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BYpass surgery with Psychological And Spiritual Support

Submission date	Recruitment status	[_] Prospectively registered
04/12/2008	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
23/12/2008	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
23/11/2012	Surgery	

Plain English summary of protocol

Background and study aims
We examined how much psychological and spiritual treatments improve recovery after coronary bypass surgery. One of our goals was to investigate if psychological or spiritual treatments are more effective for patients who actively chose one of these treatments compared to patients who wished to have treatment but didnt mind whether it was psychological or spiritual. Furthermore, we wanted to see whether patients who are at psychosocial risk (those who are anxious or depressed) before an operation might benefit from supportive treatments.

Who can participate?
The BYPASS study aimed to recruit about 1,000 female and male patients undergoing non-emergency coronary bypass surgery partially combined with valve surgery, over 18 years of age, from the Jena University Hospital and the Heart Centre Brandenburg, Bernau, Germany.

What does the study involve?
Upon hospital admission, patients were asked about their preference regarding supportive treatments: whether they preferred psychological treatments, spiritual treatments, treatments regardless of the profession of the therapist or if they did not want any supportive treatment. In one time period, patients got treatments according to their preference; in another time period, patients were asked about their preference but did not get any supportive treatment. At the end of the study, we compared patients who received psychological or spiritual support with patients, who stated a preference for, but did not get supportive treatments.

What are the possible benefits and risks of participating?
Patients who received supportive treatments benefited from an improvement in their mood. There were no known risks associated with participating in this trial.

Where is the study run from?
Jena University Hospital of Jena and the Heart Centre Brandenburg, Bernau, Germany.

When is study starting and how long is it expected to run for?
This trial started in October 2007 and finished in December 2009.

Who is funding the study?
German Research Council (Deutsche Forschungsgemeinschaft [DFG]), Germany.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
AL 562/4-1, STR 306/21-1

Study information

Scientific Title
Differential treatment effects of psychological and spiritual support on recovery and quality of life after coronary artery bypass surgery

Acronym
BYPASS

Study objectives
1. Spiritual or psychological interventions, either according to the patients' therapeutic preference or randomly assigned, will have an positive impact on recovery and health-related quality of life following bypass surgery
2. Spiritual or psychological interventions, that are applied to the patients according to their preference, will have a greater positive impact on recovery and health-realted quality of life than

randomly assigned interventions
3. Patients that are pre-operatively at psychosocial risk (high levels of anxiety or depression, lack of social support) will benefit from spiritual or psychological interventions more than patients not being at psychosocial risk

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the Friedrich Schiller University of Jena, approved on the 13th December 2005 (ref: 1663-11/05)

Study design
Partially randomised controlled multicentre trial

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 below to request a patient information sheet

Health condition(s) or problem(s) studied
Coronary artery bypass surgery partially combined with valve surgery

Interventions
Interventions, psychological as well as spiritual, are manualised and applied to the patient according to his/her individual needs at least once pre-operatively and at least once post-operatively. The total number of intervention sessions and the duration of each session depends on each participant's need.

Psychological interventions include hypnotherapeutic interventions, relaxation techniques and emotional support. Spiritual interventions include patient-oriented conversations, intercessory prayer, Lords prayer, Lords supper, anointing or blessing.

Intervention Type
Procedure/Surgery

Phase
Not Applicable

Primary outcome measure

Presence of any complication following surgery within hospital stay, and following three and six months after surgery.

Secondary outcome measures
1. Patient mobility (measured with the two-minute-walking-test) at discharge
2. Patient satisfaction, assessed by the Client Satisfaction Questionnaire (CSQ-8) at discharge
3. Health-related quality of life, assessed by the 12-item Short Form (SF-12) Health Survey at three- and six-month follow-up
4. Wellbeing, assessed by a German Mood and Wellbeing scale (BFS) at discharge, three- and six-month follow-up
5. Anxiety and depression, assessed by the Hospital Anxiety and Depression Scale (HADS) at discharge, three- and six-month follow-up
6. Self-reported pain, assessed by a Visual Analogue Scale (VAS) at discharge, three- and six-month follow-up

Overall study start date
01/10/2007

Completion date
31/12/2009

Eligibility

Key inclusion criteria
1. Male and female patients aged 18 years or older
2. Scheduled for non-emergency coronary bypass surgery partially combined with valve surgery

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
1,000

Key exclusion criteria
Emergency cases

Date of first enrolment
01/10/2007

Date of final enrolment
31/12/2009

Locations

Countries of recruitment
Germany

Study participating centre
Institute of Psychosocial Medicine and Psychotherapy
Jena
Germany
07743

Sponsor information

Organisation
German Research Council (Deutsche Forschungsgemeinschaft [DFG]) (Germany)

Sponsor details
Kennedyallee 40
Bonn
Germany
53175

Sponsor type
Research council

Website
http://www.dfg.de

ROR
https://ror.org/018mejw64

Funder(s)

Funder type
Research council

Funder Name
German Research Council (Deutsche Forschungsgemeinschaft [DFG]) (Germany) (ref: AL 562/4-1, STR 306/21-1)

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?
Protocol article	protocol	01/07/2009		Yes	No
Results article	results	01/07/2013		Yes	No