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

Recruitment status No longer recruiting	Prospectively registered		
	☐ Protocol		
Overall study status	Statistical analysis plan		
Completed	[X] Results		
Condition category	[] Individual participant data		
	No longer recruiting  Overall study status  Completed		

#### 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

# 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

#### Secondary study design

Cluster randomised trial

#### Study setting(s)

Not specified

#### Study type(s)

Quality of life

#### Participant information sheet

#### 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 measure

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

#### Secondary outcome measures

- 1. GPs: changes in prescribing behaviour and consultation related to risk status
- 2. Patients: cardiovascular risk status after six months

#### Overall study start date

01/11/2004

#### 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** 

#### Age group

Adult

#### Lower age limit

18 Years

#### Sex

Both

#### Target number of participants

1100

#### 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)

#### Sponsor details

Robert-Koch-Strasse 5 Marburg Germany 35033 +49 (0)64 2128 65120 baum@med.uni-marburg.de

#### Sponsor type

University/education

#### **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**

# 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

#### **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