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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

### Contact details
Unilever Discover
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# Additional identifiers

### Protocol serial number
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

### Primary study design
Interventional

### Study design

Randomised controlled trial

### Study type(s)
Quality of life

### 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(s)
Risk perceptions were measured by self-reported items once participants received their CVD risk information

### Key secondary outcome(s)
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

### 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

### Healthy volunteers allowed
No

### Age group
Adult

### Sex
All

### 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
United Kingdom

England

### Study participating centre
**Unilever Discover**
Bedfordshire
United Kingdom
MK44 1LQ

## Sponsor information

### Organisation
Unilever (UK)

### 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

**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 |