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Utilizing activity trackers to increase postoperative ambulation

Submission date
17/06/2015

Recruitment status
No longer recruiting

Registration date
29/06/2015

Overall study status
Completed

Last Edited
22/07/2015

Condition category
Surgery

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
We are investigating the use of activity trackers as a novel quality improvement strategy to increase postoperative ambulation (walking after surgery). Postoperative ambulation is frequently recommended in surgical guidelines, but often difficult for patients and hospital staff to comply with. Activity trackers have been successfully used in outpatient clinics as a motivation tool for ambulation and health monitoring, but have rarely been used in the inpatient surgical setting. This study aims to test how well activity trackers perform in increasing postoperative ambulation.

Who can participate?
Adult patients having an bariatric operation performed at our center (that is, laparoscopic roux-n-y gastric bypass, laparoscopic adjustable gastric band, and laparoscopic sleeve gastrectomy).

What does the study involve?
All participants are given activity trackers and then randomly allocated into one of two groups. Those in group 1 are given feedback on the number of steps they tale. Those in group 2 do not receive this feedback. The number of steps taken each day is then compared between the two groups.

What are the possible benefits and risks of participating?
The benefits of participating are limited to the use of the activity trackers and there is no financial compensation for subjects. There are no major risks to wearing the activity trackers.

Where is the study run from?
Boston Medical Center (USA)

When is the study starting and how long is it expected to run for?
March 2015 to March 2016

Who is funding the study?
Boston Medical Center Resident Quality Improvement Council (USA)

Who is the main contact?
Dr Ryan Macht

Contact information

Type(s)
Public

Contact name
Dr Ryan Macht

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Utilizing activity trackers to increase postoperative ambulation: a novel quality improvement strategy to quantify ambulation and decrease bariatric surgery complications

Study objectives
The goal of this study is to evaluate activity tracker feedback as a strategy to increase early ambulation after surgery and to assess the association of early mobility with postoperative outcomes. We hypothesize that feedback from activity trackers will increase postoperative ambulation and lead to decreased ambulation-relation complications.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Boston University Medical Center IRB, 28/01/2015, ref: H-33593

Study design

Single-center randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Not Specified

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Postoperative complications following bariatric surgery

Interventions
All subjects will receive an activity tracker following surgery with randomization into two groups:
1. Participants receive ambulation feedback as an inpatient
2. Participants do not receive any feedback

Intervention Type
Device

Primary outcome measure
Postoperative ambulation (average steps/day)

Secondary outcome measures
1. Postoperative readmission or emergency department visit
2. Venous thromboembolism
3. Postoperative complications
4. Weight loss

Patient experience outcomes will be obtained by a short survey given to all study participants at their two-week postoperative visit.

Overall study start date
01/03/2015

Completion date
31/03/2016

Eligibility

Key inclusion criteria

All patients undergoing any of the three bariatric operations performed at our center (laparoscopic roux-n-y gastric bypass, laparoscopic adjustable gastric band, and laparoscopic sleeve gastrectomy).

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
150

Key exclusion criteria
Patients undergoing revisional bariatric surgery or emergent/elective reoperations

Date of first enrolment
01/03/2015

Date of final enrolment
01/03/2016

Locations

Countries of recruitment
United States of America

Study participating centre
Boston Medical Center
One Boston Medical Center Place
Boston
United States of America
MA 02118

Sponsor information

Organisation
Boston University Medical Center Institutional Review Board

Sponsor details
560 Harrison Avenue
3rd floor, Suite 300

Boston
United States of America
02118

Sponsor type
Research organisation

ROR
https://ror.org/05qwgg493

Funder(s)

Funder type
Research organisation

Funder Name
Boston Medical Center Resident Quality Improvement Council (USA)

Results and Publications

Publication and dissemination plan
We intend to publish the results of our study in the Winter/Spring of 2016. We will publish all initial results on whether our feedback intervention with activity trackers increased postoperative ambulation. Additionally we will publish whether the amount of postoperative ambulation was associated with any clinical outcomes.

Intention to publish date
01/04/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request