

An integrative online self-help program (Deprexis®) versus waitlist control for adults with depressive symptoms

Submission date 17/04/2009	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 22/04/2009	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 22/04/2009	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Mario Weiss

Contact details
Holstenwall 7
Hamburg
Germany
20355

Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
An integrative online self-help program (Deprexis®) versus waitlist control for adults with depressive symptoms: a randomised parallel group controlled trial

Study objectives

Using an integrative online-self-help programme (Deprexis®) as an add-on to treatment as usual will reduce depressive symptoms and improve social functioning more than remaining on a waitlist and continuing to receive treatment as usual.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Local ethics committee ("Modellvorhaben Arzneimittelmanagement", Hesse Ministry of Health) approved on the 29th January 2007

Study design

Randomised parallel group controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Depressive symptoms

Interventions

The Deprexis® program consists of ten interactive modules, plus one introductory and one summary module, which can be completed at the users own speed and frequency during a period of nine weeks. The program focuses on changing unhelpful thoughts, increasing activities that convey a sense of mastery and pleasure, improving social skills, practicing relaxation exercises and increasing a sense of acceptance/mindfulness. The program is based on standard cognitive-behavioural self-help and psychotherapy treatment literature. The delivery of content is individualised to match users preferences and needs, based on their responses in an initial program module. The program does not permit users to enter text; instead, users navigate through the program by choosing from various response options that are continuously presented to them. The program is delivered via the internet and is protected by individually assigned passwords.

The control group did not receive access to the program during the first nine weeks of the study (the waiting period for the control group). During this waiting period, they were permitted to continue whatever treatment they were receiving (e.g., psychotherapy, antidepressant medication or both). After the initial waiting period, the control group also received access to the Deprexis® program for a duration of nine weeks.

Both groups were followed for six months after termination of program usage.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Depressive symptom level, measured with the German version of the Beck Depression Inventory (BDI).

For both the initial treatment group and the control (delayed treatment) group, data were collected at baseline, 9 weeks and 18 weeks. Additionally, participants in the control group completed questionnaires 9 weeks after completing the program (for those in the initial treatment group, this 9-week post-treatment timepoint coincided with the 18-week assessment point mentioned above). Both groups also completed questionnaires 6 months after their respective program usage termination.

Key secondary outcome(s)

1. Work and Social Adjustment Scale (German translation)
2. Subjective usefulness of the program, as measured by individually designed items

For both the initial treatment group and the control (delayed treatment) group, data were collected at baseline, 9 weeks and 18 weeks. Additionally, participants in the control group completed questionnaires 9 weeks after completing the program (for those in the initial treatment group, this 9-week post-treatment timepoint coincided with the 18-week assessment point mentioned above). Both groups also completed questionnaires 6 months after their respective program usage termination.

Completion date

30/06/2008

Eligibility

Key inclusion criteria

1. Aged 18 years or older, either sex
2. Indicate agreement with an electronic consent form

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

Does not meet with inclusion criteria

Date of first enrolment

01/02/2007

Date of final enrolment

30/06/2008

Locations

Countries of recruitment

Germany

Study participating centre

Holstenwall 7

Hamburg

Germany

20355

Sponsor information

Organisation

GAIA AG (Germany)

ROR

<https://ror.org/04rmmk750>

Funder(s)

Funder type

Industry

Funder Name

GAIA AG (Germany)

Results and Publications

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Not provided at time of registration