

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

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|--------------------------|-----------------------------|--|
| Submission date | Recruitment status | <input type="checkbox"/> Prospectively registered |
| 17/01/2006 | No longer recruiting | <input type="checkbox"/> Protocol |
| Registration date | Overall study status | <input type="checkbox"/> Statistical analysis plan |
| 02/03/2006 | Completed | <input checked="" type="checkbox"/> Results |
| Last Edited | Condition category | <input type="checkbox"/> Individual participant data |
| 24/06/2015 | Circulatory System | |

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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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 Research, Technology and Space, Bundesministerium für Bildung und Forschung, 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 |