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Effects of a psychotherapy intervention in depressed patients with coronary artery disease

Submission date	Recruitment status	[X] Prospectively registered
26/02/2008	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
27/03/2008	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
12/11/2021	Mental and Behavioural Disorders	

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
ZKSK-371

Study information

Scientific Title
A Stepwise Psychotherapy Intervention for Reducing Risk in Coronary Artery Disease - a randomised controlled trial (SPIRR-CAD)

Acronym
SPIRR-CAD

Study objectives
To determine the effects of a psychotherapy intervention on symptoms of depression in depressed patients with coronary artery disease.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of University of Göttingen, 25/10/2007, ref: 5/10/07

Study design
Randomised controlled multi-centre clinical trial with masked evaluation (observer)

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Depressive symptoms in patients with coronary artery disease

Interventions
Experimental intervention: Stepwise, manualised individual and group psychotherapy in addition to usual cardiological care. Patients randomised in the intervention group receive 3 sessions of individual psychotherapy (50 minutes per session, 1 session per week). Only those patients with persisting symptoms of depression receive additional 25 sessions of group psychotherapy (90 minutes per session) over 10 months (first 20 sessions on a weekly basis, then 5 sessions once a month).

Control intervention: Usual cardiological care including one psychosocial information session

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Amended as of 24/01/2011:
Changes from baseline to 18 months in depressive symptoms (HADS-D)

Initial information at time of registration:
Changes from baseline to year 1 in depressive symptoms (HADS-D)

Key secondary outcome(s))

Amended as of 24/01/2011:
The following will be monitored up to 24 months:
1. Remission of depressive disorder (Structured Clinical Interview [SCID]) at baseline and 18 months
2. Type D pattern, assessed by a self rating questionnaire (DS-14) at baseline, 1, 6, 12, 18 and 24 months
3. Health-related quality of life, evaluated by the self rating questionnaires the 36-item Short Form health survey (SF-36) and EuroQuol-5D at baseline, 6, 12, 18 and 24 months
4. Cardiovascular risk profile
5. Neuroendocrine and immunological activation
6. Coagulation
7. Heart rate variability
8. Cardiac events
9. Health care utilisation and costs

Initial information at time of registration:
The following will be monitored up to 24 months:
1. Remission of depressive disorder (Structured Clinical Interview [SCID]) at baseline and 12 months
2. Type D pattern, assessed by a self rating questionnaire (DS-14) at baseline, 1, 6, 12, and 24 months
3. Health-related quality of life, evaluated by the self rating questionnaires the 36-item Short Form health survey (SF-36) and EuroQuol-5D at baseline, 6, 12, and 24 months
4. Cardiovascular risk profile
5. Neuroendocrine and immunological activation
6. Coagulation
7. Heart rate variability
8. Cardiac events
9. Health care utilisation and costs

Completion date
30/09/2013

Eligibility

Key inclusion criteria
Amended as of 24/01/2011:
1. Gender: both
2. Minimum age: 18, maximum age: 75
3. Patients with any manifestation of coronary heart disease with recent (less than 3 months old) coronary angiograms and elevated questionnaire scores for depression (Hospital Anxiety and Depression Scale [HADS] depression subscale greater than or equal to 8)

Initial information at time of registration:
1. Gender: both
2. Minimum age: 18, maximum age: 75
3. Patients hospitalised for any manifestation of coronary heart disease with recent (less than 3 months old) coronary angiograms and elevated questionnaire scores for depression (Hospital Anxiety and Depression Scale [HADS] depression subscale greater than or equal to 8)

Participant type(s)

Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
570

Key exclusion criteria
1. Severe heart failure or other acutely life-threatening conditions
2. Severe chronic inflammatory disease
3. Current suicidal tendency
4. Severe depressive episode or other severe mental illness

Date of first enrolment
01/11/2008

Date of final enrolment
30/09/2013

Locations

Countries of recruitment
Germany

Study participating centre
University of Göttingen
Göttingen
Germany
D-37075

Sponsor information

Organisation
University of Göttingen (Germany)

ROR
https://ror.org/01y9bpm73

Funder(s)

Funder type
Government

Funder Name
Deutsche Forschungsgemeinschaft

Alternative Name(s)
German Research Association, German Research Foundation, Deutsche Forschungsgemeinschaft (DFG), DFG

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Germany

Results and Publications

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2016		Yes	No
Results article	results	01/01/2017		Yes	No
Results article	results	01/02/2018		Yes	No
Results article	gender differences results	01/10/2018		Yes	No
Results article	results	01/08/2019	05/08/2019	Yes	No
Results article	Secondary analysis in participants with depression	28/10/2021	12/11/2021	Yes	No

Protocol article	protocol	01/10/2011		Yes	No
Other publications	secondary analysis	01/05/2018		Yes	No
Other publications	secondary analysis	04/02/2019		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes