Boosting the endocannabinoid system before the treatment of anxiety symptoms

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This study has been transitioned to CTIS with ID 2024-514783-78-00 check the CTIS register for the current data. The aim of this project is to investigate CBD as a new medicine to target the ECS in the reduction of anxiety symptoms. Subsidiary aims...

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

Summary

ID

NL-OMON52231

Source
ToetsingOnline

Brief title
BOOSTCAMP

Condition

- Anxiety disorders and symptoms

Synonym
anxiety disorders and PTSD

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Anxiety, Cannabidiol, Endocannabinoid system, PTSD

Outcome measures

Primary outcome

Main study parameters regarding the effects of CBD on anxiety symptoms are measured PRE-waitlist, POST-waitlist and at 3 months FU.

Secondary outcome

Secondary parameters (effects on fear extinction and consolidation, and stress regulation) are measured PRE and/or POST-waitlist. Sleep will be measured daily during the waiting list period with an actiwatch. Further, blood will be extracted PRE- and POST-waitlist in order to determine AEA, 2-AG and CBD levels.

Study description

Background summary

Uniformed personnel display higher risks of anxiety symptoms due to increased exposure to potential traumatic events. Those who seek help rarely receive immediate access to treatment due to treatment waiting lists. Waiting lists within mental health care institutes can reach 4 months, which might lead to an increase of symptom severity and the need for more intense and longer treatments.
The endocannabinoid system (ECS) plays a role in anxiety, but also in other symptoms such as an enhanced stress reactivity and sleep difficulties. Enhancement of the ECS with cannabidiol (CBD) as evidenced by increases of endogenous cannabinoids anandamide (AEA) and 2-Arachidonoylglycerol (2-AG) may help alleviate these symptoms in patients and prevent increase in symptom severity in patients who are waiting for their treatment.

Study objective

This study has been transitioned to CTIS with ID 2024-514783-78-00 check the CTIS register

for the current data.

The aim of this project is to investigate CBD as a new medicine to target the ECS in the reduction of anxiety symptoms. Subsidiary aims of the project are to investigate the effects of CBD on fear extinction and extinction consolidation, stress regulation and sleep.

Study design

A clinical randomized placebo-controlled between-subjects trial in Dutch uniformed personnel, amongst others (former) police officers, firefighters, ambulance paramedics, military personnell or veterans.

Intervention

During a period of 2 weeks, before the start of the initial treatment, participants of the study will receive either CBD (3 x 200 mg; oral capsules) or matched placebo*s on a daily basis.

Study burden and risks

This study can make a contribution to a better understanding of the effects of CBD on anxiety symptoms and corresponding relevant mechanisms. It is expected that this study will bring little harm to patients since the risk for adverse events to CBD are low. Occurrence of possible side effects will be closely monitored. The main burden is that patients will be requested to invest time (a total 7 hours, distributed over 3 days).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

• Dutch uniformed personnel (i.e. (former) police officers, firefighters, ambulance paramedics, military personnel or veterans
• Age between 18-65
• Waiting for therapy for the treatment of a trauma and stressor-related and/or an anxiety disorder

Exclusion criteria

• Severe co-morbidity (severe major depressive or bipolar disorder and/or psychosis)
• Alcohol and/or drug dependence
• Inability to adequately read or speak Dutch
• (a history of) epilepsy or brain damage, cardiac, renal or liver abnormalities
• (a history of) allergies to medication (adverse reactions or rash)
• Individuals taking certain medications known to have potential interactions with CBD (i.e., steroids, HMG-CoA reductase inhibitors, calcium channel blockers, antihistamines, antivirals, immune modulators, benzodiazepines, anti-arrhythmic, antibiotics, anesthetics, antipsychotics, antidepressants, anti-epileptics, beta blockers, proton pump inhibitors, NSAIDs, angiotensin II blockers, oral hypoglycemic agents, and sulfonylureas)
• Used cannabis, synthetic cannabinoid, cannabinoid analogue, or any CBD or THC-containing product within 30 days of eligibility screening.
• Individuals that had been diagnosed with intestinal, liver, or renal diseases that would affect absorption or clearance of CBD
• For women: pregnant, a wish to become pregnant, or nursing

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	24-02-2022
Enrollment:	82
Type:	Actual

Medical products/devices used

Registration:	No
Product type:	Medicine
Brand name:	Cannabidiol
Generic name:	Cannabidiol
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	21-04-2021
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	23-06-2021

Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	15-04-2022
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	02-05-2022
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	22-07-2022
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	14-09-2022
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	11-04-2024
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	12-04-2024
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	02-09-2024
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	10-09-2024
Application type:	Amendment
Review commission:	METC NedMec

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
EU-CTR	CTIS2024-514783-78-00
EudraCT	EUCTR2020-003739-62-NL
CCMO	NL74835.041.21