Intervention Protocol

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Study Title:	ProACTIVE SCI Physical Activity Coaching Intervention
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Study Sites:	1. International Collaboration on Repair Discoveries (ICORD), Vancouver, BC, Canada 2. University of British Columbia, Kelowna, BC, Canada
Sponsors:	Ontario Neurotrama Foundation

SUMMARY

Purpose: To address the low levels of physical activity reported in the SCI population by providing individualized physical activity sessions and evaluating their impact on physical activity behaviour and health outcomes.

Hypothesis i: Physical activity levels will be higher in the experimental than the wait-list control group.

Hypothesis ii: Self-reported HAPA model constructs (e.g. action planning, self-efficacy) will be improved in the experimental group compared to the wait-list control group.

Hypothesis iii: Participants who report higher levels of PA will have greater improvements on arterial stiffness and secondary health outcomes (cardiovascular, fitness).

Justification: Given the number of barriers individuals with SCI face, it is not surprising that PA levels in this population are remarkably low. These low levels of PA can lead to increased risk for chronic disease and other dangerous health conditions. In particular, cardiovascular disease (CVD) is a leading cause of morbidity and mortality in the SCI population, and risk of developing CVD is increased in those who are physically inactive. Strategies tailored to individuals with SCI are needed to increase levels of PA and ultimately reduce risk for the development of such chronic diseases as CVD. Results from a recent meta-analysis of PA interventions in people with disability support that interventions that are guided by theory are more effective than those that do not use theory for increasing PA levels in this population. More specifically, an examination of over 200 people with SCI showed that the Health Action Process Approach model is well-suited to predict PA levels in this population. Further, previously successful studies have supported the use of behaviour change techniques that target specific constructs of the HAPA model (e.g. self-efficacy and planning). However, to date, interventions designed to use the HAPA model in its entirety have yet to be tested in individuals with SCI. Thus, this study will employ a comprehensive, tailored intervention using techniques to target all constructs outlined by the Health Action Process Approach model (i.e. risk perceptions, outcome expectancies, barriers, resources, self-efficacy, planning, action control) to improve levels of PA in individuals with SCI. Improvements in PA will then be examined for effects on fitness and cardiovascular function and health.

Objectives: Primary objective: To determine whether brief physical activity (PA) coaching sessions guided by the Health Action Process Approach model can change PA behaviour and psychosocial factors in individuals with chronic (>1 year post-injury)

spinal cord injury (SCI)

Secondary objective: To determine whether improvements in PA have beneficial effects on arterial stiffness (aortic pulse wave velocity; aPWV) and secondary health outcomes (cardiovascular and fitness indices) in individuals with chronic (≥ 1 year post-injury) SCI.

Research Design: This study will employ a multi-centre, randomized, wait-list controlled trial. A total of 30 participants (15 experimental, 15 wait-list control) between 18-65 years of age who have chronic SCI ≥ 1 year prior will be recruited. Physical activity measures will be taken using wrist-based accelerometers and the Physical Activity Recall Assessment for Persons with SCI. Psychosocial factors will be evaluated through questionnaires. The primary health outcome measure (aPWV), and secondary cardiovascular parameters will be assessed using a combination of echocardiography and ultrasound. Fitness will be determined using a peak oxygen consumption test on an arm-cycle ergometer. All measurement will be taken at baseline and after 9 weeks following intervention commencement. Physical activity will also be sampled mid-intervention at 4 and 7 weeks. For the wait-list control group, an additional measurement time point will be added after they have received the intervention upon completion of the control period. Training will involve weekly, 10-15 minute coaching sessions for 9 weeks. All pre- and post-assessments will take place at the Blusson Spinal Cord Centre at ICORD or the University of British Columbia Okanagan. Intervention content will be delivered over Skype or phone, and the wrist- worn accelerometers will be delivered and picked up from the participant's home during the intervention.

Statistical Analyses: Analyses will be conducted to determine the training (time), group (control vs experimental) and interaction (time x group) of all indices.

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Preamble

Increased morbidity and mortality in chronic SCI appear to be caused by inactivity-related illnesses; for example, cardiovascular disease (CVD) is the primary cause of illness and death in this population.[1] People with SCI develop CVD at younger ages and at greater rates than the able-bodied population.[2–5] Given that a sedentary lifestyle is one of the most important modifiable risk factors for CVD.[6] a logical course of action would be to increase physical activity (PA) in individuals with chronic SCI.

Despite the benefits of PA, people with SCI report some of the lowest rates of PA participation when compared to abled bodied samples and samples of other chronic diseases.[7] Given the number of barriers people with SCI face to participating in PA, strategies that are specifically tailored to promote PA to people with SCI are needed.[8,9] Previous studies have supported that the Health Action Process Approach (HAPA) model may be an appropriate guide for designing physical activity interventions for people with SCI.[10–12] To date, no intervention has explicitly tested the HAPA model and its potential use of all constructs to guide intervention content for delivery to people with SCI.

1. BACKGROUND AND PROGRAM RATIONALE

1.1 Physical inactivity and spinal cord injury (SCI)

Adults living with SCI not only exhibit lower PA levels than able bodied samples, but also show some of the lowest rates of PA participation among samples with chronic disease and disability.[7] In an epidemiological study of nearly 700 Ontarians with spinal cord injury, 50% reported engaging in no leisure time PA whatsoever.[13] These low levels of PA can significantly impact the long-term health of people with SCI.

1.2 Physical inactivity and cardiovascular disease (CVD) in spinal cord injury (SCI)

Increasing PA may have potent effects on decreasing cardiovascular disease risk, the primary cause of illness and death in people with SCI.[1] Able-bodied individuals who participate in regular PA experience a 40-50% reduction in risk of CVD compared to sedentary counterparts.[14] In addition, PA reduces CVD risk in obese individuals independent of any effect on weight.[15] Interestingly, modifications in traditional risk factors with exercise training do not fully account for the observed reduction in risk in people with SCI. For example, a literature review suggested that contrary to the able-bodied population, body mass index is not an accurate predictor of obesity and coronary heart disease in people with SCI.[16] Thus, examining the effects of exercise on other parameters that may act as surrogate measures of health status (e.g. cardiac, vascular, and fitness) are warranted. In

combining the evidence for low PA rates and the potential effectiveness of PA to improve health in people with SCI, strategies to improve the current state of physical inactivity and ultimately the health of Canadians living with an SCI are needed.

1.3 The Health Action Process Approach and physical activity interventions in spinal cord injury

The Health Action Process Approach (HAPA) model may be an effective model to guide PA intervention development for people with SCI. A large-scale cross-sectional examination has previously shown that the HAPA model can be used to predict levels of PA based on their level of motivation (i.e. pre-intender, intender, actor) [12]. Further, experimental studies have supported that targeting specific constructs of the HAPA model (e.g. self-efficacy and planning) can improve PA behaviour (Arbour-Nicitopoulos et al., 2013; Latimer-cheung et al., 2013). Thus, the evidence is building in support of the use of the HAPA model for changing PA behaviour in this population.

A limitation of these interventions is no study to date has examined the effects of an intervention that incorporates all constructs of the HAPA model. The Health Action Process Approach (HAPA) is a hybrid stage/ continuum theory [19,20]. Specifically, risk perceptions are proposed to stimulate cognitive processing to consider outcome expectations, which work reciprocally with task self-efficacy (SE) to form intentions. Planning (action planning/ coping planning) mediates the intention- action relationship [21]. Action is sustained through ongoing processes of action control. Task SE, maintenance SE, and recovery SE are implicated to play a role in intention formation, planning, and action, respectively, with task-self efficacy also important for planning, and maintenance SE also supporting action. Lastly, barriers, resources, and social supports are proposed to influence intentions, planning, and action. As previously demonstrated, planning and self-efficacy are very important constructs in the HAPA model, however, given the number of barriers people with SCI face in participating in PA it is likely that more complex interventions are needed to overcomes these barriers and facilitate sustained behaviour change. Thus, an examination of other constructs (e.g. resources, outcome expectancies, action control) that may be tailored to the participants (e.g. based on stage of motivation, identified barriers) should be examined for their role in changing PA behaviour in this population.

2. PURPOSE & HYPOTHESES

Primary objective: To determine whether brief PA coaching sessions guided by the HAPA model can change PA behaviour and psychosocial factors in individuals with chronic (>1 years post-injury) spinal cord injury (SCI)

Secondary objective: To determine whether improvements in PA have beneficial effects on arterial stiffness (aortic pulse wave velocity, aPWV) and secondary health outcomes (cardiovascular, fitness) in individuals with chronic (≥ 1 years post-injury) SCI.

Hypothesis i: Physical activity levels will be higher in the experimental than the wait-list control group.

Hypothesis ii: Self-reported HAPA model constructs (e.g. action planning, self-efficacy) will be improved in the experimental group compared to the wait-list control group.

Hypothesis iii: Participants who report higher levels of PA will have greater improvements on arterial stiffness and secondary health outcomes (cardiovascular, fitness).

3. RESEARCH DESIGN/ PROTOCOL

A multi-centre, randomized, wait-list controlled trial will be used to compare the effects of tailored PA coaching sessions *versus* no coaching on PA behaviour, psychosocial factors, and health outcomes. Eligible individuals will be randomly assigned (1:1) to either the experimental (PA coaching sessions) or wait-list control condition. Groups will be stratified by injury level, age, and site. The randomization sequence will be generated by a research assistant independent of the trial. For an overview of the protocol see Figure 1.

Figure 1. Study Overview

Day 1 testing measures include vascular measures (arterial pulse wave velocity, arterial structure, and flow mediated dilation; 30 minutes), cardiac structure and function measures (30 minutes), administration of the demographics and Health Action Process Approach model questionnaire (25 minutes), and a measurement of energy expenditure at different sub-maximal wheeling speeds to calibrate MVPA cut-points (35 minutes) for a total duration of 2 hours. Participants will be given an accelerometer to wear for the 6-day monitoring period (6.1.2) after which they will return for Day 2 testing.

Day 2 testing measures include administration of the PARA-SCI (45 minutes), a peak oxygen uptake test (45 minutes), and at baseline, the first PA coaching session will be

administered (30 minutes) whereas at post-test a semi-structured interview will be administered (30 minutes). Total duration of day 2 testing will be 2 hours. The intervention protocol is described below. During the intervention, physical activity will be sampled at two time points; accelerometer and PARA SCI data will be taken during week 4 and week 7. Following the intervention, follow-up assessments of physical activity will be sampled monthly for 12 months in the intervention group only using the Leisure Time Physical Activity Questionnaire.

INTERVENTION

Intervention Protocol:

Experimental participants will receive weekly PA coaching sessions. Each session will be 10-15 minutes in duration and delivered either face to face, over Skype, or when the former modes are unavailable, over the phone. These sessions will be recorded using a portable audio recorder. Additionally, supplemental resources may be emailed to the participants based on need throughout the intervention.

Participants' motivation to exercise will first be determined according to stages of the HAPA model. Those who identify as pre-intenders (no intention to exercise) will receive intervention strategies that focus on changing motivation to be physically active. Those identified as intenders (willing to exercise but have not started) will focus on providing resources and behavioural strategies to commence physical activity. Lastly, those identified as actors (already exercising) will receive intervention strategies that help participants maintain or improve PA behaviour.

For those in the intender or actor stage, the intervention aims to promote the international SCI PA guidelines to promote fitness (at least 20 minutes of moderate vigorous aerobic activity twice/week and strength training twice/week). For those exceeding the fitness guidelines, the international SCI PA guidelines to promote health are promoted (at least 30 minutes of moderate to vigorous aerobic activity three times/week and strength training twice/week). However, these aims will be modified based on the individual's baseline PA. During the first visit, participants' baseline PA levels will be reviewed and an appropriate PA goal to achieve in the following month will be formed. In line with small changes PA goal setting, no pre-set goal grading strategies are established.[22] In general, the goal of increasing daily PA by ten minutes on at least two days/week is provided as a guideline for grading the increase in goals. However, ultimately, the goal is the decision of the participant.

Following goal setting, barriers to participating in PA will be identified. The interventionist will select intervention strategies based on the identified barriers. A pre-formed chart of corresponding intervention strategies (e.g. use of behaviour change techniques, referral to facilities or peers, suggesting at-home exercises) was developed to aid this pairing process (Appendix A). These intervention strategies are accompanied by

a comprehensive toolkit based from the HAPA model (Appendix B). In brief, the toolkit advises on three key strategies for promoting PA to people with SCI: i) education, ii) referral, iii) tailored PA prescription.

Remaining weekly coaching sessions will review participants' progress and barriers to discuss new goals and strategies as outlined above.

Control Participants:

Control participants will complete baseline and post-testing only. Following completion of post-test measures they will be administered the same PA coaching session as the intervention group, with post-test measures being repeated upon intervention completion.

Standardization across sites

The intervention will take place in Vancouver for the months of April to July and in Kelowna from August to October. The same equipment brand and model will be used between sites where available. All intervention content, psychological, and fitness measures will be delivered by the same researcher. Although vascular and cardiac measures will be administered by different researchers in Vancouver and Kelowna, all technicians are experienced in their respective techniques, decreasing the likelihood of human error.

4. RECRUITMENT

A total of 30 participants with a chronic (>1 year post injury) spinal cord injury between 18-65 years of age will be recruited. Individuals must be competent to give informed consent, and be able to propel an arm ergometer.

Exclusion Criteria:

- History and/or symptoms of CVD or cardiopulmonary problems/disease.
- Major trauma or surgery within the last 6 months.
- Active Stage 3 or 4 pressure ulcer (based on the National Pressure Ulcer Advisory Panel classification)
- Recent (within 1 year) history of lower-extremity or non-union fracture
- Any unstable medical/psychiatric condition or substance abuse disorder that is likely to affect their ability to complete this study.
- Individuals with active medical issues such as pressure sores, urinary tract infections, hypertension, or heart disorders.
- Any cognitive dysfunction or language barrier that would prevent subjects from following English instructions.
- Subjects may be excluded at the discretion of the principal investigator due to other, unforeseen, safety issues.

Sample size calculation: Our study is powered to detect a significant condition X time effect for our primary outcome measure, min/wk of PA. A previous single-group study of adults with SCI tested the effects of a PA-enhancing intervention delivered by a peer and a fitness trainer (Latimer-Cheung et al., 2013). That study found very large, significant effects for change in min/wk of PA (d = .96). Given our two-group design, we are powering for a more modest interaction effect (d = .75). Twelve participants/condition (N = 24) are needed to yield a significant effect of this magnitude in a repeated measures ANOVA, with β = .80 and α = .05. To account for study dropouts, we are budgeting for an N of 30.

Potential participants will be identified through a variety of recruitment strategies including: posters which will be distributed among hospital locations and local community venues (e.g. local sports venues, community program centres); social media advertising (i.e., website, Facebook, Twitter); email; and at the individual's request (some participants have previously provided consent to be contacted for future studies).

5. OUTCOME MEASURES

All measurements will be collected at the International Collaboration on Repair Discoveries (ICORD) in the Blusson Spinal Cord Centre or the University of British Columbia Okanagan.

Primary Outcome Measure: Physical activity

6.1.1: Physical Activity Recall Assessment for People with Spinal Cord Injury (PARA-SCI):

Participants will be asked to complete a 3-day PA recall (PARA-SCI) guided by the co-investigator (Jasmin Ma). The recall assessment will take approximately 30 minutes to complete.

6.1.2: 6-day Physical Activity Monitoring Period

Participants will be fitted with a wrist-based tri-axial accelerometer to be worn 24 hours a day for 6 days in order to determine intensity and amount of PA. They will keep a detailed PA diary recording all leisure time PA performed during the day. The primary outcome will be minutes of PA per day equivalent to moderate intensity or higher ($\geq$ 3 SCI METs determined from individual calibrations, see 2.14) from a tri-axial wrist-worn accelerometer (GT9X, ActiGraph LLC, FL). During the intervention, the accelerometer will be picked up and dropped off to the participant's home to decrease burden. Text or email reminders (i.e. "Please don't forget to wear your accelerometer today") will be used to promote adherence to accelerometer wear.

Measurement of energy expenditure during different sub-maximal wheeling speeds for calculation of moderate-vigorous physical activity during the 6-day physical activity monitoring period

We will assess energy expenditure during different sub-maximal wheeling speeds on a treadmill (self-selected slow, medium, fast) to establish cut points relating wrist-based accelerometer counts to intensity of PA in SCI. Participants will be required to push at each of the 3 speeds for 5 min/stage to ensure steady state is reached. Resting heart rate (Polar T31 heart rate monitor, Polar Electro Inc., Woodbury, NY, US), brachial artery blood pressure (Carescape™ V100; GE Healthcare, Buckinghamshire, UK) will be measured two minutes prior to wheeling. Heart rate will be measured continuously throughout the test and blood pressure will be measured again at the end of each stage. Breath-by-breath gas exchange indices will be assessed using an online system (sensorMedics V Max). We will then relate activity counts from the accelerometer to energy expenditure in SCI METs (1 SCI MET = 2.7ml/kg/min)[23] to determine individualized cut-points for habitual PA monitoring and the subsequent determination of the amount of moderate-to-vigorous PA (≥ 3 SCI METs). Individuals classified as ASIA D (have preserved muscle function below the level of injury) who do not use a wheelchair will not complete the treadmill cut-point evaluation for safety reasons (e.g. tripping while walking). Instead, able-bodied cut-points will be applied. In addition to the wrist accelerometer, a hip accelerometer and a pedometer will be worn to validate the wrist-based values for participants classified as ASIA D.

6.1.3: Leisure Time Physical Activity Questionnaire

Participants will be asked to complete a 7-day PA recall (LTPAQ) guided by the co-investigator (Jasmin Ma). The recall assessment will take approximately 5 minutes to complete and will be done either in-person or over the phone.

Secondary Outcome Measure: Psychosocial factors influencing PA participation

6.2.1 Health Action Process Approach Model Measure

This survey will examine psychological factors that may affect PA participation. The survey will be recorded either electronically or with pen and paper depending on the respondent's preference. Survey will take approximately 25 minutes to complete, and will assess constructs related to exercise such as perceived risks, self- efficacy, planning, and social support. The demographics questionnaire will also be administered with this measure.

6.2.2 Semi-Structured Interview:

A semi-structured interview will be conducted at the end of the intervention to understand what components were and were not effective. Data will not be recorded. This feedback will be used to improve future iterations of the intervention.

Tertiary Outcome Measure: Arterial stiffness

6.3.1 Pulse Wave Velocity

aPWV (m/s) is calculated by dividing the distance between measurement sites, by the pulse transit time. Distance between the carotid and femoral arteries will be measured using measuring tape along the surface of the body, held parallel to the testing table. The pulse transit is determined from the arterial blood pressure waves, which are collected at each arterial site. A pen-like device (model SPT-301; Millar Instruments Inc., Houston, TX) will be applied to the carotid and femoral arterial sites using a light pressure to obtain arterial pressure waves. Heart rate will be recorded using a single-lead (lead I) electrocardiogram (ECG) (model ML 123, ADInstruments Inc., Colorado Springs, CO).

Quaternary Outcome Measure: Cardiovascular and Fitness Parameters

6.4.1 Arterial structure: Wall thickness and lumen diameter

Carotid arterial images will be collected using B-mode ultrasound (INFO) for 10 cardiac cycles. Images will be analyzed using internal ultrasound software to determine lumen diameter and intima-media thickness.

6.4.2 Flow mediated dilation

A tight cuff will be placed on the upper 1/3 of the forearm and will be inflated to 200mmHg for 5min to occlude blood flow. The brachial artery diameter and blood velocity will be measured 1-minute prior to cuff inflation, 30 seconds before cuff deflation, and for the subsequent 3 minutes following cuff deflation.[24] The vasodilatory response will be assessed using wall-tracking software capable of continuously assessing vessel diameter and blood flow velocity.

6.4.3 Cardiac structure and function

Cardiac images will be collected non-invasively using Doppler ultrasound (Vivid q, GE Healthcare, Buckinghamshire, UK). Briefly, apical four and two-chamber views, and parasternal short and long-axis views will be collected and stored on the ultrasound for offline analysis. Indices of interest will include volumes (end systolic (ESV), end diastolic (EDV)), diameters (intraventricular septum systole (IVSs) and diastole (IVSd), left ventricular internal diameter systole (LVIDs)), systolic function (left ventricular posterior wall systole (LVIDd) and diastole (LVPWd), ejection fraction (EF), cardiac output (CO), fractional shortening, mitral regurgitation (dP/dT)) and diastolic function (E/A, E/e' ratio, IVRT, DT).

6.4.4 Aerobic Fitness Evaluation: Peak oxygen uptake test (VO2peak)

Participants will perform a graded arm ergometer test on an electronically braked arm ergometer (Angio Rehab arm ergometer, Lode, Groningen, the Netherlands), height adjusted so that the shoulder joint is aligned with the crank axis of the ergometer. Blood pressure (Dinamap Carescape V100; GE Healthcare, Buckinghamshire, UK) and respiratory measures (Quark CPET, Cosmed, Rome, Italy) will be collected two minutes prior to exercise. Heart rate will be recorded at one-second intervals via a chest strap heart rate monitor (Garmin, Schaffhausen, Switzerland). For participants with tetraplegia who have limited handgrip function, gloves (Active Hands, Solihull, Great Britain) will be used to secure hands to the ergometer handles. Participants will be instructed to maintain a cycling rate of 50 revolutions per minute (rpm) for the duration of the test. After an initial warm-up at 0W, power output will be increased each minute at a rate of 2-5 W/min for participants with tetraplegia, or 10 W/min for participants with paraplegia, until volitional exhaustion (i.e. dropping below 30 rpm). Ratings of perceived exertion (Borg 6-20 scale)[25] will be collected in the final 10-seconds of each stage. Oxygen consumption will be recorded on a breath-by-breath basis for the duration of the test and reported as rolling 30-second averages sampled at 5-second intervals as per consensus recommendations[26]. This test is used to determine participants' peak oxygen uptake, ventilatory threshold and maximum heart rate.

6. ADVERSE EVENTS

Exercise will not be supervised by the interventionist, but physical activity recommendations will be made by a personal trainer. Participants will be advised that for up to 48 hours after exercise, the participant may experience delayed-onset muscle soreness as a result of performing strength training exercises. To minimize physical risks, the personal trainer will provide clear exercise instructions and training tips to ensure that proper technique and form are used. Participant feedback on the exercise perceived physical effort (mild, moderate or heavy) will be monitored weekly and the personal trainer will adapt the exercise plan as necessary to accommodate for this feedback.

A systematic review of adverse events reported in exercise interventions involving people with SCI was recently conducted. The limited adverse event data for upper-body training (aerobic or resistance) suggested that adverse events were rare, except for the occasional occurrence of musculoskeletal complaints.[27] Thus, it appears safe for adults with chronic SCI to exercise.

To minimize psychological and social risks in general, participants will be advised that their participation is completely voluntary, their data are completely anonymous, and that they may withdraw from the study at any time without penalty. In addition, to

minimize mental strain, the research assistant will attempt to keep the physical activity coaching sessions to less than 15 minutes, allow participants to take breaks as needed and/or discontinue participation at any time during the session.

8. ADVERSE EVENTS

The study will be overseen and monitored by Dr. Christopher West (ICORD, Vancouver, BC Canada) and Dr. Kathleen Martin Ginis (UBC, Kelowna, BC Canada), who will visit their respective sites to examine trial procedures, ensure data quality, and monitor compliance with the study protocol.

Should an adverse event occur during exercise at the Vancouver or Kelowna site, subjects will be assisted by staff trained in emergency procedures. At the Vancouver site, defibrillators and resuscitation equipment will be in the training room at all times and if required physicians are within the building to provide emergency response. All exercise sessions in Vancouver are implemented on a hospital site where the VGH Emergency Department is nearby (920 W 10th Ave). At the Kelowna site, defibrillators and resuscitation equipment are located in the adjacent lab (ARTS 183), 911 will be dialed in case of on an emergency, and if needed will be transported to Kelowna General Hospital (2268 Pandosy St- 15-20 minutes via ambulance). There is also on-campus advanced life support team who have a fast (<5 minute) response time. Their phone number (250-807-8111) is located in the lab if needed. The researcher is certified in CPR C.

Autonomic Dysreflexia (AD)

AD is a common complication with SCI at or above the sixth thoracic level (T6) and is caused by loss of cardiovascular control. AD can be a life-threatening condition if not recognized and treated properly. Symptoms include: pronounced hypertension (rapid 20-40 mm Hg systolic rise); bradycardia or tachycardia; pounding headaches; anxiety; changes in vision; nasal congestion; sweating; goose bumps; and flushed skin. When reporting cases of AD, severity will be classified into mild, moderate and severe cases, based on observed symptoms. In the event that moderate to severe AD is suspected during testing sessions, the investigator will follow the steps outlined below:

I. Have the participant sit upright or raise their head 90 degrees
II. Take off or loosen any tight or restrictive clothing
III. Monitor blood pressure every 2-3 minutes if hypertensive
IV. Empty bladder and check for kinks and blockages if using an indwelling catheter

V. Check skin for new wounds, pressure ulcers, burns, cuts, insect bites etc.
VI. Check for any other negative stimulus below the lesion level
VII. If no stimulus is found and blood pressure does not change in 2 minutes, call for medical assistance and ambulance (Dial 88 for emergency response in Vancouver General Hospital, 911 in Kelowna).

Orthostatic Hypotension (OH)

OH is a common complication of SCI where the individual is unable to maintain homeostatic blood pressure during a change in body position. Symptoms include: lightheadedness and loss of consciousness. In the event OH is suspected during testing sessions, the investigator will follow the steps outlined below:

i. Have the participant lie down in the supine position and monitor blood pressure every 2 minutes
ii. If consciousness does not return within 5 minutes, call for medical assistance (Dial 88 for emergency response in Vancouver General Hospital, 911 in Kelowna)

7. ADHERENCE

With a total of 9 physical activity coaching intervention sessions, a minimum of 6 sessions must be attended to be included for data analysis. Accelerometer wear time must exceed 600 min/day over 4 days to be included as a measure of physical activity for any given time point.

8. DATA ANALYSIS

To test hypothesis i, differences in physical activity levels will be examined using repeated measures analyses of covariance with baseline physical activity as the covariate. Where significant intervention x time interactions are found, post-hoc analyses will be conducted to determine the specific time point at which differences in physical activity between groups are found.

To test hypothesis ii, independent samples t-tests will compare post-intervention HAPA model constructs between groups.

To test hypothesis iii, we will use separate hierarchical regressions with change in physical activity entered as the predictor of change in arterial stiffness and secondary

health outcomes (cardiovascular, fitness).

9. CONFIDENTIALITY

The investigator will ensure that the anonymity of each participant is maintained and identity is protected from unauthorized parties. A unique identification number will be assigned to each participant upon study entry, which will be used to identify them for the duration of the study.

Any reports or publications about the study or any other research will not include the participant's name or any other personal identification information. If the participant desires, the investigator will provide access to the published results of the study. Participant names will not be placed on any mailing lists or sold to anyone for marketing purposes. The Research Ethics Board may have access to information about participants and data regarding the performance of the treatments on a confidential basis.

All data collected (electronic or hardcopy documents) will be coded with the unique identification numbers and stored on a password-protected computer or in a locked filing cabinet in a secure laboratory space only accessible to the study investigators. This includes data from the accelerometers and audio recordings. When data is needed to be transferred, data will be transferred via password protected zipfolder to an encrypted, password-protected USB until it is downloaded onto the password-protected computer at UBCO. The online questionnaire is administered by the UBC-hosted version of FluidSurveys. All data will be stored and backed up in Canada. All data will be kept for 5 years after publication, after which it will be destroyed.

Contact information will be used to organize testing/ training sessions and for payment only unless you have indicated that you would like to be contacted for future studies. This research is part of a PhD thesis. Results will become publically available on cIRcle (http://circle.ubc.ca).

10. REFERENCES

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