ISRCTN89237105 https://doi.org/10.1186/ISRCTN89237105

Improving participation rates by providing choice on participation mode

Submission date	Recruitment status	[_] Prospectively registered
02/07/2014	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
14/08/2014	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
17/12/2020	Circulatory System	

Plain English summary of protocol

Background and study aims
This study aims to find out how being able to choose how they participate (i.e. the participation mode) effects how many people do participate in a social network study on health-related information. We want to know which participation modes are the most popular and whether these can be improved to encourage more people to take part. Here, we investigate how many people able to choose their participation mode (a telephone interview or postal questionnaire) do take part in the survey compared with those that are offered only one participation mode.

Who can participate?
Adults (18 or older) at high risk for cardiovascular disease (CVD) or with established CVD.

What does the study involve?
The study involves two randomized controlled trials. This means that, for each trial, participants are randomly allocated to either receive an invitation to take part in the social network study with the option to choose their preferred participation mode or a similar invitation but with only one participation mode available. In trial 1, the number of people who choose to take part having been given the option of two participation modes is compared to the number that choose to take part having only been given the option of a telephone interview. In trial 2, the number of people who choose to take part having been given the option of two participation modes is compared to the number that choose to take part having only been given the option of a postal questionnaire.

What are the possible benefits and risks of participating?
There are no immediate benefits or risk for participants.

Where is the study run from?
The Scientific Institute for Quality of Healthcare, Radboud University Medical Centre Nijmegen (Netherlands)

When is study starting and how long is it expected to run for?
June 2013 to March 2014.

Who is funding the study?
The European Union Seventh Framework Programme (FP7) (Belgium)

Who is the main contact?
Professor Michel Wensing
Michel.Wensing@radboudumc.nl

Contact information

Type(s)
Scientific

Contact name
Prof Michel Wensing

Contact details
Geert Grooteplein 21
Nijmegen
Netherlands
6525 EZ

Additional identifiers

Study information

Scientific Title
Improving participation rates by providing choice on participation mode: Randomized controlled trials.

Study objectives
It is hypothesised that participation rates will be higher when respondents can choose their preferred participation mode compared to when no choice on participation mode is provided.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval not required.

The study protocol and its materials (e.g. questionnaires and letters) were submitted to the Medical Ethical Committee of Radboud University Medical Centre Nijmegen. This committee assessed that the Dutch law for medical scientific research does not apply to this research. As the research does not involve testing of body materials, it was decided that no approval was required from a local medical ethical committee as well.

Primary study design
Interventional

Study design

Randomized controlled trial

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Patients at high risk for cardiovascular disease and with established cardiovascular disease.

Interventions
This study is part of the Tailored Implementation for Chronic Diseases (TICD) project and is integrated in a program evaluation which has been designed as a two arm randomized controlled trial (NTR4069). For purposes of the program evaluation, patients received a questionnaire booklet containing mainly questions on health-related lifestyle. For purposes of the randomized controlled trials of participation rates, different invitations were included at the last page of the questionnaire booklet to invite patients for participation in a social network study on health-related information sharing. For determining whether providing choice on participation mode improved participation rates, patients were randomly allocated to receive one of two formats of invitations. On the choice format invitations, patients could indicate whether they wanted to participate in the network study by:
1. A telephone interview or
2. A postal questionnaire.
On the single format invitation, only one participation mode was offered. Invitations were varied over two trials.
Trial 1: Participation rates are compared of patients who received a choice format invitation with that of patients who received a single format invitation to participate by a telephone interview.
Trial 2: Participation rates are compared of patients who received the choice format invitations with that of patients who received a single format invitation to participate by a postal questionnaire.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Participation rate, defined as the percentage of patients who actually participated in the social networks study. That is the total number of patients who had completed an interview or questionnaire for the social networks study divided by the total number of participants in the program evaluation.

Key secondary outcome(s)
1. Conditional participation rate: Defined as the total number of patients who had completed an interview or questionnaire for the social networks study divided by the total number of patients willing to participate in the study.
2. Willingness to participate: Defined as the percentage of patients initially willing to participate in the social network study. That is the total number of patients willing to participate divided by the number of participants in the program evaluation.

The response trials are embedded within a program evaluation which has been designed as a two-arm randomized controlled trial. For this program evaluation, questionnaires containing

invitations for the response trials were send at baseline of the program. Willingness to participate and preference for participation mode, were measured up to 2 months after sending questionnaires with invitations. We planned to perform interviews and send questionnaires on behalf of the social networks study within two months after receipt of completed invitations.

Completion date
31/03/2014

Eligibility

Key inclusion criteria
1. Patients with high risk for CVD and established CVD
2. Adults aged 18 or older and who are capable of providing informed consent
3. Patients with high risk for CVD have a risk score of 20% or higher on 10-years-morbidity and mortality due to CVD
International Classifications of Primary care (ICPC) codes were used to extract eligible patients from medical records from general practices.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Diabetes mellitus
2. Pregnancy and lactation
3. Terminal illness
4. Cognitive impairments
5. Poor language skills

Date of first enrolment
01/06/2013

Date of final enrolment
31/03/2014

Locations

Countries of recruitment
Netherlands

Study participating centre
Geert Grooteplein 21
Nijmegen
Netherlands
6525 EZ

Sponsor information

Organisation
Scientific Institute for Quality of Healthcare (IQ healthcare) (Netherlands)

ROR
https://ror.org/05wg1m734

Funder(s)

Funder type
Government

Funder Name
European Union Seventh Framework Programme (FP7) within the theme HEALTH.2013.3.1-1 under grant agreement no 258837 (Belgium)

Funder Name
ZonMw (The Netherlands Organisation for Health Research and Development) project no 200310011.(Netherlands)

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	02/04/2015	17/12/2020	Yes	No