates.

The Effectiveness of a Multi-Disciplinary, Family-Centered Pediatric Weight Management Clinic: A Program Evaluation

Pediatric obesity continues to be a problem within the U.S., and there is a lack of access to specialty care for treatment. Clinical practice guidelines for the treatment of pediatric obesity remain inconsistent, and sustaining healthy behavioral changes remains a challenge. Obesity can lead to multiple chronic co-morbidities and impact quality of life for many patients. Once co-morbidities develop, patients can be referred to pediatric subspecialty clinics. Current clinical practice guidelines for pediatric obesity rely heavily on education provided by the primary care provider (PCP) or referral to a dietitian. Within our local healthcare system, there is one pediatric outpatient dietitian available for the management of pediatric obesity, and the nearest weight management program is three hours away. An evidence based, family centered pediatric weight management program allows for access to specialty treatment of pediatric obesity and may help prevent co-morbidities by addressing key lifestyle factors and promoting sustainable lifestyle changes to improve overall quality of life. This project aims to evaluate such a program.

Background

Approximately 19% of children in the United States are considered obese (Centers for Disease Control (CDC), 2021b). In the state of Indiana, one third of children birth to 5 years of age have a body mass index (BMI) at the 85th percentile or higher with half of this group meeting criteria for obesity (State of Indiana, 2021). On an even smaller scale, within Vanderburgh County, 34% of adults are obese (University of Wisconsin Public Health Institute & Robert Wood Johnson Foundation, 2021). Pediatric obesity rates have continued to increase nationally, tripling within the last 40 years (Robert Wood Foundation, 2019). Through the first year of the

COVID pandemic, when social isolation was at its peak, pediatric obesity rates in the United States rose to 22.4% among children ages 2-19 years (Robert Wood Johnson Foundation, n.d.).

Despite the increasing rates of pediatric obesity, barriers to treatment persist. Though clinical practice guidelines are inconsistent, healthcare providers agree that treating pediatric obesity and modifying lifestyle behaviors, such as eating patterns and frequency of physical activity, should be prioritized (Styne et al., 2017). Current clinical practice guidelines advocate for a multi-faceted, family-centered care model that encompasses nutrition, physical activity, mental health treatment, medication, and surgical interventions, while delivering care that addresses social determinants of health in such a way to avoid stigmatization of families (Hampl et al., 2023). Comorbidities of pediatric obesity include type 2 diabetes, hypercholesterolemia, hypertension, fatty liver disease, sleep apnea, asthma, and orthopedic issues, which not only impact physical health but also quality of life (US Preventative Task Force, 2017). Children with obesity are more likely to develop mental health concerns, such as anxiety, depression, disordered eating, and substance abuse. They are more likely to encounter bullying and body shaming at school, which may lead to increased school absences (Styne et al., 2017). However, treatment in a pediatric weight management clinic has been shown to reduce these risk factors.

Data published by the US Preventative Task Force (2017) suggest that intense behavioral interventions are effective in the treatment of weight management while acknowledging a lack of evidence to support less intense interventions. Guidelines set forth by clinical experts recommend 26 contact hours over the course of a 3–12-month period of treatment (Hampl et al., 2023). Family-centered interventions that focus on intense health behavior modification and lifestyle changes are recommended for the treatment of pediatric obesity with studies showing that family involvement has a significant effect on weight loss (Hampl et al., 2023; Styne et al.,

2017). While genetics may play a role in some cases of obesity, the predominant risk factors for obesity include consumption of energy-dense foods, poor sleep, excessive screen time, sedentary lifestyle, and stress (National Heart, Lung, and Blood Institute, 2022). A family-centered pediatric weight management clinic addressing these factors has the potential to improve the health of the community.

Obesity in general costs the United States about $173 billion dollars per year (CDC, 2021b), with $14 billion spent on pediatric obesity alone (Robert Wood Johnson Foundation, n.d.). On average, the lifetime cost of healthcare is approximately $19,000 more for an obese child as compared to a non-obese child (Finkelstein, 2014). Efforts aimed at reducing pediatric obesity will result in fewer co-morbidities, improved quality of life, and reduced healthcare costs.

Problem Statement

With a rising pediatric obesity rate, the need for specialty treatment that focuses on evidence-based family centered interventions is evident. A program evaluation was performed to evaluate the effectiveness of a pediatric weight management program at Ascension Peyton Manning Children's Hospital subspecialty clinic in Evansville, IN.

Organizational "Gap" Analysis of Project Site

In the state of Indiana, 33.9% of children ages 10-17 years are considered obese or overweight (Beacon Health System, 2021), with 28% of children considered overweight or obese in Vanderburgh and surrounding regional counties (Welborn Baptist Foundation, 2021). Within the community, there is a lack of specialized treatment for pediatric obesity, with the closest weight management clinic being three hours away. Once a co-morbidity is identified, a child

may receive specialized treatment within the pediatric subspecialty clinics. However, prior to the development of a co-morbidity, there are no specialized treatment options available.

In response, the pediatric gastroenterology clinic developed an evidence-based, multi-disciplinary pediatric weight management clinic called "All IN Wellness" to focus on lifestyle modifications addressing nutrition, sleep, screen time, and physical activity. This program addresses multiple quality health measures including a measure set forth by the Institute for Healthcare Improvement (2021). This measure aims to increase self-management, behavioral change, and collaborative goal setting by 50%. The program also addresses the Healthy People 2030 aim to "reduce the proportion of children and adolescents with obesity" (NWS-04) within the general population to a target level of 15.5% or lower, an improvement from the current rate of 19.7% (Office of Disease Prevention and Health Promotion (OASH), n.d.). "All IN Wellness" will increase access to specialized healthcare for pediatric patients with obesity, aiming to improve health outcomes and healthcare costs in the community.

Review of the Literature

Search Methods

In this review of the literature, articles were reviewed to assess the available evidence and attempt to identify any gaps within the literature regarding the effectiveness of family-centered pediatric weight managements programs on behavioral changes, quality of life, and anthropometric markers. A literature review was performed using CINAHL, PubMed, and Scout in June 2022. MeSH terms included family-centered care, pediatric obesity, pediatric weight management program, and family-centered weight management program.

Initially, a search was completed within the above-mentioned databases using the MeSH terms "family-centered care AND pediatric obesity". The search was limited to peer reviewed

articles with abstracts and those with full text available. Search results were limited to 2017-2022, resulting in 407 articles. Two additional searches were completed using the remaining MeSH terms, resulting in an additional 82 articles. After removing duplicates, a total of 299 articles remained. Systematic reviews and metanalysis were removed, yielding 258 articles. Clinical guidelines were then removed, and the article titles were searched for MeSH terms to ensure the subject of the article was focused on family-centered care specific to pediatric obesity, leaving 39 articles for review (see Figure 1). Articles with a level of evidence VI-VII were eliminated. Finally, nine articles were selected for review.

Study Design

All nine articles focused on aspects of family-centered care in relation to the treatment of pediatric obesity or compared a family-based intervention to a parent-only intervention or other controls. Studies ranged in sample size from 9 to 652 patients; occurred in medical offices, schools, and community centers; involved varying interventions and follow up periods; and possessed a low risk for bias. Study designs included randomized control trials, quasi-experimental designs, and cohort designs. Statistical analysis was completed in all but one study; seven of the remaining eight exhibited statistically significant results ($p \geq 0.05$).

Study Aims and Setting

All studies sought to evaluate family-centered care and its effects on pediatric obesity. Studies aimed to describe the following: anthropometric data such as BMI (children and parents); behaviors, such as diet and screen time; Quality of Life scores; environmental factors; physical activity levels; program engagement; factors related to program success; and sustainability of change. Studies were conducted in a variety of settings, such as clinics, community centers, and schools.

Outcomes: BMI

Of the four studies conducted in a clinical setting, three studies showed clinically significant changes to BMI or BMI z-scores (zBMI) post-intervention when compared to baseline (Else et al., 2021; Vidmar et al., 2019; Lipton-Inga et al., 2022). Bianchi-Hayes et al. (2018) did not measure BMI but rather examined effects of goal setting and physical activity with adolescent-parent dyads in a 10-week intervention, looking at self-reported weight loss, success in meeting goals, step counts, and improvements in healthy behaviors. This study noted that self-reported weight loss was not statistically significant. Else et al. (2021) showed statistically significant reduction in BMI across the intervention and both control groups. The intervention group did experience increased weight loss when compared to the referred control group but not the age-matched control group.

Many factors seemed to affect patient success throughout these studies. Else et al. (2021) noted higher weight loss in females than males while Vidmar et al. (2019) found that males were more likely to complete a program and obtained better reduction in BMI. These two studies also cited additional factors influencing BMI changes. Else et al. (2021) noted increased weight loss among younger children when compared to teens, while Vidmar et al.(2019) observed that youth with lower BMIs and no co-morbidities at baseline experienced a higher reduction of BMI post-intervention. Vidmar et al. (2019) also noted that age, ethnicity, insurance status, and parental factors (e.g., obesity, type 2 diabetes, psychiatric disorders) did not affect or predict BMI changes. Similarly, Lipton-Inga et al. (2022) found no significant predictors of zBMI changes. Though Bianchi-Hayes et al. (2018) did not measure BMI directly, the authors observed that adolescents' levels of success in achieving weight loss program goals were directly proportional to their parents' levels of success.

Within the three community-based studies, one study that set out to track BMI was unable to analyze data due to missing data and variability in measurements (Bach et al., 2021). The remaining two studies based on community interventions did not reveal statistically significant changes to zBMI post-intervention (Perdew et al., 2021; Zoellner et al., 2022). Zoellner et al. (2022) described a greater zBMI reduction in the low intensity parent-only group when compared to the family-based group, though neither was statistically significant.

The two remaining studies represent a comparison of clinical verses community setting and an unknown setting (Butte et al., 2017; Hayes et al., 2019). Butte et al. (2017) described results in age groups of 2-5, 6-8, and 9-12 years of age. This randomized control trial compared a 12-month community-centered weight management program to a primary care-centered program (Butte et al., 2017). Among children ages 2-5 years, there was no change in the percentage of the 95th percentile of BMI (%BMI_{p95}) overall. However, this group did experience a statistically significant change within the community program intensive phase with significant rebound in the transition phase. Among the 6–8-year-old group, a statistically significant reduction in %BMI_{p95} occurred within the community setting in the intensive phase with a rebound in the community group in the transition phase. The 9–12-year-old group experienced a statistically significant reduction in %BMI_{p95} in the community and primary care groups during the intensive phase with maintenance of %BMI_{p95} in the intervention group only (Butte et al., 2017). Hayes et al., (2019) did not use BMI as an independent result but rather examined factors influencing reduction in BMI, including the usage of electronic devices, which decreased from baseline to post-intervention. The authors also found a positive correlation between decreased consumption of energy-dense foods and improvements to zBMI scores (Hayes et al., 2019).

Outcomes: Behavioral Change and Quality of Life

Two of the four studies based in a clinical setting examined behavioral changes post-intervention (Bianchi-Hayes et al., 2018; Lipton-Inga et al., 2022). Bianchi-Hayes et al. (2018) noted that, among the seven adolescent-parent dyads that completed the study, all parents reported changes to overall health and fitness, with six of them reporting improvements in children's health and five reporting that other family members joined them in making healthy lifestyle modifications. Lipton-Inga et al. (2022) noted multiple statistically significant changes in healthy behaviors including increased proficiency in label reading, increased likelihood of children choosing healthy options, increased consumption of fruits and vegetables, increased water intake, reduced consumption of sweets and sugar-sweetened beverages, increased outdoor activity time, decreased screen time, increased frequency of family exercise activities, and increased overall levels of physical activity. In addition to measuring behavioral changes, the studies also looked at correlations and barriers to changes. Bianchi-Hayes et al. (2018) found that weekly step count and active minutes correlated between parent and adolescent dyads. Identified barriers included love of eating, frequent feeling of hunger, frustration when given unpreferred foods, eating out of boredom, and increased screen time (Lipton-Inga et al., 2022). Parents and adolescents reported improved health, increased episodes of fun, and increased time together (Bianchi-Hayes et al., 2018).

The three studies based in a community setting all looked at impact of the intervention on healthy behaviors or beliefs about healthy behaviors. Two studies reported improvement in healthy eating behaviors (Bach et al., 2021; Perdew et al., 2021) while the remaining study noted no significant changes in healthy eating behaviors (Zoellner et al., 2022). All three studies noted increased levels of exercise, two of them specifically noting an increase in moderate to vigorous physical activity (Perdew et al., 2021; Zoellner et al., 2022). Bach et al. (2021) described

enhanced beliefs of families that they can he healthier if they work together, aspire to reach goals despite barriers, create healthy balanced meals, improve health by drinking water, eat more fruits and vegetables, and increase physical activity, all while enjoying their favorite foods. Perdew et al. (2021) reported a statistically significant improvement in self-regulation and parental support while Zoellner et al. (2022) saw an increased number of healthy days associated with the lower intensity family-based intervention when compared to the higher intensity intervention. Perdew et al. (2021) measured improvements in screen time but did not find a statistically significant change in this area. Butte et al. (2017) examined quality of life using the Pediatric Quality of Life Inventory as well as the CDC Strength and Difficulties Questionnaire, which evaluates for conduct problems, attention deficit hyperactivity disorder (ADHD), and emotional and social issues. Among children ages 2-5, the authors detected a statistically significant decrease in the Strength and Difficulties scores in the intensive phase. In the 6–8-year-old group, there was a statistically significant decrease in the Strength and Difficulties scores and an increase in Pediatric Quality of Life scores in both groups and phases. Pediatric Quality of Life scores increased, and CDC Strength and Difficulties Questionnaire decreased among 9–12-year-olds in both groups during the intensive phase. Quality of Life scores continued to improve in the transition phase for the intervention group only (Butte et al., 2017). Of the community-based studies, only Zoellner et al. (2022) examined quality of life. Authors utilized the Pediatric Quality of Life Inventory and found improved overall scores.

Discussion

This review of the literature shows interesting results regarding the effects of family-centered care on the treatment of pediatric obesity and on various factors that influence success in these programs. The most interesting factor attributed to program completion is the correlation

of adolescents' success with parental success, suggesting that family-based care has a greater impact on child success than programs focusing on parents or children only (Bianchi-Hayes et al., 2018). Decreasing intake of low nutrient-dense foods and decreasing screen time also seem to predict more successful outcomes post-intervention (Hayes et al., 2019).

The results of the nine reviewed studies show inconsistency with respect to changes in BMI. However, all studies consistently reported healthy behavioral changes and improvements in Quality of Life scores. Of the six studies measuring changes in BMI, three of them found statistically significant changes post-intervention, two found no statistically significant changes, and one found mixed results among age groups in the study. Interestingly, the three studies that did show improvement in BMI were all clinical studies; the community-based studies found no statistically significant changes in BMI, and the study that compared clinical and community settings revealed mixed results.

Limitations

There are multiple limitations within the studies. For example, five studies possessed small sample (N=27, 18, 60) or population sizes, reducing generalizability to larger population groups. Another limitation relates to attrition rates among studies, causing reduced sample sizes through poor compliance, attendance, and loss to follow up. Attrition rates are a frequent hinderance to pediatric weight management programs with average attrition being 27-73% (Berry et al., 2021). BMI measurement methods were also inconsistent, limiting comparison between studies. Body mass index can be measured straightforward as body mass index, BMI z-scores, or BMI as the percentage of the 95th percentile. Finally, the heterogenous nature of pediatric weight management programs in the literature limits the ability to translate them into the clinical setting.

Evidence-based Practice: Verification of Chosen Option

This scholarly project completed a program evaluation of a newly developed, evidence-based family-centered pediatric weight management clinic, called "All IN Wellness" at Ascension Peyton Manning Children's Hospital Evansville by evaluating the program goals including reduction of BMI, increased healthy behaviors, and increased quality of life. This project asked the question, "How effective is a family-centered pediatric weight management program at improving behavioral, quality of life, and anthropometric markers during the initial eight weeks of treatment?"

Theoretical Framework of Evidence-based Practice Model

Pediatric obesity is a rising problem worldwide. While research suggests family-centered care is more effective than traditional dietitian visits alone (Styne et al., 2017), guidelines on the treatment of pediatric obesity are complex and inadequately address the barriers to treatment of this multifactorial disease (Hampl et al., 2023). The guidelines do, however, reiterate that behavioral changes leading to lifestyle modification should be the focus of treatment. Furthermore, guidelines must address the implications of co-morbidities and their impact on quality of life (US Preventative Task Force, 2017).

The transtheoretical model of change is a middle range theory that explains the six stages of behavioral change that a person must go through to make long-term lifestyle changes (LaMorte, 2019). The transtheoretical model of change (TTM) discusses the six steps of behavioral change including precontemplation, contemplation, preparation, action, maintenance, and termination (LaMorte, 2019), with the goal of this program being maintenance. An effective weight management program should be able to guide a patient through each phase of the process to encourage behavioral changes with a working concept as seen in Figure 2. When patients are

referred to an obesity program, they are in one of the first three steps of behavioral change: precontemplation, contemplation, or preparation. In the "All IN Wellness" program, patients were introduced to the program and assessed for readiness to change at the initial visit. Patients in the precontemplation phase were given additional information and encouraged to return, while patients in contemplation and preparation phases met with the health coach and dietitian and received program information and encouragement to proceed at the first clinic visit.

Within the stages of behavioral change, there are several processes that occur to help people make or maintain changes. These can include consciousness raising, dramatic relief, self-reevaluation, environmental reevaluation, social liberation, self-liberation, helping relationships, counterconditioning, reinforcement management, and stimulus control (LaMorte, 2019). Each week throughout the program, patients were led through several of these processes including discussion of healthy behaviors, introduction to goal setting, evaluation of the environment, and introduction to a supportive community. As patients meet with the health coach and dietitian, they were involved in individualized goal setting to encourage attainable achievements. The dietitian and health coach were trained in motivational interviewing to lead patients through the stages of change. In a systematic review by Suire (2020) looking at motivational interviewing at the parental level, most of the studies reviewed showed significant changes in both anthropometric and non-anthropometric data with motivational interviewing. Through program interventions, behavioral changes began to occur, and patients moved into the action phase as they started to understand the benefits of these changes to their own lives while becoming more self-sufficient in navigating healthy behaviors.

In a Korean study involving a comparison of a usual care group and nutritional care group examining the impact of self-efficacy and stage of change, while addressing the

transtheoretical model of change, authors suggest that increased self-efficacy of patients with individualized nutritional education can lead to a greater reduction in BMI when treating pediatric obesity (Lee et al., 2020). Kaufman et al. (2020) noted motivational interviewing as the most effective intervention for behavioral changes. Self-efficacy and motivation are important components in the behavioral change process. The eight-week intervention discussed above focused on increasing self-belief by individualized objectives within the program, specific to the patient's needs. In a study by Boff et al. (2020), self-efficacy and motivation were addressed within the intervention group using a TTM approach to increase healthy eating habits and physical activity. After 12 weeks of motivational meetings, readiness to change scores increased, noting the progression among the six steps of behavioral change (Boff et al., 2020). In another study by Ham et al. (2016), TTM-based counseling and exercise interventions showed BMI maintenance and increased self-efficacy in obese and overweight children. Self-efficacy seems to be the driving force behind individual motivation along the continuum of change (Boff et al., 2020).

Evaluating the treatment of pediatric obesity through the lens of the theoretical model of change is important to help bridge the theory-practice gap in the nursing profession. The theory-practice gap is the separation of the clinical or skilled element of nursing with theoretical knowledge (Greenway et al., 2019). For many years, treatment for obesity has been looked at through a scientific standpoint, caloric intake verses caloric expenditure. It is clear, however, that obesity is more complex, yet traditional nutritional treatment still exists, and the "calorie in, calorie out" method is still widely used. In addressing pediatric obesity through a theoretical standpoint, interventions can target the whole person exploring physical, mental, and emotional health and addressing barriers to change such as finances, education, and accessibility.

When aiding patients to sustainable behavioral changes the transtheoretical model of change incorporates the idea of patients helping themselves rather than patients relying on a mathematical equation to guide their nutritional choices. Self-awareness, self-evaluation, and self-liberation are all aspects of the transtheoretical model of change that can empower patients to progress along the continuum of behavioral change (LaMorte, 2019). This is an important step in addressing pediatric obesity and focusing not only on numerical change in BMI but the overall wellness of the patient.

Goals, Objectives, and Expected Outcomes

"All IN Wellness" is a multi-disciplinary clinical pediatric weight management program that approaches the treatment of obesity with family-centered care provided by gastroenterology specialists, a registered dietitian, a wellness coach, a psychologist, and physical and occupational therapists that aims to decrease BMI, increase overall healthy behaviors, and improve quality of life. The goal of the program evaluation was to evaluate the effectiveness of "All IN Wellness" on behavioral changes, quality of life, and anthropometric markers in the first eight weeks of treatment.

The "All IN Wellness" clinic opened to patients June 13th, 2022. Anthropometric data was collected at clinic visits during the program and recorded in visit notes at baseline and again after eight weeks. Patients answered questionnaires regarding their healthy behaviors and quality of life at baseline and after eight weeks as well, which were scanned into the medical record chart as a point of outcome data for the program. Anthropometric and questionnaire data were extracted from the medical record, entered into a HIPAA compliant RedCap database, and reviewed to assess program effectiveness.

Methods

Project Design

This DNP project was designed as a retrospective program evaluation per the CDC program evaluation framework to provide outcome data for the "All IN Wellness" clinic. Quantitative data was extracted from the electronic medical records of patients that completed the initial eight weeks of the pediatric weight management program. By examining key indicators of a program, one can measure outcome data to determine the effectiveness of the intervention and ensure that the program is achieving its intended goals (CDC, 2021c).

Project Site and Population

The project site was the pediatric weight management clinic in the pediatric subspecialty clinic at the Center for Children at Ascension Peyton Manning Children's Hospital Evansville. This center resides in Evansville, which is the third largest city in Indiana and located in Vanderburgh county. It is a hospital-based outpatient pediatric clinic that offers subspecialty services in the areas of gastroenterology, neurology, endocrinology, pulmonology, urology, hematology, medical nutrition therapy, child abuse, and complex care. These clinics provide services to patients ages birth to 18 years of age. The Center for Children serves a diverse population and provides services to patients from southern Indiana, southern Illinois, and northern and western Kentucky. The newly formed "All IN Wellness" clinic serves the same population as other clinics within the Center for Children, but inclusion criteria for the program includes patients ages 2-18 years old, with either a BMI $\geq 95^{th}$ percentile or the presence of an obesity related co-morbidity, regardless of BMI percentile. This program evaluation included patients that completed the first eight weeks of the "All IN Wellness" program, which had an initial enrollment goal of 10 participants.

The pediatric weight management clinic provides multiple services to patients including medical evaluations, dietitian services, wellness coaching, referrals, visits with pediatric psychology, and pediatric physical and occupational therapists. It is an eight-week program with one visit to clinic per week, focusing on nutrition, sleep, mindfulness, screen time, mental health, and physical activity with regular follow up with the dietitian for at least one year but up to 3 years as needed, with specialty follow up as needed. The wellness coach also takes families on a tour of a local grocery store that has partnered with the program, and patients are able to attend a cooking class through our county extension service program partner. The most significant barriers to the implementation of this project were inadequate clinical staffing and provider schedules, as coordinating multiple provider schedules within a short period of time can be very difficult. Clinic staff worked closely with administration to help coordinate provider scheduling. Attrition rate was an expected barrier as well, as weight management programs often have high dropout rates. The clinic did have a considerable list of available patients which provided several opportunities for patients to complete the program. A letter of support for this project from the medical director and practice operations manager was obtained (see Appendix A).

Measurement Instruments

For this program evaluation, a chart review of questionnaires, anthropometric markers, and demographic data available in the medical record system was performed. During the pediatric weight management program, the clinic utilized a behavioral assessment questionnaire and a quality-of-life questionnaire specific to pediatrics. Permission was requested for use of these questionnaires in clinical practice to collect outcome data, which was granted, as seen in Appendix B and C. In order to use the Kid-KINDL Quality of Life Questionnaire, a collaboration agreement was signed, as seen in Appendix D.

The Behavior Change Assessment was used to measure behavioral changes. This is a 10-item questionnaire with a Likert scale, pictured in Appendix E. Reliability was tested with an overall Cronbach's alpha of 0.71 showing good reliability (Paek et al., 2021). The researchers were also able to distinguish children with higher body mass index from children with a healthy BMI showing validity with the known group method (Paek et al., 2021).

The second measure, quality of life, was measured with the Kid-KINDL Quality of Life Questionnaire. As self-efficacy increases and behavioral changes ensue, one would expect to see increased Quality of Life scores. The Kid-KINDL is a 24-item questionnaire scored with a Likert scale. The validity and reliability of this questionnaire was examined by Erhart et al. (2009) with a study showing good reliability with the Cronbach's alpha score of 0.86 for parents and 0.83 for children overall. This study also notes that researchers were able to distinguish between children with and without additional health care needs from questionnaire results, showing validity through the known-group method (Erhart et al., 2009). There are multiple forms of this questionnaire that were used in clinic for ages 3-18 years old. There are multiple questionnaires divided by age group and parents. Examples of the child questionnaire and parent version (child ages 7-13 years and parents of 7-17 years) are found in Appendices F and G.

Anthropometric data, including weight, BMI, body fat mass and percentage, skeletal muscle mass, and visceral fat, were measured in clinic using an InBody Body Composition Analyzer. Blood pressure was measured manually or with an electronic blood pressure device upon check in at clinic visits. All the data, including questionnaires and anthropometric markers, were collected in the clinic at baseline and at week eight. Athena, which is the facility's current electronic medical record system, was utilized to retrieve data. The facility's HIPAA compliant

RedCap database was then used to help collect data and download de-identified data into Excel for data analysis.

Data Collection Procedures

For this project, the CDC's framework for program evaluation was utilized. This framework provides a custom stepwise approach to help evaluate a program or public health effort with six steps including engaging stakeholders, describing the program, focusing the evaluation design, gathering credible evidence, justifying conclusions, and ensuring use and sharing lessons learned (CDC, 2021a).

Engaging Stakeholders

The project director, clinic staff, and administrators discussed the end goals and desired outcomes of the new pediatric weight management program. It is important to evaluate new programs to ensure their effectiveness on the population being treated.

Describing the Program

As previously discussed, the pediatric weight management program, "All IN wellness" delivers a multi-specialty, family-centered approach to the treatment of pediatric obesity. Data collected throughout this program focused on healthy behaviors, anthropometric markers, and quality of life. This program is important to the Evansville and surrounding areas, as obesity rates are higher than the national average.

Focusing the Evaluation Design

The program evaluation focused on the goals of the clinic, which include increasing healthy behaviors, improving quality of life, and, over time, decreasing BMI, body fat, and visceral fat. To create sustainable lifestyle changes, one must first improve healthy behaviors to proceed to improved quality of life and BMI. A successful weight management program should

guide patients along the continuum of behavioral changes as addressed in the transtheoretical model of change (LaMorte, 2019).

Gathering Credible Evidence

Data collection for this project included anthropometric data, healthy behaviors, and quality of life.

Justifying Conclusions

Clinical practice guidelines for treating of pediatric obesity are inconsistent but suggest treatment should focus on sustainable lifestyle changes (Styne et al., 2017). The pediatric weight management clinic was designed to help families improve healthy behaviors, thus improving quality of life and decreasing the risk of co-morbidities or improving existing co-morbidities. A program of this nature is important to the overall health of the community to help lower pediatric obesity rates. This program evaluation developed the initial assessment of program effectiveness and served as outcome data that the clinic may use for additional funding, grants, and any improvements to increase quality of care for patients.

Ensuring use and sharing lessons learned

Once data was analyzed, it was presented to key stakeholders for ongoing discussions of improvements, growth, and funding for the continuation of the pediatric weight management program. As this is a new program at the facility, there were multiple learning experiences regarding operational items and patient-care factors that were reviewed and discussed to improve the program and the services provided.

Data Analysis

Descriptive statistics were initially used to analyze the demographic data. Descriptive statistics are used frequently in quantitative research and provide a summary of population data

(Trochim, n.d.). To analyze behavioral changes, Quality of Life scores, and anthropometric markers, paired t-tests were used, as this test compares data between groups before and after an intervention (Bevans, 2020). P-values were then used to determine if the measure outcomes were statistically significant (Bevans, 2021). Interval data is required for t-tests, and the overall comparison of survey results from Likert scales fits this criterion (Bhandari, 2020). Data analysis was completed through Excel as this was easily accessible and capable of performing both paired t-tests and p-values.

Cost-Benefit Analysis/Budget

There were no costs associated with this project. The effectiveness of the pediatric weight management program was evaluated through chart review. This project serves as the first set of outcome data for the new program and was discussed with key stakeholders to help the program with additional funding and grants in the future.

Timeline

This project took place from August 2022 through November 2022. IRB approval was obtained during the summer of 2022, and data collection was initiated on October 1, 2022. Data was collected for approximately twelve weeks, ending in December 2022. Data analysis was completed in February 2023. The information was then presented in March 2023 to key stakeholders as noted in Table 1.

Ethical Considerations/Protection of Human Subject

The University of Alabama (UA) Institutional Review Board approval was obtained prior to initiating the project. This project was also approved by the Ascension St. Vincent Indiana IRB before initiating data collection. Patients are protected through HIPAA which ensures protected private health information and protects the privacy of the patients (CDC, 2018).

Standards of care for the outpatient pediatric subspecialty care were carefully followed. The data that was collected in this project was deidentified. There were no additional risks to patients within this project as this was a program evaluation, and data was collected from the electronic medical record (EMR). Patients were not asked to do anything outside of what is expected within standard clinical care. Data collected from the EMR was put in the clinic's HIPAA compliant RedCap database made specifically for tracking outcome data for the clinic. From RedCap, deidentified information was downloaded into Excel sheets and stored electronically in a HIPAA-safe UA Box. Following completion of this project, data will be destroyed per IRB protocols.

Results

Demographic Data

Descriptive statistics were initially used to analyze program data. There were twelve patients enrolled in the program with the potential to complete the program by October 1, 2022. Of the twelve patients, eight of them completed the program, creating a 67% retention rate. Ages ranged from 7 years to 17 years with the mean age being 13 years. Seventy five percent of patients were female and 25% male. Eighty-three percent of patients were white, 8% were black/African American, and 8% chose "race unknown". Patients were primarily insured with Medicaid at 67%, while 33% had private insurance. All patients were severely obese with a BMI $\geq 99^{th}$ percentile with the average BMI being 35.8.

Anthropometric data was collected at week one and week eight for pre- and post-treatment assessment. There was no statistically significant change in BMI ($p = 0.15$). Though this does not indicate the hypothesized goal of a decrease in BMI, it may clinically represent BMI maintenance. There were also no statistically significant changes in weight ($p = 0.09$), BMI

percentile ($p = 0.18$), skeletal muscle mass ($p = 0.32$), percent body fat ($p = 0.14$), visceral fat level ($p = 0.09$) or blood pressure (systolic, $p = 0.15$, diastolic, $p = 0.19$). Despite a possible maintenance of BMI, there was a statistically significant increase in body fat mass throughout the initial eight weeks with $p = 0.01$. This may represent the importance of measuring body composition in this patient population in relation to BMI changes for optimal analysis.

Behavioral Assessment Data

Behavioral assessment questionnaires were analyzed to determine if any significant behavioral changes had occurred (Figure 3). The overall score for the Behavioral Assessment was statistically significant with $p = 0$, indicating an improvement in overall healthy behaviors among patients. There were 3 additional questions with statistically significant results including decreased TV/video games on weekend days ($p = 0.01$), decreased frequency of fast food ($p = 0.05$), and decreased frequency of snacks, candy, and French fries ($p = 0.02$).

Quality of Life Data

Quality of Life scores were measured with the KID-KINDL Quality of Life Questionnaire in three parts. Parents completed a specific version of the questionnaire in reference to their child. Though eight patients completed the program, only five parents fully completed the questionnaires about their children with results that were not statistically significant ($p = 0.054$). Though not statistically significant, the mean scores did increase, showing a clinically significant improvement in quality of life with the mean score at week one of 58.75 and 66.25 at week eight. This result was likely impacted by power and may be more significant than analysis shows. Adolescents ages 14-17 completed the adolescent version of the questionnaire independently, with help from the dietitian or health coach as needed. Overall adolescent Quality of Life scores were not statistically significant ($p = 0.44$). The results do

however show that total Quality of Life scores for this age group decreased overall with a mean of 61.78 at week one and 60.75 at week eight. The childhood version of the questionnaire was completed by children ages 7-13 years with the help of the dietician or health coach. The overall Quality of Life score in this age group was again not statistically significant with $p = 0.13$ but reflected the overall parent scores, showing a clinically significant increase with the mean score at week one of 53.94 and 69.38 at week eight.

Discussion

Behavioral Assessment

Pediatric obesity is a multifactorial chronic disease warranting a complex treatment program (Hampl et al., 2023). The results of this evaluation reflect the complexity of this disease. There were significant increases in overall healthy behaviors, and while there were no significant changes in BMI, Styne et al. (2017), notes that BMI maintenance in obese children may be as important as weight loss in adults. Clinically this may represent a very important trend within the first eight weeks of treatment and indicates that the program is effective in improving healthy behaviors in this population. Increasing healthy behaviors should be at the forefront of a pediatric weight management program (Hampl et al., 2023).

Anthropometric Data

Body mass index is a standard screening method for overweight and obesity in children, yet it cannot distinguish the difference of body fat mass verses lean muscle mass in children (Styne et al., 2017). Despite the BMI maintenance that was suggested in this study, body fat mass increased significantly among program participants. This indicates that a more complex measurement of anthropometric data may be more informational when evaluating for a successful weigh management program. A recent study by He et al. (2023) investigates the

accuracy of BMI verses body fat percentage and suggests that body fat percentage is a better indicator of cardiovascular and metabolic risk factors in children with obesity than is BMI. Research suggests that this is true as early as infancy, as infants with higher amounts of body fat are at increased risk of obesity prior to the age of 6 (Moore et al., 2020). These findings are relevant to not only the treatment, but also the screening of children with overweight and obesity, suggesting that research in this area should focus more on body fat measurements with bioelectrical impedance equipment rather than tradition BMI.

Quality of Life

Pediatric obesity is associated with multiple co-morbidities that may impact the physical, mental, and social aspects of life (Hoedjes et al., 2018). Though not statistically significant, child and parent-reported Quality of Life scores did improve in the initial eight weeks of treatment, which may be clinically significant. These results are impacted by power as the sample size is very small. However, results suggest that the program can be successful in increasing quality of life with the treatment of pediatric obesity from the parent and child perspective. The Quality of Life score did decrease among adolescents during the program. This may have been affected by samples size as well, but it also suggests the impact of obesity in this age group. Adolescents with obesity are more likely to be socially isolated from peers (Chen & Lu, 2022), which may have a more significant negative effect on the overall Quality of Life scores for this age group.

Limitations

This study had several limitations including small sample size and missing data. Healthy behaviors and Quality of Life scores were evaluated through questionnaires which were self-reported, leading to incomplete questionnaires and thus missing data that was not included in data analysis. Though there were a few statistically significant results, the remainder were likely

affected by the small sample sizes and could have been more positively impacted had there been a higher number of participants. Due to attrition rates and the financial burden of pediatric weight management programs, it is difficult to study larger samples sizes over longer periods of time, but this may be key to understanding sustainability of behavioral changes throughout these programs. In order to improve compliance and dropout rates, additional studies regarding attendance barriers and readiness to change are also needed (Zoellner et al., 2022), as well as further research on long-term outcomes of follow up care.

Implications

This program evaluation provides preliminary data for a multi-disciplinary, family-centered, pediatric weight management program and provides the evidence that this program successfully led to positive behavioral changes, BMI maintenance, and increased child Quality of Life scores in the initial eight weeks of treatment. However, a major barrier to evaluating effectiveness of pediatric weight management programs is the uncertainty of knowing the most effective method of BMI measurement. There are inconsistent definitions of BMI z-scores. Weight stabilization may be just as important in children with obesity than significant changes in BMI z-scores or reduction in BMI (Zoellner et al., 2022). In fact, BMI z-scores may not be as applicable to very young children with severe obesity, as weight maintenance has been recommended as the initial treatment goal in preschool-aged children (Lipton-Inga et al., 2022). Over time, the importance of BMI changes within a weight management program may not be as important of a marker of success as improvements in behavioral changes (Else et al., 2021), suggesting that additional metrics should be evaluated in pediatric obesity programs to determine the best methods for evaluating effectiveness (Vidmar et al., 2019). There are also several factors that influence changes in BMI; future studies should incorporate research on environmental

factors both in and outside of the home and their impacts on family success throughout a weight management program (Hayes et al., 2019).

There is a significant gap in the literature on the effectiveness of specialty care for the treatment of pediatric obesity, yet it is imperative that patients with obesity receive early intervention to prevent co-morbidities. Vidmar et al. (2019) suggests that the severity of obesity at baseline is the biggest predictor of improvement in BMI status, noting that early intervention is essential. Early intervention may also be a key factor in preventing self-esteem issues in older children, which may hinder success in weight management programs (Else et al., 2021). Intense, multi-disciplinary clinics are scarce due to high attrition rates and the large financial burden on healthcare facilities to sustain these types of programs (Berry et al., 2021). This pediatric weight management program is unique, as the majority of visits are billable for providers. More research is needed to examine the sustainability and cost effectiveness of a billable pediatric weight management program.

It is challenging to get consistent, replicable results from family-based pediatric weight management programs, but study results do suggest that family-centered care is an effective way to create healthy lifestyle changes and improve quality of life. Family-centered weight management programs are effective in creating healthier lifestyles by improving dietary behaviors, decreasing screen time (Hayes et al., 2019), and increasing physical activity (Bianchi-Hayes et al., 2018; Perdew et al., 2021). The most effective setting, however, for pediatric family-centered weight management programs remains to be determined.

Approaching pediatric obesity with a family-centered intervention can improve health behaviors of not only the patients and parents, but of the entire family (Bach et al., 2021) and can increase quality of life in children suffering from a chronic disease (Zoellner et al., 2022; Butte et

al., 2017). Adolescents' success in achieving individualized health goals positively correlates with parental success (Bianchi-Hayes et al., 2018), thus reiterating the importance of incorporating family-centered care in the treatment of pediatric obesity.

Conclusion

This program evaluation supports continuation of the "All IN Wellness" program, with data analysis showing an increase in healthy behaviors and improved child Quality of Life scores and anthropometric data suggesting BMI maintenance in the initial eight weeks of treatment. As pediatric obesity continues to be a prominent healthcare dilemma, clinical practice guidelines remain inconsistent, and the lack of specialty treatment ensues. Research consistently demonstrates the positive effects of multi-factorial, family-centered care for the treatment of pediatric obesity. However, specific recommendations about the delivery of care, length of interventions, and sustainability of healthy changes remain to be standardized. It is imperative that outcome data be tracked from clinical and community programs on these issues. With additional research aimed at improving patient outcomes and creating sustainable results, the "All IN Wellness" program has the potential to decrease childhood obesity rates in the Evansville area and improve the overall health of the community at large.

References

Beacon Health System. (2021). *Healthy body: Obesity/overweight.* Beacon Community Impact. https://stateofchildhoodobesity.org/states/in/

Bach, M., Shenoi, S., Winger, K., & Hendriksz, T. (2021). Healthier together: A pilot study on the implementation of a novel family centered pediatric obesity prevention program. *Journal of Osteopathic Medicine, 121*(5), 513-520. https://doi.org/10.1515/jom-2020-0143

Berry, D., Rhodes, E., Hampl, S., Young, C., Cohen, G., Eneli, I., Fleischman, A., Ip, E., Sweeney, B., Houle, T., & Skelton, J. (2021). Stay in treatment: Predicting dropout from pediatric weight management study protocol. *Contemporary Clinical Trials Communications, 22,* 100799. https://doi.org/10.1016/j.conctc.2021.100799

Bevans, Rebecca. (2020, December 14). *An introduction to t-tests: Definition, formula, and examples.* Scribbr. https://www.scribbr.com/statistics/t-test/#:~:text=A%20t%2Dtest%20is%20a,are%20different%20from%20one%20another.

Bevans, Rebecca. (2021, January 7). *Understanding p-values: Definition and examples.* Scribbr. https://www.scribbr.com/statistics/p-value/#:~:text=P%2Dvalues%20are%20used%20in,to%20reject%20the%20null%20hypothesis.

Bhandari, Pritha. (2020, October 12). *Designing and analyzing a Likert scale: What, why, and how.* Scribbr. https://www.scribbr.com/methodology/likert-scale/#:~:text=Inferential%20statistics&text=For%20ordinal%20data%20(individual%20Likert,r%20correlation%20or%20t%2Dtests.

Bianchi-Hayes, J., Schoenfeld, E., Cataldo, R., Hou, W., Messina, C., & Pati, S. (2018). Combining activity trackers with motivational interviewing and mutual support to increase physical activity in parent-adolescent dyads: Longitudinal observational feasibility study. *JMIR Pediatrics and Parenting, 1*(1), e3. https://doi.org/10.2196/pediatrics.8878

Boff, R., Dornelles, M., Feoli, A., Gustavo, A., & Oliveira, M. (2020). Transtheoretical model of change in obese adolescents: MERC randomized clinical trial. *Journal of Health Psychology, 25*(13-14), 2272-2285. https://doi.org/10.1177/1359105318793189

Butte, N. F., Hoelscher, D. M., Barlow, S. E., Pont, S., Durand, C., Vandewater, E. A., Liu, Y., Adolph, A. L., Pérez, A., Wilson, T. A., Gonzalez, A., Puyau, M. R., Sharma, S. V., Byrd-Williams, C., Oluyomi, A., Huang, T., Finkelstein, E. A., Sacher, P. M., & Kelder, S. H. (2017). Efficacy of a community- versus primary care-centered program for childhood obesity: TX CORD RCT. *Obesity, 25*(9), 1584-1593. https://doi.org/10.1002/oby.21929

Centers for Disease Control and Prevention. (2018, September 14). *Health Insurance Portability and Accountability Act of 1996 (HIPAA).* Public Health Professionals Gateway: Public Health Law. https://www.cdc.gov/phlp/publications/topic/hipaa.html#:~:text=The%20Health%20Insurance%20Portability%20and,the%20patient's%20consent%20or%20knowledge.

Centers for Disease Control and Prevention. (2021a, April 9). *Evaluation Steps.* Program Performance and Evaluation Office (PPEO). https://www.cdc.gov/evaluation/steps/index.htm

Centers for Disease Control and Prevention. (2021b, June 23). *Health and economic costs of chronic diseases.* https://www.cdc.gov/chronicdisease/about/costs/index.htm

Centers for Disease Control and Prevention. (2021c, April 9). *Indicators.* Program Performance and Evaluation Office (PPEO). https://www.cdc.gov/evaluation/indicators/index.htm

Chen, D. & Lu, H. (2022). Social alienation of adolescents with obesity in classrooms: A multilevel approach. *Journal of Adolescence, 94*(1), 81-91. https://doi.org/10.1002/jad.12001

Else V., Chen Q., Cortez A., & Koebnick C. (2021) Effectiveness of a family-centered pediatric weight management program integrated in primary care. *The Permanente Journal, 25,* 1. https://doi.org/10.7812/TPP/20.101

Erhart, M., Ellert, U.., Kurth, B., & Ravens-Sieberer, U. (2009). Measuring adolescents' HRQoL via self reports and parent proxy reports: An evaluation of the psychometric properties of both versions of the KINDL-R instrument. *Health and Quality of Life Outcomes, 7*(77). https://doi.org/10.1186/1477-7525-7-77

Finkelstein, E., Graham, W., & Malhotra, R. (2014). Lifetime direct medical costs of childhood obesity. *Pediatrics, 133*(5), 854-862. https://doi.org/10.1542/peds.2014-0063

Greenway, K., Butt, G., & Walthall, H. (2019). What is a theory-practice gap? An explanation of the concept. *Nurse Education in Practice, 34,* 1-6. https://doi.org/10.1016/j.nepr.2018.10.005

Ham, O., Sung, K., Lee, B, Choi, H, & Im, E. (2016). Transtheoretical model based exercise counseling combined with music skipping rope exercise on childhood obesity. *Asian Nursing Research, 10*(2), 116-122. https://doi.org/10.1016/j.anr.2016.03.003

Hampl, S. Hassink, S., Skinner, A., Armstrong, S., Barlow, S., Bolling, C., Edwards, A., Eneli, I., Hamre, R., Joseph, M., Lunsford, D., Mendonca, E., Michalsky, M., Mirza, N., Ochoa., E., Sharifi, M., Staiano, A., Weedn, A., Flinn, S….Okechukwu, K. (2023). Executive summary: Clinical practice guideline for the evaluation and treatment of children and adolescents with obesity. *Pediatrics, 151*(2), e2022060641. https://doi.org/10.1542/peds.2022-060641

Hayes, J. F., Balantekin, K. N., Conlon, R. P. K., Brown, M. L., Stein, R. I., Welch, R. R., Perri, M. G., Schechtman, K. B., Epstein, L. H., Wilfley, D. E., & Saelens, B. E. (2019). Home and neighborhood built environment features in family-based treatment for childhood obesity. *Pediatric Obesity, 14*(3), e12477. https://doi.org/10.1111/ijpo.12477

He, X., Zhu, Z., Zang, J., Wang, Z., Liao, P., Wang, W., Shi, Y., & Fu, C. (2022). Percent body fat, but not body mass index, is associated with cardiometabolic risk factors in children and adolescents. *Chronic Disease and Translational Medicine,* 1-11. https://doi.org/10.1002/cdt3.54

Hoedjes, M., Makkes, S., Halberstadt, J., Noordam, H., Renders, C., Bosmans, J., Baan-Slootweg., O., & Deidell, J. (2018). Health-related quality of life in children and adolescents with severe obesity after intensive lifestyle treatment and at 1-year follow-up. *Obesity Facts, 11*(2), 116-128. https://doi.org/10.1159/000487328

Institute for Healthcare Improvement. (2021). *Improvement stories: Reducing obesity with improved self-management support.* http://www.ihi.org/resources/Pages/ImprovementStories/ReducingObesitywithImprovedSelfMgmtSupport.aspx

Kaufman, T. K., Lynch, B. A., & Wilkinson, J. M. (2020). Childhood obesity: An evidence-based approach to family-centered advice and support. *Journal of Primary Care & Community Health, 11*(1),1-6. https://doi.org/10.1177/2150132720926279

LaMorte, Wayne. (2019). *The transtheoretical model (stages of change).* Behavioral Change Models. https://sphweb.bumc.bu.edu/otlt/mph-modules/sb/behavioralchangetheories/behavioralchangetheories6.html

Lipton-Inga, M., Manzanarez, B., Vidmar, A. P., Garcia, S., Fink, C., Iverson, E., & Geffner, M. E. (2022). Kids N fitness junior: Outcomes of an evidence-based adapted weight management program for children ages three-seven years. *Childhood Obesity, 18*(1), 56-66. https://doi.org/10.1089/chi.2021.0090

Moore, B., Harrall, K., Sauder, K., Glueck, D., Dabelea, D. (2020). Neonatal adiposity and childhood obesity. *Pediatrics, 146*(3), e20200737. https://doi.org/10.1542/peds.2020-0737

National Heart, Lung, and Blood Institute. (2022, March 24). *Childhood obesity.* Overweight and Obesity. https://www.nhlbi.nih.gov/health/overweight-and-obesity/childhood-obesity

Office of Disease Prevention and Health Promotion. (n.d.). Overweight and obesity. *Healthy People 2030.* US Department of Health and Human Services. https://health.gov/healthypeople/objectives-and-data/browse-objectives/overweight-and-obesity

Paek S., Roy, L., DeHaven, M., Carson, E., Barlow, S., & Kridelbaugh, L. (2021). Validity and reliability of a behavior assessment questionnaire for children with obesity. medRxiv. https://doi.org/10.1101/2021.05.12.21256827

Perdew, M., Liu, S., Rhodes, R., Ball, G. D. C., Mâsse, L. C., Hartrick, T., Strange, K., & Naylor, P. (2021). The effectiveness of a blended in-person and online family-based childhood obesity management program. *Childhood Obesity, 17*(1), 58-67. https://doi.org/10.1089/chi.2020.0236

Ravens-Sieberer, U., & Bullinger, M. (1998a). Assessing health-related quality of life in chronically ill children with the German KINDL: First psychometric and content analytical results. *Quality of Life Research, 7*(5), 399-407. https://doi.org/10.1023/A:1008853819715

Ravens-Sieberer, U. & Bullinger, M. (1998b). News from the KINDL-Questionnaire – A new version for adolescents. *Quality of Life Research*, 7, 653.

Robert Wood Johnson Foundation. (n.d.). *Fast Facts.* State of childhood obesity: Helping All Children Grow Up Healthy. https://stateofchildhoodobesity.org/data/

Robert Wood Johnson Foundation (2019). *How childhood obesity rates have changed over time.* State of Childhood Obesity: Helping All Children Grow Up Healthy. https://stateofchildhoodobesity.org/stories/how-childhood-obesity-rates-have-changed-over-time/

State of Indiana. (2021). *Ways to prevent childhood obesity.* https://www.in.gov/fssa/carefinder/provider-resources/ways-to-help-prevent-childhood-obesity/

Suire, K, Kavookjian, J., & Wadsworth, D. (2020). Motivational interviewing for overweight children: A systematic review. *Pediatrics, 146*(5), e20200193. https://doi.org/10.1542/peds.2020-0193

Styne, D., Arslanian, S., Connor, E., Farooqi, I., Murad, M., Silverstein, J., & Yanovski, J. (2017). Pediatric obesity-assessment, treatment, and prevention: An endocrine society clinical practice guideline. *The Journal of Clinical Endocrinology and Metabolism, 102*(3), 709-757. https://doi.org/10.1210/jc.2016-2573

Trochim, William. (n.d.). *Descriptive statistics.* Research Methods Knowledge Base. https://conjointly.com/kb/descriptive-statistics/

University of Wisconsin Population Health Institute & Robert Wood Foundation. (2022). *Indiana.* County Health Rankings and Roadmaps. https://www.countyhealthrankings.org/app/indiana/2021/rankings/vanderburgh/county/factors/overall/snapshot

US Preventative Services Task Force. (2017). Screening for obesity in children and adolescents: US Preventive Services Task Force Recommendation statement. *JAMA, 317*(23), 2417-2426. https://doi.org/10.1001/jama.2017.6803

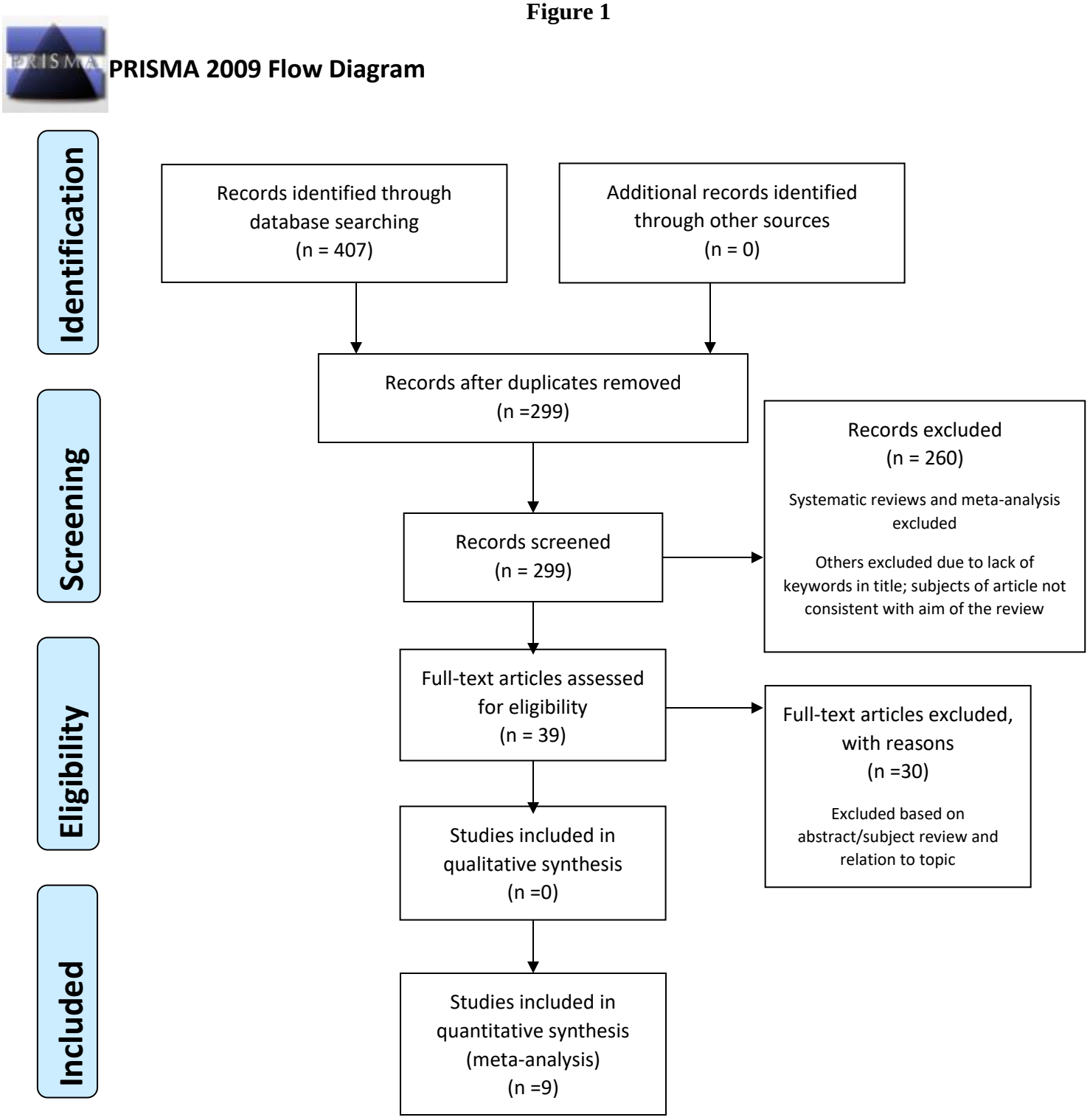
Vidmar, A. P., Fink, C., Torres, B., Manzanarez, B., Mittelman, S. D., Wee, C. P., & Borzutzky, C. (2019). Energy management for personalized weight reduction (EMPOWER) program: Three-year outcome data. *Advances in Clinical Endocrinology and Metabolism, 2*(1), 47-54.

Welborn Baptist Foundation. (2021, January). *Greater Evansville health survey.* https://www.welbornfdn.org/app/uploads/2021/03/2021-Welborn-GEHS-Book-Web.pdf

Zoellner, J. M., You, W., Hill, J. L., Brock, D. P., Yuhas, M., Price, B., Wilson, J., Montague, D. R., & Estabrooks, P. A. (2022). Comparing two different family-based childhood obesity treatment programmes in a medically underserved region: Effectiveness, engagement,

and implementation outcomes from a randomized controlled trial. *Pediatric Obesity, 17*(1), 1-14. https://doi.org/10.1111/ijpo.12840

Figure 1



From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). *P*referred *R*eporting *I*tems for *S*ystematic Reviews and *M*eta-*A*nalyses: The PRISMA Statement. PLoS Med 6(7): e1000097. doi:10.1371/journal.pmed1000097

For more information, visit www.prisma-statement.org

Figure 2

Concept Map: Pediatric Obesity and Transtheoretical Model of Change

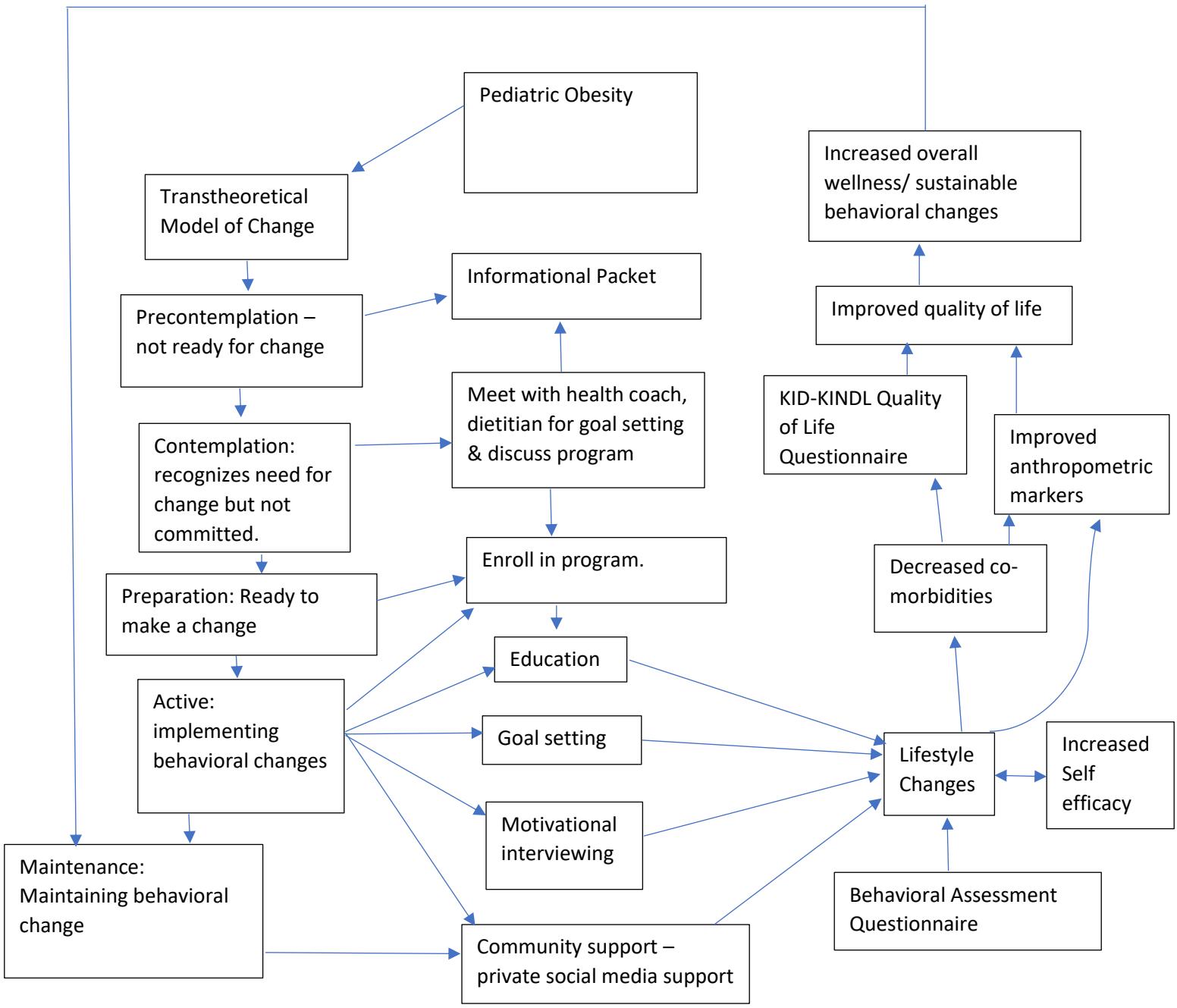


Figure 3

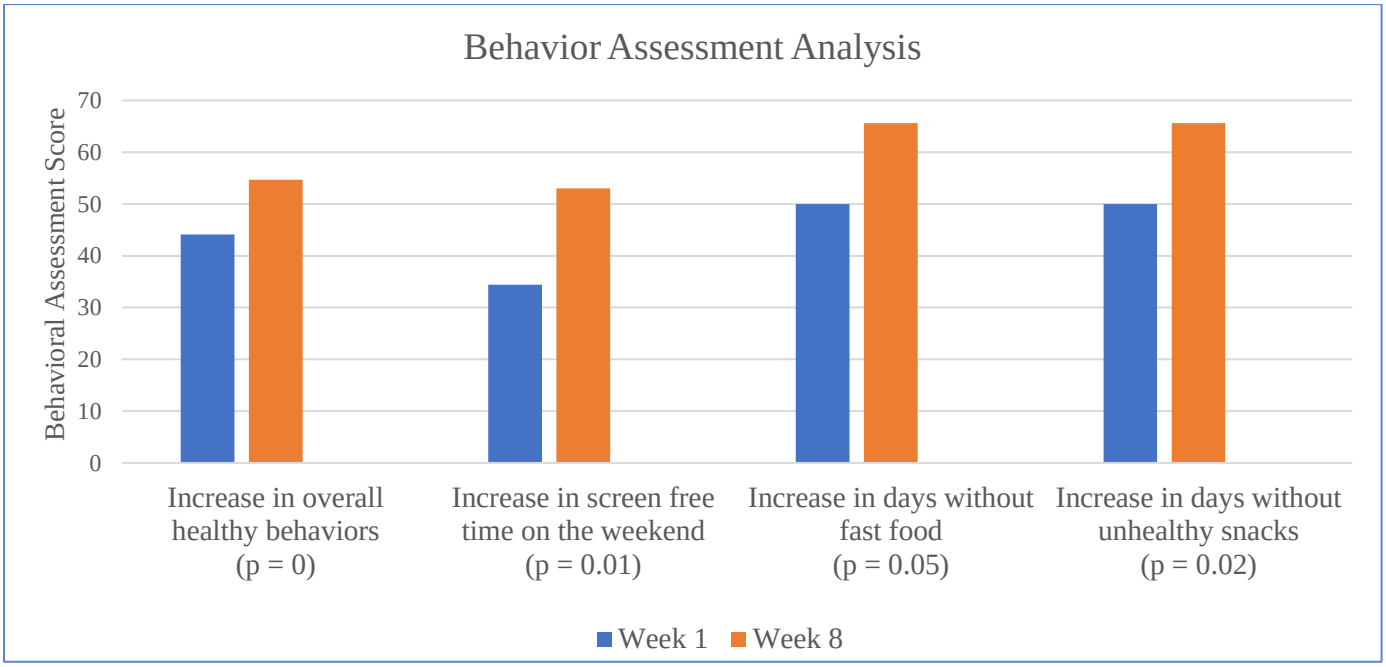

Behavior Assessment Analysis
Behavioral Assessment Score
70
60
50
40
30
20
10
0
Increase in overall healthy behaviors (p = 0)
Increase in screen free time on the weekend (p = 0.01)
Increase in days without fast food (p = 0.05)
Increase in days without unhealthy snacks (p = 0.02)
Week 1
Week 8

Table 1

Timeline for DNP Scholarly Project

Date	Action
June 27, 2022	First draft of proposal to be submitted for review by advisor.
July 4, 2022	CITI and HIPAA Training to be completed
July 15, 2022	Final proposal submitted to the IRB at Alabama and Ascension Indiana
October 1, 2022	Initiate data collection with chart review after approval from IRB
November 29, 2022	Data collection complete. Begin data analysis
February 20, 2023	Data Analysis complete. Begin final paper.
March 1, 2023	Project completed and ready to present. Project data will be presented to key stakeholders and at the DNP Intensive in late March.

Appendix A

Peyton Manning Children's Hospital
Ascension St. Vincent

Ascension Peyton Manning Children's Hospital Evansville
Center for Children
3900 Washington Ave.
Evansville, IN 47714

06/22/2022

To Whom It May Concern:

On behalf of Ascension Peyton Manning Children's Hospital Evansville, we are writing to confirm organizational support for Keri Montgomery, a DNP student at the University of Alabama, to conduct her DNP project titled, "Effectiveness of a Multi-disciplinary, Family-centered Pediatric Weight Management Clinic: A Program Evaluation". We understand that Keri Montgomery will perform a chart review of active patients within our pediatric weight management clinic "All IN Wellness", and conduct a program evaluation at the Peyton Manning Center for Children pediatric subspecialty clinic over the next eleven months, ending in May 2023. We are happy to participate in this DNP project and contribute to this important work. Therefore, as representatives of Ascenstion Peyton Manning Children's Hospital Evansville, we agree that Keri Montgomery's DNP project may be conducted at our agency/institution.

Sincerely,

Maria Del Rio, MD
Medical Director

Tiffany Horn , Ed. D., MHA
Practice Operations Manager

Peyton Manning Children's Hospital Center for Children
3900 Washington Avenue
Evansville, IN 47714

812-485-7425
ascension.org

Listening to you, caring for you.

Appendix B

From: Sarah Barlow <Sarah.Barlow@UTSouthwestern.edu>
Sent: Friday, May 20, 2022 9:51:43 AM
To: Keri Montgomery <khmontgomery@crimson.ua.edu>
Cc: Alex Reid <Aleksei.Reid@childrens.com>
Subject: [EXTERNAL] RE: Behavior Assessment Questionnaire from Validity and Reliability of a Behavior Assessment Questionnaire for Children with Obesity

Hi Keri,

Yes, you have permission. Please acknowledge in any publications.

We are glad that the publication found a reader!

Sarah Barlow

From: Keri Montgomery <khmontgomery@crimson.ua.edu>
Sent: Wednesday, May 18, 2022 10:17 PM
To: Sarah Barlow <Sarah.Barlow@UTSouthwestern.edu>
Subject: Behavior Assessment Questionnaire from Validity and Reliability of a Behavior Assessment Questionnaire for Children with Obesity

EXTERNAL MAIL

Dr. Barlow,
I am a Pediatric Nurse Practitioner in Pediatric GI at Peyton Manning Children's Hospital in Evansville, IN. I am also getting my Doctorate of Nursing through the University of Alabama.

Our pediatric GI clinic is starting a weight management/wellness clinic and my DNP project will be a program evaluation of this clinic. I am writing to seek permission to use the Behavior Assessment Questionnaire from the article, *Validity and Reliability of a Behavior Assessment Questionnaire for Children with Obesity*. I would like to have patients take this questionnaire pre and post intervention to look at behavioral changes within our program and use this as a portion my DNP Project with potential to publish. I saw that you are the corresponding author for this paper. If you are not the appropriate person to contact for permission, would you be able to direct me to the correct person/department?

Thank you in advance for your time.

Thank You,
Keri Montgomery

Keri Montgomery, CPNP-PC
University of Alabama Doctoral Student
Capstone College of Nursing
khmontgomery@crimson.ua.edu

Sent from Mail for Windows

CAUTION: This email originated from outside UTSW. Please be cautious of links or attachments, and validate the sender's email address before replying.

UT Southwestern
Medical Center
The future of medicine, today.

Appendix C

Office of Quality of Life Measures

May 24, 2022, 6:17 AM

to Ulrike, Franziska, me

Dear Keri Montgomery,

Thank you for your interest in the KINDL instruments and your email to Prof. Dr. phil. Ulrike Ravens-Sieberer. I am a co-worker of Prof. Dr. phil. Ulrike Ravens-Sieberer, working to answer all inquiries concerning KINDL.

We have received your signed collaboration form and are very happy to collaborate with you.

You can find the questionnaires as well as the manual for the questionnaires (in English) on our website: http://kindl.org/english/. Additionally, you can download the analysis files (available in English for SPSS) from http://kindl.org/english/scoring/.

For a better documentation on our side and in order to assure that requests regarding the KINDL are being dealt with as quickly as possible, we assign ID numbers to every request. In your case, it is the following number: **1692**.

It would be very helpful if you could state this number every time you contact us. This is even more important if eventually some other person from your team needs to contact us. By knowing the number, we are then able to quickly connect people to the right projects.

Furthermore, we would like to take this opportunity to inform you about the European “KIDSCREEN” project, which is probably also interesting for you: The KIDSCREEN instruments are a family of generic quality of life measures that have been designed and normed for children and adolescents aged between 8 to 18 years. It was developed simultaneously in several European countries taking children's concepts of health and well-being into consideration. This fact represents an advantage of the KIDSCREEN questionnaires in comparison to the KINDL instruments, since the psychometric properties are of higher quality. KIDSCREEN can be used as a screening, monitoring and evaluation tool in representative national and European health surveys. The KIDSCREEN project was funded by the European Commission (grant number QLG-CT-2000- 00751 within the EC 5th Framework-Programme “Quality of Life and Management of Living Resources”).

If you are interested in further information about the KIDSCREEN, you are welcome to have a look at our website: http://www.kidscreen.org.

In case of any questions, please feel free to contact us again.

Kind regards

Laeticia Hervé

Office of Quality of Life Measures in Children | Research Assistant

University Medical Center Hamburg-Eppendorf

Center for Psychosocial Medicine

Department of Child and Adolescent Psychiatry, Psychotherapy and Psychosomatics

Research Unit "Child Public Health"

Martinistraße 52, W 29

D - 20246 Hamburg

Tel.: +49 (040) 7410 58503

Fax: +49 (040) 7410 55105

Email: QOL@uke.de

Info: http://www.child-public-health.org/english/

Office of Quality of Life Measures

Jun 20, 2022, 3:05 AM (6 days ago)

to me, Ulrike, Franziska

Dear Keri Montgomery,

Thank you again for your interest in the KINDL instruments and your email to Prof. Dr. phil. Ulrike Ravens-Sieberer. I am a co-worker of Prof. Dr. phil. Ulrike Ravens-Sieberer, working to answer all inquiries concerning KINDL.

We will have the collaboration agreement signed by Prof. Dr. phil. Ulrike Ravens-Sieberer and send it to you as soon as the signature has been set.

We wish you good luck with your research project.

Kind regards,

Katharina Heinz

Office of Quality of Life Measures in Children | Research Assistant

University Medical Center Hamburg-Eppendorf

Center for Psychosocial Medicine

Department of Child and Adolescent Psychiatry, Psychotherapy and Psychosomatics

Research Unit “Child Public Health”

Martinistraße 52, W 29

D - 20246 Hamburg

Tel.: +49 (040) 7410 58503

Fax: +49 (040) 7410 55105

Email: QOL@uke.de

Info: http://www.child-public-health.org/english/

Appendix D

COLLABORATION between KINDL Group and

Name (Title): Keri Montgomery, CPNP-PC	
Institution: Peyton Manning Children's Hospital Evansville / University of Alabama	
Dept.: Center for Children	
Street: 3900 Washington Ave	
City: Evansville	State: IN
Zip (Postal) Code: 47714	Country: USA
Phone No.: (812) 485-6694	Fax: 812-485-6710
Email: keri.montgomery@ascension.org	

Billing address: VAT No.:

Institution:	
Dept.:	
Street:	
City:	State:
Zip (Postal) Code:	Country:

SUMMARY of the STUDY

Title of the Study: Effectiveness of Pediatric Weight Mangement Clinic on Behavioral Change & Quality of Life	
Type of Research: Doctorate of Nursing Scholarly Project.	
Objectives / Design: Program Evaluation reviewing Behavioral Change, Quality of Life	
Study Population (incl. number of cases, age, illnesses/diseases): All clinic participants (#TBD but likely ≤ 75) Ages 2-18 - Pediatric Obesity	
Measurement Points: Behavior Habits questionnaire, Kid-KINDL Qol Questionnaire, anthropometric data	
Other Instruments: InBody Scanner, Behavioral Habits Questionnaire, EMR chart review	
Name of the Funder: Study not funded. For DNP scholarly Project. PMCH is not-for-profit hospital	
Beginning of the Study: 6/1/2022	Expected end of the Study: 6/1/2023

SPECIFY Language AND Questionnaire Version planned to be included: English Language
Generic Core Instruments:
Kids & Parents Ages 4-6, 3-6, 7-13, 7-17, 7-17, adolescents 14-17 yo

Evansville, IN 5/19/2022 CPNP-PC
City, Date Signature (The KINDL)

IMPORTANT REMARK:

THE KINDL MAY BE USED IN THE ABOVE MENTIONED INVESTIGATIONS WHEN THE FOLLOWING AGREEMENT IS COMPLETED AND SIGNED BY "USER".

"Person, University, Company" referred hereinafter as "User" wishes to use the **KINDL**.

Prof. Dr. U. Ravens-Sieberer distributes the **KINDL** and its translations available in the following languages: Arabic, Chinese (Cantonese), Danish, Dutch, English, Finnish, French, German, Greek, Iranian (Persian), Italian, Japanese, Korean, Nepalese, Norwegian, Polish, Portuguese, Russian, Serbo-Croatian, Sinhala, Spanish, Spanish (Argentina), Spanish (Uruguay), Swedish, Taiwanese, Turkish, Vietnamese.

Therefore, User and Prof. Dr. U. Ravens-Sieberer agree as follows:

1. KINDL obligations

Prof. Dr. U. Ravens-Sieberer shall deliver the original **KINDL** and/or the translations requested by User subject to the following conditions: The translations requested are available and the present agreement is duly completed and signed by User.

2. User's obligations

2.1 No modification

"User" shall not modify, abridge, condense, adapt, recast or transform the **KINDL** in any manner or form, including but not limited to any minor or significant change in wordings or organisation in **KINDL**, without the prior written agreement of **Prof. Dr. U. Ravens-Sieberer.**

2.2 No translation

"User" shall not translate **KINDL** without the prior written agreement of **Prof. Dr. U. Ravens-Sieberer**.

2.3 No reproduction

"User" shall not reproduce the **KINDL** except for the limited purpose of generating sufficient copies for use in investigations stated hereunder and shall in no event distribute copies of the **KINDL** to third parties by sale, rental, lease, lending, or any others means.

2.4 Publication

In case of publication of study results, "User" shall cite
"Ravens-Sieberer, U., & Bullinger, M. (1998). Assessing health-related quality of life in chronically ill children with the German KINDL: First psychometric and content analytical results. *Quality of Life Research*, 7(5), 399-407. doi: 10.1023/A:1008853819715"
in the reference section of the publication.

2.5 Payment

2.5.1 *Royalty fees (Authors)*

The use of the **KINDL** for academic researchers (funded or non-funded) and non-profit organisations (= non-commercial use, e. g. Governmental Institutions; Universities or Hospitals) is free. In case of commercial use (companies and profit-organisations, e. g. Pharmaceutical companies) we kindly ask to pay a licence fee of 400 € (net) for every language version and for every questionnaire version.

2.5.2 *Distribution fees*

The use of the **KINDL** in studies will be subject to a distribution fee, but not as long as its development phase is formally completed. This collaboration, started formally during the development phase of the KINDL project, includes no distribution fee.

3. Copyright Infringement

The **KINDL** was developed **by Prof. Dr. Ulrike Ravens-Sieberer** MPH, Head of Research, Professor for Child Public Health (University Medical Center Hamburg-Eppendorf, Department of Child and Adolescent Psychiatry, Psychotherapy, and Psychosomatics, Martinistraße 52, W 29, D-20246 Hamburg). **Prof. Dr. U. Ravens-Sieberer** holds copyright over the **KINDL** and all its present and future translations. Each new translation will be made available to third parties once it is available, through **Prof. Dr. U. Ravens-Sieberer** under the conditions described in the present document. If, at any time during the term of this agreement, User learns of any infringement by a third party of any Intellectual Property Rights in connection with the **KINDL**, User shall promptly notify **Prof. Dr. U. Ravens-Sieberer**. **Prof. Dr. U. Ravens-Sieberer** will decide to institute or not proceedings against the infringing party.

4. Confidentiality

All and any information related to the **KINDL** including but not limited to the following: information concerning clinical investigations, creations, systems, materials, software, data and know-how, translations, improvements ideas, specifications, documents, records, notebooks, drawings, and any repositories or representation of such information, whether oral or in writing or software stored, are herein referred to as confidential information. In consideration of the disclosure of any such confidential information to the other, each party agrees to hold such confidential information in confidence and not divulge it, in whole or in part, to any third party except for the purpose specified in this agreement.

5. Use of name

It is agreed that **Prof. Dr. U. Ravens-Sieberer** shall not disclose, whether by the public press or otherwise, the name of **User** or **Institution** to any third party to this agreement except to the copyright holder(s) of the **KINDL**.

6. Liability

6.1 In case of breach of contract

In the event of total or partial breach by **Prof. Dr. U. Ravens-Sieberer** of any of its obligations hereunder, **Prof. Dr. U. Ravens-Sieberer's** liability shall be limited to the direct loss or damage (excluding loss of profit and operating losses) suffered by User as a result of such breach and shall not include any other damages and particular consequential damages.

6.2 In the scope of the use of the Questionnaire

Under no circumstances may **Prof. Dr. U. Ravens-Sieberer** be held liable for direct or consequential damage resulting from the use of the **KINDL**.

6.3 In the event of non-renewal of this Agreement

In the event of non-renewal of this Agreement by **Prof. Dr. U. Ravens-Sieberer** for any cause or failure by **Prof. Dr. U. Ravens-Sieberer** to conclude a new agreement with User upon the expiry of this Agreement, **Prof. Dr. U. Ravens-Sieberer** will have no liability for payment of any damages and/or indemnity to User.

7. Term and termination

This agreement shall be effective at the date of its signature by User and shall at least or until the term of the study above mentioned in SUMMARY OF THE STUDY. Either party may terminate this Agreement immediately upon providing written notice to the other party in the event of: (a) the other party's unexcused failure to fulfil any of its material obligations under this Agreement or (b) upon the insolvency or bankruptcy of, or the filing of a petition in bankruptcy or similar arrangement by the other party. Upon expiration or termination of this Agreement **Prof. Dr. U. Ravens-Sieberer** may retain in its possession confidential information as acquired from **KINDL** while under contract. The obligations which by their terms survive termination, include without limitation the applicable ownership; confidentiality and indemnification provisions of this Agreement shall survive termination.

8. Assignment

This Agreement and any of the rights and obligations of User are personal to the User and cannot be assigned or transferred by User to any third party or by operation of law, except with the written consent of **Prof. Dr. U. Ravens-Sieberer** notified to User.

9. Separate Agreement

This Agreement holds for the above mentioned study only. The use of the **KINDL** in any additional study of the User will require a separate agreement **without additional fees, unless significant updates have been added to the user manual (new edition, etc.).**

10. Entire Agreement, Modification, Enforceability

The entire Agreement hereto is contained herein and this Agreement cancels and supersedes all prior agreements, oral or written, between the parties hereto with the respect to the subject matter hereto.

This Agreement or any of its terms may not be changed or amended except by written document and the failure by either party hereto to enforce any or all of the provision(s) of this Agreement, it shall not be deemed a waiver or an amendment of the same and shall not prevent future enforcement thereof. If any one or more of the provisions or clauses of this Agreement are adjudged by a court to be invalid or unenforceable, this shall in no way prejudice or affect the binding nature of this Agreement as a whole, or the validity or enforceability of each and every other provision of this Agreement.

11. Governing law

This Agreement shall be governed by and construed in accordance with the laws of the European Union.

IN WITNESS WHEREOF, the parties hereto have caused this agreement to be executed by their duly authorised representatives as of the date first above written.

PROF. DR. U. RAVENS-SIEBERER: User/University/Company:

Name:	Ulrike Ravens-Sieberer	Name:	Keri Montgomery
Title:	Prof. Dr. phil. MPH	Title:	Pediatric Nurse Practitioner
Signature:	U. Ravens-Sieberer	Signature:	CPNP-PC
Date:	05.07.2022	Date:	5/19/2022

Appendix E

Behavior Assessment Questionnaire

Please answer the following questions to the best of your knowledge. Place a check in the box corresponding to the answer that best describes your child's health habits/activities over the past 3 months.

	0	1	2	3	4
1. How many hours of physical activity does your child participate in on a typical weekday/school day? (ie. sports, bike riding, walking, swimming, dancing, outside play. Do not include gym class)	☐ 0 hours/day	☐ 0-1 hour/day	☐ 1-2 hours/day	☐ 2-3 hours/day	☐ >3 hours/day
2. How many hour of physical activity and physical play does your child participate in on a typical weekend day? (ie. sports, bike riding, walking, swimming, dancing, outside play)	☐ 0 hours/day	☐ 0-1 hour/day	☐ 1-2 hours/day	☐ 2-3 hours/day	☐ >3 hours/day
3. How many hours does your child watch television/videos or play video/computer games on a typical weekday/school day?	☐ >4 hours/day	☐ 3-4 hour/day	☐ 2-3 hours/day	☐ 1-2 hours/day	☐ 0-1 hours/day
4. How many hours does your child watch television/videos or play video/computer games on a typical weekend day?	☐ >4 hours/day	☐ 3-4 hour/day	☐ 2-3 hours/day	☐ 1-2 hours/day	☐ 0-1 hours/day
5. How many fruit servings (1 piece or ½ cup) does your child eat on a typical day? Do not include fruit juice.	☐ 0 servings/ day	☐ 1 servings/ day	☐ 2 servings/ day	☐ 3 servings/ day	☐ 4 or more servings/ day
6. How many vegetables servings (~¼ cup cooked or 1 cup raw) does your child eat on a typical day?	☐ 0 servings/ day	☐ 1 servings/ day	☐ 2 servings/ day	☐ 3 servings/ day	☐ 4 or more servings/ day
7. How often does your child eat while watching television/videos or playing video/computer games	☐ >1 time/day	☐ 1 time/day	☐ 2-3 times/ week	☐ 1 time/ week	☐ <1 time/ week
8. How many 8 oz sugar containing beverages does your child drink on a typical day? (ie. sugared tea, lemonade, Kool-Aid, non-diet sodas, sports drinks, fruit juice, etc.)	☐ 4 or more/day	☐ 3/day	☐ 2/day	☐ 1/day	☐ 0/day
9. How often does your child eat fast food? (ie. McDonalds, Taco Bell, pizza, etc.)	☐ >1 time/day	☐ 1 time/day	☐ 2-3 times/ week	☐ 1 time/week	☐ <1 time/week
10. How often does your child eat snacks such as chips, candy, French fries, etc.?	☐ >3 times/day	☐ 2 times/day	☐ 1 time/day	☐ 2-3 times/ week	☐ <2 times/ week

Overall Score

Update 9/11/08 2008

©Copyright – Children's Medical Center Dallas

Paek S., Roy, L., DeHaven, M., Carson, E., Barlow, S., & Kridelbaugh, L. (2021). Validity and reliability of a behavior assessment questionnaire for children with obesity. medRxiv. https://doi.org/10.1101/2021.05.12.21256827

Appendix F

ID: _ _ _ _ _ _

Children's Questionnaire

Kid-KINDL®

Hello there!

we would like to know how you have been feeling during the past week, so we have worked out a few questions which we would like you to answer.

- ⇨ Please read each question carefully.
- ⇨ Think about how things have been for you over the past week.
- ⇨ Choose the answer that fits you best in each line and put a cross in the box.

There are no right or wrong answers. It's what you think that matters.

For example:	never	seldom	some-times	often	all the time
During the past week, I liked to listen to music.	☐	☐	☐	☒	☐

Date of fill out:

_____

(day / month / year)

© Kid-KINDL® / children / Ravens-Sieberer & Bullinger/ 2000 / page 1

Please tell us something about you. Please put a cross or fill in!

I am a ☐ girl ☐ boy

Age: _____ years old

How many siblings do you have? ☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ more than 5

Which type of school do you go to? _____

1. First of all, we would like to know something about your physical health...

During the past week...	never	seldom	some-times	often	all the time
1. ... I felt ill	☐	☐	☐	☐	☐
2. ... I had a headache or tummy-ache	☐	☐	☐	☐	☐
3. ... I was tired and worn-out	☐	☐	☐	☐	☐
4. ... I felt strong and full of energy	☐	☐	☐	☐	☐

2. ... then something about how you've been feeling in general...

During the past week...	never	seldom	some-times	often	all the time
1. ... I had fun and laughed a lot	☐	☐	☐	☐	☐
2. ... I was bored	☐	☐	☐	☐	☐
3. ... I felt alone	☐	☐	☐	☐	☐
4. ... I was scared	☐	☐	☐	☐	☐

3. ... and how you have been feeling about yourself.

During the past week...	never	seldom	some-times	often	all the time
1. ... I was proud of myself	☐	☐	☐	☐	☐
2. ... I felt on top of the world	☐	☐	☐	☐	☐
3. ... I felt pleased with myself	☐	☐	☐	☐	☐
4. ... I had lots of good ideas	☐	☐	☐	☐	☐

© Kid-KINDL® / children / Ravens-Sieberer & Bullinger/ 2000 / page 2

4. The next questions are about your family ...

During the past week...	never	seldom	some-times	often	all the time
1. ... I got on well with my parents	☐	☐	☐	☐	☐
2. ... I felt fine at home	☐	☐	☐	☐	☐
3. ... We quarrelled at home	☐	☐	☐	☐	☐
4. ... My parents stopped me from doing certain things	☐	☐	☐	☐	☐

5. ... and then about friends.

During the past week...	never	seldom	some-times	often	all the time
1. ... I played with friends	☐	☐	☐	☐	☐
2. ... Other kids liked me	☐	☐	☐	☐	☐
3. ... I got along well with my friends	☐	☐	☐	☐	☐
4. ... I felt different from other children	☐	☐	☐	☐	☐

6. Last of all, we would like to know something about school.

During the last week in which I was at school...	never	seldom	some-times	often	all the time
1. ... doing my schoolwork was easy	☐	☐	☐	☐	☐
2. ... I enjoyed my lessons	☐	☐	☐	☐	☐
3. ... I worried about my future	☐	☐	☐	☐	☐
4. ... I worried about bad marks or grades	☐	☐	☐	☐	☐

Thank you for helping us!

© Kid-KINDL® / children / Ravens-Sieberer & Bullinger/ 2000 / page 3

Appendix G

ID: _ _ _ _ _ _

Quality of Life Questionnaire for Children

Kid- & Kiddo-KINDL
Parents' Questionnaire KINDL[R]

Dear Parent,

We really appreciate your taking the time to complete this questionnaire about your child's well-being and health-related quality of life.

Since it is a matter of **your** own assessment of your child's well-being, please complete the questionnaire yourself according to the instructions, i.e. without asking your child.

- ⇨ Read each question carefully.
- ⇨ Think about how your child has been feeling during the past week.
- ⇨ Put a cross in the box corresponding to the answer **in each line** that fits your child best.

For example:

During the past week ...	never	seldom	some-times	often	all the time
. ...my child has slept well	☐	☐	☐	☒	☐

My Child is a: ☐ Girl ☐ Boy

Age: ____ Years

You are: ☐ Mother ☐ Father ☐ Other _____?

Date of fill out: __ / __ / __ (day / month / year)

1. Physical Well-being

During the past week ...	never	seldom	some-times	often	all the time
1. ... my child felt ill	☐	☐	☐	☐	☐
2. ... my child had a headache or tummy-ache	☐	☐	☐	☐	☐
3. ... my child was tired and worn-out	☐	☐	☐	☐	☐
4. ... my child felt strong and full of energy	☐	☐	☐	☐	☐

2. Emotional Well-being

During the past week ...	never	seldom	some-times	often	all the time
1. ... my child had fun and laughed a lot	☐	☐	☐	☐	☐
2. ... my child didn't feel much like doing anything	☐	☐	☐	☐	☐
3. ... my child felt alone	☐	☐	☐	☐	☐
4. ... my child felt scared or unsure of him-/ herself	☐	☐	☐	☐	☐

3. Self-esteem

During the past week ...	never	seldom	some-times	often	all the time
1. ... my child was proud of him-/herself	☐	☐	☐	☐	☐
2. ... my child felt on top of the world	☐	☐	☐	☐	☐
3. ... my child felt pleased with him-/ herself	☐	☐	☐	☐	☐
4. ... my child had lots of good ideas	☐	☐	☐	☐	☐

4. Family

During the past week ...	never	seldom	some-times	often	all the time
1. ... my child got on well with us as parents	☐	☐	☐	☐	☐
2. ... my child felt fine at home	☐	☐	☐	☐	☐
3. ... we quarrelled at home	☐	☐	☐	☐	☐
4. ... my child felt that I was bossing him/ her around	☐	☐	☐	☐	☐

© Kid- & Kiddo-KINDL[R] / parents / Ravens-Sieberer & Bullinger/ 2000 / page 2

5. Social Contacts

During the past week ...	never	seldom	some-times	often	all the time
1. ... my child did things together with friends	☐	☐	☐	☐	☐
2. ... my child was liked by other kids	☐	☐	☐	☐	☐
3. ... my child got along well with his/ her friends	☐	☐	☐	☐	☐
4. ... my child felt different from other children	☐	☐	☐	☐	☐

6. School

During the last week in which my child was at school ...	never	seldom	some-times	often	all the time
1. ... my child easily coped with schoolwork	☐	☐	☐	☐	☐
2. ... my child enjoyed the school lessons	☐	☐	☐	☐	☐
3. ... my child worried about his/her future	☐	☐	☐	☐	☐
4. ... my child was afraid of bad marks or grades	☐	☐	☐	☐	☐

Thank you for your co-operation!

© Kid- & Kiddo-KINDL^{R} / parents / Ravens-Sieberer & Bullinger/ 2000 / page 3

Appendix H

ASCENSION **Institutional Review Board**

WORKSHEET
EXPEDITED REVIEW

NUMBER	EFFECTIVE DATE	REVISED DATE
WRK-1101	1/21/2019	1/10/2022

The purpose of this worksheet is to provide support for Designated Reviewers conducting reviews using the expedited procedure. This worksheet may be used for guidance. It does not need to be completed or retained.

☐	**Continuing review of non-research Humanitarian Use Device (HUD) using the expedited procedure**[i]
1	**Additional Criteria For Research Involving Prisoners**[ii] (Check if **"Yes" or "N/A"**. Must be checked)
☐	If the research involves interaction with prisoners, is minimal risk, the Prisoner representative concurs with this determination, and the prisoner representative must review the research[iii]. (**"N/A"** if no Prisoners as subjects (OR no prisoner interaction.) ☐ **N/A**
Initial or continuing review must meet criteria set 3. Modifications can meet either criteria set 2 or 3.	
2	**Minor Modifications** (Check if **"Yes" or "N/A"**. All must be checked)
☐	The modifications do not affect the design of the research.
☐	The modifications add no more than Minimal Risk to subjects.
☐	All added procedures fall into categories (1)-(7) below. (**"N/A"** if no added procedures) ☐ **N/A**
3	**Initial Review, Continuing Review, or Modifications** (Check if **"Yes"** or **"N/A"**. All must be checked)
☐	The research activities (or remaining research activities) present no more than Minimal Risk to Human Subjects. (**"N/A"** if the research falls into category (8)(b)) ☐ **N/A**
☐	Identification of the subjects or their responses (or the remaining procedures involving identification of subjects or their responses) will **NOT** reasonably place them at risk of criminal or civil liability or be damaging to the their financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than Minimal Risk. (**"N/A"** if the research falls into category (8)(b)) ☐ **N/A**
☐	The research is **NOT** classified[iv]
☐	The research (or remaining research) falls into one or more of the following categories: **(Check all that apply)** ☐ (1)(a) Clinical studies of drugs when an IND is not required. ☐ (1)(b) Clinical studies of medical devices when an IDE is not required, or the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling. ☐ (2)(a) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture from healthy, non-pregnant adults who weigh ≥110 pounds where the amount drawn is ≤550 ml[v]/8 week period and collection occurs at most 2 times/week[vi] . ☐ (2)(b) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected (50 ml or 3 ml/kg[vii] whichever is less//8 week period), and the frequency with which it will be collected (at most 2 times/week[viii].) ☐ (3) Prospective collection of biological specimens for research purposes by noninvasive[ix] means. [x]

the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

[xi] Non-invasive procedures include, but are not limited to: (1) vaginal swabs that do not go beyond the cervical os; (2) rectal swabs that do not go beyond the rectum; and (3) nasal swabs that do not go beyond the nares.

[xii] Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, Doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

[xiii] Examples: Research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior.

[xiv] Long term follow up includes research interactions that involve no more than minimal risk to subjects (e.g., quality of life surveys); and collection of follow-up data from procedures or interventions that would have been done as part of routine clinical practice to monitor a subject for disease progression or recurrence, regardless of whether the procedures or interventions are described in the research protocol. Long term follow-up excludes research interventions that would not have been performed for clinical purposes, even if the research interventions involve no more than minimal risk.

[xv] OHRP recommends that IRBs use their discretion "to determine otherwise" under §46.109(f)(1) to determine that continuing review of research should be conducted at intervals appropriate to their degree of risk, but not less than once per year for research that is subject to the 2018 Requirements for expedited categories (8)(b) and (9). OHRP 2018 Requirements FAQs https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/2018-requirements-faqs/index.html

[xvi] Ibid.

Appendix I

ASCENSION **Institutional Review Board**

WORKSHEET

EXEMPTION DETERMINATION

NUMBER	EFFECTIVE DATE	REVISED DATE
WRK-1001	1/21/2019	1/10/2022

The purpose of this worksheet is to provide support for Designated Reviewers granting exemption determinations. This worksheet may be used for guidance. It does not need to be completed or retained.

1	**GENERAL EXCLUSIONS FROM EXEMPTIONS** (Check if **"Yes"**. If any are checked, the research is not exempt.)	
☐	The research is FDA-regulated.[i]	
☐	The research involves Prisoners, conducted or funded by DHHS, Department of Defense (DOD), or Veterans Administration (VA), and is NOT aimed at involving a broader subject population that only incidentally includes prisoners.	
☐	The research involves interactions with Prisoners.[ii]	
☐	The research is classified and conducted or funded by the Department of Energy (DOE) (may be reviewed by convened IRB only).[iii]	
2	**Criteria for approval of exempt research (Check if "Yes")**	
☐	The research involves no more than Minimal Risk to subjects **(Must be checked.)**	
☐	Selection of subjects is equitable (That is, the research is appropriate for the population being studied.) **(Must be checked.)**	
☐	There are interaction with subjects: **(If checked, all of the following must also be checked.)**	
☐	☐	There will be a consent process
	☐	The consent process will disclose that the activities involve research.
	☐	The consent process will disclose the procedures to be performed.
	☐	The consent process will disclose that participation is voluntary.
	☐	The consent process will disclose the name and contact information for the investigator.
	☐	There are adequate provisions to maintain the privacy interests of subjects.

2018 Requirements

NOTE: For Exempt determinations on or after January 21, 2019, complete section 3. If this study is subject to Pre-2018 Common Rule requirements or is DOJ-regulated, move to sections 4 and 5 below.

3	**The research falls into one or more of the following categories** (One or more categories must be checked)	
☐	1. Research conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of the educators who provide instruction. This includesmost research on regular and special education instructional strategies and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.	

☐	2. Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met, ☐ (i) The information obtained is recorded by the investigator in such a manner that the identity of the Human Subjects cannot be readily ascertained, directly or indirectly through identifiers linked to the subjects; OR ☐ (ii) Any disclosure of Human Subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; OR ☐ (iii) The information obtained is recorded by the investigator in such a manner that the identity of the Human Subjects can be readily ascertained, directly or indirectly through identifiers linked to the subjects, AND an IRB conducts limited IRB review. **(See "WORKSHEET: Limited IRB Review and Broad Consent (WRK-1102).")**
	☐ If the research involves children and is conducted, funded, or subject to regulation by DHHS, Department of Defense (DOD), Department of Education (ED), Environmental Protection Agency (EPA), or Veterans Administration (VA), the procedures are limited to (1) the observation of public behavior when the investigator(s) do not participate in the activities being observed or (2) the use of educational tests and at least one of the following criteria is met: ☐ (i) The information obtained is recorded by the investigator in such a manner that the identity of the Human Subjects cannot readily be ascertained, directly or indirectly through identifiers linked to the subjects; OR ☐ (ii) Any disclosure of Human Subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational achievement, or reputation.
☐	3(i). Research involving benign behavioral interventions[iv] in conjunctions with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met: ☐ (A) The information obtained is recorded by the investigator in such a manner that the identity of the Human Subjects cannot readily be ascertained, directly or indirectly, through identifiers linked to the subjects; OR ☐ (B) Any disclosure of the Human Subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; OR ☐ (C) The information obtained is recorded by the investigator in such a manner that the identity of the Human Subjects can be readily ascertained, directly or indirectly through identifiers linked to the subjects, AND an IRB conducts limited IRB review. **(See "WORKSHEET: Limited IRB Review and Broad Consent (WRK-1102).")** 3(ii). For the purposes of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else. 3(iii). If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

☐	4 Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met: ☐ (i) The identifiable private information or identifiable biospecimens are publicly available; OR ☐ (ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects; OR ☐ The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164 (HIPAA), subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); OR ☐ The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.
☐	5. Research and demonstration projects which are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of heads of bureaus or other subordinate agencies that have delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve or otherwise examine: public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs[vi]. ☐ (i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal website or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.
☐	6.[vii] Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the Department of Agriculture.
☐	7. Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts limited IRB review[viii]. **(See "WORKSHEET: Limited IRB Review and Broad Consent (WRK-1102).")**
☐	Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use. **(See "WORKSHEET: Limited IRB Review and Broad Consent (WRK-1102).")**

Pre-2018 Requirements: *NOTE: If this study is subject to 2018 Common Rule requirements, complete section 3 above.*		
4	**One of the following is true:**	
☐	☐ The research is DOJ-regulated. ☐ The review is related to research determined to be exempt prior to January 21, 2019, and the organization continues to apply Pre-2018 requirements to some or all research initiated prior to January 21, 2019.	
5	**The research falls into one or more of the following categories (one or more categories must be checked)**	
☐	☐	1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as: (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. (Both the procedures involve normal education practices and the objectives of the research involve normal educational practices.)
	☐	2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that Human Subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the Human Subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation. In addition:
		☐ If the research involves children and is conducted, funded, or subject to regulation by DHHS, Dept. of Defense (DOD), Dept. of Education (ED), Environmental Protection Agency (EPA), or Veterans Administration (VA), the procedures are limited to (1) the observation of public behavior when the investigator(s) do not participate in the activities being observed and (2) the use of educational tests. (**"N/A" if the research does not involve children or is not conducted, funded, or otherwise subject to by these agencies.**)
	☐	3. Research involving the use of educational tests[x], survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if: (i) the Human Subjects are elected or appointed public officials or candidates for public office; or (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
	☐	4.[xi] Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. (**For research conducted, funded, or otherwise subject to regulation by any federal agency "existing" means "existing at the time the research is proposed." Otherwise, it means "existing at the time the research is proposed or will exist in the future for non-research purposes."**)
	☐	5. Research and demonstration projects which are conducted by or subject to the approval of Dept. or Agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs. In addition: (Check if "**Yes**". All must be checked)
		☐ The program under study delivers a public benefit[xii] or service[xii]
		☐ The research or demonstration project is conducted pursuant to specific federal statutory authority.
		☐ There is no statutory requirement that the project be reviewed by an IRB.
		☐ The project does not involve significant physical invasions or intrusions upon the privacy of subjects.
		☐ The funding agency concurs with the exemption.
	☐	6.[xiv] Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the Dept. of Agriculture.

[i] The organization's policy is to not grant exemptions to FDA-regulated research in category (6).
[ii] AAHRPP Tip Sheet 18: Review of Research involving Prisoners and the Role of the Prisoner Representative.
[iii] DOE N 443.1

[v] For VA Research, the limited IRB review must be completed prior to approval by the R&D Committee.
[xiv] Note that for FDA-regulated research exemption (6) is an exemption from IRB review in 21 CFR §56, but unlike DHHS regulations is not an exemption from FDA requirements for consent in 21 CFR §50. If an organization's policy is to grant exemptions to FDA-regulated research in category (6), then additional criteria for such exemptions would be that consent will be obtained in accordance with 21 CFR §50.20 and §50.25, and the consent will be either be documented in writing in accordance with 21 CFR§50.27 or waived in accordance with 21 CFR §56.109(c)(1).