

# RCT for evaluation of a personalized online decision aid for colorectal cancer screening participation

No registrations found.

<b>Ethical review</b>	Not applicable
<b>Status</b>	Recruiting
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON20959

### Source

Nationaal Trial Register

### Health condition

Colorectal cancer

## Sponsors and support

**Primary sponsor:** ZonMW

**Source(s) of monetary or material Support:** ZonMW

## Intervention

## Outcome measures

### Primary outcome

Decisional conflict

### Secondary outcome

clarity of values, deliberation, anxiety, risk perception, intention to participate, usability and acceptability

# Study description

## Background summary

Most decisions in health care require a balancing of harms and benefits. Although people may make these decisions intuitively, informed decision making requires an explicit balancing of harms and benefits. Individuals making an informed decision therefore need to be aware of the harms and benefits relevant to their own situation. In situations with multiple outcomes, balancing harms and benefits for each of those outcomes to come to an overall decision may be challenging. The decision to participate in a nationwide screening program may be one of those situations, where different persons may weigh the potential harms and benefits of screening in different ways, and have a different risk profile for the screening condition. Benefit harm analyses can be used to assess the pros and cons of a decision in a quantitative way. Benefit-harm analyses can thereby help in tailoring the information and supporting the decision making of possible screening participants.

This RCT is part of a research project in which we aimed to develop a personalized web-based decision aid which enables individuals to make a well-informed decision about participation in colorectal cancer (CRC) screening. First, we assessed the benefit-harm balance for FIT-based CRC screening versus no screening as a function of certain characteristics and preferences of the invitees. We then developed a web-based decision aid based on the benefit-harm analysis, which visualized the benefit-harm balance for the individual. In this RCT, we will investigate whether participants who use this personalized decision aid with benefit-harm assessment, are more certain about their decision whether to participate in CRC screening, as compared to participants who use a decision aid without such as personalized benefit-harm assessment. In addition, we will user-test the usability and acceptability of the decision aid with benefit-harm assessment in the intervention arm of the study.

## Study objective

Participants who use the decision aid with benefit-harm assessment have a lower mean score on the decisional conflict scale than participants who use the existing decision aid.

## Study design

Primary and secondary outcomes are measured in an online questionnaire after participants have used the decision aid. Participants decide for themselves when they want to participate in the study between July 5 and August 16

## Intervention

using an online decision aid with benefit-harm assessment

## Contacts

### Public

Amsterdam UMC  
Linda Pluymen

0646798279

### Scientific

Amsterdam UMC  
Linda Pluymen

0646798279

## Eligibility criteria

### Inclusion criteria

men and women aged 45-55 years

### Exclusion criteria

none

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

### Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	05-07-2021
Enrollment:	324
Type:	Anticipated

## IPD sharing statement

**Plan to share IPD:** Undecided

## Ethics review

Not applicable  
Application type: Not applicable

## 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	NL9666
Other	ZonMW : 2021/26866/ZONMW

## Study results