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Health promotion and cardiovascular risk reduction among people with spinal cord injury: physical activity, healthy diet and maintaineance after discharge.

Introduction

The incidence of a spinal cord injury (SCI) in Denmark is 10-15/mill. annually [1]. It is a life changing event that affects all bodily functions below the level of lesion with significant costs for the individual and society, and requires highly specialized interdisciplinary rehabilitation aiming at the highest possible level of independent functioning. The rehabilitation at Clinic for Spinal Cord Injuries in Eastern Denmark (CSCI) generally includes functional training, strength training, cardiovascular exercise and fine motor training of the upper extremities. Moreover continuously assessment and action is taken in relation to circulation, respiration, thermoregulation, bowel, bladder, skin, pain and spasticity, as well as aids compensating the level of functioning, including communication aids and splinting. Counseling related to social and economic issues, sexual function and psychological issues is provided if needed.

On the long-term, SCI and its impairments predispose to increased cardiovascular risk and is one of the most frequent causes of premature death among people with SCI [2] [3]. However, patient education including individualized counselling on long term cardiovascular risk is not systematically integrated at early stages of specialized SCI rehabilitation at CSCI, which may be a missed opportunity to target the link between the injury-related immediate impact on functionality and long-term health consequences. Likewise, systematic health promotion related to BMI, diet, smoking, alcohol intake and PA is not provided systematically, and assessment of metabolic profile and body composition is not a part of standard care. A systematic approach related to health care promotion may ensure that all patients at CSCI receive information and knowledge related to health promotion and the risk of cardiovascular disease which may also support patient adaptation and adherence to recommended physical activity (PA) and healthy diet.
Therefore, the cardiovascular risk factor, including consequences of an inactive lifestyle and weight gain during and after the primary rehabilitation, defines the primary systematic approach in the current controlled study and sub-investigations.

The course of overweight

The prevalence of overweight among people with SCI is high and is conservatively estimated to 66% [2]. In a Swedish cohort of wheelchair dependent people with paraplegia, 27- 36% had a cardiovascular risk profile requiring treatment. When Body Mass Index (BMI) adjusted to SCI was entered into the risk model, 80% had a risk profile requiring treatment [3]. Energy expenditure decreases significantly the first weeks after injury and remains low throughout the primary rehabilitation, with the possibility of decreasing even more the following years. Body fat and body weight also decreases in the acute phase, before increasing in the subacute phase towards the same level as before the time of injury [4]. A longitudinal study with participants ranging from 19-60 years of age and neurological level AIS A-D (54% where incomplete at follow up), found an average loss of lean body mass corresponding to 20,5 and 15, 1% in the lower extremities and trunk respectively during the first year after injury. The course among people with SCI during and after discharge from the primary rehabilitation in Denmark is not known. BMI increases gradually, and especially during the first years after discharge from the primary rehabilitation. A Dutch prospective cohort study found that BMI increased gradually with a prevalence of overweight of 28 % during the primary rehabilitation and 54 % at follow up 5 years after discharge [5]. Similar inventories do not exist for people with SCI in Denmark. Obese people with SCI achieve a lower

level of functioning during primary rehabilitation than people with normal weight [6], and more knowledge about prevention, treatment and managing overweight among people with SCI is warranted among health care professionals in the clinical setting. [7]. Overweight in people with SCI is associated with increased risk of depression, while physical activity may contribute to a decreased prevalence of depression and increased quality of life [8, 9]. The relationship between these variables in a Danish setting is not known.

Impact of physical activity on health and fitness

In the general population physical activity (PA) is associated with beneficial effects on diseases contributing to the metabolic syndrome including reduced fat mass, and may prevent weight gain as well as maintaining body weight after weight loss, and combined with diet the effect increases [10]. High aerobic capacity has an independent prophylactic effect on comorbidities due to obesity, and greater aerobic capacity is associated with greater cardiovascular health [11]. Evidence based exercise guidelines for cardiometabolic health in people with SCI recommends a minimum of 30 minutes of moderate to vigorous aerobic exercise three times weekly to reduce cardiovascular risk factors [12]. An increased amount of PA in newly injured people with SCI is associated with more favorable lipid profiles and increased VO2peak during and after discharge from primary rehabilitation [13]. Changes in physical capacity during primary rehabilitation and the years after discharge has previously been described with an increase in VO2peak of 24% during the early phase of rehabilitation, and with a further increase one year after discharge. Koppenhagen et al found that VO2peak, despite different trajectories, increased over all in 88% of the participants during a period of 5 years [14, 15]. The course of VO2peak during and after discharge from primary rehabilitation in a Danish context is not known. After discharge from the primary rehabilitation the amount of PA in people with SCI is varying and 50- 63 % indicates to participate in little or no sports activity on a weekly basis. The majority of those who are physical active are active at mild to moderate intensity (54% and 68% respectively) [8, 16]. Intra- and extra personal factors are influencing participation in PA, including self-efficacy related to being physically active [17]. Therefore a new paradigm is focusing on avoiding inactivity [16]. The amount and intensity of PA in people with SCI in a Danish setting is not known. An association between self-reported PA and adherence to national nutritional guidelines is not necessarily present, and therefore focus on both elements is necessary during lifestyle changes [18].

Prevention and treatment of cardiovascular risk factors

In the literature an interdisciplinary approach to prevention and treatment of cardiovascular risk factors among people with SCI with a focus on diet, PA and behavioral interventions is recommended [16] [19]. A few studies have investigated the effect of multimodal interventions comprising of diet, PA and behavioral interventions, or some of these components, in people with SCI and the effect on different outcome measures such as bodyweight, BMI, lean body mass, physical capacity and PA among others and with overall promising results [20] [17, 21] [22].

A multimodal intervention is supported by people with a movement disability, including people with SCI. Crucial components in the interventions, of which several also acts as outcome measures, are autonomy in relation to decision making related to PA, support and follow up from health care professionals as well as mentors with SCI, information about PA in relation to the diagnosis, and finally behavioral interventions using goalsetting and feedback trough physical tests etc. [23]. The conclusion of the systematic review by Greaves et al. is identical and states that interventions comprising of diet, PA, social support, increased frequency of follow ups, and the inclusion of goal setting and feedback, are most effective to promote weight loss and PA. Besides the above mentioned, the systematic review recommend, on the basis of strong evidence, interventions in the

clinical setting that contains both group sessions and individual sessions as well as interdisciplinary interventions that focus on maintaining PA and healthy diet [24].

An interdisciplinary and multimodal approach as described above needs an institutional strategy in order to be implemented in a clinical setting. To the best of our knowledge there is a gap in the literature describing the efficacy of interventions targeted towards cardiovascular risk reduction, and descriptions of the implementation of the multimodal approaches as elements in patient education in a clinical setting, thus describing not only the effect of the multimodal intervention but also the effectiveness.

Objectives

The aim of the study is to develop and implement a uniform and systematic approach, in complement to standard rehabilitation, in relation to patient education containing information and recommendations about cardiovascular risk factors, and health care promotion with an early off-set in the SCI diagnosis during primary rehabilitation.

Study Design

The study consists of a primary study designed as a controlled pre-post multi modal pragmatic clinical intervention study, with 6-months of follow up and a historic control conducted as a prospective cohort study

Sub-investigations

BMI is considered a high risk determinant due to the impact of overweight on the cardiovascular risk profile and level of functioning [3]. Therefore a prospective representative longitudinal national survey of BMI is conducted in collaboration with Spinal Cord Injury Center of Western Denmark, before the onset of the controlled intervention, and serves as historic control (sub-study 1). Additional objective outcomes measures will be collected at CSCI during the historic survey period including physical activity, physical capacity and body composition. Accordingly, two sub-studies regarding test – retest reliability of a VO2 peak test (sub study 2) and a multi sensor accelerometer (sub study 3) respectively will be performed for two reasons. First, VO2 peak and accelerometry are considered valid methods to measure the effect, amount and intensity of physical activity at discharge from the primary SCI rehabilitation. Secondly, these measures will be collected repeatedly during the prospective controlled implementation study and serve as individual motivational components in the patient-clinician educative PA communication, besides being exact outcome measures. For this reason assessing the test retest reliability of the two procedures is essential (see timeline in figure 2).

Participants and eligibility criteria

All newly injured patients within the last 12 months with a SCI admitted at CSCI are included regardless of , etiology to the spinal cord lesion, neurological level or completeness* [1]of the lesion if informed consent is retrieved and they are 18 years of age or older. In sub study 1 all newly injured people with SCI admitted at the SCI Centre of Western Denmark are also included.

Exclusion criteria for the VO2peak test in sub study 2 includes motor complete SCI (AIS A and B) at C4 level or above, and assisted ventilatory function. Other exclusion criteria are the presence of decubitus, severe spasticity or musculoskeletal problems considered at risk of aggravation during testing or preventing completion of the test.

Sub study 3 includes a convenience sample of 20 patients aiming at ensuring a broad variation of age, gender, neurological level and completeness of SCI.

Methods and analysis

Patient involvement

A user panel consisting of both newly injured as well as experienced people with SCI was established and involved in the early phase of the protocol development. All the participants were hospitalized at CSCI when they were interviewed about their perception of the present health promoting practice at the clinic. The user panel called for more information in the early phase of rehabilitation about cardiovascular risk, PA and diet as well as more support and guidance about being physical active and appropriate diet, which is the main aim of the project.

[1] The completeness of the injury is graded according to the ASIA Impairment Scale (AIS). AIS is used to determine the degree of motor and sensory function below the level of the SCI. A complete or incomplete injury is defined as absence or presence of sensory and motor function in the most caudal sacral segment. A = complete; B = sensory incomplete without motor function > 3 levels below the motor level of injury on both sides of the body; C = motor incomplete, with preserved motor function below the level of injury and where > 50% of the key muscles below the injury level have a degree < 3 by MMT; D = motor incomplete with preserved motor function below the level of injury and where > 50% of key muscles below the injury level have a degree > 3 by MMT; E = normal sensory and motor function in all segments.

Primary study. A systematic interdisciplinary multimodal intervention which, as a part of usual care, facilitates PA, healthy diet and maintenance after discharge through strategic patient education, with the aim of decreasing cardiovascular risk

This pre-post study includes all patients with a new SCI who are admitted at CSCI during a period of 12- 18 months including follow up 6 months after discharge from primary rehabilitation. Approximately 70 patients with a new SCI are admitted to CSCI annually and with a great variation in length of rehabilitation. Therefore complete data sets from admission to follow up are expected for approximately 50-60 patients during this period.

Intervention

The multimodal intervention will be an integrated part of usual care during the project period, and all newly injured patients will receive all the multimodal components, or parts of them, dependent on eg. the level of injury. Rehabilitation of the physical level of functioning and physical capacity will take place unchanged as usual and is a mandatory core component of highly specialized SCI rehabilitation. Therefore: decisions made by the patient during the intervention about PA, are exclusively related to PA besides the mandatory rehabilitation programme during hospitalization.

A central part of the intervention is to create a uniform and systematic approach to education of the patients about cardiovascular risk factors, PA and a healthy diet through a systematization of the existing setting and treatment interventions, In the process of preparing and reorganizing the institutional approach towards addressing cardiovascular risks, pre-education of the interdisciplinary health care personnel and peers with SCI, clarifying the roles of each profession in relation to the targeted patient education, are mandatory. Moreover, pocket cards with evidence based recommendations related to PA and diet in people with SCI are provided to all health care professionals and peers with SCI.

The patients receive information and instructions about PA and healthy diet through targeted strategic patient education based on principles that includes an individualized face to face interaction between patients and health care professionals, while working towards, and improving a specific health related outcome through adherence to the working processes as e.g. lifestyle or medicine. [28: Møller et al. 2014; Møller et 2016].

Patient education is generally carried out by all the health care professions in different educational settings of patients and their relatives [25, 26], with a focus on clarifying the importance of PA and a healthy diet. The overall strategic approaches to cardiovascular risk factors, beginning at the onset of the primary SCI rehabilitation and integrated into the existing setting at predetermined time points throughout the rehabilitation continuum, constitutes the aims for secondary and tertiary cardiovascular prevention. This involves training sessions [27], and feedback on physiological outcome measures and tests, that also serves as motivational tools. Additionally, a motivational conversation, goal setting meetings, tools for shared decision making [28] [24] [29], and use of mentors with SCI are also integrated as components supporting decision making about PA and healthy diet habilitation.

All components of the strategic intervention are offered the patients as a mandatory part of the systematic intervention, ensuring that information and education of the patients is provided and decisions about PA and healthy diet are made. However, the extent to which the patients engage in ie. decision making and goalsetting about PA and healthy diet) is an individual decision. Deciding not to set goals or make

decisions about PA and healthy diet, is respected by the interdisciplinary health care professionals in respect of the patients autonomy.

Several outcome measures used to evaluate the intervention at admission, discharge and at follow up 6 months after discharge, are also part of the intervention as a motivational component and comprises of the following: Body Mass Index (BMI), body composition, Dual- energy X-ray Absorptiometry (DEXA), physical capacity (VO2peak), physical activity (Actiheart multisensor accelorometer) and blood samples describing metabolic profile. BMI is part of usual care while body composition evaluated by a body scan (DEXA) is part of usual care at discharge, and therefore the study applies two additional scans to the patients. The following assesments are not a part of standard rehabilitation: Physical capacity is assessed by exercises already being a part of standard rehabilitation and the assessment is non-invasive while a mask covering nose and mouth measures the patients expired air. The patients ventilation is not impaired and the patient can terminate the test at any time. Physical activity is measured by an activity monitor attached to the patient`s chest by two surface electrodes and is non-invasive. The monitor is individually calibrated to the patients by heart rate measures obtained during the assessment of physical capacity. The patients will perform the daily activities they would do regardless of the assessment and no new task will be required. The assessments of physical capacity and physical activity will be assessed twice to measure the reproducebillity of the measurements. A blood sample (5ml) will be collected at the same time as a standard blood sample related to standard rehabilitation is collected. In this way only one needlestick will be applied to the patient. The analysis describing metabolic profile will be performed immediately after and the blood sample will not be stored.

Outcome measures evaluating the intervention comprises furthermore more of level of functioning (Spinal Cord Injury Independence Measure (SCIM III)) and neurological status (International Standards for Neurological Classification of Spinal Cord Injury (ISNCSCI)), quality of life (International SCI Quality of Life Basic Data Set (QoL SCI)), depression (Patient Health Questionnaire- 2 (PHQ-2)), are all a part of standard rehabilitation and will be collected from the medical record for research purpose according to the law on data handling. The following questionnaires are not a part of standard rehabilitation. Amount of physical activity (Leisure Time Physical Activity Questionnaire for people With Spinal Cord Injury (LTPAQ-SCI)), self- assessed ability to be physically active (Exercise Self Efficacy Scale for people with Spinal Cord Injury (ESES)), and measure for a varied and healthy diet in an appropriate amount (Nordic monitoring of diet, physical activity and overweight (NORMON)). Measure of shared decision making related to the two patient decision aids for PA and healthy diet (Shared Decision Making Questionnaire (SDM-Q-9)) is only used at discharge.

The primary study is possible due to the length of stay during initial rehabilitation at CSCI, which is in average 85 and 86 days respectively for people with incomplete tetra- and paraplegia while average length of stay is 110- and 123 days respectively for people with complete tetra and paraplegia (originates from internal inventory). The study is highly dependent of the interdisciplinary health care professionals and the patients' adherence to the new intervention. The interdisciplinary health care professionals adherence to the intervention is described and secured by a process inspired by a previously used prospective effect and process evaluation for complex trials[30]. At least 75% of the health care professionals have to agree that a specific element of strategic patient education has become a part of clinical practice routines before it is considered implemented. This evaluation is repeated for each of the five pre-defined implementation phases every 6-8 weeks throughout the intervention period by the project manager. Likewise pre-defined

barriers for the implementation process is evaluated, and the amount of answers indicating perceived barriers for implementation is evaluated throughout the intervention period every 6-8 weeks by the project manager.

Patient adherence may be challenged as described previously where patients missed out in average 2.5 hours weekly of their rehabilitation [31]. Patient adherence to the intervention is described by protocol registration by the patient's primary nurse, who will document the patients participation in the different targeted education elements in which they are expected to participate. The protocol is placed in the patient folder. On the other hand a study from 2016 found that the most important factors facilitating participation in clinical studies were the possibility of learning more about SCI and health which is made possible in the intervention study [32]. A review by Van Wyk et al. emphasizes that patient education is an important part of the interdisciplinary rehabilitation of people with SCI and recommend an individualized approach and the use of different settings in which the patient can receive the education [29].

Sub study 1. Prospective representative national survey of Body Mass Index.

This study includes all patients with a new SCI hospitalized at CSCI or SCI Center of Western Denmark during a period of 10 months whereby 100 patients are expected to participate. Data concerning BMI, level of functioning (SCIM III)) and neurological status (ISNCSCI) are collected at both centers. Patients with a new SCI (within the last 12 months) who are admitted for rehabilitation several months after the time of injury, are also included in the prospective survey. Therefore BMI at the time of injury is collected for all patients at admission to primary rehabilitation from both the patient's medical record and by asking the patient about weight and height at the time of injury. At CSCI, BMI every 6 week, quality of life (QoL SCI)), depression (PHQ-2)), amount of physical activity (Leisure Time Physical Activity Questionnaire for people With Spinal Cord Injury (LTPAQ-SCI)) and self- assessed ability to be physically active (ESES) will be collected addtionally during this period, at admission, discharge and at follow up 6 months after discharge. A measure for physical capacity (VO2peak), physical activity(Actiheart multisensor accelorometer) and bodycompostion (DEXA) is performed as well at discharge. Data from this sub study serves as a historic control for the Intervention study.

Sub study 2. Test-retest reliability of a VO2 peak test

This study includes all patients participating in sub study 1 who are able of performing the test at discharge from primary rehabilitation. The patients are allocated by randomization to a test session of either intra- or interrater reliability. Four different pre -defined exercise protocols are used due to the complexity of a SCI in order to reach pre-defined criteria for VO2peak. For people with an incomplete SCI, a seated cross-trainer is used (NuStep T5XR®) with incorporated standard- and a modified test protocol in the equipment software. Equipment and modified protocol is reliable in people with traumatic brain injury and has been validated in healthy persons [33, 34]. In people with an incomplete SCI the equipment is safe, and involves a large amount of muscle mass ensuring completion of the test [35]. In case the equipment and protocols are difficult to use for people with a complete tetraplegia, paraplegia or very deconditioned patients, which may hinder reaching VO2peak, an armcrancking ergometer will be used (SCI FIT Pro1®). The test protocols used on the SCI FIT armergometer is established from the most common protocols for people with tetra and paraplegia during rehabilitation, reported in a recent systematic review [36]. If predefined criteria for VO2peak is not reached at test 1, a more suitable protocol is chosen for test 2 in order to reach VO2peak, and retested at test 3.The test-retest study takes place at discharge, separated

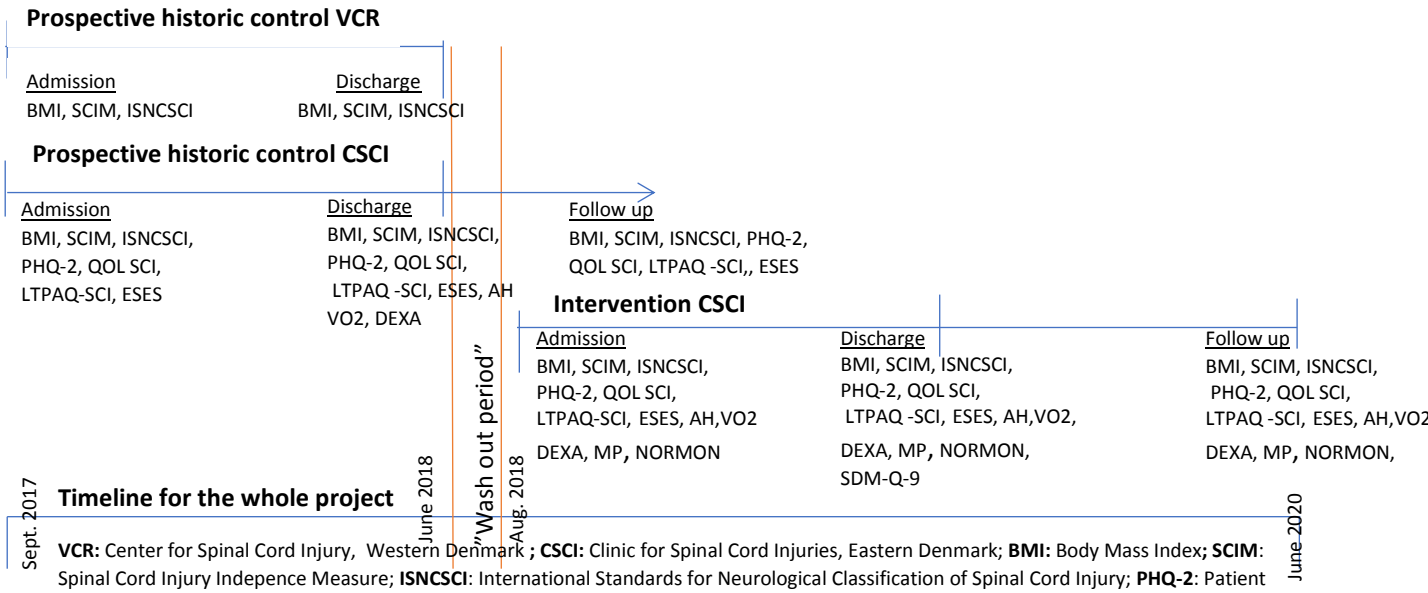
by 48 hours or within maximum 5 days between tests at the same time of the day. The participants refrain from caffeine, alcohol and intensive physical exercise on the day of testing as well as tobacco smoking two hours before the test. Bladder emptying is to be performed before the test. The measurement is non-invasive while the patients expired air is analyzed through a mask covering the patients mouth and nose and with unimpeded respiration. The patient decides when the test is terminated.

Sub study 3. Test-retest reliability of a multi censor accelerometer.

This study includes a convenience sample of 20 patients ensuring a representative sample of para- and tetraplegia, complete and incomplete injuries, age and sex.The equipment used for monitoring amount and intensity of PA consists of sensors registering acceleration and heart rate, and is placed on the thorax of the participant with two surface electrodes. The equipment has previously been used in wheelchair dependent people with SCI, although the reliability of the equipment in an inpatient setting has not previously been assessed [37]. The precision of the equipment is higher when calibrated individually to the participant using measures of energy expenditure during rest and during an exercise testing whereby heart rate is retrieved as well. [68]. In this study individual calibration will be made and during the VO2peak test described in sub study 2, and continuous measurements of amount and intensity of PA will be made during a period of 2- 4 days, where the patients will be physically active just as normal. The patients will not be performing new tasks or physical activities. The test-retest is performed 4 -2 weeks before discharge on identical days of the week , over a period of two weeks.

Figure 2.

Timeline for all sub studies and used outcome measures



VCR: Center for Spinal Cord Injury, Western Denmark **; CSCI:** Clinic for Spinal Cord Injuries, Eastern Denmark; **BMI:** Body Mass Index**; SCIM**: Spinal Cord Injury Indepence Measure; **ISNCSCI**: International Standards for Neurological Classification of Spinal Cord Injury; **PHQ-2**: Patient Health Questionnaire- 2; **QOL SCI**: International SCI Quality of Life Basic Data Set; **LTPAQ-SCI**: Leisure Time Physical Activity Questionnaire for people With Spinal Cord Injury; **ESES**: Exercise Self Efficacy Scale **;AH Actiheart (accelerometer); VO2peak**:peak oxygen uptake **;DEXA**; Dual-energy X-ray Absorptiometry **MP**: Metabolisk profil;**; NORMON: Nordic monitoring of diet, physical activity and overweight; SDM-Q-9: 9-item Shared Decision Making Questionnaire**

Outcome measures

All outcome measures will be collected at admission, discharge and follow-up 6 months after discharge. At CSCI data for BMI is also collected every 6`th week during the hospitalization period.

Primary outcome

- ***Oxygen uptake*:** Is measured as VO2peak during a maximal exercise test and is gold standard for measuring aerobic capacity. For people with a SCI several test protocols have been used [36].]

Secondary outcomes

***Objective physical activity*:** Is measured in a sub-sample in the historic control cohort and the participants in the intervention study with a multisensor device (Actiheart®) recording accelerations and heart rate. It is previously used for wheelchair users with a SCI and individual calibration is important to get the most accurate data [38].

***Bodyweight*:** Is measured as Body Mass Index (BMI) which is the most widely used outcome measure for measuring bodyweight in people with SCI. BMI is not sensitive enough to distinguish between fat mass and lean body mass nor overweight in people with SCI. Lowering the cut-off for overweight to 25kg/m^2 the sensitivity increases although this adjustment is not used consequently in the literature [39]. BMI is already collected as part of the existing routines every week and data for BMI every 6`th week until discharge will be included in the project. Some newly injured are admitted to primary rehabilitation several months after the time of injury, and the course of bodyweight may already have changed significantly since the time of injury. Therefore BMI at the time of injury is collected from the patient journal from the initial hospitalization during the acute stage and by asking the patient at admission to primary rehabilitation about the height and weight at the time of injury.

***Body composition*:** Is determined by Dual energy x-ray absorptiometry (Dexa) which is gold standard for assessing obesity and body composition although cut-off values for people with SCI has not been established [39].

***Metabolic profile*:** Consists of CRP as a marker for inflammation, BP, Lipid profile: Total cholesterol, Triglycerides, HDL cholesterol, LDL cholesterol which all are included in the International SCI Endocrine and Metabolic Function Basic Data Set, as well as Hemoglobin A1c as a marker for carbohydrate metabolism, and is included in the International SCI Endocrine and Metabolic Extended Data Set [40, 41]. The analysis will be performed on the basis of an already existing blood sample in the present clinical practice.

***Level of functioning*:** Is determined by the Spinal Cord Injury Independence Measure III (SCIM III) which is a valid and reliable outcome measure designed to assess level of functioning in people with SCI in a clinical setting and in research [42] [43, 44]. The SCIM is composed of 19 items that assess 3 domains.1 Self-care (6 items, scores range from 0-20). 2 Respiration and sphincter management (4 items, scores range from 0-40). 3 Mobility (9 items, scores range from 0-40). The total SCIM scores range from 0 to 100. SCIM III is already collected as part of the existing routines at CSCI.

***Neurological status*:** Is determined by the International Standards for Neurological Classification of Spinal Cord Injury (ISNCSCI) and is the most widely used classification in people with SCI [45, 46]. The classification tool involves a sensory and motor examination to determine the neurological

level of the injury and whether the injury is complete or incomplete. The ISNCSCI defines neurological level as the most caudal level at which sensory and motor function are intact. The completeness of the injury is graded according to the ASIA Impairment Scale (AIS). AIS is used to determine the degree of motor and sensory function below the level of the SCI. A complete or incomplete injury is defined as absence or presence of sensory and motor function in the most caudal sacral segment. A = complete; B = sensory incomplete without motor function > 3 levels below the motor level of injury on both sides of the body; C = motor incomplete, with preserved motor function below the level of injury and where > 50% of the key muscles below the injury level have a degree < 3 by MMT; D = motor incomplete with preserved motor function below the level of injury and where > 50% of key muscles below the injury level have a degree > 3 by MMT; E = normal sensory and motor function in all segments. ISNCSCI Is already collected as part of the existing routines at CSCI.

***Depression**:* Is measured by the Patient Health Questionnaire- 2 (PHQ-2) which is a generic outcome measure for measuring depression. In people with SCI a cut-off score of 3 is associated with a sensitivity of 83,3% and specificity of 95,7% [47]. PHQ-2 is already collected at admission as part of the existing routines at CSCI

Quality of Life: Is measured by the International SCI Quality of Life Basic Data Set (QoL SCI) which consists of three questions regarding satisfaction with life in general as well as physical and mental health. It is a valid outcome measure with good internal consistency [48] [49]. QoL SCI is already collected at discharge as part of the existing routines at CSCI.

***Self - reported physical activity*:** Is measured by the Leisure Time Physical Activity Questionnaire for people with Spinal Cord Injury (LTPAQ-SCI) which is a self- administered questionnaire concerning leisure time PA, including amount and intensity the past 7 days. LTPAQ-SCI uses a scale for perceived exertion which is validated against VO2-peak and the Borg-scale. Reliability and validity of the self- reported activity level is satisfactory in the moderate and high intensity area [11]. For people hospitalized during primary rehabilitation, defining leisure time may be difficult. Therefore an instruction defining leisure time in this context was formulated describing leisure time PA as being PA that is not part of the patients weekly schedule, is not planned together with the health care professionals as part of the rehabilitation and is not self- administered exercise which is planned or scheduled as part of the rehabilitation. Therefore leisure time PA is any kind of spontaneous PA that is not planned or schedule together with a physiotherapist or other health care professionals. This kind of necessary PA is described in the additional question developed for the study. The question will be designed as the original questions and the same intensity scale is used.

***Self- assessed ability to be physically active*:** Is measured by the Exercise Self Efficacy Scale for people with Spinal Cord Injury (ESES) which is an outcome measure developed for assessing self- efficacy related to PA in people with SCI, and consists of 10 questions which are answered on a 0-4 scale. ESES is reliable with a high internal consistency (Cronbach`s alpha 0,94). Also content validity in the form of face and construct validity are satisfactory [50].

Measure of shared decision making related to patient decision aids for PA and healthy diet: Is measured by the 9-item Shared Decision Making Questionnaire (SDM-Q-9),and describes the process of Shared Decision Making between health care professionals and the patient from the patient's perspective. SDM-Q-9 consists of nine statements, which can be rated on a six-point scale from "completely disagree" (0) being the worse score to "completely agree" (5) being the better score. Summing up all items leads to a raw total score between 0 and 45.

***Measure for a varied and healthy diet in an appropriate amount*:** Is measured by the Nordic monitoring of diet, physical activity and overweight (NORMON). The questionnaire Is used to measure the course in dietary habits and explores how often 16 food indicators are consumed. The food indicators are chosen in a way that reflects the diets nutritional quality. An association between the frequency of food indicator intake and the overall nutritional value of the diet is present. Several of the chosen food indicators are recommended in the national nutritional recommendations, and through the questions, it is possible to achieve knowledge about how many of the participants who eat fish twice a week, how many who eat six pieces of fruit or vegetables a day etc. The questionnaire was validated in 2009 against existing questionnaires about diet [51]. The outcome measure is developed in a Nordic collaboration and has been used for common monitoring of the diet habits, physical activity level and overweight of the Nordic population in 2011 and 2014 [52]. In the Ph.D project the questions related to alcohol intake and smoking are also used.

Clinical implications of the project

The project will contribute to a uniform and increased focus as well as knowledge among the interdisciplinary health care professionals at CSCI and VCR, about preventing cardiovascular risk factors and health promotion. The project will also contribute to organizational changes including implementation of new work flows and knowledge about how these changes all together contributes to the initiation and maintaineance of PA and healthy diet. Even though new treatment initiatives are introduced, a lot of the existing workflows and settings are used and the intervention is expected to continue as a part of the standard treatment at CSCI after the project is terminated, and hopefully contribute to prevent cardiovascular disease in future newly injured people with SCI.

Trial registration

The project is reported to the Danish Data Protection Agency (RH-2017-345, I-Suite nr.:06052). The primary study and all substudies in the project are registered individually at Clinicaltrials.gov. Positive, negative and inconclusive results will all be published.

Data storage

Informed consent is obtained by the Ph.D student in conjunction with the procedure for recruitment of participants.

Data from the patient journals in Epic and the different outcome measures used, is stored in a web based database (Redcap) which is created by the regional Centre for IT, Medico and Telephony (CIMT), with limited access and ID- code, to which pseudo anonymized data is transferred directly, or via an encrypted USB-stick. An identification list is stored in a locked cabinet at CSCI, local 3403.

Data is stored until December 31, 2027 after which paper material is shredded and data files are deleted.

Statistics

The intervention study and follow up is performed as a pragmatic study and includes, with a few exceptions, all newly injured patients with SCI admitted to primary highly specialized rehabilitation at CSCI. Patients will be included during a time period of 18 months corresponding to approximately 50 – 60 patients. Due to the rareness of the morbidity a power calculation is not performed for the primary outcome prior to the intervention, but it is assumed that the total

participant number in the intervention and in the historic control cohort, will be comparable to the existing scientific literature.

Numeric continuous data collected at admission, discharge and follow up is reported descriptively as mean and standard deviation together with 95% confidence intervals, or as median, upper and lower quartile as well as interquartile range. Changes over time is reported on the basis of paired t-test. In subproject 3 and 4 the reliability of the outcome measures is analyzed by paired t-test, Pearsons product moment correlation and coefficient of variation or Intraclass correlation coefficient between the test- retest sessions.

Recruitment of participants:

All newly injured patients who are admitted for rehabilitation at CSCI during the project period are included in the primary intervention study as it becomes a part of usual care during the project period. The patients are identified by the primary investigator through internal lists of all inpatients and future admissions. Information about the study is provided to the patients by the Ph.D student and informed consent is retrieved in order to use anonymized data relevant to the study. Likewise all newly injured patients who are admitted for rehabilitation at CSCI or SCI Center of Western Denmark during the prospective representative national survey (substudy 1) are included and information about the study is provided to the patients and informed consent is retrieved.

The patients are informed by the Ph.D student within two weeks after admission to CSCI. The information (in writing and oral) takes place at the patients bed with the door closed and when no other actions in relation to the patient are taking place. The patient is informed that he/she may discuss participation with close relatives before deciding participation, and that he/she may await deciding participation until relatives (or other another person) are able to discuss participation in the study with the Ph.D student together with the patient. Informed consent is ideally retrieved within 2 weeks after admission, and the patients will have at minimum 24 hours to decide whether to participate, but the patient will be given all the time needed to decide whether to participate or not.

Ethical considerations

During the intervention period all newly injured patients who are admitted for rehabilitation are offered the treatment and tests included in the intervention to the extent they are able to participate depending on eg. the level of lesion and completeness of the injury, as this is a part of usual care and will continue as a part of usual care after termination of the project. The intervention in the project is closely related with the content of the present rehabilitation, why the risk of pain and discomfort related to the elements in the intervention is considered modest. There are no side effects to the intervention.

It is assumed that any risks is by far surpassed by the therapeutic gains such as an expected risk reduction of cardiovascular disease and consequently mortality.

Any unintended events related to the elements of the intervention is reported according to existing guidelines. Any compensation is covered by the normal procedures for patients entitled to compensation for unintended harm during their hospitalization.

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The project gruop in relation to the Ph.D projektet consist of senior researcher Tom Møller (UCSF, head supervisor), professor Fin Biering-Sørensen (Neuroscience centre Rigshospitalet, Clinic for Spinal Cord Injuries, co-supervisor and clinical responsible medical doctor), Docent Lone Schou (Metropol, co- supervisor), professor Lis Adamsen (UCSF), senior researcher Julie Midtgaard (UCSF), head nurse Hanne Folden Lindholdt (Clinic for Spinal Cord Injuries), leading therapist Janni Sleimann (Clinic for Spinal Cord Injuries Clinic for Spinal Cord Injuries), clinical nurse specialist Line Dalsgaard (Clinic for Spinal Cord Injuries) and center manager nurse (Vibeke Freilev (Neuroscience centre, Rigshospitalet.

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Interests of conflict

The Ph.D student has no interests of conflict related to the project in general or any of the subprojects

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