# 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**

lleostomy 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

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#### 020-5664995

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# **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  $\leq$ 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
Туре:	Anticipated

### **IPD** sharing statement

Plan to share IPD: No

Plan description n/a

# **Ethics review**

Positive opinion Date: Application type:

27-08-2020 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** NTR-new Other **ID** NL8895 METC AMC : 75119

# **Study results**

Summary results n/a