

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

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

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

Primary study design

Interventional

Study design

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

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