Cannabidiol enhancement of exposure therapy in patients with phobias.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28305

Source
NTR

Health condition

Phobic anxiety disorders, fobische angststoornissen

Sponsors and support

Primary sponsor: Utrecht University
Source(s) of monetary or material Support: ZonMW

Intervention

Outcome measures

Primary outcome

The primary outcome measure will be the fear questionnaire (FQ, Marks and Mathews 1979).

Secondary outcome

At all timepoints clinical questionnaires are administered: Beck Anxiety Inventory, Beck Depression Inventory, Body Sensations Questionnaire, Social Phobia and Anxiety Inventory, Treatment inventory of costs in Psychiatric patients, and EuroQol five dimensions. This also includes the Panic Disorder Severity Scale, Mobility Inventory and Agoraphobic Cognitions

Questionnaire for patients with panic disorder with agoraphobia, and the Liebowitz Social Anxiety Scale for social phobia patients. The Clinical Global Impression, Subjective Units of Distress Scale and assessment of the quality of the sessions are administered weekly. Furthermore, an experimental assessment of fear learning using a fear conditioning paradigm is done, and blood is drawn twice to investigate CBD blood levels and (epi)genetics.

Study description

Background summary

Phobic anxiety disorders are among the most prevalent disorders. The estimated lifetime prevalence is estimated at 19%. Also the estimated health care costs are high: 42 billion dollars in the USA annually. Antidepressants and cognitive behavioural therapy are effective but a substantial patient group shows insufficient improvement due to these standard treatments.
Research has yielded solid evidence that the cannabinoid system in the brain is involved in the modulation of anxiety. Specifically, it seems to be influencing extinction of conditioned fear responses. An advantage of cannabidiol as opposed to cannabis (with THC) is that it doesn’t produce the ‘high’ feeling what THC (on itself or as part of cannabis) does. Patients possibly can benefit from the anxiolytic effect of cannabidiol. Cannabidiol is administered preceding cognitive behavioural therapy with exposure (exposure to a feared stimulus). If cannabidiol is found to be effective it might lead to adjustment of the guidelines.

Study objective

The aim of this research project is to investigate cannabidiol as a new medicine to target the cannabinoid system in the reduction of anxiety disorder symptoms. The research question is whether cannabidiol, as an augmentation strategy of exposure therapy in patients with phobic disorders (panic disorder with agoraphobia and social phobia), can speed up and/or increase the magnitude of change due to behavior treatment. We specifically want to target those subjects in whom previous treatment as usual (with SSRIs and/or psychotherapy) has not yielded in sufficient response to treatment, since it is this group that needs treatment enhancement most and therefore may benefit most from treatment enhancement with cannabidiol.

Study design

Baseline, 1st to 8th treatment, mid-treatment (week after 5th treatment), post-treatment (week after 8th treatment), follow up at 3 and 6 months

Intervention

Cannabidiol (capsule) or placebo (capsule), in combination with exposure therapy with response prevention (ERP)

Contacts

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Eligibility criteria

Inclusion criteria

Patients will be invited to participate when they fulfill the diagnoses mentioned here-above, and provided that they have not or only partially responded to evidence-based treatment (either a full treatment with an SSRI (at least 12 weeks of sufficient dose) and/or at least 10 sessions of cognitive behavioural therapy) in the year preceding referral to the outpatient clinics.

Exclusion criteria

Patients with co-morbid severe psychiatric disorders diagnosed with the SCID-I (severe major depressive or bipolar disorder, psychosis, dependence of alcohol and drugs), with mental deficiency (IQ<80) or inability to adequately read or speak Dutch will be excluded (assessed using a neuropsychological Test (NLV; Schmand et al. 1992), as well as persons with (a history of) epilepsy or brain damage, renal or liver abnormalities, and a history of allergies to medication (adverse reactions or rash).
Regular use of benzodiazepines and of antipsychotics will be an exclusion criterion, contunued use of SSRIs will be permitted, provided that dosages are kept constant during the study. Lastly pregnant or breastfeeding women will be excluded from the study.

Study design

Design

Study type:	Interventional
Intervention model:	Factorial
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-06-2015
Enrollment:	72
Type:	Anticipated

Ethics review

Positive opinion

Date:	13-03-2015
Application type:	First submission

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	NL4846
NTR-old	NTR5100
Other	: ZonMW protocol nr. 40-41200-98-9269

Study results