Participant Information Sheet

Study title: **Home use of TENS for bladder function improvement in chronic spinal cord injury: a pilot translational study**

Funded by: **Lottery Health Research R-LHR-2021-153393**

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Lead institution: University of Auckland

Study Site: Participant's home

Contact phone number: +64 022184324

Ethics committee ref.: **21/STH/171**

Australian New Zealand Clinical Trials Registry

(ACTRN12621000869875p)

You are invited to take part in a study on transcutaneous electrical nerve stimulation for improvement of bladder function in people with chronic spinal cord injury. 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 will happen after the study ends. You do not have to decide today whether you will participate in this study. This document is 11 pages long, including the Consent Form. Please make sure you have read and understood all the pages.

Voluntary Participation and Withdrawal From This Study

Your participation in this study is your choice. If you choose not to take part in the study, you will not be affected in any way. You can pull out at any time from the study and this will not affect your future healthcare or your relationship with the University of Auckland. This Participant Information Sheet will help you decide if you would like to take part. The study investigator can also give you further support and answer any questions you may have. Before you decide, you may want to talk about the study with other people, such as your caregiver, whānau, friends, or healthcare providers. If you decide that you wish to take part,

you will need to give us your permission. This will be done through the signed consent form, which you can choose between paper-based or electronic (online) platforms. You have the right to withdraw from this study at any time. Your contribution is entirely voluntary and if you chose to withdraw any remaining data will be destroyed at that point, but data that have already been collected and processed will continue to be used.

WHAT IS THE PURPOSE OF THE STUDY?

New Zealand has a significant number of people (3,500) suffering from spinal cord injury (SCI). Bladder dysfunction after SCI occurs in most cases and has a major impact on the quality of life for individuals and a major impact on families. Our recent systematic literature review and meta-analysis have found that the use of transcutaneous electrical nerve stimulation (TENS) can improve bladder function following SCI. This study aims to evaluate whether TENS is safe and feasible to be performed at home and whether it improves bladder function in people with chronic SCI.

HOW IS THE STUDY DESIGNED?

Twenty adults with chronic SCI (>1 year post-injury) who currently utilise clean intermittent catheterisation (CIC) for bladder management will be recruited. Initial screening will be performed via a telephone call or video conference between you and the investigator. If you are interested, you will be given a video demonstration of the procedures. If you meet the inclusion criteria, you will be eligible for the study and sent an approved consent form to review and sign. Your informed consent must be obtained prior to enrolment in the study or completing questionnaires other than the self-screening survey. You will participate from home and will receive a package within 5-7 working days after you consent.

TENS is a non-invasive therapy used for over 30 years by physicians and physical therapists as an effective pain relief solution. We are going to use the TENS device in the new approach by applying electrical stimulation to the surface of the skin near the site of the nerve associated with the urinary system. The transcutaneous electrostimulation will be delivered using a FDA-approved portable device (Omron TENS HV-F128) via skin-surface electrodes. The stimulation is applied at the junction of your buttock and upper thigh for 15 minutes daily to achieve an effect on the bladder function without causing skin injury. The device can be run by either you or someone else like a caregiver. You will be asked to record daily information in the “bladder diary” and monitor the safety of using TENS at home. The investigator will telephone you weekly to collect the written data and hear how you are doing with the device. Upon completing the 4-week study, you will be asked to complete some questionnaires (available either on paper or via secure online platforms) and return your records with the TENS device using the courier service provided.

WHO CAN TAKE PART IN THE STUDY?

You can take part in this study if you:

- Are able to read and understand English
- Are aged 18-75 years, living in the North or South Island
- Have spinal cord injury with varying causes e.g., trauma, infection, tumours, disc herniation
- Have a level of injury T12 or above
- Have been neurologically stable for ≥ 12 months
- Have a stable bladder, and no symptoms of urinary tract infection
- Have been medically stable for urination ≥ 3 months

- Are using clean intermittent catheterisation (CIC) to empty your bladder
- Have normal cognition and language
- Are not currently pregnant, or have febrile pathology, cachexia, malignant cancer, or any cancer at the stimulation site
- Do not have any skin problem preventing electrode placement (e.g., bedsore, pressure ulcer at the perineum)
- Do not have cardiac pacemaker or implanted electronic medical devices

WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?

Study procedures and assessments at each step

Activities	0	W1	W2	W3	W4
Self-screening survey	X				
TENS video demonstration (3D animation)	X				
Phone call or video conference	X				
Informed consent	X				
Participant information questionnaire	X				
Neurogenic bladder symptom score (NBSS) baseline	X				
TENS tutorial and practice on dummy (video conference)	X				
Home					
Intervention (TENS – 4 weeks)		□ - - - -	- - - - -	- - - - -	- - - -□
Bladder diary and adverse event recording (4 weeks)		□ - - - -	- - - - -	- - - - -	- - - -□
Phone call or video conference weekly		X	X	X	X
NBSS / TENS satisfaction questionnaire after TENS use					X
Completion Data					X

The study will be undertaken at your home and you should have a telephone and internet connection available at your home. There is no need to attend face-to-face visits during study setup, however we will need to contact you via phone call or video conference (approx. 20 mins) each week to update your information and monitor safety and progression. There will be two options to collect your data during 4 weeks of the study using webpage/mobile app or paper-based documents sent to your home address depending on your convenience. Our research investigator will support you through the study and help you with any queries. If you decide to take part, we will ask you to follow these steps:

Screening	• If you contact us, we will tell you where to get more details and a self-screening survey. • If you meet the inclusion criteria after completing the self-screening survey, you will be invited to watch a video and to allow us to contact you by phone call or video conference at a suitable time. • When we call you, we will go through some pre-screening questions and explain the study. You can also ask questions (this will take approx. 10 mins). • If you are eligible, we will post you the participant information sheet and consent form. You can choose to access them either paper-based or online platform. You will need to complete the informed consent (hard copy or electronic documents) and send back to us prior to your enrolment in the study.
1st week	• After we receive the signed consent form, you are enrolled in this trial. A study package will be posted to your home address for self-intervention and data collection. The package contains one TENS device, practicing model,

	urine container for volume measurement, and printed documents (e.g., device instruction, study protocol, questionnaires, bladder diary). • An online platform is also available if it is more convenient than paper-based data records. You can securely access the same information as paper-based documents via our webpage and mobile app using your own computer and smartphone with the internet. We will provide you the URL with a unique study code to log in to the webpage and download the study app on your smartphone. This online platform requires your own password for data protection. • Before starting the intervention (TENS), you will need to complete the following: 1. Participant information questionnaire 2. Baseline questionnaire (asking questions about your bladder problem/symptoms and quality of life) 3. Baseline bladder diary containing the frequency (count per day) and volume (mL per collection) of intermittent catheterisation, urine leakage episodes, and bladder sensation • Once you have received the study package, we will set up our video conference. You can invite your caregiver to join in order to learn how to use the TENS device and complete the protocol. We will have a live tutorial on using TENS on a dummy (mannequin torso) and you can show us your practice on the practicing model. • A webpage (www.neurotrial.auckland.ac.nz) with video demonstration /tutorials and all information will be available for you. We can also arrange a home visit if you are really struggling to use the device, unless the COVID-19 restriction is above alert level 1. • After training, you will be able to perform the procedure by yourself or with assistance of your family or a caregiver. You will be able to use the TENS device with the fixed setup mode for 15-minute stimulation daily (auto-off setting). • After that, you or your caregiver (involving caregiver is recommended if you lack skin sensation in those areas) will check the skin symptoms and record any side effects that occur during and after using TENS (e.g. skin redness or burn at the electrode sites, nausea, headache, etc.). • The volume of urine will be measured after each clean intermittent catheterisation using the measuring container provided. We only need you to record the volume and then you can dispose of the urine in your usual way. • In the first week of the study, you will be asked to record in your bladder diary each time you finish clean intermittent catheterisation, with the urine volume. If you use the online system, your data will be sent to us from your computer or smartphone. If you use paper-based documents, you will post them back to us at the end of the study. • You will be telephoned weekly to collect the information from the bladder diary and monitor the side effects of using TENS.
2nd - 4th week	• In weeks 2-4, you will use the TENS device and record the urine volume in the bladder diary every day. • In the beginning of each week, notifications by text message, email and/or

	in the study app will remind you when and what you need to do. • You will be called weekly to capture the same information from the bladder diary and to monitor any side effects of using TENS.
Completion	• At the end of the 4th week, notification by text message, email or the study app will prompt you to complete the follow-up questionnaires and the final assessment (approx. 20 mins) available in both paper-based and secure online platforms. • A questionnaire about your satisfaction with the TENS device and asking you about other observed changes including fatigue, pain, spasticity, bowel habit, and sexual function changes will be included in the final assessment. • After finishing the 4-week TENS protocol, the bladder diary will be continued for one more day to monitor ongoing function. • You will courier the recorded documents with the TENS device back to us in a courier bag provided by us.

WHAT ARE THE POSSIBLE RISKS OF THIS STUDY?

TENS unit delivers gentle massage-like pulses, providing "tapping" or "pulsating" feeling on the skin areas. It may produce visible muscle twitching. In general, there are few side effects of electric stimulation e.g.
- Discomfort due to muscle contraction or pain: in this case, you can choose to reduce the intensity by 20% by pressing the “SOFT” button for gentle stimulation. If the pain persists you can turn the intensity dial from level 6 to 5.
- Skin irritation: it is common for redness to occur on the skin at the site of the electrodes. This typically disappears within an hour of removing the electrode. In some cases, the redness remains the next day, which is likely to be because your skin is sensitive to the adhesive used and if so, a hypoallergenic skin-electrode will be provided.
- Skin inflammation and electrode burn under the electrodes are unlikely to occur because of the low intensity of the electrical current (50 mA-Level 6), special burst mode (4-second stimulation and 1-second pause), the short duration of 15 minutes and the auto-off function. If you notice persisting skin inflammation longer than 24 hours, change the site of electrode pads nearby the previous areas in an alternating day would be a helpful solution. In the unlikely event that you get electrode burn at the skin beneath electrode areas, please contact us for advice and see a healthcare provider.

If your use of the device is interrupted or altered, we need you to report how you manage problems e.g. lowering the intensity setting, relocating the electrode pads, reducing the duration of stimulation or contacting our research team.

We suggest applying the TENS device between 8 am and 1 pm. This schedule will be suitable for managing any TENS side effects which will be experienced during the daytime. TENS will not be applied while you are sleeping to avoid the risk of skin irritation while you cannot sense it.

Urinary tract infection (UTI): there is no direct association between using TENS and UTI. In most cases, the infection occurs due to the sterile technique of CIC or long-term use of CIC.

Autonomic dysreflexia may occur in people with spinal cord injuries with lesions at or above thoracic level 6 (T6). It makes your blood pressure dangerously high and combined with very low heartbeats, and symptoms such as nausea, headache, blurred vision, sweating, nasal stuffiness, can lead to potentially life-threatening complications. This happens when your autonomic nervous system overreacts to something below the damaged spinal cord and may be caused by stimulation of the skin, distension of the urinary bladder (urine retention)

or colon (fecal compaction) and/or muscle spasms. However, the chances of this happening due to the use of TENS are very small. Based on our extensive review (scientific literature published between 1947-2020), there were no reports of autonomic dysreflexia associated with the use of TENS device to improve bladder dysfunction in people with SCI. Additionally, a study shows that using TENS can prevent and treat autonomic dysrefexia in chronic SCI. We believe this protocol can be applied safely at home by you and/or your caregiver(s).

If you do experience the symptoms described above, the first thing to do is to remove the electrodes from your body and sit up or raise the head to 90 degrees. If you can lower your legs, do so. Next, loosen or remove any constricting clothing. If you have a blood pressure monitor, ask your caregiver to check your blood pressure. A blood pressure reading of 20mm to 40mm Hg above baseline may be a sign of autonomic dysreflexia. If you don't have the blood pressure monitor, check the 20% drop of your normal heart rate from the baseline during resting position. Call an ambulance (111) and let them know that you suspect autonomic dysreflexia, so you can be transferred to the nearby hospital. If you are unsure, or have limited symptoms of autonomic dysreflexia, but do not have a blood pressure monitor, please contact the research team (24/7 available on a mobile phone: 0221843224), contact your normal healthcare provider or call an ambulance (111).

Symptoms of skin reaction, urinary tract infection and autonomic dysreflexia will be monitored and enquired about via telephone calls or video conference every week throughout the duration of the study. If you have any questions, you will be able to contact one of our study investigators by phone at any time (24/7 available on 0221843224) during the study. The investigator will be responsible for collecting and reporting adverse events during the study.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

We hope that this therapy can improve bladder function in chronic SCI without side effects. The study will add to health research knowledge regarding the safety and feasibility of TENS for use at home for bladder management in people with chronic SCI. The results from this research will be translated into a larger clinical trial to provide more evidence on the health benefits and cost-effectiveness for people with chronic SCI. These include: reducing complications (urinary tract infection, kidney damage); decreasing the usage, and therefore side effects, of medications for SCI; reducing the level of caregiver support required from family and community; and producing significant savings in time and cost for healthcare providers. This study may show that TENS can improve long-term health-related quality of life for people living with SCI in the New Zealand community. This project is a partnership with the Auckland Spinal Rehabilitation Unit, and it is allied with the NZ spinal cord impairment action plan by the Ministry of Health to support people with SCI to enhance their health outcomes and maximise their quality of life.

WILL ANY PAYMENT BE MADE?

After completing the 4-week study, you will be offered a $100 gift voucher in thanks for your time and effort.

WHAT IF SOMETHING GOES WRONG?

In the unlikely event, 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?

All information that you provide will remain strictly confidential. We need to collect personal details such as your name and contact information to communicate with you throughout the study. This information will be stored separately from any other personal data we collect like your ethnicity, age or any health information. No material that could personally identify you will be used in any reports on this study. All information collected during the study will be stored securely by The University of Auckland for 10 years. All computer records will be password protected. All future use of the information collected will be strictly controlled in accordance with the Privacy Act, 1994. If you wish, we can also send you a summary of the results.

During this study, video and telephone calls will not be recorded and no information from your hospital or GP records will be collected. The investigator will keep the information about you and your study participation, including the results of the study assessments with questionnaires and the bladder diary. If you consent to take part in this study, that means you consent to the collection of this information.

We will assign you a code number, and all your information will be recorded against this to keep your identity confidential. The only person able to link the code with your name is Dr Sam Paritt, who will keep the coding list in a locked filing cabinet. The researchers will analyse the data of the whole group and report on averages, so no individual will be identifiable. The data will be used for scientific publications and presentations.

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 investigators/researchers and any study information sent to the sponsor (Lottery Health Research). Instead, you will be identified by a code. The researcher will keep a list linking your code with your name, so that you can be identified by your coded data if needed. The study results may be published or presented, but not in a form that would reasonably be expected to identify you.

Future Research Using your Information.

If you agree, your coded information may be used for future research related to transcutaneous electrical nerve stimulation (TENS) and bladder dysfunction (neurogenic bladder). If you agree, your coded information may also be used for other medical and/or scientific research related to the current study. Your data may also be added to information from other studies to form much larger sets of data.

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 data recorded during the study.

If you have any questions about the collection and use of information, please ask the investigator.

Rights to Withdraw your Information.

You may withdraw your consent for data collection at any time by informing the investigator. If you withdraw your consent, your study participation will end, and the study team will stop collecting information from you.

Data collected prior to your withdrawal will continue to be used and included in the study, to ensure the aims of the study are met.

Use of New Technologies (Webpage, Mobile App)

If you wish, study data can be collected and managed using the Research Electronic Data Capture software (REDCap, Version 6.12.1, Vanderbilt University) managed by the University of Auckland. REDCap is a secure, password protected web application for building and managing online databases and surveys designed to support data capture for clinical research studies worldwide. Instead of using paper documents, you can choose to use the REDCap to access questionnaires, the bladder diary, assessments and video tutorials available via the webpage and mobile app.
This online platform does not share information with any third parties and does not access unrelated information for advertising or other commercial purposes. The mobile app may also be used instead of paper documents and it is free of charge. The app has clear privacy guidelines on how data are used and stored. All electronic recordings will be password-protected and stored in the appropriate University of Auckland managed storage.

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

You may withdraw from the study or stop using the device at any time if you find it bothersome or ineffective and any such events will be recorded as a study outcome. If you have any questions, you will be able to contact the study investigator by phone, video conference or email at any time during the study.

Upon completing the 4-week study, you will return the bladder diary and the TENS device using a pre-paid courier service.

CAN I FIND OUT THE RESULTS OF THE STUDY?

You will be provided with a plain English summary of study results, if you request it by ticking the box on the consent form.

WHO IS FUNDING THE STUDY?

The Lottery Health Research Committee gives funding (R-LHR-2021-153393) for this study.

WHO HAS APPROVED THE STUDY?

This study has been approved by an independent group called the Health and Disability Ethics Committee (HDEC, Ethics ref: 21/STH/171), who checks that the study meets established ethical standards. The trial has been registered on the Australian New Zealand Clinical Trial Registry (ANZCTR: ACTRN12621000869875p).

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:

Primary investigator: Dr Sam Paritt

Telephone number: Mobile 0221843224
Email: s.paritt@auckland.ac.nz

Maori cultural support: Responsiveness to Māori (R2M) team
The Office of Tumuaki and Te Kupenga Hauora Māori (TKHM), Faculty of Medical and Health Sciences (FMHS), University of Auckland
Telephone number: +64 9 373 7599
Email: R2M@auckland.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/

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

Project: Home use of TENS for bladder function improvement in chronic spinal cord injury: a pilot translational study

Investigator: Dr Sam Paritt

Please read the following statements and if you agree with them, sign the form

I have read or have had read to me in my first language, and I understand the Participant Information Sheet.
I have been given enough time to consider whether to participate in this study.
I have had the opportunity to use 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 Participant Information Sheet (this maybe an electronic copy or can be a hard copy if required from your study investigator).
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 me.		
I consent to the study staff collecting and processing my information, including information about my health.		
I understand that my participation in this study is confidential and that no information which could identify me personally will be used in any reports on this study		
I understand the compensation (ACC) procedures in case of injury during the study.		
I consent to my GP being informed about my participation in the study if any significant abnormal results are obtained during the study.		
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.		
I understand my responsibilities as a study participant.		
I agree to be re-contacted by the study team in the future for more information, to be invited to take part in future studies, or for longer term follow up.	Yes ☐	No ☐
I wish to receive a $100 gift voucher after completing the 4-week study and returning the TENS device with all documents to the research team.	Yes ☐	No ☐
I wish to receive a summary of the study results.	Yes ☐	No ☐

Declaration by participant:

☐ I hereby consent to take part in this study.

Participant's name: _____

Signature: _____ Date: _____

☐ I hereby give permission to my caregiver to consent on my behalf to take part in this study.

Witness statement (caregiver):
The participant was unable to sign this consent form because of their physical condition.
I confirm that I was present as a witness for the consent process for this study. I confirm that the participant named above was read the information in the consent document and that the participant has agreed to take part in the research study.

Witness's name: _____

Signature: Date:

Declaration by a member of the 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: Dr Sam Paritt

Signature: Date: