

# Evaluating an e-mental health program ('deprexis') as adjunctive treatment tool in psychotherapy for depression

<b>Submission date</b> 28/05/2014	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 03/06/2014	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 19/06/2015	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Major depressive disorder (MDD), or clinical depression, is a serious, disabling mental disorder. Symptoms include persistent low mood, low self-esteem and a loss of interest or pleasure in normally enjoyable activities. It can adversely affect a patients family, work or school life, sleeping and eating habits, and general health. It can also have implications for society at large. Several web-based treatment programmes (interventions) for MDD have been shown to alleviate depressive symptoms. However, it is not known whether using web-based interventions in combination with primary treatment (i.e. regular psychotherapy) have an additional effect when compared to regular psychotherapy alone. The main aim of the study is to evaluate whether traditional psychotherapy plus access to a web-based self-help programme is better at treating MDD than psychotherapy alone.

### Who can participate?

800 participants are recruited by therapists who are members of the Deutsche PsychotherapeutenVereinigung (DPTV; association of German psychotherapists).

### What does the study involve?

Participants will be randomly allocated to psychotherapy plus access to the web-based self-help programme (group 1) or traditional psychotherapy (group 2). While participants in group 2 receive psychotherapy as usual, participants in group 1 also have access to the self-help programme deprexis. There are no costs for using the programme for either patients or therapists during the study. All participants are asked to fill out self-report questionnaires at pre-treatment, post treatment (12 weeks) and then again 6 months after treatment.

### What are the possible benefits and risks of participating?

As all participants receive traditional face-to-face psychotherapy conducted by licenced psychotherapists (with or without access to the web-based self-help programme), we do not expect any specific risk associated with a participation in this study. Participants in group 1 may benefit more from the treatment than participants in group 2. It is possible, however, that the web-based programme might have some negative side effects that are, as yet, unknown.

Where is the study run from?

The University of Bern (Switzerland), the University of Zurich (Switzerland), the Deutsche PsychotherapeutenVereinigung (DPTV), and the GAIA AG (Hamburg, Germany)

When is the study starting and how long is it expected to run for?

April 2014 to June 2015. Recruitment of participants is ongoing until January 2015.

Who is funding the study?

Swiss National Science Foundation (Switzerland)

Who is the main contact?

Prof. Dr. Thomas Berger

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## Contact information

### Type(s)

Scientific

### Contact name

Prof Thomas Berger

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## Additional identifiers

### Protocol serial number

N/A

## Study information

### Scientific Title

Evaluating an e-mental health program ('deprexis') as adjunctive treatment tool in psychotherapy for depression: design of a pragmatic randomized controlled trial

### Acronym

IN-OPT

### Study objectives

The main objective of the study is to evaluate a treatment approach for major depressive disorders (MDD) in which an empirically validated web-based self-help program (deprexis) is used as an adjunctive tool in regular face-to-face psychotherapeutic treatment. This treatment approach will be compared with traditional psychotherapy (without the adjunctive tool) in a

sample of depressed outpatient clients by means of a pragmatic RCT in routine care. The main research questions are whether psychotherapy plus a web-based online depression program is superior to traditional psychotherapy with regard to a primary depression measure and secondary outcomes such as quality of life, anxiety, somatic symptomatology, psychological empowerment and efficiency of the treatment (i.e., reduction of number of sessions). In addition, we intend to evaluate how helpful patients as well as therapists rate the blended treatment and whether the addition of a web-based tool is associated with negative side effects (e.g. regarding the therapeutic alliance).

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Ethics Committee of the German Psychological Association (DGPs), 16/08/2013, ref. TB072013  
Hamburg Chamber of Psychotherapists, 18/12/2013

### **Study design**

Two-armed randomised controlled trial comparing regular psychotherapeutic treatment with face-to-face psychotherapeutic treatment plus a web-based self-help treatment

### **Primary study design**

Interventional

### **Study type(s)**

Treatment

### **Health condition(s) or problem(s) studied**

Major depressive disorders

### **Interventions**

1. Intervention group: Psychotherapy plus web-based online platform (deprexis): Participants in the intervention group receive access to the deprexis platform. Trained, certified psychotherapists introduce the patients to the use of the program. There are no costs for patients or therapists for the program use during the study. Deprexis provides psychoeducational information and exercises that are mainly based on cognitive-behavioral psychotherapy and aim at decreasing depressive symptoms. Deprexis includes ten modules plus one summary module: (1) psychoeducation, (2) behavioral activation, (3) cognitive restructuring, (4) mindfulness and acceptance, (5) interpersonal skills, (6) relaxation, (7) physical activity and lifestyle modification (e.g., sports and alimentation), (8) problem-focused approaches, (9) expressive writing and schema-focused contents, (10) positive psychology as well as emotion-focused-interventions.
2. Control group: Psychotherapy without Deprexis: Patients in the control group receive regular psychotherapy according to the clinical judgment of the therapists. The behavior of the therapists is not deliberately influenced by the study. In case of interest, participants in the control condition will get access to deprexis after completion of the study.

Therapists: All therapists are licensed and members of the Deutsche Psychotherapeutenvereinigung (DPTV). Most participating psychotherapists in the study identify themselves as being eclectic with a focus on cognitive-behavioral therapy, but also psycho-dynamically oriented therapists take part in the study.

## **Intervention Type**

Other

## **Phase**

Not Applicable

## **Primary outcome(s)**

Depressive symptomatology as measured with the Beck Depression Inventory (BDI-II).

Timepoints of assessment: pretreatment, posttreatment (12 weeks), follow-up (6 months)

## **Key secondary outcome(s)**

Measures 1 to 7 are assessed at pretreatment, posttreatment (12 weeks), and at follow-up (6 months)

1. Symptoms of anxiety assessed with the German version of the 7-item Generalized Anxiety Disorder Scale (GAD-7)
2. Somatic symptomatology as assessed with the somatic symptom module of the Patient Health Questionnaire (PHQ)
3. Quality of life assessed with the Short-Form Health Survey-12 (SF-12)
4. Questionnaire for the evaluation of psychotherapeutic progress (FEP-2) to measure the dimensions well-being, symptoms, interpersonal relationships, and incongruence with respect to approach and avoidance goals
5. Web Screening Questionnaire (WSQ) to screen for common mental disorders. The WSQ is a 15-item self-report instrument screening for frequent mental disorders
6. Suicidal tendencies as assessed with the Suicidal Behaviours Questionnaire-Revised (SBQ-R)
7. Psychological empowerment as assessed with an adapted version of the scale by Spreitzer
8. Depression diagnosis as assessed by the licenced therapists conducting the treatment (only pre-and posttreatment)
9. Working Alliance Inventory Short (WAI-S; adapted version) as assessed by patients and therapists (week 6; week 12)

## **Completion date**

01/06/2015

## **Eligibility**

### **Key inclusion criteria**

We include adults

1. Aged 18 or over
2. Suffer from a MDD according to the International Classification of Diseases (ICD-10; i.e., F32.- depressive episode, F33.- Recurrent Depressive Disorder, F34.- Persistent Affective Disorder, F38.- Other Affective Disorder, F39 Unspecified Affective Disorder)
3. Who have a Beck Depression Inventory (BDI-II) sum score over 13
4. Who have sufficient knowledge of the German language
5. Who have Internet access and sufficient knowledge to use it (based on self-report)
6. Who are willing to give informed consent

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

We will exclude subjects who:

1. Have a known psychotic or bipolar disorder
2. Suffer from a chronic depression with onset in childhood (based on clinical judgment)
3. Show a notable suicidal risk (based on clinical judgment of the therapists)

**Date of first enrolment**

01/04/2014

**Date of final enrolment**

01/01/2015

## **Locations**

**Countries of recruitment**

Germany

Switzerland

**Study participating centre**

**Fabrikstrasse 8**

Bern

Switzerland

3012

## **Sponsor information**

**Organisation**

Swiss National Science Foundation (Switzerland)

**ROR**

<https://ror.org/00yjd3n13>

# Funder(s)

## Funder type

Research organisation

## Funder Name

Swiss National Science Foundation (Switzerland) Ref. PP00P1\_144824 / 1

## Alternative Name(s)

Schweizerischer Nationalfonds, Swiss National Science Foundation, Fonds National Suisse de la Recherche Scientifique, Fondo Nazionale Svizzero per la Ricerca Scientifica, Fonds National Suisse, Fondo Nazionale Svizzero, Schweizerische Nationalfonds, The Swiss National Science Foundation (SNSF), SNF, SNSF, FNS

## Funding Body Type

Private sector organisation

## Funding Body Subtype

Trusts, charities, foundations (both public and private)

## Location

Switzerland

# Results and Publications

## Individual participant data (IPD) sharing plan

### IPD sharing plan summary

#### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	08/10/2014		Yes	No