Improving the preoperative status of patients undergoing major surgery

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To evaluate the feasibility of (1) the use of the Beter Voorbereid* application and the study procedures of a randomized controlled trial (finished in June 2019) and (2) evaluating the effectiveness of the *Beter Voorbereid* application on improved...

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

Summary

ID

NL-OMON53078

Source
ToetsingOnline

Brief title
IMPRESS

Condition

- Gastrointestinal therapeutic procedures

Synonym
major invasive surgery

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,SIA-RAAK subsidie

Intervention

Keyword: education, preoperative, surgery, webbased

Outcome measures

Primary outcome

(1) The main study endpoint is on feasibility.

Feasibility of the use of BeterVoorbereid* application will be assessed by usability questions (Net promotor score and other usability questions; all patients in the intervention arm) and by semi-structured telephone interviews (random selection of 20 patients in the intervention arm).

(2) The main study endpoint is effectiveness.

The effectiveness will be evaluates using a physical functioning questionnaire on several timepoints, until 12 weeks after hospital discharge

Secondary outcome

(1) we explore whether the use of this eHealth app leads to changes in preoperative lifestyle (i.e. exercise and/or smoking cessation and/or and/or nutrition) compared to control patients. Feasibility of the study procedures will be assessed using registration of patient recruitment and participation and monitoring of data collection.

(2) 'global health', patient satisfaction, global perceived effect, lifestyle changes, length of hospital stay, postoperative complications

Study description

Background summary

The eHealth application *Beter Voorbereid* is a mobile eHealth application that uses a set of questions to map a patient*s lifestyle risk factors for delayed postoperative recovery in patients undergoing major surgery. Based on the life style of the patient, a tailored preoperative lifestyle advise is provided. Additonal guidance by a physiotherapist will be advised based on the level of pre-operative physical functioning and/or present medical risk factors.

Study objective

To evaluate the feasibility of (1) the use of the Beter Voorbereid* application and the study procedures of a randomized controlled trial (finished in June 2019) and (2) evaluating the effectiveness of the *Beter Voorbereid* application on improved functional recovery after surgery when compared to control patients.

Study design

(1) Feasibility study (pilot randomized controlled trial) (finished)
(2) Effectiveness study (RCT)

Intervention

Use of an eHealth application for prehabilitation of surgical patients in the preoperative period. The intervention group is compared to control subjects receiving usual care.

Study burden and risks

There are minimal risks associated with this study. Patients in the intervention group may increase their daily activities and/or visit a physiotherapist. Moreover, all patients included in this study will be followed until the 12 weeks after hospital discharge, with a minimal set of questions per time point (4 post-discharge time points with maximum of 10 minutes per time point to fill in questionnaire).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Age >= 18 years old
Indication for postoperative hospital stay (minimum of two nights)
One or more lifestyle risk factor
Informed consent

Exclusion criteria

Emergency surgery
Unable to work with the eHealth application
Dutch language inproficiency
No access to a tablet or smartphone
Planned for brain surgery
Less than 7 days between inclusion and surgery
Already participating in intensive pre-operative care pathway (including exercise program)
Already participating in a conflicting study (to be determined per participating center)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-11-2018
Enrollment:	580
Type:	Actual

Medical products/devices used

Generic name:	eHealth appllication (app) with personalized lifestyle advices
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	19-07-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	13-11-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	31-03-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Approved WMO Date:	14-03-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 28174
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL61503.029.18
OMON	NL-OMON28174