Participant Information Sheet

[Sensitized Points Acupuncture for Chronic Low Back Pain: A Feasibility Study]

Formal Study title: Sensitized Points Acupuncture versus Routine Integrative Acupuncture for Chronic Low Back Pain: a Randomized-Controlled Feasibility Study

Sponsor: Professor David Baxter, 325 Great King Street, School of Physiotherapy, University of Otago, Dunedin 9016, New Zealand.

Lead Researcher: Ms. Huijuan Tan

Study Site: Pro Acupuncture Clinic, Dunedin

Contact phone number: 0220768652

Ethics committee ref.: 2022 FULL 11076

You are invited to take part in a study on whether a larger clinical trial is possible to investigate two different types of acupuncture for chronic low back pain. Whether or not you take part is your choice. If you don't want to take part, you don't have to give a reason. If you do want to take part now, but change your mind later, you can pull out of the study at any time.

This Participant Information Sheet will help you decide if you'd like to take part. It sets out why we are doing the study, what your participation would involve, what the benefits and risks to you might be, and what would happen after the study ends. We will go through this information with you and answer any questions you may have. You do not have to decide today whether or not you will participate in this study. Before you decide you may want to talk about the study with other people, such as family, whānau, friends, or healthcare providers. Feel free to do this.

If you agree to take part in this study, you will be asked to sign the Consent Form on the last page of this document. You will be given a copy of both the Participant Information Sheet and the Consent Form to keep.

This document is 10 pages long, including the Consent Form. Please make sure you have read and understood all the pages.

VOLUNTARY PARTICIPATION AND WITHDRAWAL FROM THIS STUDY

Being part of this study is voluntary and you are free to withdraw at any time and for any reason without experiencing any disadvantage.

WHAT IS THE PURPOSE OF THE STUDY?

The aim of this preliminary study is to check whether a larger clinical trial is possible to investigate two different types of acupuncture for chronic low back pain.
Chronic low back pain is very common in New Zealand. It impairs physical function, and influences emotion, which might further impact patients' quality of life. Acupuncture is considered a safe and effective treatment for this condition, and acupuncture treatment for pain is supported by ACC.
There are many ways to do acupuncture. For example, using different acupuncture points, or treating those points by different methods. Our research question is: whether there is any difference in benefits between two ways of doing acupuncture. We hope to better understand the clinical benefits of applying acupuncture to tender acupoints for chronic low back pain. This study will inform the feasibility and design of carrying out a large study. In addition, it will provide evidence to improve acupuncture practice in treating chronic low back pain.

HOW IS THE STUDY DESIGNED?

Our study will recruit 30 people in Dunedin. We will do a screening assessment to make sure of your eligibility. If you're eligible, you will be randomized to one of the two groups. It means there is an equal chance of being in any one of the groups. You do not choose the group you are in. 15 people are required for each group.

Each group will use different acupuncture protocols. Both acupuncture schemes are safe and potentially effective in reducing your back pain. Group A will receive simple acupuncture treatment on tender acupuncture points. Group B will receive a package of care based on Traditional Chinese Medicine (TCM), it will include standard acupuncture and "cupping". Cupping is a widely used method to reduce pain in TCM. We will use pump to make negative pressure inside cups to stimulate your back muscles.

Group A will receive acupuncture treatments twice per week, for 4 weeks; Group B will receive acupuncture treatments twice per week, and cupping once per week, for 4 weeks. Each treatment will last for about 50 minutes. A board-certified acupuncturist will do the treatments. All treatments will be carried out at an accredited acupuncture clinic in Dunedin.

We assess the effectiveness of these two treatments on symptoms before and after treatment. Self-report scales will be used to do assessments. At the screening assessment, you will be asked to complete some scales about your back pain severity. Then we can make sure of your eligibility. Scales are simple and easy to answer, which will take about 5 minutes. We will send you scales via either email or post, or we'll call you to ask those questions verbally. If you are eligible, you will receive baseline assessment by scales before starting your first treatment; and you will be asked to complete scales once per week during the period of treatment, and 12 weeks after treatment completes (follow-up). Follow-up assessment can be completed via emailing electronic forms, or via on-the-spot assessment at the acupuncture clinic. Your preference will be asked at the end of study. These assessments should take about 15 minutes each. You will be offered one more free acupuncture session as a "koha" for completing follow-up assessment. A different

researcher will do all assessments, He / She will not know your treatment group. This "blinding" of assessors is important to reduce bias in the study.

As this is a feasibility study, it is important you can commit to the scheduled appointment, and that you are able to complete the follow-up assessment to make this study feasible.

WHO CAN TAKE PART IN THE STUDY?

We are seeking adults who have had low back pain for more than 3 months.

Inclusion Criteria:
(1) Participants should be adults (aged ⩾18 years old);
(2) Have chronic LBP (with or without leg pain) for more than 3 months;
(3) The average score of Numeric Pain Rating Scale (NPRS) is more than 3 points out of a maximum 10 points;
(4) Agree to sign informed consent.

Exclusion Criteria:
Participants will be excluded if they report any of the following conditions:
(1) Serious spinal disorders including malignancy, vertebral fracture, spinal infection, inflammatory spondylitis, cauda equine compression;
(2) Scheduled surgery;
(3) Received acupuncture in the last 4 weeks;
(4) Serious internal disorders: respiratory, circulatory, endocrine, system diseases, etc;
(5) Have a restricted ability to make independent decisions about their participation;
(6) Unable to communicate in English or Chinese;
(7) Clotting disorders, or taking anticoagulant agent;
(8) Current or scheduled pregnancy, lactation period.

WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?

Should you agree to take part in this project, you will be asked to complete some screening questions. We'll send you the scales via email or post, or we'll call you to ask verbally. The scales will verify your eligibility, and it should take around 5 minutes. If eligible, you will be allocated to one of two treatment groups. Each group will receive different acupuncture protocols for 8 sessions. The treatment will be conducted at an acupuncture clinic in Dunedin, and each session will take about 50 minutes. You will receive the baseline assessment by scales before starting the first treatment; and you will be asked to complete scales once per week during the period of treatment, and 12 weeks after treatment completes (follow-up). Each assessment will take around 15 minutes. You will be offered one more free acupuncture session as a "koha" for completing follow-up assessment.

We will ask questions related to:
1) General information, such as your age, gender, ethnicity, etc.;

2) Low back pain related health information, this includes your symptoms and how these impact on your life;
3) Your satisfaction with study procedures, and your views on acupuncture.

All scales are self-reported, and easy to complete. There is no question that may be sensitive or cause embarrassment.

During the course of the acupuncture treatment, if you're experiencing ongoing and intolerable back pain will be advised on pain killers (such as paracetamol); or consult your pharmacist or GP if you are uncertain of what medication to take. We ask that any pain killers received throughout the study are recorded by participants, including the date, and details of treatment. After completing the trial treatments, patients who suffer ongoing and intolerable back pain in follow-up stage will be advised on other treatment options according to their preference and need, like massage, medications, physiotherapy, etc. Any other treatments received will be recorded by participants, including the date, and details of treatment.

WHAT ARE THE POSSIBLE RISKS OF THIS STUDY?

This study is safe, and risks to participants are considered minimal.

For acupuncture treatment, after putting in the needles, the acupuncturist will carefully adjust the needles to make a sensation called "Deqi". It feels like numbness, soreness, or heaviness. This sensation shows that the needle has successfully stimulated the point. If you are receiving acupuncture for the first time, this might feel like mild discomfort; however, it will disappear after a few minutes.

Adverse events will be categorised as minor or severe. The following will be considered minorOne possible side effect to acupuncture treatment is slight bleeding / bruise at the site of needling;this is uncommon and minimal. One of the two groups will receive cupping in addition to acupuncture. A common side effect of cupping is temporary bruising. This is normal as a reaction to patients having cupping therapy. It won't cause any discomfort, and will disappear within a week.
In contrast, uncommon and unexpected complications that require medical review and follow up such as exacerbation of symptoms, dizziness or infection, will be classified as severe adverse events. If these prove to be common occurrences these might result in the termination of the study.
Acupuncture has been shown to be an effective therapy for chronic low back pain, and it has been recommended as a possible first-line non-pharmacological treatment for this condition.
While some people fail to respond to acupuncture, it is highly unusual for acupuncture to cause a marked increase in pain. If you do experience an increase in pain, that is either marked, or prolonged (i.e. beyond 48 hours), we will review the treatment – as a research team and by data monitoring committee. In the first instance, we will advise you of the appropriate course of action given your presentation e.g. reassurance of normal response, resort to usual pain relief, or referral to seek advice from a medical practitioner. Where appropriate, we will suggest you to withdraw from the study, and refer to your general practitioner to seek for further medical help. Your general practitioner will be notified of

participation. You will be asked to record your medication choices and changes for the study and notify the researchers and your general practitioner if you have exacerbations of pain.

As acupuncture is an effective method for chronic low back pain, you are not likely to have severe mental illness that related to back pain during treatment. You're encouraged to inform researchers of any negative emotion you have, and this will be dealt with to the best of our ability. Support involves referring you to a suitable health professional or specialist within a reasonable time period after completing the questionnaire. If you're distressed, you will be treated kindly and only withdrawn if it affects the study or the study affects your mental health.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

Acupuncture treatment is strongly recommended by American College of Physicians as a first line, non-pharmacologic intervention for chronic low back pain. Cupping is the most commonly used adjunctive therapy in acupuncture practice, and many evidence has shown that cupping is an effective therapy of chronic low back pain. Both the treatments in two groups in this study have potential benefits in relieving pain and improving function of patients with chronic low back pain. All treatments are free.

WHAT ARE THE ALTERNATIVES TO TAKING PART?

Treatment is available for your low back pain from acupuncturist or physiotherapists in private practice for which you must pay. You can also get free treatment funded by the government and available at the hospital. You must be referred for this service by your GP, and there may be a waiting list. Your GP and pharmacist can advise you about pain medication. Lots of information on managing your low back pain is available on-line. Look for national organisations such as NZ Health Navigator for reliable information.

WILL ANY COSTS BE REIMBURSED?

You will not have to pay for any of your acupuncture treatment.

WHAT IF SOMETHING GOES WRONG?

Ethical approval has been granted by HDEC: ref. 2022 FULL 11076
In the unlikely event you were injured in this study, you would be eligible to apply for compensation from ACC. This is like claiming for injury from an accident at work or at home. It 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 will not affect your cover.

WHAT WILL HAPPEN TO MY INFORMATION?

During this study the researchers will record information about you and your study participation. This includes the results of any study assessments. You cannot take part in this study if you do not consent to the collection of this information.

Identifiable Information

Identifiable information is any data that could identify you (e.g. your name, date of birth, or address). Only the research team will have access to your identifiable information. To make sure your personal information is kept confidential, information that identifies you will not be included in any report generated from the research. Instead, you will be identified by a code. The clinical trial administrator will keep a list linking your code with your name, so that you can be identified by your coded data if needed. The results of the study may be published or presented, but not in a form that would reasonably be expected to identify you.
For participants in the sensitized-point acupuncture group, photographic information of the points on your back and lower limbs will be collected; these pictures will be only focused on those points without any identifiable feature included. The pictures will be coded by participants' ID (i.e. that is not be able to be identified), and will be stored confidentially in a designated computer that only research team can access with a password.

Future Research Using Your Information.

If you agree, your coded information may be used for future research related to chronic low back pain or acupuncture treatment. You will not be told when future research is undertaken using your information. Your information may be shared widely with other researchers. Your information may also be added to information from other studies, to form much larger sets of data. You will not get reports or other information about any research unrelated to the current study that is done using your information.

Your information may be used indefinitely for future research unless you withdraw your consent. However, it may be extremely difficult or impossible to access your information, or withdraw consent for its use, once your information has been shared for future research.

You will also be asked if you are willing to be contacted and invited to participate in similar studies in the future conducted by the current research team. Any future study would have to be approved by an Ethics Committee, and would involve accessing your contact information.

Security and Storage of Your Information.

Your identifiable information is held at the University of Otago during the study. After the study it is transferred to a secure archiving site and stored for at least ten years, then destroyed. All storage will comply with local and/or international data security guidelines.

Risks.

Although efforts will be made to protect your privacy, absolute confidentiality of your information cannot be guarantee. Even with coded and anonymised information, there is no guarantee that you cannot be identified. The risk of people accessing and misusing your information (e.g. making it harder for you to get or keep a job or health insurance) is

currently very small, but may increase in the future as people find new ways of tracing information.

This research includes basic information such as your ethnic group, geographic region, age range, and sex. It is possible that this research could one day help people in the same groups as you. However, it is also possible that research findings could be used inappropriately to support negative stereotypes, stigmatize, or discriminate against members of the same groups as you.

Rights to Access Your Information.

You have the right to request access to your information held by the research team. You also have the right to request that any information you disagree with is corrected.

Please ask if you would like to access the results of your screening and safety tests during the study. You may access other study-specific information before the study is over, but this could result in you being withdrawn from the study to protect the study's scientific integrity.

If you have any questions about the collection and use of information about you, you should ask the lead researcher Ms. Huijuan Tan.

Rights to Withdraw Your Information.

You may withdraw your consent for the collection and use of your information at any time, by informing Ms. Huijuan Tan.

If you withdraw your consent, your study participation will end, and the study team will stop collecting information from you.

If you agree, information collected up until your withdrawal from the study will continue to be used and included in the study. You may ask for it to be deleted when you withdraw, unless you withdraw after the study analyses have been undertaken.

WHAT HAPPENS AFTER THE STUDY OR IF I CHANGE MY MIND?

- You are a volunteer in this study and are free to withdraw from the research without experiencing disadvantage. You can withdraw by informing your acupuncturist, or the lead researcher (Ms. Huijuan Tan).
- You have the right to access information collected about you as part of the study.

CAN I FIND OUT THE RESULTS OF THE STUDY?

A summary of results will be written and circulated to study participants. This may be up to one year after you have finished the study.

We have put this study on a clinical trials register (ANZCTR ref no. ACTRN12621001426875). You can access details about the trial including the results via their website (http://www.anzctr.org.au/) using the reference number above.

WHO IS FUNDING THE STUDY?

This study is funded by Ph.D. scholarship from University of Otago, and Ph.D. research budget from School of Physiotherapy. These were awarded to Ms. Huijuan Tan, School of Physiotherapy, University of Otago.

WHO HAS APPROVED THE STUDY?

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 HDEC has approved this study.

The scientific aspects of this study have been approved by a peer reviewer Dr. Ramakrishnan Mani, a senior lecturer in School of Physiotherapy, University of Otago.

WHO DO I CONTACT FOR MORE INFORMATION OR IF I HAVE CONCERNS?

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

Name Ms. Huijuan Tan **Position** Ph.D. candidate **Department** School of Physiotherapy **Phone:** 0220768652 **Email:** huijuan.tan@postgrad.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 Maori health support please contact:
Katrina Anne Potiki Bryant (Ngai Tahu, Kati Mamoe, Waitaha, BPhty)
Kaiarahi Maori, Professional Practice Fellow
University of Otago School of Physiotherapy
(03) 4797473
(021)1140304
katrina.bryant@otago.ac.nz

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

Consent Form

[Sensitized Points Acupuncture for Chronic Low Back Pain: A Feasibility Study]

Please tick to indicate you consent to the following

I have read, or have had read to me in my first language, and I understand the Participant Information Sheet.		
I have been given sufficient time to consider whether or not to participate in this study.		
I have had the opportunity to use a legal representative, whanau/ 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 have 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 medical 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.	Yes ☐	No ☐
If I decide to withdraw from the study, I agree 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 and of any significant abnormal results obtained during the study.	Yes ☐	No ☐
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 ☐
I am willing to be contacted for future similar research	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: