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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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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 measure
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)

Secondary outcome measures
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

Overall study start date
01/11/2008

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
569

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
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Sponsor information

Organisation
University of Göttingen (Germany)

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Sponsor type
University/education

Website
http://www.med.uni-goettingen.de

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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?
Protocol article	protocol	01/10/2011		Yes	No
Results article	results	01/07/2016		Yes	No
Results article	results	01/01/2017		Yes	No
Results article	results	01/02/2018		Yes	No
Other publications	secondary analysis	01/05/2018		Yes	No
Results article	gender differences results	01/10/2018		Yes	No
Other publications	secondary analysis	04/02/2019		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