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

Submission date
28/05/2014

Recruitment status
No longer recruiting

Registration date
03/06/2014

Overall study status
Completed

Last Edited
19/06/2015

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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?
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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
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

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

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
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 lincenced and members of the DeutschePsychotherapeutenVereinigung (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 measure
Depressive symptomatology as measured with the Beck Depression Inventory (BDI-II).
Timepoints of assessment: pretreatment, posttreatment (12 weeks), follow-up (6 months)

Secondary outcome measures
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)

Overall study start date
01/04/2014

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
800

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
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Sponsor information

Organisation
Swiss National Science Foundation (Switzerland)

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Sponsor type
Research organisation

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, SNF, SNSF, FNS

Funding Body Type
Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location
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?
Results article	results	08/10/2014		Yes	No