# BYpass surgery with Psychological And Spiritual Support

Submission date	Recruitment status No longer recruiting	<ul><li>Prospectively registered</li></ul>		
04/12/2008		[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 nonemergency 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?
Dr Jenny Rosendahl
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# **Contact information**

### Type(s)

Scientific

#### Contact name

**Prof Bernhard Strauss** 

#### Contact details

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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