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Multicentre randomised trial of 'once only' flexible sigmoidoscopy screening for prevention of bowel cancer morbidity and mortality

Submission date
06/04/2000

Recruitment status
No longer recruiting

Registration date
06/04/2000

Overall study status
Ongoing

Last Edited
25/06/2025

Condition category
Cancer

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Bowel cancer is the fourth most commonly diagnosed cancer in the UK. Bowel cancers develop slowly from common bowel growths or polyps, so removing them can help prevent cancer. Screening with flexible sigmoidoscopy (also called ‘bowel scope’ or Flexi-scope) involves insertion of a thin flexible tube with a light and camera on the end into the bowel to examine the inner surface. Small bowel polyps can be removed during screening. The aim of the UK Flexible Sigmoidoscopy Screening Trial (UKFSST) was to determine whether having just one flexible sigmoidoscopy screen at around 60 years of age could prevent bowel cancer from developing and reduce the number of deaths from bowel cancer. The trial also aimed to determine how long any benefit lasts, and what is the best age to do the screening examination.

Who can participate?
Men and women who were aged 55–64 years and registered at a participating GP practice between November 1994 and March 1999.

What does the study involve?
The UKFSST was a randomised controlled trial. People who participated in the trial were randomly assigned to receive either flexible sigmoidoscopy screening or no screening (which was the usual care offered at the time of the trial).

What are the possible benefits and risks of participating?
Potential benefits of participating in the UKFSST included the possibility of being assigned to screening and having polyps detected and removed. Possible risks included adverse physical and psychological effects associated with the screening procedure and screening results. Individuals who participated in the trial but who were not assigned to screening received usual care and so were not worse off for having participated.

Where is the study run from?
The UKFSST recruited people from 506 GP practices that served 14 UK hospitals: 11 in England, two in Wales, and one in Scotland. Flexible sigmoidoscopy screening was done in endoscopy clinics at the hospitals.

When is the study starting and how long is it expected to run for?
Recruitment for the study and flexible sigmoidoscopy screening started in November 1994 and was completed in March 1999. The researchers have been following the participants since then, and will continue to follow them through 2024. The data will then be analysed and results written up, and the study will be completed by the 31st March 2027.

Who is funding the study?
National Institute for Health Research (NIHR) Health Technology Assessment (HTA) Programme (UK)

Who is the main contact?
Dr Amanda J Cross
amanda.cross@imperial.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Amanda Cross

ORCID ID
https://orcid.org/0000-0002-0893-2377

Contact details
Imperial College London
St. Mary's Campus
Norfolk Place
London
United Kingdom
W2 1PG
-
amanda.cross@imperial.ac.uk

Additional identifiers

Protocol serial number
G9615910

Study information

Scientific Title
Multicentre randomised trial of 'once only' flexible sigmoidoscopy screening for prevention of bowel cancer morbidity and mortality

Acronym
UKFSST

Study objectives
Primary aims:
1. To quantify the reduction in incidence and mortality
2. To determine the duration of efficacy of a single flexible sigmoidoscopy
3. To determine the optimum age for the examination
4. To evaluate health service research implications to permit an informed decision at the end of the trial about the suitability for implementation within a national screening programme

The criteria to be evaluated include:
1. Uptake, acceptability and impact
2. Quality control of the procedure
3. Cost-effectiveness

Ethics approval required
Old ethics approval format

Ethics approval(s)
South East MREC, ref: MREC/03/1/002

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Screening

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

Interventions
'Once only' flexible sigmoidoscopy screening/control

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Incidence, mortality from colorectal cancer

Key secondary outcome(s))
Psychological morbidity, costs to the NHS

Completion date

31/03/2027

Eligibility

Key inclusion criteria
All 55-64 year old men and women from selected general practices

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
167882

Key exclusion criteria
1. If incapable of providing informed consent
2. Patients with a personal or family history of bowel cancer (greater than two family members)
3. A recent sigmoidoscopy or colonoscopy
4. Severe illness or life expectancy of less than 5 years

Date of first enrolment
01/07/1995

Date of final enrolment
28/02/2014

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Imperial College London
London
United Kingdom
W2 1PG

Sponsor information

Organisation
Medical Research Council (MRC) (UK)

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (MRC) (UK)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to the terms and conditions of the data sharing agreements the researchers hold with third party data providers and their section 251 approval. However, anonymised, aggregated data may be made available upon application to the CSPRG: https://www.csprg.org.uk/patient-data/ and https://www.csprg.org.uk/contact-us/.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	baseline results	13/04/2002		Yes	No
Results article	results	01/03/2003		Yes	No

Results article	results	08/05/2010		Yes	No
Results article	results	01/04/2017		Yes	No
Results article	results	01/10/2018		Yes	No
Results article	results	01/03/2019		Yes	No
Results article	Associations between Adenoma Detection Rates and Long-Term Colorectal Cancer Incidence and Mortality	12/09/2020	05/05/2022	Yes	No
Results article	21-year follow-up	19/07/2024	23/07/2024	Yes	No
Protocol article	trial design	01/09/2001	05/05/2022	Yes	No
Basic results		15/03/2019	26/03/2019	No	No
Other publications	Between-center variation in adenoma detection rates	01/05/2004	05/05/2022	Yes	No
Other publications	Patient-reported outcomes following flexible sigmoidoscopy screening	01/12/2012	05/05/2022	Yes	No
Other publications	Uptake of Flexible Sigmoidoscopy at 14 months	20/09/2015	05/05/2022	Yes	No
Other publications	efficacy and acceptability of two methods of self administered bowel preparation for flexible sigmoidoscopy screening	03/06/2000	05/05/2022	Yes	No
Other publications	pilot examining rates of attendance, yield of neoplasia, and adverse effects	01/04/1998	05/05/2022	Yes	No
Other publications	uptake of population-based, flexible sigmoidoscopy screening	21/07/2010	05/05/2022	Yes	No
Other publications	15-Year Benefits of Sigmoidoscopy Screening on Colorectal Cancer Incidence and Mortality : A Pooled Analysis of Randomized Trials	01/11/2022	14/11/2023	Yes	No
Other publications	secondary, observational analysis	23/06/2025	25/06/2025	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes