"Phobias under control".

No registrations found.

Ethical review Not applicable

Status Recruitment stopped

Health condition type -

Study type Interventional

Summary

ID

NL-OMON21113

Source

NTR

Brief title

FocD (Fobieen onder controle Doelmatigheid)

Health condition

Anxiety disorders

Phobias

Angststoornissen

Fobieen

Sponsors and support

Primary sponsor: Vrije Universiteit Faculteit der Pedagogiek en Psychologie

Afdeling Klinische Psychologie

Head of department: prof. dr. P. Cuijpers

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Address: Transitorium, van der Boechorststraat 1, room 2B-81

Source(s) of monetary or material Support: ZorgOnderzoek Nederland Medische

Wetenschappen (ZONMW)

Intervention

Outcome measures

Primary outcome

- 1. Fear Questionnaire (FQ);
- 2. Beck Anxiety Inventory (BAI);
- 3. Center for epidemiologic studies- Depression (Ces-D).

Secondary outcome

- 1. Client Satisfaction Questionnaire (CSQ);
- 2. Short Form- Helath and labour Questionnaire (SF-HLQ);
- 3. Quality of life in Economic evaluations (EQ-5d);
- 4. Trimbos/imta Tic-P questionnaire for costs associated with psychiatric illness (Tic-P);
- 5. Cut-Anoyed-Guilty-Eye opener (CAGE -alcohol guestionnaire).

Study description

Background summary

Although several meta-analyses have shown that internet-based guided self-help is effective in the treatment of anxiety disorders, the cost-effectiveness in mental health care settings has not been studied well. We will conduct a randomized non-inferiority study in which we examine the relative cost-effectiveness of internet-based guided self-help as compared to usual care.

We will test the hypothesis that guided self-help is not less effective than care-as-usual. Based on international studies we expect this intervention to be effective. Care as usual is mostly pharmacotherapy or psychological treatment. A total of 320 clients suffering of a phobia from 4 institutes of mental health care institutions will be randomized to care-as-usual or guided self-help.

The intervention is an internet-based guided self-help course (Fobieën onder controle) which is based on

exposure. The control group receives a selfhelpbook. The primary outcome measure is level

of phobic symptoms, anxiety and depression. Secondary outcomes will be panic-symptoms, satisfaction with the intervention and the use of alcohol and or drugs.

Study objective

We want to test the hypothesis that internet based guided self-help is not more expensive and not less effective than usual care for patients with phobias.

Study design

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- 2. 5 weeks:
- 3. 3 months:
- 4. 6 months;
- 5. 9 months.

Intervention

The internet course (Fobieën onder controle) is based on exposure therapy. This 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.

The intervention consists of five weekly parts, and includes reading materials and homework assignments for every week. The internet-based intervention is already available and is tested in a pilot project. During the therapy the patient has about five contact moments with the coach (total time per client 50 to 75 minutes). The coaching is aimed at supporting the patients to work through the intervention and assignments, not to develop a therapeutic relationship. The coaching is given by Mthese students from our faculty, who will receive a training from the developers of the intervention. Integrity of the intervention is checked by an independent psychotherapist.

The control group will receive care as usual.

Contacts

Public

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Scientific

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Eligibility criteria

Inclusion criteria

Patients who are diagnosed with a social-, agora-, or specific phobia in a mental health care institute are eligible. To confirm the diagnosis a diagnostic interview will be done by an independent research assistant.

Inclusion criteria are:

- 1. Being 18 years or older;
- 2. Having access to the internet;
- 3. Being motivated to work with a guided self-help intervention.

The use of medication is accepted, as long as this was started before the referral to the mental health care institute, the use is stable and the patient has no intention to change it.

Exclusion criteria

- 1. Another severe psychological disorder (psychotic disorder, bipolar disorder);
- 2. An increased risk for suicide:

3. Co-morbidity is no reason for exclusion, as long as the phobia is the primary disorder.

Study design

Design

Study type: Interventional

Intervention model: Parallel

Allocation: Randomized controlled trial

Masking: Single blinded (masking used)

Control: Active

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 01-10-2010

Enrollment: 320

Type: Actual

Ethics review

Not applicable

Application type: Not applicable

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

NTR-new NL2116 NTR-old NTR2233

Other CCMO: 30976

ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

Kok, R. N., van Straten, A., Beekman, A. T. F., Bosmans, J. E., de Neef, M., & Cuijpers, P. (2012). Effectiveness and cost-effectiveness of web-based treatment for phobic outpatients on a waiting list for psychotherapy: protocol of a randomised controlled trial. BMC Psychiatry, 12(1), 131. doi:10.1186/1471-244X-12-131

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Kok, R. N., van Straten, A., Beekman, A. T. F., & Cuijpers, P. (2014). Short-Term Effectiveness of Web-Based Guided Self-Help for Phobic Outpatients: Randomized Controlled Trial. Journal of Medical Internet Research, 16(9), e226. doi:10.2196/jmir.3429