

CANNABIDIOL YOUTH ANXIETY STUDY (CANCAN STUDY)



FREQUENTLY ASKED QUESTIONS

PARTICIPANT INFORMATION

What does anxiety disorder mean?

Anxiety disorders are among the most prevalent mental health conditions in young people, affecting 7% of adolescents in Australia. These include generalised anxiety disorder, social anxiety, panic disorder, specific phobia, agoraphobia, and separation anxiety disorder. Symptoms vary for different individuals, but can include feeling anxious, nervous, tense, or restless. People with an anxiety disorder may feel very sensitive to criticism or extremely self-conscious. They may worry about things that aren't likely to happen. These symptoms may cause them to become withdrawn or avoid difficult or new situations that make them anxious. They may have more difficulty than usual coping with work, school or relationships. For some people, these symptoms will get worse without help. For others, the symptoms may lessen or go away. It is for this reason that providing a range of effective treatments for young people is so important.

What treatments are there for anxiety symptoms experienced by young people?

There are two main categories of evidence-based treatments available – pharmacological treatments (medicine) and psychological therapies such as cognitive behavioural therapy (CBT).

Why is Orygen running this trial?

Current treatments available don't work for everyone so Orygen is investigating a potential new treatment known as cannabidiol. Orygen's hope is that by testing potential new treatments we will be able to find effective treatments with limited side effects.

CANNABIDIOL

Is cannabidiol the same as cannabis or medical marijuana?

No. Cannabidiol is only one out of many compounds that are found in the cannabis plant. Unlike other substances found in the cannabis plant (for example, tetrahydrocannabinol (THC)), cannabidiol does not make people 'high'.

Cannabidiol is extracted from the cannabis plant, purified and does not contain relevant quantities of other substances such as THC.

Aren't there other drugs you can try? Why does it have to be cannabidiol?

Cannabidiol has been tested as a treatment for people with anxiety disorders, and other illnesses such as epilepsy and psychotic disorders. Cannabidiol was found to reduce the severity of anxiety symptoms in young people and adults in several small studies, and it is important to test whether it is safe and effective in larger groups of young people.

Will the young people on the study get addicted to cannabidiol?

No. Unlike THC, cannabidiol is not addictive. In fact, it has been used to treat cannabis addiction in other research trials as it opposes some of the effects of THC.

None of the previous studies have indicated that cannabidiol may be addictive in young people or adults.

What amount of cannabidiol will you be giving participants?

Research participants will be randomly allocated to one of two groups:

- Group one will take 600mg-800mg cannabidiol daily;
- Group two will take a placebo (no cannabidiol) each day for 12 weeks.

Orygen researchers decided on these doses based on previous studies testing cannabidiol in young people and adults with anxiety, psychosis and epilepsy.

How are you going to make sure participants don't take more than that?

Trial participants will receive only a certain number of cannabidiol capsules at each study visit, or as appropriate to prescribe for that individual. In addition, Orygen researchers will monitor the number of capsules taken, as well as blood levels of cannabidiol.

Will participants know which group they're in?

No. Participants and researchers will not know which group each participant has been allocated to. Only the pharmacy will know this so they can provide the right medication. This means the results are less likely to be biased and the researchers can compare improvements within each group without making assumptions based on whether or not participants are taking CBD.

How will you know if the cannabidiol is working?

Researchers and clinicians will use a range of psychiatric measures, including a questionnaire, to evaluate the effectiveness of cannabidiol. These are well-established approaches that are used in clinical research to measure improvements in symptoms.

Will people on the study be smoking the cannabidiol?

No. The cannabidiol will be administered as a capsule and cannot be smoked or inhaled.

Will cannabidiol show up on drug tests?

It is possible that the CBD capsules can cause a positive result for THC on a urine test. This is because even though the capsules contain at least 98% pure CBD, they may still contain very low levels of THC and other metabolites than can cause positive THC results on very sensitive tests. The study team will discuss this with you in detail before you decide whether you would like to participate in the study.

Where is Orygen getting the cannabidiol from?

The cannabidiol used in our study is a natural product extracted from cannabis plants and is distributed by a pharmaceutical company that is fully compliant with the quality and safety standards mandated in the industry.

Can someone continue using cannabidiol after the trial has concluded? If so, who will pay for it?

Cannabidiol can only be prescribed in Australia via a special access scheme and its cost is currently not subsidised by the Pharmaceutical Benefits Scheme. Trial participants who wish to access cannabidiol following the trial will need to cover the cost themselves. The research team encourages participants who are interested in continuing to take cannabidiol after the trial to speak to their GP.

CLINICAL TRIAL

What is a clinical trial?

Clinical trials are systematic research investigations where new treatments or other interventions are tested in patients under the strict surveillance of one or more ethics committees. This trial will be run under the guidance of a human ethics committee operated by the University of Melbourne.

How many people are going to be participating in the trial?

The research team is planning to enrol up to 180 participants in this trial.

How long will the trial go for?

Participants will take the study medicine (or placebo) for 12 weeks. In total, Orygen researchers expect the trial to run for about three years.

Trial preparations began in July 2022, with recruitment of participants from October 2024. The trial will finish around October 2027.

Where is the trial being run?

Participants will be recruited from the community in metropolitan Melbourne and Perth.

The trial is being conducted at the following centres:

- Orygen Clinical Trials Unit in Parkville
- headspace Midland (Perth, Western Australia)
- headspace Osborne Park (Perth, Western Australia)
- headspace Joondalup (Perth, Western Australia)
- Youth Axis (Perth, Western Australia)
- UWA (Perth, Western Australia)
- headspace Craigieburn (Melbourne, Victoria)
- headspace Melton (Melbourne, Victoria)
- headspace Glenroy (Melbourne, Victoria)
- headspace Sunshine (Melbourne, Victoria)
- headspace Werribee (Melbourne, Victoria)

TRIAL PARTICIPATION

How do I participate in this trial?

To participate in this trial, eligible participants based in Melbourne or Perth can self-refer or be referred by their GP or mental health care provider. Get in touch via email on CANCANStudy@orygen.org.au

If a young person at one of the centres above appears to be eligible, a research assistant may approach them to ask if they would like to take part in the project.

A referral from participants' regular GP will be required before starting the study treatment.

What age does someone have to be to take part in the trial?

Young people aged between 12 and 25, inclusive, can participate in the study.

Aren't 12-year-olds too young to be taking cannabidiol?

The age range of participants in this trial is similar to the age range of participants in other trials of cannabidiol (e.g. for epilepsy). It is important to know if this potential new treatment is effective for participants under the age of 18, as they represent a large proportion of headspace clients. Any participants aged under 18 will require the consent of a parent or guardian.

I'll be turning 26 soon, can I still be part of the trial?

Yes, if you are enrolled in the trial while still aged 25.

What psychosocial support will participants receive during the trial?

Participants will continue to receive treatment as usual with their current mental health care provider. Participants who are not currently receiving psychosocial treatment can be connected with a mental health clinician through Orygen for the duration of the study treatment period.

Who do I contact about a young person I care for taking part in the trial?

To find out more about the study or to contact the research team please email CANCANstudy@orygen.org.au