IMproving the PReoperative StatuS of patients undergoing major surgery

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28174

Source
NTR

Brief title
IMPRESS

Health condition

Major surgery with an indication for postoperative hospital stay

Sponsors and support

Primary sponsor: VUmc
Source(s) of monetary or material Support: Foundation Innovative Alliance – Regional Attention and Action for Knowledge circulation (SIA-RAAK).

Intervention

Outcome measures

Primary outcome

Course of functional recovery, PROMIS CAT Physical Functioning

Secondary outcome

Functional recovery, GPE/PROMIS CAT Physical Functioning – In-hospital physical symptoms, physical functioning and psychological functioning – Social participation, PROMIS CAT Social Participation – Patient satisfaction – Global Health – Lifestyle risk factors – Peri-operative factors

Study description

Background summary

Rationale: The eHealth application ‘Beter Voorbereid’ is an 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 lifestyle risk profile of the patient, a tailored preoperative lifestyle advise is provided. Furthermore, the patient can use the eHealth application to make an appointment with a local physiotherapist to improve the physical fitness of the patient under supervision. The eHealth application can be displayed on a smartphone and tablet. The application is offered to the patient during his/her visit to the preoperative outpatient clinic. It is currently unknown whether the use of an app to advice patients in improving their pre-operative lifestyle is more beneficial than usual care in enhancing functional recovery after surgery.

Objective: To investigate whether use of the ‘Beter Voorbereid’ application is associated with improved functional recovery after surgery when compared to control patients

Study design: A multicenter randomized controlled trial (RCT) will be conducted.

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.

Main study outcomes: Primary outcome is the course of functional recovery after surgery. Secondary outcomes are functional recovery, in-hospital physical symptoms, physical functioning and psychological functioning, social participation, patient satisfaction, global health, lifestyle risk factors and peri-operative factors.

Study objective

The use of the ‘Beter Voorbereid’ eHealth application modifies risk behaviour and improves the patients functional capacity which leads to a better functional recovery after surgery.

Study design

Five time points, at baseline and 1 week, 3 weeks, 6 weeks and 12 weeks after hospital discharge.

Intervention

The eHealth application is a mobile application, which participants have to download to their device. The app can be used on smartphones and tablets.
Participants receive support in optimizing their health and lifestyle in the peri-operative period. Participants with an indication to enhance preoperative physical fitness have the possibility to enhance their fitness under supervision of a specialized local physiotherapist, who can be found via the app. The total package of advices may include smoking cessation, lowering of alcohol intake, nutritional advices and exercise advices (physical activity increase and/or muscle strengthening). The advices consists of specific tasks the patient can perform based on the personal profile of the patient. Advices are provided in the pre-operative period, as well as in the direct post-operative period. The participant receives feedback on the tasks performed using the application.

Contacts

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Eligibility criteria

Inclusion criteria

Patients age 18 years or older undergoing major surgery with an indication for postoperative hospital stay will be recruited within the participating hospitals. In order to be eligible to participate, the patient must meet the following criteria:
1. Age ≥ 18 years old
2. Indication for postoperative hospital stay (minimum of two nights)
3. One or more lifestyle risk factors (smoking , alcohol intake, exercise/physical activity, nutrition/weight)
4. Informed consent

Exclusion criteria

1. Emergency surgery
2. Unable to work with the eHealth application
3. Dutch language inproficiency
4. No access to a tablet or smartphone
5. Less than 7 days between inclusion and surgery
6. Planned for brain surgery (due to possible cognitive impairments post-surgery and related problems with filling in questionnaires)
7. Already participating in intensive pre-operative care pathway (including exercise program/physiotherapy)
8. 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)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2020
Enrollment:	480
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	14-05-2020
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 53078
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL8623
CCMO	NL61503.029.18
OMON	NL-OMON53078

Study results