Methods for evaluating the extent to which different ways of presenting evidence of the effects of health care help people make decisions that are consistent with their own values: a randomised trial

Submission date	Recruitment status	Prospectively registered
04/01/2007	No longer recruiting	Protocol
Registration date	Overall study status	Statistical analysis plan
28/02/2007	Completed	Results
Last Edited	Condition category	Individual participant data
03/10/2007	Other	Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

HIPPO 1

Study information

Scientific Title

Acronym

HIPPO pilot

Study objectives

Pilot study - development of methodology to:

- 1. Analyse which of several presentations of evidence of treatment effects best help people to make treatment decisions congruent with their own values
- 2. Compare visual analogue scales and category rating scales as value elicitation instruments

Ethics approval required

Old ethics approval format

Ethics approval(s)

This study was approved by the ethics review board at the University at Buffalo on the 15 May 2002 with several renewals.

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

N/A

Interventions

Six different summary statistics presenting ten year risk reduction effect of statins on coronary heart disease in the treatment of hypercholesteremia.

The methodological aspects reported in this study include comparison of two value elicitation instruments (visual analogue scales and category rating scales), four theory-grounded

approaches to weighting elicited values, and six summary statistics to evaluate the extent to which they promote decisions consistent with elicited values. In addition, we report hypothesis generation and sample size calculation for a randomised controlled trial comparing the same six summary statistics for communicating evidence of reduced risk of coronary heart disease, as well as on the feasibility of conducting this type of Internet-based randomised trial.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

- 1. Acceptance or rejection of statin treatment
- 2. Estimated probability to accept or reject statin treatment in relation to value score

Secondary outcome measures

- 1. To investigate the feasibility of conducting Internet-based randomised trials comparing different risk reduction presentations
- 2. To compare two methods of eliciting values
- 3. Four ways of weighting the elicited values to calculate a total value
- 4. To generate hypotheses and calculate sample size for a confirmatory study comparing six summary statistics for communicating evidence of reduced risk of Coronary Heart Disease (CHD) with statin therapy for treatment of high cholesterol

Overall study start date

31/10/2002

Completion date

04/12/2002

Eligibility

Key inclusion criteria

- 1. 18 years old
- 2. Fluent in English or Norwegian
- 3. Must give informed consent

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

770

Key exclusion criteria

Not meeting inclusion requirements

Date of first enrolment

31/10/2002

Date of final enrolment

04/12/2002

Locations

Countries of recruitment

Norway

United States of America

Study participating centre

Norwegian Knowledge Centre for the Health Services

Oslo Norway 0130

Sponsor information

Organisation

Norwegian Research Council (Norway)

Sponsor details

P.O. Box 2700 St. Hanshaugen Oslo Norway 0131

Sponsor type

Government

Website

http://www.forskningsradet.no

ROR

https://ror.org/00epmv149

Funder(s)

Funder type

Government

Funder Name

Norwegian Research Council (Norway) (project 135210 - A series of randomised trials comparing different ways of presenting health evidence on the Internet)

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