ERAS APPtimize: a mobile application to involve patients in the pathway of a intestinal surgery

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The use of an interactive app during the perioperative period, when undergoing colorectal surgery, will activate and stimulate patients and therefore result in higher compliance to the ERAS-protocol.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON29410

Source
Nationaal Trial Register

Brief title
ERAS APPtimize

Condition

- Gastrointestinal therapeutic procedures

Health condition

Colorectal surgery

Research involving
Human

Sponsors and support

Primary sponsor: Academic Medical Center (AMC), Department of Surgery

Source(s) of monetary or material Support: Academic Medical Center (AMC)

Intervention

- Other intervention

Explanation

Outcome measures

Primary outcome

The primary outcome is the overall compliance to the ERAS protocol measured as a mean of the percentages of the single ERAS protocol elements which patients are actively involved in.

Secondary outcome

Postoperative data < 30 days

Length of hospital stay

Overall morbidity < 30 days

Complications - major

Complications - minor

Reoperations

Readmission <30 days

In-hospital mortality

Gastrointestinal

Tolerate solid food

Absence of nausea

Passage of first flatus

Passage of first stool

Weight - preoperative

Weight - at discharge

Activity

Mean preoperative physical activity

Postoperative physical activity

Fatigue

Pain

Perceived pain daily postoperative - discharge

Compliance with intake of (pain) medication

PROMS

General quality of life

Gastro-intestinal quality of life

Physical Activity

Patient satisfaction

Study description

Background summary

Perioperative care within colorectal surgery is systematically defined in the ‘Enhanced Recovery After Surgery’ (ERAS) program. This program aims to improve perioperative care in a multimodal way to ensure early but safe release from the hospital. Adequate compliance to the elements of the ERAS protocol is multifactorial with room for improvement through patient involvement, which will enhance the post-operative outcomes such as length of stay in hospital. The aim of this study is to improve compliance to the ERAS protocol. Therefore an application for smartphone will be developed to be used by the patient undergoing colorectal surgery. Objective of this study is to generate evidence that a mobile app can activate and stimulate a patient resulting in improved compliance to the ERAS protocol.

Study objective

The use of an interactive app during the perioperative period, when undergoing colorectal surgery, will activate and stimulate patients and therefore result in higher compliance to the ERAS-protocol.

Study design

Internvention group:

3 weeks prior to surgery download application

1 week prior to surgery start wearing activity tracker

After 3 weeks post-surgery stop wearing activity tracker

Control group:

1 week prior to surgery start wearing activity tracker

After 3 weeks post-surgery stop wearing activity tracker

Intervention

ERAS App, a patient centered mobile application

Contacts

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Eligibility criteria

Age

Adults (18-64 years)
Adults (18-64 years)
Elderly (65 years and older)
Elderly (65 years and older)

Inclusion criteria

- Individuals scheduled to undergo colorectal surgery due to:

o Inflammatory bowel disease

o Colorectal cancer

- Adults aged >18 years

- Possession of a smartphone operated with iOS 8 and up or Android 4.3 and up

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:

- Palliative surgery or surgery with additional radio- or chemotherapy

- Severe comorbidity which could complicate the postoperative course

- Patients with a Karnofsky score ¡Ü40

- Incompetence of understanding the Dutch language

- Visual impairment, unless well corrected with visual aids

- Physical disabilities limiting the use of a mobile application, such as Parkinson¡¯s disease

- When pre-operatively is estimated that following the ERAS protocol postoperative is not feasible

- Multiple organ resection

Study design

Design

Study phase:	N/A
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-10-2019
Enrollment:	140
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Approved WMO

Date:	09-11-2017
Application type:	First submission
Review commission:	MEC Academisch Medisch Centrum (Amsterdam) Kamer G4-214 Postbus 22660 1100 DD Amsterdam 020 566 7389 mecamc@amsterdamumc.nl

Study registrations

Followed up by the following (possibly more current) registration

ID: 52407
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL7109
NTR-old	NTR7314
CCMO	NL63874.018.17
OMON	NL-OMON52407

Study results