

# Mailing of the Faecal Occult Blood Test (FOBT) to increase compliance to colorectal cancer screening and to reduce costs

<b>Submission date</b> 08/09/2009	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 18/05/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 29/12/2020	<b>Condition category</b> Cancer	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**Protocol serial number**  
N/A

## Study information

**Scientific Title**

Effect of mailing of the Faecal Occult Blood Test (FOBT) on compliance to colorectal cancer screening and on front office costs: a randomised controlled trial

**Acronym**

FOBT postale

**Study objectives**

European Commission Guidelines on cancer prevention recommend to the member states the implementation of colorectal cancer screening programmes based on the Faecal Occult Blood Test (FOBT) every two years in the population 50-70 years old. In Italy, colorectal cancer screening is affected by low compliance. Furthermore the front office activities to give the faecal sampler to the participants are time and cost consuming. A direct mailing strategy of the faecal sampler could increase compliance and could reduce the resource consumption of the front office activities.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Ethics approval is not required as this study involves only service provision that is already recommended by the European Commission.

**Study design**

Randomised controlled trial

**Primary study design**

Interventional

**Study type(s)**

Screening

**Health condition(s) or problem(s) studied**

Compliance to colorectal cancer screening

**Interventions**

The trial is recruiting at the following four centres: Viterbo, Latina, Firenze, Abruzzo

Group 1: Participants randomised to either direct mailing of the FOBT or re-call letter

Group 2: Participants randomised to either direct mailing of the FOBT or invitation letter

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome(s)**

Compliance to screening at 60 days after mailing (of the FOBT or of the letter).

**Key secondary outcome(s)**

Costs of mailing compared to front office.

**Completion date**

31/12/2009

## Eligibility

**Key inclusion criteria**

Group 1 (non responders): all the target population (both males and females, age 50-70) invited for a new round of screening and who did not responded to the first invitation letter and is eligible for a re-call letter.

Group 2 (responders to previous screening): all the people who responded to the previous screening round (both males and females, age 52-70) and are eligible for being invited to a new screening round

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**Total final enrolment**

7415

**Key exclusion criteria**

Group 1: None

Group 2: A previous positive test including FOBT, flexosigmoidoscopy and colonoscopy

**Date of first enrolment**

01/03/2009

**Date of final enrolment**

31/12/2009

## Locations

**Countries of recruitment**

Italy

**Study participating centre**

Laziosanità - Agenzia di Sanità Pubblica

Rome

Italy  
00198

## Sponsor information

### Organisation

Ministry of Health, Centre for Diseases Prevention amd Control (Italy)

### ROR

<https://ror.org/00svmjx28>

## Funder(s)

### Funder type

Government

### Funder Name

Ministry of Health, Centre for Diseases Prevention amd Control (Italy)

## Results and Publications

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Not provided at time of registration

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/09/2011	29/12/2020	Yes	No