School of Medicine
Faculty of Medical and Health Sciences
Level 1, Building 507,
22-30 Park Ave,
Auckland, New Zealand
auckland.ac.nz/fmhs
The University of Auckland
Private Bag 92019
Auckland 1142
New Zealand

Participant Information Sheet

A Cannabis-Based Medication for Sleep in Chronic Back Pain: A Randomised Crossover Trial

Formal Study title:	Long-Term Effects of a Cannabis-Based Medication on Sleep in Chronic Back Pain: A Randomised Crossover Trial
Sponsor:	The University of Auckland
Study site:	Tauranga Hospital
Lead researcher:	Dr Saad Anis
Contact phone number:	021 0251 7180
Ethical approval reference:	HDEC 2025 FULL 22406

Taking part in this research is your choice.

You do not have to take part.

If you choose not to take part or withdraw from the study, your normal care will not be affected.

- You will be given time to decide whether you want to take part in this study.
- The study team will discuss the study with you and answer any questions you have before you decide.
- You may talk to family, whānau, friends, or healthcare providers before you decide.
- If you need help understanding this information or would like support, please contact the research team (details at the end). We can arrange an in-person clinic appointment with you, with a support person if you wish.
- If you have private medical insurance, you may wish to check whether this study will impact your cover.
- If you decide to take part, you will be asked to sign the Consent Form. You will also be given a copy of this information sheet.
- If you change your mind about taking part, you can withdraw from the study at any time by telling the study team.
- There may be no direct benefit to you from taking part in this study, and there may be risks of injury or illness.

Introduction

We are seeking people to participate in a study looking at the effect of Helius THC10:CBD10 Full Spectrum (*the product*) for treating sleep problems in people with chronic back pain. This is a medicinal oil extracted from the cannabis plant containing THC and CBD (tetrahydrocannabinol and cannabidiol). It is produced in New Zealand by Helius Therapeutics. Your participation would take seven months, with your sleep continuously monitored for that period.

Chronic back pain is pain that lasts longer than three months. It can disrupt daily activities, affect sleep, and reduce overall quality of life. It can often lead to poor sleep.

The product is a natural compound that may help reduce pain and improve sleep. It is approved in New Zealand and has been prescribed for some conditions, but its long-term effects on sleep in people with chronic back pain are not clear.

What is the aim of this study?

This study will look at whether Helius THC10:CBD10 Full Spectrum is useful for treating sleep problems in people with chronic lower back pain.

What type of study is this?

This is a placebo-controlled crossover randomised double-blind superiority trial.

Placebo-controlled:	This means that the study uses a placebo to compare against the Helius THC10:CBD10 Full Spectrum. The placebo is formulated to be the same as the medicinal oil, but does not contain THC or CBD.
Crossover:	This means that you will receive the placebo and Helius THC10:CBD10 Full Spectrum one after the other.

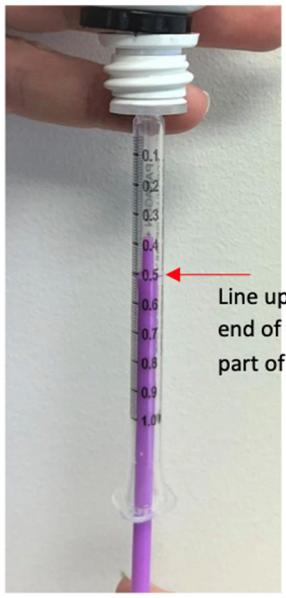
Randomised:	This means you will be assigned to first receive either Helius THC10:CBD10 Full Spectrum or placebo randomly (by chance), with equal chance of either. You will not be able to choose which group you are in.
Double-blind:	This means that you and the study team won't be informed which product you are getting during each period, but the study doctor can find out if needed in an emergency. You can find out which product you received first/second after the study has ended.
Superiority:	This means that we want to see if Helius THC10:CBD10 Full Spectrum is superior to a placebo

How is the study designed?

Study sites	The study is being run at Tauranga Hospital and Whakatāne Hospital.
Participants:	About 20 people will be recruited.
Time in study:	You will be in the study for about seven months.
Study visits:	You will have five scheduled study visits. You may be asked to come in for extra visits if needed.

How will I take the study products?

Helius THC10:CBD10 Full Spectrum is a plant extract in an oil that is held under the tongue. The placebo will be taken in the same way. To take it, you draw the oil up in a syringe (provided with the medication) as illustrated below. You will be asked to take it about one hour before bed. You will be provided with more instructions in a study information pack.



Who can take part in the study?

To take part in the study you must:

- Have chronic back pain with insomnia.
- Be 25 years old or older.
- Be able to converse and read in English.
- Be able to download and use our data collection app for iPhone or Android.
- Be registered with a GP.

You cannot take part in this study if you:

- Your treatment for pain or sleep has changed in the past six months.
- You plan to have major surgery in the next year.
- Your use of cannabis-based medication would be against the terms of any or employment, sport or volunteer activities.
- You test positive for cannabis at the first clinic visit.
- You regularly consume other forms of cannabis or recreational drugs and would not be able to stop for three months before the study and for the duration of the study.
- You have a physical or mental health condition that could increase the risk of side-effects.
- You take medication that might interact with cannabis.
- You are pregnant, planning to become pregnant, or breastfeeding.

There are other criteria you must meet to be eligible for the study. The study team will discuss all of them with you to make sure that your participation is safe.

What will taking part in the study involve?

Screening

If you decide to take part, you will be asked to sign an online consent form. After signing the consent form, you will be directed to a questionnaire that will help us find whether you are suitable to participate in the study. This is called Screening. If your questionnaire results show that you are eligible, Dr Anis will check your medical records for issues that might mean you cannot safely participate. If he considers that you are eligible to participate, he will contact your GP to confirm that they consider it safe for you to participate.

You will be told if you can take part once all your results have been checked. If you can take part, you will be added to a list of eligible participants. We will randomly select participants from that list. Most people in that list will be contacted to participate, but there is a chance that you will not. If that were the case, you would be contacted when selection has finished.

Dosing and follow-up

On the first day of participation, you will attend a clinic visit with Dr Anis at the Chronic Pain Service at Tauranga Hospital (891 Cameron Road, Tauranga). At that visit, we will take baseline measurements so that we can compare them to later in the study. You will be guided through the installation and setup of the study app (MyCap) on your smartphone and be provided with the wrist-worn activity monitor. You will complete some questionnaires and undergo a urine test for cannabis. If that test is positive, you will be withdrawn from the study.

There will be four further clinic visits (five in total) every 6-8 weeks. Each visit will be scheduled with your input, and last about an hour. You will be reminded of your clinic visit via the study app.

The procedure for each visit will be roughly the same as the first, and your final visit will include a debrief where you can be informed of the order in which you took the products.

For the two weeks after the first clinic visit, we will record your sleep without you taking any product. After two weeks, you will be asked to collect your first bottle of the product from the Tauranga Hospital Pharmacy (829 Cameron Road, Tauranga), and to start taking it.

We will ask you to take the product nightly for three months (12 weeks), then take no product for two weeks (a 'washout' period), followed by the other product for three months. You will be asked to start at a dose of 0.2ml and increase by 0.2ml per day (that is, to 0.4ml, 0.6ml, and so on), until you reach the maximum dose of 1.0ml. If you feel adverse effects, you can continue at a lower dose. However, you must not take more than 1.0ml per night.

Further bottles of the product will be available to collect from Tauranga Hospital Pharmacy once per month. You will be asked to return the previous bottle each time you pick up a new one so that we can measure your total dose.

You will also be asked to wear an activity monitor on your wrist for the seven-month duration of the study. This will monitor your activity and ambient light level to measure how well you are sleeping. The device you will be wearing is called the Motionwatch 8 made by Camntech (see image on the next page). At each hospital visit we will download information from the device and change the battery. You will return the device at the end of the study. The devices are carefully cleaned between participants, and you may choose to clean it yourself.

Figure 1. The Camntech Motionwatch 8

Each morning, we will use the study app to ask you how well you slept, the times you went to sleep, turned out the lights and got up, and if you have noticed any side effects of the product. This should not take more than a minute or two. For the first two weeks on each product, we will ask you each morning what your dose was. After that, we will ask you weekly. These regular questions should not take longer than a couple of minutes to respond to. Every two weeks, we will ask you to complete a few more questionnaires more thoroughly measuring your sleep, pain, and experiences. These should take approximately 20 minutes to complete.

If you lose access to your device with the study app, please inform the study team immediately via phone or text message.

You may be asked to come to extra visits if the study team thinks this is needed for safety or other reasons. If the study team identifies any significant abnormal results during the study, we will tell your GP.

Early withdrawal visit

If you decide you want to withdraw from the study, please let us know. The study team will ask you to come in for a final visit, to debrief and retrieve the activity monitor.

Study Assessments

Informed consent	You will read and sign an informed consent form before you take part.
Eligibility check	We will check that you qualify for the study using your responses to a questionnaire and checking your medical records. We will also ask for your GP's contact details and record their agreement that you participate.
History and demographics	We will review your medical history, medications and lifestyle choices relevant to the study and record your age, gender, and ethnicity.
Questionnaires	You will fill in some questionnaires about your pain, sleep, dosage of the product, and any adverse effects you might experience. These will be delivered on your smartphone via the study app, or via a device provided by the study team.
Urine tests	We will collect urine samples to confirm presence or absence of cannabis. This will occur at each clinic visit.
Health and Medication Check	We will ask you about any changes in your health and any changes to your medications. This includes prescription and over-the-counter medications, herbal or homeopathic remedies, and nutritional supplements.
Sleep diary	Each morning you will be asked to report the time that you went to bed, the time that you turned off the lights, the time that you woke up, and the time that you got out of bed. This will be combined with your activity monitor data to assess your sleep.
Activity Monitoring	You will wear an activity monitor on your wrist. This will help the study team learn about your sleep. Please see the activity monitor user guide for more information.

What are my responsibilities during the study?

You should:

- Respond to questionnaires delivered via the study app.
- Wear your activity monitor for the whole study.

- Attend clinic visits with Dr Anis at Tauranga Hospital as scheduled or reschedule if you cannot.
- Collect a bottle of the study product from the pharmacist at Tauranga Hospital every four weeks and return the previous bottle (with any unused product).
- If you lose access to your device with the study app, inform the study team immediately via phone or text message.

You must not:

- Fail to attend clinic visits without notice – you may be withdrawn from the study.
- Consume cannabis products not provided by the study.
- Drive, operate heavy machinery, or perform any other dangerous or prohibited activity within 10 hours of taking the study product, or if feeling impaired.

What are the possible benefits of the study?

There may be no direct benefits to you from being in the study.

What are the possible risks of the study?

You may experience some side effects from Helius THC10:CBD10 Full Spectrum. You will be monitored for risks and side effects while you are in the study.

You should contact us if you experience any changes in your health.

Your GP or other healthcare professionals may be contacted if we have concerns about your health, including your mental health. We will discuss this with you prior to contacting other parties, unless that is believed not to be in your best interests.

If you experience side effects, we recommend reducing the dose to manage them. If the side effects are severe, your participation may be withdrawn, either by yourself or by the research team.

You must ensure that the use of cannabis-based medication does not breach the terms of any employment, volunteer or sporting activities that you are involved in.

Risks of Helius THC10:CBD10 Full Spectrum

Side effects are common with cannabis-based medications, but are seldom serious. Helius THC10:CBD10 Full Spectrum is a cannabis-based medication that contains equal parts of two compounds, THC and CBD. These compounds are naturally found in the cannabis plant. The product is made in New Zealand and meets the quality and safety standards set by the New Zealand Medicinal Cannabis Agency. The product we are testing has been approved for use in New Zealand. It has, however, *not* been studied specifically for long-term effects on sleep in participants with chronic back pain.

Cannabis-based medications like this one have been used by many people worldwide for managing pain and sleep problems. Studies have shown that side effects are generally mild to moderate and include things like dry mouth, drowsiness, or dizziness. Serious side effects are uncommon, especially when the medication is used at low doses under medical supervision.

We will regularly check up to ensure your safety, and the research team will be available to discuss any concerns you might have during the study.

Side effects and their frequencies are listed below:

Very common (seen in at least 10 in 100 people)

- Dry mouth

Common (seen in 1-10 in 100 people)

- Sedation or drowsiness
- Dizziness or light-headedness
- Gastrointestinal symptoms, including diarrhoea
- Anxiety or paranoia
- Cognitive impairment
- Fatigue
- Headache
- Increased heartrate
- Tolerance and Dependence
- Drug Interactions
- Liver Enzyme Elevation

Uncommon (seen in less than 1 in 100 people)

- Psychosis

Driving or Operating Heavy Machinery

You must not drive or operate heavy machinery for 10 hours after consuming the study product. You may still be impaired after ten hours and must not drive or operate machinery if you feel impaired.

The Land Transport Act 1998 (as amended by the Land Transport (Drug Driving) Amendment Act 2022 (in force since 11th March 2023) governs driving under the influence. Section 11A and Section 12 prohibit driving while impaired by a qualifying drug (THC is one such drug).

There is a risk that you may return a positive drug driving test result while using cannabis-based medications. If you test positive for cannabis use while driving, you may have a legal defence (Sections 64(1A) & 64(1B)) as long as:

- You were prescribed cannabis by a registered medical practitioner
- You followed the provided instructions
- You were not impaired

Managing Mental Health and Well-being During the Study

As part of this study, you will be asked to complete questionnaires about your pain, sleep, quality of life, and mental health. These may include questions on distress, anxiety, depression, substance use, and other sensitive topics.

How we review your responses

- The study team will review all completed questionnaires within 24 hours.
- If responses indicate distress, depression, or other concerns, the Principal Investigator (Dr Anis) will contact you and your GP to discuss and establish an appropriate response plan.
- The phone number for the mental health crisis service is attached at the back of this leaflet, and you can contact them at any time.

How we manage serious concerns

- If a questionnaire suggests a high level of distress, suicidal thoughts, or a serious mental health risk, you may be referred to a crisis support service or mental health services.

- If your responses indicate an immediate risk to yourself or others, the study team will take immediate action. This will include immediately contacting yourself and your GP to make an urgent management plan. It may involve discussion/contact with mental health services, a crisis support service or the emergency services.

You may contact the study team directly if you are in distress or require support. Participation in this study is voluntary, and your well-being is our priority. If you feel that participation is affecting your well-being, you may withdraw from the study at any time.

Allergic Reactions

If you are allergic to anything, tell us before you join the study. Some symptoms of allergic reactions are listed below. Tell the study doctor or nurse straight away if you have any of these symptoms. If not treated promptly, an allergic reaction could become life-threatening:

- Rash
- Wheezing and difficulty breathing
- Dizziness and fainting
- Swelling around the mouth, throat, or eyes
- A fast pulse
- Sweating

Life-threatening or fatal allergic reactions can occur. However, severe reactions are very rare. If you have a severe allergic reaction, seek treatment immediately by dialling 111 or going to an Emergency Department.

Unknown risks

There may be risks of Helius THC10:CBD10 Full Spectrum that are not yet known. You could have a side effect that has not been reported before.

New Information

If new information becomes available about Helius THC10:CBD10 Full Spectrum, the study doctor will discuss it with you.

Reproductive risks and contraception

Being in this study may result in risks to a foetus or baby. If you are pregnant or breastfeeding, you will not be able to take part. You must not get pregnant during this study. If you could become pregnant, you must use effective contraception during the study.

We will discuss effective contraception options with you, and how long they must be used for. Further details will be provided in the Participant Information Pack.

Will any costs be reimbursed?

There are no costs associated with taking part in this study, nor will you be paid. At each clinic visit you will be reimbursed with a $40 supermarket voucher as recognition of your contribution to the study.

What if something goes wrong?

If you were injured in this study, you would be eligible **to apply** for compensation from ACC just as if you were injured in an accident at work or home. This does not mean that your claim would

be automatically accepted. You would have to lodge a claim with ACC, which could take some time to assess. If your claim were accepted, you would receive funding to assist in your recovery.

If you have private health or life insurance, you may wish to check with your insurer to ensure that participating in this study won't affect your coverage.

What will happen to my urine samples?

You will be asked to supply a urine sample at each clinic visit, which will be tested by dipping a testing stick into it, and the remainder returned or disposed of according to hospital protocol (incineration). If you test positive at the first clinic visit, you will be withdrawn from the study.

Tests at following visits will be placed in an opaque container and given to an independent examiner. Neither you nor the research team will see those tests, as they would tell us what product you are taking, and we are not supposed to know. The presence or absence of cannabis, as indicated by the test, will be recorded by the independent examiner, and then the test will be disposed of according to hospital protocol. No samples will be stored or sent to any laboratory. A karakia will *not* be available at the time of disposal.

What will happen to my information?

We will collect information ('data') about you and your study participation. We only collect information needed for the study, to contact you, or to identify your medical records. You cannot take part in the study if you do not want us to collect any of this information.

This study will form part of the doctoral thesis of Dr Anis, which is being completed at the University of Auckland.

Identifiable information – this information traces directly to you.

Examples?	Information carrying your name, birthdate, contact details,
How is it stored?	Digitally on secure University of Auckland servers
Who has access?	Members of the research team responsible for contacting you Your GP or usual doctor (if needed) Study auditors (see below)
How long is it kept?	For at least 10 years

Coded information – this information is labelled only with your unique study ID

Examples?	All your information that is loaded into the study database.
How is it stored?	Digitally on secure University of Auckland servers
Who has access?	The research team The University of Auckland Helius Therapeutics
How long is it kept?	For at least 10 years

Anonymised information – cannot be traced back to you

Examples?	Information that has had the unique ID code removed and identifiers concealed (e.g., only age range instead of date of birth)
How is it stored?	On a secure database
Who has access?	Access is not restricted
How long is it kept?	For at least 10 years

Privacy Statement for the Study Mobile App

Information will be collected using the MyCap mobile app. You will be entering data into a mobile device. While the data resides on the mobile device, you own all the data that you have created or modified. Your data is then sent to a server at the University of Auckland. After data is sent to

the server, it will be owned by the University. Your data is treated as private. All attempts are made to secure the data from outside interception.

Storage

Your data are stored in an encrypted databases on your mobile device and transferred to the parent server hosted at the University of Auckland. This data will be accessible by the research team.

Extra information about my data

The research team may need to share your identifiable information in the rare event of a serious threat to public health or safety, or to the life or health of you or another person, OR if the information is required in certain legal situations.

Audits

The study may be audited. Audits make sure studies are being carried out properly. Auditors need access to your identifiable study data and relevant health records to do this. Audits may be done by the Sponsor, NZ or overseas regulatory agencies, or the approving Ethics Committee.

Data Access

You have the right to request access to information about you held by the research team, including the results of tests and procedures. You also have the right to request that any information you disagree with is corrected.

Study Withdrawal

You can ask the study team to stop collecting information about you at any time. This will end your participation in the study. No further information will be collected after you withdraw. Any data that we have collected until that point will be included in the study.

Data Storage

After the study, your identifiable and coded data will be stored for at least 10 years in a secure storage facility. Your anonymised data will be stored indefinitely on secure electronic servers. All storage will comply with local and/or international data security guidelines.

Data Risks

Although efforts will be made to protect your privacy, absolute confidentiality cannot be guaranteed. There is a risk that people may access or use your information in ways that you may not be acceptable to you. Data sent overseas will be governed by overseas laws. These may not give as much protection as New Zealand law and will not observe Te Tiriti o Waitangi.

Could the study end earlier than planned for me?

If you wish to withdraw from the study, please let us know. We will need to collect your activity monitor and would prefer to give you a brief end-of-study assessment.

We may withdraw you from the study if we believe it is not in your best interests to continue. We will discuss any withdrawal decisions with you and provide health care advice where appropriate. Other reasons that you may be withdrawn from the study are:

- You tested positive for cannabis at the first clinic visit.
- You need treatment that is not allowed in this study.
- You did not follow the instructions for the study.
- The study is stopped.
- You have a serious reaction or illness or injury that is not related to the study.

Helius THC10:CBD10 Full Spectrum is available for prescription by a doctor, but is not currently subsidised by the government. It costs approximately $100 for a 30ml bottle, which is about a month's supply.

Can I find out the results of the study?

If requested, we will provide with a plain English summary of the study results within six months of the final completion of the study using your study contact details. Note that publication may take a few years.

The study is registered with the Australian New Zealand Clinical Trials Registry (ANZCTR). Trial registration number is ACTRN12623000870651p 14/08/2023. You may access the details from its website: anzctr.org.au**.**

Who is funding the study?

The University of Auckland is the sponsor of the study and is running the trial with funding from the Australia and New Zealand College of Anaesthetists and support from Te Whatu Ora Hauora a Toi Bay of Plenty. Helius Therapeutics is providing Helius THC10:CBD10 Full Spectrum and the placebo.

Data and samples that lead to discoveries and inventions, or the development of a commercial product, will be owned by the University of Auckland. You will not have rights to ownership or benefit financially. The research team will only receive their ordinary wages for conducting this research.

Who has approved the study?

This study has been approved by an independent Health and Disability Ethics Committee (HDEC), who check that studies meet established ethical standards, by Te Whatu Ora Hauora a Toi Bay of Plenty, and by the University of Auckland. This study was approved by the Central HDEC on {DATE} (Reference: 2025 FULL 22406).

The study has also been approved by the Health Research Council's Standing Committee on Therapeutic Trials (SCOTT), which undertakes scientific assessment of applications to conduct trials and makes recommendations to the Director-General of Health on whether or not trials should be approved.

Who do I contact for more information or if I have concerns?

If you have any questions, concerns or complaints about the study at any stage, you can contact:

Name: Dr Saad Anis

Phone: 02102517180

Email: saad.anis@auckland.ac.nz

If you wish to contact Dr Anis' primary academic supervisor, please contact:

Name: Dr Matthew Moore

Phone: 09 923 2899

Email: matthew.moore@auckland.ac.nz

If you wish to contact the Sponsor, please contact the Head of the Department of Anaesthesiology at the University of Auckland:

Name: Professor Simon Mitchell

Phone: 09 923 2569

Email: sj.mitchell@auckland.ac.nz

If you want to talk to someone who isn't involved with the study, you can contact an independent health and disability advocate at:

Website: https://www.advocacy.org.nz/

-Phone: 0800 555 050

Email: advocacy@advocacy.org.nz

For Māori Cultural support, please contact:

Name: Linda Pattinson

Phone: 07 579 8565

Email: research@bopdhb.govt.nz

For mental health emergencies, contact your local Mental Health Crisis Hotline at:

Tauranga 0800 800 508

Whakatane 0800 774 545

You can also contact the health and disability ethics committee (HDEC) that approved this study on:

Phone: 0800 4 ETHIC

Email: hdecs@health.govt.nz