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The InterHerz project - a web-based psychological treatment for cardiac patients with depression

Submission date	Recruitment status	[ ] Prospectively registered
08/08/2012	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
16/08/2012	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
12/05/2014	Mental and Behavioural Disorders	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Patients with heart disease often suffer from depression. Depression is known to have a negative impact on the progression of heart disease. The aim of the study is to investigate whether depressed patients with a heart disease benefit from a web-based treatment called deprexis.

Who can participate?
To participate you must be 18 years old or older, diagnosed with a heart disease and feel depressed.

What does the study involve?
If you decide to participate in the study, you will be randomly assigned to one of two groups. Both groups receive access to the web-based treatment called deprexis but at different time points. One group can start with the web-based treatment immediately after giving their written informed consent, and the other group receives access after a waiting period of 10 weeks. The aim of the study is to compare these two groups. Therefore, all participants will be assessed at three different time points (before receiving access to the treatment, after 10 weeks and after 6 months). The assessments will involve a phone interview and a number of questionnaires.

What are the possible benefits and risks of participating?
The benefits of the study are a reduction of depressive symptoms. Previous research has shown that participants felt better and healthier after the treatment. There are no known negative side effects related to the treatment. However, it is unclear as to what extent depressed participants with a heart disease benefit from deprexis.

Where is the study run from?
University of Bern (Switzerland).

When is study starting and how long is it expected to run for?
The study has started in March 2012 and will continue to recruit participants until April 2014.

Who is funding the study?
University of Bern (Switzerland).

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
The InterHerz project - a web-based psychological treatment for cardiac patients with depression: a randomized controlled trial

Acronym
InterHerz

Study objectives
The primary aim of the study is to investigate whether a web-based psychological treatment for cardiac patients with depression is effective to reduce depression and perceived stress. It is assumed that participants of the treatment group show lower depression levels and less perceived stress after the treatment compared with the wait-list control group. Further, we expect higher levels of perceived social support, and improved quality of life in the intervention group.

The secondary aim is to investigate a mid-term benefit of the psychological treatment at follow-up after six months. We hypothesize that all participants at six months compared with pre-treatment show reduced depression levels, reduced stress perception, improved perceived social support and improved quality of life.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Faculty of Human Sciences Ethics Committee, University of Bern, 02/03/2011, ref: 2011-02-151

Study design
Randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Patients with cardiovascular diseases and depressive symptoms

Interventions
Comparing a web-based intervention with a waitlist-control condition

The intervention is a web-based psychological treatment called deprexis evaluated in previous trials. Deprexis was developed to reduce depressive symptoms in patients without any somatic disease. The program consists of 10 content modules. All modules can each be completed in 10 to 60 minutes, depending on the users reading speed, interest, motivation, and individual path through the program. The modules cover a variety of therapeutic content that is broadly consistent with a cognitive-behavioral perspective. Participants are guided by a clinical psychologist through their work with this self-help program.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. Depression levels by BDI-II (Hautzinger et al., 2006), and clinical depression by the Patient Health Questionnaire (Gräfe et al., 2004) and by a clinical interview according to the Structured Clinical Interview for DSM Diagnosis SCID (APA, 2000).

Key secondary outcome(s))
1. Stress perception by Perceived Stress Questionnaire PSQ (Fliege et al., 2005)
2. Social support by the ENRICHD Social Support Inventory ESSI (Cordes et al., 2009)

3. Quality of life by the WHOQOL-BREF (Angermayer et al., 2000)
4. Health behavior#
5. Client satisfaction by the Client Satisfaction Questionnaire CSQ (Schmidt & Wittmann, 2002)

Completion date
01/04/2014

Eligibility

Key inclusion criteria
1. Adults who suffer from any cardiovascular disorder (including coronary heart disease, chronic heart failure, and arrhythmias)
2. Written informed consent
3. Are 18 years or older
4. Have symptoms of depression (as defined by scoring above a cut-off of 9 on the Beck Depression Inventory (BDI-II)
5. Are of sufficient knowledge of German language
6. Have access to the Internet

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Any acute health threatening disease (e.g. cancer)
2. Any severe psychiatric illness (e.g. psychosis, dementia)
3. Suicidal thoughts or suicidal plans, or
4. A unstable heart condition

Date of first enrolment
01/03/2012

Date of final enrolment
01/04/2014

Locations

Countries of recruitment
Switzerland

Study participating centre
University of Bern
Bern
Switzerland
3012

Sponsor information

Organisation
University of Bern (Switzerland)

ROR
https://ror.org/02k7v4d05

Funder(s)

Funder type
University/education

Funder Name
University of Bern, Department of Clinical Psychology and Psychotherapy (Switzerland)

Results and Publications

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	28/12/2012		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes