The effect of cannabidiol (40mg) on fear conditioning

No registrations found.

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

Summary

ID

NL-OMON28165

Source
NTR

Health condition

anxiety disorders

Sponsors and support

Primary sponsor: Utrecht University (UU)
Source(s) of monetary or material Support: NWO (Aspasia grant)

Intervention

Outcome measures

Primary outcome

Both subjective and objective parameters pertaining to fear conditioning and fear extinction will be assessed, the main physiological measure is the fear potentiated startle reflex.

Secondary outcome

Questionnaires, skin conductance responses.

Study description

Study objective

The objective is to investigate the effect of cannabidiol (synthetic) as compared to placebo in facilitating fear extinction and reducing fear retention and reinstatement.

Study design

fear acquisition, fear expression, fear extinction, fear retention, reinstatement

Intervention

Cannabidiol (synthetic) in ethanol solution, inhaled via a vaporizer

Contacts

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Eligibility criteria

Inclusion criteria

- Male or female volunteers between 18 and 40 years.

- Judged to be in good physical and mental health on the basis of the medical history according to self-report.

- Have a normal binocular acuity, corrected or uncorrected.

- Female participants must declare they are on reliable birth control.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:

- Have a history of any disease, e.g. neurological disorders, psychiatric disorders, which in the opinion of the investigator may confound the results of the study.

- Present any other conditions in that in the investigators', the subjects' personal or the physicians' opinion may confound the results of the study.

- History of psychotic disorder/psychosis and/or having a first/second degree family member with (a history of) psychotic disorder/psychosis.

- Current diagnosis of an Axis I or Axis II psychiatric disorder, or suffering from an Axis I or Axis II psychiatric disorder within 4 weeks prior to the study.

- Current respiratory disease or history of respiratory disease.

- Current asthma or history of asthma.

- Acute cardiac disease and/or history of cardiac disease.

- History of abuse or current regular use of cannabis more than once a week.

- Have been using psychoactive drugs in the four weeks prior to the study.

- Known hypersensitivity to CBD.

- Exposed to cannabinoids with adverse reactions.

- Have a history of severe allergy or general drug hypersensitivity.

- Current drug use or indications, from urine screening, of current drug use.

- History of epilepsy.

- Reduced startle activity, defined as no discernible response in at least 3 startle stimuli presented at screening.

- Pregnancy, i.e., a positive β-HCG urine test.

- Lactating.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2015
Enrollment:	48
Type:	Anticipated

Ethics review

Positive opinion

Date:	30-06-2015
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	NL5037
NTR-old	NTR5266
Other	NL49138.041.14 : METC

Study results