

Internet-based treatment of phobias in specialized mental health care: a cost-effectiveness study

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Anxiety disorders and symptoms
Study type	Interventional

Summary

ID

NL-OMON38233

Source

ToetsingOnline

Brief title

Phobias under Control

Condition

- Anxiety disorders and symptoms

Synonym

anxiety disorder, phobias

Research involving

Human

Sponsors and support

Primary sponsor: Vrije Universiteit

Source(s) of monetary or material Support: ZonMW Doelmatigheid

Intervention

Keyword: cognitive behaviour therapy, internet-based treatment, phobias, randomized trial

Outcome measures

Primary outcome

The primary outcome measure is the Fear Questionnaire. This questionnaire assesses the level of anxiety (or avoidance) of different situations.

Secondary outcome

Secondary outcomes include: generalised anxiety (BAI), panic (PDSS-R), depressive symptoms (CES-D), alcohol use (CAGE), satisfaction with care (CSQ8), quality of life (EQ5-D), health care use and absenteeism. Health care use and absenteeism will be translated into costs and used in the economical analyses.

We will also register the number (and type) of contacts in regular mental health care. All questionnaires will be completed via the internet.

Measurements will be conducted after inclusion (and informed consent), after 5 weeks, 3 months, 6 months, 9 months and 12 months.

Study description

Background summary

Anxiety disorders cause a high burden of disease. They are ranked second in comparison with all other somatic and psychiatric diseases. Of all the different anxiety disorders phobias are the most prevalent ones (social phobia, specific phobia or agoraphobia). Seventeen percent of the Dutch population suffers from a phobia of which 11% in the last year. The prevalence of social phobia is 4.8%, of agoraphobia 1.6% and specific phobia 7.1%. Moreover, there is a high co-morbidity rate. Almost half of all patients with a social phobia also suffer a mood disorder, and almost two thirds suffers from another anxiety disorder. Next to the high burden of disease, the impairments in daily

functioning, the economic costs are substantial.

Study objective

Several meta-analyses have shown that guided self-help through the internet is effective in treating anxiety disorders. However, the cost-effectiveness of guided self-help in regular mental health care has not been studied yet. In the current project we study the cost-effectiveness of a guided web-based self-help intervention for phobia patients in regular mental health care. In this equivalence trial we want to demonstrate that introducing guided self-help leads to the same clinical effects but costs less.

Study design

We will perform a randomised trial with phobic patients who present themselves for treatment in regular mental health care. They will be randomised to (1) the guided web-based self-help intervention or (2) care-as-usual. The self-help intervention is offered right after the initial registration, during the waiting period for regular treatment. All patients, in both groups, will be offered regular treatment after 5 weeks.

Intervention

The intervention is based on a published self-help book (written by drs. Manja de Neef and prof. Cuijpers), which was used in a series of television programme on self-help for phobias (by broadcasting company Teleac/Not). This treatment is based on exposure therapy in which the patients gradually exposes himself or herself to the feared situation. Exposure has been examined and has been found to be effective in many studies. The intervention consists of five weeks. Weekly the patient receives new information as well as home work assignments. The patients receive weekly feedback online on the homework assignments by trained coaches. This support is provided by the researchers from the department of clinical psychology. Integrity is checked by an independent psychotherapist who will review the feedback. The internet-based intervention is already available and is currently tested in a pilot project.

Study burden and risks

not applicable

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

- (1) patients with a DSM-IV phobic disorder (social, agoraphobia, or specific)
- (2) 18 years or older
- (3) access to the internet
- (4) motivated to work with a guided self-help intervention

Exclusion criteria

Another severe psychological disorder (psychotic disorder, bipolar disorder) and/or an increased risk for suicide.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Health services research

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	16-09-2010
Enrollment:	320
Type:	Actual

Ethics review

Approved WMO	
Date:	16-06-2010
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	26-10-2011
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	06-09-2012
Application type:	Amendment
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	NL30976.029.10