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TITLE: Loneliness and Its Relation to Health in People with Spinal Cord Injury

PRINCIPAL INVESTIGATOR: Susan Robinson-Whelen, Ph.D.

CONTRACTING ORGANIZATION: Baylor College of Medicine, Houston, TX

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14. ABSTRACT The objective of this study is to enhance the understanding of loneliness in people with SCI and examine its relation to psychological and physical health through a longitudinal survey study. We propose four specific aims designed to enhance the understanding of 1) the experience of loneliness in people with SCI, 2) the contextual factors (e.g., demographics, disability characteristics) related to loneliness, 3) the relation between loneliness and psychological and physical health in people with SCI, and 4) the extent to which loneliness predicts health independent of contextual variables, including social isolation. We will conduct a national longitudinal survey study of 350 people with SCI. Participants will complete the survey at baseline and again 12 months later. Findings will have the potential to both advance SCI research by informing intervention development and improve clinical care by alerting health care providers of the importance of addressing loneliness in their patients.						
15. SUBJECT TERMS Spinal cord injury, loneliness, social isolation, physical health, psychological health						
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TABLE OF CONTENTS

	Page
1. Introduction	4
2. Keywords	4
3. Accomplishments	4
4. Impact	9
5. Changes/Problems	9
6. Products	9
7. Participants and Other Collaborating Organizations	10
8. Special Reporting Requirements	11
9. Appendix Contents	12
10. Appendices	12

1. Introduction

Research with the general population demonstrates the adverse effects of loneliness on health. Few studies, however, have addressed loneliness and its relation to health in people with SCI who often lack opportunities for social connection. The objective of this study is to enhance the understanding of loneliness in people with SCI and examine its relation to psychological and physical health through a longitudinal survey study. We propose four specific aims designed to enhance the understanding of 1) the experience of loneliness in people with SCI, 2) the contextual factors (e.g., demographics, disability characteristics) related to loneliness, 3) the relation between loneliness and psychological and physical health in people with SCI, and 4) the extent to which loneliness predicts health independent of contextual variables, including social isolation. With input from a community advisory board (CAB) of men and women with SCI, we are conducting a national longitudinal survey study of 350 people with SCI. Participants complete the survey at baseline and again 12 months later. Findings will have the potential to both advance SCI research by informing intervention development and improve clinical care by alerting health care providers of the importance of addressing loneliness in their patients.

2. Keywords

Spinal cord injury, loneliness, social isolation, physical health, psychological health

3. Accomplishments

What were the major goals of the project?

Specific Aims 1-4	Timeline Yr/Qrtr	Progress
Major Task 1 – Study Initiation		
Secure approval from BCM's IRB	Y1Q1	Completed
Secure approval from UM's IRB	Y1Q1	Completed
Secure approval from TIRR-MH	Y1Q1	Completed
Secure USAMRMC Office of Research Protections (ORP) approval	Y1Q1-Y1Q2	Completed
Hire/train research assistant(s)	Y1Q1	Completed
Conduct regular meetings with research team	Y1Q1-Y3Q4	Completion ongoing
Convene/hold Community Advisory Board (CAB) meetings	Y1Q1-Y3Q4	Completion ongoing
Maintain IRB/HRPO approval for docs and protocols	Y1Q1- 3Q4	Completion ongoing
<i>Milestone: IRB approvals, USAMRMC ORP approval, TIRR- MH approval</i>	Y1Q2	Completed
Major Task 2 – Prepare for National Survey Study Data Collection		
Finalize list of measures	Y1Q1	Completed
Develop screening interview, consent script, consent form	Y1Q1-Y1Q2	Completed
Develop T1 and T2 surveys using Qualtrics	Y1Q1-Y1Q2	Completed
Establish procedures for study implementation	Y1Q1-Y1Q2	Completed
Develop/produce recruitment flyers, promotional items, news blurbs, posts, and recruitment letters	Y1Q2	Completed
Create/maintain databases for collecting participant data, tracking participant progress, and tracking recruitment activities	Y1Q2-Y3Q4	Database created; maintenance ongoing

<i>Milestones Achieved: *Procedures finalized for Beta Test Screening interview; *Qualtrics survey developed for Beta Test *Databases created</i>	Y1Q2	Completed
Major Task 3 – Conduct Beta Test		
Conduct beta test with CAB	Y1Q2-Y1Q3	Completed
Revise procedures/docs based on beta	Y1Q2-Y1Q3	Completed
<i>Milestone(s) Achieved: All materials and procedures revised and ready for full survey study</i>	Y1Q3	Completed
Major Task 4 – Implement Full Study To be completed Y1Q3 – Y3Q3		
Distribute recruitment materials to organizations across the U.S.	Y1Q3-Y2Q3	Completed
Screen and enroll 350 participants in the national survey study	Y1Q3-Y2Q3	Completed with T1 sample size of 346
Collect T1 data	Y1Q3-Y2Q3	Completed
Collect T2 data	Y2Q3-Y3Q3	T2 data collection was completed during Y3Q4
<i>Milestone Achieved: Data collection complete on 7% of sample Data collection complete on 39% of sample Data collection complete on 58% of sample Data collection complete on 84% of sample Data collection complete on 100% of sample</i>	Y2Q3 Y2Q4 Y3Q1 Y3Q2 Y3Q3	T2 data collection began during Y3Q2 and was completed during Y3Q4.
Major Task 5 – Data Entry, Management, and Analysis To be completed Y1Q3 – Y3Q3		
Maintain data management systems and create/maintain comprehensive data codebook	Y1Q3-Y3Q4	Data management systems have been created and data codebook has been completed; maintenance is ongoing
Conduct weekly data checks, test quality and integrity of the dataset	Y1Q3-Y3Q4	Completed for T1 and T2
Complete data scoring and data consolidation of contextual variables	Y2Q3	Ongoing
Analyze data and test hypotheses (cross-sectional analyses to begin Y2Q4; longitudinal analyses to begin Y3Q3)	Y2Q4-Y3Q4	Ongoing
Present results to the advisory board for input on interpretation and ideas for dissemination to consumers	Y2Q4-Y3Q4	Completed for T1 data; pending for T2 data results.
<i>Milestone Achieved: Data analysis and interpretation complete</i>	Y3Q4	Pending/Underway
Major Task 6 – Dissemination of Findings and Fact Sheets		
Complete deliverable reports to CDMRP	Y1Q1-3QY4	This is the third annual report.
Present findings at scientific meetings	Y2Q4-Y3Q4	Presentations of results are ongoing for T1 data and pending for T2 data
Prepare/submit manuscripts to peer-reviewed journals	Y2Q4-Y3Q4	Submissions are ongoing for T1 data and pending for T2 data
Develop Fact Sheets/materials with CAB for health care/disability service providers	Y2Q4-Y3Q4	Planned after data analysis is complete
Prepare final report for CDMRP	Y3Q4	NCE requested - Due end of NCE (2023)
<i>Milestone Achieved: Dissemination of study findings complete</i>	Y3Q4	New milestone date Y4Q4

What was accomplished under these goals?

Major Task 1 (Study Initiation) –

- Throughout Year 3, we have maintained IRB approval from Baylor College of Medicine (Protocol #H-45581) and the University of Montana (UM IRB #166-19). Given the late start of data collection (due to COVID-related data collection changes and approvals), we submitted a no cost extension request in June 2022. The NCE has been approved with an end date of August 31, 2023.
- We have continued to hold regular bi-weekly investigator meetings. In addition, PI Susan Robinson-Whelen has met weekly with Lead RA Rodriguez.
- In Year 3 we met with our community advisory board (CAB) three times (October 2021, May 2022, and July 2022). During the meetings we discussed study milestones/updates, presented data on COVID-19 and loneliness from T1, and collected feedback from our CAB members regarding their thoughts and interpretations of the findings. Additionally, we brainstormed ideas for disseminating study findings. We have started the vendor process to ensure CAB members are compensated for the remaining planned CAB meetings. CAB members have been notified that we plan to meet three more times between now and the end of the NCE.

Major Task 2 (Prepare for National Survey Study) –

All major tasks regarding preparation for the national survey study were completed in Year 1 of the project.

Major Task 3 (Conduct Beta Test) –

We completed the beta testing with our CAB and revised procedures and documents accordingly in Year 1. We received approval of those modifications by HRPO in December 2020.

Major Task 4 (Full Study Implementation) –

- As noted in the previous annual report, a total of 346 participants completed the T1 survey between December 2020 and July 2021. During the reporting period reflected in the current annual report, RA Rodriguez began collecting T2 data in December 2021 and completed T2 data collection in August 2022. As shown in the Consort Diagram in the Appendix, we collected T2 data on 320 participants, with 318 of them completing the survey (1 completed approximately 35%, 1 completed approximately 40% of the survey). This represents an 8% attrition rate which is notably less than the projected 15% attrition in the original grant application. The final, post-attrition sample size estimated in the original grant proposal was 300; thus, we satisfied the sample size requirements of our power analyses.
- At the start of the T2 data collection, we once again enlisted the help of an additional TIRR Memorial Hermann Spinal Cord Injury and Disability Research (SCIDR) RA, Diana Gonzalez, to help with payment tracking and mailing. Lead Project RA Rodriguez conducted Ms. Gonzalez' training on the payment protocol for the project. Ms. Gonzalez and lead RA Rodriguez were in contact weekly to verify payments were being sent and to resolve any issues. Ms. Gonzalez worked on the project at 10% FTE from January 2022 through the end of the reporting period.
- Throughout T2 data collection, RA Rodriguez entered data in RedCAP on participants who completed the survey via interview or mail-in paper-and-pencil format. She also examined open-ended comments to the T2 survey to identify any participants requesting follow-up contact or sharing feedback on their experience that needed to be addressed.

Major Task 5 (Data Management and Analysis) –

- We have been engaged in data management and analysis activities throughout the reporting period. We conducted data checks and examined missing and outlier data points of T1 data. We completed scoring of the T1 data and consolidated demographic and other contextual variables from the T1 dataset. We also continued to add to the comprehensive data codebook as new variables were generated.
- Throughout T2 data collection, RA Rodriguez conducted weekly exports of the T2 data for routine data checks and stored the data on the secure server in protected file folders dedicated to the project.
- Dr. Robinson-Whelen met with study statisticians while working on cleaning, coding, and scoring of the T1 cross sectional data.
- Dr. Robinson-Whelen and the study investigators worked with the statisticians to analyze the T1 data. Addressing the first objective (examining whether the construct of loneliness was similar in people with SCI

to that of the general population), we found that the originally proposed bifactor model provided an adequate fit to the data and provided a better fit than any of the alternative models tested. This addressed Aim 1 Hypothesis 1a (H1a) suggesting that the construct of loneliness was similar to that of the general population. It also offers evidence that the scale measures a single general loneliness factor made up of both negatively and positively worded items and that a single score can be used to represent loneliness in subsequent data analyses.

- The relation between loneliness and our measure of social isolation (CHART Social Integration Scale) was $|.37|$, considered a moderate correlation, thus largely supporting H1b suggesting that loneliness and social isolation were distinct constructs that were not strongly related.
- Examining T1 responses to the 20 individual items of the UCLA-V3 Loneliness Scale as well as the scored scale, we found that 8 loneliness items were endorsed by more than half of the sample (who reported *sometimes* or *often* feeling this way) with an additional 4 items endorsed by at least a third of the sample. The items with the highest endorsement include feeling “left out” (25% felt this way *often* and an additional 41% felt this way *sometimes*) and feeling “isolated from others” (30% felt this way *often* and an additional 30% felt this way *sometimes*). The average score for the 20-item scale in our sample was 46.15 ($SD=13.9$). Comparing our sample mean to that of a number of studies in the literature, the loneliness scores in our sample were notably high.
- Exploring cross-sectional associations with loneliness, we found loneliness was related to a number of demographic and disability-related variables, although most effect sizes were relatively small. Stronger relations were found between loneliness and health-related variables. The strongest associations were found with social characteristics, most notably satisfaction with social participation. In multiple linear regression analyses, the variables accounting for significant independent variance were severity of secondary conditions, social isolation, social support, and satisfaction with social participation. In addition, time since injury was a significant predictor of loneliness, but only among those unemployed. Greater time since injury appeared to only offer an advantage to people who were unemployed. These results have been accepted for presentation at the Annual American Congress of Rehabilitation Medicine (ACRM) Conference in Chicago in November of 2022.
- Although not in the original proposal, we added questions about the perceived impacts of the COVID-19 pandemic on participants’ psychosocial health, health/health behavior, social engagement, and use of alcohol, tobacco, and other drugs. We found far more negative than positive impacts. Examining predictors of psychosocial impacts, multiple regression analyses revealed that women, people with more unmet needs for assistance, and those in poorer health reported greater psychosocial health impacts of the pandemic. Those who were Black and those who were more satisfied with their social participation reported less negative impact on their psychosocial health. These results were presented at the Annual Conference of the American Spinal Injury Association (ASIA) in New Orleans in May 2022 and the associated manuscript is in press in the journal *Rehabilitation Psychology*.
- Given literature on the impacts of trauma and abuse on loneliness as well as psychological and physical health, we included a 4-item lifetime abuse screen that asked about lifetime physical, sexual, and disability-related abuse experience. We analyzed these data and have plans to present the findings at the Annual ACRM Conference in Chicago in November 2022. Briefly, we found that more than a third (37%) reported some lifetime abuse (30% physical, 9% sexual, 17% disability-related). Demographic characteristics were not strongly related to IPV although women experienced sexual abuse more than men. People with greater disability severity and greater need for assistance were significantly more likely to experience disability-related abuse. Disability-related abuse (e.g., refusal to provide assistance with essential activities of daily life) contributed significant unique variance in explaining all four measures of psychological health and well-being. Clearly, more research on IPV in the context of SCI is needed including the impact of disability-related abuse on psychological health outcomes.

Major Task 6 (Dissemination) –

- Quarterly reports outlining the continued progress of the SCI Study have been regularly submitted throughout the current funding period. This report constitutes the third annual report submitted.
- Much of our dissemination activities will occur during the NCE year as we have just completed T2 data collection. We have, however, already begun dissemination of findings from our T1 data analyses. We provide a brief list here and have the references listed below under “Products”.

- A medical student partnered with us and presented findings from our COVID-19 analysis on the impacts of the pandemic on psychosocial health at the Baylor College of Medicine's 22nd Henry JN and James K Alexander Medical Student Research Symposium in March of 2022.
- We presented findings of the impacts of the COVID-19 pandemic on psychosocial health, health/health behavior, social engagement, and use of alcohol, tobacco, and other drugs as well as the predictors of psychosocial health impacts at the annual ASIA conference in New Orleans, LA in May 2022.
- We submitted two abstracts based on T1 data (one on lifetime abuse experience and one on the experience and predictors of loneliness) to ACRM's 2022 annual conference. Both abstracts were accepted and will be presented at the meeting in Chicago in November 2022 (during the upcoming quarter).
- We have submitted a manuscript presenting findings from our COVID-19 findings to the journal *Rehabilitation Psychology*. The paper has been accepted and is currently in press.
- We have been invited to present findings on the impact of the COVID-19 pandemic to the TIRR Memorial Hermann Management Council in the upcoming quarter (September 2022). In addition to providing study results, we plan to include a discussion of how the findings might inform practice for those providing clinical services to patients through the TIRR Memorial Hermann network of rehabilitation hospitals and clinics.

What opportunities for training and professional development has the project provided?

- We were approached by a Baylor College of Medicine Medical Student who had an interest in our research and a potential interest in focusing her career in rehabilitation medicine. She expressed interest in working on this project. She conducted a literature search on COVID-19 and people with disabilities and specifically COVID-19 and people with SCI. She assisted with the literature review and background section of the paper being developed for publication. She also submitted an abstract based on this work for presentation at Baylor College of Medicine's 22nd Henry JN and James K Alexander Medical Student Research Symposium 2022. Her abstract submission was presented at the symposium in March of 2022.

How were the results disseminated to communities of interest?

Thus far, results have been disseminated to our community advisors of people with SCI, to academic audiences attending an SCI-specific conference (ASIA), and to the BCM medical community of medical students and faculty. In the upcoming quarter, we will be presenting results at an additional rehabilitation-specific conference (ACRM) as well as at a monthly meeting of the TIRR Memorial Hermann Management Council representing administration as well as managers of clinical services. We have already begun discussing ideas for broader dissemination to consumers with our CAB members, but we anticipate most of our dissemination efforts will be conducted during our NCE after our T2 data have been scored, merged with our T1 data, and analyzed.

What do you plan to do during the next reporting period to accomplish the goals and objectives?

- In the next reporting period, we will initially focus on data management and creation of the final dataset. We will evaluate aberrant data, clean, score, collapse contextual variables, and merge the T2 dataset with the current T1 dataset. We will continue to update the data codebook so that all variables, including new T2 variables, are correctly referenced in the codebook.
- During the NCE, we will then expand our data analysis activities to those questions and hypotheses that require use of our longitudinal data. In addition, since we continued to collect data on the impacts of the pandemic as part of the T2 survey, we look forward to examining change over time in perceived impacts of the COVID-19 pandemic.
- We will also continue during the NCE to focus on dissemination of findings from analyses of baseline (T1) data while also expanding those efforts to include dissemination of findings from our longitudinal analyses. Dissemination activities will include submitting abstracts and presenting at scientific meetings, preparing and submitting manuscripts to peer-reviewed journals, and developing fact sheets/materials for consumers and service providers.
- We will continue to meet with our CAB who will provide input and feedback on findings and our interpretation of those findings and will advise and guide our development of consumer-oriented materials.

4. Impact

What was the impact on the development of the principal discipline(s) of the project?

Nothing to report until data analysis and dissemination are complete

What was the impact on the other disciplines? - Nothing to report until data analysis and dissemination are complete

What was the impact on technology transfer? - Nothing to report until data analysis and dissemination are complete

What was the impact on society beyond science and technology? - Nothing to report until data analysis and dissemination are complete

5. Changes/Problems

Changes in approach and reasons for change

There have not been any additional changes since the submission of the first annual report.

Actual or anticipated problems or delays and actions or plans to resolve them

There were unanticipated delays in the start of study recruitment and enrollment. As a result, T1 data collection began 8 months later than originally planned. This obviously impacted when we could begin collection of 12-month post T2 data. Although we were able to increase the pace of enrollment, we were only able to complete T2 data collection in August 2022 (the original study end date). As a result, we requested a NCE, which we anticipate will give us adequate time to complete data management, data analysis, and dissemination activities.

Changes that had a significant impact on expenditures

There have been no changes that posed a significant impact on expenditures in Year 2.

Significant changes in use of care of human subjects, vertebrate animals, biohazards, and/or select agents - Nothing to report.

Significant changes in use or care of human subjects - Nothing to report.

Significant changes in use or care of vertebrate animals - Nothing to report.

Significant changes in use of biohazards and/or select agents - Nothing to report.

6. Products

Publications, conference papers, and presentations

Journal publications

Robinson-Whelen, S., Hughes, R. B., Taylor, H. B., Holmes, S. A., Rodriguez, J. & Manohar, S. (2022). Impacts of the COVID-19 pandemic on people with spinal cord injury. *Rehabilitation Psychology* (in press).

Books or other non-periodical, one-time publications - Nothing to report.

Other publications, conference papers, and presentations

Robinson-Whelen, S., Hughes, R. B., Taylor, H. B., Holmes, S. A., Rodriguez, J., Staggars, K. A., & Minard, C. G. (2022). *Examining Loneliness and Its Correlates in a Sample of People with Spinal Cord Injury*. Accepted for presentation at the American Congress of Rehabilitation Medicine Annual Meeting, Chicago, IL (November, 2022).

Robinson-Whelen, S., Hughes, R. B., Taylor, H. B., Holmes, S. A., & Rodriguez, J. (2022). *Examining Lifetime Abuse Experiences of People with Spinal Cord Injury*. Accepted for presentation at the American Congress of Rehabilitation Medicine Annual Meeting, Chicago, IL (November, 2022).

Robinson-Whelen, S., Hughes, R. B., Taylor, H. B., Holmes, S. A., & Rodriguez, J. (2022, May 19). *Examining the Impact of COVID-19 on People with Spinal Cord Injury: The Role of Gender and Other Personal Characteristics*. Presentation at the Annual Scientific Meeting of the American Spinal Injury Association (ASIA), New Orleans, LA.

Manohar, S., & Robinson-Whelen, S. (2022, March). Examining the impact of COVID-19 pandemic on the psychosocial health and health behavior of people with spinal cord injury. Accepted for presentation at the 2022 Henry J. N. Taub & James K. Alexander Medical Student Research Symposium.

Website(s) or other Internet site(s) - Nothing to report

Technologies or techniques - Nothing to report

Inventions, patent applications, and/or license - Nothing to report

Other Products - Nothing to report

7. Participants and Other Collaborating Organizations

What individuals have worked on the project?

Name:	Susan Robinson-Whelen, PhD – No Change
Name:	Heather Taylor, PhD – No Change
Name:	Rosemary Hughes, PhD – No Change
Name:	Jessica Rodriguez, BS – Change from 9 person months to 6 person months Role: Project Coordinator

Has there been a change in the active other support of the PD/PI or senior/key personnel since the last reporting period? Yes

New Support Received During the Last Reporting Period:

Mindfulness Meditation Training and Home Practice in Persons with SCI: A pilot study

1R34AT011530-01A1, NIH's National Center on Complementary and Integrative Health (NCCIH)

This project had a start date of 04/01/2022. Drs. **Robinson-Whelen** (12% fte) and **Taylor** (5% fte) are involved at a small fte as co-Investigators. This change in active other support did not impact the effort on the project that is the subject of the current project report.

Measuring Symptom Clusters in People with Sudden-Onset Disabilities

R01NR018684, NIH's National Institute of Nursing Research (NINR)

The subaward to TIRR Memorial Hermann for this project had a start date of 09/05/2021. **Dr. Taylor** is involved at a small fte (10% fte) as a co-Investigator. This change in active other support did not impact Dr. Taylor's effort on the project that is the subject of the current project report.

iManage Sexual Wellness: Development of a Symptom-monitoring/Self-management Program to Enhance Sexual Wellness after SCI and TBI

90DPCP0010, National Institute on Disability, Independent Living, and Rehabilitation Research (NIDILRR)

The subaward to TIRR Memorial Hermann for this project had a start date of 09/01/2021. **Dr. Taylor** is involved at a small fte (7% fte) as a co-Investigator. This change in active other support did not impact Dr. Taylor's effort on the project that is the subject of the current project report.

What other organizations were involved as partners?

Organization Name: TIRR Memorial Hermann

Location of Organization: Houston, TX

Partner's contribution to the project:

In-kind support: Makes computers, software, equipment available to TIRR-MH Co-I/RA

Facilities: TIRR-MH Co-I/RA use TIRR-MH facilities/office space for project activities

Collaboration: TIRR-MH Co-I/RA collaborate with PI and UM Co-I on project activities

Organization Name: University of Montana, Rural Institute for Inclusive Communities

Location of Organization: Missoula, MT

Partner's contribution to the project:

In-kind support: Makes computers, software, equipment available to UM Co-I


Facilities: UM Co-I uses UM facilities/office space for project activities

Collaboration: UM Co-I collaborates with PI and other project personnel on project activities

8. Special Reporting Requirements

Collaborative Awards – Not applicable

Quad Chart -

Loneliness and Its Relation to Health in People with Spinal Cord Injury																											
PI: Susan Robinson-Whelen, Ph.D.		Org: Baylor College of Medicine																									
Award Amount: \$607,008.00																											
<p>Study/Product Aim(s)</p> <p>We aim to enhance understanding of:</p> <ul style="list-style-type: none"> the experience of loneliness in people with SCI, including veterans; the contextual factors (demographics, disability characteristics) related to loneliness; the relation between loneliness and psychological and physical health in people with SCI; and the extent to which loneliness predicts psychological and physical health independent of the influence of contextual variables, including social isolation <p>Approach</p> <p>With input from a community advisory board of people with SCI, we plan to conduct a longitudinal national survey study of 350 civilians and veterans with SCI. Surveys will include contextual variables as well as measures of loneliness, social isolation, and physical and psychological health administered at baseline and 12 months later, allowing us to examine cross-sectional as well as longitudinal associations</p>		<div style="display: flex; justify-content: space-between;"> <div style="border: 1px solid black; padding: 5px; width: 30%;"> <p>You can feel just as lonely in a crowd ~Anonymous</p> </div> <div style="text-align: center;">  </div> <div style="border: 1px solid black; padding: 5px; width: 30%;"> <p>One of the major issues [for people with SCI] is loneliness, which of course is very present in the early days of injury but continues throughout our lives. ~Veteran with SCI serving on the project's Community Advisory Board</p> </div> </div> <p>Accomplishments:</p> <ul style="list-style-type: none"> Longitudinal data was collected on 320 study participants – an 8% rate of attrition. Data on the impacts of the pandemic on psychosocial health have been presented at one local symposium, one national scientific conference, and have been accepted for publication in <i>Rehabilitation Psychology</i>. Study findings regarding characteristics predicting loneliness and correlates of lifetime abuse experience have been accepted for presentation at the annual meeting of the American Congress of Rehabilitation Medicine (ACRM) in November 2022. 																									
<p>Timeline and Cost</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: left;">Activities</th> <th style="text-align: center;">FY1</th> <th style="text-align: center;">FY2</th> <th style="text-align: center;">FY3</th> </tr> </thead> <tbody> <tr> <td>Obtain approvals/maintain regulatory compliance; Prepare documents/materials for survey study</td> <td style="text-align: center;">█</td> <td></td> <td></td> </tr> <tr> <td>Beta test materials, procedures, databases; Revise based on beta test input</td> <td style="text-align: center;">█</td> <td></td> <td></td> </tr> <tr> <td>Recruit, screen, enroll, and collect data at baseline and at 12 months</td> <td></td> <td style="text-align: center;">█ Modified</td> <td></td> </tr> <tr> <td>Analyze data, disseminate study results to academic and consumer audiences</td> <td></td> <td></td> <td style="text-align: center;">█</td> </tr> <tr> <td>Estimated Budget (\$607K)</td> <td style="text-align: center;">\$212K</td> <td style="text-align: center;">\$199K</td> <td style="text-align: center;">\$196K</td> </tr> </tbody> </table> <p>Updated: 29 SEPTEMBER 2022 (Annual Report 2022)</p>		Activities	FY1	FY2	FY3	Obtain approvals/maintain regulatory compliance; Prepare documents/materials for survey study	█			Beta test materials, procedures, databases; Revise based on beta test input	█			Recruit, screen, enroll, and collect data at baseline and at 12 months		█ Modified		Analyze data, disseminate study results to academic and consumer audiences			█	Estimated Budget (\$607K)	\$212K	\$199K	\$196K	<p>Goals/Milestones by Funding Year (FY)</p> <p>FY1 Goals – Study Start-up and Survey Preparation</p> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> Secure approvals; hire/assign staff, convene advisory board <input checked="" type="checkbox"/> Prepare all materials and databases for study implementation <input checked="" type="checkbox"/> Conduct beta test and revise based on input <input checked="" type="checkbox"/> Connect with community organizations and begin recruitment <p>FY2 Goal – Survey Implementation</p> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> Complete recruitment, enrollment, and survey completion of baseline survey <input checked="" type="checkbox"/> Retain participants through attrition reduction survey <input checked="" type="checkbox"/> Score and analyze baseline data <p>FY3 Goals – Survey Completion, Data Analysis, and Dissemination</p> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> Begin and complete 12 month surveys <input type="checkbox"/> Analyze and interpret longitudinal data with input from advisory board <input type="checkbox"/> Disseminate findings through local and national conferences, academic journals, consumer-oriented materials; Prepare final report <p>Comments/Challenges/Issues – A no cost extension (NCE) was requested and approved to complete grant activities. A NCE was required due to a delayed start to make revisions to the survey because of the pandemic and to obtain approval of those revisions.</p>	
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9. Appendices

9a. Consort Diagram

