Evaluation of evidence-based patient information on colorectal cancer screening

Submission date Recruitment status Prospectively registered 13/06/2008 No longer recruiting [] Protocol [] Statistical analysis plan Registration date Overall study status 10/07/2008 Completed [X] Results Individual participant data **Last Edited** Condition category 10/11/2011 Cancer

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Anke Steckelberg

Contact details

University of Hamburg
Unit of Health Sciences and Education
Martin-Luther-King-Platz 6
Hamburg
Germany
20146
ASteckelberg@uni-hamburg.de

Additional identifiers

Protocol serial number 01EL0714

Study information

Scientific Title

Acronym

Study objectives

Evidence-based patient information leads to more informed choices in colorectal cancer screening than traditional information.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Local Ethics Committee in Hamburg. Date of approval: 05/06/2008 (ref: PV2955)

Study design

Double-blind randomised controlled trial

Primary study design

Interventional

Study type(s)

Screening

Health condition(s) or problem(s) studied

Healthy adults

Interventions

Experimental intervention: Evidence-based patient information on colorectal cancer screening and interactive teaching modules on diagnostics and risk. The interactive teaching modules are available online, and the participants are free to decide how long and how often they use the tool to study on their own.

Control intervention: Standard patient information

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Informed choice, consisting of the following three dimensions:

- 1. Knowledge
- 2. Uptake of colorectal cancer screening
- 3. Attitude towards colorectal cancer screening

Informed choice is measured using the validated questionnaire "Measure of Informed Choice" 6 weeks after the intervention has been provided.

Added as of 05/03/2009:

Data analyses of knowledge, attitude and uptake questionnaires will be performed according to a predefined coding guide, which has been deposited at a staff member not involved in the study. Data entry and analyses will be carried out blinded.

Key secondary outcome(s))

Knowledge on colorectal cancer screening and uptake, surveyed within the primary endpoint are analysed separately as secondary endpoints.

Uptake is also surveyed 6 months after the intervention has been provided. In addition, uptake is verified with data from the Statutory Health Insurance Company Gmünder Ersatzkasse (GEK) at 6 months.

Completion date

31/03/2009

Eligibility

Key inclusion criteria

- 1. Both males and females
- 2. Age: 50 75
- 3. No colorectal cancer
- 4. Insured persons of the Statutory Health Insurance Company Gmünder Ersatzkasse (GEK)

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

No exclusion criteria

Date of first enrolment

01/06/2008

Date of final enrolment

31/03/2009

Locations

Countries of recruitment

Germany

Study participating centre University of Hamburg

Hamburg

Sponsor information

Organisation

Federal Ministry of Education and Research (BMBF) (Germany)

ROR

https://ror.org/04pz7b180

Funder(s)

Funder type

Government

Funder Name

Federal Ministry of Education and Research (BMBF) (Germany)

Alternative Name(s)

Federal Ministry of Research, Technology and Space, Bundesministerium für Bildung und Forschung, Federal Ministry of Education and Research, BMBF

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Germany

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type

Details

Results articleresults02/06/2011YesNoParticipant information sheetParticipant information sheet11/11/202511/11/2025NoYes