Please let the study team know if you need an interpreter.

PARTICIPANT INFORMATION SHEET

Brain network stimulation for chronic low back pain.

Formal Study title: High-definition transcranial infraslow gray noise stimulation for chronic low back pain: A double-blinded randomised controlled clinical trial.

Sponsor: University of Otago.

Lead Study Doctor: Dr Divya Adhia,
Department of Surgical Sciences,
Dunedin School of Medicine.

Study Site: Dunedin hospital.

Contact phone number: 0211167594

Ethics committee ref.: 2024 FULL 21891

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 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 and the signed consent.
- 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

You are invited to take part in a study evaluating the effect of a non-invasive brain stimulation technique, designed to improve pain and function in people with chronic low back pain.

Chronic low back pain is a significant and growing health challenge, accounting for a significant proportion of years lived with disability worldwide. Changes in the functional connectivity (i.e., how the brain regions talk to each other) between the pain processing brain networks have been shown by several brain imaging studies in people with chronic low back pain.

This study will use a non-invasive brain stimulation (i.e., transcranial electrical stimulation) technique to modify the altered functional connectivity between the brain regions responsible for pain processing. The results obtained from this study will help us to develop new treatments for improving pain and function in individuals with chronic low back pain.

The non-invasive brain stimulation technique is investigational, which means that it is not approved for general use by the New Zealand Health Authority.

Investigational items must be tested in studies like this one before they can be approved for use. We have tested this brain stimulation design in approximately 44 healthy adults, 20 people with depression and 24 people with generalized anxiety disorders.

What is the aim of this study?

This study looks at non-invasive brain stimulation in people with chronic low back pain to see:

- How effective non-invasive brain stimulation is at improving pain intensity in people with chronic low back pain?
- How safe non-invasive brain stimulation is and what side effects there may be?
- What study participants think of the study procedures and of the non-invasive brain stimulation as a future treatment technique for chronic low back pain.

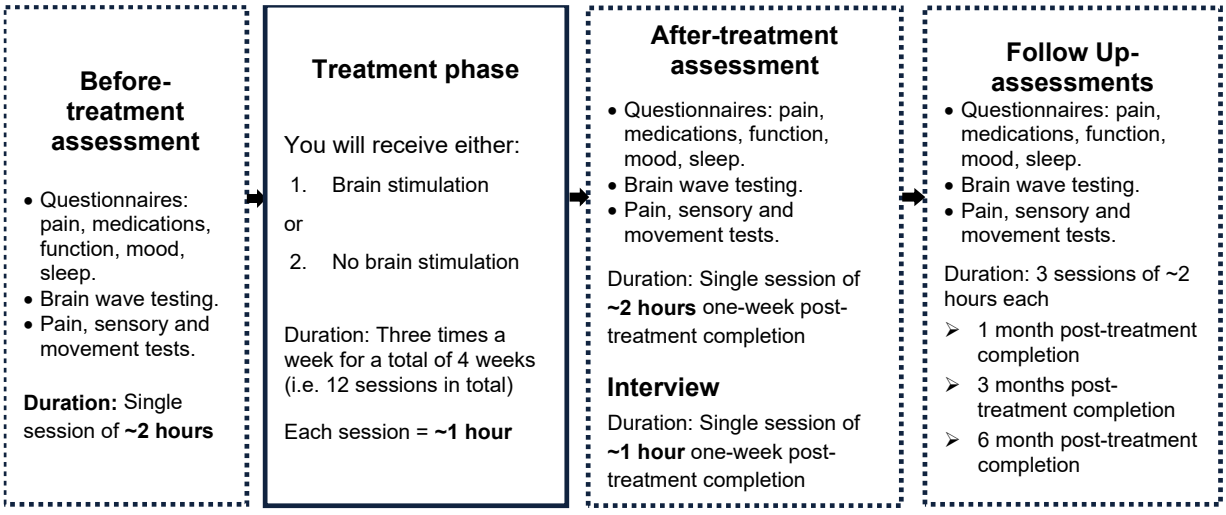
What type of study is this?

This is a placebo-controlled randomized blinded study.

Placebo-controlled	This means the study uses a placebo (sham stimulation) to compare against the active brain stimulation. A placebo looks the same but does not contain active brain stimulation.
Randomised	This means you will be assigned to receive either active brain stimulation group or sham stimulation group randomly (by chance). You have a 50% in 100% chance of getting active brain stimulation. You have a 50% in 100% chance of getting sham stimulation. You will not be able to choose which group you are in. However, at the end of the study, if active brain stimulation shows positive effect on pain intensity, and if you were randomised to the *Sham Stimulation* group, then you may be able to receive active brain stimulation intervention for additional sessions should you wish after completion of your 6 months follow up session.
Blinded	This means that you and the study team don't know which brain stimulation you are getting, but the study doctor can find out if needed in an emergency. You can find out which brain stimulation technique (active/sham) you received after the study has ended.

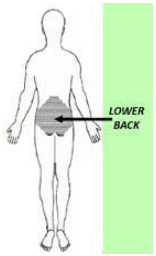
How is the study designed?

Study Sites	This study is being run in Dunedin and in New Zealand only.
NZ Participants	About 164 people will be recruited from New Zealand.
Time in Study	You will be in this study for about 7 months.
Number of Study Visits	You will have scheduled 18 study visits in total (12 for the intervention, 1 for interview, and 5 for the assessment). Please see Picture 1. You may be asked to come for extra visits if needed.



Picture 1. Study phases and time-commitment for each phase

Who can take part in the study?

To take part in this study you must:		
✓	Be aged between 18 to 75 years on the day of the consent.	
✓	Have significant pain in the lower back area (as shown in Picture) with or without accompanying leg pain and functional difficulties for minimum duration of 6 months.	
You cannot take part in this study if you:		
✗	Have known or suspected serious spinal pathology (fracture, lumbar canal stenosis, cancer, inflammatory or infective diseases of the spine; cauda equina syndrome, or widespread neurological disorder)	
✗	Have suspected or confirmed pregnancy or are less than six months post-partum	
✗	Have inflammatory arthritis (e.g., Rheumatoid arthritis, Fibromyalgia, or Gout)	
✗	Had a recent injury to your back in the last 3 months	
✗	Had a recent steroid injection in your back in the last 3 months	
✗	Underwent any neurosurgical procedures or had spinal surgery in the past 12 months or are scheduled/waiting for any major surgical procedures or steroid injections during the stimulation or follow-up period	
✗	Have current or a history of neurological conditions (e.g. Stroke, Multiple sclerosis, Spinal cord or peripheral nerve injuries or neuropathy), or psychiatric disorders (except depression and anxiety disorders)	
✗	Have a history of cancer, or currently receiving/scheduled for receiving therapy for cancer	
✗	Have cognitive impairments (dementia, Alzheimer's disease)	
✗	Alcohol or substance abuse	
✗	History of epilepsy or seizures	
✗	Presence of any electronic implants (e.g., pacemaker), metal implant in the body (particularly head and neck), or spinal cord stimulator.	

What will taking part in the study involve?

Screening (Week -2 to -1)

If you decide to take part, you will be asked to sign the consent section at the end of this form.

The study team will then check whether you meet all the criteria to take part. This is called Screening.

- Screening must be done within 7 to 14 days before starting the rest of the study.
- Screening will be done on a single day. You will be asked to complete a screening questionnaire online. Following this, the lead researcher may contact you either by phone or by email to confirm eligibility or clarify any criteria if needed.
- You will be told if you can take part once all your results have been checked.
- You will also be asked to provide contact details of your GP or other current provider. We will tell your GP or other current provider that you have agreed to take part in this study.

If during the screening phase, you are deemed to be not eligible or if you choose not to participate in the study, then all the information/data collected from you will be deleted immediately.

Intervention (Week 1 to Week 4)

You will be required to attend a total of twelve brain stimulation sessions (approximately 1-hour each, three sessions per week, for four consecutive weeks), at the Dunedin School of Medicine laboratory (6th floor Dunedin Hospital, 201 Great King Street). At each session, you will have to wear a cap with electrodes attached to it on your head (see Picture 2). The researcher will ask permission before touching your head at each session. The researcher will apply electrode gel to your scalp to capture better signal quality. During this time, you will be asked to fill in some questionnaires about any side effects that you might have perceived from the previous sessions.

Picture 2. Brain stimulation device and the intervention position

Following the setup, you will receive the investigational product for 30min at each session, while you rest (see Picture 2). You will be asked to close your eyes and relax for 30min without falling asleep. You will be asked to report any sensations (e.g. itching, tingling) that you feel

during the session and rate the intensity of the sensation on a 0–10-point scale, where 0=None & 10=Worst imaginable, at intervals of 10mins.

Assessments: Baseline and Follow-up

Assessments will be done at baseline (in the week 0), immediately post-completion of the intervention (in the week 5), and at the follow-up of one-month (in the week 8), three-months (in the week 16) and six-months (in the week 28) post-completion of intervention.

Study visits will include in-person site visits at the Dunedin hospital and will take ~2 hours for each assessment session.

At each visit you will complete some of the assessments listed on the next page.

The table on page 7 gives a summary of what will happen at each visit.

You may be asked to come to extra visits if the study team thinks this is needed for safety or other reasons.

If your study doctor identifies any significant abnormal results during the study, they will tell your GP.

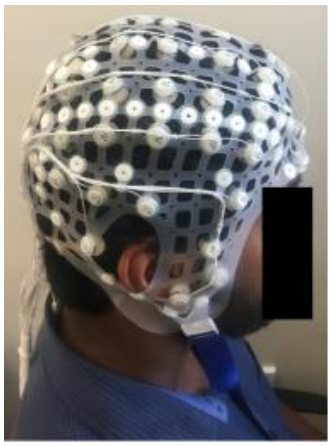
Interview (Week 5)

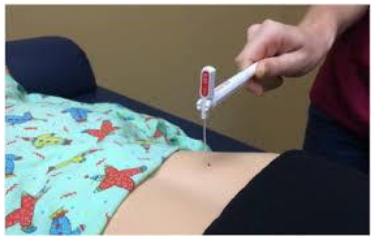
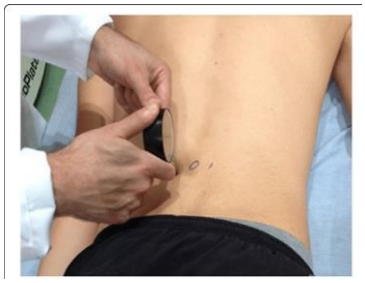
After completion of the brain stimulation and the assessment session in week 5, you will be invited to take part in an interview about your experiences with the brain stimulation approach. The interview will use an open-ended question. You will be able to talk freely. You can refuse to answer any question(s) if you wish. The interview will be recorded with audio-recorders. The recording will be written out word for word. You can comment on your written-out interview if you wish. After completion of the written-out interview, the audio recording will be deleted.

Early withdrawal visit

If you decide you want to withdraw from the study, please let us know.

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.
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 (location, nature, intensity, type) and how much pain affects your functional activities, quality of life and well-being, psychological states (e.g., mood, emotional regulation), current medication history (including pain relief), the presence of other health issues if any, and sleep. You will also be asked about your thoughts and beliefs associated with pain. These questions will be answered on an electronic device. You will learn how to use it during screening. However, a paper copy of the questionnaires will also be available if you prefer.
Brain wave testing (EEG) 	An electroencephalogram (EEG) is a test to record the activity of the brain regions. You will be asked to wear a cap with electrodes attached to it (see Picture). According to Tikanga Māori and Pacific culture, the head is considered sacred *"he tapu te upoko"*. The researcher will obtain permission from you before touching your head, and respect other cultural aspects (e.g., not sitting directly on pillows/tables; not passing food over anybody's head, etc.). You will rest in a comfortable chair with your eyes closed for 10 minutes and your brain activity will be recorded. An electrode will also be placed on your chest to record your heart activity, and two electrodes will be placed on two fingers of the same hand to measure changes in the skin's electrical properties.
Movement tests	You will be asked to perform forward and backward bending movements repeatedly for 20 times. For the forward bending test, you will be asked to pick up a pencil placed on the floor and then place it back to the floor again repetitively. For the backward bending test, you will be asked to see a mark placed on the ceiling behind you repetitively. You can stop performing the repetitions of movements if your pain gets worse. You will also be asked to perform some functional tasks such as putting on socks, picking up a piece of paper, bending to touch toes knee straight, move from lying position to sitting with leg straight, and repetitively lifting of 5 kg box from floor to waist for 1 minute. For all the movement tests, you will also be asked to rate your intensity of pain on a 0–100-point scale, where 0 = No pain and 100 = Worst imaginable pain, at the start of the test and following completion of the test.

Pain sensation testing  	Following brain wave testing, simple test procedures recording your perception of pain sensation will be tested over your low back regions and the wrist region (i.e. a non-painful body part for comparison purposes). The following test procedures will be administered: ➢ **Repeated light touches** with a thin and blunted nylon filament - You will be asked to tell us whether you are feeling a sensation of touch or of pain. If you feel pain on repeated contacts, you will be asked to rate your intensity of pain on a 0-100 scale, where 0 = No pain and 100 = Worst imaginable pain. (See picture) ➢ **Pressure to pain sensation testing** - Pressure will be gradually applied using a rubber-tipped pressure device. You will be asked to indicate immediately when the pressure sensation changes to discomfort or when you first feel pain. (See picture) ➢ **Allodynia** is a painful response to a usually nonpainful stimulus. A paintbrush will be stroked on your back region, and you will be asked to rate the level of pain experienced. ➢ **Cold sensitivity testing-** An ice cube will be pressed against the skin of the back region firmly for 10s and you will be asked to rate the level of pain experienced on 0-100 scale.
Cognitive tests  	You will be asked to complete some memory tasks on a computer, and to respond to them as soon as possible. You will be presented with words printed in different colors (see picture) on a computer screen, and you will be asked to recognize the color of the word and respond using one of the keys on the keyboard. This is known as the Stroop Task.

Study Visits

	Screening	Baseline Assessment	Brain stimulation sessions												Interview	Post intervention assessments			
Week	**-2 to -1**	**0**	**1**			**2**			**3**			**4**			**5**	**5**	**8**	**16**	**28**
Study Visit number	-	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
Visit Length (hours)	-	2	1.5	1	1	1.5	1	1	1.5	1	1	1.5	1	1.5	1	2	2	2	2
Informed consent	✓																		
Eligibility check/ Questionnaires	✓																		
History & demographics	✓																		
Pain questionnaire		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Other questionnaires (function, mood, etc)		✓													✓	✓	✓	✓	✓
Movement tests		✓													✓	✓	✓	✓	✓
Brain wave testing		✓	✓			✓			✓			✓		✓	✓	✓	✓	✓	✓
Pain sensation testing		✓													✓	✓	✓	✓	✓
Cognitive testing		✓				✓			✓			✓		✓	✓	✓	✓	✓	✓
Brain stimulation treatment			✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓					

What are my responsibilities during the study?

You should:	
✓	Continue your pain medications/ exercises/ other treatments for the duration of the trial, but the type and dosage will be recorded throughout the duration of the trial
✓	Record any changes to the existing treatments throughout the duration of the trial

As electrical activity of the brain can be affected by various factors, we request You should not:	
✗	Drink alcohol for 24 hours before the assessment sessions
✗	Smoke for 4 hours before the assessment session
✗	Consume caffeinated drinks for one hour before the assessment session
✗	Apply any hair products (oil, gel) before the assessment or brain stimulation sessions or apply hair dye for the duration of the trial
✗	Change your existing treatments for the duration of the trial
✗	Start new treatments for the duration of the trial

What are the possible benefits of the study?

- There may be no direct benefits to you from being in the study.
- It is a possibility that your low back pain intensity and function might improve.

What are the possible risks of the study?

You may experience some side effects from the brain stimulation procedure. 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.

You will be closely monitored for your responses during all the testing procedures, and sufficient rest will be provided between each testing procedure. Any side effects of the investigational product will be formally recorded and addressed if medical attention is required.

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 believed to be contrary to your best interests.

Risks of brain stimulation:

Previous studies show that this type of brain stimulation is a safe procedure. The common side-effects reported by previous studies are presented in box below. Most side effects are mild and disappear soon after the stimulation.

Very common (seen in at least 10 in 100 people)
• Tingling sensation at the stimulation site (during stimulation) • Itching under stimulation electrodes (during stimulation) • Transient redness under stimulation electrodes
Common (seen in 1 - 10 in 100 people)
• Headache • Fatigue
Uncommon (seen in less than 1 in 100 people)
• Insomnia • Nausea • Increased dreaming
Rare (seen in less than 1 in 1000 people)
• Onset of Seizures

Rare risks include the onset of seizures. In the unlikely event that this occurs, the stimulation will be stopped immediately. We have previously tested the same stimulation design in healthy people (n=130), people with mood disorders (44) and chronic low back pain (n=40) and it was safe, with **no** reported case of seizures.

Other risks include that there may be no benefits, and the brain stimulation may not improve your pain or functional levels, or any initial improvements may wear off.

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 investigator 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 after leaving the study site, seek treatment immediately by dialing 111 or going to an Emergency Department.

Assessment risks

For pain sensation testing, we do not anticipate any form of discomfort that would last following the test procedures. You may feel mild pain, tingling, or pins and needles sensation in your back during testing. These ranges of sensations should usually disappear quickly following the testing. A slight reddening of the skin may stay following the pressure to pain sensation testing, and it should go within hours of testing.

Some of the psychological questionnaires and the cognitive test might cause distress, in which case your GP or current health provider will be notified, and you will be referred to a psychologist if needed.

Unknown risks

There may be risks of brain stimulation procedure 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 the brain stimulation intervention, the study doctor will discuss it with you.

Will any costs be reimbursed?

There are no costs associated with taking part in this study, nor will you be paid.

Study-specific costs will be paid for by the University of Otago and the Health Research Council. You will still have to pay for your non-study related medical care.

You will receive a koha of $30 grocery or petrol vouchers at the last follow-up assessment. This is not subject to tax.

You will be reimbursed for travel expenses associated with the study (such as buses, taxis or parking) to a value of $10 per hour per visit (i.e., a total of $270). Reimbursement is not subject to tax.

We could arrange Driving Miss Daisy as a transport option for travel if needed.

What if something goes wrong?

If you were injured in this study, you would be eligible **to apply** for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery.

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

What will happen to my information?

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

Identifiable information – *this information traces directly to you.*	
Examples?	*e.g. information carrying your name, initials, birthdate, contact details, or NHI number; voice or video recordings*
How is it stored?	• Paper: under restricted access at University of Otago, Dunedin School of Medicine, until the end of the study, then at a secure storage facility. • Electronic: on secure password protected University of Otago servers
Who has access?	• Local study staff and health services that do your study assessments • Study monitors, to make sure data is collected properly • Study auditors (see below)
How long is it kept?	For at least 10 years

Coded information – *this information is labeled only with your unique study ID*	
Examples?	*All your information that is loaded into the study database.*
How is it stored?	• On a secure electronic server that complies with New Zealand data security guidelines.
Who has access?	• The research team and the Sponsor. • Regulatory or other governmental agencies worldwide.
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.*
How is it stored?	On a secure international database.
Who has access?	Access is not restricted
How long is it kept?	Indefinitely

Extra information about my data

The study investigator 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. Information collected up until this point will continue to be used, to protect the quality of the study.

Data Storage: After the study, your identifiable data will be stored for at least 10 years in a secure storage facility. Your coded and anonymized 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 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 laws.

Māori Data

Māori data is a potential taonga. Māori data sovereignty permits Māori organisations to access coded Māori data, to support Māori development aspirations.

Could the study end earlier than planned for me?

If you wish to withdraw from the study, please let us know. We may ask if you could complete some end-of-study assessments if you withdraw early.

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 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.

The brain stimulation will not be available to you after the study.

Can I find out the results of the study?

Information relating to this study, such as a summary of results, will be available at Australia New Zealand Clinical Trial registry (http://www.ClinicalTrials.gov).

The results of the study will also be published in an international scientific journal or presented, but not in a form that would reasonably be expected to identify you. Only a summary of the data will be mentioned in the research publication. The data included in the publication will in no way be linked to any specific person, and your identity will not be recorded with the data.

You can choose to be sent a copy of the study results once the study is over. You can select this in the consent form below. These will be available in approximately December 2027.

Who is funding the study?

This study is being partly funded by the Health Research Council, and the Brain Health Research Centre through a Philanthropist.

Data and samples that lead to discoveries and inventions, or the development of a commercial product, will be owned by the University of Otago and the Health Research Council. You will not have rights to ownership or benefit financially.

Dunedin School of Medicine, University of Otago will receive payment from the Health Research Council and the Brain Health Research Centre for conducting this research. The study team members will only receive their ordinary wages for conducting this research.

Who has approved this study?

The ethical aspects of this study has been approved by an independent group of people called a Health and Disability Ethics Committee (HDEC), who check that studies meet established ethical standards.

The Northern B HDEC has approved this study.

Who do I contact for more information?

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

Name: Dr. Divya Adhia **Position**: Senior Research Fellow **Department:** Department of Surgical Sciences, University of Otago, Dunedin.	**Phone number:** 03 470 9337 **Email**: divya.adhia@otago.ac.nz
Name: Professor Dirk De Ridder **Position**: Professor of Neurosurgery **Department:** Department of Surgical Sciences, University of Otago, Dunedin.	**Phone number:** 03 470 9337 **Email**: dirk.deridder@otago.ac.nz
Name: A/Professor Ramakrishnan Mani **Position:** Associate Professor **Department:** Centre for Health, Activity and Rehabilitation Research, School of Physiotherapy, University of Otago, Dunedin	**Phone number:** 03 479 4249 **Email:** ramakrishnan.mani@otago.ac.nz
Name: Professor John Reynolds **Position**: Professor of Anatomy **Department:** Department of Anatomy, University of Otago, Dunedin.	**Phone number:** 03 479 5781 **Email**: john.reynolds@otago.ac.nz
Name: Professor Paul Glue **Position**: Psychologist **Department:** Department of Psychological Medicine, University of Otago, Dunedin.	**Phone number:** 03 470 9430 **Email**: paul.glue@otago.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 on:
Phone: 0800 555 050
Fax: 0800 2 SUPPORT (0800 2787 7678)
Email: advocacy@advocacy.org.nz
Website: https://www.advocacy.org.nz/

For Māori cultural support please contact:
Mr. Johnnie Potiki
03 476 9986
j.potiki@gmail.com

You can also contact the health and disability ethics committee (HDEC) that approved this study on:
Phone: 0800 400 569 (Ministry of Health general inquiries)
Email: hdecs@health.govt.nz

CONSENT FORM

Brain network stimulation for chronic low back pain.

Formal Study title:	High-definition transcranial infraslow gray noise stimulation for chronic low back pain: A double-blinded randomised controlled clinical trial.
Sponsor:	University of Otago.
Lead Study Doctor:	Dr Divya Adhia
Study Site:	Dunedin hospital
Contact phone number:	0211167594
Ethics committee ref.:	2024 FULL 21891
24-hour number	0211167594

Please let your study doctor know if you need an interpreter.

I have read, or have had read to me, and I understand the Participant Information Sheet.		
I have been given sufficient time to consider whether or not to take part in this study.		
I have had the opportunity to use a legal representative, whānau/ family support or a friend to help me ask questions and understand the study.		
I am satisfied with the answers I have been given regarding the study and I will be given a copy of this consent form and information sheet.		
I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time without this affecting my usual care.		
I consent to the research staff collecting and processing my information, including information about my health.		
I consent to my information being sent overseas.		
If I decide to withdraw from the study, I understand that the information collected about me up to the point when I withdraw may continue to be processed.	Yes □	No □
I consent to my GP or current provider being informed about my participation in the study.		

I consent to my GP or current provider being informed of any significant abnormal results obtained during the study.		
I agree to an approved auditor appointed by the New Zealand Health and Disability Ethics Committees, or any relevant regulatory authority or their approved representative reviewing my relevant medical records for the sole purpose of checking the accuracy of the information recorded for the study.		
I understand that my participation in this study is confidential and that no material, which could identify me personally, will be used in any reports on this study.		
I understand the compensation provisions in case of injury during the study.		
I know who to contact if I have any questions about the study in general.		
I understand my responsibilities as a study participant.		
I wish to receive a summary of the results from the study.	Yes □	No □

Declaration by participant:
I hereby consent to take part in this study.

Participant's name:

Signature: Date:

Declaration by member of research team:

I have given a verbal explanation of the research project to the participant and have answered the participant's questions about it.

I believe that the participant understands the study and has given informed consent to participate.

Researcher's name:

Signature: Date: