

# Glioma: Reducing Anxiety by consuming cannabinoids - GRASS study. Treating anxiety with CBD in glioma patients - A randomized-controlled trial

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To investigate the effect of a three-week treatment with cannabidiol (CBD) on anxiety in patients with a primary brain tumor that have no active oncological treatment. Depression, fatigue and general quality of life are secondary outcome measures....

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Completed
<b>Health condition type</b>	Nervous system neoplasms malignant and unspecified NEC
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON54278

### Source

ToetsingOnline

### Brief title

GRASS study: Treating anxiety with CBD in glioma patients

### Condition

- Nervous system neoplasms malignant and unspecified NEC
- Nervous system neoplasms malignant and unspecified NEC

### Synonym

brain tumor, glioma or other primary brain tumor

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Vrije Universiteit Medisch Centrum

**Source(s) of monetary or material Support:** Cancer Center Amsterdam

## Intervention

**Keyword:** Anxiety, Cannabidiol, Gliomas, Quality of Life

## Outcome measures

### Primary outcome

The primary study outcome is anxiety, as measured with the state-subscale of the state-trait anxiety inventory (S-STAI). Anxiety and distress will also be measured using the hospital anxiety and depression scale (HADS) and the beck anxiety inventory(BAI).

### Secondary outcome

Secondary study outcomes are:

- Depressive complaints as measured with the Beck Depression Inventory (BDI)
- Sleep, measured with the Pittsburgh Sleep Quality Index (PSQI)
- Quality of life as measured with the European Organisation for Research and Treatment of Cancer (EORTC) Quality of Life Questionnaire-Core 30 (EORTC-QLQ-C30) and the Brain tumor-specific HRQOL (EORTC QLQ-BN20)
- Fatigue, measured with the CIS20r subscale

## Study description

### Background summary

Gliomas are primary malignant brain tumors that are incurable to date and lead to a severely reduced quality of life. For these tumors only palliative oncological treatment exist. Due to the short life expectancy, improving

quality of life is essential in these patients. Many glioma patients currently use non-medicinal cannabinoids for presumed symptom relieve. Cannabidiol (CBD) is freely available in the Netherlands, which presumably leads to this cannabinoid being the most frequently used. Studies are lacking that investigated the effect of cannabinoids on well-being in this population. Consequently, a knowledge gap exists. At present health care providers cannot advice their neuro-oncological patients on the use of cannabinoids nor can they prescribe this medication. The main symptoms during the stable phase disease are fatigue, depressed mood and anxiety.

## **Study objective**

To investigate the effect of a three-week treatment with cannabidiol (CBD) on anxiety in patients with a primary brain tumor that have no active oncological treatment. Depression, fatigue and general quality of life are secondary outcome measures. This study is part of the GRIP-project, a platform trial to investigate interventions aimed at improving quality of life in patients with brain tumors in five intervention arms.

## **Study design**

A double-blind, placebo-controlled crossover study. Patients will be randomized to 600 mg CBD or placebo as first treatment. CBD or placebo will be administered during three weeks followed by a washout period of two weeks before the second treatment period starts.

## **Intervention**

All patients will receive both 600 mg CBD and a placebo.

## **Study burden and risks**

The risks for patients participating in this study compromise toxicity from CBD. Most frequently reported adverse effects are drowsiness and fatigue. Liver functions will be monitored as they can increase after CBD use. The questionnaires can be time-consuming and be a burden to patients to some extent. On the other hand, patients will possibly experience a decrease in anxiety, depressive symptoms and an increase in sleep quality and general quality of life. As cannabinoids are currently extensively used by glioma patients, we consider the benefit of filling the existing knowledge gap to outweigh the burden of potential side effects.

## Contacts

### Public

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### Scientific

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

- diagnosis of primary brain tumor;
- $\geq 18$  years of age;
- moderate to severe anxiety, defined as S-STAI score  $\geq 44$  at moment of screening;
- ability to understand and sign informed consent in Dutch;
- stable disease, i.e. no oncological treatment for  $\leq 2$  months prior to inclusion;
- no radiological progression on the most recent MRI, not older than 6 months, and no clinical progression within the most recent two months.

## Exclusion criteria

- corticosteroid use, unless in a stable dose  $\geq 8$  weeks;
- regular cannabis use currently or in past history ( $\leq 2$  weeks);
- substance abuse (defined as use of hard drugs, or alcohol use more than 3 units per day);
- history of psychosis or anxiety disorder;
- alterations in SSRI/SNRI use or dosage during the prior two months;
- psychological or psychiatric treatment during the prior two months aimed at anxiety;
- current pregnancy or have given birth less than three months ago;
- currently breastfeeding;
- KPS  $\leq 70$ ;
- uncontrolled hyperthyroidism;
- severe liver disorders (AST, ALT and/or gamma-GT more than three times the upper limit);
- severe kidney disorders (eGFR  $\leq 30$ ).

## Study design

### Design

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

### Recruitment

NL	
Recruitment status:	Completed
Start date (anticipated):	21-02-2022
Enrollment:	55
Type:	Actual

## Medical products/devices used

Product type:	Medicine
Brand name:	Arvisol
Generic name:	cannabidiol

## Ethics review

Approved WMO	
Date:	24-06-2021
Application type:	First submission
Review commission:	METC Amsterdam UMC

Approved WMO	
Date:	07-07-2021
Application type:	First submission
Review commission:	METC Amsterdam UMC

Approved WMO	
Date:	07-11-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Approved WMO	
Date:	22-12-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Approved WMO	
Date:	19-01-2023
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Approved WMO	
Date:	06-04-2023
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Approved WMO	
Date:	21-06-2023
Application type:	Amendment
Review commission:	METC Amsterdam UMC

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

ID: 20540

Source: NTR

Title:

### In other registers

Register	ID
Other	NL9623
EudraCT	EUCTR2020-004294-48-NL
CCMO	NL76031.029.21