A Digital Intake Tool for colorectal cancer screening programs

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This study will evaluate if a pre-colonoscopy consultation at the outpatient clinic can be replaced by an eHealth tool for FIT positive participants who are referred for colonoscopy.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Gastrointestinal neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON21455

Source
NTR

Brief title
DIT trial

Condition

- Gastrointestinal neoplasms malignant and unspecified

Health condition

Population screening, colorectal cancer, eHealth.

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus University Medical Center
Source(s) of monetary or material Support: TKI Life Science and Health

Intervention

- Other intervention

Explanation

Outcome measures

Primary outcome

The primary outcome of this study is an adequate bowel preparation defined as a Boston bowel preparation score of 6 or higher.

Secondary outcome

- Participation rate

- Response rate

- Colonoscopy adherence

- Safety: are participants correctly classified as low risk?

- Outpatient reduction

- Knowledge transfer

- Patient experience: satisfaction and anxiety

- Cost-effectivenees

Study description

Background summary
Each year more than 2.2 million people aged 55-75 years are invited for the national colorectal cancer (CRC) screening program. Around 5%, which corresponds to 77.000 screenees yearly, have a positive FIT and will be referred for colonoscopy. Currently this population is seen at an outpatient clinic before colonoscopy is carried out to assess morbidity, risk of complications and informing patients about the procedure and CRC risk. For symptomatic patients, this face-to-face intake is successfully replaced by a digital route in some endoscopic centres. In contrast to symptomatic patients most of the screenees are healthy. Therefore, we assume that it will also be possible to shift this type of health care to a more home- based setting by using a digital intake tool in colorectal cancer screening programs tailored for FIT positives. This will facilitate screenees and health care providers,

improve capacity for outpatient visits and reduce health care costs. In this study we will assess the applicability of a digital intake tool in the Dutch colorectal cancer screening program in participants with a positive FIT who are referred for colonoscopy.

Study objective
This study will evaluate if a pre-colonoscopy consultation at the outpatient clinic can be replaced by an eHealth tool for FIT positive participants who are referred for colonoscopy.

Study design
This is a prospective multicentre study with a non-inferiority design to evaluate

the feasibility of the DIT in a CRC screening population. The DIT will triage all participants and inform them about CRC risk, colonoscopy, sedation and provide bowel preparation instructions.

Intervention
An eHealth assessment and education tool for evaluating and educating FIT positive participants who are referred for colonoscopy, 'the Digital Intake Tool'.

Contacts

Public
Erasmus MC
Manon Spaander

N.A.
Scientific
Erasmus MC
Manon Spaander

N.A.

Eligibility criteria

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

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria: - Aged 55 – 75 - Participant of the national colorectal cancer screening program -

Positive result (>47ug/g hemoglobin/g feces) on FIT screening - A good understanding of the Dutch language of the participant or having a relative with good understanding of the Dutch language who is able to guide the participant - Access to internet and a device which is suitable for use of the digital intake tool

Exclusion criteria

- Inability or refusal to provide informed consent - People with a visual disability (the DIT will contain some essential visual information) - People with a functionally illiteracy and therefore not able to complete and understand the Patient Information Form (PIF).

Study design

Design

Study phase:	N/A
Study type:	Interventional
Intervention model:	Single
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	Historical
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	12-10-2021
Enrollment:	1100
Type:	Actual

IPD sharing statement

Plan to share IPD: No

Ethics review

Approved WMO Date:	21-04-2021
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

ID: 51979
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL9315
CCMO	NL74890.078.20
OMON	NL-OMON51979

Study results

Summary results
N.A.