ISRCTN10525659 https://doi.org/10.1186/ISRCTN10525659

Personalized colorectal cancer screening: a randomized trial

Submission date 24/10/2025	**Recruitment status** Recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 27/10/2025	**Overall study status** Ongoing	
Last Edited 27/10/2025	**Condition category** Cancer	

Plain English summary of protocol

Background and study aims
CRC screening is crucial for reducing CRC mortality. Over 2.7 million people in Switzerland are eligible for screening, often in programs organized by their Canton. These programs are facing challenges. The most common screening method used, colonoscopy, is effective but invasive. There is a limited number of gastroenterologists who can perform it. These two factors contribute to long wait times and low participation in screening programs. The fecal immunochemical test (FIT) (looking for hidden blood in the stool) is non-invasive and easy to do. It can be more widely available and is equally effective as colonoscopy in reducing CRC mortality among people at lower risk. However, it is underused because people often overestimate the need to have a very sensitive test because they think they have a high CRC risk (while they usually don't) and want a colonoscopy.

This research is looking at a more tailored approach to colorectal cancer (CRC) screening in Switzerland. The study aims to figure out if risk-based screening for CRC using a risk calculator (QCancer) and previous test results can work as well as the current approach (offering both FIT and colonoscopy). At the same time, the goal is to find out if this approach costs less and is less of a burden for participants than the current one. This study will also assess whether mailing FIT kits to people at lower risk and giving more guidance to people at higher risk (navigation) will lead to more people completing the screening tests.

Who can participate?
Volunteers without symptoms aged between 50 and 74 years old who haven't had a screening test recently, residing in a canton whose screening center is recruiting.

What does the study involve?
This multi-centre randomised controlled trial in Switzerland compares risk-based screening with standard screening invitations. The study uses a non-inferiority design, aiming to show that risk-based screening detects as many cancers and precancers as the current approach. It is anticipated that risk-based screening will be more efficient, reducing both costs and the number of colonoscopies performed.

Participants will be randomly divided into three groups:
1. Risk-based screening alone
2. Risk-based screening plus interventions to increase participation (Mailed FIT kit if they are at low risk or more guidance if they are at higher risk).
3. Current approach (also called usual care).

What are the possible benefits and risks of participating?
The main benefits of participating are potentially receiving your personalized risk information and interventions to facilitate screening completion. A potential risk is increased anxiety if you learn you are at higher risk. However, higher risk participants will receive information about how to participate in screening and discuss their risk with their general practitioner.

Where is the study run from?
Unisanté Laussanne, Switzerland.

When is the study starting and how long is it expected to run for?
January 2025 to June 2029. The study will enrol from November 2025 to May 2026.

Who is funding the study?
Swiss National Science Foundation

Who is the main contact?
Dr Kevin Selby, kevin.selby@unisante.ch

Contact information

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Public, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
33IC30_221652

Study information

Scientific Title
PREcision ScrEeniNg for ColoRectal Cancer: a Randomized Non-inferiority Trial (PRESENT-CRC)

Acronym
PRESENT-CRC

Study objectives
Aim 1: Assess whether individualized, risk-based CRC screening recommendations using the QCancer calculator and previous faecal haemoglobin values are non-inferior to standard screening invitations for the detection of advanced neoplasia after 3 years of follow-up.
Aim 2: Assess whether targeted interventions to increase participation (mailed FIT and patient navigation) are superior to risk-based recommendations alone to encourage appropriate test completion in low- and high-risk participants, respectively.
Aim 3: Assess whether risk-based CRC screening is cost-effective compared to standard screening invitations.

Ethics approval required
Ethics approval required

Ethics approval(s)
submitted 23/10/2025, Canton Vaud Research Ethics Commission (Av. de Chailly 23, Lausanne, 1012, Switzerland; +41 21 316 18 30; scientific.cer@vd.ch), ref: 2025-00727

Study design
Multi-site parallel-group individually randomized single-blind non-inferiority study

Primary study design
Interventional

Study type(s)
Screening

Health condition(s) or problem(s) studied
Colorectal cancer screening

Interventions
The trial statistician calculated a randomization plan with varying block sizes and implemented it in the REDCap randomization module.

Intervention 1: Risk-based screening recommendations. Participants receive an invitation letter and brochure communicating their 15-year risk for CRC and recommending a risk-appropriate screening test.
Intervention 2: Screening recommendations and interventions to increase participation. The same letters and brochures are provided as Intervention 1, with additional interventions to increase screening completion: participants at lower risk will be mailed fecal immunochemical tests (FIT), and offered telephone-based patient navigation to those at higher risk to help organize a colonoscopy if no colonoscopy has been done 4 months post-randomisation.
Active Comparator: Usual care. Participants of the control group will receive the standard invitation letter and brochure used by the participating cantonal screening programs. They are not provided with their 15-year risk of CRC or a recommendation between FIT and colonoscopy.

Intervention Type
Other

Primary outcome(s)
Advanced colorectal neoplasia, defined as the proportion of participants with at least 1 of the following: adenoma > 1 cm; adenoma of any size with high-grade dysplasia; adenoma with villous or tubulovillous histology (≥25% villous); serrated lesion > 1 cm; serrated lesion of any size with high-grade dysplasia; traditional serrated adenoma (any size); and, adenocarcinoma, measured using data collected from patient medical records, at 3-year follow-up

Key secondary outcome(s))
Secondary outcome measures are assessed using data collected from patient medical records:
1. Colonoscopy completion among high-risk participants, defined as the proportion of participants with at least one colonoscopy recorded by the organized screening program, at 1-year follow-up
2. Fecal immunochemical test (FIT) completion among low-risk participants, defined as the proportion of participants with at least one FIT result recorded by the colorectal cancer screening program, at 1-year follow-up
3. Overall screening participation, defined as the proportion of participants with at least one colonoscopy or one FIT recorded by the colorectal cancer screening program, at 1-year follow-up
4. Number needed to scope, defined as the number of colonoscopies performed per advanced neoplasia detected, at 3-year follow-up
5. Overall screening participation by socioeconomic status at 1-year follow-up. This outcome will be calculated in the same way as overall screening participation. Comparisons will be stratified by deciles of the Swiss Socio-Economic Position (Swiss-SEP) score, an address-based, area-level index, to assess whether the intervention's effect on participation varies by socioeconomic position.

Completion date
30/06/2029

Eligibility

Key inclusion criteria
1. Aged between 50 and 74 years old
2. Residing in a canton whose screening center is recruiting for the trial
3. Having provided informed consent

Participant type(s)
Population

Healthy volunteers allowed
No

Age group
Other

Lower age limit
50 years

Upper age limit
74 years

Sex
All

Key exclusion criteria
People at very high risk of CRC or already up to date with screening are excluded. Specifically, those:
1. With current symptoms suspicious for colorectal cancer (i.e. rectal bleeding, unusual weight loss, etc.)
2. With a medical condition requiring colonoscopy surveillance at a shorter than 10-year interval
3. Having had a colonoscopy within 9.5 years or a FIT within 1.5 years

Date of first enrolment
17/11/2025

Date of final enrolment
30/06/2026

Locations

Countries of recruitment
Switzerland

Study participating centre
Screening program of the canton of Bern - Krebsliga beider Basel
Petersplatz 12
Basel

Switzerland
4051

Study participating centre
Screening program of the cantons of Basel-City and Basel-Country - Krebsliga beider Basel
Petersplatz 12
Basel
Switzerland
4051

Study participating centre
Screening program of the canton of Fribourg - Ligue fribourgeois contre le cancer
Rte St-Nicolas-de-Flüe 2
Fribourg
Switzerland
1701

Study participating centre
Screening program of the canton of Geneva - Fondation Genevoise pour le Dépistage du Cancer
Boulevard de la Cluse 43
Geneve
Switzerland
1205

Study participating centre
Screening program of the canton of Vaud - University Center for Primary Care and Public Health (Unisanté)
Route de la Corniche 21
Lausanne
Switzerland
1010

Sponsor information

Organisation
Centre universitaire de médecine générale et santé publique, Lausanne

ROR
https://ror.org/04mcdza51

Funder(s)

Funder type
Government

Funder Name
Schweizerischer Nationalfonds zur Förderung der Wissenschaftlichen Forschung

Alternative Name(s)
Schweizerischer Nationalfonds, Swiss National Science Foundation, Fonds National Suisse de la Recherche Scientifique, Fondo Nazionale Svizzero per la Ricerca Scientifica, Fonds National Suisse, Fondo Nazionale Svizzero, Schweizerische Nationalfonds, The Swiss National Science Foundation (SNSF), SNF, SNSF, FNS

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Switzerland

Results and Publications

Individual participant data (IPD) sharing plan
After publication of the primary results, the data that support the findings of this study will be shared on the Unisanté data repository under restricted access. Only the data for which a signed consent was obtained will be shared. Identifiable data (e.g., name, date of birth, contact information) will not be shared. Participants will provide consent for the reuse of their data in a coded form. To ensure data protection, data will be curated by the documentation and data unit of Unisanté before sharing. Contact: Dr Kevin Selby, kevin.selby@unisante.ch.

IPD sharing plan summary
Available on request, Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 2.0	04/08/2025	27/10/2025	No	Yes
Protocol file	version 3.0	04/08/2025	27/10/2025	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes