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Title: Role and Utilization of Texting in Childhood Obesity within an Outpatient-ACN Setting

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Study Purpose and Rationale

Obesity is defined as a body mass index (BMI) at or above the 95th percentile of body mass index (BMI) for age[i]. Over the last few decades, childhood obesity has reached epidemic levels around the world, in developed countries as well as in developing countries. In the United States, there was a drastic rise in obesity rates amongst children from 5 percent in 1978 to 18.5 percent in 2016, affecting over 13.7 million children[ii]. When analyzed by age, the prevalence of obesity was 13.9% among 2- to 5-year-olds, 18.4% among 6- to 11-year-olds, and 20.6% among 12- to 19-year-olds[ii]. Additionally, those who identified as Hispanic or non-Hispanic blacks had the highest rates of obesity amongst all groups, with 25.8 and 22.0 percent respectively, when compared to the prevalence amongst non-Hispanic whites, of 14.1 percent[ii]. Many longitudinal studies have shown that there is considerable connection between obesity before the age of five and adolescent obesity. A large study done in the United States by Cunningham et al. revealed that children who were overweight in kindergarten were four times as likely to become obese by 8th grade, compared to normal-weight children[iii]. The severity of obesity was also an important indicator of persistence of obesity; 47 percent of children who had mild obesity in kindergarten remained obese in adolescence compared to 70 percent amongst children who had severe obesity (BMI 99th percentile) [iii]. Similarly, in a large study from Germany by Geserick et al., while investigating adolescent obesity through prospective analyses, they found that nearly 90% of the children who were obese at 3 years of age were overweight or obese in adolescence[iv]. Further, they noted that the most rapid weight gain had occurred in these children between the ages of 2 and 6 years, which highlights how critical early identification and intervention is for these children[iv]. In studies with longer-term follow-up, these findings were shown to persist into adulthood, especially for those who had an obese parent or guardian[v].

There is considerable discussion and research underway of causes and contributions toward childhood obesity. The exact mechanism of obesity development is believed to be multifactorial, impacted by environmental factors, cultural background, and lifestyle preferences. In addition, there is supporting evidence that increased portion sizes, excessive sugary beverage intake, and decrease in physical activity have played a major role in the climbing rates of obesity [vi, vii]. The ecological model, described by Davison et al., suggests that risk factors for childhood obesity include dietary intake, physical activity, and sedentary behavior[viii]. Similarly, numerous well-designed studies have shown associations between intake of sugar-containing beverages or low physical activity and the development of obesity or metabolic abnormalities [vii, ix]. Other factors that have been considered causal towards the rise in obesity include an increase in glycemic index for food, portion sizes, and fast food services, along with diminished family presence at meals, decreased structured physical activity, an increase in screen time amongst children, and foundational components within an environment (such as safety of neighborhoods and availability of playgrounds) [vii, ix, x]. Obesity is known to have a vast impact on both physical and psychological health in children. Childhood obesity has been associated with numerous conditions, most notably affecting the cardiovascular, endocrine, and gastrointestinal systems. In terms of cardiovascular effects, children with obesity are

approximately three times as likely to have hypertension than non-obese children, with elevated blood pressure detection in up to 50 percent of children and adolescents with obesity in the clinic setting[xi]. Similarly, over half of obese children have lipid abnormalities detected, along with several markers of subclinical atherosclerosis[xii]. Amongst obese adolescents, 7 to 25 percent have an increased chance of developing type 2 diabetes mellitus (T2DM), falling under the ‘prediabetic’ range, and up to 4 percent may have overt T2DM [xiii]. Obesity in adolescent females also causes increased risk of hyperandrogenism and early-onset polycystic ovary syndrome (PCOS), which may cause hirsutism, acanthosis nigricans, acne, and menstrual irregularities[xiv]. Furthermore, obesity can cause a spectrum of liver abnormalities, called nonalcoholic fatty liver disease (NAFLD), which is the most common cause of liver disease and children[xv]. Obese children also have an overall increased risk of slipped capital femoral epiphysis (SCFE) and tibia vara (Blount disease), along with a greater prevalence of fractures, musculoskeletal pain, and impaired mobility[xvi]. In addition, approximately 10 percent of obese children have clinically significant sleep apnea, which in turn can lead to cognitive and behavioral issues[xvii].

In regards to combating childhood obesity, the pediatric providers play a critical role, especially in the outpatient setting. Current data supports that substantial hours of patient-provider contact is necessary to improve a child’s weight status. Systematic reviews show that behavioral interventions of moderate or high intensity (defined as 26 to 75 hours or >75 hours of provider contact, respectively) are effective in achieving short-term (up to 12 months) weight improvements in children[xviii]. Several studies have assessed the efficacy of obesity prevention in pediatric primary care settings [xix, xiv]. Patrick et al. designed a randomized control study to compare a 12-month intervention aimed at reducing sedentary behavior, promoting physical activity, and promoting healthier nutrition in children, to a control group that received information unrelated to obesity, that was initiated in the outpatient setting and then delivered to patients by mail or phone calls[xx]. They found that the intervention improved self-reported sedentary behavior, fruit and vegetable intake, and physical activity among boys[xx]. Similarly, Kubik et al. conducted a pilot study using a natural experiment design, and showed that their practice-based intervention successfully increased parental intent to give their children 5 or more servings of fruits and vegetables per day[xi]. Likewise, Schwartz et al. used primary care-based motivational interviewing to improve eating and sedentary behaviors through a 6-month nonrandomized feasibility study, which was found to be feasible, with parents reporting that it helped them change family eating habits[xii]. Along with nutritional habits, other important factors (such as screen time and physical activity level) have also improved with primary-care based interventions, such as the one conducted by Ford et al., which was a randomized controlled pilot and feasibility trial that led to an overall decrease in television watching and an increase in physical activity and was shown to be feasible[xiii].

However, despite the growing evidence that increased provider-patient contact time and long-term primary care-based interventions are effective in combating the factors contributing to childhood obesity, there remain a myriad of obstacles that prevent this from being widely implemented, namely the lack of time (for providers and patients), resources, and reimbursement for obesity prevention. Nevertheless, in recent years, technology has proven to be extremely beneficial and efficacious in communicating with patients, and more providers and patients have begun to rely on it to facilitate care[xv]. One way to continue the crucial conversations around

obesity control and management amongst children is to communicate with patients via texting after an initial provider visit. Not only will this initiative provide succinct, accurate information that patients can continue to reference, it serves as a reminder and encouragement to adapt healthier habits, and also considerably reduces the expenditure of time, effort, and money required for patients to be seen in-person. This study will determine if this is feasible, effective, efficient, and whether or not patients are responsive and act upon information provided through a texting platform.

Study Design

This research proposal intends to study process measures and feasibility of routine communication via texting with overweight/obese patients and/or their parents in regards to nutrition and physical activity. Further, to elucidate whether that communication will facilitate integration of healthier dietary practices and increased physical activity within patients. Texts will be sent on a weekly basis over a six-month period, related to general nutritional and physical activity recommendations, customized texts based on the patients' SMART goals, and other topics pertinent to childhood obesity (i.e. screen time and sleep practices). All text message content will be obtained from current recommendations and guidelines by the Centers for Disease Control and Protection (CDC), and pre-approved resources from the NYP - Columbia database, along with approval from a Columbia University Irving Medical Center (CIUMC) employed dietician, nutritionist, and exercise physiologist (sample texts attached). Patients will take part in a pre-study and post-study survey, to assess their level of motivation to make changes to their current nutritional and physical activity, their current behaviors related to nutrition and physical activity, their SMART (smart, measurable, attainable, relevant, time-bound) goals over the study period, and basic knowledge related to nutrition and physical activity (surveys attached). They will also have monthly questionnaires regarding their progress on meeting their SMART goals, which will be sent via text messaging using the NYP-Columbia phone. Quantitative data will be obtained from the questionnaires along with the pre-and-post study surveys, which utilize Likert scales to assess behavior and attitudes towards implementing change.

Study Drugs/Devices

None

Statistical Procedures

For this study, there will be pre-and-post study surveys completed by the patients and/or parents. Survey data will be obtained using Qualtrics. Demographics and height, weight and BMI will be obtained from the electronic medical record. All data, including protected health information, will be stored on a password-protected Sharepoint account that is only accessible by members of the research team. Data will include process measures such as texts read and the survey and questionnaire will include close-ended questions with Likert scales to measure behavior and attitude of patients towards making healthier changes, and overall improvement in knowledge on topics sent via text messaging. Data will be analyzed using SAS 9.4 and will include descriptive statistics such as percentages, and McNemar's tests will be utilized to compare pre-and post-categorical data.

Study Subjects

Eligibility:

Patients above the age of 4, with a BMI greater than 95th percentile (based on the World Health Organization weight percentiles), and with the ability and willingness to receive routine text messages from a healthcare provider over a six-month period.

Recruitment:

All potential subjects will be recruited by their primary care providers at the four resident-based clinics, within the Ambulatory Care Network (ACN) that are affiliated with NYP-Columbia. Patients will be given the option to join the study by their PCP (either resident or faculty member), and if agreeable, will have their contact information (full name, MRN, phone number) sent to the research team via secure health messaging (SHM) within the EPIC EMR system. Patients will also be given contact information for the researchers if they prefer to contact the team directly. Patients will be informed that this is an optional study, and will have no effect on their care or treatment as a patient by the PCP. A member of the research team will reach out to the patient to confirm and reiterate the information.

Informed Consent/Assent

If guardian and patient agree to participate the research team member will obtain informed consent from guardians and assent from patients above age 12 prior to study.

Confidentiality

All patient surveys will be sent using Qualtrics and all patient data will be stored on a password protected Sharepoint account only accessible to the research team. Data will be de-identified and presented in an aggregate manner and no protected health information will be stored, included, or utilized within the text messages sent.

Potential Risks

There is minimal risk to the subject in this study. A potential risk to participants is breach of confidentiality in regards to protected health information from the patient survey (patient identification, past medical history, and measures of height, weight, and BMI). However, to reduce this risk, as mentioned above, all survey data will be de-identified and stored in SharePoint site that is available only to study team members.

Potential Benefits

There is great potential for benefit of participants in this study. Based on current research, ongoing communication between patients and providers have proven to be beneficial in aiding in patients making healthier nutritional choices and increasing physical activity. Receiving weekly text messages will enable patients to continue learning about current recommendations on these topics, presented in a compact, comprehensible manner that is not overwhelming. They will also receive recommendations on other pertinent topics that may help their child's overall physical and emotional well-being such as healthy sleep practices, cutting down on screen time, recipes, and exercise videos. In addition, patients will receive monthly customized texts for their SMART goals, which will serve as a reminder and encouragement for working towards their objective. Even if patients are unable to fully achieve their goals, they will still benefit from the knowledge

gained in these pertinent topics throughout the six-month period, that may help them make healthier choices either now or in the future.

Alternatives

Patients may choose not to participate in the study and continue to receive usual care.

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