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

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

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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
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Wales
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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 summary

Not 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