Randomised controlled trial of the Caring Connections intervention to reduce loneliness and perceived social isolation in persons with spinal cord injuries and disorders: study protocol

Sherri L LaVela 1,2, Robert W Motl 3, Beverly Gonzalez 1, Elizabeth Tarlov 1,4, Keith Aguina 5, Charles H Bombardier 6

ABSTRACT

Introduction Perceived social isolation and loneliness are understudied in individuals with spinal cord injuries and disorders (SCI/D). The few existing studies reported that they are common, yet poorly treated, in persons with SCI/D. We developed an intervention called Caring Connections (CC) aimed at reducing loneliness and perceived social isolation in persons with SCI/D. CC is a peer-based, recurrent letter writing programme designed to provide moments of positivity. We will conduct and evaluate a randomised controlled trial (RCT) to assess changes in loneliness and social isolation outcomes between the CC intervention and control conditions in community-dwelling individuals with SCI/D.

Methods and analysis RCT to compare outcomes of community-dwelling individuals with SCI/D undergoing the CC intervention to an attention control group (receiving informational materials on life domains important to a good quality of life). Eligible participants include adults with chronic SCI/D who have been injured for ≥1 year. The primary outcome is loneliness, measured using the UCLA (University of California, Los Angeles) 3-item Loneliness Scale. Other outcomes include perceived social isolation and social support. A post-trial process evaluation will assess perceived benefits, negative impacts and satisfaction with the intervention, and areas for improvement. We will test the hypotheses of reduced loneliness and perceived social isolation in the CC intervention arm from baseline to 6 months and will also measure the magnitude of effect (difference between CC arm and attention control arm). We will use generalised linear models for repeated measures. We will assume a one-tailed, cα=0.05 level of significance for comparisons. Process outcomes will be analysed using mixed methods, including frequencies for the rating items and thematic analysis for open-ended item responses.

Ethics and dissemination This study has received Hines Veterans Affairs Institutional Review Board approval (#1673654). Findings will be disseminated widely through healthcare organisations, peer-reviewed publications and conferences.

Trial registration number NCT05295108

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This study will use a randomised controlled design with an active attention control group to evaluate an intervention intended to reduce perceived social isolation and loneliness in persons with spinal cord injuries and disorders (SCI/D).

⇒ This intervention will fill a knowledge gap in SCI/D care, since there have been no intervention studies, to date, aimed at reducing perceived social isolation and loneliness.

⇒ Caring Connections is a peer-based intervention which is significant because peers with SCI/D play an important role in improving social health, mental health and quality of life in persons with SCI/D.

⇒ The study is limited to Veterans with SCI/D receiving care from Veterans Affairs (VA) facilities, findings may differ for Veterans with SCI/D receiving care outside the VA or civilians with SCI/D.

⇒ Due to the nature of the intervention, we are unable to blind assignment into intervention and control conditions; however, because data collection is self-reported, lack of researcher blinding should have minimal impact on outcome reporting.

INTRODUCTION

In 2018, a national survey 1 concluded that loneliness levels reached an all-time high, with over one-third of the US adults feeling alone or isolated. Loneliness and perceived social isolation are subjective feelings of not belonging, lacking companionship, feeling left out, detached, avoided, unknown and isolated even when around others. 2 Perceived social isolation and loneliness contribute to high blood pressure, poor sleep and high cortisol 3 and predict depression, cognitive decline, cardiovascular disease and premature death. 15 A meta-analysis found that poor social health heightens health risks as much as smoking 15 cigarettes a day or having an
People experiencing perceived social isolation have higher rates of avoidable and high-cost healthcare services, such as hospital readmissions and long hospitalisations. Older adults who are socially isolated are 4–5 times more likely to be hospitalised than those who are not socially isolated and a high level of loneliness is positively associated with a greater number of hospitalisations. In various populations, poor social health is associated with higher use of primary care visits, urgent care and emergency department visits and nursing home admission. To date only a handful of studies have examined loneliness and/or perceived social isolation in persons with spinal cord injuries and disorders (SCI/D), but none have offered actions to mitigate the problem. These studies have shown that loneliness is common in persons with SCI/D, yet it is poorly managed. One study showed that one-third of the individuals with SCI/D felt isolated, left out and lacked companionship at least some of the time. Another study showed that 51% reported feeling isolated from others, 47% reported lack of companionship and 44% felt left out. This study found that loneliness was higher in persons with SCI/D compared with existing data for middle age and older adults without SCI/D. A study by Newman et al reported that social isolation was higher in individuals with tetraplegia versus paraplegia. Loneliness is linked to low life satisfaction in persons with SCI/D.

In persons with SCI/D, actual, as well as perceived, barriers may prevent opportunities for social interaction and cause perceptions of separation, resulting in an increased risk of social isolation, loneliness and other poor social health outcomes. Living with SCI/D results in varying degrees of disability which may radically change the dynamics of the individual’s social well-being and feelings of connection to others. Individuals with SCI/D have smaller social networks than the general population, and both network size and quality is reduced following an SCI/D. Additionally, secondary health conditions, such as pain, pressure injuries and bowel/bladder issues have a significant adverse effect on postinjury social health and participation.

Mental and emotional health are undertreated in persons with SCI/D in healthcare and rehabilitation settings and associated indicators that are highly impacted by community living factors, such as loneliness and social isolation, may be better addressed in the community setting. Community-based interventions targeting social isolation and loneliness offer an opportunity to reduce health inequities in groups that are particularly vulnerable, such as older adults, and may be relevant to the SCI/D population. Additionally, interventions using peers have been shown to strengthen feelings of social connection and encourage help seeking engagement in and adherence to recommended treatment for mental and emotional health concerns, and are particularly recommended to improve mental health in persons with SCI/D.

The impact of peer-involved interventions may be particularly strong in the military Veteran community. Due to their common experiences, Veterans may be more accepting and responsive to interventions involving a peer. Capitalising on the shared military experience and camaraderie of Veterans, coupled with the shared experience of having an SCI/D, peer-based interventions may be an unrealised opportunity to improve social and emotional health. Although the Veterans Affairs (VA) has been a leader in incorporating peers as an adjunct to social, emotional and mental health treatment, adoption of this approach in community-based interventions needs further testing. Collectively, the high degree of perceived social isolation and loneliness combined with undertreatment in the healthcare setting, potential overuse of unnecessary healthcare services due to isolation/loneliness, and SCI/D-specific barriers preventing social interaction support the need for a peer-based intervention delivered to persons with SCI/D in the community setting.

Theoretical framework: basis for the Caring Connections Intervention. The study intervention evaluated in the current study is rooted in the biopsychosocial framework, wherein social isolation and loneliness are factors of interactions between an individual’s body, mind and social factors. It is also built on the principles of the Broaden and Build Theory of Positive Emotion which posits that micro-moments of positivity create positive emotions that improve social health. The Caring Connections intervention (described in detail below) is a peer-based, facilitated, recurrent letter writing programme designed to provide moments of positivity to reduce loneliness and perceived social isolation in persons with SCI/D.

The overall study objective is to conduct and evaluate a fully powered randomised controlled trial (RCT) to assess changes in loneliness and perceived social isolation outcomes between the Caring Connections intervention and attention control condition in community-dwelling individuals with SCI/D.

Hypothesis 1: There will be a reduction in loneliness in participants assigned to the Caring Connections intervention group compared with the attention control group post the 6-month intervention time period.

Hypothesis 2: There will be a reduction in perceived social isolation in participants assigned to the Caring Connections intervention group compared with the attention control group post the 6-month intervention time period.

METHODS AND ANALYSIS

Study design

We will conduct a two-arm parallel RCT involving community-dwelling individuals with SCI/D. We will compare participants receiving the Caring Connections intervention to an attention control condition. Outcomes will be assessed at baseline and after the 6-month
intervention. The study will be conducted from May 2022 to April 2025. Figure 1 shows the study flow diagram.

Setting
The VA SCI/D System of Care includes 25 regional SCI/D Centres (or Hubs), which provide comprehensive, coordinated, lifelong care delivered by interdisciplinary teams to US. military Veterans. The SCI/D Hubs are linked with over 100 SCI/D Spoke sites at other VA medical centres and outpatient clinics. VA cares for over a quarter of the individuals with SCI/D in the US.

Study participants
Identification (sampling pool)
We will identify individuals with SCI/D for recruitment from the VA administrative databases (CDW, VSSC SCI/D Registry). During a recent 5-year period (2016–2021), there were 17,999 patients with SCI/D who had at least one healthcare encounter across the VA system of care (VA CDW, Bartle, 2021 and SCI/D Registry, Sippel, 2021). We will obtain the SCI/D sample, variables needed for recruitment and contact information from the VA databases (a successful process in our prior work) for the most recent available 5-year period.

Baseline survey (to determine RCT eligibility and pre-trial outcomes). We will mail invitation letters to a random sample of 15% of the identified approximately 17,999 Veterans with SCI/D who have used the VA healthcare system within a recent 5-year period. A random sample from the sampling pool will be identified using SAS statistical software. We have had success recruiting via mailed invitation letter/survey packet in the past research. We estimate inviting 2,700 individuals to participate in the baseline survey and we anticipate a 40%–62% response rate based on our previous mailed survey experience with Veterans with SCI/D,24 36 which would provide responses from 1,080 to 1,674 individuals. We expect this to provide a sizeable number of respondents that will be eligible (based on UCLA-3 (University of California, Los Angeles) loneliness score assessed in the baseline survey) to invite for participation in the RCT. Because the prevalence of SCI/D is much lower in women than men, about 6% of the Veterans with SCI/D are women,36 we will over-sample women, as is often done in SCI/D research37 38 to increase representation of women participants. The invitation letters will be sent to an oversample of women with the goal of enrolling 20% women, which is substantially higher than the 6% typically observed in the population of Veterans with SCI/D.

Eligibility criteria
Inclusion criteria. Our target population will include adult Veterans with chronic SCI/D (duration of injury ≥1 year); this may include those with traumatic and non-traumatic SCI/D, and may include SCI, non-malignant neoplasms resulting in neurological deficit; vascular insults of a thromboembolic, haemorrhagic or ischaemic nature; cauda equina syndrome producing neurological deficit; inflammatory disease of the spine, spinal cord or cauda equina resulting in non-progressive neurological deficit; and demyelinating disease of the spinal cord. RCT eligibility includes presence of moderate-to-high loneliness (UCLA-3 loneliness score >4).39 40

Exclusion criteria. Individuals with new injuries (injury duration <1 year) will be excluded as it is plausible that social isolation and loneliness may more likely occur after the first year of injury when individuals have transitioned to the community and may no longer be surrounded by people consistently for help with their acute care needs.41 There are no SCI/D level or severity exclusions, as we wish to reach a diverse group of individuals.

Informed consent
Our Institutional Review Board determined the requirements for informed consent. Given the minimal risk, we were approved to waive written consent authorisation in lieu of an informational letter that fully describes the study (including randomisation) that is mailed with the initial survey along with verbal confirmation at the time of trial enrollment.

Sample and randomisation for RCT
We will offer enrollment to 62 participants randomly chosen from the pool of initial survey respondents who met eligibility criteria (moderate-to-high baseline loneliness, UCLA-3 score ≥4) and who agreed to be contacted again at the time of the baseline survey. The purpose of this random selection will be to reduce the possibility of selection bias and confounding that could possibly result from (1) convenience sampling and (2) participants being selected for the trial based on factors associated with...
outcomes of the study. We will conduct sequential rolling enrollment until we have achieved our target sample (including replacement of the dropouts, as needed). The research team will call potential participants to describe the study, confirm informed consent and enroll them if interested. The project coordinator will randomise the individuals at 1:1 into either the intervention (n=31) or the attention control condition (n=31). Random allocation to the study arm will be computer-generated by the programme analyst using SAS random number generator.

**Sample size determination for RCT**

We based our sample size determination on the range of minimum effect sizes reported in a meta-analysis of loneliness interventions. We conservatively estimated that there will be a 4.65% reduction in the primary outcome, the loneliness score, of the intervention arm compared with the attention control arm. The sample size of 62 will satisfy the hypothesis that will be tested using loneliness score reduction over 6 months. We varied our effect size from 0.2 to 0.5, as reported by Masi et al for loneliness intervention trials and assumed a common SD between the different arms to be 0.6. Assuming an effect size of 0.3 and a common SD of 0.6, a sample size of 62 will provide adequate power (≥0.80) for the RCT.

**Patient and public involvement statement**

We have involved patients in the early discussions of the intervention development in the proposal planning phase. We have included a Lived Experience Consultant who is a Veteran with SCI/D as a member of the research team (also an author on this paper) who will provide the perspective of individuals with SCI/D throughout the project. In 2021, we had a meeting with a Veteran Engagement Panel to obtain feedback on this project. Of 13 members, 4 were Veterans with an SCI/D. One panel member, a Veteran with an SCI/D, expressed that ‘this social isolation study is critical. I can say firsthand that it has negative effects and needs a study and a program developed to assist people with SCI/D in the comfort of their own home’. A woman Veteran with SCI/D noted that ‘we don’t always get to connect with others who are just like us’ and that ‘letters from our peers is a positive strategy to combat isolation’. Many members had specific ideas on intervention components, content of letters and delivery details which were incorporated into the intervention design. We will meet again with the Engagement Panel to solicit continued feedback.

**Trial duration**

In a meta-analysis of interventions to reduce loneliness in middle aged and older adults, the randomised group study intervention durations ranged between 6 weeks and 12 months, 11 lasted 3 months or less, 2 were 5 months and 3 lasted 8 months or longer. In a scoping review of interventions to address social isolation and loneliness for older adults, the duration of most interventions ranged between 3 to 24 weeks, with two exceptions one lasting up to 18 months and another up to 36 months. Interventions that have seen improvements in loneliness and social isolation have ranged in duration from 1.5 months to >1 year, with the majority taking place over a 3–6 month time period. As such, we will deliver the intervention and attention control components over 6 months.

**Intervention**

The Caring Connections intervention considers the biopsychosocial contextual factors in the lives of individuals with SCI and how these factors are associated with social health and embodies principles of Broaden and Build Theory of Positive Emotion to mitigate social isolation and loneliness by improving feelings of social connection and receiving micro-moments of positivity and creating positive emotion. The Caring Connections intervention will consist of non-demanding (contact is initiated by the letter writer and no actions or demands are placed on the recipient) messages of care and concern delivered to individuals with SCI/D who had moderate-to-high loneliness scores on the baseline survey. The caring messages will be in the form of structured, yet personalised mailed letters from one consistent volunteer who also has an SCI/D, providing long-term and steady contact from a relatable peer. Intervention participants will receive a letter every month over a 6-month period. Following a standardised set of principles, letters will contain cheerful expressions of care and positivity. The investigators will provide a brief training and work with volunteer peers with SCI/D to write the letters.

**Enlisting volunteer peer letter writers.** We will enlist individuals with SCI/D to volunteer as a peer ‘letter writer’ from several sources (VA, SCI Model Systems, SCI Advocacy groups) using a ‘Call for Volunteers’ announcement. The call for volunteers will ask interested peer volunteers to contact the study team for more information. All letters written by volunteers will be sent to the study team to do a brief ‘check’ to ensure no inappropriate content is included and no contact information of the peer volunteer is included. To maintain privacy of intervention letter recipients, the study team will share only first names of letter recipients and will mail the letters to recipients. The study team will also maintain a database to remind letter writers to prepare follow-up letters at appropriate time points.

**Attention control**

We designed our control condition based on the guidelines of Mohr and colleagues. We will mail informational materials to individuals with SCI/D in our control group at the same time points over 6 months as our intervention letter mailings. The informational materials will discuss life domains that are important to a good quality of life. Topics include community living, physical/healthy living, safety and security, social/spirituality, advocacy/engagement and employment/volunteering. We will draw information for each topic from the Knowledge Base of evidence in SCI.
Translation Center SCI Factsheets and the LifeCourse Nexus library.

Data collection
At the end of the intervention, we will administer the post-test survey (containing validated scales to repeat measurement of loneliness and perceived social isolation outcomes) to individuals with SCI/D from the intervention and control groups. This post-test survey will be conducted within the first month after the last mailed materials. In addition to repeating the outcome scales and some objective social support questions, the post-test survey will include interview questions to assess intervention experiences and acceptability quantitatively (described below). We will use random data entry checks to ensure data quality.

Outcomes
A combination of secondary data from patient medical records and a patient information form included with the initial survey will be used to collect demographic, injury and health (chronic and secondary) characteristics. The patient information survey form will collect demographic variables, including sex, age, race, ethnicity, education, employment, marital status, living arrangement, presence of caregiver; injury variables include injury type, duration, level and aetiology. Health variables include general health, physical health, mental health, chronic conditions and SCI-related secondary conditions, in addition to loneliness and social isolation (validated scales described below). We will use both sources (where needed, for example, missing survey data) to populate data for participants. We have used this combination of medical record databases and primary data collection to obtain this information for Veterans with SCI/D successfully in previous research.

Two scales will provide pre-intervention and post-intervention primary and secondary outcome scores for the intervention and control group trial participants.

Primary outcome
Loneliness. The primary outcome is loneliness. We will use the 3-item Loneliness Scale, which is an abbreviated version of the 20-item Revised UCLA Loneliness Scale, with satisfactory reliability as well as concurrent and discriminant validity in a large US population and internal consistency, and convergent and divergent validity in individuals with SCI/D. We selected the 3-item Loneliness Scale because (1) the correlation between the 3-Item Loneliness Scale and the Revised-UCLA is high (over 0.80), (2) it is the preferred robust modality for telephone administration (Hughes 2004), (3) it has been validated in the SCI/D population and (4) it has been widely used to evaluate intervention effectiveness in randomised group comparison research. The scale asks how often the respondent feels they lack companionship, feels left out and feels isolated from others.

Scoring of Loneliness Scale. Rated from 1 (hardly ever) to 3 (often), items are summed to create a score ranging from 3 to 9 with higher scores reflecting greater loneliness. A score of 3 is considered as low, 4–5 as moderate, and ≥6 as high, several studies have used 6 or above as the cut-point for high loneliness. Eligible trial participants will have moderate-to-high loneliness scores, defined as a score of 4 or above.

Secondary outcomes
Perceived social isolation. The Patient-Reported Outcomes Measurement Information System (PROMIS) Social Isolation item bank, available under the Social Health domain will be used to evaluate our participants’ perceptions of social isolation. This instrument includes eight items to assess perceptions of being left out, isolated, avoided, excluded, detached or unknown by others. Higher scores indicate worse self-reported perceived social isolation.

Exploratory outcomes
The pre-surveys and post-surveys also contain items to examine objective measures of social connectedness/support (presence of informal caregiver, living alone, frequency of socialisation with friends/family, frequency of participation in organised group(s)) and healthcare use (use/location of services, frequency of unmet medical care needs).

Process outcomes
Quantitative. The post-intervention survey contains Likert-type rating items to assess perceived benefit, perceived negative impacts and satisfaction with the intervention.

Qualitative. Of Caring Connections intervention participants, we will also ask semi-structured interview questions to assess how the intervention impacted feelings of perceived social isolation and loneliness and provision of moments of positivity. We will also ask participant’s opinions on the format and delivery of the letters and their suggestions on improving the intervention.

Statistical analysis
Pre-intervention (baseline) survey scores for the primary outcome, loneliness, will be scored for eligibility criteria for the trial. Descriptive statistics (mean, SD) will be used to characterise the sample. Bivariate analysis (χ² and t-tests) will be used to compare demographic and health characteristics of the two groups. The proposed modelling approach will take into account the two-arm clinical trial design that will compare Caring Connection treatment arm to attention control arm participants, the random assignment, the repeated measures, longitudinal
data that will be collected over 6 months and the covariates of interest (stratification variables). We will assume a one-tailed, $\alpha=0.05$ level of significance for comparing Caring Connection arm to control arm. We will use generalised linear models for repeated measures. These regression models: (a) model time-by-arm variations for our outcome, (b) control appropriately for within-subject correlation, (c) can be elaborated in simple ways to handle missing data and (d) can include baseline covariates and stratification variables as appropriate. We will let $Y_{ij}$ denote the loneliness outcome being analysed for the $i$th study participant at the $j$th study visit. We will consider transforming our outcome with a log transformation if it shows to be skewed and at that time our outcome will be denoted as $Y_{ij}^* = g(Y_{ij})$ where $g(.)$ will represent the log transformation function. Under the mentioned approaches, our model will take the following form:

$$Y_{ij} = \alpha_j + \beta_j R_i + \mu_i + \theta X_i$$

where $R_i$ indicates the arm assignment (Caring Connection treatment arm=1, control arm=0), $\alpha_j$ is the time specific intercept, $\beta_j$ is the time-specific effect of Caring Connection treatment arm with control arm and $X_i$ contains important/stratification covariates we might want to adjust for in the model with $\theta$ being their effects. We will make the standard assumption that $\mu_i \sim N(0, \tau^2_\mu)$ is a random effect that captures the between-subject variability, and that the error terms are normally distributed with a correlation matrix $\Sigma$.

Using this model, we will test the hypothesis of loneliness score decreasing in the Caring Connection arm at the 6-month time point, and also measure the magnitude of effect (difference between Caring Connection arm and control arm). The null hypothesis of the effect of Caring Connection arm at designated time points will be denoted as $\beta_j = 0$. If the magnitude of effect is relatively stable over time, we will assume a common intervention effect over time, which yields a more powerful test of treatment effect. Next, we will look for patterns in the reduction of loneliness scores in the Caring Connection arm and the control arm, and the difference between the two arms. From our proposed model, the expected loneliness scores of the control arm at baseline and follow-up assessment is $\alpha_j$. We will conduct an overall trend test for the change in loneliness score in the Caring Connection arm (where the expected loneliness scores are $\alpha_j + \beta_j$) for the baseline and follow-up time periods) and for the difference between the two arms.

Process outcomes will be analysed using mixed methods. Analysis will include calculation of descriptive statistics (frequency, mean, SD) for the quantitative items, including participant’s ratings of benefits, negative impacts and satisfaction with the intervention. The open-ended item responses will be analysed by two to three experienced qualitative researchers using Braun and Clarke’s six-step thematic analysis approach. This includes familiarising themselves with the data to gather a broad sense of meaning, generating initial codes and codebook and coding data using in vivo and descriptive open coding. The researchers will then review coded data to find themes that represent patterns of meaning and to explore relationships among themes, assessing fit and making modifications by either relocating or discarding codes and then fine-tuning themes until thematic saturation is achieved, culminating with steps to name and define conceptually significant themes.50

ETHICS AND DISSEMINATION
This study has received Hines VA Institutional Review Board (IRB) approval (#1673654). Human subjects will be recruited for this study by invitation. The Hines VA IRB will oversee compliance with IRB policies and provision of human subject protection. All investigators and study personnel will be certified in research ethics and human subjects training. All data will be stored in password protected files behind a secure firewall system. We do not anticipate any ethical or safety concerns but will monitor and report any adverse outcomes.

The VA SCI/D National Program office endorses this intervention and recognises the importance of the problem and the many potential health and psychosocial implications of perceived social isolation and loneliness in Veterans with SCI/D and will help disseminate the findings and implement the intervention, including offering to the attention control group. If the RCT is successful, we plan to disseminate the findings widely to promote adoption of our intervention strategies to mitigate perceived social isolation and loneliness in individuals with SCI/D. If successful, we will share a procedures manual, peer training materials and implementation evaluation tools to increase spread and diffusion. We will publish manuscripts in key peer-reviewed journals to disseminate further and share links on social media resources geared to health providers, public health practitioners, behavioural scientists and rehabilitation researchers. We will present our findings at research and medical conferences.

Author affiliations
1 Center of Innovation for Complex Chronic Healthcare (CINCHC), US Department of Veterans Affairs, Edward Hines Jr. VA Hospital, Hines, Illinois, USA
2 Department of Physical Medicine and Rehabilitation, Northwestern University Feinberg School of Medicine, Chicago, Illinois, USA
3 Department of Kinesiology and Nutrition, University of Illinois at Chicago, Chicago, Illinois, USA
4 Population Health Nursing Science, University of Illinois at Chicago, Chicago, Illinois, USA
5 Veterans Engagement Committee, US Department of Veterans Affairs, Edward Hines Jr. VA Hospital, Hines, Illinois, USA
6 Department of Rehabilitation Medicine, University of Washington, Seattle, Washington, USA

Twitter Sherri L LaVela @lavela

Contributors Each author (SLL, RWM, BG, ET, KA, CHB) made substantial contributions to conception and design of the study, drafted the article or revised it critically for important intellectual content; and gave approval of the submitted manuscript. SLL acquired financial support for the project leading to this manuscript. SL, RWM, BG, ET, KA and CHB made substantial contributions.

Open access
to conception and design of the study. SL, RWM, and CHB made contributions to the project administration and management. SLL, RWM, BG, KA, and CHB made substantial contributions to the acquisition of data and will be involved in analysis and interpretation of data. All authors (SLL, RWM, BG, ET, KA, and CHB) have been involved in writing the manuscript, have given final approval of the version submitted and agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

**Funding** This work was supported by the Craig H. Neilsen Foundation. Psychosocial Research Studies and Demonstration Projects (Award #864046: Caring Connections: A programme to alleviate social isolation and loneliness in individuals living with spinal cord injury); 30 April 2022 to 29 April 2025; principal investigator: SLL.

**Disclaimer** The views expressed in this manuscript are those of the authors and do not necessarily reflect the position or policy of the Department of Veterans Affairs or the US government.

**Competing interests** None declared.

**Patient and public involvement** Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

**Patient consent for publication** Not applicable.

**Provenance and peer review** Not commissioned; externally peer reviewed.

**Open access** This is an open access article distributed in accordance with the Creative Commons Attribution Non Commercial (CC BY-NC 4.0) license, which permits others to distribute, remix, adapt, build upon this work non-commercially, and license their derivative works on different terms, provided the original work is properly cited, appropriate credit is given, any changes made indicated, and the use is non-commercial. See: http://creativecommons.org/licenses/by-nc/4.0/.

**ORCID iD** Sherri L LaVela http://orcid.org/0000-0001-9900-0120

**REFERENCES**

1 Cigna. US loneliness index. survey of 20,000 Americans, examining behaviors driving loneliness in the US, 2018. Available: https://www.cigna.com/assets/docs/newswire/loneliness-survey-2018-full-report.pdf [Accessed 15 Feb 2022].

2 Holt-Lunstad J, Smith TB, Baker M, et al. Loneliness and social isolation as risk factors for mortality: a meta-analytic review. *Perspect Psychol Sci* 2015;10:227–37.

3 Cacioppo JT, Hawkley LC, Norman GJ, et al. Loneliness and social isolation in the elderly: an exploration et al. 2022;11:696–900. doi:10.1136/bmjopen-2022-063246

4 Agarwal G, Lee J, McLeod B, et al. Examination of the relationships among social networks and loneliness on health and life satisfaction in people with spinal cord injury/Dysfunction. *Arch Phys Med Rehabil* 2021;102:2109–16.

5 Robinson-Whelen SS, Taylor HB, Feltz M, et al. Loneliness among people with spinal cord injury: exploring the psychometric properties of the 3-Item loneliness scale. *Arch Phys Med Rehabil* 2016;97:1728–34.

6 Newman SD, Li C, Krause JS. Social isolation after spinal cord injury: indicators from the longitudinal aging study. *Rehabil Psychol* 2018;64:1–108.

7 Hitzig SL, Cimino SR, Alavinia M, et al. Examination of the relationships among social networks and loneliness on health and life satisfaction in people with spinal cord injury/Dysfunction. *Arch Phys Med Rehabil* 2021;102:2109–16.

8 Agarwal G, Lee J, McLeod B, et al. Examination of the relationships among social networks and loneliness on health and life satisfaction in people with spinal cord injury/Dysfunction. *Arch Phys Med Rehabil* 2021;102:2109–16.

9 Tough H, Brinkhof MWG, Siegrist J, et al. The impact of loneliness and relationship quality on life satisfaction: a longitudinal dyadic analysis in persons with physical disabilities and their partners. *J Psychosom Res* 2018;110:61–7.

10 Tzonichaki L, Kleifaras G. Paraplegia from spinal cord injury: self-esteem, loneliness, and life satisfaction. *OTJR* 2002;22:96–103.

11 Vaillant GE. *Alcoholics*. 2nd edn. Cambridge, MA: Harvard University Press; 1996.

12 Berardo A, Forni E, Romani S, et al. Social networks and secondary health conditions: the critical secondary team for individuals with spinal cord injury. *J Spinal Cord Med* 2012;35:330–42.

13 Cimino SR, Hitzig SL, Craven BC, et al. An exploration of perceived social isolation among persons with spinal cord injury in Ontario, Canada: a qualitative study. *Disabil Rehabil* 2022;44:3400–9.

14 Guilcher SJT, Catrine Craven B, Bassett-Gunter RL, et al. An examination of objective social disconnectedness and perceived social isolation among persons with spinal cord injury/dysfunction: a descriptive cross-sectional study. *Disabil Rehabil* 2021;43:89–75.

15 LaVela SL, Heinemann AW, Etingen B, et al. Social networks and secondary health conditions: the critical secondary team for individuals with spinal cord injury. *J Spinal Cord Med* 2012;35:330–42.

16 Newman SD, Li C, Krause JS. Social isolation after spinal cord injury: indicators from the longitudinal aging study. *Rehabil Psychol* 2018;64:1–108.

17 Hitzig SL, Cimino SR, Alavinia M, et al. Examination of the relationships among social networks and loneliness on health and life satisfaction in people with spinal cord injury/Dysfunction. *Arch Phys Med Rehabil* 2021;102:2109–16.

18 Tough H, Brinkhof MWG, Siegrist J, et al. The impact of loneliness and relationship quality on life satisfaction: a longitudinal dyadic analysis in persons with physical disabilities and their partners. *J Psychosom Res* 2018;110:61–7.

19 Tzonichaki L, Kleifaras G. Paraplegia from spinal cord injury: self-esteem, loneliness, and life satisfaction. *OTJR* 2002;22:96–103.

20 Vaillant GE. *Alcoholics*. 2nd edn. Cambridge, MA: Harvard University Press; 1996.

21 Guilcher SJT, Casciaro T, Lemieux-Charles L, et al. Social networks and secondary health conditions: the critical secondary team for individuals with spinal cord injury. *J Spinal Cord Med* 2012;35:330–42.

22 Cimino SR, Hitzig SL, Craven BC, et al. Examination of perceived social isolation among persons with spinal cord injury in Ontario, Canada: a qualitative study. *Disabil Rehabil* 2022;44:3400–9.

23 Isaksson G, Skär L, Lexell J. Women’s perception of changes in the social network after a spinal cord injury. *Disabil Rehabil* 2005;27:1013–21.

24 LaVela SL, Etingen B, Miskevics S, et al. What determines low satisfaction with life in individuals with spinal cord injury? *J Spinal Cord Med* 2019;42:236–44.

25 Battalio SL, Jensen MP, Molton IR. Secondary health conditions and social role satisfaction in adults with long-term physical disability. *Health Psychol* 2019;38:445–54.

26 Piatt JA, Nagata S, Zalt M, et al. Problematic secondary health conditions among adults with spinal cord injury and its impact on social participation and daily life. *J Spinal Cord Med* 2016;39:693–8.

27 Bombardier CH, Azuero GB, Fann JR. Management of mental health disorders, substance use disorder, and suicide in adults with spinal cord injury. *J Spinal Cord Med* 2021;44:102–62.

28 Kharicha K, Iliffe S, Manthorpe J, et al. What do older people experiencing loneliness think about primary care or community based interventions to reduce loneliness? A qualitative study in England. *Health Soc Care Community* 2017:25:1733–42.

29 Goetter EM, Bui E, Weiner TR, et al. Pilot data of a brief veteran peer intervention and its relationship to mental health treatment engagement. *Psychol Serv* 2018;15:453–6.

30 Wittleder S, Smith S, Wang B, et al. Peer-Assisted lifestyle (pal) intervention: a protocol of a cluster-randomised controlled trial of a health-coaching intervention delivered by veteran Peers to improve obesity treatment in primary care. *BMJ Open* 2021;11:e043013.

31 Long JA, Ganetsky VS, Camanuco A, et al. Effect of peer mentors in diabetes self-management vs usual care on outcomes in US veterans with type 2 diabetes: a randomized clinical trial. *JAMA Netw Open* 2020;3:e2016369.

32 Chinman M, Oberman RS, Hanusa BH, et al. A cluster randomized trial of adding peer specialists to intensive case management teams in the Veterans health administration. *J Behav Health Serv Res* 2015;42:109–21.

33 Stinemans MG, Steim JE. The biopsychosocial-ecological paradigm: a foundational theory for medicine. *Pm R* 2010;2:1035–45.

34 Guiltner BL. The role of positive emotions in positive psychology. *The broaden-and-build theory of positive emotions. Am Psychol* 2001;56:218–26.

35 Guiltner BL. Positive emotions broaden and build. *Adv Exp Social Psych* 2013;47:1–53.

36 LaVela SL, Heinemann AW, Etingen B, et al. Relational empathy and holistic care in persons with spinal cord injuries. *J Spinal Cord Med* 2017;40:30–42.

37 Krause JS, Broderick L. Outcomes after spinal cord injury: comparisons as a function of gender and race and ethnicity. *Arch Phys Med Rehabil* 2004;85:355–62.

38 Jackson AB, Dijkers M, Devivo MJ, et al. A demographic profile of new traumatic spinal cord injuries: change and stability over 30 years. *Arch Phys Med Rehabil* 2004;85:1740–8.
Hughes ME, Waite LJ, Hawkley LC, et al. A short scale for measuring loneliness in large surveys: results from two population-based studies. *Res Aging* 2004;26:655–72.

Basu A, Kim HH, Basaldua R, et al. A cross-national study of factors associated with women’s perinatal mental health and wellbeing during the COVID-19 pandemic. *PLoS One* 2021;16:e0249780.

Dickson A, Ward R, O’Brien G, et al. Difficulties adjusting to post-discharge life following a spinal cord injury: an interpretative phenomenological analysis. *Psychol Health Med* 2011;16:463–74.

Masi CM, Chen H-Y, Hawkley LC, et al. A meta-analysis of interventions to reduce loneliness. *Pers Soc Psychol Rev* 2011;15:219–66.

O’Rourke HM, Collins L, Sidani S. Interventions to address social connectedness and loneliness for older adults: a scoping review. *BMC Geriatr* 2018;18:214.

Mohr DC, Ho J, Hart TL, et al. Control condition design and implementation features in controlled trials: a meta-analysis of trials evaluating psychotherapy for depression. *Transl Behav Med* 2014;4:407–23.

Model Systems Knowledge Translation Center. Spinal cord injury Factsheets. Available: https://msktc.org/sci/factsheets [Accessed 2 Feb 2022].

Lifecourse nexus library. Available: https://www.lifecoursetools.com/ [Accessed 2 Feb 2022].

Agarwal G, Pirrie M, Gao A, et al. Subjective social isolation or loneliness in older adults residing in social housing in Ontario: a cross-sectional study. *CM AJ Open* 2021;9:E915–25.

Steptoe A, Shankar A, Demakakos P, et al. Social isolation, loneliness, and all-cause mortality in older men and women. *Proc Natl Acad Sci U S A* 2013;110:5797–801.

Health Measures. Social isolation item bank. PROMIS. Available: https://www.healthmeasures.net/explore-measurement-systems/promis/intro-to-promis/list-of-adult-measures [Accessed 14 Apr 2021].

Braun V, Clarke V. Using thematic analysis in psychology. *Qual Res Psychol* 2006;3:77–101.