A digital intake tool for FIT based colorectal cancer screening programs

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In this study we will assess the applicability of a digital intake in the Dutch colorectal cancer screening program in participants with a positive FIT who are referred for colonoscopy.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Gastrointestinal neoplasms malignant and unspecified
Study type	Observational non invasive

Summary

ID

NL-OMON51979

Source
ToetsingOnline

Brief title
DIT trial

Condition

- Gastrointestinal neoplasms malignant and unspecified

Synonym
Evaluation screening colonoscopy, intake appointment population screening colonoscopy

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: TKI - Life Science and Health

Intervention

Keyword: Colorectal cancer, Digitization, Population screening

Outcome measures

Primary outcome

Applicability of a digital intake tool for FIT positive screenees in the national CRC screening program who are referred for colonoscopy in terms of efficacy defined as:

- Need for repeat or rescheduled colonoscopies due to poor bowel preparation. Defined as a percentage of >= 90% participants with good bowel cleanliness during first colonoscopy.

Secondary outcome

Secondary study parameters/endpoints (if applicable)

- Participation rate
- Number of patients that have fully completed the DIT and for who no face-to-face appointment at the outpatient clinic was needed to be scheduled.
- Anxiety before and after the DIT by using a questionnaire
- Evaluating participants satisfaction by using questionnaires after the DIT and after screening colonoscopy
- Knowledge transfer to participants by using a questionnaire after DIT
- Colonoscopy adherence rate after the DIT
- Workability for health care staff by using a questionnaire
- Evaluating the motives for choosing a digital tool over a face-to-face consult to gain more insight into the needs of patients
- Evaluating the economic impact of a DIT by performing a cost-effectiveness

analysis

Study description

Background summary

Each year more than 2.2 million people aged 55-75 are invited for the national colorectal cancer (CRC) screening program. Around 5%, which corresponds to 77.000 screenees, receive a positive FIT and are being 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. In symptomatic patients some endoscopic centers successfully replaced this face-to-face intake for a digital route, but in the Dutch screening program a face-to-face visit belongs to standard care. In contrast to symptomatic patients most of the screenees are healthy. Therefore we assume that it is possible to shift this type of health care to a more home based setting by using a digital intake in colorectal cancer screening programs tailored for FIT positives. It facilitates screenees and health care providers, improves capacity for outpatients visits and reduces health care costs by providing a safe and validated DIT. Each year more than 2.2 million people aged 55-75 are invited for the national colorectal cancer (CRC) screening program. Around 5%, which corresponds to 77.000 screenees, receive a positive FIT and are being 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. In symptomatic patients some endoscopic centers successfully replaced this face-to-face intake for a digital route, but in the Dutch screening program a face-to-face visit belongs to standard care. In contrast to symptomatic patients most of the screenees are healthy. Therefore we assume that it is possible to shift this type of health care to a more home based setting by using a digital intake in colorectal cancer screening programs tailored for FIT positives. It facilitates screenees and health care providers, improves capacity for outpatients visits and reduces health care costs by providing a safe and validated DIT.

Study objective

In this study we will assess the applicability of a digital intake in the Dutch colorectal cancer screening program in participants with a positive FIT who are referred for colonoscopy.

Study design

Prospective observational single centered cohort study and has a future

perspective to extend to a multicenter study.

Study burden and risks

Potential benefit:
Using a digital intake could mean the introduction of a less invasive and equally effective modality for patients who are being evaluated for screening colonoscopy. It might facilitate screenees and health care providers, improve capacity for outpatients visits and reduce health care costs by providing a safe and validated DIT for FIT positive screenees that can be done at home. Moreover, a digital intake with health animations improves information provision to FIT positive screenees. It has been shown that spoken animation is the best way to communicate complex health information to participants with low health literacy. Improved knowledge about the substantial CRC (or advanced precancerous lesions) risk in combination with adequate information regarding colonoscopy will lead to better shared decision making.

Potential risk
Some studies suggest that shared decision making in a digital setting could be less effective than a physical visit. However it has been rejected in multiple studies. Especially regarding to digital tools for colonoscopy. Digital information provision tools are already implemented for symptomatic patients and appeared to be as effective as nurse counselling. Patients were even more satisfied with the amount of information provided by the digital intake as they demonstrated a better overall comprehension. Another potential risk concerns loss to follow up regarding colonoscopy in patients who do not fully complete the digital intake and therefore do not receive an appointment for screening colonoscopy. This is conquered by the fact every participant will be contacted by phone after receiving hyperlink to the DIT. Final potential risk is a lack in the digital tool where questions about the medical status of the patient does not gain all information that is needed to perform an adequate evaluation of the patient in work up for colonoscopy. However current screening colonoscopy intakes are being executed by a nurse who is following a standardized questionnaire which is compiled by the RIVM. This same documented questions is used in the digital intake tool. So digital evaluation will be at least as careful as current evaluation. When the complication risk is increased, a patient will be referred to a face to face intake or will be contacted by phone after the digital intake procedure. In this way, outpatient capacity is tailored to those patients with increased risks.

Burden:
To assess the DIT a number of five questionnaires will be asked to complete on top of the regular questions about a patient*s medical condition. This can be done at home at any suitable time, no extra physic visits are needed. No potential risks are related to these *study* questionnaires.

Altogether we therefore consider the risks and burden low and minimal.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion 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 severe visual disability (the digitale intake 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 type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	11-10-2021
Enrollment:	1300
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

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

Approved WMO Date:	01-09-2021
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	09-12-2021
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	09-05-2022
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	16-01-2023
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	06-06-2024
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 21455
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL74890.078.20