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Protocol

Effect of home-based acupressure on constipation in people with spinal cord injury: A study protocol for a randomized controlled trial with a mixed-method approach

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ABSTRACT

Introduction: People with spinal cord injuries often experience constipation. Common surgical and conservative treatments for constipation may have long-term adverse events that outweigh their benefits in relieving symptoms temporarily. This proposed study aims to investigate the effects of acupressure on constipation, quality of life, psychosocial well-being, and bowel habits in a community-based spinal cord injury population.

Methods: This two-parallel-group, open-label controlled trial will randomly assign 78 eligible participants to the intervention or control groups. After receiving defecation education, the intervention group will perform 10-days of self-operated or caregiver-assisted acupressure manually, while the control group will conduct a manual light touch on the abdomen. The study will assess participants' constipation severity as the primary outcome, along with secondary outcomes including quality of life, psychosocial well-being, bowel habits, and participants' perceptions of acupressure. Participants' perceptions of acupressure will be assessed through semi-structured focus group interviews after intervention. Other measurements will be taken at baseline, immediately post-intervention, and at a 1-month follow-up. The generalized estimating equations and content analysis will be employed to analyze the intervention effect and interview data, respectively.

Discussion: This study will be the first to evaluate the effect of applying acupressure in people with spinal cord injuries to improve their constipation. The intervention may offer an alternate, non-invasive therapy option for individuals with spinal cord injuries who live in the community.

Trial registration: This study is registered on ClinicalTrials.gov, ID: NCT05558657. Register date: September 28, 2022.

1. Introduction

Spinal cord injury (SCI) is a multi-sensory, motor, and autonomic dysfunction caused by a variety of acute and chronic central nervous system lesions [1]. With the development of transportation, construction, and other industries, the incidence of SCI is increasing year by year. In 2019, there were estimated to be 0.7–1.2 million incident cases of total SCI globally with an age-standardized prevalence rate of 231–290 per 100,000 people, causing a significant impact on all aspects of the patient's life and placing a heavy burden on the family and society [2]. In Hong Kong, according to the hospital authority, there are thousands of people with SCI in the community, with approximately 200 new instances of SCI caused by accidents each year [3]. Despite the vast number of people with SCI in the community, they usually do not receive sufficient rehabilitation as compared to those immediately after SCI [4].

Abbreviations: SCI, Spinal cord injury; TCM, Traditional Chinese Medicine; RCT, Randomized controlled trial; CAS, Constipation assessment scale; PAC-QoL, Patient Assessment of Constipation Quality of Life Questionnaire; DASS-21, Depression Anxiety Stress Scales 21; ITT, intention-to-treat.

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Because of impaired autonomic function, sensory deficits, motor paralysis, decreased physical mobility, and associated psychological factors, people with SCI are prone to experience neurogenic bowel dysfunction, with constipation being a commonly reported symptom [5,6]. Studies have indicated that constipation affects 27 % to 62 % of people with SCI [7,8], significantly surpassing the general population's constipation rate of 12–17 %. [9]. Constipation in people with SCI can cause a series of serious sequelae, such as hemorrhoids and bowel obstruction, leading to poor physical health and increased hospitalization rates [10]. Due to the impairment of physical functioning, constipation also adversely affects the quality of life of people with SCI [11,12]. In addition, constipation has a detrimental effect on mental health. A cross-sectional research in Taiwan investigated 142 people with SCI and found that decreased bowel function was associated with depression [13]. Indeed, constipation also places an extra burden on the healthcare system. According to a 2019 report by the Bowel Interest Group, constipation contributed to 163,100 hospital days annually in the United Kingdom, costing the National Health Service £162 million to manage [14].

At present, the treatment of constipation can be broadly divided into surgical and conservative approaches [15]. Surgeries, such as the Malone antegrade continence enema, percutaneous endoscopic colostomy, and sacral anterior root stimulator, have been verified to have beneficial effects [16]. However, due to its invasiveness, irreversibility, and potential complications, surgery is only recommended for people with severe chronic constipation unresponsive to other treatment options [16]. Laxatives are the most commonly used conservative treatment, but long-term use may lead to drug dependence, sometimes aggravate constipation, and even cause colonic melanosis [17].

Accordingly, treatment with fewer adverse events and free of drug-drug interaction for constipation is required. Studies have begun to emphasize the effect of complementary and alternative treatments for constipation. A number of complementary and alternative therapies, such as acupuncture [18], abdominal massage [19], and biofeedback [20], have been tested for the prevention and treatment of constipation. Acupressure is a non-invasive complementary therapy based on the fundamental principles of traditional Chinese medicine (TCM). By manually applying pressure along meridian-positioned acupoints, acupressure can stimulate the flow of qi (the energy that restores equilibrium within the body) and subsequently regulate visceral functions to treat diseases [21,22]. The role of acupressure in relieving constipation has been demonstrated in different populations. A randomized controlled trial among patients with constipation showed that perineal self-acupressure could significantly improve bowel function, quality of life, and health and well-being when compared with those receiving standard treatment [23]. A systematic review of five randomized controlled trials (RCT) showed that auricular acupressure had a positive effect on normalizing stool shape and reducing constipation symptoms in patients with leukemia undergoing chemotherapy [24]. Acupressure in patients with psychiatric conditions also demonstrated significant effectiveness in improving constipation symptom severity (Cohen's d = 1.0) and quality of life (Cohen's d = 0.5) compared to sham acupoints acupressure [25].

To the best of our knowledge, the application of acupressure in treating constipation in the SCI population has yet to be studied. Therefore, we designed this RCT to determine the effect of acupressure on the constipation of community-dwelling people with SCI.

2. Methods

2.1. Aims and research hypotheses

This study aims to evaluate the effect of home-based acupressure on alleviating constipation in individuals with SCI living in the community and to explore the participants' perceptions of this intervention. We hypothesize that compared to the control group, participants in the acupressure group will show significantly greater improvements in (1) severity of constipation, (2) perceived quality of life, (3) psychosocial well-being, and (4) bowel habits.

2.2. Study design

It will be an open-label, two-parallel-arm RCT with a mixed-method approach. Eligible participants will be randomly assigned to an intervention or control group for a 10-day intervention and a 1-month follow-up. Employing a qualitative descriptive design [26], focus group interviews will be conducted with participants in the intervention arm after the acupressure to investigate their perspectives on strengths, weaknesses, and suggestions for improving the intervention. This protocol is reported following the guideline of the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) [27], a SPIRIT schedule of enrollment, interventions, and assessments is shown in Table 1. The flow chart of the study is presented in Fig. 1. This study has been registered in ClinicalTrials.gov (No: NCT05558657).

2.3. Participants

Inclusion criteria for study participation include: (1) being Hong Kong residents aged 18 years or older, (2) having an SCI diagnosis for over 6 months and living in the community, (3) demonstrating the willingness and ability to learn and engage in acupressure (or having a caregiver to assist if self-operating is not feasible), and (4) experiencing difficulties with defecation (less than three defecations per week) [28] or having concerns related to defecation.

Individuals with SCI will be excluded from the study if they meet any of the following criteria: (1) currently undergoing other TCM treatments or receiving interventions related to defecation or bowel functions, (2) being unable to attend the training sessions due to personal reasons, (3)

Table 1
SPIRIT schedule of enrollment, interventions, and assessments.

Time point	Study period			
	Screening	T0: 0 day treatment (baseline)	T1: 10 day treatment	T2: 1 month after treatment
Enrolment				
Eligibility screen	X			
Informed consent	X			
Allocation	X			
Interventions				
Acupressure & defecation education		X	X	
Abdomen touching & defecation education		X	X	
Assessments				
Basic information		X		
CAS		X	X	X
PAC-QoL		X	X	X
DASS-21		X	X	X
The frequency of laxative/enema use		X	X	X
Frequency & duration of defecation		X	X	X
Perceptions of acupressure			X	
Adverse events recording		X	X	X

CAS Constipation Assessment Scale, PAC-QoL Patient Assessment of Constipation Quality of Life Questionnaire, DASS-21 Depression Anxiety Stress Scales 21.

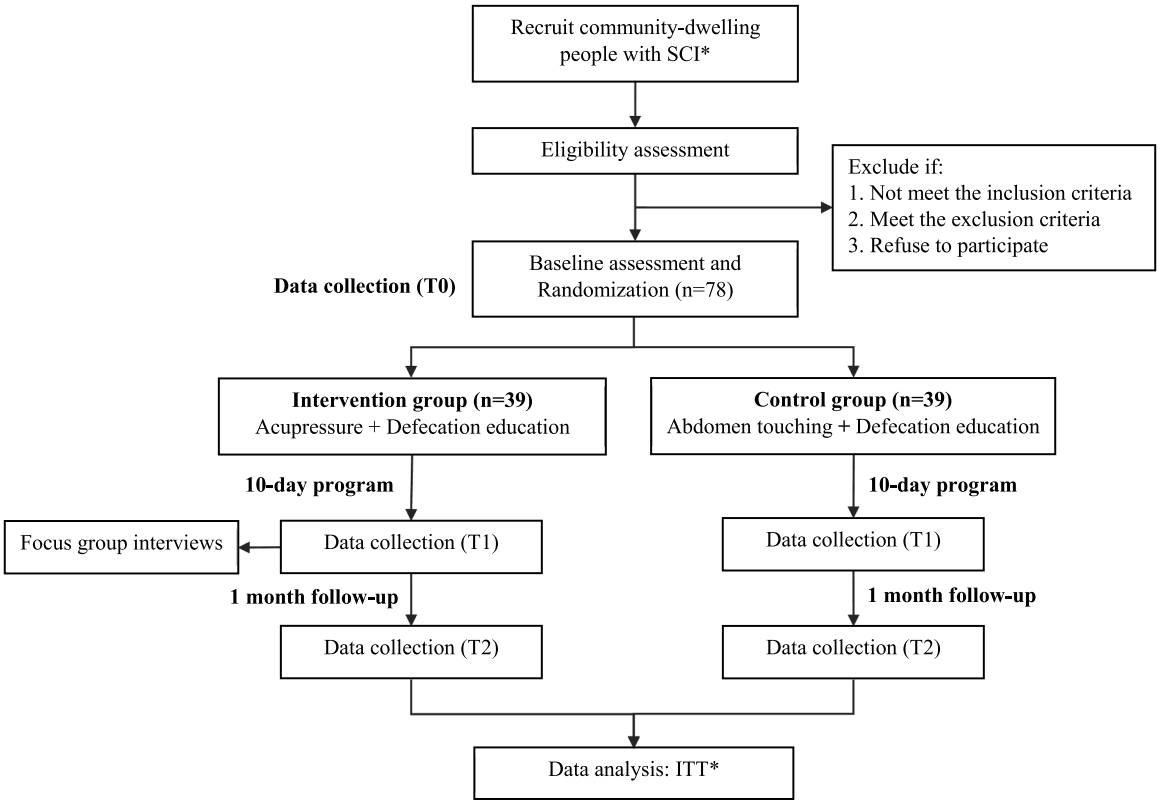

Fig. 1. Flow chart of the study. **SCI spinal cord injury, ITT: intention-to-treat.*

having a history of gastrointestinal organic disease, or (4) having severe metabolic diseases, cardiovascular, cerebrovascular, or mental illnesses.

2.4. Sample size

In the absence of previous similar research on acupressure for constipation in the SCI population, this study estimated sample size based on the effect size of acupressure in improving the constipation of patients with psychiatric conditions in a previous double-blind RCT (Cohen's $d = 1.0$) [25]. Taking into account a moderate intervention effect (Cohen's $d = 0.7$), 2-tailed tests of significance, and an attrition rate of 15 %. It is determined that a total of 78 participants, with 39 in each group, is needed for a statistical power of 80 %, and an alpha level of 5 % according to an independent-sample *t*-test using the statistical program G*Power version 3.1.9.7 [29].

The focus group interviews will utilize purposive sampling, with 4–6 participants included in each group. To ensure a diverse range of perspectives, participants (in the intervention arm) with the largest and the least difference in scores on the Constipation Assessment Scale [30] before and after the acupressure will be preferentially recruited for the interviews. The sample size will be determined based on data saturation, where concurrent data collection and analysis are conducted until no new information is obtained [31].

2.5. Recruitment

Study participants will be recruited from the "Hong Kong Direction Association for the Handicapped", a non-governmental organization devoted to helping Hong Kong citizens with severe disabilities like SCI. Potential participants will be contacted by phone and/or email to extend an invitation, and advertising materials will also be used to promote attendance. Following the 10-day acupressure intervention, change scores on the Constipation Assessment Scale will be calculated. A project assistant will invite the purposive sample that meets the aforementioned eligibility criteria via mobile messages, ensuring representation from participants who experienced both improved and worsened constipation symptoms in each focus group. The trial is currently in the participant recruitment stage, which began on March 1st, 2023.

2.6. Randomization and blinding

Eligible participants will be randomly and equally assigned to intervention and control groups using the block randomization method. The six participants adjacent to each other at the time of inclusion in the study will be used as a block, with 20 different possible permutations for each block. A specific block group will be selected based on random numbers generated by SPSS 26.0, and the assignment will be set according to that block for the six participants included. To ensure allocation concealment, the random assignment will be performed by an administrative staff outside the research team using an online randomization service website Sealed Envelope (https://sealedenvelope.com/).

Upon completion of informed consent and baseline assessment, participant numbers will be entered into the Sealed Envelope website to determine group assignment. The group assignment will subsequently be disclosed to the research team and participants. Because of the intervention's nature, participant blinding will not be performed. However, participants will be reminded to maintain confidentiality and refrain from discussing intervention details with individuals in the control group to prevent potential contamination. The staff responsible for data entry and analysis will be unaware of the group allocation.

2.7. Trial procedures and follow-up

Each participant will have an online interview conducted by a project assistant for screening and three follow-up visits (baseline, post-intervention, and 1-month follow-up). Upon enrollment, eligibility screening will be performed and informed consent will be sought from participants. An online self-reported baseline assessment will be

conducted after recruitment and before randomization. The baseline evaluation will comprise participant sociodemographics, SCI-related information, and outcome indicators (including CAS, PAC-QoL, DASS-21, and bowel habits).

Prior to the start of the interventions, participants will be given a pre-made diary. They will be instructed to record their defecation and completion of assigned interventions during the study period. During the study, the same project assistant will monitor the groups daily via WhatsApp, track attendance and dropouts through diaries, and gather questions or concerns about interventions from participants. These inquiries will be addressed regularly by a Chinese medicine practitioner.

Participants will be asked to complete the same online outcome questionnaires (including CAS, PAC-QoL, DASS-21, and bowel habits) at post-intervention and one-month follow-up, using a link provided through WhatsApp. Additionally, after the post-intervention assessment, two researchers (one serving as the facilitator and the other as the observer, both with master's degrees in psychology) will conduct the online (Zoom) focus group interviews. The interviews will last approximately 40–60 min and will be video-recorded with participants' consent.

2.8. Interventions

First, apart from the assigned intervention, participants in both groups will receive defecation education through a booklet developed by the research team (Appendix A). The booklet will cover the concept of constipation, its causes, effects, and preventive strategies based on established guidelines and relevant research evidence [6,10]. These strategies encompass guidance on creating a balanced meal plan and maintaining adequate hydration, engaging in regular physical exercise to enhance gastrointestinal motility, establishing regular defecation habits, and understanding appropriate defecation environments and postures.

2.8.1. Intervention group: acupressure on the abdomen, back, and limbs

The intervention protocol was developed based on a comprehensive review and followed by expert validation. Specifically, according to TCM theories and previous research evidence [25,32-34], we selected LI4 (Hegu), ST36 (Zusanli), ST25 (Tianshu), and RN12 (Zhongwan) acupoints as the acupressure scheme. The protocol was then reviewed by a panel of seven TCM experts (including TCM practitioners and university professors) for suitability in relieving constipation. Experts recommended the inclusion of acupoints on the back, in addition to the abdomen and limbs, to address the incomplete sensations experienced by individuals with SCI. The Bladder Meridian of Foot Taiyang was advised to supplement the back acupoints, as it facilitates intestinal peristalsis and relieves constipation. Through consultations and modifications, the final regimen consisted of 11 acupoints on the abdomen (RN12 for Zhongwan, RN4 for Guanyuan, and ST25 for Tianshu), back (BL20 for Pishu, BL21 for Weishu, BL22 for Sanjiaoshu, BL23 for Shenshu, BL24 for Qihaishu, and BL25 for Dachangshu), and limbs (LI4 for Hegu and ST36 for Zusanli). The specific location and function of each acupoint are shown in Table 2.

Participants or their caregivers will perform home-based acupressure, guided by video demonstrations conducted by a TCM expert. Before conducting an acupressure session, participants or caregivers will receive instructions on study preparations and precautions. This will involve practicing the basic manual techniques of pressing, kneading, and pushing using a pillow as a practice tool before applying them to the body. Participants will be advised to assume a comfortable supine or sitting position, with the TCM expert demonstrating how to use a pillow to support the knees and back accordingly. Additionally, the video demonstration will provide detailed explanations and instructions on the specific locations of the 11 acupoints involved in the intervention and the corresponding manual techniques to be applied.

Building upon the previous acupressure program [25], each acupressure session in this study will have a duration of approximately 15 min and will be conducted twice daily, 30 min after meals, for a consecutive period of 10 days. Participants will have the option to choose between two sets of acupressure: (1) Acupressure of the abdominal and back acupoints in a seated position, or (2) Acupressure of the abdominal and limb acupoints in a supine position. During the acupressure sessions, participants or their caregivers will apply pressure to specific acupoints utilizing different techniques and frequencies. The links to the full set of acupressure can be found in Appendix B and C.

Table 2
The specific location and function of acupoints.

Acupoints	Location	Function
RN12	4 cun[a] above the navel along the midline of the abdomen	Adjust viscera *qi* and blood, invigorate the spleen, and replenish *qi*
RN4	3 cun below the navel along the midline of the abdomen	Promote the yang *qi* of the internal organs, and regulate the spleen and stomach
ST25	2 cun lateral to the navel	Relax the large intestine, regulate *qi*, and eliminate stagnation
BL20 BL21 BL22 BL23 BL24 BL25	1.5 cun lateral to the posterior midline, below the spinous processes from T11 to L4	BL20 and BL23 can help to invigorate the spleen and kidney; BL21 can establish harmony in the stomach; BL22 can help to improve borborygmus and abdominal distension; BL24 and BL25 can improve abdominal distension and hemorrhoids
LI4	The midpoint of the radial side of the second metacarpal bone	Clear heat, open the orifices, and promote gastrointestinal peristalsis
ST36	4 finger-breadth below the tip of the kneecap, lateral to the ridge of the bone	Regulate the spleen and stomach, improve the efficiency of *qi* and blood circulation

[a] cun: the unit of measurement for acupoints, and 1 cun is equal to the width of the inter-phalangeal joint of the thumb.

2.8.2. Control group: manual light touch of the abdomen

After receiving training in abdomen touching techniques from a TCM expert, the project assistant will guide control group participants or their caregivers in performing manual light touch on the abdomen. This touch can be applied in any direction or body position and will take place in the participants' home setting. In keeping consistent with the intervention group, abdomen touching will also be administered twice daily for approximately 15 min each for 10 days.

2.8.3. Training and intervention fidelity

To ensure proficiency in acupressure techniques, participants will undergo training before the formal intervention. Throughout the training period, participants will receive acupressure video demonstrations via WhatsApp, any questions regarding the intervention will be addressed by a Chinese medicine practitioner for guidance and assistance. The fidelity of the intervention will be assessed by recording the frequency of the specified intervention in the participants' diary. Completion of at least 50 % of the acupressure and abdomen touching sessions will be considered successful completion of the program for the intervention and control groups, respectively.

2.9. Assessments

2.9.1. Sociodemographic and clinical information

A sociodemographic and clinical information form will be used to collect baseline data. Participants' sociodemographic information includes age, gender, residence, marital status, education, employment, ethnicity, and monthly household income. Clinical information will be extracted from the participants' medical histories with their consent, including the duration (time since injury), cause (traumatic/non-

traumatic), type (tetraplegia/paraplegia), location (cervical/thoracic/lumbar/sacral), extent (complete/incomplete injury) of SCI.

2.9.2. Primary outcome

The primary outcome is the severity of constipation as measured by the Constipation Assessment Scale [30]. This 8-item scale is often used to assess symptoms of constipation in the past 7 days, including bloating, number of farts, frequency of bowel movements, pain associated with bowel movements, etc. Participants will be asked to rate each item on a 3-point Likert scale, each item is scored from 0 (no problem) to 2 (severe problem). A higher total score implies more severe constipation symptoms. The Chinese version of this scale has been culturally adapted to the Chinese context and has demonstrated good reliability (Cronbach's α=0.791) and content validity [35].

2.9.3. Secondary outcomes

The secondary outcomes include quality of life, psychosocial well-being, bowel habits, and participants' perceptions of acupressure:

1) The Patient Assessment of Constipation Quality of Life Questionnaire will be employed to measure the quality of life of participants [36]. This 28-item questionnaire includes 4 domains: physical discomfort (items 1–4), psychosocial discomfort (items 5–12), worries and concerns (items 13–23), and satisfaction with constipation symptoms and treatment (items 24–28). The questionnaire investigates the quality of life of people in the past two weeks, using a 5-point Likert scale, assigning 0–4 points for various discomforts from "not at all" to "extremely". Each domain score and total score are the average scores of the domain items and all items, respectively. Higher scores indicate poorer quality of life. The questionnaire has demonstrated good test-retest reliability (intraclass correlation coefficient=0.84) and internal consistency (Cronbach's α=0.93) in the Chinese constipation population [37].
2) The Depression Anxiety Stress Scales 21 will be used to measure participants' psychosocial well-being [38,39]. This 21-item scale consists of three subscales of depression, anxiety, and stress, and each subscale contains 7 items. The scale investigates the negative emotional experience or the corresponding physiological response in the last week. Higher scores imply more severe negative affectivities with grading on a 4-point Likert scale. This scale has shown good psychometric properties in Hong Kong Chinese-speaking people [40].
3) Bowel habits will be assessed during each visit by recording the frequency of laxative and glycerine enema use, as well as the frequency and duration of defecation in the past week.
4) To evaluate participants' perceptions of the acupressure, focus group interviews will be conducted at post-intervention. The semi-structured interview questions will mainly include the experience and perception of the program, the difficulty of implementing acupressure, the suggested improvements, etc. The interview guide can be found in Appendix D.

2.10. Safety

Participants will be advised to inform the research team of any adverse effects experienced during treatment and follow-up. Although previous research has not reported any serious adverse effects related to acupressure [41], participants or their caregivers will still be reminded to remain vigilant for any unexpected reactions to acupressure. In the event that participants exhibit symptoms of autonomous dysreflexia, such as headaches or upper body sweating [42], they should cease acupressure immediately and rest with their heads elevated. If symptoms persist, appropriate referral and prompt treatment should be sought. Additionally, participants will be instructed to examine their skin before each acupressure session, and if any wounds, boils, swelling, scars, or tenderness are present, acupressure may not be suitable. In such cases, participants may skip that particular area or consult the research team for alternative acupoints.

2.11. Data analysis

Quantitative and qualitative results will be reported following the guidelines of the Consolidated Standards of Reporting Trials [43] and the Consolidated Criteria for Reporting Qualitative Studies [44], respectively.

Quantitative analysis will be performed using IBM SPSS 26.0 software. All statistical tests will be two-sided, and a p-value < 0.05 will be considered statistically significant. Descriptive statistics will be used to summarize the data based on the types and distributions of the variables (i.e., means and standard deviations, median and interquartile range, frequencies and percentages). Baseline characteristics will be compared between the intervention and control groups, as well as between the study sample and the dropout sample. The chi-square test will be employed for categorical variables, while the *t*-test and Mann-Whitney U test will be used for continuous variables with normal and skewed distributions, respectively. Any covariates that exhibit a significant association at baseline will be adjusted for during the analysis of intervention effects.

The effect of acupressure will be evaluated using an intention-to-treat approach as the primary analysis. If the percentage of missing values exceeds 5 %, the missingness mechanisms will be analyzed, and multiple imputation will be conducted. Generalized estimating equations will then be employed to test the main effects of group, time, and group $\times$ time interaction effects [45]. Post-hoc comparisons will be conducted to assess significant between-group differences based on the estimated marginal means derived from the generalized estimating equation models. Additionally, a sensitivity analysis using per-protocol analysis will be conducted to analyze the intervention effect between the intervention and control groups [46]. Finally, subgroup analyses will be performed between certain variables (for example, self-help and caregiver-lead acupressure, or complete and incomplete SCI).

Qualitative analysis will be conducted utilizing NVivo 11 (QSR International [Americas] Inc.). After the focus-group interviews, the recordings will be transcribed verbatim immediately. Content analysis will be utilized for analyzing the transcripts [47,48]. Two researchers will independently conduct the analysis process, which includes the following steps [49]: (1) Reading each transcript multiple times to fully comprehend the content; (2) Dividing the text of the transcripts into meaningful units and condensing them into a shortened and precise version; (3) Identifying ideas and words with similar meanings to establish new codes; (4) Categorizing the codes derived from the transcripts to address the research questions. Following independent data validation, a research team meeting will be held to discuss and re-categorize codes through continuous comparisons.

2.12. Data management and quality assurance

The questionnaires will be checked for completeness immediately after completion. Data entry verification and quality checks will be conducted through random audits of 10 % of cases. An administrative staff outside the study will be in charge of regularly monitoring the efficiency, reliability, and security of data collection. The database will be password-protected and will only be accessible to the research team. In addition, all participants' information will be kept for 5 years after the study ends, after which it will be destroyed. Any discrepancy will be reached by consensus through discussion with the research team.

For qualitative data, the thick description method will be employed to increase transferability. An audit trail for the entire research process will be kept to enhance the confirmability and dependability of the research.

2.13. Ethical considerations

This study has been approved by the Institutional Review Board of the Hong Kong Polytechnic University (HSEARS20221031003) and will be conducted under the guidance of the Declaration of Helsinki. Any changes to the protocol will be reported to the Committee. After a detailed explanation of the research purpose, benefits, potential risks, and the rights of participants, informed consent forms from all participants will be obtained. All information about participants will remain anonymous and confidential, and only authorized personnel in the research team will have access to the data. Participation in the study for community-dwelling participants is voluntary, and they can withdraw at any time without penalties.

2.14. Dissemination

The findings will be published in a peer-reviewed academic journal. Registered participants will receive the results of this study on request. Research results may also be presented at academic seminars or conferences.

3. Discussion

This study aims to fill a research gap by conducting the first RCT to evaluate the effect of acupressure in managing constipation among community-dwelling residents with SCI in Hong Kong. Given the limited utilization of acupressure for constipation in this population, this study holds the potential to address significant health concerns and provide insights into the future application of acupressure as a treatment modality for constipation in individuals with SCI.

Our study possesses several notable strengths. First, acupressure presents an attractive non-invasive therapeutic option that is likely to be more readily accepted by individuals [21]. Unlike other alternative therapies such as acupuncture, acupressure eliminates the risk of adverse effects such as bleeding and hematoma due to its non-invasive nature [50]. Furthermore, it avoids hygienic concerns associated with other acupoint interventions, such as blood-borne diseases resulting from improper needle usage. Second, in the absence of readily available community-based rehabilitation services, the self-operated or caregiver-assisted acupressure in our study offers a practical and accessible intervention method. Participants and their caregivers can easily administer acupressure following detailed guidance and supervision from Chinese medicine specialists. This approach extends the potential benefits of acupressure to a larger population of community-dwelling individuals with SCI, facilitating the management of their constipation. Third, our study adopts a comprehensive measurement by assessing the effects of acupressure on constipation, quality of life, psychosocial well-being, and bowel habits, as well as exploring participants' perceptions of the intervention. This holistic evaluation offers a deeper understanding of the physical and psychological benefits that acupressure could provide to individuals with SCI and also suggests potential avenues for further intervention enhancement. Last, the proposed RCT will address the existing gap in the literature by providing high-quality evidence to support the implementation of acupressure as a treatment modality for constipation in the SCI population.

Several potential limitations should be considered in this study. First, the intervention duration of 10 days may restrict the assessment of long-term benefits from acupressure. Future research could explore the incorporation of intensive sessions that facilitate the integration of acupressure into daily life. Second, the one-month follow-up period in this study, based on a previous study among individuals with psychiatric constipation [25], may limit the evaluation of the long-term effects of the acupressure program. Extending the follow-up duration would be valuable for a more comprehensive understanding of the sustained impact. Third, the assessment of constipation in this study relied on the Constipation Severity Scale, bowel habits results, and participants' daily diary records. However, the absence of the comprehensive International SCI bowel function basic data set, which offers a more comprehensive evaluation of neurogenic bowel dysfunction, could be considered a limitation [51]. Future investigations should expand their focus to include neurogenic bowel dysfunction and utilize the standardized assessment provided by this data set. Additionally, the determination of SCI severity in this study was based on the type and extent of SCI, rather than following the International Standards for Neurological Classification of SCI [52]. To ensure consistency and comparability across studies, future research needs to incorporate these international standards, enabling a more standardized assessment of SCI severity.

4. Conclusion

This protocol provides healthcare workers with information on the application of acupressure in community-dwelling individuals with SCI. The anticipated results of this study will contribute evidence to determine the effect of acupressure in managing constipation among the SCI population.

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CRediT authorship contribution statement

Yan Li: Writing – review & editing, Writing – original draft, Supervision, Project administration, Methodology, Funding acquisition, Conceptualization. **Jiaying Li:** Writing – review & editing, Writing – original draft, Project administration, Methodology. **Mengqi Li:** Writing – review & editing, Writing – original draft, Project administration, Methodology. **Yuen Shan Ho:** Writing – review & editing, Methodology, Conceptualization. **Tsz Ching Sun:** Writing – review & editing, Writing – original draft, Project administration, Methodology. **Shanshan Wang:** Writing – review & editing, Methodology. **Wai Kit Wong:** Writing – review & editing, Conceptualization. **Shiping Zhang:** Writing – review & editing, Methodology, Conceptualization. **Rick Kwan:** Writing – review & editing, Conceptualization. **Arnold YL Wong:** Writing – review & editing. **Wing Fai Yeung:** Writing – review & editing, Methodology, Conceptualization.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Data availability

Deidentified research data will be made publicly available when the study is completed and published.

Acknowledgements

We acknowledge the expert panel in reviewing our intervention and their critical feedback on the intervention manual. As of March 2024, over 60 individuals with SCI have successfully enrolled in the study. We sincerely appreciate the interest shown by individuals with SCI in participating in this research.

Supplementary materials

Supplementary material associated with this article can be found, in

the online version, at doi:10.1016/j.eujim.2024.102360.

Appendix

Appendix A Defecation education material.

Appendix B Full set of seated position acupressure (abdomen and back): https://www.youtube.com/watch?v=8EjnVK0Np90.

Appendix C Full set of supine position acupressure (abdomen and limbs): https://www.youtube.com/watch?v=Mynn1VStUMQ.

Appendix D Focus group interview guide.

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