

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

<b>Submission date</b> 17/04/2009	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 22/04/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 22/04/2009	<b>Condition category</b> 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

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**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

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
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