Effectivemess of an Augmented Digital Diabetes Prevention Program for Adults With Prediabetes Having Elective Total Hip Arthroplasty: A Randomized Control Trial

FUNDER: Anesthesiology Research Department

PROTOCOL NO.: 2023-2194

VERSION & DATE: Version 1; November 7, 2023

TABLE OF CONTENTS

PROTOCOL SYNOPSIS

Protocol Title:	Effectiveness of an Augmented Digital Diabetes Prevention Program for Adults With Prediabetes Having Elective Total Hip Arthroplasty: A Randomized Control Trial
Protocol Number:	2023-2194
Protocol Date:	11/7/2023
Sponsor:	Anesthesiology Department
Principal Investigator:	Stephanie Cheng
Products:	N/A
Objective:	The aim of this study is to determine if completion of the Diabetes Prevention Program (DPP) via the Transform 10 website can significantly decrease hemoglobin A1c (HbA1c) levels and Body Mass Index (BMI) in prediabetic individuals undergoing total hip arthroplasty (THA) procedure.
Study Design:	Randomized Clinical Trial
Enrollment:	114
Subject Criteria:	Inclusion: • Planned primary total hip arthroplasty for the indication of osteoarthritis at facility • Age 18 -64 • Overweight (BMI 25+ or 22+ if Asian) • HbA1c 5.7%-6.4% • Predicted ability to walk following procedure • English or Spanish speaking • Able to provide informed consent • Willing to accept a random assignment • Readiness for change • ASA 1 or 2
	Exclusion: • Not meeting all inclusion criteria • Diagnosed with Type I or II diabetes • Diagnosed with congestive heart failure, coronary

	artery disease, chronic obstructive pulmonary disease, pulmonary hypertension • Diagnosed with dementia or probable Alzheimer's disease • Taking oral hypoglycemic agents other than Metformin • Participating in a concurrent weight management program outside of HSS current protocol • Unable to engage in walking as physical activity post-procedure • Had bariatric surgery within the past 3 years or planning surgery within the next 12 months • Anti-obesity or diabetes therapy within the preceding 4 months • Any mental health condition, including eating disorders or alcohol/substance use, which would preclude full participation • Self-report as currently pregnant or within 6 weeks of having given birth (or planning to become pregnant in the next 12 months) • Unstable cardiac disease (i.e. heart attack/failure or stroke in the last 6 months, or currently in cardiac rehabilitation) • On dialysis or an active organ transplant list • Chronic kidney disease • Untreated thyroid disease • Cancer within the last 5 years unless skin cancer (i.e. currently or within the last 5 years in chemotherapy or radiation treatment) • Unwilling to accept random assignment
Study Duration:	2 years
Data Collection:	**Sources:** Epic, Medical Records, Transofrm10 website, and Patient Reported **Variables:** Name, MRN, DOB, Race, Gender, Ethnicity, Height, Weight, Initial BMI, HbA1c, Active Minutes, Co-morbities, Medications to manage pre-existing conditions, Postoperative complications, ICU admission, Patient readmission, Postoperative length of stay, Postoperative health-related quality of life, Payer source
Statistical Analysis:	Proposed analysis: Two-sided paired t-test Interim analysis planned? No Alpha level 0.05

	Beta or power level: 0.80 Number of groups being compared: 2 Resulting number per group: 57 Total sample size: 114

1.0 INTRODUCTION

Poor glycemic control is an increasingly prevalent risk factor, with one in three adults in the United States living with prediabetes. Each percentage increase in HbA1c has been shown to be associated with increased major perioperative complications, ICU admission, and hospital length of stay. Further, the preoperative period is considered a 'teachable moment' in healthcare. The prevalence of obesity in patients undergoing total hip arthroplasty is disproportionately higher than in the general population. Given most patients have improved gradual ability to walk, and an operative procedure represents a teachable moment in healthcare, the perioperative period represents a novel distribution strategy.

2.0 PRODUCT DESCRIPTION

The 6 month long diabetes prevention program is offered via an interactive website called Transform10. This is a self-paced curriculum which covers:

- Strategies to overcome emotional eating using cognitive behavioral therapy principles.
- Improving cardiovascular function with capacity-matched training programs using participants estimated cardio scores.
- An introductory-level course for increasing muscle and bone density foundation via strength training.
- Education regarding physical therapy and expectations for patients.

3.0 OBJECTIVE OF CLINICAL STUDY

The aim of this study is to determine if completion of the Diabetes Prevention Program (DPP) via the Transform 10 website can significantly decrease hemoglobin A1c (HbA1c) levels and Body Mass Index (BMI) in prediabetic individuals undergoing total hip arthroplasty (THA) procedure. As part of the standard procedure of the Centers for Disease Control (CDC)-approved DPP program, all study participants will report their active minutes and weight via the Transform10 website throughout the 6 month-long programs. In addition, participants will have a repeat Hba1c test ordered at the end of the program by the medical director as part of routine procedures. The primary outcome of interest is change in percent of body weight before and after a 6-month intervention period. The secondary outcomes consist of change in percent HbA1c, postoperative outcomes, patient satisfaction, and patient readiness for change.

4.0 STUDY HYPOTHESES

1. An augmented digital diabetes prevention program is an effective strategy for weight loss in adults with prediabetes undergoing elective total hip arthroplasty.

2. An augmented digital diabetes prevention program is an effective strategy to decrease HbA1c in adults with prediabetes undergoing elective total hip arthroplasty.
3. An augmented digital diabetes prevention program is an effective strategy to improve postoperative outcomes and patient satisfaction in adults with prediabetes undergoing elective total hip arthroplasty.

5.0 STUDY DESIGN

5.1 Study Duration

2 years

5.2 Endpoints

5.2.1 Primary Endpoint

- Body mass index will be measured at pre-surgical screening and again after a 6 month and 12-month period. The percentage change in body weight will be recorded at program completion and 6 months prior to program completion.

5.2.2 Secondary Endpoints

- Hemoglobin a1c levels will be measured at pre-surgical screening and again after a 6 month and 12-month period. The percent change in hba1c level will be recorded.
- Postoperative complications, ICU admission, patient readmission, and postoperative length of stay will be recorded from Epic from post-operative care unit (PACU) admission to 12 months post-surgery.
- Patient satisfaction will be a questionnaire that is asked by the Transform10 website 1 year after surgery. This questionnaire assess how satisfied patients have been with their post operative pain management.
- Patients will be asked 8 questions upon access to the Transform10 program to assess their level of readiness for change. Each question asks if the patient is capable of a task and the responses range from "Sure I can", "Think I can", "Not sure I can", "Don't think I can".
- The health-related quality of life questionnaire will be asked via the transform10 website. This assesses how a patient's pain has impacted their day to day lives 12 months after their day of surgery.

5.3 Study Sites

Hospital for Special Surgery- Main Campus

6.0 STUDY POPULATION

6.1 Number of Subjects

A total of 114 subjects will be enrolled.

6.2 Inclusion Criteria

Subjects of either gender will be included if they:

- Planned primary total hip arthroplasty for the indication of osteoarthritis at facility
- Age 18 -64
- Overweight (BMI 25+ or 22+ if Asian)
- HbA1c 5.7%-6.4%
- Predicted ability to walk following procedure
- English or Spanish speaking
- Able to provide informed consent
- Willing to accept a random assignment
- Readiness for change
- ASA 1 or 2

6.3 Exclusion Criteria

Subjects will be excluded from the study if they:

- Not meeting all inclusion criteria
- Diagnosed with Type I or II diabetes
- Diagnosed with congestive heart failure, coronary artery disease, chronic obstructive pulmonary disease, pulmonary hypertension
- Diagnosed with dementia or probable Alzheimer's disease
- Taking oral hypoglycemic agents other than Metformin
- Participating in a concurrent weight management program outside of HSS current protocol
- Unable to engage in walking as physical activity post-procedure
- Had bariatric surgery within the past 3 years or planning surgery within the next 12 months
- Anti-obesity or diabetes therapy within the preceding 4 months
- Any mental health condition, including eating disorders or alcohol/substance use, which would preclude full participation
- Self-report as currently pregnant or within 6 weeks of having given birth (or planning to become pregnant in the next 12 months)
- Unstable cardiac disease (i.e. heart attack/failure or stroke in the last 6 months, or currently in cardiac rehabilitation)
- On dialysis or an active organ transplant list
- Chronic kidney disease
- Untreated thyroid disease

- Cancer within the last 5 years unless skin cancer (i.e. currently or within the last 5 years in chemotherapy or radiation treatment)
- Unwilling to accept random assignment

6.4 Randomization

A computer-generated, 1:1 ratio randomization schedule with blocks of sizes 4 and 6 will be created by a statistician not otherwise involved in the study.
Participants will be randomized to 1 of 2 groups:

- Group 1 Diabetes Prevention Program Intervention Group
- Group 2 Diabetes Prevention Program Delayed Intervention Group

7.0 PROCEDURES

7.1 Surgical Procedure

Total Hip Arthroplasty

7.2 Medical Record Requirements

EPIC

7.3 Data Collection

The following data will be collected:

Pre-operative/Baseline

- basic demographic data
- patient weight & height, BMI, HbA1c

Surgical procedure

- date of surgery
- type of surgery

Follow-up visits (6 weeks, 1 year)

- HbA1c
- Postoperative health-related quality of life questionnaire
- Patient satisfaction questionnaire

7.4 Schedule of Assessments

Procedures	Day(s) prior to surgery	Pre-surgical screening	Pre-op (holding Area)	POD 1 (24 hours after surgery)	6 months after day of surgery	12 months after day of surgery
Identify eligible patients before surgery	X					
Obtain consent (e-consent or in person)	X					
Transform 10 website			X (Intervention Group)		X (Control Group)	
HbA1c Test		X (Both Groups)			X (Both Groups)	X (Both Groups)
Patient Satisfaction and Health-related quality of life survey (HRQOL)						X (Both Groups)

8.0 STATISTICAL ANALYSIS

Proposed analysis:

Two-sided paired t-test

Interim analysis planned? No

Alpha level: 0.05

Beta or power level: 0.80

Number of groups being compared: 2

Resulting number per group: 57

Total sample size: 114

9.0 ADVERSE EVENT ASSESSMENT

All Adverse Events (AEs) will be reported in the final study report. Definitions for Adverse Event (AE) used in this study are listed below and are based on FDA and international guidelines:

9.1 Adverse Event (AE)

Any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product which does not necessarily have to have a causal relationship with this treatment. An adverse event (AE) can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding, for example), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not considered related to the medicinal (investigational) product.

9.2 Serious Adverse Events (SAE)

The event is serious and should be reported to FDA when the patient outcome is: Death, Life-threatening, Hospitalization (initial or prolonged), Disability or Permanent Damage, Congenital Anomaly/Birth Defect, Required Intervention to Prevent Permanent Impairment or Damage (Devices), Other Serious (Important Medical Events).

9.3 Adverse Event Relationship

Relationship to study: definitely, probably, possibly, not related.

10.0 INVESTIGATOR RESPONSIBILITIES, RECORD AND REPORTS

10.1 Subject Consent and Information

Research assistants will screen the co-investigating surgeons' patients undergoing ambulatory total hip arthroplasty surgery. Screening will involve reviewing the patient's EPIC chart to ensure that they meet the inclusion criteria and are not excluded due to any of the exclusion criteria listed. Patients who meet the inclusion criteria will be identified as potential study participants. After the investigating anesthesiologists have confirmed the eligibility of all potential participants, one of the research assistants will call the patient, explain the rationale for the study, and ask if the patient is interested in participating.

10.2 Subject Data Protection

Subject privacy and confidentiality will be maintained through the storage of study data in a password-protected computer database maintained by the Research Director and accessible only to the principal investigator, in addition to other IRB-approved study personnel. Each subject will be assigned a unique study number for identification in the study database. This unique study number will not be derived from or related to information about the individual. The key linking this unique study number to patient identifiers (i.e., name, medical record number, date of birth, registry number) will be maintained in a different password-protected database maintained by Research Director, to which only the primary investigator will have access.

10.3 Staff Information

Primary Investigator: Stephanie Cheng, MD
Research Assistant: Miriam Sheetz 646-714-6685
Angela Puglisi 646-714-6849

10.4 Protocol Reviews

Study protocol reviewed and approved by:

- Anesthesiology CRP
- Hospital for Special Surgery Institutional Review Board

11.0 REFERENCES

1. https://www.cdc.gov/diabetes/data/statistics-report/index.html
2. Wexler DJ, Nathan DM, Grant RW, Regan S, Van Leuvan AL, Cagliero E. Prevalence of elevated hemoglobin A1c among patients admitted to the hospital without a diagnosis of diabetes. J Clin Endocrinol Metab. 2008 Nov;93(11):4238-44. doi: 10.1210/jc.2008-1090. Epub 2008 Aug 12. PMID: 18697862; PMCID: PMC2582564.
3. Flocke SA, Clark E, Antognoli E, Mason MJ, Lawson PJ, Smith S, Cohen DJ. Teachable moments for health behavior change and intermediate patient outcomes.

Patient Educ Couns. 2014 Jul;96(1):43-9. doi: 10.1016/j.pec.2014.03.014. Epub 2014 May 1. PMID: 24856449; PMCID: PMC4427843.

4. Kirley K, Sachdev N. Digital Health-Supported Lifestyle Change Programs to Prevent Type 2 Diabetes. Diabetes Spectr. 2018 Nov;31(4):303-309. doi: 10.2337/ds18-0019. PMID: 30510384; PMCID: PMC6243222.
5. Cha E, Kim KH, Umpierrez G, Dawkins CR, Bello MK, Lerner HM, Narayan KM, Dunbar SB. A feasibility study to develop a diabetes prevention program for young adults with prediabetes by using digital platforms and a handheld device. Diabetes Educ. 2014 Sep-Oct;40(5):626-37. doi: 10.1177/0145721714539736. Epub 2014 Jun 20. PMID: 24950683; PMCID: PMC4169327.