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| Participant Information Sheet **Alternative and complementary medicine for Veteran’s with pain and distress** | | |
| Department of Preventive and Social Medicine, University or Otago, 18 Frederick Street, Dunedin 9016 |  | | | |
| Study Doctor: Associate Professor David McBride (LtCol RNZAMC, Standby Reserve)  Study Site: National  Contact phone number: 027 253 5451  Ethics committee ref.: |  |  | |  |
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We are inviting adults who can consent for themselves to take part in a study on alternative and complementary medicine to help relieve pain and distress. 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, and it won’t affect the care you receive. 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: you do not have to give consent now, but may log in and out of the system at any time prior to giving consent.

If you decide to proceed further you will be asked to give your consent by clicking on the link on the consent form which will be found at the very end of this information sheet. You will be emailed a copy of both the Participant Information Sheet and the consent form to keep.

This email will also contain a personal study link, valid for the duration of the study, which will allow you to access the questionnaires.

This document is 9 pages long, including the Consent Form. Please make sure you have read and understood all the pages.

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| **Voluntary Participation and Withdrawal From This Study** |

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, and it won’t affect the care you receive.

## What is the purpose of the study?

We have previously shown that distress is a problem in a significant minority of New Zealand military Veterans, also that mobility, carrying out usual activities, and pain or discomfort cause at least some problems for a significant proportion. We believe that ‘Battlefield Acupuncture,’ developed by the United States military and delivered by placing very small needles on the external ear, delivered in tandem with a particular form of ‘talking therapy’, focussed action and commitment therapy (FACT), teaching that thoughts and feelings should be accepted and acted upon. An alternative choice will be traditional Rongoā Māori healing. We hope that both will be acceptable forms of treatment, and would like to find out if they are more effective in improving symptoms of pain and distress than ‘usual approaches’ to health management, how Veterans tend to deal with health complaints.

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| **How is the study designed?** |

This is a randomised trial involving at least 130 Veterans, defined as those who have ever served in the New Zealand Defence Force. If you agree to participate in this study, you will randomly allocated to receive either the treatment, or a comparison group in which you case you will manage your own health as you usually do: there is a 50:50 chance you will be allocated to treatment. If you are allocated to treatment, you can choose either Battlefield Acupuncture with ACT or Rongoa Māori.

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| **Who can take part in the study?** |

All New Zealand military Veterans, defined as those who have ‘ever served in the New Zealand Defence Force, are eligible.

## What will my participation in the study involve?

If you decide to participate by clicking the link in the email, you will be asked to give us, for safety purposes, your contact information and preferred method of contact, the contact details for your GP, which is a safety requirement) and which treatment you would prefer, if randomised to that group, acupuncture and FACT or Rongoa Māori, providing the latter is available where you live, it may not be. If so, you will be asked (by email txt or phone) whether you wish to have acupuncture.

There are six questionnaires in the study, if answering all six they should take less than 10 minutes each to complete, see the table below.

The questionnaires can be found here:

[https://blogs.otago.ac.nz/veteranshealth/**acupuncture-2**/](https://blogs.otago.ac.nz/veteranshealth/acupuncture-2/)

The results will be analysed at each point in time to see if the treatment is being successful, if pain and distress are being reduced. After you receive your personal link you can go to the first questionnaire at any time. The first questionnaire is a short wellbeing survey. If you have a score low on this, you will be contacted by Associate Professor David McBride (LtCol RNZAMC, Standby Reserve) who will carry out a short interview and discuss whether you should see your GP. If you consent to this he will refer you and refund your consultation fee.

**Table, questionnaire time-frame**

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| **Time point** | **Instrument** |
| Baseline (at entry to study) | Distress, Pain, disability, sleep quality, post traumatic stress, psychological flexibility |
| 12 weeks (after entry, and so on) | Distress, pain and disability |
| 24 weeks | Distress, pain and disability |
| 36 weeks | Pain, disability, sleep quality, post traumatic stress, psychological flexibility |

You will receive an email reminding you to complete the 12, 24 and 36 week questionnaires at the corresponding time after you start the study.

If you are randomised to treatment, this usually lasts between 8 and 12 weeks depending on how you respond. If you have chosen acupuncture, each session involves placing miniature gold-plated needles in the ear, which typically fall out within 2-3 days, or you can choose to remove them after day 3. These will be placed by registered Acupuncturists who have been trained in the technique. Each session will last about an hour.

During the session the clinician will use focussed action and commitment Therapy (FACT) which encourages people to embrace their thoughts and feelings rather than fighting or feeling guilty for them. There are usually less than four short 20 min sessions, which explore if you are getting ‘stuck’ by unhelpful thoughts, emotions, painful memories or uncomfortable physical symptoms. These cannot be deleted, but sometimes can just be observed as what they are. The clinician will help you explore ways to do this, if you consent to do this. More information on the sessions can be found here:

<https://blogs.otago.ac.nz/veteranshealth/files/2023/01/Fact-process21.pdf>

Or these can be mailed to you using the contact details on page 6.

Rongoa Māori techniques include Romiromi, the physical bodywork that uses Haemata and Haematua (acupressure points) to release trapped energy in the body that is causing ailments or illness; Mirimiri - Includes Korero (discussions), Takutaku (incantations), Waiata (song) and Whatumanawa accessing Taha Wairua (metaphysical or spiritual elements) associated with the injury or illness, and Rongoā Wairaku - plant medicines applied either topically or ingested to support healing. Due to the individual nature of patients, each practitioner will determine which or encompass all aspects under the modality of Rongoa Maori to assist with the Veteran’s health and state of being.

If you are randomized to the control group, you should look after your health as you normally do, you do not need to do anything special, but we would be grateful if you complete the questionnaires. We recognize that you may be disappointed that you are not receiving treatment and should call Dr McBride if this is so, he will discuss options with you.

After the initial analyses are done, and if the results show a statistically significant improvement in pain and distress, we will contact you around February to March 2023 (we trust sooner than this) to see if you would still like to participate in treatment. We will either fund these sessions or assist you with a claim through ACC or Veterans Affairs. You will not have to provide any further data.

## What are the possible risks of this study?

The side-effects of acupuncture may be discomfort or minor bruising, and occasionally dizziness. The ACT sessions may awaken unpleasant memories. Unfortunately, we cannot predict whether treatment will have a benefit. Your therapist will usually be aware of these effects, but you should also mention them at the time. Help is available. Your therapist will record adverse effects (but not any other personal information) as part of the study.

Dr McBride will be alerted to this, and should contact you. His contact details are:

Phone/txt 027 253 5451

email david.mcbride@otago.ac.nz

The NZDF 24/7 Helpline: is also available to all serving NZDF members and veterans:

0800 NZDF 4U (0800 693 348 or 0800 189 910)

No Duff is an extensive network of volunteers across NZ, the majority of whom are operationally experienced, serving and former members of the NZDF. NO DUFF NZ provides an important bridging link between contemporary veterans and support agencies like the RSA and Veterans’ Affairs. They can be contacted at:

Mobile/txt 022 307 1557 or [noduff.ngo@gmail.com](mailto:noduff.ngo@gmail.com)

Veterans Affairs NZ can be contacted on: 0800 483 8372 (0800 4 VETERAN)

You will also be able to contact the RSA and their District Support Services Team, the local contact details are available on a list which will be found at:

https://www.rsa.org.nz/get-support/support-for-veterans/

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| Northland DSM | Charlie Lamb | dsm.northland@rsa.org.nz | 027 208 1355 |
| Auckland | Ari Panapa | dsm.auckland@rsa.org.nz | 021 0859 0254 |
| Waikato | King Country | Bay of Plenty DSM | Tricia Hague | dsm.waikato@ra.org.nz | 027 388 6243 |
| Wairarapa | Hawkes Bay | East Coast DSM | Janet Castell | dsa.wairarapa@rsa.org.nz | 027 239 1008 |
| Central DSM | Rob Todman | robt@rsa.org.nz | 021 256 2180 |
| Wellington DSM (acting) | Rob Todman | robt@rsa.org.nz | 021 256 2180 |
| Nelson | Marlborough | Westland DSM | John Capill | dsm.marlborough@rsa.org.nz | 021 029 48679 |
| Canterbury DSM | Wendy Clark | dsm.canterbury@rsa.org.nz | 027 233 3794 |
| Otago | Southland DSM | Niall Shepherd | dsm.otago@rsa.org.nz | 027 600 3104 |

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| **What are the possible benefits of this study?** |

The possible benefits are a reduction in pain and an increase in psychological ‘flexibility,’ in other words an ability to cope with unpleasant thoughts.

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| **What are the alternatives to taking part?** |

The alternatives are to seek acupuncture from a member of Acupuncture New Zealand <https://www.acupuncture.org.nz/>

Rongoa Māori may be available locally, contact Ruatau Perez through Te Whare Hauora [tearateatea@gmail.com](mailto:tearateatea@gmail.com)

FACT is available through a number of providers, you should discuss the options with your GP, or contact Dave McBride.

## Will any costs be reimbursed?

At the initial visit, the practitioner will assess how your treatment will be funded

If you are eligible for ACC support, the practitioners are ACC registered and will submit an electronic claim on your behalf.

If you have deployed on operations you may be eligible for support from NZVA.

If you have an accepted service-related condition, the therapist will complete a treatment expenses claim form in the usual way.

If not registered with NZVA they will, with your consent complete a treatment and rehabilitation claim form, and forward this to Dr McBride who will help you register

We have treatment funding for 64 participants and practitioners will invoice the study direct.

If you decide to participate, you will also be entitled to a payment of $75 as recompense for some of your time, and if you are not receiving reimbursement for your travel (to treatment or GP visits) we can assist with this up to $150 in total. If you have additional costs, or need travel costs please email [david.mcbride@otago.ac.nz](mailto:david.mcbride@otago.ac.nz) and he will arrange funding and support for you.

## 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?

During this study the researchers and practitioners will record information about you and your study participation. This includes the medical information usually collected by health practitioners, which will not be part of the study and remain confidential, and the results of the questionnaires which you complete.

**Identifiable Information**

Identifiable information is any data that could identify you (e.g. your name, date of birth, or address). Dr Dave McBride and the study data manager will have access to your identifiable information. The following bodies may also request identifiable information:

The ethics committees, or government agencies from New Zealand or overseas, may ask for these details if the study or site is audited. Audits are done to make sure that participants are protected, the study is run properly, and the data collected is correct.

Your usual doctor, if a study procedure gives an unexpected result that could be important for your health. This allows appropriate follow-up to be arranged with your GP, which is why we are asking for your permission to contact them. For safety purposes, this is a requirement of participation.

**De-identified (Coded) Information**

To make sure your personal information is kept confidential, information that identifies you will not be included in any report generated by the any study information sent to the University of Otago. Instead, you will be identified by a code. Dr Dave McBride will keep a list linking your code with your name, so that you can be identified by your coded data if needed.

The following groups may have access to your coded, de-identified data:

The University of Otago, for the purposes of this study.

Regulatory or other governmental agencies.

Other researchers, to build upon existing knowledge rather than repeating it, to replicate the results, or to carry out meta-analyses, which combine the results of studies. This data may be sent internationally, but will be held on a secure data sharing site, a ‘clinical trials registry’ available only to registered researchers and the data will be de-identified. You can choose to opt out of this this by ticking the box.

The results of the study will be published or presented, but not in a form that would reasonably be expected to identify you.

**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 10 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 guaranteed. 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.

**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.

If you have any questions about the collection and use of information about you, you should ask Dr Dave McBride at his contacts given above.

**Rights to Withdraw Your Information.**

You may withdraw your consent for the collection and use of your information at any time, by informing Dr Dave McBride.

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.

If you agree to sharing your anonymous data with other researchers, please note that it may not be possible to withdraw your data.

**What happens after the study or if I change my mind?**

If you change your mind, you can simply tell your treating practitioner: you don’t have to give a reason. You can also contact (using the contact details below) Dr Dave McBride. You may ask for your data to be deleted when you withdraw, unless you withdraw after the study analyses have been undertaken in which case your data will have contributed to the study.

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| **Can i find out the results of the study?** |

You can expect to receive the results of the study in June 2023, published on the study web site. if you tick the last box on the consent form, you can have a ‘plain language’ summary emailed to you. The results will also be submitted to a scientific journal for review, typically taking around 3 months, which should be in September 2023, and you can also tick the box to get this forwarded to you.

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| **Who is funding the study?** |

The study is being funded by Lottery Health.

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| **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 Northern B HDEC has approved this study.

## 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:

Dr Dave McBride, Associate Professor (LtCol RNZAMC, Standby Reserve)

Telephone027 353 5451

Emaildavid.mcbride@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](mailto:advocacy@advocacy.org.nz)

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

For Maori health support please contact:

Ruatau Perez, Te Whare Hauora [tearateatea@gmail.com](mailto:tearateatea@gmail.com)

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



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| Consent Form **Alternative and complementary medicine for Veteran’s with pain and distress** |

**Please tick to indicate you consent to the following**

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| 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 de-identified information being shared with other researchers, to include in their research. | 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**. For safety purposes, this is a requirement for participation.** | Yes | |  | |
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| 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 plain language summary of the results from the study. | Yes | | No | |
| I wish to receive a copy of any published paper | Yes | | No | |
| If randomized to treatment, I would choose | | AAAcupuncture | Rongoa | |

**By clicking on the link below**

I hereby consent to take part in this study.

<https://psm-dm.otago.ac.nz/redcap/surveys/?s=4WML948D3X>