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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 02/03/2006	**Overall study status** Completed	
Last Edited 24/06/2015	**Condition category** Circulatory System	

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

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