

The effect of cannabidiol (40mg) on fear conditioning

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

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28165

Bron

Nationaal Trial Register

Aandoening

anxiety disorders

Ondersteuning

Primaire sponsor: Utrecht University (UU)

Overige ondersteuning: NWO (Aspasia grant)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Factorieel
Toewijzing:	Gerandomiseerd
Blinding:	Dubbelblind
Controle:	Placebo

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-09-2015
Aantal proefpersonen:	48
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	30-06-2015
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5037
NTR-old	NTR5266
Ander register	NL49138.041.14 : METC

Resultaten