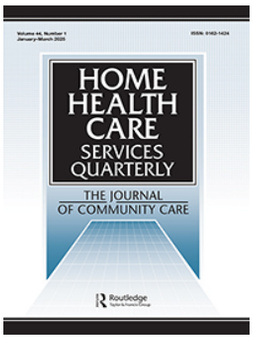

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Home-based intervention and monitoring in spinal cord injury: evaluating method and compliance in a telehealth trial

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ABSTRACT

Telehealth, accelerated by the COVID-19 pandemic, has become essential in-home health care, particularly for individuals with spinal cord injury (SCI). However, traditional telehealth often lacks adequate remote intervention and monitoring for SCI patients. This study evaluated a novel telehealth trial using transcutaneous electrical stimulation (TES) with innovative approaches to improve bladder function in SCI patients. Fifteen participants completed daily 15-minute TES sessions over four weeks, supported by courier-delivered equipment, video conferencing, and online assessments with self-reported monitoring at home. The trial achieved 100% adherence, with 80% of participants expressing confidence in device use and 87% indicating willingness to continue TES. Most participants found the device user-friendly, and 66% reported symptom improvement. This study highlights the potential of telehealth trials to enhance access to care, improve patient outcomes, and promote health equity in home care settings, particularly during periods of restricted in-person healthcare delivery.

KEYWORDS

Electrical stimulation; neurogenic bladder; spinal cord injury; telehealth; tele-trial

Introduction

Telehealth has been part of home health care services for many years, but its adoption worldwide was slow until the COVID-19 pandemic significantly accelerated its use, particularly among individuals with disabilities such as spinal cord injury (SCI) (Simpson et al., 2022). Traditional telehealth services

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did not fully address all aspects of SCI care, especially daily continuous intervention and monitoring in a safe and convenient home environment (Mirbaha et al., 2023). The advent of internet and mobile technologies has further evolved telehealth, with the pandemic highlighting the challenges of accessing healthcare services and maintaining physical distancing (Khong et al., 2022; Touchett et al., 2022). The tele-trial model represents an innovative approach to extending clinical trials beyond conventional settings, particularly benefitting participants in rural and remote areas (Sabesan et al., 2023). By bringing clinical trials to participants' homes, this model has the potential to increase participation and reduce geographical barriers to cutting-edge telemedicine research.

In this study we selected urinary dysfunction following SCI, for the telehealth trial because this chronic medical condition significantly impacts quality of life and imposes a substantial clinical burden (Tan et al., 2025). Nearly 80% of SCI patients experience some degree of bladder dysfunction within a year of injury, and 16–33% are hospitalized annually for urological complications (Crescenze et al., 2021; Liu et al., 2024). Neurogenic bladder, common in patients with chronic SCI, inevitably results in urological complications that require close monitoring and long-term adequate bladder management (Kim et al., 2025). The primary goals and priorities of this management include preserving urinary function, decreasing urological complications, improving quality of life, and achieving compatibility with patients' lifestyles (Chen et al., 2022). The use of transcutaneous electrical stimulation (TES) at the sacral dermatomes was selected as the intervention due to its demonstrated safety, exploitability, and potential to improve bladder function in SCI patients (Parittotokkaporn et al., 2020; Shendy et al., 2015; Walsh et al., 2001). Despite these benefits, such electrotherapies are typically performed in clinical settings, leading to high costs and limited accessibility due to the need for frequent visits and close monitoring (Palermo et al., 2025).

This study addresses whether integrating the telehealth trial with home-based TES can enhance patient satisfaction and compliance, while providing insights into the feasibility, accessibility, and limitations of this innovative approach in real-world settings. We aim to establish a new telehealth trial for remote intervention and monitoring of home-administered electrotherapy in SCI research.

Methods

This study was conducted from February 2021 to January 2023, with funding provided by Lottery Health Research New Zealand (funding number: R-LHR-2021-153393). Patient recruitment commenced in August 2021, with the final participant enrolled in July 2022. Data collection for follow-up continued through November 2022.

Study design

The research was structured as a longitudinal intervention study, receiving approval from the University of Auckland's Human Participants Ethics Committee and the Health and Disability Ethics Committee (21/STH/171). The study was also registered with the Australia New Zealand Clinical Trials Registry (ACTRN12621000869875). In response to the challenges posed by the COVID-19 pandemic, the study adhered to clinical trial regulations by utilizing telehealth and postal services for participant recruitment, informed consent, and the four-week at-home trial.

Recruitment and study participants

Participants were adults with chronic SCI, defined as being neurologically stable for more at least one year post-injury, who had urinary dysfunction managed with clean intermittent catheterization (CIC). They expressed interest in the study and met the inclusion criteria outlined in Table 1. We employed a digital recruitment strategy, utilizing flyers, community and library notice boards, and social media platforms to publicize the clinical research study and attract participants. Additionally, we partnered with the Catwalk Spinal Cord Injury Research Trust, New Zealand Spinal Trust, and the New Zealand Spinal Cord Injury Registry to reach potential participants through their networks and media channels.

Table 1. Inclusion/Exclusion criteria.

Inclusion	Exclusion
• 18–75 years old, living in New Zealand	• Normal voluntary urination control at home
• Neurologically stable SCI for ≥12 months	• Other diagnoses to explain incontinence (UTI, bladder stones, multiple sclerosis, TBI, Stroke, etc.)
• SCI may have varying causes: traumatic and non-traumatic SCI e.g., infection, tumors, disc herniation, etc.	• Cutaneous pathology preventing electrode placement e.g., bedsore, pressure ulcer at the perineum
• Level of injury T12 or above (upper motor neuron bladder dysfunction) with no lower motor neuron lesions	• Known lower motor neuron pathology to the sacral nerve, bladder or the lower urinary tract
• Clean intermittent catheterization to empty bladder	• History of autonomic dysreflexia
• Stable bladder, no symptoms of UTI	• Inability to participate in assessments due to dementia, cognitive impairment, language difficulties
• Medically stable for urination ≥3 months	• Current pregnancy, febrile pathology, UTI, cachexia, malignant cancer, cancer at the stimulation site
• Able to understand risks and benefits of participating in the study	• Demand-type cardiac pacemaker or implanted electronic medical devices

SCI: Spinal Cord Injury; UTI: Urinary Tract Infection; TBI: Traumatic Brain Injury.

Description of the telehealth process

Participants were first invited to watch a short 3D animation video demonstrating the procedure (Supplementary material). They were then contacted via phone or video conference for pre-screening questions and to receive an explanation of the study. Participants received the participant information sheet and consent form, available either as a paper copy or through an online platform, for review and signature. Upon completing the signed consent process, they were officially enrolled in the study and asked to complete a questionnaire. For participants with quadriplegia who were unable to sign, a third party or caregiver provided consent on their behalf.

Participants partook in the study from their homes, receiving a delivery package containing protocol instructions, a self-reporting bladder diary, a training model and a TES device with accessories. This package was sent within 5–7 working days after the investigator confirmed receipt of the signed consent form. All participants were contacted via phone or video conference to explain the four-week protocol, which included pre- and post-TES assessments, a daily 15-minute TES intervention with adverse event recording, and completion of follow-up questionnaires (Figure 1). The Neurogenic Bladder Symptom Score (NBSS) was used to assess bladder dysfunction in SCI patients, demonstrating strong construct and known-groups validity. It also showed high reliability, with a Cronbach's alpha of 0.85 and an intraclass correlation coefficient > 0.75, supporting its use in research and clinical settings (Welk et al., 2018). Participants were also contacted weekly to collect information from their bladder diaries (available in both paper-based and secure online formats) and to monitor any side effects of TES while tracking the protocol's progress.

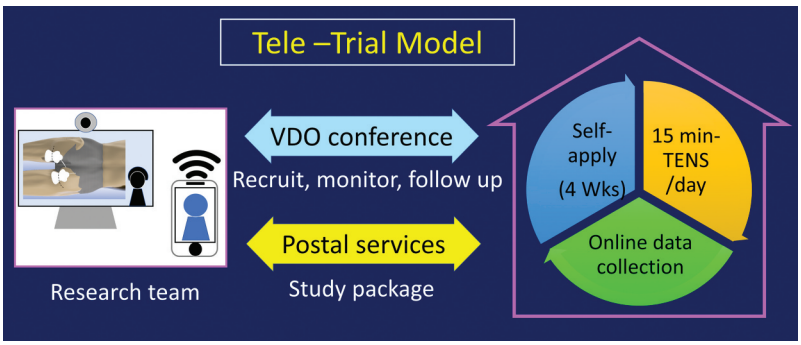

Figure 1. Tele-trial model utilizing telehealth and postal services for participant recruitment, consent, and the execution of a 4-week trial in participants' homes.

Intervention

A noninvasive portable unit (Omron HV-F128 Premium TENS) was used, featuring a battery-operated electrical circuit with a fixed mode setting. TES was administered using two surface electrode pads (6 × 8 cm) placed over the S3 dermatomes at the junction of the buttock and upper thigh (Walsh et al., 2001). Participants received the intervention at an intensity of 50 mA, with a stimulation frequency of 25 hz and a pulse width of 400 μs. The device was set to a burst mode, delivering 4 seconds of stimulation followed by a 1-second pause, for a total of 15 minutes daily over a 4-week period. This Auto-Off feature was designed to achieve a modulating effect without causing skin injury. The 50 mA intensity was specifically chosen to avoid muscular contractions, as indicated by Level 6 on the device's intensity dial. These parameters were selected based on a recent systematic review of TES settings (45–80 mA, 10–50 hz, 200 μs–200 ms, 10–30 minutes) for improving neurogenic bladder function in individuals with SCI (Parittotokkaporn et al., 2020).

Participants and their caregivers received live training via video conference, which included a demonstration of how to apply TES using a mannequin, along with hands-on practice on a gluteal model (Koyuncu et al., 2011). This simple dummy (Figure 2d), made from conductive aluminum tape on a plastic sheet for participants, was first used in SCI research for the TES testing purpose. Additionally, an online animation video, instruction manual, and research team contact information were made available upon request (Figure 2).

After completing the 4-week study, participants filled out final questionnaires and surveys, available in both paper-based and secure online forms. The satisfaction survey and questionnaires were adapted from the Patient Satisfaction Questionnaire (PSQ), originally developed by Ware and colleagues (Ware et al., 1983). The PSQ has demonstrated strong psychometric properties, including content validity and reliability, for assessing healthcare satisfaction across multiple domains, including medical device usability evaluation (Thayaparan & Mahdi, 2013). Following survey completion, they then returned the completed documents and the TES device using the provided courier service (Table 2).

Data collection and monitoring

During enrollment, participants' data were collected via telephone call or video conference and entered into a data spreadsheet. Clinical demographics and the motor level of incomplete SCI were consistently obtained through interviews, all conducted by the same investigator. Neither video nor telephone calls were recorded, and no information from hospital or GP records was collected. Medications that could affect bladder function were documented. Participants or their caregivers performed daily skin inspections at the

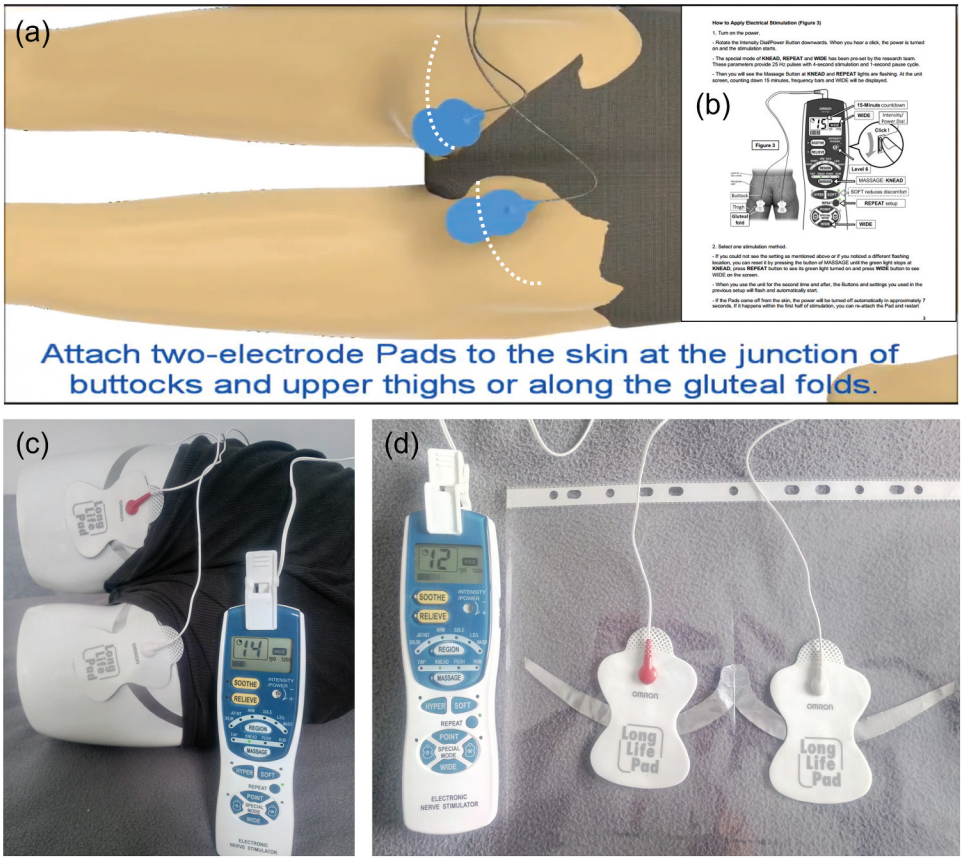

Figure 2. Interventional training options: (a) animation tutorial video, (b) printed instruction manual, (c) live demonstration via video conference using a mannequin, and (d) hands-on practice with a gluteal model.

Table 2. Timeline of the protocol per participant, weeks in study protocol.

Activities	0	W1	W2	W3	W4
Self-screening survey	X				
TES 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				
TES tutorial and practice on dummy (video conference)	X				
Home					
Intervention (TES – 4 weeks)		☐			☐
Bladder diary and adverse event recording (4 weeks)		☐			☐
Phone call or video conference weekly		X	X	X	X
NBSS/TES satisfaction questionnaire after TES use					X
Completion and return					X

NBSS: Neurogenic Bladder Symptom Score; TES: Transcutaneous Electrical Stimulation.

electrode sites before and after each stimulation session, recording the findings in a logbook. Alternatively, study data could be collected and managed using the Research Electronic Data Capture Tool (REDCap, Version 6.12.1, Vanderbilt University), administered by the University of Auckland. REDCap is a secure web platform designed for building and managing online databases and surveys to support data capture in clinical research studies (Harris et al., 2019; Harvey, 2018).

Data analysis

Descriptive statistics were employed to calculate the percentage of adherence to the prescribed TES protocol, offering insights into the feasibility, compliance, and satisfaction with TES therapy at home. To assess changes in NBSS over the study period, mean score differences were calculated by comparing post-TES scores with baseline (pre-TES) scores. Given the small sample size, the Shapiro-Wilk test was used to assess data normality (Ghasemi & Zahediasl, 2012). Statistical significance ($p < .05$) was determined using paired t-tests.

Results

Sample description

During the COVID-19 restrictions, 41 individuals with spinal cord injuries were screened for this study. Of these, 24 met the inclusion criteria and were invited to participate, with 18 providing consent. However, 2 participants did not respond to further contact after receiving the study packages prior to TES training. Additionally, 1 participant withdrew before beginning stimulation due to an unrelated medical issue that required hospitalization and bowel surgery (Figure 3).

All 15 subjects who consented to participate began the TES protocol and completed the 4-week trial. Participant characteristics are detailed in Table 3. The participants had a median age of 43 years with an interquartile range (IQR) of 18.5 years, and the median time since injury was 4.0 years, ranging from 1 to 16 years. The group comprised 10 females and 5 males. Among them, 5 had quadriplegia, 10 had paraplegia, and 4 had complete injury. Six participants were on anticholinergic bladder medications, 6 had received Botulinum toxin (Botox) injections for bladder management, and 3 used supplements to prevent urinary tract infections (UTIs). No participants withdrew or dropped out after initiating the 4-week protocol.

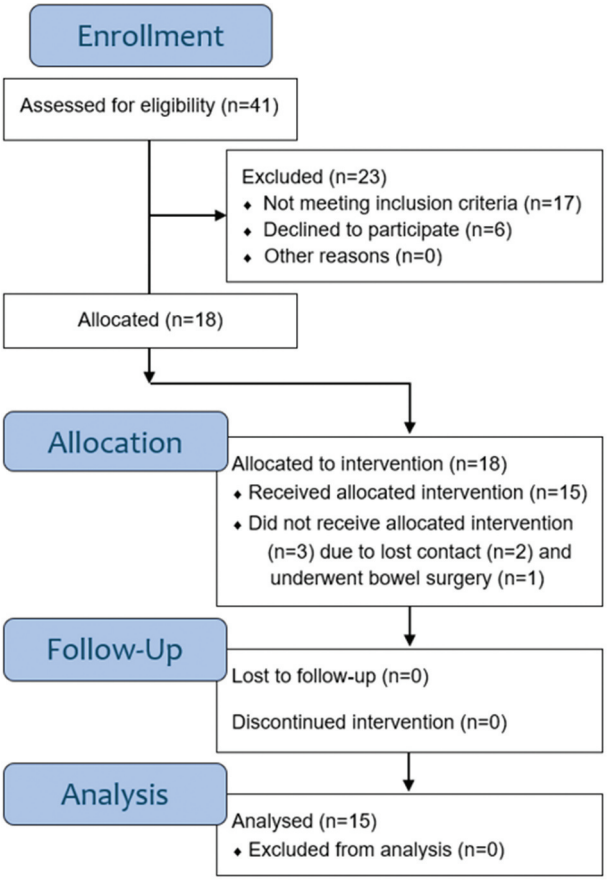

Figure 3. Participant recruitment flow diagram.

Safety and adverse events

TES therapy was generally well-tolerated, with typical reactions, for instance, mild muscle and anal sphincter contractions and tingling at the stimulation site. No significant adverse events, such as pain, discomfort, allergies, skin irritation, electrical burns, or autonomic dysreflexia, were reported. Four participants noted cloudy or foul-smelling urine, which resolved with hydration and without UTI symptoms; urine tests remained negative throughout the 4-week trial, and participants were closely monitored.

Compliance and satisfaction

All 15 subjects (100%) completed the 4-week TES protocol, including the questionnaires and surveys, demonstrating strong adherence to the study. Participants expressed 80% confidence in using the TES device throughout the trial, with 97% finding it easy to operate daily. Additionally, 87% of

Table 3. Study participants and description.

Subject	Age (y)	Gender	DSI (y)	LOI	ASIA	Medications	Bladder management
1	49	M	2.5	C7	B	Solifenacin	CIC
2	32	F	2	T4–5	C	none	CIC
3	52	M	5.5	T4	A	Solifenacin	CIC+Botox
4	35	F	5.5	T4	A	Oxybutynin	CIC+Botox
5	43	F	5	T11	D	D-mannose	CIC
6	44	F	2	C6–7	D	none	CIC+PFMEs
7	48	M	16	T12	C	Solifenacin	CIC+Botox
8	65	F	4	T11–12	B	D-mannose	CIC+PFMES
9	56	M	9	C7	D	Potassium Citrate	CIC
10	43	F	1	T12	D	none	CIC
11	30	F	5	T4	A	none	CIC
12	30	F	7	T4–6	B	none	CIC+Botox
13	28	M	3	C7	A	Solifenacin	CIC+Botox
14	21	F	3	T10	B	Solifenacin	CIC+Botox
15	24	F	2	C5	C	none	CIC
Median	43 IQR 18.5	10F, 5M	4.0 (1–16)	5C, 10T	4A,4B,3C,4D		

ASIA: American Spinal Injury Association Impairment Scale; BOTOX: Botulinum Toxin injection; CIC: Clean Intermittent Catheterization; DSI: Duration Since Injury (yrs); LOI: Level of Injury; PFME: Pelvic Floor Muscle Exercise; SCI: Spinal Cord Injury; C: Cervical; T: Thoracic.

participants indicated a desire to continue using TES for bladder function improvement, and 80% would recommend the device to others with SCI. While 77% of participants were overall satisfied with the TES device, 66% reported symptom improvement. The device was well-received in terms of safety and comfort, with 97% reporting no complications and 94% feeling comfortable using it. Moreover, 96% found the instructions clear, and 85% found the device easy to attach and remove, highlighting its user-friendliness (Figure 4).

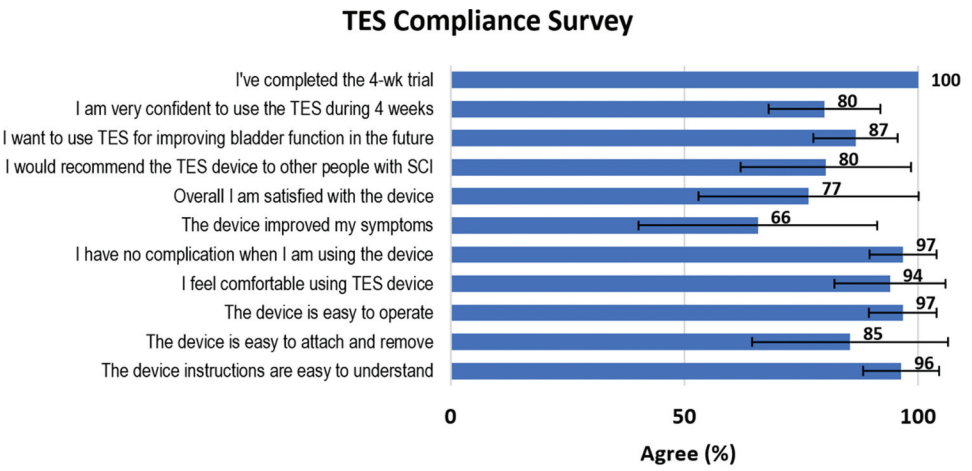

Figure 4. Mean responses with standard error bars to questionnaires on the TES compliance survey.

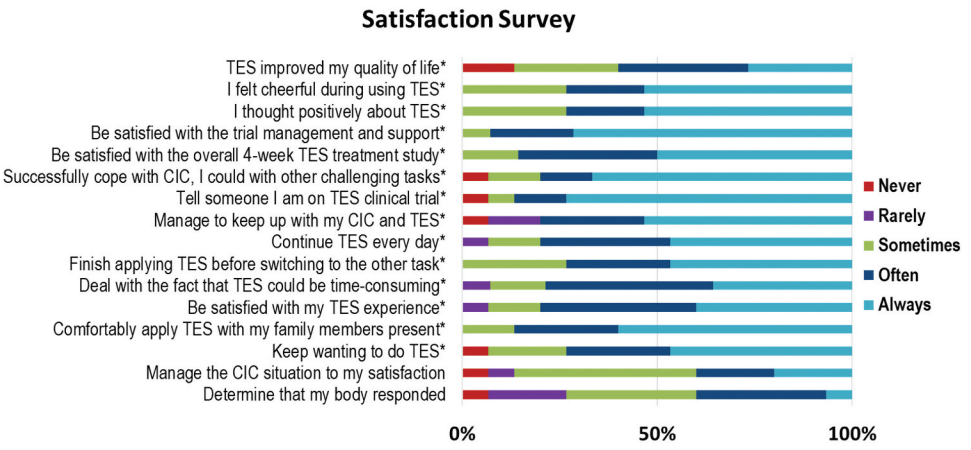

Figure 5. Participant responses to the TES satisfaction survey, graded on a 5-point likert scale (1 = never to 5 = always). One-sample t-tests compared mean scores against the neutral midpoint (3), with asterisks (*) denoting statistically significant differences ($p < .05$).

Seven of the 15 subjects were completely satisfied (always) with the overall 4-week TES treatment at home, while 10 subjects were strongly satisfied (always) with the trial management and support (Figure 5). Notably, 53.3% of participants reported always feeling cheerful and thinking positively about TES throughout the trial. Additionally, 66.7% expressed confidence in managing other challenging tasks alongside their regular CIC routine, and 73.3% of participants shared their involvement in the TES clinical trial with others. Although 46.7% of participants consistently applied TES daily and finished the treatment before moving on to other tasks, 42.9% acknowledged that TES could be time-consuming. While 60% felt comfortable using TES around family members, only 46.7% were always motivated to continue using TES. The trial also highlighted that 46.7% of participants were sometimes able to manage their CIC situation to their satisfaction, and 33.3% felt that their bodies responded to the treatment. Overall, these results indicate a generally positive response to TES, with a majority of participants expressing satisfaction, confidence, and willingness to integrate TES into their daily routines, despite some challenges.

The NBSS is a validated 24-item questionnaire that evaluates bladder symptoms such as incontinence, storage, voiding, and consequences, with higher scores (0 to 78) indicating a greater neurogenic bladder symptom burden (Welk et al., 2018). Pre- (baseline) and post-TES NBSS scores are shown in Table 4. A reduction of more than 25% in the total NBSS was reported by 7 subjects. Statistical analysis showed significant symptom improvement in ten participants (66.7%, $p < .05$), with a large treatment effect ($d = 1.24$, 95% CI [0.72–1.76]). Improvements varied substantially between individuals, ranging from 20.0% to 93.3% reduction in symptoms,

Table 4. Measurement of NBSS, quality of life and functional improvement.

	NBSS			Improved function				
Subject	Pre->Post	Reduced (%)	TES- improved QoL	Bladder	Bowel	Sexual	Spasticity	Muscle weakness
1	11->5*	−55	Often	Yes				
2	15->1*	−93	Always	Yes	Yes		Yes	Yes
3	21->19	−10	Often	Yes		Yes		
4	26->24	−8	Sometimes	Yes				
5	29->28	−3	Always	Yes	Yes			Yes
6	23->17*	−26	Sometimes	Yes	Yes			
7	37->29*	−22	Often					
8	32->31	−3	Often	Yes				
9	16->10*	−38	Never		Yes			
10	23->15*	−35	Sometimes	Yes	Yes			
11	33->21*	−36	Often					
12	19->17	−11	Always	Yes				
13	35->23*	−34	Sometimes	Yes	Yes	Yes		
14	37->28*	−24	Never	Yes				
15	15->12*	−20	Always	Yes		Yes	Yes	
	10 cases p < .05	7 cases >25%	2/15 Never	12 cases	6 cases	3 cases	2 cases	2 cases

NBSS: Neurogenic Bladder Symptom Score; QoL: Quality of Life. *$p < .05$, paired t-test.

demonstrating that TES therapy offers clinically relevant benefits for managing neurogenic bladder symptoms. According to the satisfaction questionnaire, 13 subjects felt that TES improved their quality of life, with ratings of Sometimes (4 subjects, 26.7%), Often (5 subjects, 33.3%), and Always (4 subjects, 26.7%). However, 2 subjects disagreed due to issues with urinary leakage and lack of improvement in bladder function, respectively. Additionally, 12 out of 15 subjects reported improvement in bladder function, while 6 reported improvements in bowel function, 3 in sexual function, 2 in spasticity, and 2 in muscle weakness (Table 4).

Discussion

Telehealth trial implementation efforts

The telehealth trial utilized multiple methods to support the project, including a webpage, mobile app, phone calls, SMS alerts, messaging

apps, e-mail, video conferencing, video tutorials, live demonstrations/training, and postal/courier services, ensured that participant had multiple options to choose, and the study could proceed despite pandemic restrictions. There is potential benefit in developing an all-in-one telehealth trial platform that integrates these various components. Such a unified platform could streamline participant recruitment, administrative tasks, clinical trial management, data collection, and engaging communication throughout the trial process, leading to greater efficiency and cost-effectiveness. Conducting clinical trials remotely minimized interpersonal contact, reduced travel costs, maintained participant safety, allowed treatment with family support, and potentially improved delivery methods and clinical outcomes in home-based health care (Nomali et al., 2023).

Limitations and challenges

We initially planned to enroll 20 participants in the study over a 12-month period. While 41 individuals accessed self-screening and contacted our research team, only 24 were deemed eligible, and 15 consented to participate and completed the 4-week study. We hypothesize that the low enrollment rate may be due to the limited number of individuals with SCI who use CIC. Most of the SCI patients experience bladder dysfunction and use different bladder management options, such as drug treatment, CIC, indwelling catheterization, condom catheter for men, Credé maneuver, suprapubic cystostomies, or other surgical interventions (Mansoor & Rathore, 2019). Although nearly 60% of patients who cannot void voluntarily after SCI perform CIC at discharge from rehabilitation, only half of them continue this practice at the 5-year follow-up (Zlatev et al., 2016). A significant limitation of this study was the restricted internet access, which potentially affected participation rates, particularly among participants in remote areas. As the study primarily relied on online platforms and video calls, the lack of broadband infrastructure in remote locations and the high cost of internet services may have hindered the recruitment of some potential participants (Bernard et al., 2024; Patsakos et al., 2024). This valuable information was brought to our attention by one of our participants, highlighting a technical issue we had not initially anticipated.

Opportunities and future

The COVID-19 pandemic significantly impacted study recruitment and participant engagement. During the initial 5 months, 10 participants completed the 4-week trial, benefiting from increased availability during lockdowns to perform daily TES sessions and maintain self-reported bladder diaries. However, as restrictions eased and work routines resumed, 3 participants

completed the study with daily TES sessions and final questionnaires but neglecting the daily bladder self-records. To address this adherence decline, digital tools such as AI voice assistants, which have shown promise in supporting self-care and monitoring at home, can facilitate more frequent and effortless data collection, potentially enhancing engagement and adherence to the study protocol (Duong & Valero, 2024). Additionally, as a pilot trial, this study had notable limitations including a small sample size, short intervention duration, and lack of long-term follow-up. Nevertheless, it provided valuable preliminary data, establishing the feasibility of a remote, self-administered intervention with monitoring and demonstrating potential safety and clinical benefits. These findings will inform larger controlled trials to further explore home health care benefits, including cost-effectiveness through reduced hospital visits and the long-term impact on quality of life for individuals with SCI.

Conclusion

This study demonstrates the feasibility and high compliance of a telehealth trial for home-based TES therapy in SCI patients, with all participants successfully completing the protocol. The study showed strong user satisfaction and potential for improving bladder function, while overcoming access barriers typically faced by SCI patients. These findings suggest that telehealth approaches could set a new standard for remote intervention and monitoring in SCI research, advancing telemedicine and home health care.

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Disclosure statement

No potential conflict of interest was reported by the author(s).

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Clinical trial registration

Australia New Zealand Clinical Trials Registry (https://www.anzctr.org.au): ACTRN126 21000869875.

Data availability statement

Data is available on request by contacting the corresponding author.

Ethic statements

This clinical study has been approved by the Health and Disability Ethics Committee (21/STH/171) and is registered with the Australia New Zealand Clinical Trials Registry (ACTRN12621000869875).

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