Appendix B. DATA MANAGEMENT PLAN

Version: 2

Date: 10 Jan 2022

Protocol [Sensitized Points Acupuncture versus Routine Integrative Acupuncture for Chronic Low Back Pain: Protocol for a Randomized-Controlled Feasibility Study]

Sponsor: Prof. David Baxter

Site: Pro Acupuncture Clinic, 34 Bank Street, North East Valley, Dunedin 9010

Co-ordinating Investigator: Huijuan Tan

CONTENTS

1 INTRODUCTION

This Data Management Guide outlines how data will be handled during the study (Sensitized Points Acupuncture versus Routine Integrative Acupuncture for Chronic Low Back Pain: a Randomized-Controlled Feasibility Study) and after its completion.

2 STUDY STRUCTURE

The Sponsor will enlist the support of the named Contract Research Organisation (CRO) to co-ordinate the Study. The Sponsor is responsible for supervising any and all outsourced activities.

TABLE 1. STUDY STRUCTURE

Sponsor	Prof. David Baxter [325 Great King Street, School of Physiotherapy, University of Otago, Dunedin 9016]
Contract Research Organisation	Not applicable
Lead Site (New Zealand)	Pro Acupuncture Clinic [34 Bank Street, North East Valley, Dunedin 9010]
Co-ordinating Investigator	Huijuan Tan [325 Great King Street, School of Physiotherapy, University of Otago, Dunedin 9016]

3 ORGANISATIONAL DATA GOVERNANCE OVERSIGHT

Not applicable.

4 CONSENT FOR DATA COLLECTION AND USE

All participants will be informed of, and provide consent for, the collection and use of their data for the purposes of this study, and for any mandatory secondary uses.

5 DATA COLLECTION

Data will be collected from the following sources:

- Direct communication with the participant
- Study assessments, including questionnaires and interviews

Data will be collected primarily by the designated study staff. All study personnel involved in data collection will be trained in GCP, study protocol, and collection requirements.

Collection of data will be limited to that necessary for the specified purposes of the study.

6 PRIVACY AND CONFIDENTIALITY

Participants' privacy and confidentiality will be respected through the protection of their data as outlined in this plan. The Investigator will comply with legal and regulatory requirements regarding the privacy and confidentiality of participants' data.

Participants have the right to access and correct personal data held by the site. Other results may be available on request, and may result in the participant being withdrawn from the study.

6.1 BREACH OF PRIVACY / CONFIDENTIALITY

A breach of privacy means unauthorised or accidental access to, or disclosure, alteration, loss, or destruction of a participant's information.

In the event participant privacy and confidentiality is breached

during the study, the following steps will be taken:

- Action will be taken to reduce the risk of harm following the breach. Where possible, the recipient will be contacted and asked to destroy or return any electronic the disclosed material.
- The participant will be informed of the breach as soon as practicable (unless notification would be likely to prejudice the health of the participant (after consultation with the participant's health practitioner, where practicable), and provided with support as required.
- A site and Sponsor quality review will be conducted to ascertain factors contributing to the breach, and any corrective action required to prevent future breaches.
- The approving HDEC will be informed.
- For notifiable privacy breaches of privacy under the Privacy Act 2020, the New Zealand Privacy Commissioner will be notified in accordance with that Act.

7 FORMS OF DATA

7.1 IDENTIFIABLE DATA

Some study data will be collected in identifiable form.

Source documents refer to identifiable data collected for the purposes of this study. Identifiable data includes the participant's name, age, gender, ethnicity, and contact information.

Collected data will be deidentified (remove all identifiers) as soon as is practicably possible, and replace it with a participant ID code. All participants attending for baseline assessment will be assigned a unique identification code (PID). This will be used on all versions of data collection forms.

The key for the PIDs will be kept separately on the PI's computer in a password protected file. As a result, all data are de-identified as it is collected. The researcher should maintain a separate list linking participant ID with identifiers. No research data will be stored in an identifiable form.

7.2 De-identified Data

De-identified data in this study includes but is not limited to:

- Case Report Forms.
- Photographic information of the sensitized points on participants' back and lower limbs
- Safety and screening results entered into the analysis data set.
- Communications from the site to the Sponsor.

De-identified data will carry the participant's unique study code. The Investigator will retain a log linking participant code with identifiers. This log will not be made available to Sponsor.

All data sent to Sponsor will be de-identified. All data generated by these parties will be in de-identified form. No attempt will be made to re-identify participants.

7.3 Anonymous / Anonymised Data

De-identified data may be anonymised prior to being made available for future research (see Section 7.2.1). Anonymised data will be irreversibly stripped of the unique participant code and any other identifiers.

Participants will be informed that anonymised data is unable to be accessed, corrected, or withdrawn; and that return of individual results will not be possible.

8 Access to and Use of Data

Collected data will be used to answer the research questions and fulfil the study requirements described in the study protocol, and for the secondary purposes outlined in Sections 7.4 and 7.5.

8.1 Identifiable Data

Identifiable data may be accessed by the following groups:

- The Investigator and designated study staff, to fulfil protocol requirements.
- The Sponsor and its authorised representatives, in the event of a compensation claim by a participant.
- The Health and Disability Ethics Committee, for legal and regulatory purposes.
- Health, regulatory, or government agencies, for legal and regulatory purposes.
- The participant's GP or appropriate specialist, to inform them of study participation, and in the event of an incidental finding of potential clinical significance.

Rarely, it may be necessary for the Investigator to share identifiable data with people or groups not listed above – for example, in the event of a serious threat to public health or safety, or to the life or health of the participant or another person; or if the data is required for certain legal situations.

8.2 De-identified Data

De-identified data may be accessed and used by the following groups:

- The Investigator and suitably trained and experienced study staff, to conduct the study.
- Sponsor, for source data verification purposes.
- The Health and Disability Ethics Committee, to comply with legal and regulatory duties.
- Health, regulatory, or government authorities, to comply with legal and regulatory duties.

De-identified data may be included in published study results including, but not limited to, peer-reviewed publications, and scientific meetings.

8.3 [Anonymous/Anonymised] Data

Anonymised data may be accessed and used by the groups described in Section 8.2.

Anonymised data may also be made available to other researchers, as described in Section 8.5.

8.4 Sending of Data Overseas

Not applicable.

8.5 Future Use of Data

De-identified or anonymised data will be used by the Sponsor for future medical or scientific research as specified below:

- unspecified purposes which are directly related to the study question(s)
- unspecified purposes which are related to the item and/or condition under study

De-identified or anonymised data will be made available to other researchers on request for future research as specified above or will be added to data from other sources to form larger datasets.

In all cases, the Sponsor must be satisfied that appropriate Data Management Plans are in place and that ethical approval for use has been obtained in accordance with local laws and regulations.

8.6 Commercial Use of Data

Not applicable.

8.7 Data Linking

Not applicable.

8.8 DATABANK / REGISTRY

Not applicable.

9 STORAGE AND DESTRUCTION OF DATA

9.1 IDENTIFIABLE DATA AND SOURCE DOCUMENTS

During the study, study-specific source documents will be maintained in a locked cabinet at the University of Otago during the study.

Post-study, study-specific source documents will be archived at a secure archiving site in University of Otago.

Source documents will be retained for at least 10 years, then destroyed by shredding that leaves no possibility for reconstruction of information.

9.2 DE-IDENTIFIED DATA

Identifiable data will be converted to a de-identified form at the study site, at which point it is entered into electronic case report forms and sent through a secure server to the sponsor. Coded study information will be kept by the sponsor in secure, cloud-based storage indefinitely. The storage complies with international and national regulatory requirements for electronic data capture systems in the countries where it is used. Data entry will be limited to designated study staff trained and experienced in transcribing data for this purpose.

De-identified data will carry code. The Investigator will retain a log linking participant code with identifiers. This log will not be made available to Sponsor.

De-identified data is stored long-term by the Sponsor in a secure cloud-based server indefinitely.

10 CONSULTATION

Consultation regarding data management will be undertaken with the following relevant community: Maori.

10.1 MĀORI DATA SOVEREIGNTY

During the study, data may be collected from participants identifying as Maori.

Personal and health information is a tāonga (treasure) and will be treated accordingly.

Formal Māori consultation for this study will be completed as part of the Locality Approval Process for New Zealand study site(s). Any recommendations for additional measures to improve Māori rights and interests in relation to data will be acted upon.

11 RETURN OF RESULTS

Screening and safety results will be provided to participants on request.

Participants have the right to request a lay summary of study results.

11.1 INCIDENTAL FINDINGS

In the event that a study assessment returns a result of potential clinical significance, the participant will be informed. The participant's usual doctor or an appropriate specialist will be notified, and follow-up will be arranged.

11.2 RESULTS ARISING FROM FUTURE RESEARCH

11.2.1 Data

No future unspecified research is planned for data collected in this study.

Results will not be made available to participants of any future research conducted using data collected in this study. Participants are informed of this in the PISCF.

11.2.2 Databank / Registry

Not available.

12 WITHDRAWAL OF DATA

Participants may withdraw consent for the collection of data at any time, without providing a reason.

Should a participant withdraw consent, no further data will be collected by study staff.

Data collected prior to the participant's withdrawal will continue to be used and analysed. Participants may ask for it to be deleted when they withdraw, unless they withdraw after the study analyses have been undertaken.

APPENDIX

Not Applicable.