Towards fully automated psychotherapy for adults:
BAS - Behavioral Activation via mobile phone and internet
A pilot study

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Mood disorders and disturbances NEC
Study type	Interventional

Summary

ID

NL-OMON34580

Source
ToetsingOnline

Brief title
BAS

Condition

- Mood disorders and disturbances NEC

Synonym
clinical depression, dreariness

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: behavioral activation, depression, unguided self-help intervention

Outcome measures

Primary outcome

The primary outcome of this study is the number of depressive symptoms measured

by the CES-D questionnaire.

Secondary outcome

Secundary outcome measures are:

- anxiety (HADS)

- cognition (ATQ)

- mastery (Pearlin mastery scale)

- activities (PES)

- neuroticism (NEO-FFI)

- contentment with course (own design)

Study description

Background summary

Most depressive disorders are treated by general practitioners and psychologists in primary care. Although internet-based self-help has been proven to be an effective alternative for face-to-face treatment, several studies have shown that these interventions are only effective when professional therapists help patients to work through the treatment. However, in the current project, a collaboration between clinical psychological and artificial intelligence researchers, we are developing an internet intervention

which is supported by an internet-connected smart-phone, which will guide the patient through the intervention, instead of a therapist. The type of intervention we will use (activity scheduling, also called behavioral activation treatment) has been shown to be effective in many earlier studies, and can also be expected to be effective as an unguided internet + smart-phone intervention.

Study objective

We would like to test the system in a pilot study with vulonteers with mild depressive symptoms. The goals of this pilot are twofold:
1) We want to know how easy to use the system is and how content the volunteers are with this form of treatment en support.
2) We would like to get an idea of the effects of the intervention, mostly whether the volunteers show less symptoms of depression after undergoing the intervention.

Study design

In this pilot we want to perform a randomised controlled trial. The participants will be randomly distributed over an intervention group and a control group that will be put on a waiting list. This last group will undergo the intervention after three months.

Intervention

The intervention group will follow the course which is based on behavioral activation therapy. The course consists of 5 parts that can be executed via a webiste and a mobile phone application. During the intervention, the participants learn techniques to monitor their mood and daily activities and to learn the relationship between these two. Then, the participants learn to make a plan to increase the number of pleasant activities and with that to have more social interation with their environment.

Study burden and risks

Participants will fill out a questionnaire three time. The burden of the course is very low: the course consists mainly of planning more pleasant activities. There are no risks involved.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Score of ><= 20 with the K10, mild to moderate depression diagnoses with CIDI interview

Exclusion criteria

No or heavy depressive complaints

Study design

Design

Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	18-10-2010
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

Date:	19-08-2010
Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL32709.029.10