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

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The main objective of this study is to investigate whether quality of life can be improved by personalised and timed guidance, and/or use of the peer-support platform; as provided by a patient-centred mobile application.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal inflammatory conditions
Study type	Interventional

Summary

ID

NL-OMON52197

Source
ToetsingOnline

Brief title
Stoma APPtimize

Condition

- Gastrointestinal inflammatory conditions
- Gastrointestinal neoplasms malignant and unspecified
- Gastrointestinal therapeutic procedures

Synonym
colorectal cancer, inflammatory bowel disease

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: MLDS en SIDN fonds

Intervention

Keyword: colorectal surgery, mobile application, quality of life, stoma (ostomy)

Outcome measures

Primary outcome

Quality of life

Secondary outcome

Postoperative data < 30 days

• Length of hospital stay: continuous variable, measured in days

• Complications - major: ordinal variable, Clavien Dindo Classification of surgical complications (III-V)

• Complications - minor: ordinal variable, Clavien Dindo Classification of surgical complications (I-II)

• Overall morbidity within the first 30 days postoperative

• Reoperations: dichotomous variable, Yes/No

• Readmission <30 days: dichotomous variable, Yes/No

• In-hospital mortality: dichotomous variable, Yes/No

• Number of outpatients visits: continuous variable,

• Self-reported problems related to a stoma: nominal ordinal

Postoperative data < 90 days

• Complications - major: ordinal variable, Clavien Dindo Classification of surgical complications (III-V)

• Complications - minor: ordinal variable, Clavien Dindo Classification of surgical complications (I-II)

• Overall morbidity within the first 90 days postoperative

• Reoperations: dichotomous variable, Yes/No

• Readmission <90 days: dichotomous variable, Yes/No

• Number of outpatients visits: continuous variable,

• Self-reported problems related to a stoma: nominal ordinal

Postoperative data < 180 days

• Complications - major: ordinal variable, Clavien Dindo Classification of surgical complications (III-V)

• Complications - minor: ordinal variable, Clavien Dindo Classification of surgical complications (I-II)

• Overall morbidity within the first 180 days postoperative

• Reoperations: dichotomous variable, Yes/No

• Readmission <180 days: dichotomous variable, Yes/No

• Number of outpatients visits: continuous variable,

• Self-reported problems related to a stoma: nominal ordinal

Postoperative data < 1 year

• Complications - major: ordinal variable, Clavien Dindo Classification of surgical complications (III-V)

• Complications - minor: ordinal variable, Clavien Dindo Classification of surgical complications (I-II)

• Overall morbidity within the first 180 days postoperative

• Reoperations: dichotomous variable, Yes/No

• Readmission <180 days: dichotomous variable, Yes/No

• Number of outpatients visits: continuous variable,

• Self-reported problems related to a stoma: nominal ordinal

PROMS

• General quality of life: measured with the WHOQoL: questionnaire consisting of ordinal variables

• Stoma quality of life: measured with the Stoma-QoL questionnaire consisting of ordinal variables

• Disabillity: measured with the WHODAS2 questionnaire consisting of ordinal variables

• Psychosocial adaption measured with the OAI-23 questionnaire consisting of ordinal variables

• Patient satisfaction questionnaire: measured with a self-developed patient satisfaction questionnaire consisting of ordinal variables

Study description

Background summary

Having a stoma often has a negative impact on the self-image and daily functioning of the patient, resulting in a reduced quality of life. Patient

education and -guidance is of crucial importance for patients having a stoma. Patients have to adapt to and cope with the new situation, which might be difficult and result 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.

Study objective

The main objective of this study is to investigate whether quality of life can be improved by personalised and timed guidance, and/or use of the peer-support platform; as provided by a patient-centred mobile application.

Study design

Multicenter single blinded randomized controlled trial, with a control group

Intervention

A mobile applicaton offering personalised and timed guidance and information -such as operation-specific information and the associated care path. Also, they have access to a peer-support platform. Based on the date of surgery and discharge, a timeline is generated within the application. Information becomes available when it's relevant for the patient. Information is brought to the user's attention with pushnotifications.

Besides informing patients and motivating them to participate in their own care pathway, the app has a function in registering study outcomes,

Study burden and risks

Both the control group as well as the intervention group will receive care conform the current standard and use a mobile application. The only difference is the personalised and timed information and peer-contact within the intervention group, therefore no additional risks are associated with participation in this trial. Burden of participation is restricted to the completion of five different questionnaires

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ

NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Individuals undergoing colorectal surger to receive an ileostomy or colostomy,
Adults >18 years of age
Possession of a smartphone operated with iOS 9.0 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:	Single blinded (masking used)
Control:	Active
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-03-2021
Enrollment:	208
Type:	Actual

Medical products/devices used

Generic name:	Stoma-APPtimisation;a patient centered mobile application to accompaniate patients undergoing ostomy
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	15-12-2020
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-02-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-03-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	

Date:	13-10-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	04-11-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	13-12-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-01-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	10-02-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	28-03-2022
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

No registrations found.

In other registers

Register	ID
CCMO	NL75119.018.20