Does a Virtual Coach Offer a Better Solution for Weight Reduction in Ventral Hernia Patients with Obesity?

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PROTOCOL

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Protocol Template

1. Title: Does a Virtual Coach Offer a Better Solution for Weight Reduction in Ventral Hernia Patients with Obesity?

2. Investigators:

- Principal Investigator: Jana Sacco MD
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- Student: Zach Littlefield, MD; Supervisory Chair: Cassandra White, MD; Committee member: Brian Celso, PhD

3. **Abstract:** Many ventral hernia patients are obese and have trouble losing weight. Obesity is a known risk factor for hernias and perioperative complications. Wound and systemic complications increase the likelihood of both hernia recurrences and hospital readmissions. Additionally, postponement of surgery for failure to achieve an optimal weight prior to elective operations may delay care, and often increases the complexity of the surgery and postoperative complications. While preoperative weight optimization is generally recommended prior to operations, ventral hernia patients with obesity often struggle with weight loss. The medical/scientific question to address is: can the use of a more technologically advanced tool to overcome the physical, psychological, and social barriers that interfere with weight reduction prior to surgery minimize the adverse effects of surgical delay? The purpose for this research is to create a MyChart-enabled virtual coach that assists obese patients lose weight prior to ventral hernia surgery. We intend to show how the use of a virtual coach is more effective in preoperative weight reduction prior to ventral hernia repair over usual care. Correspondingly, this may lower unplanned hospital readmissions. For this Pragmatic Clinical Trial, where randomization is not possible, we will implement the use of propensity score matching that sorts individuals into different study arms as if randomly assigned. The primary outcome is the average net amount of time-dependent weight change per group over six months. Secondary outcomes are for the intervention group, patient satisfaction with the virtual coach and for both groups, quality of life. We will also identify areas of social and economic disadvantage that may contribute to higher obesity rates. Machine learning (ML) modeling will be used to determine the important features for weight lost over the course of the study. The impact of this work will be to demonstrate efficacy and realized workflow efficiencies within a hospital-based surgery clinic.

4. **Background:** Over two million abdominal surgeries are performed in the United States annually and approximately 20-25% of these patients will go on to develop an incisional ventral hernia. Individuals with obesity frequently find themselves the targets of prejudicial attitudes from others and the social stigma attached to obesity. The obesity epidemic in the U.S. has only exacerbated hernia repair complications following surgical procedures. Additionally, the postponement of surgery for weight reduction further increases the likelihood of post-operative complications. Any delay in achieving optimal weight prior to elective surgery may result in more complex operations or the possible need for emergency surgery while waiting for elective repair. Perioperative complications such as wound infection can likely result in hospital readmissions.

   Preoperative weight optimization is generally recommended prior to any ventral hernia surgery and is even more important for open operations that are associated with a higher incidence of surgical site infection. Despite the availability of a variety of programs for weight loss, there appear to be inconsistencies in engagement, high attrition rates, and poor sustained weight loss over time. Furthermore, many weight loss programs fail to consider ideal strategies to reach and engage diverse audiences that address social determinants related to obesity or to scale programs to maximize effectiveness. Thus, there remain significant social and economic disparities based on race and ethnicity, which also lead to surgery delays. Hence, pre-operative weight optimization reduces both complications from hernia repair and hernia recurrence reducing the possibility of hospital readmission.

5. **Specific Aims:**

   Aim 1: Develop a system that utilizes a MyChart-enabled virtual coach designed to facilitate weight loss for patients awaiting hernia repair surgery that couples with their EPIC Electronic Health Record (EHR).

   Aim 2: Conduct a two-arm, pragmatic clinical trial that compares the use of the integrated virtual coach to standard of care on preoperative weight loss for hernia repair patients.

   Aim 3: ML modeling with patient demographics and the Area Deprivation Index (ADI) which provides a socio-economic score for each hernia repair patient to explore weight-related social determinants of health (SDOH).

6. **Research Plan:**

   For Aim 1, we will engage in formative work to build and adapt the MyChart-enabled virtual coach with existing evidence-based persuasive weight-loss message content. We will then beta test the virtual coach to establish usability and

functionality in a minimum viable product while in development with basic features, but enough to attract end-users. Additionally, we will construct a library of weight-loss message content based on the numerous inquiries from hernia patients with obesity who utilized the virtual coach service provided through their EHR platform. The inquiries will be collated and indexed by frequency and importance to build an AI-enabled Chatbot for an Agency for Health Research and Quality grant.

For Aim 2, we will engage hernia surgery patients and offer the use of our MyChart-enabled virtual coach to aid patients with obesity who elected to undergo non-surgical weight reduction prior to ventral hernia surgery. A comparator group will consist of those patients who chose to receive usual care and follow a patient-directed weight loss strategy, however, consent to participate. The comparator group will be recommended to diet and exercise prior to surgery by his or her surgeon. Propensity score matching will be utilized as a statistical technique to form a control group as if individuals were randomly assigned.

For Aim 3, we will develop a ML algorithm to detect features for obese hernia surgery patients based on type of weight loss strategy and SDOH for a more precise risk assessment of surgery outcome based on the role of those social determinants associated with obesity. To complete this aim, we will utilize information readily available in the EHR to evaluate a ML classification model and risk stratify patients based on demographics and SDOH with a high degree of accuracy. A supervised approach wherein a ML algorithm will be built with a training set, then tested on a separate dataset to refine and validate the model. We will make the most of our patient data through the use of technology that incorporates SDOH influences on the diverse ethnic and social population of the Jacksonville area.

Research setting: The research setting is the University of Florida College of Medicine-Jacksonville (UFCOM–J) located at UF Health Jacksonville, FL in the city's urban core and serves as the region's safety-net hospital. The 2021 estimated population of Duval County, (Jacksonville) Florida is 1,021,827. In Duval County, 66.2% of adults, approximately 676,500 are overweight or have obesity. Many University of Florida College of Medicine-Jacksonville (UFCOM-J) outpatient clinics within the City of Jacksonville and surrounding areas treat these individuals with obesity.

Methodology

Participants: Patients diagnosed with obesity who are required to lose weight prior to ventral hernia repair.

Inclusion criteria: Patients 18 years of age and older with a Body Mass Index (BMI) of 30 and above and diagnosed with Obesity by the ICD 10 Code: E66.9 who have been evaluated by a surgeon and offered elective ventral hernia repair Also, have a complete medical record that allows for statistical calculations to be performed.

Exclusion criteria: Pregnant females, patients with severe mental disorders, prescribed psychiatric medications associated with weight gain, a history of a Substance Use Disorder, patients on long-term steroid therapy, and patients with insufficient medical records.

Instruments

The Body Mass Index (BMI) is a person's weight in kilograms (or pounds) divided by the square of height in meters (or feet). The BMI is categorized as underweight(under 18.5 kg/m2), normal weight(18.5 to 24.9), overweight (25 to 29.9), or obese (30 or more) based on tissue mass and height. A high BMI can indicate high body fatness.

Satisfaction with the virtual coach will be measured by a single question, “How satisfied are you with the virtual coach.” and rated on a 7 point Likert scale, from 1, Not satisfied at all, 4 Neutral to 7, Very satisfied.

The 12-question HerQLes is a self-reported outcome measure assessing the impact of health on an individual's everyday life and has been validated as a hernia specific quality of life measure.

The Area Deprivation Index (ADI) measures neighborhood disadvantage using a combination of 17 variables such as income, education, employment, and housing quality, and is often used to inform health delivery and policy, especially for the most disadvantaged neighborhood groups. This measure has been validated and is actively used by a number of organizations including the Centers for Medicare and Medicaid Services. The ADI using neighborhood disadvantage is often used to inform health delivery and policy, especially for the most disadvantaged neighborhood groups.

Procedures

This is a Pragmatic Clinical Trial research design. The University of Florida Institutional Review Board will act as the approval body for this study. We will first obtain approval for the study from the UF Institutional Review Board. Our plan for recruiting trial participants will occur during routine clinical care in the outpatient surgery settings to maximize generalizability of the trial’s results. There are also comprehensive disease registries embedded in the EPIC EHR for recruitment purposes. We will consent participants while explaining that choosing to opt out does not have any bearing on their treatment. As our patient population is approximately 50% African American, we do not anticipate any specific barriers to recruitment diversity. We also have the presence of an electronic health record (EPIC EHR) system that has a long-standing record for its maturity within our healthcare system that is fully integrated with other data systems.

To access the virtual coaching application, we provide a digital health technology (MyChart-enabled virtual coach) that couples with their EHR to encourage adherence to recommended weight loss practices. The virtual coach monitor, a Registered Nurse, will respond to inquiries by participants in a timely fashion from a library of evidence-based information on weight and weight management strategies. The virtual coach will base solutions from a weight neutral approach that serves as an alternative to usual care. The virtual coach will provide instruction on practices for weight loss that focus on such topics as mindful eating, healthy food choices, and increased physical activities for reaching a more optimal weight. The virtual coach will have monthly weight check-ins with each patient to assess progress and will intermittently send words of encouragement and conversation starters to increase engagement. Additionally, the EPIC-based platform will allow people to engage more directly with a system prior to surgery that helps them stay on track while providing support for patients who struggle with changing habits or behaviors closely linked to their diet and physical activity. Multiple data points will be collected including the magnitude of weight change preoperatively, number of interactions and degree of satisfaction with the virtual coach. Those who choose usual care although consent to participate will be in the comparator group and receive direction to focus on weight, dieting and exercise. Additionally, both the intervention and comparator groups will complete a baseline HerQLes and again at six months or during their preoperative testing, whichever comes first.

We will develop a ML model using the UFCOM-J EPIC database, the most comprehensive source of locally derived information on hospital admissions and treatment outcomes in our area. Provided in electronic format, this encounter-level data will include patient baseline characteristics (e.g. demographics such as age, sex, race, ethnicity, BMI, and ADI), dates and results of diagnostic tests, disease characteristics, proposed treatments (e.g. surgery), and payer (e.g. type of insurance or uninsured). The University of Florida has the UF Integrated Data Repository database (IDR) for extraction of digitized EHR data. We will validate and characterize our ML model based on the UF IDR. The purpose of using a ML approach is to produce a model that classifies patients into risk groups that will be enhanced with the data from the ADI for a more precise analysis associated with SDOH. Our investigators are familiar with typical strategies used to recruit participants routinely served in the healthcare setting. Additionally, the research infrastructure to support using the EPIC EHR for the study will be through the Center for Data Solution (CDS) that is comprised of three hubs: Advanced Analytics: houses analysts with expertise in data science, machine learning, database architecture, and bioinformatics. Epidemiology: to assist with translation of results to ensure that our work has lasting impact on the diverse patient population in our Florida communities. Biostatistics: offer traditional analysis for both retrospective and prospective studies.

Statistical Analysis Plan

Descriptive summaries will be frequencies and percentages for categorical variables and, medians, and quartiles for numeric variables. Unadjusted comparisons between groups (virtual coach vs usual care) will be done using the Pearson's Chi-square test (or Fisher's exact test) for categorical data, and using Independent t-tests (or the nonparametric Wilcoxon rank sum tests) for continuous data to measure the degree of difference between the pre-surgery and post-surgery weight loss. The primary outcome is the average net amount of time-dependent weight change per group over six months. Secondary outcomes are for the intervention group, patient satisfaction with the virtual coach and for both groups, quality of life. Multiple regression modeling, adjusting for all covariates, will be used to determine the contribution of the predictor variables with the outcome weight lost over the course of the study. A time-dependent weight variable will be calculated to control for the repeated measures.

For this Pragmatic Clinical Trial, where randomization is not possible, we will implement the "real-world" use of propensity score matching. The model assumes that individuals are sorted into different study arms as if randomly assigned. Regression essentially projects the behavior of individuals in one group outside the observed range to form a comparison for the other at common values of the covariate. This method will be utilized to specify a function measuring the proximity of one case to another based on the time-dependent weight variable. Cases will be grouped to minimize the distance between matched cases and unlike regression, the various forms of matching do not presume linearity.

For the ML modeling, traditional analyses such as univariate and multivariable logistic regressions will be employed to compare model predictive power with the ML algorithm. As the ML model is more exploratory, we will compare various classification techniques such as logistic regression, decision trees, random forest trees, neural networks, gradient boosted trees, naïve Bayes and support vector machines. Those models will be evaluated using receiver operating characteristic curves (ROC) and their area under the curve (AUC). The level of significance will be set at 0.05.

Sample Size, Power, Data Safety and Management Plan

The total sample size estimated for the main research analysis include both virtual coach participants and usual care participants. The sample size calculation was performed using an alpha of 0.05, beta 0.20, a 10% dropout rate, and based on the assumption in the primary outcome of a 7% weight change between the two groups. This also assumes a two fold increase in quality of life for the virtual coach participants compared to the control group. Thus, a total of 60 patients are estimated to be needed for randomization. IBM Corp. All analyses will be done in SPSS® Version 29.0 Released 2022. IBM SPSS Statistics for Windows, Version 29.0. Armonk, NY: IBM Corp.

There a no Data Safety Monitoring Board (DSMB) or an oversight committee for this research project.

Data Management Plan and Data Confidentiality: Models and statistical analysis will be performed using mainstream software and libraries. Data collected will be entered and stored exclusively on the REDCap research site (a UF secure site maintained solely for protecting research data) and de-identified.

7. **Possible Discomforts and Risks:** Physical risk related to the behavioral intervention is minimal. While this is a minimal risk study, there is always a potential for loss of patient confidentiality to the subject. Measures to prevent these risks are that participation in the study will be voluntary and not impact standard clinical medical care. We take significant measures to avoid loss of confidentiality, including only allowing authorized, IRB approved, study personnel to have access to subject records. We also strive to prevent the loss of confidentiality by keeping all paper documents locked in secure files and keeping electronic data stored in password-protected databases. As an extra precaution, all study data and university computers are secured in a badge-access only building, further preventing the possibility of data being compromised. Furthermore, the data collected will be entered and stored exclusively on the REDCap research site (a UF secure site maintained solely for protecting research data) and de-identified.

8. **Possible Benefits:** There are no potential benefits associated with participation for research subjects. However, the proposed research will be used to develop interventions to improve safety and outcomes for future surgical patients.

9. **Conflict of Interest:** The study investigators have no conflicts of interest to declare.