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ORIGINAL RESEARCH

Home-Based Exercise Enhances Health-Related Quality of Life in Persons With Spinal Cord Injury: A Randomized Controlled Trial

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Abstract

Objective: To assess the influence of a home-based exercise intervention on indices of health-related quality of life (HRQOL) in persons with spinal cord injury (SCI).

Design: This was a randomized controlled trial (HOMEX-SCI; ISRCTN57096451). After baseline laboratory testing and a week of free-living physical activity monitoring, eligible participants were randomly assigned (2:1 allocation ratio) to a home-based moderate-intensity upper-body exercise intervention group (INT, n=13), or a lifestyle maintenance control group (CON, n=8), for 6 weeks.

Setting: Home-based with short laboratory visits immediately before and after the intervention/control period.

Participants: Inactive participants (N=21) with chronic (>1yr) SCI (injury level <T4).

Intervention: Participants assigned to the INT completed 4, 45-minute moderate-intensity (60%-65% peak oxygen uptake) arm-crank exercise sessions per week for 6 weeks. Participants assigned to the control group (CON) were asked to maintain their habitual physical activity behavior.

Main Outcome Measures: Secondary outcome measures were assessed, including physical and mental component scores (PCS and MCS) of health-related quality of life (HRQOL), fatigue, global fatigue (FSS), and shoulder pain index (WUSPI). Cardiorespiratory fitness (CRF), objectively measured habitual moderate-to-vigorous physical activity (MVPA), and exercise self-efficacy (ESE) were also assessed at baseline and follow-up.

Results: Changes in the PCS ($P=.017$) of the Short Form 36 Health Survey (SF-36), ESE ($P=.011$), and FSS ($P=.036$) were significantly different between the 2 groups, with moderate to large effect sizes ($d=0.75$-1.37). Various HRQOL outcomes demonstrated likely to very likely positive inferences in favor of the INT group following the 6-week exercise intervention. Changes in ESE were significantly ($P<.01$) associated with changes in PCS ($r=0.62$), MCS ($r=0.71$), FSS ($r=-0.71$), and global fatigue ($r=0.57$).

Conclusions: A 6-week upper-body exercise intervention improved indices of HRQOL in persons with SCI. Improvements were associated with increases in ESE. While this intervention demonstrated a positive effect on perceived physical functioning, future interventions should aim to support social and mental functioning and exercise maintenance.

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Disability can negatively affect physical activity behavior.[1] The reasons for the adoption of a more sedentary lifestyle are multifactorial, but the perceived psychosocial and environmental barriers to engage in physical activity are numerous for wheelchair users living with a spinal cord injury (SCI).[2,3] Consequently, persons with SCI are relatively inactive[4] and new ways to support the initiation of physical activity in this population are needed.

Besides an increased incidence of chronic diseases (eg, cardiovascular disease, type 2 diabetes),[5] persons with SCI have significantly elevated levels of fatigue, anxiety, depression, and poorer exercise self-efficacy (ESE) compared to nondisabled controls.[6,7] This is important because physical activity can

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improve quality of life for people with SCI and ESE is considered a modifiable predictor of physical activity behavior change, specifically in this population.[8-12] Therefore, it is essential to develop strategies capable of improving ESE in order to increase physical activity participation and accrue enhancements in quality of life.

Educational interventions, covering physical activity, nutrition and lifestyle management, have been shown to improve ESE and self-rated health, and result in fewer and less severe secondary conditions in persons with SCI.[13,14] Following a 9-month, twice-weekly strength and arm-ergometry intervention, participants reported significantly higher levels of satisfaction with physical function, level of perceived health, overall quality of life, and less pain than a control group.[15] However, these findings have not been demonstrated with shorter term, higher volume aerobic exercise training per se. Moreover, it has previously been suggested that upper-body exercise, primarily arm-crank ergometry as a training modality, might contribute to shoulder overuse injuries and trigger the onset of pain.[16] Therefore, the available evidence is currently inconclusive about whether upper-body arm-crank exercise is an effective treatment modality for improving health-related quality of life (HRQOL) in persons with SCI. Furthermore, a lack of access to gym facilities and exercise equipment, as well as poor information and support, have been identified as key barriers to exercise for adults with SCI.[17-19] Therefore, the provision of exercise equipment and a tailored exercise program within a home setting could provide a mastery experience and help enhance ESE in people with SCI.

A recent meta-analysis on physical activity and wellbeing among individuals with SCI noted that most of the evidence to date has been from cross-sectional studies, with little consistency in the constructs and measures of HRQOL.[20] Therefore, the aim of this study was to test the hypothesis that a 6-week home-based upper-body exercise intervention would improve HRQOL component scores compared to a lifestyle maintenance control group (CON), in persons with SCI. In keeping with Dijkers'[21] conceptualization of HRQOL and supported by previous research,[10,20,22] it was hypothesized that physical activity behavior would positively correlate with objective measures of physical and mental component scores (derived from the short-form 36 health survey [SF-36]). These summary component scores describe what the individual can achieve in both the physical and psychological domains. In addition, and grounded on the propositions of social cognitive theory,[23] it was further hypothesized that exercise barrier self-efficacy would positively correlate with quality of life.[10,12]

List of abbreviations:

CON	**lifestyle maintenance control group**
CRF	**cardiorespiratory fitness**
ESE	**exercise self-efficacy**
ESES	**Exercise Self-Efficacy Scale**
FSS	**Fatigue Severity Scale**
HOMEX-SCI	**home-based upper-body exercise randomized controlled trial**
HRQOL	**health-related quality of life**
INT	**home-based moderate-intensity upper-body exercise intervention group**
MVPA	**moderate-to-vigorous physical activity**
SCI	**spinal cord injury**
SF-36	**Short Form 36 Health Survey**
Vo_2peak	**peak oxygen uptake**
WUSPI	**Wheelchair User Shoulder Pain Index**

Methods

Study design

This randomized controlled trial (HOMEX-SCI; ISRCTN57096451) was approved by the National Research Ethics Service Committee. A detailed trial protocol has previously been published[24] and is in accordance with current Consolidated Standards of Reporting Trials guidelines.[25] It should be noted that the primary outcome measures related to biomarkers of cardiometabolic disease are reported elsewhere.[26] Data reported in this article are based on the secondary outcome measures associated with HRQOL.

Participants were initially recruited by displaying advertisements on national disability charity websites, online forums, and social media networking sites. Members of our Patient and Public Involvement (PPI) group, who met the inclusion criteria, were notified directly via email. Written informed consent was obtained from all participants. After baseline laboratory testing and a week of free-living physical activity monitoring, eligible participants were randomly assigned (2:1 allocation ratio) to a home-based moderate-intensity upper-body exercise intervention (INT), or a lifestyle maintenance control group (CON), for 6 weeks. Minimization was used to ensure balance between the 2 groups for baseline characteristics of; age, body mass, level of spinal cord lesion, and physical activity level. All participants attended the Centre for DisAbility Sport and Health (DASH) laboratory at the University of Bath, on 2 occasions, for baseline (wk 0) and follow-up testing (wk 7). The same experimental procedures were performed during both baseline and follow-up testing. It should be noted that we did not plan an intention to treat (ITT) analysis but instead a treatment exposure analysis (TEA), where only participants that complied with the intervention were included in the final analyses.

Sample size

The sample size was calculated for the primary outcome measure (ie, fasting serum insulin concentration), as detailed in the previously published trial protocol.[24] It was estimated that 9 participants would be required to detect a statistically significant change in insulin sensitivity in the INT group, based on an estimated effect size (Cohen d) of 1.1. The power was set at 0.8 and the alpha at 0.05. However, a 2:1 allocation ratio was adopted in anticipation of more dropouts in the INT compared to CON. There were concerns that by the end of the study the INT group sample might not be sufficiently large enough to have adequate power for our planned statistical analyses. Consequently, a computer program was used to calculate sample size adjustments for 2 groups with unequal size, to account for any consequences of unequal allocation on statistical power. Also, taking into account an expected drop-out rate of approximately 15%, we aimed to recruit at least 24 (INT: 16, CON: 8) participants with chronic paraplegia.

Participants

Participant eligibility criteria were as follows: aged between 18-65 years, inactive (habitual physical activity level; PAL <1.60); chronic (>1yr) spinal cord lesion below the second thoracic level; no immediate plans to alter diet and/or physical activity behavior;