The effect of different cardiovascular risk presentation formats on individuals intentions, understanding and emotional affect.

Submission date	Recruitment status No longer recruiting	Prospectively registered		
19/11/2009		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
12/01/2010	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant data		
05/11/2010	Circulatory System			

Plain English summary of protocol

Not provided at time of registration

Study website

http://www.myheartrisk.co.uk

Contact information

Type(s)

Scientific

Contact name

Prof Glyn Elwyn

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

n/a

Study information

Scientific Title

The effect of different cardiovascular risk presentation formats on individuals intentions, understanding and emotional affect: A Randomised Controlled Trial using a web-based risk formatter

Acronym

myheartrisk

Study objectives

The overall aim of this trial is to compare the effects of different graphical cardiovascular risk presentation formats on individuals' intention to reduce risk, understanding of risk information, emotional affect and worry about future heart disease.

The study will be conducted remotely, amongst individuals without established cardiovascular disease, using an on-line cardiovascular risk assessment and questionnaires.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethical approval received from the Medical Dental School Research Ethics Committee (MDSREC), Cardiff University (ref: 09/27)

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Prevention

Participant information sheet

Participant information is found on the first few pages of the website

Health condition(s) or problem(s) studied

Primary prevention, cardiovascular risk assessment, patient education

Interventions

All respondents access the website remotely. They will be randomly assigned to one of four conditions and will have their risk assessed by answering questions about their risk factors. They will be presented with their 10-year risk of having a coronary heart disease event in one of three formats. All respondents will be asked to complete a post-intervention questionnaire.

Control groups: There are two control groups. The first control comprises a pre-intervention questionnaire and presents risk in a bar graph format. The second control group presents risk in a bar graph format without the pre-intervention questionnaire. These two control groups are to account for the potential Hawthorne effect of the four groups, and enable a comparison of responses between those who are asked to think about their cardiovascular risk before viewing actual risk, against those who are not.

Intervention groups: The two intervention groups present risk in either a pictogram or metonym format.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

All outcomes measured by post-intervention questionnaire.

Emotional affect and worry about future heart disease will be assessed at baseline as well.

- 1. Intention to change behaviour
- 2. Understanding of risk information
- 3. Emotional affect
- 4. Worry about future heart disease

Secondary outcome measures

Sub-components of Theory of Planned Behaviour relating to reducing cardiovascular risk:

- 1. Attitudes
- 2. Subjective norms
- 3. Perceived behavioural control

Overall study start date

01/01/2010

Completion date

30/06/2010

Eligibility

Key inclusion criteria

Male and females aged between 45 and 64 years, who have not been previously diagnosed with coronary heart disease

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

800

Key exclusion criteria

- 1. Below the age of 45 or over the age of 64 years
- 2. Previous diagnosis of cardiovascular disease
- 3. Inability to read English
- 4. Inability to access to a computer with the internet
- 5. Inadequate IT skills

Date of first enrolment

01/01/2010

Date of final enrolment

30/06/2010

Locations

Countries of recruitment

United Kingdom

Wales

Study participating centre Department of Primary Care and Public Health

Cardiff United Kingdom CF14 4YS

Sponsor information

Organisation

Cardiff University (UK)

Sponsor details

Research and Commercial Division 7th floor, McKenzie House

30 - 36 Newport Road Cardiff Wales United Kingdom CF24 0DE DaviesKP2@cf.ac.uk

Sponsor type

University/education

Website

http://www.cardiff.ac.uk/index.html

ROR

https://ror.org/03kk7td41

Funder(s)

Funder type

University/education

Funder Name

Cardiff University (UK)

Alternative Name(s)

Funding Body Type

Private sector organisation

Funding Body Subtype

Universities (academic only)

Location

United Kingdom

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 summaryNot provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	30/07/2010		Yes	No