Spinal Cord (2008) 46, 216–221

www.nature.com/sc

ORIGINAL ARTICLE

Establishing evidence-based physical activity guidelines: methods for the Study of Health and Activity in People with Spinal Cord Injury (SHAPE SCI)

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Study design: Prospective, observational cohort study.
Objectives: This paper describes the rationale and methodology for the Study of Health and Activity in People with Spinal Cord Injury (SHAPE SCI). The study aims to (1) describe physical activity levels of people with different injury levels and completeness, (2) examine the relationship between physical activity, risk and/or presence of secondary health complications and risk of chronic disease, and (3) identify determinants of physical activity in the SCI population.
Setting: Ontario, Canada.
Methods: Seven hundred and twenty men and women who have incurred a traumatic SCI complete self-report measures of physical activity, physical activity determinants, secondary health problems and subjective well-being during a telephone interview. A representative subsample ($n = 81$) participate in chronic disease risk factor testing for obesity, insulin resistance and coronary heart disease. Measures are taken at baseline, 6 and 18 months.
Conclusion: SHAPE SCI will provide much-needed epidemiological information on physical activity patterns, determinants and health in people with SCI. This information will provide a foundation for the establishment of evidence-based physical activity guidelines and interventions tailored to the SCI community.
Spinal Cord (2008) **46,** 216–221; doi:10.1038/sj.sc.3102103; published online 24 July 2007

Keywords: exercise; methodology; lifestyle; chronic disease; secondary complications; evidence-based practice

Introduction

It has been suggested that people with spinal cord injury (SCI) are the most physically inactive members of society.[1] Indeed, a recent study[2] found that people with SCI spent less than 2% of their waking time engaged in any leisure time physical activity (LTPA) whatsoever (LTPA is, activity that requires energy expenditure and that people choose to do in their free time). As inactivity has been associated with a wide range of secondary health complications (for example, pressure sores, depression and chronic pain) and with the greatest chronic health threats to people with SCI (that is, heart disease, diabetes and obesity), inactivity represents a serious population health issue.[3]

Increasing physical activity (PA) among individuals with varying degrees of paralysis is not a simple matter. Activity programs and information on how PA can promote health are two of the services most desired but least available to people with SCI.[4] The lag in developing and providing these services is at least partly due to the absence of evidence-based guidelines for prescribing PA to people with SCI. Practitioners simply do not know what types or amounts of activity to prescribe to improve particular health and fitness outcomes in people with tetraplegia or paraplegia. The limited data that exist on these topics have been derived from cross-sectional studies of highly select samples and

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Received 7 March 2007; revised 2 June 2007; accepted 3 June 2007; published online 24 July 2007

from very small, quasi-experimental exercise training studies.[5] Without large-scale, epidemiological studies of the relationship between health and activity in persons with SCI, it is virtually impossible to develop PA guidelines and prescriptions for this population. The Study of Health and Activity in People with SCI (SHAPE SCI) was designed to meet this need. We present herein a description of SHAPE SCI, including study objectives, design and methodology. In a series of forthcoming reports, we will present the study outcomes and resulting PA guidelines.

Study overview

SHAPE SCI is a multi-center study of PA and health in people who have incurred a traumatic SCI, which utilizes an observational, prospective design. Consistent with seminal epidemiological studies in the general population (for example, Harvard Alumni, Framingham) and the focus of SCI health and PA research to date, LTPA is used as the operational definition of PA in the present study.

Study measurements occur at baseline and at 6 and 18 months after baseline. These time points were chosen to account for any seasonal variations in PA that may exist and to assess how PA relates to changes in health over both shorter (that is, 6 months) and longer (that is, 18 months) periods. Measures consist of (a) questionnaires completed during a telephone interview, and (b) chronic disease risk factor data collected in the homes of a subset of participants.

The study objectives are as follows:

1. To describe PA levels in the SCI population (and sub-populations defined according to injury level and completeness) with specific reference to the number of min/day spent on mild-, moderate- and heavy-intensity PA and the most frequently performed types of PA.
2. To examine the relationship between PA levels, risk and/or presence of secondary health complications and risk of chronic disease in the SCI population and sub-populations.
3. To identify individual, social and environmental determinants of PA.

The following hypotheses are proposed:

1. Participants will report more minutes of mild-intensity than moderate- or heavy-intensity LTPA regardless of injury level or completeness. Furthermore, given their greater functional limitations, people with tetraplegia will report less mild-, moderate- and heavy-intensity PA than those with paraplegia; people with complete injuries will report less mild-, moderate- and heavy-intensity activity than those with incomplete injuries.
2. There will be a negative, dose–response relationship between time spent engaged in mild-, moderate- and heavy-intensity PA and the presence and/or risk of secondary health problems and the risk of chronic disease.
3. Consistent with studies of the general population,[6] measures of individual, social and environmental factors will be significant prospective predictors of mild-, moderate- and heavy-intensity PA.

Method

Sample size

Separate sample size calculations were computed for the questionnaire and risk factor data collection segments of the study. Sample size for the questionnaire segment was based on the goal of accurately measuring PA within 5 min/day. In the general population, a 10 min difference in PA can be considered clinically meaningful.[7] Given their extreme deconditioning, smaller differences, perhaps of <5 min duration, may be clinically meaningful in the SCI population. Preliminary PA data derived from 102 men and women with SCI[8] were applied to the formula, $n=[2\ (s^2_{\text{pooled}})/y]$, where s^2_{pooled} is the pooled variance across lesion levels (paraplegic and tetraplegic) and injury completeness (complete and incomplete), and y represents a 10% error tolerance. Allowing for 5–10% participant attrition, an n of 720, divided across the four levels $\times$ completeness subgroups, allows us to accurately measure mild, moderate and heavy PA within 5 min/day.

Sample size for the risk factor segment was calculated using the same preliminary data[8] and Power & Precision Version 2.0.44 (Biostat, Englewood, NJ, USA). Eighty-one participants are needed to have 80% power ($\alpha=0.05$) to detect an R^2 of 0.10 for the PA variables as predictors of the chronic disease risk factors, after controlling for seven covariates in a regression model. An R^2 of 0.10 was selected as the smallest effect considered of clinical or substantive significance. The risk factor data are collected from a representative subsample ($n=81$) of men and women drawn from the larger ($n=720$) cohort.

Recruitment

Participants are recruited by four regional SCI rehabilitation and research centers in Ontario, Canada. These are as follows: Parkwood Hospital (London); Hamilton Health Sciences—Chedoke Site and McMaster University (Hamilton); Lyndhurst Hospital and Toronto Rehabilitation Institute, Lyndhurst Centre (Toronto); and St Mary's of the Lake Hospital and Queen's University (Kingston). Participants are recruited from lists of former SCI patients at each center who have consented to be contacted for research purposes, and through advertisements in local newspapers and SCI-relevant publications, presentations at events for people with SCI, mailings to SCI community groups, clinics and word of mouth. Interested volunteers are screened for eligibility. Eligible individuals are then scheduled for a telephone interview for the questionnaire segment of the study. Participants recruited by the Hamilton site are screened further for eligibility for the risk factor testing segment of the study (see Table 1 for all inclusion/exclusion criteria).

Study measures

Telephone interview measures are summarized below, with additional details shown in Table 2.

Table 1 Inclusion and exclusion criteria for the questionnaire and risk factor testing segments of SHAPE SCI

Inclusion criteria	*Exclusion criteria*
Questionnaire segment	*Questionnaire segment*
Traumatic SCI	Non-traumatic SCI
Diving	Infection (tuberculosis, discitis, arachnoiditis)
Fall	Multiple sclerosis
MVA	Tumor
Recreational MVA	Syringomyelia
Gunshot wound	Transverse myelitis
Knife wound	Amyotrophic lateral sclerosis
Crush injury	Chronic inflammatory demyelinating polyneuropathy
Industrial accident	Rheumatoid arthritis
Disc lesion	Guillain-Barré syndrome
Atrial venous malformation (sudden onset)	Spina bifida
Aneurysm repair	Other
Cervical myelopathy	
Currently residing in Ontario	
⩾18 years of age	Participant has been told that he or she has a cognitive or memory impairment
Primary mode of mobility outside the home requires assistance (manual or power wheelchair, walker, braces, cane)	Primary mode of mobility outside of the home is independent walking
Traumatic SCI occurred at least 12 months before study enrolment	
Proficient in reading and speaking English to understand interview questions	
Risk factor testing	*Risk factor testing*
Available for testing within 2 weeks of questionnaire completion	Unable to transfer self (with assistance) between wheelchair and bed
Live within a 200-km radius of McMaster University	

Abbreviations: MVA, motor vehicle accident; SCI, spinal cord injury.

1. *Background information:* Demographic, injury and health history data are collected to assess and potentially control for variables that may influence risk for secondary complications, chronic disease or PA.
2. *Physical activity*: PA is measured with the Physical Activity Recall Assessment for People with SCI (PARA-SCI).[8] The PARA-SCI was developed and validated for administration via telephone using a structured, standardized interview protocol. During the interview, respondents recall the type, frequency, duration and intensity of all activities performed over the previous 3 days that required physical exertion. Participants use the PARA-SCI activity intensity guidelines to classify the intensity of each activity.[8] The interviewer codes each activity as LTPA (see Table 3 for examples) or lifestyle activity (for example, occupational activity, activities of daily living). The PARA-SCI measure of LTPA has demonstrated adequate test-retest reliability, criterion validity,[8] construct validity[2] and responsiveness to change after a PA counselling intervention.[16]
3. *Predictors of PA:* In addition to the unmodifiable variables captured by the background questionnaire, we are examining potentially modifiable predictors of PA drawn from social cognitive and social ecological frameworks.[18,19]
4. *Secondary health complications:* The prevalence and impact of specific medical conditions are assessed.
5. *Subjective well-being:* Well-being is assessed with a battery of instruments that have been well-validated and extensively used in large-scale studies of people with SCI.

The *chronic disease risk factor measures* are presented in Table 4. These are the variables measured during the home visits to assess obesity and risk for diabetes and coronary heart disease.

Procedures

The study protocol has been approved by the research ethics boards at each participating investigator's institution.

Using a random numbers table, eligible participants are randomly assigned to a telephone interview date (Monday to Friday) to control for any biases associated with completing the PA measure on a particular day of the week. Participants complete the baseline, 6- and 18-month interviews on the same day of the week. Before the interview, participants are mailed an information letter, a consent form, and a copy of the PARA-SCI activity intensity classification guidelines. A trained interviewer contacts the participant at a scheduled time and obtains verbal consent before data collection. Verbal consent is reconfirmed at the 6- and 18-month interviews.

The interview begins with the background information questions. Order of presentation of the remaining questionnaires is systematically rotated to minimize response biases. The interview takes approximately 45 min to complete. At the end of the baseline and 6 months interviews, participants are scheduled for their next interview. (If a participant indicates any suicidal ideation over the past 2 weeks in response to the depression measure, the study site coordinator immediately contacts a psychological counsellor who telephones the participant and provides brief counselling and resources.)

Participants involved in the risk factor testing are mailed a separate information letter, a consent form, and instruction sheet. They are asked to fast and avoid alcohol, caffeine and exercise for 12 h before data collection. All home visits occur within 14 days of the telephone interview and are conducted by a Kinesiologist trained in phlebotomy and a research assistant. The information letter is reviewed and the participant provides written informed consent before any testing occurs. Consent is reconfirmed at the 6- and 18-month home visits. Depending on the participant's abilities, it takes 60–90 min to complete all measures. Participants are paid a $10 honorarium at each home visit and receive a personalized report summarizing their results upon study completion.

Table 2 Variables measured during the telephone interviews

Demographics	*General health*	*Secondary complications*	*Health-related quality of life*	*Predictors of physical activity*
Age (years)	Perceived health[9]	Incidence and impact of the following conditions[a] Spasticity	Life satisfaction[10]	Pre-injury activity levels
Sex	Pain[9]		Motor functional independence[11]	Activity intentions[12]
Date of SCI	Cigarettes smoked/day	Overuse injury	Depression[13]	Outcome expectations[12]
Level and cause of SCI	Alcoholic drinks/week	Fatigue	Handicap[14]	Social support[15]
ASIA classification	Height	Urinary tract infection		Self-efficacy[16]
Primary mode of mobility outside home	Weight	Respiratory infection		Neighborhood environment[17]
Ethnicity		Pressure sores		
Education		Pain		
Marital status		Osteoporosis		
		Broken bones/joint dislocation		
		Blood clot/deep vein thrombosis		
		Overweight		

[a]At the baseline and 18-month assessments, participants report on these conditions with reference to the past 12 months. At the 6-month assessment, participants report on these conditions with regard to the past 6 months.

Table 3 Examples of LTPA measured by the PARA-SCI

LTPA category	*Specific examples*
Resistance training	Lifting weights Resistance band exercises
Cardiovascular exercise	Arm or leg ergometry Body-weight supported treadmill training Wheeling Aerobics Pool walking Functional electrical stimulation
Sports participation	Basketball, rugby, sledge hockey, volleyball, athletics, skiing, billiards, bowling, water skiing
Play	Playing with children Playing with pets Playing catch
Hobbies	Gardening Woodworking

Abbreviations: LTPA, leisure time physical activity; PARA-SCI, Physical Activity Recall Assessment for People with SCI.

Training and quality control

All interviews are conducted by trained research assistants. Research assistants and data collection coordinators from each site attended a full-day workshop conducted by SHAPE SCI investigators (KAMG and AEL). The study protocol was reviewed and questionnaire administration was rehearsed. Workshop attendees received a 42-page training manual as reference. Since this initial workshop, to accommodate staff turnover at each site, a 'Train the Trainer' approach has been implemented. New staffs receive a training manual and attend an on-site (1.5–2 h) training session with the data collection coordinator. Before a new research assistant can begin scheduling and conducting interviews, s/he must successfully complete a mock telephone interview with AEL.

To ensure adherence to the study protocol, research assistants complete a checklist after each interview. Interview quality is monitored through periodical reviews of audio-taped interviews (taped with participants' consent). AEL reviews the interview, paying particular attention to proper administration of the PA measure. Research assistants receive written feedback regarding protocol implementation. No deviations from the protocol affecting data quality have been noted to date.

Table 4 Variables measured during the home visits for the risk factor testing segment of SHAPE SCI

Dimension	*Measure(s)*	*Brief description of methods*
Anthropometry/ body composition	Weight	Wheelchair scale
	Length	Spine board and tape measure
	Waist circumference	Tape measure (three sites: lowest rib, iliac crest, midpoint between lowest rib and iliac crest)
	Fat mass, fat-free mass	Whole body bioelectrical impedance analysis
Biochemistry	Insulin	Chemiluminescent immunometric assay
	Glucose	Hexokinase method
	Total cholesterol, HDL-cholesterol, triglycerides	Enzymatic colorimetric test
	LDL-cholesterol	Friedewald equation[20]
	High-sensitivity C-reactive protein	Automated nephelometry assay
Blood pressure	Blood pressure	Right arm, in sitting position, after 5-min rest
Diet	Energy; total fat; saturated, monounsaturated and polyunsaturated fats; carbohydrate; dietary fiber; sugar; protein; alcohol; selected vitamins and minerals	Multiple-pass 24 h recall

Abbreviations: HDL, high-density lipoprotein; LDL, low-density lipoprotein.

Data entry and management

All questionnaire data are forwarded to the McMaster University site (that is, the central study administration site)

for data entry. With the exception of the PARA-SCI, all questionnaire responses are entered directly into an SPSS (Statistical Package for the Social Sciences; SPSS Inc., Chicago, IL, USA) version 14 database. The PARA-SCI data are entered into a customized, web-based system that facilitates data storage, manipulation and analysis of the four types of PA information assessed: activity type, frequency, intensity and duration.

Blood samples are analyzed at the McMaster Medical Centre Department of Laboratory Medicine. Biochemistry results and all other data collected during the risk factor tests are then forwarded to the University of Guelph where they are entered and managed under the supervision of ACB. With the exception of the dietary recall data, all data are entered directly into an SPSS database. The dietary data are entered into ESHA Food Processor SQL (ESHA Research Inc., Salem OR, USA; updated with the 2005 Canadian Nutrient File).

Retention strategies

A multi-method approach is used to maximize participant retention. At baseline, participants receive a reminder phone call the day before their interview. At follow-up, participants receive a reminder postcard upon which the PARA-SCI intensity classification guidelines and the interview date are printed. Reminder calls are placed 1 week and 1 day before scheduled follow-up interviews. In addition, study newsletters are sent to participants approximately once per year.

Participants who are unavailable during their scheduled interview time are rescheduled in accordance with their randomly assigned interview day. Participants who cannot be reached to complete their interviews are called intermittently 15 times over 4 weeks. Participants are considered dropouts only when they cannot be contacted for the baseline or the 18-month interview.

Analyses

Descriptive statistics will be used to summarize all study measures. A repeated measures, general linear model multivariate procedure will be used to examine the effects of injury level (paraplegia/tetraplegia) and completeness (complete/incomplete), on the dependent measures of mild-, moderate- and heavy-intensity PA (Hypothesis 1). With regard to Hypothesis 2, prospective logistic regression analyses will be conducted to examine relationships between PA and dichotomous health outcomes. Prospective, hierarchical multiple regression analyses will be used to examine relationships between PA and continuous outcomes. Analyses will control for diet, demographic and health history variables as necessary.

With regard to Hypothesis 3, prospective, hierarchical regression analyses will be conducted. Mild-, moderate- and heavy-intensity PA will each be regressed on the predictors in separate models, as different variables may predict different PA intensities. After controlling for demographics, predictors will be entered in blocks of unmodifiable (that is, injury characteristics, health history) and modifiable variables (individual-level cognitions, social environment, physical environment). Significant beta weights will be taken as evidence of significant predictors.

Discussion

The absence of large-scale, prospective cohort studies of the relationship between health and activity in persons with SCI has severely impeded the development of PA guidelines and activity-enhancing interventions for this population. SHAPE SCI was designed to provide important, basic information that will allow researchers and interventionists to move forward to provide much-needed PA guidelines, resources and programs. Specifically, data derived from SHAPE SCI will be used to

- identify the types and amounts of activity that appear most conducive to physical and psychological well-being;
- identify modifiable factors within the person (for example, attitudes, self-efficacy) and the environment (for example, social support, accessible fitness facilities) that can be targeted for PA-enhancing interventions;
- develop evidence-based exercise prescriptions for use in randomized controlled trials;
- provide a benchmark against which future interventions can be measured.

Ultimately, we anticipate that SHAPE SCI data will provide a foundation for the development of evidence-based PA guidelines for people with SCI. These guidelines would parallel PA resources available to the general population, providing information on the specific types and amounts of activity needed to improve particular health and fitness outcomes among people with diverse neurological impairments. Given the potential physical and psychological benefits of PA to people with SCI,[21] SHAPE SCI represents a vital step toward meeting the needs of the SCI community with regards to providing evidence-based, SCI-specific PA information.

Acknowledgements

This study is funded by an Operating Grant from the Canadian Institutes of Health Research (CIHR). Preparation of the paper was supported by a CIHR New Investigator Award, awarded to the first author.

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