

Protocol Outline

Protocol Title: Use of Text messaging for positive reinforcement to help improve quality of life in pediatric patients with obesity.

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I. Abstract

Background and Significance:

Pediatric obesity has become a public health crisis in the United States. Although research has been conducted surrounding this topic, rarely does this research utilize mobile technology to promote accountability in children. Limited research has been done looking at any potential relationship between use of mobile apps and the benefit for quality of life in this patient population.

Hypothesis:

We hypothesize that providing positive reinforcement through text messaging to children living with obesity will improve their overall quality of life.

Specific Aims:

This study primarily aims to evaluate the utility of mobile technology in improving the quality of life of children living with obesity. Another aim of this study is to assess mobile technology's role in promoting accountability in children with obesity.

Brief Methods:

We will recruit patients between the ages of 13 and 18.

We will administer a pre and post survey regarding quality of life for pediatric obese patients. This survey has been well studied and used in numerous other studies. The family will be given recommendations on various ways to increase physical activity weekly. These patients will then receive positive reinforcement for completed exercises through text messages.

II. Background and Significance/Preliminary Studies

Pediatric obesity has become a public health crisis in the United States. The prevalence of overweight and obese children has increased anywhere from two to three-fold among various age groups in the last few decades. The American Academy of Pediatrics (AAP) has outlined the unique role of pediatricians in the prevention of pediatric obesity. By following children throughout a large portion of their lives, pediatricians can encourage healthful behaviors and promote family engagement¹. The AAP has also emphasized the importance of health supervision

to promote increased levels of physical activity and early recognition of pediatric obesity in patients².

In public health practice, HRQOL can be utilized to understand a patient's perception of their own physical and mental health³. In addition, the assessment of quality of life in children can pose unique problems due to children's perception of illness, interpretation of questions, and perspective on disease time course⁴. One study has found that children in the United States living with a chronic medical condition are among those with the poorest HRQOL⁵. Several studies have shown that patients with obesity have lower self-reported health, especially in the youngest adolescents (ages 12-14).

Many studies have been conducted to determine the utility of mobile applications or text messaging systems in changing the behavior of children with pediatric obesity. Few, however, have used mobile applications or text messaging to assess accountability in health decisions and the quality of life outcome for these children.

One particular study, concluded that the use of coaching through twice-weekly text messages and telephone contact every other month improved the quality of life outcome in children ages 2-12 years old with a BMI > 85th percentile from primary care practices in Massachusetts⁶. Many studies have created applications or web-based interventions of their own to decrease pediatric obesity. FitKids, a community-level intervention in Memphis, TN, utilized a mobile website to support parents and children in achieving healthier lifestyles¹⁰. Another study used a multi-component intervention, "HAPPY ME," that included a wearable device¹¹.

It is evident that the majority of studies conducted include the interplay of multiple resources and forms of technology to promote behavior change. Studies have also been conducted to determine the quality and content of commercially available mobile applications. In 2014, a large iTunes app search coded 62 total apps for adherence to the American Academy of Pediatrics guidelines for preventing pediatric obesity and found scores to be consistently low¹². Another study showed similar results, indicating that commercially available apps for children had moderate quality overall and scored highest in functionality rather than information quality¹³.

These findings suggest that many commercially available mobile applications are insufficient in changing behavior outcomes in children with pediatric obesity. On the other hand, little has been discovered about the impact mobile applications can have on the quality of life in these children by holding them accountable for their health decisions.

This research project hopes to add to the literature other ways to help improve quality of life for this patient population with simple text messaging and potentially help them improve their overall lifestyle and general health.

III. Study Aims

Our study hopes to investigate the relationship between positive reinforcement for exercise activities in pediatric patients living with obesity and quality of life. We hypothesize that providing positive reinforcement through text messaging to children living with obesity will improve their overall quality of life.

IV. Administrative Organization

Patients will be recruited from the Loyola University Medical Center outpatient clinic during their well visit with their primary care physician. The principal investigator or co-PI will screen the patients being seen in the outpatient center by age and BMI that are automatically populated for each visit on the schedule page. Once a patient is identified as a potential research subject, the PI or co-PI will approach the attending to let them know that the patient is a good candidate and confirm that they are an appropriate patient for the study. If the attending agrees, then the research team will approach the family about the study while they are in clinic to see if they are interested in participating in the study.

V. Study Design

This will be a prospective interventional cohort study following a group of patient patients with obesity. Informed consent will be obtained from the parents from a member of the research committee. Informed assent will also be obtained from the patient from a member of the research committee.

VI. Study Procedures

We will review the schedule in the pediatrics department daily and approach all patients that meet our inclusion criteria listed below. Per standard of care for patients with obesity, they have a scheduled follow up for a weight check at regular intervals that can include one month, 3 months or 6 months.

Inclusion criteria:

- A. Ages 13-18
- B. BMI >95%
- C. Has a cell phone

Exclusion criteria:

- A. Developmental delay and inability to read
- B. Does not have a cell phone**

The 40 subjects will be randomly assigned to either a control group or an intervention group.

Survey

A 23 item PedsQL 4.0 pre-survey will be administered to pediatric patients to establish a baseline at their wellness visits. The parent of the patient will also complete the PedsQL survey. The patients' BMI and blood pressure will be recorded. At the end of the 6 month period, the same PedsQL 4.0 will be administered again to both the patient and parent at the scheduled 6 month weight check that is standard of care.

We will use a text message application created by the Loyola informatics team. This application will be able to text the subjects using their cell phone number via an email service from the provider. For example, 123456789@cellservice provider.com. This allows the research team to send text messages through an application without using a personal phone number. In addition, it offers automatic responses that will save them when sending messages to the patient.

For six months, patients in the study will receive a text message twice per week.

Text messaging

There will be two groups within this study—a control group and an intervention group. For the control group, they will receive two text messages weekly. The first text message will ask if they completed the recommended activity. When they respond, they will receive a second text message stating, "Thanks for your response."

In the intervention group, the first text message will ask if they completed the recommended activity. If they respond yes, they will receive a positive reinforcement response comprising the words "Great job! We're so proud of you! Keep up the good work!". If they respond no, they will receive a text message stating "Thanks for your response".

Study Activities: See attached schedule for details

The weekly activities we will recommend for the subjects include:

1. Walking for 30 minutes 3 times a week
2. Speed walk for 30 minutes 3 times a week
3. Walk up and down stairs for 30 minutes 3 times a week
4. Jogging for 30 minutes 3 times a week
5. Jumping jacks for 30 minute 3 times a week

Data:

All patient data will be stored in a secure REDCap database located at hsddb.luhs.org/redcap.

Statistical analysis:

In this study, patients who are age 18 and under with a BMI in at least the 95th percentile will be randomized to an intervention or control text-messaging cohort using a 1:1 random allocation. Subsequently, they will be asked to complete assigned exercises. For six months, these patients will receive a text message twice per week asking whether they completed their assigned exercises. For those in the intervention group, when they respond "Yes", they will receive a positive reinforcement response comprising the words "Great job! We're so proud of you! Keep up the good work!". Otherwise, when they respond "No", they will receive a message saying "Thanks for your response". For those assigned to the control group, they will always receive the message "Thanks for your response" regardless of whether they complete or do not complete the assigned exercises.

Six months following randomization, one goal of the proposed study is to test the null hypothesis that average total score on PEDSQ4.0 questionnaire between the two groups are equal. With a proposed sample size of 20 assigned to receive the positive reinforcement response and 20 assigned to receive the control response (N = 40), the study will have power of 80.0% to yield a statistically significant result. This computation assumes a mean difference between the two

cohorts of 14.8 points (corresponding to means of 81.8 for the positive reinforcement cohort and 67.0 for the control response cohort) and a common within-group standard deviation of 16.3 points⁷. This computation also assumes the criterion for significance (alpha) is 0.05 and that the test will be 2-tailed, meaning an effect in either direction will be interpreted.

Recommended Protocol Text for the Analysis Plan

Patients under age 18 with a BMI in at least the 95th percentile will be asked to complete assigned exercises and will receive text messages asking them if they completed such exercises. At baseline and the end of the study, the participants will complete the 23-item PEDSQ4.0 assessment. For each participant, the baseline value will be subtracted from the 6-month value. An independent samples t-test will be used to compare this delta score between the cohort assigned to receive the positive reinforcement response and the cohort assigned to receive the control response. For this comparison, the normal distribution assumption of the delta score will be assessed using QQ plots and outliers will be assessed using box plots. The homogeneity of variances assumption will be assessed using Levene's test. If any parametric assumption is strongly violated, a non-parametric Wilcoxon rank-sum test may be used to compare ranked PEDSQ4.0 scores between the two cohorts. All analyses will be completed using SAS version 9.4 (Cary, NC) by a Biostatistician in the Clinical Research Office.

VII. Safety Monitoring Plan

There are no adverse events that could be associated with text messages we will send to the subjects. We will send these text messages on Monday early evening between the 5pm to 6pm. We chose this time because they will not be in school and are unlikely to be driving or doing activities that they could be distracted from when they receive the text, which could cause harm.

If there is an adverse effect, we will ask the subjects to notify the principal investigator of the project. We will review safety information once a month.

VIII. Literature Cited

References

- 1 Daniels et al. The role of the pediatrician in primary prevention of obesity. *Pediatrics*. 2015;136(1):e275
- 2 Snyder, et al. American academy of pediatrics. *Congenital Heart Disease*. 2012;7(2):200-201.
- 3 Health-Related Quality of Life (HRQOL) | CDC. (2018). Retrieved from <https://www.cdc.gov/hrqol/index.htm>
- 4 Eiser, et al. A review of measures of quality of life for children with chronic illness. *Archives of disease in childhood*. 2001;84(3):205-211.
- 5 Simon, et al. Assessment of children's health-related quality of life in the united states with a multidimensional index. *Pediatrics*. 2008;121(1):e118.
- 6 Swallen, et al. Overweight, obesity, and health-related quality of life among adolescents: The national longitudinal study of adolescent health. *Pediatrics*. 2005;115(2):340.
- 7 Schwimmer, et al. Health-related quality of life of severely obese children and adolescents. *JAMA*. 2003;289(14):1813-1819.

- 8 Williams, et al. Health-related quality of life of overweight and obese children. *JAMA*. 2005;293(1):70-76.
- 9 Taveras, et al. Comparative effectiveness of clinical-community childhood obesity interventions: A randomized clinical trial. *JAMA Pediatrics*. 2017;171(8):e171325.
- 10 Ullmann, et al. Memphis FitKids: Implementing a mobile-friendly web-based application to enhance parents' participation in improving child health. *BMC Public Health*. 2018;18(1):1-12.
- 11 Yang, et al. Interventions for preventing childhood obesity with smartphones and wearable device: A protocol for a non-randomized controlled trial. *International journal of environmental research and public health*. 2017;14(2):184.
- 12 Wearing et al. iPhone app adherence to expert-recommended guidelines for pediatric obesity prevention. *Childhood Obesity*. 2014;10(2):132-144.
- 13 Schoeppe, et al. Apps to improve diet, physical activity and sedentary behaviour in children and adolescents: A review of quality, features and behaviour change techniques. *The International Journal of Behavioral Nutrition and Physical Activity*. 2017;14.