

Evaluation of evidence-based patient information on colorectal cancer screening

Submission date 13/06/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 10/07/2008	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 10/11/2011	Condition category Cancer	<input type="checkbox"/> Individual participant data

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
01EL0714

Study information

Scientific Title

Acronym

EVA DK

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

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Screening

Participant information sheet

Patient information can be found at: http://www.chemie.uni-hamburg.de/igtw/Gesundheit/images/pdf/Probandeninformation_2008.pdf (in German)

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 measure

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.

Secondary outcome measures

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.

Overall study start date

01/06/2008

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

Age group

Adult

Sex

Both

Target number of participants

1,140

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

Germany

20146

Sponsor information**Organisation**

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

Sponsor details

Hannoversche Strasse 28-30

Berlin

Germany

10115

ASteckelberg@uni-hamburg.de

Sponsor type

Government

Website

<http://www.bmbf.de/en/>

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 Education and Research, BMBF

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Germany

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date**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?
Results article	results	02/06/2011		Yes	No