

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

Submission date 08/08/2012	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 16/08/2012	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 12/05/2014	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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?
Nadine Messerli-Bürgy, PhD
nadine.messerli@psy.unibe.ch

Study website
<https://www.online-therapy.ch/interherz/home.php>

Contact information

Type(s)
Scientific

Contact name
Dr Nadine Messerli-Bürgy

Contact details
University of Bern
Dept. of Clinical Psychology and Psychotherapy
Gesellschaftsstrasse 49
Bern
Switzerland
3012
nadine.messerli@psy.unibe.ch

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design

Randomised controlled trial

Study setting(s)

Other

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

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 measure

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).

Secondary outcome measures

1. Stress perception by Perceived Stress Questionnaire PSQ (Fliege et al., 2005)
2. Social support by the ENRICH 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)

Overall study start date

01/03/2012

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

80 (n=40 participants per group)

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)

Sponsor details

Dept. of Clinical Psychology and Psychotherapy

Gesellschaftsstrasse 49

Bern

Switzerland

3012

nadine.messerli@psy.unibe.ch

Sponsor type

University/education

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

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	28/12/2012		Yes	No