# Alternative and complementary medicine as a pathway to care for New Zealand military Veterans experiencing pain and distress.

## Study investigators

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# Introduction.

We have previously shown that distress is a problem in a significant minority of New Zealand military Veterans,[1] also that mobility, carrying out usual activitiesnand pain or discomfort cause at least some problems for a significant proportion of them.[2] We believe that ‘Battlefield Acupuncture,’ an auriculotherapy developed by the United States military, delivered in tandem w ith a particular form of ‘talking therapy’, Action and Commitment Therapy (ACT), teaching that thoughts and feelings should be accepted and acted upon, or for Māori, traditional Rongoa Māori healing, would both be acceptable forms of treatment, and more effective in improving symptoms of pain and distress than their usual approaches to health management.

# Background

We have shown that mental health problems are prevalent in the New Zealand Veteran community, 10% of Veterans have scores on Post-traumatic Stress Disorder Checklist Military (PCL-M) indicative of clinical PTS injury (PTSI) and 30% have significant PTSI symptoms.[1]

Pain and discomfort are also a problem, our recent findings showing that, in comparison with the New Zealand population, a greater proportion of Veterans reported problems with mobility, usual activities, and pain or discomfort. Psychological flexibility, as measured by the Action and Acceptance Questionnnaire II, and better sleep quality were associated with higher self-reported health, while distress, as measured by the GHQ-12, was associated with diminished health.[2]

We also know that Veterans have a peculiar pattern of symptom reporting, multi system illness, with a discernible pattern of symptoms reported on factor analysis: firstly arthro-neuromuscular distress, secondly cognitive distress, and thirdly psycho-physiological distress, those with PTSD having a high symptom count.[3] Worryingly, a small proportion of Australian Veterans with high symptom counts developed chronic diseases including sleep apnoea, psychological disorders, and cardiovascular conditions.[4] In keeping with this pattern, they also demonstrated a range of other risk factors: a high prevalence of obesity, high waist circumference, and harmful alcohol use. They also had poorer physical and mental health.[4]

Furthermore, there are significant barriers to seeking care. In a cross-sectional survey, we found that 33% of Veterans were lonely,[5] loneliness being correlated with psychological distress, and 43% being uncomfortable in accessing supports. A follow up qualitative survey assessed how Veterans conceptualise loneliness.[6] three themes emerged, Veteran-centric ‘driving’ factors, social connectedness, and barriers to accessing support. Significant barriers to accessing health care were stoicism and the perception of ineffective services. Social and geographic isolation were risk factors, as were anxiety and depression. Military culture, in particular stoicism, the ability to ‘harden up’ in the face of adversity, was a significant barrier, along with perceived problems of accessibility and effectiveness of services, a particular problem being that therapists had a poor understanding of the Veteran experience and culture.

The pain-relieving effects of acupuncture are recognised, albeit with study design difficulties leading to ‘low to moderate quality evidence’,[7] and acupuncture treatment for pain management is supported by the Accident Compensation Corporation. In Military Medicine, Battlefield Acupuncture has been reported to reduce acute pain, and has become widely adopted for pain management by the United States military.[8] For psychological symptoms, ACT has been shown as a relatively simple approach to reduce distress and to improve sleep through increasing psychological flexibility.[9] Both have been found effective, however acupuncture has been particularly useful for those who have an aversion to talk therapies.[10]

Traditional Rongoā Māori Healing Techniques will also be offered to to those randomised to the treatment arm if a practitioner is available in the local area.

# Aims of Study.

We aim to see if either Battlefield Acupuncture and ACT, or Rongoa Māori, are more effective in reducing symptoms of pain and distress than ‘usual care,’ how veteran manage their own symptoms.

# Research hypotheses

1. That the presenting Veterans will have complex pain problems characterized by arthro-neuromuscular distress, cognitive distress, and psycho-physiological distress.
2. That Veterans experiencing complex problems have barriers to accessing health care, and ‘usual care’ does not include health seeking behaviour.
3. That the therapeutic practices of Acupuncture, ACT and Rongoa Māori will assist Veterans in taking an active role in their own management.
4. That these practices will have greater efficacy than usual care alone in reducing distress, the primary outcome measure.
5. That the secondary outcome measures, pain, disability, sleep quality and symptoms of PTSI will be reduced, and that psychological flexibility will increase.

# Study design

A randomised clinical trial comparing either Battlefield Acupuncture and ACT or Rongoa Māori to ‘usual care.’

## Study setting.

Multi centre nationwide.

## Study population

Eligible participants will be Veterans, defined as anyone who has served in the military, presenting with multiple or complex symptoms with a pattern corresponding to that shown in table 1. At least one musculoskeletal symptom will be required, and evidence from factor 2 that there is at least one psychological symptom.

Table 1, factor grouping of symptoms in Multi System Ilness

|  |  |  |
| --- | --- | --- |
| Factor 1 | Factor 2 | Factor 3 |
| problems with sexual functioning | loss of concentration | diarrhoea |
| passing urine more often | feeling distant | stomach cramps |
| loss of balance or coordination | unrefreshing sleep | nausea |
| Loss of sensation hands/feet | Forgetfulness | feverish |
| tingling or burning hands/feet | sleeping difficulties | sore throat |
| joint pain | Avoidance | tender glands |
| joint stiffness | Fatigue |  |
| muscle aches/pains | distressing dreams |  |
| Wheezing | Startle |  |
| Shortness Of Breath | difficulty speaking |  |

The main pathway used by Veterans to access health care support will be through their General Practitioners, but they may seek initial advice from New Zealand Veterans Affairs or the RSA District Support Advisers. Each of these referring groups will be given information about the symptom profile of patients, or clients, that may be helped by this therapy: we will ask the Royal New Zealand College of General Practitioners to advertise the study in their newsletter *ePulse*. The GPs will refer the patient or client to the nearest participating Acupuncturist and to the study web-site for registration as a potential participant. For funding purposes, General Practitioners can make an ACC claim to cover the costs of treatment (Acupuncture and Rongoa Māori practioners are ACC registered), NZVA Case Managers can authorise treatment for eligible Veterans, RSA District Support Advisers can authorise access to regional welfare funds, and study funding is available for those who do not have other means.

## Acupuncture

The Chair of Acupuncture New Zealand (AcNZ) is a member of the study team (RT), and has sent details of the study to the 760 members in both the North and South Islands. Should gaps be detected, direct contact with practitioners should help fill these. AcNZ also has a practitioner search engine on their website which is shortly being updated to allow a search for ‘Veteran.’[11]

Battlefield acupuncture is a form of auriculotherapy where a sequence of small gold plated needles is placed in the ear, typically remaining for three days, when the patient is told to remove them. Their most likely mode of action is through the release of endorphins. Registered Acupuncturists are already qualified to offer this treatment modality and for most practitioners it would be a refresher course for this technique. Council members and members of local convenors continuing professional development (CPD) groups will be trained through a specific course: “Battlefield acupuncture and working with trauma,” in which practitioners are taught the indications for the technique, and how to pair, cluster and insert the needles.[12] COVID contingencies mean that this would be delivered by webinar or through CPD ‘small group’ teaching.

Acupuncturists routinely identify patterns of lifestyle, sleep patterns, movements, thought patterns and emotions. We will adopt the training manual developed by Dr Robyn Walser, a psychologist with the US Department of Veteran’s Affairs, for the Lang et al. study [9] She has confirmed that this can be adapted to train acupuncturists in the ACT techniques. Each weekly session will include a mindfulness exercise and homework (Appendix).

## Rongoa Māori

Ruatau Perez, a skilled practitioner in Rongoa Māori, is also a member of the study team, and he and his Practitioners will use the techniques as follows: 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.

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.

All Rongoā Māori practitioners will receive further training online or in small groups from Ruatau Perez, a skilled practitioner and teacher, to further understanding of the techniques specific to PTSD and other symptoms experienced by Veterans. Ongoing support throughout the program will also be offered for practitioners across the country.

## Practitioner ‘Veteran competency’ training.

Specific on-line training modules have been identified by the RSA to ensure that practitioners are ‘culturally competent’, and are prepared for the issues that may be raised.[13] These are available on line from PsychArmour,[14] which includes a certification process recognised for AcNZ CPD points.

## Recruitment procedures.

Study administration will be carried out on-line using REDCap. a secure web-based application for building and managing online surveys and databases, which we have used successfully in several Veteran projects. Each potential participant will be registered and receive an email with a link to the study site.

On accessing the link, the purpose of the study will be explained through a patient information sheet, and informed consent sought at this time by clicking a link on the consent form.

**Participant Safety**

The GP will be asked screen potential participants using the Mini International Neuropsychiatric Interview (MINI) where indicated, and carrying out appropriate referral. Screening of potential participants will also be carried out on-line using the GHQ-12, and if exceeding the cut-off score, will be stopped at that point and asked to contact the PI (Dr (LtCol) Dave McBride by text, phone or email, who will carry out a telephone consultation and refer if indicated.

**Study procedures**

Randomisation will be carried out on-line using the REDCap randomisation module, a study number allocated and the local therapist informed of the allocation by email: for those entering the treatment arm either acupuncture and ACT or Rongoā Māori, the latter as as an option if a practitioner is available locally. These modalities of treatment will be compared with ‘usual care,’ how the Veteran usually manages their health condition (see the following section). At the initial visit, the practitioner will obtain informed consent for treatment, carry out their usual physical evaluation, use the auricular acupuncture technique and record clinical information according to their usual practice. They will then follow the 12 week ACT programme (see the Appendix).

**Data Collection**

The survey instruments will be delivered on-line at base-line, or by post if requested. Participants will be asked about any healthcare advice (and where sought) in the previous 2 months and use of alcohol and analgesia. The schedule is shown in table 2.

Table 2, schedule of questionnaires.

|  |  |
| --- | --- |
| **Time point** | **Instrument** |
| Baseline | Pain, distress, disability, sleep quality, post traumatic stress, psychological flexibility |
| 12 weeks | Distress, pain and disability |
| 24 weeks | Distress, pain and disability |
| 36 weeks | Distress pain, disability, sleep quality, post traumatic stress, psychological flexibility |

All outcomes will be measured at baseline; distress, pain and disability measured at 12 weeks and 24 weeks and all measures will be repeated at 36 weeks.

For the 24 and 36 week questionnaires, a link to the survey will be emailed to all participants at the appropriate time, or the appropriate paper questionnaire mailed on request, and two reminders sent in case of non-response.

## Outcome measures.

***Primary***

The primary outcome instrument will be distress, assessed using the 12 item General Health Questionnaire (GHQ-12), scored using a four point scale (0-3) and summing the 12 items to give a total score, with higher scores indicating elevated distress.[15]

***Secondary***

The secondary outcomes will include:

1. Pain.

Assessed by *The Dallas Pain Questionnaire* (DPQ),[16] a 16-item visual analogue tool for the purpose of evaluating a subject’s cognitions about the effect (%) of chronic pain on four aspects of their lives: 1) daily activities including pain and intensity, personal care, lifting, walking, sitting, standing, and sleeping; 2) work and leisure activities including social life, travelling, and vocational; 3) anxiety-depression; and 4) social interest that includes interpersonal relationship, social support, and punishing responses.

2. Disability

Measured using the *Sheehan Disability Scale*,[17] with three items rated on an 11-point scale ranging from 0 (not at all) to 10 (extremely). This measures impairment in work, social, and family settings, and is sensitive to symptom change and differences between active and control treatments.

3. Sleep quality

To be assessed with the *Sleep Condition Indicator* (SCI).[18] This assesses insomnia as described in the Diagnostic and Statistical Manual of Mental Disorders version 5 (DSM-V). The SCI consists of eight items rated from 0-4, the total scores being scaled to a range of 0 to 10, where higher scores represent better sleep.

4. Post Traumatic Stress.

Symptoms of Post-Traumatic Stress will be assessed using the *post-traumatic stress disorder* (PTSD) *checklist for DSM 5, the* PCL-5.[19] The PCL-5 includes 20 items that ask about DSM-5 symptoms of PTS, with response options ranging from 1 ‘Not at all’ to 5 ‘Extremely’.

5. Psychological flexibility

Measured with the 10-item *AAQ-II*.[20] Items are answered on a 7-point scale, with options ranging from ‘never true’ to ‘always true’. The items are summed to obtain a total score (possible range 10 to 70), with higher scores indicative of greater psychological flexibility.

**Analysis plan**

The primary end point is at 12 weeks when treatment ends.

The primary analysis will be a t-test comparing GHQ12 scores between the two arms. Regression analysis will be used to adjust for any baseline imbalances and for the secondary analyses looking at change over time (allowing for repeated measures) for all outcomes.

A sample size of 64 in each group will ensure there is at least 80% power to detect a 10-point change in GHQ 12 scores assuming that the standard deviation is 20 and with a 5% significance level.

**Ethical considerations.**

*Risks to participants*

Using the referral pathways i.e. via GPs, the NZVA and RSA, means that most Veterans will have been clinically assessed prior to recruitment. At entry, potential participants will be screened by completing the GHQ-12, and if exceeding the cut-off score, will be screened using the Mini International Neuropsychiatric Interview (MINI) administered by the PI, and referred to a mental health professional if indicated.

There is a small chance that treatment, either physical or the ACT intervention, may elicit unwelcome memories. The participant information sheet (PIS) will list the contact details, including the mobile number, of the PI, along with details of the New Zealand Defence Force 24/7 helpline, NZVA, a link to the RSA District Support Advisors page and the contact details for No Duff, an extensive network of volunteers across NZ, the majority of whom are operationally experienced, serving and former members of the NZDF. They are skilled at crisis management.

Adverse effects of acupuncture have been reported to include haematoma, bleeding and skin bruising, however Battlefield Acupuncture is less invasive. In a study of 11,046 Veterans, common reasons for stopping were recorded as “the patient asked you to stop, the patient felt dizzy/lightheaded, or the patient fainted.” Of one clinic systematically recording information in this trial, of 1946 patients, 12 (0.6%) were noted as having a complication from the procedure, primarily being asked to stop for reasons of dizziness or discomfort.[21]

Clinicians will be asked to report adverse events to the PI, and follow up questionnaires will have a free text field for partcipants to record such events. These will be reviewed by an internal safety committee

*Data security*

Clinical information will be held by practitioners in accordance with the Health Information Privacy Code and the study data management plan. The questionnaire data will be held securely on the RedCap system, and participants will identifiable during the data collection phase at which time only the PI and the data manager will have access. The data will then be de-identified, but the contact details will be retained on a separate file, with access restricted to the PI and data manager. The data will then be retained on the secure University system for at least five years.

*Withdrawal from the study*

Participants are informed that they are free to withdraw from the study at any time without without giving a reason and without detriment to themselves. This may include either withdrawal from treatment only, or withdrawal from data collection alone, however we would prefer to process the data up to the time of withdrawal.

**Significance.**

*He Ara Oranga*, the Report of the Government Inquiry into Mental Health and Addiction, highlighted the increasing demand for mental health services, the rising use of pharmacological treatment, and inequities in access to psychological services. Using ‘talking therapies’ is seen as a viable way forward, but faces the barrier of the limited number of psychologists available to treat the more seriously affected patients.[22] The alternative suggestion was to involve counsellors and social workers in treatment at ‘the milder end of the spectrum.’[23] Acupuncturists and Rongoa Māori practitioners are skilled in ‘talking through’ problems, so this proposal addresses a pathway to care for Military Veterans with pain and distress, integrating a ‘Veteran acceptable’ complementary and alternative medicine (CAM) approach to address their needs. There is no reason why the approach should not be successful in similar groups: First Responders and Public Safety Personnel, or indeed the general public.

**Main Activities**

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| --- | --- | --- |
|  | **Activity - Description** | **Who is responsible for activity?** |
| **1** | Writing and disseminating survey information | DMcB, DB, YB |
| **2** | Initialising the REDCap survey database, timelines, reminders and data extraction | BDeG  |
| **3** | Descriptive analysis at baseline, and analysis at 12 weeks. Follow up at 12, 24 and 36 weeks.  | RT |
| **4** | Write up and dissemination | All |

**Time line**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Year 1 – 01/04/2022 to 31/12/2022** | **Interim report** | **Year 2 -– 01/01/2023 to 31/01/2023** | **Final report &** **financial reconciliation** |
| **Activity** | 01/0431/05 | 01/06-31/09 | 01/10-31/12 |  | 01/01-30/04 |  |  |  |
| **1** Train  |  |  |  |  |  |  |  |  |
| **2** Baseline and Treat |  |  |  |  |  |  |  |  |
| **3** 12 week report |  |  |  |  |  |  |  |  |
| **4** 24 week report |  |  |  |  |  |  |  |  |
| **5** 30 week report (final) |  |  |  |  |  |  |  |  |
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**Project Management**

We have a team with in-depth experience of project management, including major Health Research Council funded studies. We are therefore experienced in managing projects which require on-line surveys, have allowed sufficient time for recruitment and entry of data and will ensure that milestones are achieved.

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