

Utilizing activity trackers to increase postoperative ambulation

Submission date 17/06/2015	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 29/06/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 22/07/2015	Condition category Surgery	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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 take. 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-related 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

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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