ISRCTN71348772 https://doi.org/10.1186/ISRCTN71348772

Randomized phase III trial: a decision aid in cardiovascular prevention - risk consultation related to absolute and relative risk

Submission date
17/01/2006

Recruitment status
No longer recruiting

Registration date
02/03/2006

Overall study status
Completed

Last Edited
24/06/2015

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title

Randomized phase III trial: a decision aid in cardiovascular prevention - risk consultation related to absolute and relative risk

Acronym
ARRIBA

Study objectives
A consultation based on ARRIBA leads to:
1. An improved quality of counselling (patient's perceived assessment scale)
2. Changes in prescribing behaviour based on risk status

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical Committee of the University of Marburg, 18/10/2004, ref: 134/04

Study design
Two-arm parallel controlled cluster randomized intervention study

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Cardiovascular disease

Interventions
1. Intervention:
a. Advanced training (continuing education) in shared decision-making, risk calculation, risk communication and the use of decision aids
b. Advanced training in ARRIBA (decision aid and consultation)
2. Control:
Controls receive training after termination of the study

Intervention Type
Other

Phase
Phase III

Primary outcome(s)
Patient's attitude towards consultation (patient's perceived assessment scale)

Key secondary outcome(s))
1. GPs: changes in prescribing behaviour and consultation related to risk status
2. Patients: cardiovascular risk status after six months

Completion date

31/10/2006

Eligibility

Key inclusion criteria
1. Age >18 years
2. Written informed consent
3. Measurement of cholesterol

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
Insufficient mental or verbal ability

Date of first enrolment
01/11/2004

Date of final enrolment
31/10/2006

Locations

Countries of recruitment
Germany

Study participating centre
University of Marburg
Marburg
Germany
35033

Sponsor information

Organisation
University of Marburg, Department of General Practice and Family Medicine (Germany)

ROR
https://ror.org/01rdrb571

Funder(s)

Funder type
Government

Funder Name
Bundesministerium für Bildung und Forschung

Alternative Name(s)
Federal Ministry of Education and Research, BMBF

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Germany

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	01/06/2012		Yes	No
Results article	results	02/07/2013		Yes	No