



Commentary on “A pragmatic randomized controlled trial testing the effects of the international scientific SCI exercise guidelines on SCI chronic pain: protocol for the EPIC-SCI trial”

Sara J. Mulroy¹

Received: 15 May 2020 / Accepted: 18 May 2020 / Published online: 8 June 2020
© International Spinal Cord Society 2020

This edition of *Spinal Cord* features a protocol paper for a randomized clinical trial designed to evaluate the effects of exercise on bodily pain for individuals with spinal cord injury (SCI) [1]. In addition to addressing an important topic, this well-designed trial includes features that will enhance the likelihood of its success and relevance to the SCI population at large. The intervention, Exercise guideline Promotion and Implementation in Chronic SCI (EPIC-SCI), contains both physiological and behavioral components. The physiological component utilizes an exercise regime based on current international guidelines on exercise and physical activity for individuals with SCI. The intervention also includes behavioral components that are critical to attain and sustain a new lifestyle behavior such as physical exercise in any population. Importantly, this behavioral approach was developed by the research team in partnership with people with SCI to ensure its suitability to the intended population. In a prior study, they tested the behavioral intervention in a cohort of individuals with SCI and demonstrated that it led to increased exercise levels that were sufficient to significantly improve aerobic fitness at the end of the 8-week intervention [2]. Moreover, self-reported levels of physical activity remained elevated at a 6-month follow-up. Now, they want to determine whether exercise will positively affect chronic pain in this population.

One of the unique and commendable features of this trial is the researchers' effort to utilize a pragmatic design to enhance the likelihood that results could be generalized to real-world practice. The authors utilized the PRagmatic–Explanatory Continuum Indicator Summary-2 scores [3]

to indicate whether specific study design features were intended to reflect circumstances encountered in real-life or were more constrained and necessary to identify explanatory mechanisms underlying the relationship between exercise and its effects on chronic pain. The team selected a time frame for the study that will provide information on the ability of participants to continue the exercise program over a full year. The EPIC study will provide exercise bands for people lacking financial resources, which will reduce disparities and ensure that the cohort is representative of the SCI population. Typically, financial and environmental access to appropriate exercise facilities and equipment is often a barrier to exercise for individuals with SCI. In addition, participants are provided the flexibility to exercise at home, in a community gym, or at the research exercise facility. A fitness trainer will provide instruction in the individualized exercise program with an in-person introduction and a second review session after 3 months. This feature is designed to be representative of a level of instruction provided to new members of a gym, although the trainers in this EPIC-SCI study have SCI-specific training and experience. Participants will then engage in the exercise without direct supervision, but with external support. The behavioral intervention includes exercise adherence monitoring and guidance provided by exercise counselors via 15-min weekly phone/video contacts throughout the 6-month intervention to assist participants with progression of exercise intensity and goal setting as well as to check on participants' health and safety. The level of support provided through the behavioral intervention is reported to mimic health practices in British Columbia (Canada), but is not widely available in many other countries. This trial may provide evidence that could serve as recommendations for provision and insurance coverage for equipment and services to facilitate adoption of physical exercise for health in the SCI population.

✉ Sara J. Mulroy
smulroy@dhs.lacounty.gov

¹ Rancho Los Amigos National Rehabilitation Center, Downey, CA, USA

Although not a specified aim of the current study, the design allows for investigation of other barriers to exercise after SCI. In addition to motivational barriers to lifestyle change and limitations of access to adapted exercise facilities, individuals with SCI, as a group, have multiple secondary conditions over their lifespan that negatively affect their ability to engage in and sustain a physical exercise program. The database of the SCI Model System funded by the National Institute of Disability, Independent Living, and Rehabilitation Research provides a unique window into the incidence of these secondary conditions over time in a large population of individuals with SCI throughout the United States. In 2019, follow-up information regarding respondents' health and function over the previous year was collected from 2092 participants who ranged from 1 to 45 years post injury [4]. The annual rate of rehospitalization was ~33% in the first year post injury and 25–30% in the following years. The average duration of hospitalization was 20 days per year. The most common reason for rehospitalization was disease of the genitourinary system followed by disease of the skin. Over 50% of all respondents reported having at least one urinary tract infection requiring an antibiotic in the last year, regardless of whether they were hospitalized. Incidence of pressure injury in the last 12 months was 25–30%. These adverse events are in addition to general illnesses that may require a period of reduced activity and indicate that, in a typical year, many individuals with SCI would have an interruption in ongoing exercise routines.

Investigators in this proposed trial will evaluate outcomes using an intent to treat primary analysis in addition to a per-protocol analysis (i.e., participants with >80% exercise prescription adherence). A comparison of these results will identify the impact of significant nonadherence regardless of the underlying reason. Exercise counselors will also document any health issues that impeded exercise participation at the weekly support contacts. Though not in the current analysis plan, this information could identify the effects of major secondary health conditions that are

common after SCI on an individual's ability to continue and benefit from a physical exercise program. To fully generalize results of physical exercise interventions to the broader SCI population, we will need to understand the impact of common health conditions as well as the associated interruptions in the program. As one of the first trials involving participants with SCI to address pragmatism formally in the experimental design [5], the investigators in this trial are to be commended for their efforts to ensure that their results are relevant to the intended end users.

Compliance with ethical standards

Conflict of interest The author declares no conflict of interest.

Publisher's note Springer Nature remains neutral with regard to jurisdictional claims in published maps and institutional affiliations.

References

1. Martin Ginis KA, van der Scheer JW, Todd KR, Davis JC, Gaudet S, Hoekstra F, et al. A pragmatic randomized controlled trial testing the effects of the international scientific SCI exercise guidelines on SCI chronic pain: protocol for the EPIC-SCI trial. *Spinal Cord*. 2020. <https://doi.org/10.1038/s41393-020-0478-7>.
2. Ma JK, West CR, Martin Ginis KA. The effects of a patient and provider co-developed, behavioral physical activity intervention on physical activity, psychosocial predictors, and fitness in individuals with spinal cord injury: a randomized controlled trial. *Sports* 528 *Med*. 2019;49:1117–31.
3. Loudon K, Treweek S, Sullivan F, Cheesbrough G, Donnan P, Thorpe KE, et al. The PRECIS-2 tool: designing trials that are fit for purpose. *Br J Med*. 2015;350:2147.
4. National Spinal Cord Injury Statistical Center. Spinal Cord Injury Model System 2019 Annual Report. <https://www.nscisc.uab.edu/public/2019%20Annual%20Report%20-%20Complete%20Public%20Version.pdf>.
5. Burke SM, Tomasone JR, Scim NV, Ma JK, Harden SM, Wolfe DL, The SCIRE Research Team. Physical activity self-management interventions for adults with spinal cord injury: Part 2—Exploring the generalizability of findings from research to practice. *Psych Sport Exerc*. 2018;37:286–95.