Spinal Cord (2012) 50, 718–727

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REVIEW

Systematic review of the methodological quality and outcome measures utilized in exercise interventions for adults with spinal cord injury

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Study design: Systematic literature review.
Objectives: The primary aims of this study were to evaluate the methodological quality of exercise intervention studies in adults with spinal cord injuries (SCIs); and to classify the reported outcome measures according to the International Classification of Functioning, Disability and Health (ICF).
Methods: Electronic searches of PubMed, CINAHL, SPORTDiscus, PsychINFO, Scopus and the Cochrane Center Register of Controlled Trials from 2001 to 2011 were performed. Selected studies were evaluated for methodological quality using the Downs and Black checklist. Outcome measures were extracted and linked to categories of the ICF using standardized linking rules.
Results: Two-hundred forty abstracts were retrieved, 57 studies met eligibility criteria. The mean methodological quality score was 14.7 ± 3.2 out of 28 on the Downs and Black checklist. Three-hundred seventy four outcome measures were extracted with 333 concepts linked to 35 second-level ICF categories across the four components.
Conclusion: Studies of exercise interventions for adults with SCI included in this review are generally low in methodological quality, primarily reporting outcomes related to the Body Functions and Body Structures components of the ICF. It is recommended that studies employ more vigorous methodological designs to reduce bias and confounding, and include outcome measures targeting more categories in the Activities and Participation component so as to reflect the potential benefits of exercise on health and functioning in this population.
Spinal Cord (2012) **50,** 718–727; doi:10.1038/sc.2012.78; published online 10 July 2012

Keywords: spinal cord injury; exercise; physical activity; outcome measures; ICF; methodological quality

INTRODUCTION

Spinal cord injuries (SCIs) lead to impairment or loss of function below the level of injury. Impairment or loss of function may ultimately lead to activity limitations, restricted participation in a variety of activities and limitations in community involvement due to restricted mobility.[1–3] Lack of physical activity in adults with SCI has been shown to increase adiposity, alter lipid metabolism and affect cardiovascular function.[4–6] These changes may increase a person with SCI's risk for mortality as observed in able-bodied adults.[7] Therefore, increasing levels of physical activity for individuals with SCI is advocated.[8]

Studies have shown increasing physical activity may be beneficial for individuals with SCI.[4,9] Previous reviews pertaining to exercise and SCI have focused primarily on improvements in physical capacity measures,[9–11] without relating the outcome measures to the categories and components of the International Classification of Functioning, Disability and Health (ICF).[12] A recent review that linked outcome measures to the ICF in people with SCI reported a large number of outcomes were related to 'Body Structures' and 'Body Functions' components.[13] This particular review evaluated a random sample of any study involving individuals with SCI without specifically addressing exercise interventions. Linking outcome measures from exercise intervention studies to the ICF is helpful, as it provides a knowledge base about which ICF categories, domains and components have been most frequently targeted, and which areas need to be addressed further in future studies.

Another issue related to studies on exercise interventions in adults with SCI is methodological quality. Evaluating methodological quality of studies on exercise interventions not only provides a guide for clinicians and exercise professionals to make informed decisions on adopting the best available evidence in their practice, but also increases researchers' awareness of areas of methodological deficiency. This information is beneficial when designing studies to avoid those pitfalls and improve scientific quality. Although randomized controlled trials (RCTs) are typically viewed as the highest quality of study,[14] poorly designed RCTs will not provide evidence that is superior to other study designs.

The purpose of this systematic review was to (1) assess the methodological quality of prospective studies on exercise interventions in adults with SCI and (2) classify the reported study outcome measures according to the ICF.

MATERIALS AND METHODS

This systematic review was conducted in four major steps. First, we performed an extensive search of several commonly used literature databases to locate studies on exercise and SCI, and selected studies that met eligibility criteria.

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Received 9 January 2012; revised and accepted 7 June 2012; published online 10 July 2012

Second, studies were scored for methodological quality using the Downs and Black checklist.[15] Third, outcome measures were extracted from each eligibile study. Finally, the concepts within the outcome measures were linked to the categories of the ICF.

Methodological quality and level of evidence

The Downs and Black checklist was designed to evaluate the methodological quality of both randomized and nonrandomized comparative studies.[15] The checklist consists of 27 items that address the following methodological components: reporting, external validity, internal validity (bias and confounding) and power. Twenty-six items were rated either as yes (=1) or no/unable to determine (=0), and one item was rated on a 3-point scale (yes=2, partial=1, and no=0). Scores range from 0 to 28 with higher scores indicating a better methodological quality of the study. The following cut-points have been suggested to categorize studies by quality: excellent (26–28), good (20–25), fair (15–19) and poor ($\leqslant$14).[16] Adequate psychometric properties of the Downs and Black checklist, such as internal consistency, test–retest reliability, inter-rater reliability and criterion validity, have been reported elsewhere.[15] The checklist has been ranked in the top six quality assessment tools suitable for use in systematic reviews.[17]

In addition, for studies utilizing the RCT design, ratings were extracted from the Physiotherapy Evidence Database (PEDro) at www.pedro.org.au.[18] The PEDro scale consists of 11 items with each item awarding one point when the criterion specified in the item is satisfied. The first item is not included to calculate the PEDro score. Scores range from 0 to 10 with higher scores indicating a better methodological quality of the RCT. The following cut-points were suggested to categorize studies by quality: excellent (9–10), good (6–8), fair (4–5) and poor ($\leqslant$3).[19] The PEDro scale has demonstrated adequate reliability for use in systematic reviews of exercise intervention RCTs.[20] Finally, the strength of evidence of the exercise intervention studies was determined using a modified Sackett's levels of evidence (Table 1).[21] The levels are ranked 1 through 5 and represent the degree of scientific evidence from clinical studies, with 1 being the highest and 5 the lowest level of evidence.

The ICF

The outcome measures of the exercise intervention studies were classified using the ICF taxonomy. The ICF is organized into four main components: (1) Body Functions, (2) Body Structures, (3) Activities and Participation, and (4) Environmental Factors.[12] Each of the four components consists of various domains (that is, chapters). Within each domain/chapter, categories and subcategories are denoted by additional digits.[22] The ICF uses an alphanumeric system to classify each outcome measure. Letters (b-body functions, s-body structures, d-activities and participation and e-environmental factors) represent the four components, followed by a numeric code starting with the chapter number (one digit) indicating the first level, followed by the second level (two digits) and the third and fourth levels (one digit each), which represent an increase in the level of precision in describing the outcome measures.[22] For example, 'power of the quadriceps' would follow the code for chapter 7 'Neuromusculoskeletal and movement-related functions' of the component 'Body Functions' which is b7 (first level), then 'muscle power functions' is b730 (second level), and finally 'power of muscles in lower half of the body' is b7303 (third level). Outcome measures extracted from the selected studies were linked to categories in the ICF using linking rules established by Cieza *et al.*[23,24] Linking rules include the following: all meaningful concepts within each outcome measure are identified, the aim with which the measure used is considered, outcome measure should be linked to the most precise ICF category, and if information is insufficient for making a decision or the concept is not contained within the ICF, the domains are coded *nd* (not definable) or *nc* (not coded).[23,24]

Table 1 Modified Sackett's levels of evidence

Level	*Study design*
1	RCT (PEDro score $\geqslant$6)
2	RCT (PEDro score <6), prospective controlled trial, cohort
3	Case control
4	One-group pretest–posttest, case series
5	Case report

Abbreviations: PEDro, Physiotherapy Evidence Database; RCT, randomized controlled trials.

Eligibility criteria

We aimed to include studies that provided original data on the effects of exercise training in adults with SCI. Studies were eligible for inclusion if the independent variable was an exercise intervention lasting at least 4 weeks in duration with a focus other than task-specific training that is typically conducted in clinical rehabilitation settings (that is, outpatient physical therapy). To be included, the exercise intervention had to be described with a specific frequency, duration and mode, including both aerobic and/or strength training. Studies were excluded if the outcome measures of the prescribed intervention were only task-specific, such as studies utilizing body-weight supported treadmill training (BWSTT) with outcomes only focused on that task (for example, improvements in gait). Additional exclusion criteria were: not employing a prescribed exercise intervention that had a known frequency, duration and mode (for example, physical activity promotion interventions), respiratory muscle training interventions or studies that included participants with common comorbidities of SCI (for example, traumatic brain injury).

Search strategy

All types and etiologies of SCI were included to provide a comprehensive, unbiased review of the literature. Electronic databases in PubMed, CINAHL, SPORTDiscus, PsychINFO, Scopus and the Cochrane Center Register of Controlled Trials were last searched on 11 October, 2011. Searches were limited to studies published after 2001 (year of publication of the ICF), english language, adult ($\geqslant$18 years) and human studies. Search terms included: exercise, physical activity, resistance training, spinal cord injur*, parapleg*, quadripleg* and tetrapleg*.

Data extraction

Articles were reviewed independently by two authors (SS and LS). First, articles were evaluated for methodological quality using the Downs and Black checklist.[15] Quality scores for RCTs were extracted from the PEDro. Study designs were determined by the primary reviewer (SS) with agreement from the second reviewer (LS). The intraclass correlation coefficient for Downs and Black methodological quality scores between the two reviewers was 0.90. When discrepancies in ratings between reviewers were more than one scoring point, discussion between reviewers with consultation from a third party (SB) was sought to resolve the difference.

Second, outcome measures within each article were extracted by the primary reviewer (SS). Outcome measures were linked to the ICF independently by two reviewers (SS and LS) using standard linking rules.[23,24] We aimed to use the most precise ICF category (that is, the highest level) possible. For example, quadriceps strength would be linked to the ICF category b7303 'power of muscles in lower half of the body' instead of the broader (that is, lower level) category b730 'muscle power functions.' The Kappa coefficient for the agreement between the two reviewers on classifying the ICF codes of the components was 0.79. Discrepancies in linking outcomes were discussed between reviewers with consultation from a third party (JL) when necessary.

RESULTS

Study design

A total of 240 abstracts were retrieved, 57 studies met the eligibility criteria (Figure 1). Study design, intervention type, methodological quality scores and outcome measures of these 57 studies are presented in Table 2.[25–81] Of the 57 studies, study designs included RCTs (n=7), prospective controlled trials (n=9), one-group pretest–posttest design (n=33), case series (n=4) and case reports (n=4). The number of subjects in each study ranged from 1 to 34 (median=10). The most common mode of intervention was

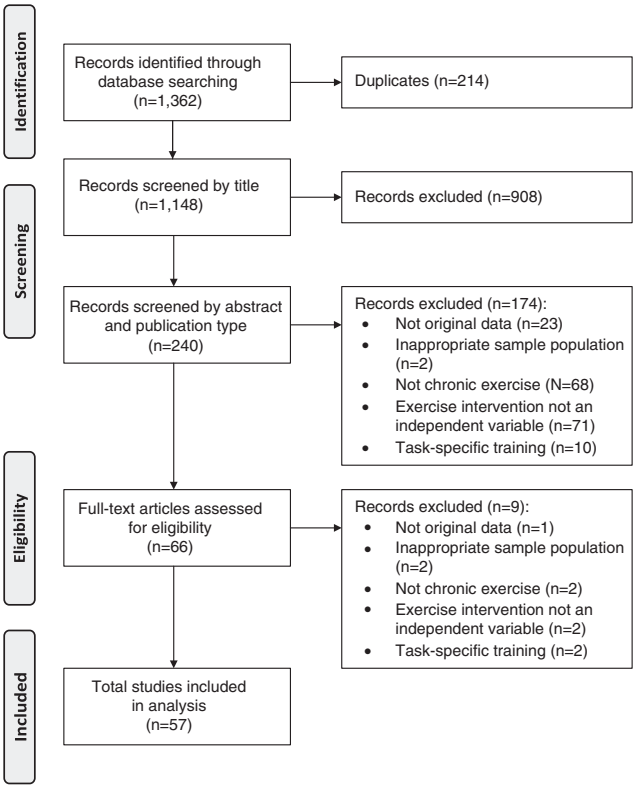

Figure 1 Description of the search strategy.

functional electrical stimulation cycling ($n=13$), followed by BWSTT ($n=10$) and functional electrical stimulation resistance training ($n=9$). Interventions were performed 3–4 days per week with a range of 10–120 min of exercise per session for a mean duration of 18 weeks (s.d. = 18.5 weeks, three studies were $\geqslant 1$ year duration).

Methodological quality

The distribution of methodological quality scores based on the Downs and Black checklist are presented in Figure 2. The distribution of scores followed a normal distribution (mean = 14.7, median = 15).[15] For the seven RCTs, the PEDro scores ranged from 1–8, with a median of 5. Three studies were qualified as level 1 evidence using the modified Sackett's criteria.[10]

Outcome measures linked to the ICF

A total of 374 outcomes were extracted from the selected studies. For those outcome measures that belong to multi-item surveys, we attempted to retrieve survey documents to include as many ICF codes as possible. Tables 3–5 represent the first and second-level ICF categories with frequency of occurrences in the coded outcome measures. Frequency of occurrence refers to the total number of outcome measures (including survey items) that were linked to a unique ICF code. In 'Body Functions,' 5 of 8 first-level categories were addressed, 1 of 7 'Body Structures' categories was addressed, 1 of 9 'Activities and Participation' categories were addressed, and 1 of 5 'Environmental Factors' categories was addressed. There were 41 outcome measures that were not coded to the ICF (listed as not coded, personal factors, or quality of life). Measures that could not be linked to a specific ICF category included quality of life and some anthropometric measures such as waist to hip ratio. Figure 3 represents the percentages of the ICF categories referred to by the outcome measures. A total of 333 concepts could be linked to 35 unique second-level ICF categories.

DISCUSSION

Of the exercise interventions for people with SCI studies evaluated in this report, the overall methodological quality of the studies was fair according to the suggested categorization scheme for the Downs and Black score. There were very few trials with good methodological quality, or that qualified as level 1 evidence according to the modified Sackett's criteria. Even though exercise is considered to be beneficial for health and is often recommended for people with SCI, this systematic review revealed that there are insufficient numbers of high quality studies of exercise interventions in people with SCI to support the health and function benefits of exercise for this population. In addition, the outcome measures that are typically included in these exercise intervention studies mainly targeted 'Body Functions' without adequately addressing the ICF component of 'Activities and Participation.' It is recommended that the impact of any improvements in body functions and structures from exercise interventions should also be evaluated for their effects on activities and participation.

Study design and methodological quality

Results of this systematic review give an overview of the current research design and methodological quality issues for studies examining exercise interventions for individuals with SCI. The majority of studies utilized either a one-group pretest–posttest or a nonrandomized controlled design. These findings are in agreement with other reviews of exercise interventions in people with chronic conditions. Two recent reviews of exercise interventions for individuals with traumatic brain injury and muscle disease, yielded only six and three RCTs, respectively.[82,83] Both reviews concluded that insufficient high quality evidence exists for exercise interventions in these two populations.

Inability to recruit a sufficiently large sample and group heterogeneity in the SCI population may partly explain the frequent use of lower-quality study designs. Given the characteristics of the SCI population, RCTs for this population tend to be small with a high drop-out rate.[14] This is in agreement with the review by Martin-Ginis and Hicks addressing exercise research issues in this population.[14] Owing to lack of higher levels of evidence in exercise interventions for people with SCI, current consensus on its efficacy is largely based on well-conducted nonrandomized or single-group studies.

In regard to the scoring of the review studies using the Downs and Black checklist, some studies did not satisfy the criteria because information was not included within the publication. According to the Downs and Black scoring criterion, if the study did not explicitly state a certain requested methodology for a particular item, that item must be scored as not satisfying the criterion. The methodological rating criteria that were most frequently not satisfied in the papers we reviewed were related to blinding, randomization, representativeness of the sample group and adjustment for confounding factors in data analysis. Adequate adjustment for confounding in analysis was a fairly subjective criterion and depended on the rater's opinion of whether or not confounding factors exist. As the SCI population is a heterogeneous group, variables such as lesion level, completeness and age should be controlled for statistically, particularly if the study design did not employ randomization or group matching.

The Downs and Black checklist includes a criterion concerning appropriate statistical tests,[15] however it is unclear if there was adequate control for the risk of type I errors among the reviewed

Table 2 Study design and description of relevant studies that met inclusion criteria

References	*Intervention type*	*Quality scores*			*Study type*	*Outcome measures*		
		D and B	*PEDro*	*Level*		*Improvement*[a]	*Decline*	*No change*
Ashe[25]	FES cycling	9	—	4	C. series	BMD, % of lean, % of fat	—	—
Bizzarini[26]	UE erg and resistance training	12	—	4	Pre/ Post	FES cycle workload	—	Weight, body composition[b], testosterone/cortisol ratio, CPK level
Bjerkefors[27]	Kayak ergometer	17	—	4	Pre/ Post	Transfer height, WC propulsion, platform mount height	—	WC agility
Bjerkefors[28]	Kayak ergometer	20	—	4	Pre/ Post	Multidirectional shoulder strength[b]	—	—
Bjerkefors[29]	Kayak ergometer	19	—	4	Pre/ Post	Trunk displacement during perturbation	—	—
Bogie[30]	Implanted NMES	15	—	4	Pre/ Post	Ischial pressure	—	Total interface pressure
Bougenot[31]	Wheelchair ergometry	14	—	4	Pre/ Post	VO_2, VCO_2, tolerated power, SpO_2	—	HR, peak ventilation, tidal volume
Carvalho[32]	FES + BWSTT	11	—	2	PCT	Muscle CSA (quadriceps)	—	—
Carvalho[33]	FES + BWSTT	14	—	2	PCT	Bone biochemical markers	—	BMD (lumbar, femur)
Chen[34]	FES cycling	13	—	2	PCT	BMD (femur, tibia)	—	BMD (calcaneus)
Clark[35]	FES knee extension, ankle dorsiflexion	20	—	2	PCT	Body composition	BMD (total)	BMD (hip, spine)
Coupaud[36]	BWSTT	13	—	5	C. report	Bone mineral content, BMD (total, trabecular), muscle CSA (quadriceps)	Fat CSA (quadriceps)	Bone CSA (femur)
Crameri[37]	FES cycling	12	—	4	Pre/ Post	FES cycle workload, muscle fiber type[b], muscle CSA (quadriceps), muscle capillarization (quadriceps), citrate synthase level, hexokinase level	—	—
de Groot[38]	UE erg	14	5	2	RCT	VO_2, Power output, blood lipids[b]	—	Insulin sensitivity
De Mello[39]	Aerobic exercise	11	—	4	Pre/ Post	Leg movements during sleep	—	—
Dolbow[40]	UE erg	9	—	5	C. report	VO_2, % body fat	—	BMD (total)
Dyson-Hudson[41]	UE erg	22	—	2	PCT	WUSPI score[b]	—	—
Effing[42]	BWSTT	15	—	4	Pre/ Post	Case series- varied by subject		
El-Sayed[43]	UE erg	16	—	2	PCT	VO_2, ventilation max, workload	—	Blood lipids[b]
Gerrits[44]	FES knee extension	11	—	4	C. series	Mean blood velocity, systolic inflow volume	—	Peak blood velocity, Minimum blood velocity, End-diastolic velocity
Gerrits[45]	FES cycling	15	—	4	Pre/ Post	FES force, fatigue resistance	—	Contraction/relaxation speed (quadriceps)
Gerrits[46]	FES knee extension, ankle dorsiflexion	14	—	4	Pre/ Post	Knee extension. strength, Fatigue resistance (quadriceps), succinate dehydrogenase (quadriceps)	—	Myosin type I, muscle fiber diameter (quadriceps), alpha-glycerophosphate dehydrogenase (quadriceps)
Giangregorio[47]	BWSTT	13	—	4	C. series	Walking duration, walking speed, BWS, % lean mass, muscle CSA (quadriceps)	BMD (femur, tibial, lumbar)	Bone biochemical markers
Giangregorio[48]	BWSTT	17	—	4	Pre/ Post	Walking duration, walking speed, BWS, body composition, muscle CSA (quadriceps)	BMD (total)	BMD (spine, femur, tibia), bone biochemical markers
Gorgey[49]	NMES + resistance knee flex/ extension	9	—	5	C. report	Muscle CSA[b], IM fat, subcutaneous fat, NMES resistance	—	—

Table 2 (Continued)

References	*Intervention type*	*Quality scores*			*Study type*	*Outcome measures*		
		D and B	*PEDro*	*Level*		*Improvement*[a]	*Decline*	*No change*
Gregory[50]	LE resistance and plyometric training	10	—	4	C. series	Torque (knee extension, plantarflexion), Rate of torque development (knee extension, plantarflexion), activation deficit (knee extension, plantarflexion)	—	—
Griffin[51]	FES cycling	16	—	4	Pre/Post	Ride time, power, body composition, OGTT, AIS[b]	—	Cholesterol
Grigorenko[52]	Sea kayaking	15	—	2	PCT	Acceleration of change (sagittal)	—	COP change[b], velocity of change[b], acceleration of change (frontal)
Harvey[53]	FES + PRT on single quadriceps	20	8	1	RCT	Quadriceps strength (voluntary), perception of exercise effectiveness	—	Quadriceps strength (stim), quadriceps endurance (voluntary, stim), perceived ability, satisfaction w/ program
Heesterbeek[54]	Hybrid FES cycling + UE erg	16	—	4	Pre/Post	Leg volume, VO_2	—	Peak ventilation, peak HR, power output
Hicks[55]	PRE upper extremity, UE erg	20	5	1	RCT	Walking score, BWS, speed, distance, life satisfaction, satisfaction w/ physical function	—	Depression, perceived health, perceived ability for IADL
Hicks[56]	BWSTT	16	—	4	Pre/Post	Peak HR, BP, UE strength[b], power output, satisfaction w/ physical function, satisfaction w/ appearance, pain, stress, depression, PQOL, perceived health	—	—
Jacobs[57]	Circuit resistance training	13	—	4	Pre/Post	Fatigue resistance, VO_2, UE strength[b]	—	Elbow flexion/extension strength
Jacobs[58]	Endurance or resistance	17	—	4	Pre/Post	VO_2, Power, UE strength[b]	—	Peak ventilation, peak HR, peak RPE
Jeon[59]	FES cycling	15	—	4	Pre/Post	OGTT	—	Insulin secretion, Insulin sensitivity
Jeon[60]	FES rowing	15	—	4	Pre/Post	Fasting glucose, fasting leptin	—	Body composition, fasting insulin, insulin resistance
Kakebeeke[61]	FES cycling	10	—	5	C. report	BMD (femur), thigh CSA, Fat CSA (thigh, lower leg), peak HR, VO_2, blood lactate	—	Muscle CSA (lower leg)
Kern[62]	FES knee extension/flexion	18	—	4	Pre/Post	Knee extension torque, muscle composition (quadriceps)[b]	—	—
Kjaer[63]	FES cycling	11	—	4	Pre/Post	Quadriceps: hexokinase, lactate dehydrogenase, citrate synthase, hydroxyacyl-3-dehydrogenase	—	—
Latimer[64]	PRE UE erg and resistance training	14	2	2	RCT	Exercise influences depression through stress, independent of pain.		
Latimer[65]	PRE UE erg and resistance training	18	1	2	RCT	Stress, depression, PQOL	—	—
Liu[66]	FES cycling	15	—	4	Pre/Post	Thigh girth, body composition, knee flex/extension torque	—	—
Mahoney[67]	FES knee extension	14	—	4	Pre/Post	CSA (quadriceps)	—	OGTT, fasting insulin
Martin-Ginis[68]	UE erg and resistance training	22	6	1	RCT	Pain, stress, self-efficacy, perceived control, PQOL, depression, satisfaction w/ physical function, satisfaction w/ appearance	—	—
Mohr[69]	FES cycling	11	—	4	Pre/Post	GLUT-4 transport level, Insulin-stimulated glucose uptake	—	OGTT
Nash[70]	circuit resistance training	15	—	4	Pre/Post	UE force, VO_2 peak, anaerobic power, WUSPI score[b]	—	—
Phillips[71]	BWSTT	13	—	4	Pre/Post	BWS, gait velocity, glucose tolerance, insulin response, substrate oxidation, GLUT-4 level, muscle hexokinase, muscle metabolites	—	Body composition

Table 2 (Continued)

References	*Intervention type*	*Quality scores*			*Study type*	*Outcome measures*		
		D and B	*PEDro*	*Level*		*Improvement*[a]	*Decline*	*No change*
Sk□ld[72]	FES cycling	13	2	2	RCT	LE muscle volume	—	Spasticity[b], body composition, body weight
Soyupek[73]	BWSTT	14	—	4	Pre/ Post	Resting HR, FVC, inspiratory capacity, depression	—	BP, Maximum inspiratory pressure, FEV1, FEV1/FVC, expiratory reserve volume, forced expiratory flow, slow vital capacity
Stewart[74]	BWSTT	14	—	4	Pre/ Post	Ambulatory capacity, cholesterol, muscle fiber CSA (VL), muscle fiber composition (VL)[b], citrate synthase (VL)	—	—
Stoner[75]	FES knee extension	16	—	4	Pre/ Post	Flow-mediated dilation (posterior tibial artery)	—	Artery vessel diameter (posterior tibial artery)
Sutbeyaz[76]	Breathing exercises and UE erg	13	—	4	Pre/ Post	VO_2, Peak HR, HR reserve, minute ventilation, SpO_2, power output (UE), exercise time	—	BP
Thijssen[77]	FES cycling & UE erg	13	—	4	Pre/ Post	VO2, thigh bloodflow, vessel diameter, vascular resistance, thigh volume, fatigue resistance	—	Forearm bloodflow, calf bloodflow, mean wall shear weight, forearm circumference, Lower leg volume
Valent[78]	Hand cycling	19	—	4	Pre/ Post	Power output (UE), VO_2, shoulder abduction strength	—	RER, peak HR, SpO_2, elbow flexion/ extension strength, shoulder IR strength, FVC, peak expiratory flow
Valent[79]	Hand cycling	17	—	2	PCT	Power output (UE), shoulder strength[b], elbow flexion strength	—	Peak HR, resting HR, VO_2, FVC, shoulder flexion/extension strength, elbow extension strength, wheelchair capacity
Van Duijnhoven[80]	FES cycling	16	—	2	PCT	—	—	Malondialdehyde level, superoxide dismutase level, glutathione peroxidase level
Wheeler[81]	FES rowing	16	—	4	Pre/ Post	VO_2, SpO_2	—	ventilation volume, RER, peak HR

Abbreviations: AIS, ASIA impairment score; BMD, bone mineral density; BMI, body mass index; BP, blood pressure; BWS, body weight support; BWSTT, body weight supported treadmill training; COP, center of pressure; CPK, creatine phosphokinase; C. report, case report; C. series, case series; CSA, cross-sectional area; D and B, Downs and Black; FES, functional electrical stimulation; FEV, forced expiratory volume; FVC, forced vital capacity; GLUT, glucose transporter; HR, heart rate; LE, lower extremity; NMES, neuromuscular electrical stimulation; OGTT, oral glucose tolerance test; PCT, prospective controlled trial; PEDro, Physiotherapy Evidence Database; PQOL, perceived quality of life; PRE, progressive resistance exercise; Pre/Post, one group pretest-posttest design; PRT, progressive resistance training; RCT, randomzied controlled trial; RER, respiratory exchange ratio; RPE, rating of perceived exertion; SpO_2, oxygen pulse; UE erg, upper extremity ergometry; VL, vastus lateralis; WC, wheelchair; WUSPI, wheelchair user's shoulder pain index.
[a]Improvement indicates physiologically desirable change.
[b]Multiple items included within measure.

studies. Some studies included a large number of outcome measures, particularly that measuring multidirectional upper-extremity strength; however, the statistical analyses did not always indicate if appropriate statistical adjustments were utilized. Owing to the inherent risk of type I error, researchers should be cautious when considering the inclusion of a high number of outcome measures that address the same research question.

Outcome measures linked to the ICF

The most commonly addressed outcomes were related to 'muscle power functions' (b730). Within this second-level category, however, muscular strength and power are considered together. This was problematic for outcome measures in exercise intervention studies because power and strength are often considered as different concepts, whereas in the ICF, they share the same code. In addition, 'power of muscles in lower half of the body' is a third-level code; however, there is no corresponding code for power of muscles in upper half of the body. As a result, only the second-level code was used to address upper-extremity strength.

We occasionally had difficulty determining the usefulness of the code 'fatiguability' (b4554) due to the overlapped concept of muscle function when the outcome measure was specific to skeletal muscle fatigue. To overcome this difficulty we chose to code muscle fatigue to 'muscle endurance functions' (b740) and general fatigue to 'fatiguability' (b4554). Another example was 'respiration functions' (b440) that is closely related to exercise tolerance but was utilized for multiple outcomes concerning items such as tidal volume and forced vital capacity.

'General metabolic functions' (b540) was also frequently addressed in the published reports. For the studies examined, this code typically included the outcomes of glucose tolerance as measured by oral glucose tolerance test and blood lipids. We also coded cholesterol and triglyceride levels within this category as they are a component of fat metabolism. When considering components of metabolic syndrome, the b540 category is a useful descriptor because it covers both glucose tolerance and blood lipid levels.

'Body Structures' component was commonly coded within the extracted outcome measures. The most frequent occurrence was

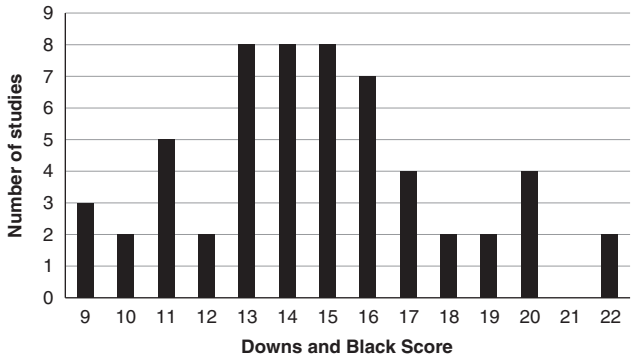

Figure 2 Methodological quality score distribution based on the Downs and Black checklist. Possible range of scores 0–28.

Table 3 Frequency of second-level categories of the ICF relative to body functions

ICF code	*Description*	*Frequency*
Chapter 1: Mental functions (12)		
b134	Sleep functions	2
b152	Emotional functions	10
Chapter 2: Sensory functions and pain (5)		
b270	Sensory functions related to temperature and other stimuli	2
b280	Pain	3
Chapter 4: Functions of the cardiovascular, hematological, immunological and respiratory systems (81)		
b410	Heart functions	13
b415	Blood vessel functions	14
b420	Blood pressure functions	4
b430	Hematological functions	4
b440	Respiration functions	21
b455	Exercise tolerance functions	25
Chapter 5: Functions of the digestive, metabolic and endocrine systems (50)		
b530	Weight maintenance functions	15
b540	General metabolic functions	16
b545	Water, mineral, and electrolyte balance functions	9
b555	Endocrine gland functions	10
Chapter 7: Neuromusculoskeletal and movement-related functions (84)		
b730	Muscle power functions	67
b735	Muscle tone functions	4
b740	Muscle endurance functions	1
b750	Motor reflex functions	1
b755	Involuntary movement reaction functions	7
b760	Control of voluntary movement functions	4

Abbreviation: ICF, International Classification of Functioning, Disability and Health.

'structure of the lower extremity' (s750). Within the s750 code we included muscle size, muscle fiber size and muscle cross-sectional area. We chose to use this category (s750) for bone mineral density (BMD) when a specific lower extremity site was stated as an outcome measure. When considering total BMD, following standard linking rules by Cieza *et al.*[23,24] the lower-level code s7 was used. However, total BMD may also refer to the ICF 'Body Functions' component of 'maintaining mineral balance' (b5451).

Table 4 Frequency of second-level categories of the ICF relative to body structures

ICF code	*Description*	*Frequency*
Chapter 7: Structures related to movement (54)		
s730	Structure of the upper extremity	1
s740	Structure of the pelvic region	1
s750	Structure of the lower extremity	45
s760	Structure of the trunk	4
s770	Additional musculoskeletal structures related to movement	3

Abbreviation: ICF, International Classification of Functioning, Disability and Health.

Table 5 Frequency of second-level categories of the ICF relative to activities and participation and environmental factors

ICF code	*Description*	*Frequency*
Activities and Participation		
Chapter 4: Mobility (33)		
d410	Changing basic body position	1
d420	Transferring oneself	7
d430	Lifting and carrying objects	4
d450	Walking	11
d465	Moving around using equipment	8
d475	Driving	2
Chapter 5: Self-care (8)		
d510	Washing oneself	2
d540	Dressing	6
Chapter 6: Domestic life (2)		
d640	Doing housework	2
Environmental Factors		
Chapter 1: Products and technology (4)		
e120	Products and technology for personal indoor and outdoor mobility and transportation	4

Abbreviation: ICF, International Classification of Functioning, Disability and Health.

The most frequent code within the 'Activities and Participation' component was d450 'walking.' This outcome measure may be overrepresented due to the high number of studies using BWSTT. In studies where the exercise intervention was BWSTT, the outcome measure walking time was frequently used. Examining walking in light of tolerated walking time during BWSTT is coded under the 'Activities and Participation,' however, as an outcome measure during BWSTT, walking could be better suited to the 'gait pattern functions' (b770) category of the 'Body Functions.' Within the 'Activities and Participation' there is also a code for 'mobility'(d4). This includes using assistive devices such as a wheelchair or scooter. Under the category of 'mobility' is d465 'moving around using equipment.' This second-level code might be a better representation of mobility from an activities and participation standpoint than 'walking' (d450) among people with chronic conditions such as SCI, because the important concept is the ability to move around in one's environment, not necessarily the ability to walk.

The ICF component 'Activities and Participation' replaces the International Classification of Impairments, Disabilities and Handicaps concept of handicap.[84] The important difference between the two models is that 'Activities and Participation' refers to an individual's ability to fulfill a role within their specific life situation.[84] Handicap is

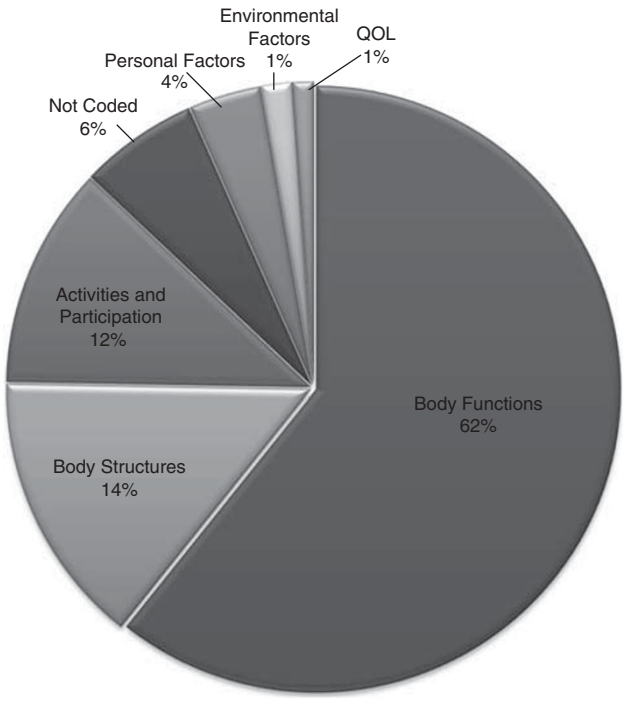

Figure 3 Percentage of outcome measures linked to specific ICF categories. A total of 374 outcomes were extracted.

referred more specifically to fulfillment of roles as defined by society.[84] Specific instruments for measuring participation in wheelchair users have been developed within the past 10 years.[85,86] Previous reviews have found multiple validated and reliable instruments that can be used to assess participation by wheelchair users.[1,85,86] The results of the current review indicate that the concept of participation is still not being well addressed as an outcome of exercise interventions for individuals with SCI, despite the availability of these instruments.

The 'Environmental Factors' component includes social support, assistive technology and aspects of the natural environment. Within the 57 studies evaluated for this review, we extracted only one second-level category within the 'Environmental Factors' 'products and technology for personal indoor and outdoor mobility and transportation' (e120). When considering the effects of an exercise intervention, some aspects of the 'Activities and Participation' will be affected by one's environment such as climate and the accessibility and availability of appropriate equipment; however, these were not addressed as an outcome measure by the studies evaluated in this review.

Outcome measures that fell into the categories of 'not defined,' 'not coded' or 'Personal Factors,' component such as quality of life and self-efficacy are currently recognized as weaknesses within the ICF. Some outcome measures that fell into the category of 'not coded' could potentially be incorporated in the existing taxonomy but currently there is not an adequate fit. For example, muscle biochemistry, which involves both body structures and functions, but there are no specific codes for muscle biochemistry within either component.

Limitations

The studies included in the current review were selected from papers published over a 10-year period from 2001 to 2011. The ICF was introduced in 2001, bringing increased awareness and attention to researchers and scientists that encouraged inclusion of outcome measures that assessed domains other than body structures and functions.[87,88] Noreau and Shephard[89] also indicated in their review of studies on exercise after SCI that studies were heavily weighted toward body structures and functions, although they did not use current ICF language. We acknowledge that there were significant contributions to the literature on exercise and SCI before 2001, but including exercise papers before this time would certainly have biased our findings even more as there were few studies with outcome measures that targeted domains other than body structures and functions.[89]

IMPLICATIONS

The results of this review indicate that studies focusing on exercise interventions for individuals with SCI face both methodological and measurement deficiency. The methodological quality of the studies for this review was generally low. Previous research has suggested that nonrandomized study designs are more frequently conducted due to inherent difficulties in studying chronic condition populations, such as SCI.[14] Although some evidence for efficacy of exercise interventions for people with SCI has been gleaned from this review, it is necessary for researchers to improve the methodological quality of studies to definitively determine efficacy of the interventions.

Methodological quality can be improved in future studies that utilize nonrandomized controlled designs by improving statistical control for confounding factors such as lesion level and level of completeness. Given that small sample size and heterogeneous characteristics of the participants are always an issue to conducting exercise intervention research in this population, higher methodological quality studies could be achieved by using multi-site RCTs that would allow for a greater number of participants to be recruited. High drop-out rates were another main issue that reduced the methodological quality of the reviewed studies. Future exercise intervention studies for this population may benefit from improving the research design and developing sophisticated incentive strategies to improve participant retention.

Using the ICF as a reference, the results of this review indicate that the majority of outcome measures are classified under the components of 'Body Functions' and 'Body Structures,' with 'Environmental Factors' being the least frequently addressed. We believe that future research may benefit from evaluating the influence of environmental factors related to exercise interventions for individuals with SCI. The most frequently addressed category in the 'Activities and Participation' was walking; however, this may have been overrepresented due to a relatively high proportion of reviewed studies ($n = 10$, 17.5%) using BWSTT. Within the ICF, walking is coded under the 'Activities and Participation' component; however, for individuals with SCI, walking as an outcome measure may be more accurately coded under the 'Body Functions' component if walking was conducted in a controlled setting such as on a treadmill. Whereas, walking in a natural environment such as in one's home or the community may more accurately reflect participation.

Measurement instruments are available to assess participation for people with SCI; however, to our knowledge, they have not been widely implemented as an outcome measure for exercise interventions for people with SCI. Currently available evidence indicates that outcome measures of exercise intervention for individuals with SCI are primarily targeted at body functions and body structures. Future research on the efficacy of exercise interventions on individuals with SCI should place increased emphasis on the outcome measures related to activities and participation, and attempt to include the influence of environment.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

ACKNOWLEDGEMENTS

We would like to thank Susan Smith for her assistance with the search strategy used in this review.

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