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Evaluation of a CVD risk assessment tool for the promotion of healthier lifestyles

Submission date	Recruitment status	[_] Prospectively registered
17/05/2011	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
26/05/2011	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
30/07/2013	Circulatory System	

Plain English summary of protocol

Background and study aims
Percentage risk formats are commonly used to show cardiovascular disease (CVD) risk, but people can find them difficult to understand. The aim of this study is to compare the impact of providing a CVD risk message in either the traditional percentage risk format or using an analogy of risk (Heart-Age) on participants risk perceptions and intention to make lifestyle changes. The Heart-Age is the age corresponding to someone of the same gender with the same CVD risk level but with normal risk factors.

Who can participate?
A total of 400 healthy men and women who are obese and/or smokers and therefore at a higher risk of developing CVD.

What does the study involve?
Participants will be randomly allocated to one of two groups. In group 1, participants will receive their CVD risk in the percentage format. In group 2, participants will receive their CVD risk in the Heart-Age format. Participants' reactions will be measured after receiving this CVD risk information.

What are the possible benefits of participating?
Participants allocated to the Heart-Age risk message may gain a better understanding of their future risk of CVD and a higher intention to stop smoking, eat healthier and do more exercise. No potential side effects are expected as a result of this intervention.

Where is the study run from?
The study will be conducted online in the UK.

When is the study starting and how long is it expected to run for?
The study started in January 2008 and ran for 1 month.

Who is funding the study?
Unilever

Who is the main contact?
Dr Robert Hurling
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Contact information

Type(s)
Scientific

Contact name
Dr Robert Hurling

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
UCR2007-1003

Study information

Scientific Title
Evaluation of a CVD risk assessment tool for the promotion of healthier lifestyles: a randomised controlled trial

Acronym
CVD risk study

Study objectives
To compare the impact of providing a cardiovascular (CVD) risk message in either a traditional format (percentage risk) or using an analogy of risk (heart age) on participants' risk perceptions and intention to make lifestyle changes

Ethics approval required
Old ethics approval format

Ethics approval(s)

Independent Ethics Committee in Unilever; South of England approved in December 2007

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Cardiovascular risk prevention

Interventions
1. Each group has 200 participants
2. There will only be a single message provided and participants' reactions were measured after receipt of this CVD risk information:
Group 1: A percentage CVD risk message group, in which participants received an online risk message of their CVD risk in the format of a percentage
Group 2: A Heart-Age CVD risk communication message group, in which participants received an online risk message of their CVD risk in the format of a heart age (this is the age corresponding to someone of the same gender with the same CVD risk level but with normal risk factors)

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Risk perceptions were measured by self-reported items once participants received their CVD risk information

Secondary outcome measures
The following were measured by self-reported items once participants received their CVD risk information:
1. Intention to stop smoking (for smokers only)
2. Eat healthier
3. Do more physical activity

Overall study start date
30/01/2008

Completion date
28/02/2008

Eligibility

Key inclusion criteria
1. Body mass index (BMI) above/and 30 and/or smoker
2. 30-60 years old, either sex
3. Not diagnosed with a heart condition (e.g. heart attack or angina)
4. Not diagnosed with cancer
5. Willing to sign the informed consent form
6. Computer and internet literate

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
400

Key exclusion criteria
1. BMI < 29.9 and non-obese
2. <30 years old and >60 years old
3. Diagnosed with cancer
4. Diagnosed with a heart-condition (heart attack or angina). This is because algorithms predict risk of first CVD event, not recurrent events
5. Any other chronic disease of the major organs (e.g. kidney failure)
6. Not willing to sign online consent form
7. Not literate in use of computer and the internet

Date of first enrolment
30/01/2008

Date of final enrolment
28/02/2008

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Unilever Discover
Bedfordshire
United Kingdom
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Sponsor information

Organisation
Unilever (UK)

Sponsor details
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Sponsor type
Industry

ROR
https://ror.org/05n8ah907

Funder(s)

Funder type
Industry

Funder Name
Unilever (UK)

Alternative Name(s)
Unilever Global, Unilever PLC, U

Funding Body Type
Government organisation

Funding Body Subtype

For-profit companies (industry)

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	01/10/2010		Yes	No