ISRCTN64953693 https://doi.org/10.1186/ISRCTN64953693

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

Registration date
22/04/2009

Overall study status
Completed

Last Edited
22/04/2009

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

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
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

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
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 measure
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.

Secondary outcome measures
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.

Overall study start date
01/02/2007

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
200 at post-treatment

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)

Sponsor details
Holstenwall 7
Hamburg
Germany
20355

Sponsor type
Industry

Website
http://www.gaia-group.com

ROR
https://ror.org/04rmmk750

Funder(s)

Funder type
Industry

Funder Name
GAIA AG (Germany)

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