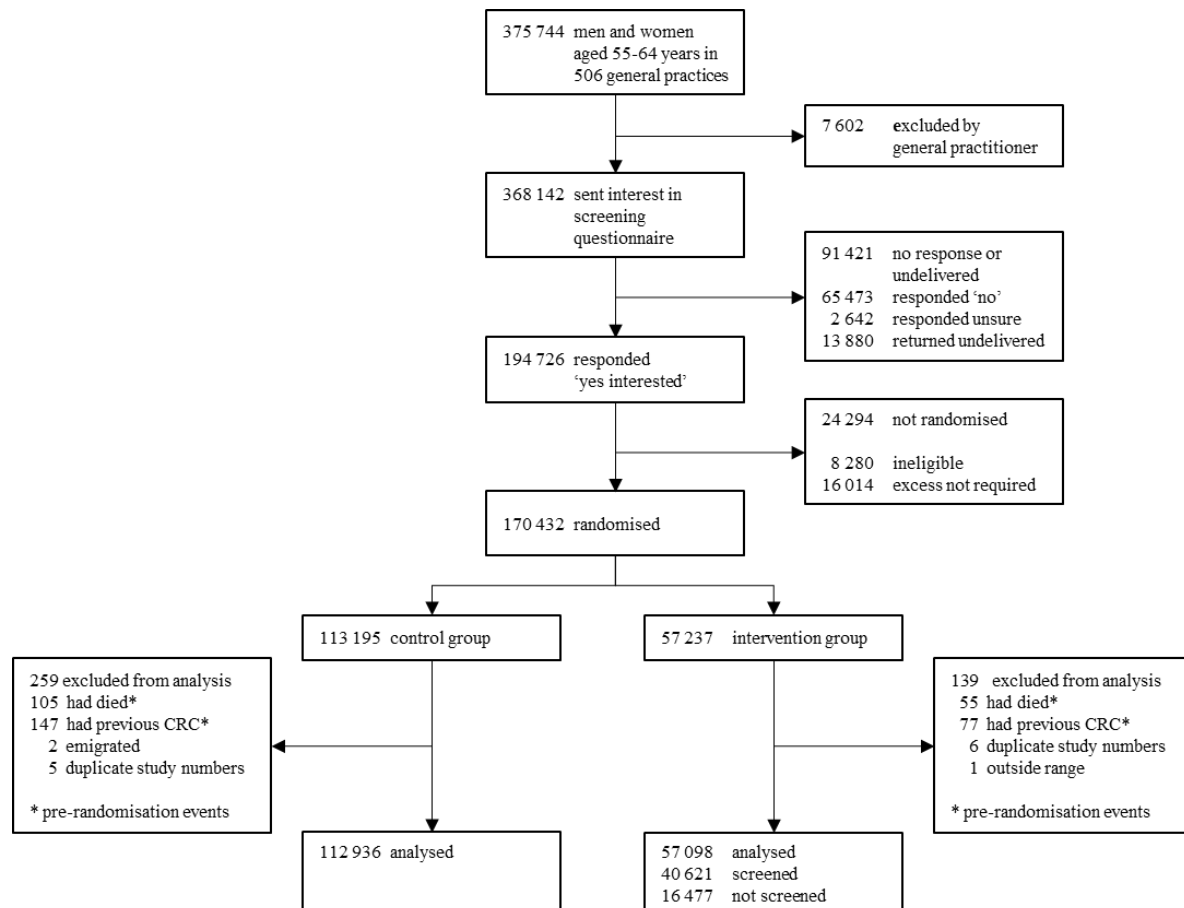


## Participant flow

### Study CONSORT flow diagram.

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## Baseline Characteristics

### Participant characteristics by randomisation and compliance with screening

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|                                     |               |  | Invited to screening group<br>(n = 57,098) |                       |                            |                        |
|-------------------------------------|---------------|--|--|-----------------------|----------------------------|------------------------|
|                                     |               |  | Control group<br>(n = 112,936)             | Total<br>(n = 57,098) | Not screened<br>(n=16,447) | Screened<br>(n=40,621) |
| <b>Age at randomisation (years)</b> |               |  | 60.0 (2.9)                                 | 60.0 (2.9)            | 60.1 (2.9)                 | 60.0 (2.9)             |
| <b>Sex</b>                          |               |  |  |                       |                            |                        |
|                                     | Male          |  | 55,339 (49)                                | 27,995 (49)           | 7,506 (46)                 | 20,489 (50)            |
|                                     | Female        |  | 57,597 (51)                                | 29,103 (51)           | 8,971 (54)                 | 20,132 (50)            |
| <b>Household size</b>               |               |  |  |                       |                            |                        |
|                                     | Single person |  | 71,556 (63)                                | 36,237 (63)           | 10,855 (66)                | 25,382 (62)            |
|                                     | Two person    |  | 41,248 (37)                                | 20,770 (36)           | 5,584 (34)                 | 15,186 (37)            |
|                                     | Other         |  | 132 (0.1)                                  | 91 (0.2)              | 38 (0.2)                   | 53 (0.1)               |
| <b>Length of follow-up (years)*</b> |               |  | 17.1 (16.4-17.8)                           | 17.1 (16.4-17.8)      | 17.0 (15.4-17.6)           | 17.1 (16.6-17.9)       |

Numbers are mean (standard deviation), n (%) or median (IQR).

\*Years from date of randomisation to date of death, emigration, loss to follow-up, or 31 December, 2014.

## Outcome Measures

Primary outcome measures: Incidence, mortality from colorectal cancer

### Colorectal cancer incidence and mortality in control and intervention groups

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| Primary outcome measure       | Control group<br>(n = 112,936) |                     | Invited to screening group<br>(n = 57,098) |                     | Hazard ratio (95%<br>CI);<br>intervention vs<br>control group | p-value |
|-------------------------------|--------------------------------|---------------------|--|---------------------|---|---------|
|                               | Cases                          | Rate (95% CI)       | Cases                                      | Rate (95% CI)       |   |         |
| Incidence                     |                                |                     |  |                     |   |         |
| All-site colorectal cancer    | 3,253*                         | 184 (178-191)       | 1,230*†                                    | 137 (130-145)       | 0.74 (0.70 - 0.80)  | <0.0001 |
| Distal colorectal cancer‡     | 1,987§                         | 112 (107-117)       | 592†§                                      | 66 (61-71)          | 0.59 (0.54 - 0.64)  | <0.0001 |
| Proximal colon cancer         | 1,255§                         | 71 (67-75)          | 612†§                                      | 68 (63-74)          | 0.96 (0.87 - 1.06)  | 0.436   |
| Mortality                     |                                |                     |  |                     |   |         |
| Colorectal cancer¶            | 996**                          | 56 (53-60)          | 353**                                      | 39 (35-43)          | 0.70 (0.62 - 0.79)  | <0.0001 |
| Distal colorectal cancer‡¶    | 544††                          | 31 (28-33)          | 149††                                      | 17 (14-19)          | 0.54 (0.45 - 0.65)  | <0.0001 |
| Proximal colon cancer¶        | 403††                          | 23 (21-25)          | 185††                                      | 21 (18-24)          | 0.91 (0.76 - 1.08)  | 0.262   |
| Non-colorectal cancer causes¶ | 25,413                         | 1,427 (1,410-1,445) | 12,926                                     | 1,433 (1,408-1,458) | 1.00 (0.98 - 1.03)  | 0.736   |
| All cause                     | 26,409                         | 1,483 (1,465-1,501) | 13,279                                     | 1,472 (1,447-1,497) | 0.99 (0.97 - 1.01)  | 0.460   |

Rates are per 100,000 person-years.

\*108 site not specified cancers were included, 72 in controls and 36 in the invited to screening group. Only the earliest cancer was counted for patients with more than one cancer. †140 patients had cancers detected at baseline screening (126 distal cancers and 14 proximal cancers). ‡Distal was defined as the rectum and sigmoid colon. §71 patients had both a distal and a proximal cancer (30 were synchronous and 41 were metachronous): 61 patients were controls and 10 were in the invited to screening group. ¶Deaths certified by the Office for National Statistics as colorectal cancer as underlying cause of death by automatic coding. \*\*51 deaths in patients with unspecified site cancers were included, 36 controls and 15 invited to screening. ††17 deaths occurred among patients with both a proximal and a distal cancer diagnosed (13 controls and 4 invited to screening) and these deaths were excluded from the site specific deaths.

*Secondary outcome measures:*

**Acceptability and psychological impact of flexible sigmoidoscopy screening**

|  | <b>Number of respondents</b> |
|--|------------------------------|
| <b>Questionnaires completed on day after flexible sigmoidoscopy</b>  |                              |
| Number of completed questionnaires*  | 39,671 (98.4)                |
| How much pain did you feel during the test?  |                              |
| None or mild pain  | 31,327 (79.8)                |
| Moderate   | 6,871 (17.5)                 |
| Severe   | 1,076 (2.7)                  |
| Was the test more painful or less painful than you expected?   |                              |
| Less painful than I expected   | 16,530 (42.4)                |
| About the same as I expected   | 14,717 (37.8)                |
| More painful than I expected   | 7,724 (19.8)                 |
| <b>Follow-up questionnaires (at 3 or 6 months)</b>   |                              |
| Number of completed questionnaires*  | 36,865 (91.4)                |
| How much embarrassment did you feel during your flexible sigmoidoscopy test?                                       |                              |
| Quite a lot or severe embarrassment  | 1,801 (5.0)                  |
| On balance, were you glad you had the test?  |                              |
| Glad had test  | 35,668 (98.3)                |
| If a friend asked you if they should have the flexible sigmoidoscopy test, would you encourage or discourage them? |                              |
| Would encourage or strongly encourage  | 35,109 (96.6)                |

Numbers are n (%).

\*Not every question was answered on completed forms. Percentages are of those who responded to the particular question.

## Adverse events

### Adverse effects in participants attending flexible sigmoidoscopy screening

|                                | Number of participants |
|--------------------------------|------------------------|
| <b>Serious adverse events</b>  |                        |
| Gastrointestinal bleeding      | 105 (0.3)              |
| Glutaraldehyde-induced colitis | 13 (0.03)              |
| Death                          | 11 (0.03)              |
| Cardiovascular-related         | 8 (0.02)               |
| Respiratory-related            | 1 (0.002)              |
| Lung cancer                    | 1 (0.002)              |
| Septicaemia                    | 1 (0.002)              |
| Gastrointestinal perforation   | 5 (0.01)               |
| Acute myocardial infarction    | 2 (0.005)              |
| Pulmonary embolism             | 1 (0.002)              |
| <b>Other adverse events</b>    |                        |
| Vasovagal episode              | 95 (0.2)               |

Numbers are n (%). Percentages are of the 40,674 participants who attended flexible sigmoidoscopy screening.