Stoma APPtimize: Improving quality of life of patients having a stoma by offering personalised and timed guidance in a patient-centred mobile application

No registrations found.

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

Summary

ID

NL-OMON25267

Source
Nationaal Trial Register

Brief title
Stoma APPtimize

Health condition

Ileostomy and colostomy

Sponsors and support

Primary sponsor: Academic Medical Center (AMC), Department of Surgery
Source(s) of monetary or material Support: Maag Lever Darm Stichting (MLDS) & SIDN fonds

Intervention

Outcome measures

Primary outcome

Quality of life

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
Number of outpatients visits
Self-reported problems related to a stoma
Postoperative data < 90 days
Overall morbidity < 90 days
Complications - major
Complications – minor
Reoperations
Readmission <90 days
Number of outpatients visits
Self-reported problems related to a stoma
Postoperative data < 180 days
Overall morbidity < 180 days
Complications - major
Complications – minor
Reoperations
Readmission <180 days
Number of outpatients visits
Self-reported problems related to a stoma
Postoperative data < 1 year
Overall morbidity < 1year
Complications – major
Complications – minor
Reoperations
Readmission <1year
Number of outpatients visits
Self-reported problems related to a stoma
PROMS
General quality of life
Stoma quality of life
Disabillity
Psychosocial adaption
Patient satisfaction

Study description

Background summary

Patient education and guidance is of crucial importance for patients having a stoma. Patients have to adapt to the new situation and coping with a stoma might be difficult, resulting in insecurities. Insecurities are reported to lead to a variety of psychosocial problems. Self-efficacy is known to be associated with a reduction of these psychosocial problems and stoma-related morbidities. The main objective of this study is to investigate whether self-reported quality of life can be enhanced by offering a personalised and timed guidance in a patient-centred mobile application.

Study objective

Patients supported by the intervention version of the app will report a significantly higher quality of life than cancer patients having a stoma who are supported by the control version of the app.

Study design

T0: Installation of the appliction after informed consent
T1: 2 weeks after surgery;
T2: 1 month after surgery;
T3: 3 months after surgery;
T4: 6 months after surgery;
T5: 12 months after surgery

Intervention

Personalized and timed information and guidance in the Stoma-APPtimize application

Contacts

Public
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M.P. Schijven

020-5664995
Scientific
Amsterdam UMC, locatie AMC
M.P. Schijven

020-5664995

Eligibility criteria

Inclusion criteria

- Individuals scheduled for elective or emergency colorectal surgery, ending in
o ileostomy
o colostomy
- Adults aged >18 years
- Possession of a smartphone operated with iOS 9 and up or Android 8.0 and up

Exclusion criteria

- Patients with a Karnofsky score ≤40
- 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

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-12-2020
Enrollment:	208
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Plan description
n/a

Ethics review

Positive opinion
Date: 27-08-2020
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
NTR-new	NL8895
Other	METC AMC : 75119

Study results

Summary results
n/a