

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

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

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Prof Norbert Donner-Banzhoff

**Contact details**  
University of Marburg  
Department of General Practice and Family Medicine  
Robert-Koch-Strasse 5  
Marburg  
Germany  
35033  
+49 (0)64 2128 65119  
norbert@med.uni-marburg.de

## 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?
<a href="#">Results article</a>	results	01/06/2012		Yes	No
<a href="#">Results article</a>	results	02/07/2013		Yes	No