Promoting Physical Activity in People who Have a Long-standing Spinal Cord Injury

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Promoting Physical Activity in People who Have a Long-standing Spinal Cord Injury

Bevorderen van fysieke activiteit bij mensen met een chronische dwarslaesie

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General introduction

Spinal cord injury

A spinal cord injury (SCI) is damage to any part of the spinal cord. SCIs often result in the permanent loss of motor, sensory and autonomic function below the site of the injury, with the lowest unharmed part of the spinal cord referred to as the neurological level of the injury. In addition to the neurological level, the severity of the injury is indicated by its completeness: a complete SCI results in the loss of all sensory and motor function below the injury; with an incomplete SCI, some sensory and/or motor function is retained. Tetraplegia indicates that the arms, hands, trunk, legs and pelvic organs have all been affected by the SCI. With paraplegia, arm function is spared but all or part of the trunk, legs and pelvic organs are affected.[1] SCIs can be the result of a traumatic insult, such as a fall or a traffic or work accident, or they can have a non-traumatic aetiology, such as being due to a vascular disease or tumour.[2] In the Netherlands, the incidence of traumatic SCI is estimated to be 14 per million people per year; the incidence of non-traumatic SCI is similar.[2]

SCIs not only result in loss of motor, sensory and autonomic function, but also in secondary health conditions (SHCs), being defined as "physical or psychological health conditions that are influenced directly or indirectly by the presence of a disability or underlying physical impairment".[3] SCIs can be associated with SHCs such as bladder and bowel disorders, pressure ulcers, spasticity, upper-extremity pain, and cardiovascular and respiratory problems.[3, 4] Compared to the general population, individuals with an SCI are at greater risk of being overweight[5] and of developing cardiovascular diseases and type 2 diabetes.[6] When an SCI is long-standing, there can be additional problems. For instance, ageing with an SCI can be accompanied by the development of SHCs or an increase in their number.[7] Compared with individuals with a recent SCI, those with a long-standing SCI experience more SHCs[3] and have lower levels of physical activity.[8, 9] Therefore, attention to these problems is needed to help people with SCI to stay healthy as they age.

Physical activity with a chronic SCI

Many individuals with a long-standing SCI have a seriously inactive lifestyle.[4, 10, 11] Because they have fewer opportunities to be active, and they experience more barriers to activity, their risk of inactivity is higher than for able-bodied people and for those with other chronic disorder. [12] An inactive lifestyle with SCI is associated with physical deconditioning and the increased incidence of SHCs;[13-16] conversely, a higher activity level has been found to be associated with several physiological and psychological benefits. [17-19] For instance, a recent study showed that increasing physical activity levels led to an increase in physical capacity and a decrease in the incidence of SHCs.[20] Therefore, improving their level of physical activity is an important treatment goal for individuals with SCI.

A logical consequence of the importance of physical activity is the need for methodologically sound ways to measure it for research and clinical practice. Various methods and devices are available for the measurement of physical activity. A common approach is via a self-reported questionnaire; however, this has limitations, such as its subjectivity, the risk of recall bias and a tendency of individuals to overestimate their levels of physical activity.[12] In recent decades, activity monitors have been developed and applied to obtain objective measurements; it is generally accepted that this method provides more valid measurements of daily physical activity. [21] However, for individuals confined to wheelchairs, the variety of activities that can be measured with an activity monitor is limited. This needs further development.

Behavioural intervention for a more active lifestyle

A major challenge for clinical practice is how to achieve behavioural change that results in a patient adopting a more physically active lifestyle. It is sometimes assumed that such a behavioural change can be achieved through interventions that focus only on the physical aspects of increasing the patient's fitness and physical capacity, such as hand cycle training. However, studies have shown that this approach does not result in higher levels of physical activity over the long term.[8, 9, 12] Thus, further strategies or techniques are necessary to promote behavioural change.

One option is to use interventions directly aimed at changing the individual's behaviour. Theoretical models can provide a fundamental basis for such behavioural interventions. For example, the Transtheoretical Model of Change, Theory of Planned Behaviour, proactive coping theory and social cognitive theory have been applied in health-related behavioural change interventions. The Theory of Planned Behaviour[22] assumes that intention is required to perform a new behaviour, and that this intention is influenced by attitude, subjective norms and the individual's perceived level of behavioural control (self-efficacy). The Transtheoretical Model of Change[23] can be used to assess an individual's stage of readiness to act with regard to a new behaviour, such as a more physically active lifestyle. In this model, the five stages of change start with pre-contemplation (such as a lack of intention to change exercise behaviour) and end with maintenance (where the individual has changed his or her behaviour and maintained this change for more than 6 months).[24] Proactive coping[25] is a specific form of problem-focused coping in which an individual takes action to prevent unwanted behavioural events, such as by making action plans. Social cognitive theory[26] holds that an individual can directly obtain part of their knowledge through observing other people within the context of social interactions, experiences and external media influences.

There is overlap in the determinants of change in these models. One of the most modifiable of the determinants is self-efficacy,[27] which is the confidence of an individual in his or her ability to perform a desired behaviour, such as regular physical activity. Determinants such as self-efficacy can be influenced by applying the behavioural change techniques described in the models, such as motivational interviewing, self-monitoring, mastery experiences, action planning and goal-setting. These may therefore offer promising techniques for changing the behaviour of individuals with SCIs.[28-30] Combining these techniques may be more successful than using a single strategy. [29]

Studies have demonstrated positive effects of behavioural interventions aimed at increasing physical activity in people with SCIs.[31-33] However, there are still some gaps in our knowledge. First, most of these studies included subjects with a relatively recent SCI (<5 years post-injury). Their results cannot be generalized to individuals with a more long-standing SCI, whose behaviour may need to be addressed in a different way. For instance, these people may have grown accustomed to living with their SCI, and their behaviours may have developed into habits that are not easily changed.[34] Second, most of these previous studies were based on a single theory or theoretical model. It is questionable whether this approach results in the most effective treatment; a more eclectic approach may be better. Finally, most of these studies did not report long-standing effects. A minimum of six months may be needed to evaluate whether behavioural change has been maintained.[35]

In the main study described in this thesis, we did not favour a single, specific theoretical behavioural change model. Instead, we combined the Transtheoretical Model of Change, the Theory of Planned Behaviour and proactive coping theory into one model (figure 1). We believe this combined model covers every aspect of behavioural change towards a more active lifestyle. Furthermore, the combined model allowed us to develop a pragmatic behavioural intervention from various individual and combined evidence-based behavioural change techniques.

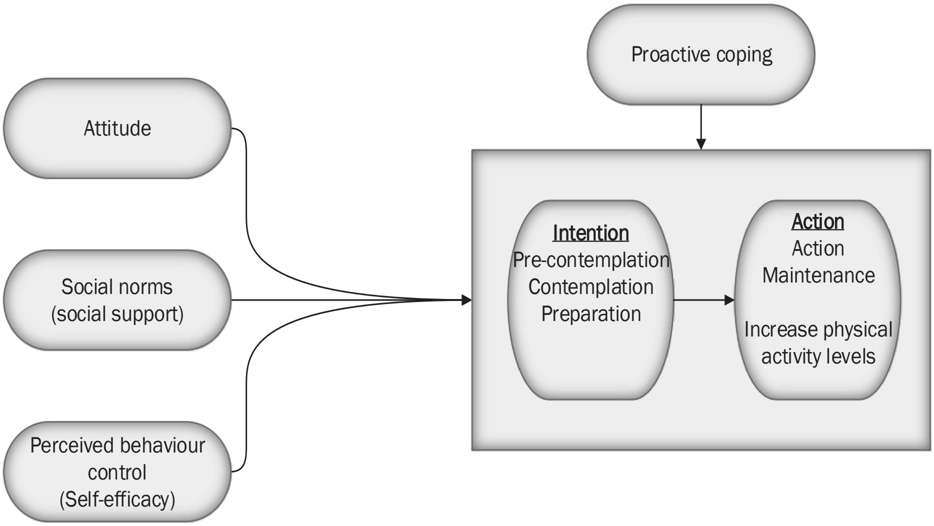

Figure 1 Theoretical model

HABITS and ALLRISC studies

A behavioural intervention based on the combined model of behavioural change was implemented and evaluated in a randomized controlled trial (RCT), the HABITS (Healthy Active Behavioural IntervenTion in SCI) study. The aim of this study was to evaluate the effectiveness of a structured self-management intervention to promote an active lifestyle in inactive individuals with a long-standing SCI.

The HABITS study formed part of the wider ALLRISC (Active LifestyLe Rehabilitation Interventions in aging SCI) research programme, which was developed to address problems related to physical activity, deconditioning and SHCs in people who had lived with an SCI for at least 10 years. [36] This multicentre national programme (started in 2010) was embedded within The Netherlands' SCI clinical rehabilitation research network (www.scionn.nl). It was a continuation of the Umbrella project, a longitudinal cohort study that followed patients with SCIs during their initial clinical rehabilitation and for up to five years after this. [36]

ALLRISC considered several aspects of increasing physical activity in people with SCIs: the long-term consequences of SCI; the preservation of an active lifestyle and fitness; the prevention of SHCs to increase activities, participation, health, and quality of life in individuals living into old age with an SCI; and interventions to improve these aspects in the context of rehabilitation follow-up care. Its main objectives were as follows:

1. To obtain a better understanding of the importance and requirements of regular rehabilitation aftercare in the context of the long-term preservation of an active lifestyle and fitness, to prevent SHCs, and to increase activities, participation, health and quality of life in people living into old age with a chronic SCI;
2. To develop evidence-based components and guidelines for an SCI rehabilitation aftercare system in The Netherlands.

ALLRISC established four studies to provide information on the prevalence and impact of an inactive lifestyle, deconditioning and SHCs on functioning and quality of life in individuals with a long-standing SCI, as well as on the preventive role of fitness, an active lifestyle and behavioural management. The four studies were conducted within a multidisciplinary, multicentre collaboration of eight Dutch rehabilitation centres with an SCI unit and four research groups.

The studies included three RCTs and one cross-sectional study. The aim of the cross-sectional study was to establish the prevalence and impact of SHCs in people with a long-standing SCI and to examine possible determinants for the SHCs. [37] HABITS was the first of the three ALLRISC RCTs. The aim of the second RCT was to investigate the effects of low-intensity wheelchair training on wheelchair-specific fitness, wheelchair performance, physical activity level and propulsion techniques in physically inactive people with a long-standing SCI. [38] The aim of the third RCT was to examine the effects of a 16-week programme of exercise using a hybrid cycle or hand cycle on cardiovascular disease risk factors in people with a long-standing SCI. [39]

Outline of this thesis

This thesis describes studies that developed and evaluated the 16-week HABITS intervention, a structured self-management active lifestyle intervention for people with a long-standing SCI, and investigated the mechanisms underlying the results of the intervention. In addition, the thesis describes the development and validity testing of a new objective measure of physical activity. For further insight, the association between exercise self-efficacy and physical activity is examined in a larger similar population, the ALLRISC cross-sectional study.

Chapter 2 describes the design of our HABITS RCT study. In **chapter 3** we studied the validity of an activity monitor that detects self-propelled wheelchair driving as a measure of physical activity. In **chapter 4** we studied the relationship between self-efficacy and physical activity, based on cross-sectional data from the ALLRISC study. In **chapter 5** we describe the results of the randomized controlled trial of the effectiveness of a self-management intervention called HABITS on behavioural and secondary outcomes. Based on the data of the HABITS study, **Chapter 6** focusses on the underlying working mechanisms of our theoretical model. **Chapter 7** contains the general the discussion wherein the main findings are summarized and discussed.

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2

Randomized controlled trial of a self-management intervention in persons with spinal cord injury: design of the HABITS (Healthy Active Behavioural IntervenTion in SCI) study

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Abstract

Purpose: To evaluate the effectiveness of a 16-week self-management intervention on physical activity level and self-management skills (self-efficacy, proactive coping and problem solving skills) in persons with chronic SCI.

Method/Design: Multicentre randomized controlled trial (RCT). Eighty persons with a SCI for at least 10 years and aged 18 to 65 will randomly be assigned to the intervention (self-management) or the control group (information provision). During the 16-week self-management intervention (one home-visit, 5 group- and 5 individual sessions) active lifestyle will be stimulated and self-management skills will be taught. Data will be collected at baseline (T0), 16 (T1) and 42 (T2) weeks after baseline. Primary outcome measure is level of daily physical activity (self-report/objectively measured). Secondary outcome measures are self-managements skills, stage of behaviour change and attitude.

Conclusion: This is the first RCT on self-management in people with chronic spinal cord injury. This trial will provide knowledge on the effects of a self-management intervention on physical active lifestyle in persons with a long-term SCI.

Introduction

In the general population, inactivity is a well-known risk factor for the development of secondary health conditions (SHCs). Physical activity (PA) can counteract these problems and may lead to potential health benefits.[1] Many persons with chronic spinal cord injury (SCI) show a serious inactive lifestyle.[2-6] Due to less opportunities and barriers to be active, the risk of inactivity is higher for this population in comparison to able-bodied persons and persons with other chronic disorders,[7] hence extra attention is needed.

An inactive lifestyle in persons with SCI has been associated with de-conditioning and secondary health conditions,[8-10] and a higher activity level has found to be associated with several physiological and psychological benefits.[8-18] Therefore, encouraging an active lifestyle is important in this population. Interventions conducted to promote PA in persons with SCI showed moderate benefits.[19, 20] Furthermore, none of these interventions were evaluated on the long-term. Educational programs to promote PA or to prevent specific secondary health conditions in SCI showed effectiveness on knowledge transfer.[21, 22] However, self-management interventions showed that providing only information is insufficient to change behaviour.[23-28] Behavioural interventions are needed to implement health-related goals[23-28] and to facilitate behaviour change.[29-31]

Self-management

Self-management is an important factor in the development and treatment of an inactive lifestyle, SHCs and de-conditioning in persons with SCI.[18, 19] A suitable definition of self-management is given by Barlow, 2002 p.178;[31] "*Self-management refers to the individual's ability to manage the symptoms, treatment, physical and psychosocial consequences and lifestyle changes inherent in living with a chronic condition. Efficacious self-management encompasses ability to monitor one's condition and to affect the cognitive, behavioural and emotional responses necessary to maintain a satisfactory quality of life*".

To stimulate effective self-management, education programs should incorporate more behavioural and active learning strategies in addition to knowledge transfer in order to change specific behaviours.[23, 24, 26, 32] Furthermore, persons have to be intrinsically motivated[33, 34] and able to perform the suitable action at the right time.[31] Different theories and concepts support the potential benefits of effective self-management, as there are: 1) Self-regulation,[35] which is defined as the way in which people control and direct their own actions in order to meet their goals, 2) Proactive coping, which assumes that people do not only react on threatening situations, but that they can also anticipate on situations that may threat or influence their goals in the future,[36, 37] 3) Problem solving, which entails a complex process that includes two broad components: problem orientation and problem-solving skills,[21, 38] and 4) Social cognitive theory,[39] which is related to self-efficacy, that suggests that confidence in one's ability to perform certain behaviour is strongly related to one's ability to perform that behaviour.[39] Similar self-management interventions have shown to be effective in preventing health problems and in modifying behaviour in different chronic disorders.[31, 40, 41] However, the effects of such a self-management intervention has to our knowledge, never been evaluated in persons with chronic SCI.

The current **H**ealthy **A**ctive **B**ehavioural **I**nterven**T**ion in **S**CI (HABITS) study aims to evaluate the effects and mechanisms of a structured self-management active lifestyle intervention in persons with SCI. This study is part of the research program "Active LifestyLe Rehabilitation Interventions in aging Spinal Cord injury" (ALLRISC),[42] that has been developed to address problems related to PA, de-conditioning and SHCs in persons who have a SCI for at least 10 years.[43] It is hypothesized that this intervention will show beneficial effects on (1) a more active lifestyle, (2) self-management skills, such as proactive coping, problem-solving ability and self-efficacy, and (3) that participants with improvements in self-management skills will show more favourable effects on active healthy lifestyle than participants who do not improve in self-management skills.

Methods and design

Study design

HABITS is a multicentre randomized-controlled trial. The experimental group receives a 16-week self-management intervention targeted at physical active & healthy lifestyle. The control group will only receive information about active lifestyle in SCI, including one information meeting and a booklet on how to stay fit with SCI.[44] The four participating rehabilitation centres (RC's) are Rijndam (Rotterdam), De Hoogstraat (Utrecht), Adelante (Hoensbroek), and Het Roessingh (Enschede). Measurements take place at the beginning of, directly after and half a year after termination of the intervention (figure 1).

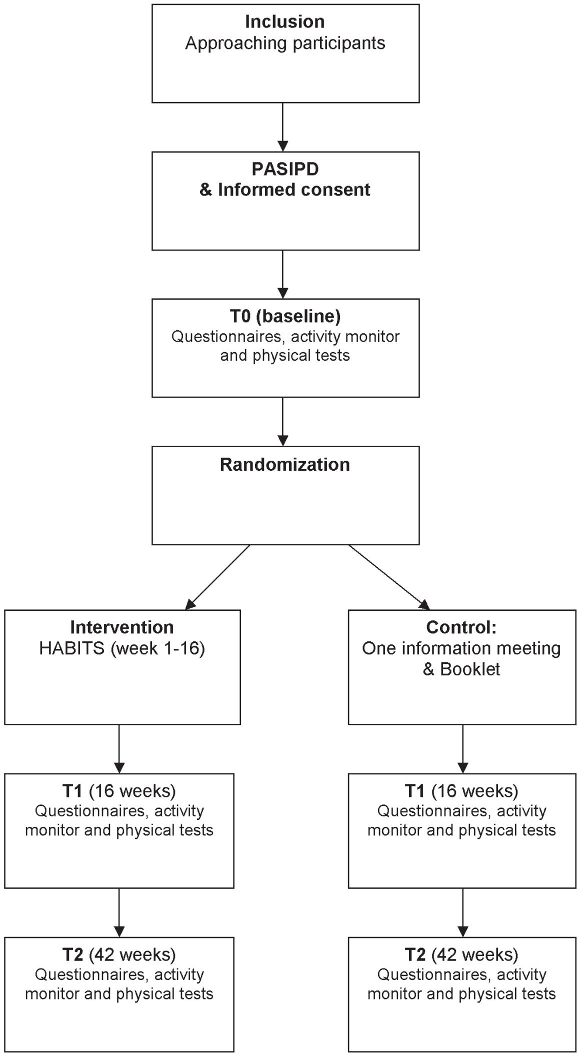

Figure 1 Flowchart study

Ethical approval

Multicentre approval was granted by the Erasmus MC Medical Ethics Committee, The Netherlands, Local approval was granted by all participating centres.

Blinding

The randomization within each centre to the intervention or control groups will be done by an independent investigator who will not be involved in the interventions, measurements or the analysis of the data. In each rehabilitation centre (RC) there will be one research assistant that will perform all the tests. This person is not involved in the self-management intervention of the participants and will be blinded for the allocation of groups.

Sample Size

The size of the study sample (N=80) is based on a power analysis with a power of 80%, alpha=0.05, and an expected increase of 30 minutes per day in the duration of dynamic activities (wheelchair-driving, general movement; as assessed with the accelerometry-based activity monitor) in the experimental group compared to no change in duration of dynamic activities in the control group. The calculations are based on levels of daily physical activity as found in persons with SCI in previous studies of our department. [7,45]

Participants

Inclusion criteria

Adults with a spinal cord injury will be eligible for inclusion if they meet the following criteria:

- Age: 28-65 years
- Time since injury (TSI): at least 10 years
- PASIPD score (Physical activity scale for individuals with physical disabilities) lower than the 75th percentile of a Dutch SCI population. The cut-off score is 30.[46]
- The participant should be able to use a hand-rim wheelchair.

Exclusion criteria

Participants will be excluded from the study if they meet any of the following criteria:

- Progressive disease or severe co-morbidities
- Psychiatric problems that would interfere with the study
- Insufficient knowledge of the Dutch language to understand the purpose of the study and the testing methods
- No intention to change exercise behaviour in the next 6 months

Recruitment

Participants will be recruited from the participating centres. The physician of the department will pre-select former inpatients using information from medical charts. Persons who meet the inclusion criteria regarding age, TSI, and wheelchair mobility will receive the patient information letter. One week later the person is contacted by the research assistant to check the other in- and exclusion criteria and to provide the opportunity to ask questions. If they are eligible and willing to participate they will be asked to sign the informed consent form.

Randomization

Directly after the first measurement participants will be randomly allocated to the control or experimental group per RC by means of blocked randomization per centre, with a block size of 6. A statistician will make a randomization scheme.

Intervention

Theoretical framework

This study is based on a theoretical framework (see figure 3) that serves as scientific background and was used to design the intervention and to select outcome measures. This theoretical framework combines two well-known models: Theory of Planned Behaviour (TPB)[47] and the Transtheoretical Model (TTM).[48] TPB assumes that intention is required to perform (new) behaviour, and intention is influenced by attitude, subjective norms, and perceived behavioural control.[47] The Transtheoretical Model of Behaviour Change assesses an individual's readiness to act on a new healthier behaviour,[48] which also applies to active lifestyle exercise behaviour.[49] The 5 stages of (exercise) change (SToC) range from pre-contemplation (no intention to change exercise behaviour) to maintenance (people changed their exercise behaviour and maintained this change for more than 6 months), see figure 2.[48] In this framework we define "intention" (TBP) as the first three stages of the TTM and "behaviour" (TBP) the last two stages of TTM. In addition, we assume that proactive coping facilitates the step from intention to performing behaviour. Positive effects between proactive coping and behaviour change are found in different studies.[40, 50-52]

Sessions

The self-management intervention consists of one home visit, 5 individual- and 5 group sessions, during a total of 16 weeks. The content of the intervention is described in table 1.

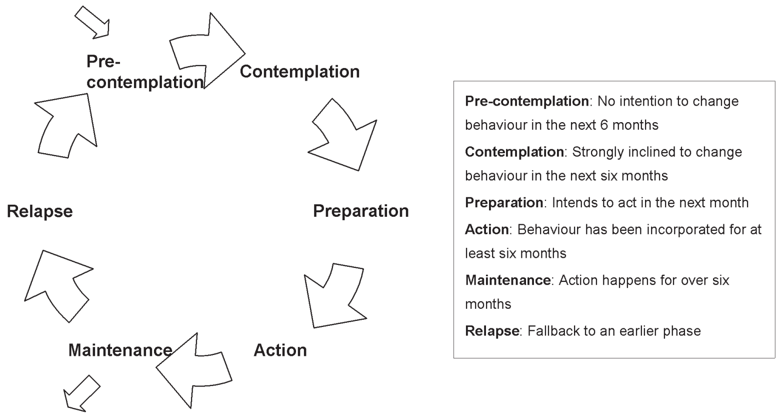

Figure 2 Stages of behaviour change.

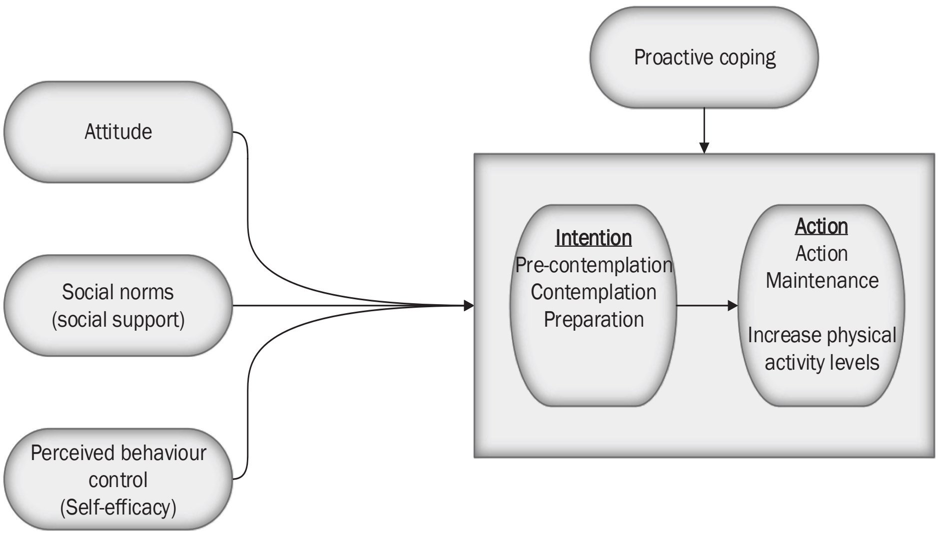

Figure 3 Theoretical framework

Table 1 Overview HABITS intervention different sessions

Week	Home visit	Group session	Individual session
1	Start of HABTIS Home visit		
2			
3		1: Introduction Active lifestyle vs. Health	
4			Telephone session 1
5		2: Sports & leisure PA	
6			Telephone session 2
7		3: Healthy lifestyle & Dealing with emotions	
8			
9			Telephone session 3
10			
11		4: Communication & Social support	
12			
13			Telephone session 4
14		5: Booster session	
15			
16			Telephone session 5

Home visit

During the home visit the counsellor gets an impression of the participant, and investigates the participants' stage of exercise change. [53] This enables the counsellor to tailor the intervention to the participant. [54] Furthermore the environment (at home and outdoors) will be observed for PA possibilities.

Group sessions

Group sessions will be used as a tool to motivate participants on specific behaviours and to enhance their self-efficacy. Contributing factors include methods from the social cognitive theory,[39, 41] like peer support and mastery experiences.

The group sessions have different themes (see table 1) associated with self-management, PA and health, but share the same format; feedback, short introduction- and interactive elaboration of the theme and making action/coping plans. The group number will be between 6 and 8. Each session will last about two and a half hours.

Individual sessions

The individual sessions are used to monitor the participants on their exercise- and health behaviour and to provide extra support by the counsellor. For practical reasons, these sessions will be executed by telephone.

Counsellor

The intervention will be provided by a counsellor who has experience in the treatment of persons with SCI (e.g. physiotherapist, occupational therapist or a specialized nurse), and followed training in motivational interviewing (MI). MI is a directive client-centred counselling style to elicit behaviour change by helping clients to explore and resolve their ambivalence towards change. [55] MI has been shown an effective approach to change behaviours and lifestyle,[56] and support has been found for the clinical utility of this technique in exercise settings. [57]

To be good self-managers, participants have to be self-reliant in finding information, and solutions for problems.[40, 41] Therefore, learning how to seek and utilize recourses is also part of the intervention, and it is the task of the counsellor to take up a supporting and facilitating role.[41, 58] In addition the intervention has to be closely tuned to the goals and expectations of the participants in order to motivate them to change their current behaviour. [21, 41] This will be accomplished by linking the different sessions to self-chosen goals of the participants.

Intervention recourses

Action & Coping plans

A stepwise action & coping plan (based on the proactive coping plan of Aspinwall et al.[36] and other effective interventions [36, 37, 50] concerning PA- and health goals will be made by the participant during the sessions. This plan helps the participant formulate self-chosen, concrete, and achievable goals. Using action plans to promote PA has found to be effective in individuals with SCI. [59]

Odometers

Participants will receive feedback on their activity level by using odometers which register the distance travelled with a wheelchair. Odometers are an effective technique for promoting PA. [60, 61]

Counsellors manual and workbook

The counsellor receives a manual including a detailed description of the content of the different sessions and directives on how different parts of the sessions can be executed. A self-guided workbook for participants will be used as a reference book for the intervention and will contain small assignments to allow the participants to prepare for the sessions.

Measurements

Primary outcome measures

Self-report daily physical activity

Self-reported level of PA will be assessed by the Physical Activity Scale for Individuals with Physical Disabilities (PASIPD). [62] The PASIPD consists of 11 items concerning sports, hobbies, household- and work-related activities. The questionnaire assesses the number of days a week and the hours a day a certain activity has been performed during the past 7 days. The total score of the PASIPD is created by multiplying the average hours per day for each item by a Metabolic Equivalent value (METs) associated with the intensity if the activity, MET*hour/week. The PASIPD was able to discriminate between persons with paraplegia and with tetraplegia ($p<0.02$). PASIPD scores further showed significant moderate correlations (0.36-0.51, $p<0.01$) with measures of social functioning, and significant weak to moderate correlations with fitness parameters

(0.25-0.36, $p<0.05$). [46] The PASIPD is the best questionnaire for physical activity available in the Dutch language.

Objectively measured level of everyday physical activity (PA).

To objectively measure the level of daily PA, an accelerometer-based device (ActiGraph GT3X+ (AG)) will be used. [63] One AG will be worn on the wrist and one will be attached to a wheel of the wheelchair. In this way, independent wheelchair driving, being pushed, and other arm activity can be distinguished.

Participants will wear the AG continuously for 5 consecutive days, except while swimming, bathing or sleeping. To avoid measurement bias, the goal and working principle of the activity monitor will only be explained to the participants after all measurements have been completed. During the measurement they receive the instruction to continue their ordinary daily activities. The parameters that will be analysed are duration of wheelchair-driving and static activities (e.g. lying and sit still) per day.

Secondary outcome measures

Self-management skills

Self-management skills are measured with two scales: (1) The SCI exercise self-efficacy scale,[64] which measures perceived self-efficacy for various types of physical exercise in persons with SCI. This self-report scale includes 10 items; answers can be given on a 4 point Likert scale (1: not at all true up to 4: exactly true). Internal consistency was 0.93. (2) The Utrecht Proactive Coping Competence scale,[65] which assesses an individual's experienced competency with regard to the various skills associated with proactive coping. This self-report scale includes 21 items; answers can be given on a 4 point Likert scale (1: not capable up to 4: very capable). Internal consistency was between 0.83 and 0.95, and test-retest reliability was between 0.45 and 0.82.

Stage of exercise change

The Questionnaire University of Rhode Island continuous measure questionnaire (URICA- E2) [53] assesses the stage of change for regular exercise and is based on the TTM [48] and a previous questionnaire, the URICA. [66] The URICA-E2 measures the six stages of change (figure 3) related to exercise. The URICA-E2 consists of 24 items with statements concerning the different stages of exercise change. The items are given on a 1–5 scale, from 'strongly disagree' to 'strongly agree'. Internal consistency of this questionnaire was 0.80-0.93. [67]

Attitude

Attitude will be measured using the questionnaire Exercise: Decisional Balance. This questionnaire reflects the individual's relative weighing of the pros and cons of changing exercise behaviour. [68] The questionnaire consists of 10 statements (5 con's, 5 pro's). The importance of each statement to exercise or not to exercise is asked on a 5-point Likert scale ranging from 1 (not at all) to 5 (extremely). Mean internal consistency was 0.8 for the pro subscale, and 0.7 for the cons subscale., Test–retest reliability was 0.84 and 0.74 for the pros and cons, respectively. [68]

Other evaluated outcome measures

The following outcome measures will be evaluated for descriptive reasons and for comparison with the other three ALLRISC studies. These outcome measures will not be fully described but only mentioned here.

Secondary health complications (Spinal Cord Injury Secondary Conditions Scale [69] & Questionnaire Health Problems Spinal Cord Injury [70]), Social support (Social Support for Exercise Behaviour Scale [71]), Demographics (gender, age, smoking, drinking, living situation, medication and re-admission to rehabilitation and/or hospital), Functional Independence (Spinal Cord Independence Measure III [72, 73]), Mood (Mental Health Inventory-5 [74, 75]), Fatigue (Fatigue severity scale [76-78]), Participation (The Utrecht Scale for Evaluation of Rehabilitation-Participation [79]), Quality of Life (five items from the World Health Organization quality of life assessment. [80, 81]

In addition the following physical measurements will be performed: Lesion characteristics (International spinal cord injury core data set [82] and the neurological classification of spinal injury developed by the American Spinal Injury Association (ASIA-A) [83]), Anthropometry data (height, body mass, waist circumference), Pulmonary function (Forced expiratory Volume in one minute (L/%predicted)) [84-86] and Aerobic capacity (VO2peak (L/min)/ POpeak (watts)) measured during a wheelchair treadmill test.[87, 88]

A process evaluation will be conducted with the cases that have been randomized in the intervention group. Both quantitative and qualitative data on applicability, compliance, satisfaction and barriers to the protocol will be gathered at the end of the intervention.

Statistics

Multilevel regression analysis will be the main statistical technique to test for differences between the intervention and the control group at the three test moments, as well to test for differences within both groups across the three test moments. This technique allows for missing values and can correct for differences between the participating centres. Level of significance will be $P<0.05$. For all multilevel analyses MLwiN software [89, 90] will be used.

Discussion

Comparison with other studies

This study is unique in implementing a self-management intervention in SCI in which activity and health behaviour are stimulated by improving self-management skills through a behavioural intervention. There are other studies that use self-management- or other active learning strategies to stimulate physical activity, but these strategies are in most studies an addition to a physical training programme. [91]

Strengths and limitations

This study utilizes a theoretical framework to develop a self-management intervention, and to explain the results of the evaluation study. Earlier self-management interventions lack such a scientific background. [92] However, it will still be difficult to identify the effective elements of the interventions, because of the multifaceted nature of this intervention.

The HABITS intervention, if proven effective, can be used as a versatile self-management intervention. Enhancing self-management skills is a very general tool for behaviour change. For instance the target of the intervention, active lifestyle in this study, can easily be changed. The same applies to the target population.

Physical activity is the primary outcome of this study, but it is possible that participants improve in their stages of change, self-management skills, or exercise attitude, but not yet actually perform new PA behaviour yet, and no change is detected on the AG or the PASIPD. [47, 93, 94] However changing forward in the SToC or changing attitude and self-management-skills will be also be seen as positive effects of the study. These secondary outcome measures are a prerequisite to change behaviour. If there are any improvements on these outcome measures, behaviour change in terms of level PA is still possible.

Persons who are unwilling to change their exercise behaviour the next 6 months will be excluded from the study. This probably excludes an important group of subjects in which Motivational Interviewing might have a positive effect. [57] However, it is unlikely that those persons would consent to participate in the study. Finally, it might be considered that it can be easier to establish behaviour change towards PA in the early stages of SCI. However, another PA trial from our group [42] is already been executed in this population, testing a slightly different intervention.

This trial will show whether this self-management intervention has a positive effect on changing physical active lifestyle in persons with long-term SCI. Additionally it should determine if self-management skills can be enhanced and whether they affect PA behaviour and health. The results of this trial are expected in 2014.

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3

Valid detection of self-propelled wheelchair driving with two accelerometers

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Abstract

Objective: This study assessed whether self-propelled wheelchair driving can be validly detected by a new method using a set of two commonly used accelerometers.

Methods: In a rehabilitation centre, 10 wheelchair-bound persons with spinal cord injury (SCI) (aged 29-63 years) performed a series of representative daily activities according to a protocol including self-propelled wheelchair driving and other activities. Two ActiGraph GT3X+ accelerometers were used; one was attached at the wrist, the other to the spokes of the wheelchair wheel. Based on the movement intensity of the two accelerometers, a custom-made algorithm in MatLab differentiated between self-propelled wheelchair driving and other activities (e.g. being pushed or arm movements not related to wheelchair driving). Video recordings were used for reference. Validity scores between the accelerometer output and the video analyses were expressed in terms of agreement, sensitivity and specificity scores.

Results: Overall agreement for the detection of self-propelled wheelchair driving was; 85% sensitivity was 88% and specificity 83%. Disagreement between accelerometer output and video analysis was largest for wheelchair driving at very low speed on a treadmill, wheelchair driving on a slope on a treadmill, and being pushed in the wheelchair whilst making excessive arm movements.

Conclusion: Valid detection of self-propelled wheelchair driving is provided by two accelerometers and a simple algorithm. Disagreement with the video-analysis was largest during three atypical daily activities.

Introduction

Self-propelled wheelchair driving is generally the most important physical activity for persons who are unable to walk, such as those with a spinal cord injury (SCI). Wheelchair-bound persons are at higher risk of an inactive lifestyle, which might result in deconditioning and health problems. [1-4] It is important to identify to what extent wheelchair-bound people are physically active in their daily living, e.g. to tailor treatment and evaluate interventions. Different methods are available to gain insight into the amount of wheelchair driving. Although, for example, questionnaires are used, they are limited with respect to their validity and reliability. [5] For objective evaluation of wheelchair driving, various accelerometer-based systems are available. However, these devices differ depending on which aspect of wheelchair driving is being measured. For example, the amount of wheelchair driving can be measured by attaching an accelerometer to the spokes of a wheelchair wheel. [6] However, this method does not allow to distinguish between self-propelled wheelchair driving and passive wheelchair driving (e.g. being pushed). Another option is to attach an accelerometer to the wrist(s); however, with this method self-propelled wheelchair driving cannot be distinguished from upper-limb activities. [7]

These limitations can be solved by the use of activity monitors consisting of several accelerometers distributed over the body (e.g. at the arms, waist and legs). [5, 8] In this way, different postures can be detected and wheelchair driving can be deduced. Validity studies have shown that, although such monitors are valid for quantifying self-propelled wheelchair driving [5, 8], they are complex with respect to configuration and data analysis, are a considerable burden to wear, and are relatively expensive.

Theoretically, it can be assumed that objective and methodologically sound measurement of self-propelled wheelchair driving is possible with a less complex accelerometer configuration. A simple device consisting of one accelerometer attached to the wrist and another attached to the spokes of the wheelchair seems feasible to measure the amount of self-propelled wheelchair driving. However, this latter method has not yet been described and tested for validity.

The aim of this study therefore is to assess whether this new method including a set of two accelerometers yields a valid detection of self-propelled wheelchair driving. To achieve this, we performed a validation study where 10 people with a SCI performed daily activities.

Methods

Participants

Ten persons with SCI were selected on availability from the Rijndam Rehabilitation Centre; both inpatients and outpatients were allowed to participate. Inclusion criteria were: age 18-65 years, experience with wheelchair driving for at least 3 months (wheelchair driving is the primarily mobility method), and wheelchair driving by use of two hands. Exclusion criteria were: individuals not able to use a hand-rim propelled wheelchair independently for longer distances (i.e. > 100 m).

The study was approved by the Medical Ethics Committee of the Erasmus MC, University Medical Center Rotterdam. Informed consent was obtained from all patients.

Theoretical background

Wheelchair-bound persons can perform several physical activities while sitting in their wheelchair. For example, they can use their arms for self-propelled wheelchair driving or for different types of upper-limb activities related to e.g. self-care, office work, and arm exercises. Self-propelling a wheelchair differs from other upper-limb activities by simultaneous movement of the arms and the wheelchair wheels. This concept can be used to distinguish self-propelled wheelchair driving from other activities. Other 'activities' include all activities (with the exception of self-propelled wheelchair driving), such as upper-limb activities, sitting in a wheelchair without arm movements, and passive wheelchair driving such as being pushed with or without upper-limb activities.

Accelerometers are sensitive to detect accelerations due to movement and allow prolonged measurement in daily life. The number of counts per time interval (mostly used in accelerometer research and which expresses the intensity of movement) seems appropriate for the purpose of detecting self-propelled wheelchair driving. By attaching and synchronizing one accelerometer to the wrist and the other accelerometer to the spokes of the wheelchair, both arm and wheel movements can be measured simultaneously; this allows reliable quantification of the amount of self-propelled wheelchair driving.

Accelerometry

Two ActiGraph GT3X+ accelerometers were used. [9] The ActiGraph GT3X+ includes a 3D accelerometer. One accelerometer was worn at the dorsal side of the wrist using a wristband. The other accelerometer was attached to the spokes of the wheelchair (as close as possible to the axis) using a strong Velcro band allowing no undesired movements. A sample frequency of 30 Hz and an epoch time of 1 s was used for analysis of the ActiGraph data. We developed an algorithm in MatLab that differentiates between self-propelled wheelchair driving and other activities (figure 1). The algorithm was based on the vector counts of both ActiGraph accelerometers. Prior to the present study, we determined the settings for the algorithm based on several test measurements. These test measurements were performed with both wheelchair users and non-users and included activities like wheelchair driving at several speeds and manoeuvring.

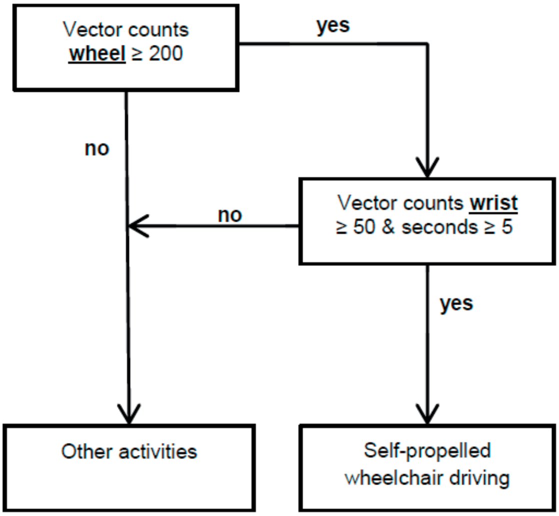

Figure 1 Flow diagram of the algorithm self-propelled wheelchair driving

Protocol

In the rehabilitation centre participants were asked to perform a standard set of activities, partly in a movement laboratory and partly in a semi-natural setting (including a simulated apartment). The activity protocol consisted of several activities which were assumed to be representative for everyday life in people with SCI, including different types of self-propelled wheelchair driving, e.g. hand-rim wheelchair driving and hand biking (see table 1). In addition, some critical activities were added to the protocol, i.e. activities that are potentially vulnerable to be falsely detected, such as being pushed whilst making excessive arm movements. Participants only performed activities that they were able to execute.

Table 1 Performed activities and differences in duration of determined self-propelled wheelchair driving from video analysis and accelerometry.

Activities					
Standard protocol	**N**	**Total duration video analysis (s)**	**Total duration ActiGraph GTX3+ (s)**	**Absolute difference (s)[a]**	**Percentage difference (%)[b]**
1 minute wheelchair driving on a treadmill at 1 km/h	9	546	469	-77	14
1 minute wheelchair driving on a treadmill at 2 km/h	10	539	522	-17	3
1 minute wheelchair driving on a treadmill at 4 km/h	10	528	514	-14	3
1 minute wheelchair driving on a slope on a treadmill at 4 km/h:	8	356	306	-50	14
Once round (gymnastic hall) at slow speed wheelchair driving on flat ground	10	666	636	-30	5
Once round (gymnastic hall) at normal speed wheelchair driving on flat ground	10	515	510	-5	1
Once round (gymnastic hall) rapidly wheelchair driving on flat ground	10	385	382	-3	1
Once round (gymnastic hall) at slow speed hand cycling on flat ground	4	187	179	-8	4
Once round (gymnastic hall) at normal speed hand cycling on flat ground	4	159	154	-5	3
Once round (gymnastic hall) rapidly hand cycling on flat ground	4	137	135	-2	1
Being pushed, with participant's arms hanging still (1 minute)	10	0	0	0	
Being pushed while participant's hands are moving (1 minute)	10	0	258	258	
Manoeuvring, e.g. turning around or changing from position in the area (1 minute)	10	230	235	5	-2
Other (mainly sitting still between activities):	6	98	108	10	-10

Semi-natural setting (activities performed in own manner and pace)	N	Total duration video analysis (s)	Total duration ActiGraph GTX3+ (s)	Absolute difference (s)[a]	Percentage difference (%)[b]
Driving independently towards the practice apartment	10	118	122	4	-3
Opening the door, driving through and closing the door	9	134	140	6	-4
Transfer to bed	6	0	1	1	
Laying supine on bed	6	0	1	1	
Transfer back to wheelchair	6	5	5	0	0
Driving to the kitchen via elevator	10	648	665	17	-3
Driving to a draining board; doing the dishes; cleaning up the dishes	10	192	218	26	-14
Driving towards the hallway	10	406	391	-15	4
Putting on a coat	9	0	0	0	
Wheelchair driving outdoors	9	824	793	-31	4
Hand-biking outdoors	3	174	155	-19	11
Other (mainly sitting still between activities):	6	7	10	3	

[a] ActiGraph GTX3+ minus video data. [b] Percentage differences are given if total duration of the video analysis is >50 s

3

Reference method

During execution of the protocol, video-recordings were made with a handheld digital video camera as reference to the ActiGraph data. The camera was focused on the plane of the wheel of the wheelchair. During the activities that were performed in the semi-natural setting the camera was not stopped, so that the time between the activities were also included in the analysis. All video recordings were analysed separately by two independent researchers. Activities were scored per second as self-propelled wheelchair driving, or other activities. 'Self-propelled wheelchair driving' was defined as: Independently propel oneself to another location, while sitting in a wheelchair or hand bike, as a result of arm power. This definition also includes propelling oneself for smaller distances, such as manoeuvring. All other activities were defined as 'other activities'. In case of any disagreement, a third reviewer was included to achieve consensus.

Data analysis

The continuous outcome of the ActiGraph accelerometers was compared with the continuous outcome of the video analysis, both with a time resolution of 1 s. The following validity measures were calculated per measurement:

Agreement: Percentage of correct classification by the accelerometers

Sensitivity: Percentage of correct classification of self-propelled wheelchair driving divided by time of actual self-propelled wheelchair driving

Specificity: Percentage of correct classification of other activities divided by time of actual other activities

In addition, the duration in seconds of self-propelled wheelchair driving as established by accelerometry and the video analysis were calculated for each measurement in total and for each activity of the protocol separately. Differences between accelerometry and the video analysis were provided in both seconds and percentages.

Statistical analysis

The individual and group mean for the total protocol was calculated for the sensitivity, specificity and agreement scores. The mean difference in duration of self-propelled wheelchair driving determined by accelerometry and video analysis was tested with a T-test. Statistical significance was set at a p-value <0.05. Differences between video analysis and accelerometry for duration of self-propelled wheelchair driving were also expressed in a Bland Altman plot.

Results

A total of 10 participants with SCI (10 males; mean age 44.8 ± 11.5 years) were included. Of all participants, 80% had a thoracic or low cervical lesion (C7 and below) and 20% had a high cervical lesion (C6 and higher). Table 2 presents the characteristics of the participants. Not all activities in the testing protocol could be performed by all the participants; Table 1 presents an overview of the performed activities.

Table 2 Characteristics of the study participants.

Participant number	Sex	Age (years)	Lesion level	Time since injury (years)	Complete/incomplete lesion
1	male	29	T4	8	Complete
2	male	60	T10	12	Complete
3	male	34	T12	16	Complete
4	male	48	T7	12	Complete
5	male	63	T3	13	Complete
6	male	40	C7	13	Incomplete
7	male	35	T12	1	Complete
8	male	45	C4	14	Incomplete
9	male	55	T4	12	Complete
10	male	39	C5	0.5	Complete

Agreement between the video analysis between the two researchers was 95.6% (range 92.3%-98.5%) per measurement per individual participant. Mean duration (SD) of the measurements was 21.7 (6.0) min per participant. According to the video analysis, 52.6% of the total measurement time was spent on self-propelled wheelchair driving.

Agreement between video data and accelerometry

The total agreement between the video-analysis and the accelerometer data was 85.2%, with agreement per measurement ranging from 76.7% to 92.3% (table 3).

Sensitivity, specificity

The overall sensitivity for the detection of self-propelled wheelchair driving was 88.3% (range 83.1%-93.0%). The overall specificity was 83.3% (range 72.6%-91.2%) (table 3).

Table 3 Validity scores.

Participant number	Sensitivity (%)	Specificity (%)	Agreement (%)
1	87.8	91.2	89.3
2	86.3	82.4	80.7
3	83.1	78.5	76.7
4	87.4	86.1	86.6
5	86.1	85.1	84.8
6	90.0	88.0	87.7
7	91.6	79.1	87.2
8	88.5	72.6	80.9
9	93.0	84.5	92.3
10	89.3	85.4	85.7
Group mean	**88.3**	**83.3**	**85.2**

Duration

Based on the video analyses, the summed duration of self-propelled wheelchair driving was 6,854 s, and 6,182 s for other activities. According to accelerometry, these durations were 6,909 s (+0.80%) and 6,127 s (-0.90%), respectively. On average, per measurement the detection of self-propelled wheelchair driving was overestimated by 5.5 s (SD 34) ($p = 0.60$) (Figure 2). Table 1 provides an overview of the duration of determined self-propelled wheelchair driving for each activity. The largest differences in the detection of self-propelled wheelchair driving between accelerometry and video-analyses were found for being pushed while the arms were moving, wheelchair driving at low speed on a treadmill, and wheelchair driving on a slope on a treadmill.

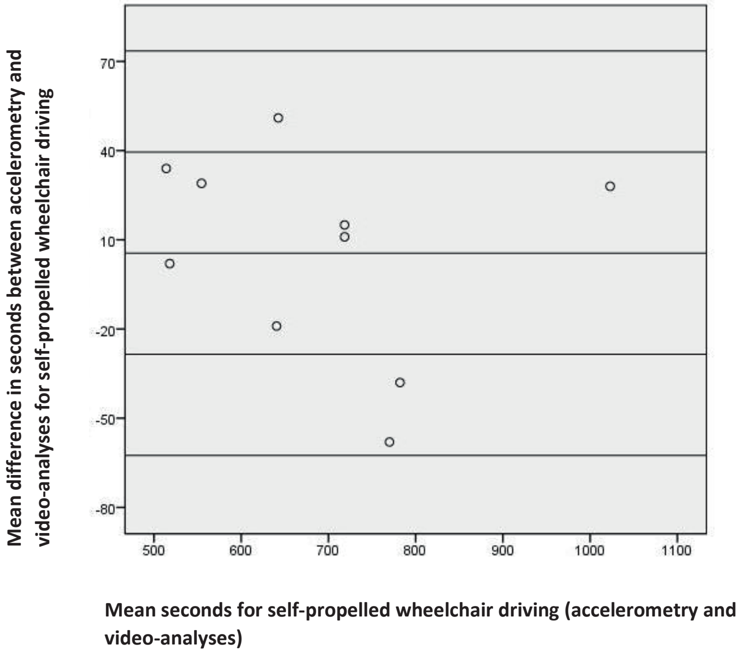

Figure 2 Difference between video analysis and accelerometry for self-propelled wheelchair driving

Discussion

In the present study, we assessed whether self-propelled wheelchair driving could be validly detected using two accelerometers; one attached to the wrist, the other to the spokes of a wheelchair wheel. The overall validity scores appeared to be adequate; these percentages were 85.2 (agreement), 83.3 (sensitivity), and 83.3 (specificity).

When looking at the results of specific activities of the protocol, it showed that disagreement between the accelerometer device and video analysis was larger in three activities. Two of them were wheelchair driving at a very low speed on a treadmill and wheelchair driving on a slope on a treadmill. Post-hoc analyses of the video recordings of these activities indicated that the movements made during these activities were somewhat abnormal. This was partly caused by the very slow speed on the treadmill, e.g. this speed was slower than the self-selected over ground speed. The unnatural character of wheelchair driving on a treadmill was most strongly expressed in these activities.

A third main source of disagreement was the activity in which the wheelchair was being pushed while the participants was asked to make arm movements. However, this instruction resulted in participants making excessive arm movements without any breaks. As a result, the vector counts of the accelerometer at the wrist exceeded the threshold of 50 counts/s and, therefore, self-propelled wheelchair driving was detected instead of other activities. Again, we feel that the way this activity was performed does not reflect normal daily behaviour. It can be assumed that in daily life wheelchair-bound individuals will make less extreme and less prolonged arm movements. As a result, the threshold for self-propelled wheelchair driving will not (or will seldom) be exceeded. Although these activities are not necessarily representative for real life, and thereby will only have a weak effect on daily life validity, they pointed out well where the algorithm may go wrong. This allows people considering using the device in the future to make an informed assessment of whether these activities are likely to compromise their study or not.

A strength of our study is that daily activities were partly performed in a natural setting that invited participants to perform the activities at their own pace and in their own way. Therefore, these activities were performed in the most natural way possible, which allows more easily generalization to a daily life setting. This part of the protocol showed one activity with a larger difference between accelerometry and video: while doing the dishes self-propelled wheelchair driving was overestimated from accelerometry (14%). Post-hoc analyses of the video recordings indicated that sometimes the wheelchair moved while participants were making arm movements at the same time; e.g. the participants reached out for a towel while the wheelchair was moving, or participants pushed themselves away from the sink. Despite the fact that these activities were different from self-propelled wheelchair driving, they were detected as such by accelerometry. However we do not believe this misclassification is undesirable for the analysis because the nature of the movements is similar to self-propelled wheelchair driving and therefore these activities can also be detected as physical activity.

Although our method does not differentiate between different types of self-propelled wheelchair driving (e.g. hand-cycling and hand-rim wheelchair driving), it was able to distinguish these types of self-propelled wheelchair driving as a class distinct from other activities. In this study, although no differences were found in the validity of the detection of these two types of self-propelled wheelchair driving, it should be noted that only 4 individuals performed hand-cycling. Further, persons with a cervical SCI use different wheelchair propulsion techniques (pulling movement) compared to individuals with a thoracic lesion (pushing movement). [8] However, the present results do not suggest that validity depends on the level of the lesion (thoracic or cervical).

The method used in the present study is relatively simple; this applies to both the sensor configuration (only two sensor units) and the analysis algorithms. Moreover, the methodology can be used in other applications. In the present study we used the ActiGraph accelerometer and MatLab algorithms, but this approach can also be used with other brands of accelerometers and signal analysis software.

The use of only one accelerometer attached to the body implies minimal burden when worn compared with other instruments. [5, 8] Further, he two ActiGraph accelerometers can perform measurements for more than 1 week. Also, the ActiGraph accelerometers are water resistant (including rain and splashing water) and therefore can be used without any harm when people use their wheelchair outside.

In this study the ActiGraph accelerometer was placed close to the centre of the wheel in order to standardize the measurements, but the placement of the ActiGraph on the wheel should not affect the output. However, practical disadvantages can arise when individuals make use of several wheelchairs (then, the wheelchair accelerometer needs to be replaced) and when people are only partially wheelchair bound (because then walking, for example, will be less well detected).

Limitations

Although we aimed to make the measurement setting as natural as possible, the measurements were performed in a rehabilitation centre and not in the daily life setting of the participants; this may have influenced performance of the activities. We aimed to select activities that were as representative as possible, as well as activities expected to be potentially difficult to detect. Nevertheless, the final protocol is a limited selection, in which three of the activities were less representative for activities of normal daily life.

Future research

This study was performed in wheelchair-bound individuals with a spinal cord injury. Although our measurement method is probably also applicable in other populations (e.g. among individuals with multiple sclerosis or stroke) this has yet to be explored. As discussed, although the concept we used might be generalized to other synchronized accelerometers and analysis software, investigation of the most optimal thresholds is still required.

In this study, self-propelled wheelchair driving was the activity of interest. Therefore, we did not differentiate between different types of activities within the 'Other activities' category. For example, upper-limb movements not related to wheelchair driving might be an activity of specific interest. This activity may be partially detected by the original software of the accelerometers. Additional research is needed to explore the potential of these more detailed analyses.

Conclusion

This study shows that valid detection of self-propelled wheelchair driving is provided by two accelerometers (one attached at the wrist, the other to the spokes of a wheelchair wheel) and a simple algorithm. The method is able to differentiate between self-propelled wheelchair driving and other activities (e.g. being pushed, or arm movements not related to wheelchair driving). Disagreement with the video-analysis was larger in three atypical activities performed by the participants.

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4

Exercise self-efficacy is weakly related to engagement in physical activity in persons with long-standing spinal cord injury

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Abstract

Aims: Many people with a long-standing spinal cord injury have an inactive lifestyle. Although exercise self-efficacy is considered a key determinant of engaging in exercise, the relationship between exercise self-efficacy and physical activity remains unclear. Therefore, this study examines the relationship between exercise self-efficacy and the amount of physical activity in persons with long-standing spinal cord injury.

Methods: This cross-sectional study included 268 individuals (aged 28-65 years) with spinal cord injury ≥ 10 years and using a wheelchair. Physical activity was measured with the Physical Activity Scale for Individuals with Physical Disabilities. Exercise self-efficacy was assessed with the Spinal cord injury Exercise Self-Efficacy Scale. Univariate and multivariable regression analyses were performed to test for the association between exercise self-efficacy and physical activity, controlling for supposed confounders.

Results: Univariate regression analysis revealed that exercise self-efficacy was significantly related to the level of daily physical activity (β=0.05; 95% CI 0.04-0.07; 15% explained variance; $p<0.001$). In multivariable regression analysis exercise self-efficacy remained, explaining a significant additional amount of the variance (2%; $p<0.001$) of physical activity.

Conclusion: Exercise-self efficacy is a weak but independent explanatory factor of the level of physical activity among persons with long-standing spinal cord injury. Longitudinal trials are needed to study the impact of interventions targeting an increase of exercise self-efficacy on the amount of physical activity performed.

Introduction

Improvements in medical care have increased the life expectancy of people with a spinal cord injury. [1] Therefore, because the number of people aging with a spinal cord injury is increasing, it is important to maintain a stable health status and functioning in this group. [2] This presents new challenges for those aging with spinal cord injury and their healthcare professionals. [2]

Physical activity is considered to be an important determinant of health, both in the general population and in people with a long-standing spinal cord injury. [3, 4] Physical activity has different components, including involvement in participation in daily exercise (including sports), leisure activities, and other physical activities (for example housekeeping, work, and travelling). Higher physical activity levels in people with spinal cord injury are associated with the prevention or reduction of secondary health conditions, physiological and psychological benefits, and higher quality of life.[5-8] However, even compared to other populations with chronic disabilities, physical activity levels in people with spinal cord injury are very low. [9] Therefore, optimizing the amount of physical activity is of great importance to improve the health and quality of life in people with spinal cord injury.

To optimize levels of physical activity, it is necessary to focus on the key factors that support a behavioural change towards a more active lifestyle. In most behavioural change models self-efficacy is such a key factor. [10] Self-efficacy has been defined as 'one's belief in one's own ability to complete tasks and to reach goals',[11] and can be considered as a general personality factor or as a task-specific factor. In the first case, self-efficacy can be regarded as a stable personal characteristic that is difficult to change.[12] When self-efficacy is seen as a task-specific factor, for example in terms of exercise self-efficacy,[10] it appears to be an easier target for interventions to support behavioural changes favouring higher amounts of physical activity. [3, 10]

Although not completely in line with the given definition of physical activity, with exercise as one of its components, exercise self-efficacy has also been defined as: "The confidence of individuals to plan and carry out physical activities and/or exercise based on their own volition".[13] Exercise self-efficacy is significantly correlated with the amount of physical activity in the general population,[3] and in people with spinal cord injury.[14, 15] However, the spinal cord injury studies did not specifically aim at people with long-standing spinal cord injury. We do not know whether the relationship between exercise self-efficacy and physical activity is the same for people with a long-standing spinal cord injury.

Furthermore, people with a long-standing spinal cord injury are more at risk of an inactive lifestyle and developing more SHCs.[16] To counteract this SHCs it is probably helpful if people with a long-standing spinal cord injury become more physically active.[15,17] There has been much attention focused on increasing physical activity in people with recent spinal cord injury compared with people who have a long-standing spinal cord injury.[2]

Furthermore, those studies focused on specific components of physical activity, such as exercise, sports activities and/or leisure physical activities; other daily physical activities for example transportation to a work or supermarket by a wheelchair or doing chores around the house, were disregarded. [14, 15] Because the contribution of these activities to the total amount of physical activity is substantial, it is relevant to examine the relation of exercise self-efficacy and physical activity in a broader perspective. Therefore, the present study examines the relation between exercise self-efficacy and the overall level of physical activity in persons with a long-standing spinal cord injury. We hypothesize that there is a significant relation between exercise self-efficacy and overall physical activity in people with a long-standing spinal cord injury, even when controlled for possible confounders.

Materials and Methods

Study design

For the purpose of the current study cross-sectional data from a large Dutch cohort study (ALLRISC)[2] was used. In the ALLRISC study, participants were recruited from eight rehabilitation centres in the Netherlands with a specialized SCI unit.[16] The aim was to include 30-35 persons per centre. Based on an expected response rate of 50%, 62 persons per centre were invited by means of a random sample drawn at each centre.

The study protocol was approved by the Medical Ethics committee of the University Medical Centre Utrecht, and by all participating centres.

Participants

Persons with SCI were eligible for inclusion if they met the following criteria: having sustained their SCI at least 10 years before the study and aged 18-35 years at that moment; current age 28-65 years long-standing; using a wheelchair for their daily mobility (at least for distances ≥ 500 m); and being able to propel a hand-rim wheelchair. This age range was chosen to include individuals with long-standing SCI while minimizing the effects of aging in general. Participants were excluded from the study if they had a progressive disease or severe co-morbidities, psychiatric problems that could affect the procedures, or if they had insufficient knowledge of the Dutch language to understand the purpose of the study and the evaluation methods.

Recruitment and consent

The physician of the rehabilitation centre's Spinal cord injury department pre-selected former inpatients using information from medical records. Individuals who met the inclusion criteria received the patient information letter. Two weeks later they were contacted by telephone by a research assistant to check.

Procedure

Participants were invited for a one-day visit to the rehabilitation center for an aftercare check-up by the local spinal cord injury rehabilitation physician, and tests were performed by a trained research assistant. Before this visit participants were asked to complete a self-report questionnaire.

Included participants

For the purpose of this study participants were included if they completed the questionnaire, the aftercare check-up and got the Spinal Cord Independence Measure III administered at the rehabilitation centre.

Measurements

The main variables of interest were self-reported daily physical activities and exercise self-efficacy. Both were part of the self-report questionnaire.

Self-reported level of physical activities was assessed by the Physical Activity Scale for Individuals with Physical Disabilities (PASIPD). Internal consistency of the PASIPD is reported to be 0.83 to 0.95, and test-retest reliability 0.45 to 0.82.[19] The Dutch version of the PASIPD consists of 11 items covering all components of physical activity, such as sports, hobbies, and household and work-related activities. The questionnaire assesses the number of days per week and the hours per day a certain activity was performed during the past 7 days. The total score of the PASIPD is computed by multiplying the average hours per day for each item by a metabolic equivalent value (MET) associated with the intensity of the activity, MET*hour/week;[20] the total PASIPD score ranges from 0 to 182.3.

The Spinal Cord Independence Measure III exercise self-efficacy scale[13] measures self-reported self-efficacy and includes 10 items with a 4-point response scale ranging from (1): not at all true to (4): exactly true. An example of an item is: "I am confident that I can overcome barriers and challenges with regard to physical activity and exercise if I try hard enough". The total score ranges from 10 to 40. The internal consistency and test-retest reliability was 0.93 and 0.81, respectively.[21]

In the analyses, several confounders were taken into account. From the demographic variables, age and gender were selected. Level of functional independence was included as confounder by using the Spinal Cord Independence Measure III,[22, 23] a functional status measure developed for people with spinal cord injury. Spinal cord injury measure III includes the following areas of daily function: self-care [sub score (0-20), respiration and sphincter management (0-40) and mobility (0-40)]. The total score ranges from 0 to 100; the higher the score, the higher the level of functional independence. This variable was included in the analysis, since people who function more independently in their daily life have more possibilities to be physically active.[24]

Because lesion characteristics are related to the level of physical activity,[20] we evaluated time since injury, age of onset, and the type of spinal cord injury according to the ASIA impairment scale (AIS),[25] based on a neurological examination. Additionally, type of spinal cord injury was assessed as tetraplegia (a lesion at or above the Th1 segment) or paraplegia (a lesion below Th1).

Also, as secondary health conditions are associated with lower levels of physical activity [26] they were assessed during a consultation with the physician; in this meeting, the presence and severity of the problems were assessed.[18] For the analyses we summed the presence of the most common of spinal cord injury -specific secondary health conditions,[27, 28] including; cardiovascular diseases, pulmonary diseases, urinary disorders, perianal disorders, decubitus, problematic spasms, autonomous dysreflexia, hypotension, thrombosis, edema, neurogenic heterotopic ossification, fractures, respiratory problems and pain (musculoskeletal and neuropathic pain). The secondary health conditions score ranges from 0 to 19.

Data-analyses

Log-transformation of the physical activity score was necessary to obtain a normal distribution of the residuals. Descriptive statistics of the demographic variables, lesion characteristics and the main outcomes were performed. The association between exercise self-efficacy and physical activity was first examined by univariate (simple) regression analysis, followed by nested multivariable regression analysis to investigate possible confounding (age, gender, independent functioning, lesion characteristics, secondary health conditions). In the multivariable analyses, multi-collinearity was deemed present if any two independent variables were highly correlated with each other ($R > 0.8$). When multi-collinearity was present between two variables, the one that showed the weakest association with physical activity was excluded from the model. Two nested regression models, one excluding and one including exercise self-efficacy in the predictors set, were compared by means of the Fisher-test, to determine whether the addition of exercise self-efficacy significantly improved the goodness of fit of the model. Alpha was set at 0.05.

We have performed sub analyses where we divided the PASIPD outcomes in two subcategories performing sports activities (yes/no) and daily activities not sports related (METS) and we have performed the same analyses as our main association in this article.

Results

The ALLRISC long-standing follow-up study included 282 participants; of these, 268 completed both the self-reported questionnaire and the aftercare check-up at the rehabilitation centre and were selected for the current final analysis. Table 1 presents the characteristics of the study population.

The mean and median PASIPD score for physical activity were 19.4 METs-h/d (SD 20.6) and 12.7 METs-h/d [IQR 5.7-26.3], respectively. Figure 1 shows how the different components of physical activity contribute to the total physical activity score.

Table 1 Characteristics of the study population (n=268)

Variable	n	%	Mean (SD)
Male	197	73	
Age in years: mean (SD)			47.7 (8.8)
Highest level completed education			
- Prevocational practical education or less	28	10.5	
- Prevocational theoretical education and secondary education	72	26.8	
- Higher vocational education and university	137	51.4	
- Missing	31	11.3	
Paid work	105	39.2	
Retired	6	2.2	
Married or permanent partner	163	60.9	
Time since injury in years, mean (SD)			24.0 (9.1)
Age at onset of SCI in years: mean (SD)			23.9 (4.7)
Motor complete SCI	221	82.8	
Paraplegia	159	59.3	
Daily physical activity (MET, range 0-183)			19.4 (20.6) 12.7 [5.7 - 26.3] *
Exercise self-efficacy (range 10-40)			31.4 (7.8)
Functional independence (range 0-100)			56.4 (18.5)
Health problems (range 0-19)			5.3 (2.8)

*Median [IQR]

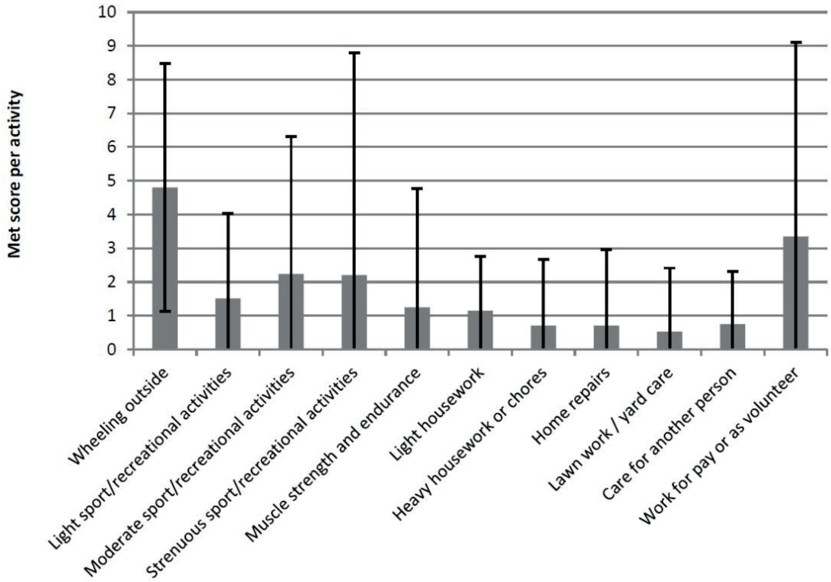

Figure 1 Median (IQR) PASIPD score per activity measured by the PASIPD.

Association between exercise self-efficacy and physical activity

Figure 2 shows the relation between exercise self-efficacy and log-transformed level of physical activity. Univariate regression analysis modelling the log-transformed physical activity upon exercise self-efficacy showed a significant positive association (LOG β= 0.05, 95% CI 0.04-0.07) explaining 15% of the total variation in log-transformed level of physical activity.

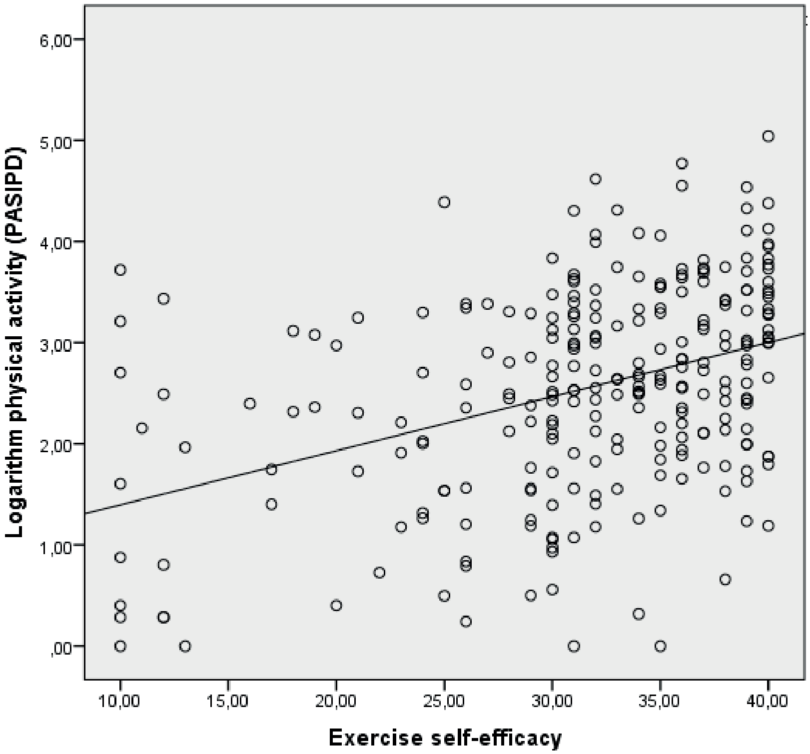

Figure 2 Relation between exercise self-efficacy and the logarithm physical activity

Table 2 Regression analyses overall physical activity

Univariate regression analyses						
	Unstandardized Coefficients		**Standardized Coefficients**		**95% CI**	
Model	LOG β	SE	Beta	Sig.	Lower bound	Upper bound
(Constant)	0.90	0.30		0.00	0.40	1.40
Exercise self-efficacy	0.05	0.01	0.40	0.00	0.04	0.07

Multivariate regression analyses						
	Unstandardized Coefficients		**Standardized Coefficients**		**95% Confidence interval**	
Model	LOG β	SE	Beta	Sig.	Lower bound	Upper bound
(Constant)	1.82	0.48		0.00	0.88	2.76
Exercise self-efficacy	0.02	0.01	0.17	0.01	0.01	0.04
Gender	-0.16	0.12	-0.07	0.20	-0.40	0.08
Functional independence	0.02	0.00	0.41	0.00	0.02	0.03
Health problems	0.00	0.02	0.01	0.83	-0.04	0.04
Time since injury	-0.02	0.01	-0.16	0.00	-0.03	-0.01
Lesion level	-0.14	0.13	-0.07	0.25	-0.39	0.10
Completeness SCI	-0.40	0.15	-0.15	0.01	-0.69	-0.11

Dependent variable: Logarithm of Physical Activity (PASIPD)

Sub analyses with the PASIPD outcomes in two subcategories performing sports activities (yes/no) and daily activities not sports related

We found a significant association between self-efficacy and performing sports activities (LOG β= 0.04, 95% CI 0.03-0.06), and we have found that there is still a significant association between self-efficacy and daily activities which are not sports related (LOG β= 0.01, 95% CI 0.02-0.05).

Discussion

In this group of individuals living with a spinal cord injury for (on average) 24 years, the present study shows an independent significant relationship between exercise self-efficacy and the overall amount of physical activity. Although we cannot draw causal conclusions, these data might indicate that enhancing exercise self-efficacy is a way to enhance physical activity, even in people living with of spinal cord injury for many years.

The present findings are in accordance with other studies reporting that exercise self-efficacy is significantly related to physical activity.[14, 15] Nevertheless, we examined this association in more detail. First, the regression coefficient of the relation between exercise self-efficacy and physical activity seems low (LOG β=0.02, β=1.02) compared to the scale and range of the Physical Activity Scale for Individuals with Physical Disabilities.

However, this regression coefficient should be considered in relation to the mean and median Physical Activity Scale for Individuals with Physical Disabilities score we found (19.4 and 12.7, respectively), and the range of the exercise self-efficacy scale (Range: 30; Min/max: 10/40). Therefore, a gain on the Physical Activity Scale for Individuals with Physical Disabilities score of 1.02 is expected when exercise self-efficacy improves by one step. In addition, a maximum gain of 30.60 on the Physical Activity Scale for Individuals with Physical Disabilities score can be achieved by focusing on exercise self-efficacy alone. Furthermore, we found that exercise self-efficacy alone explains 15% of the variance of physical activity. Although this percentage seems low, bearing in mind that the level of physical activity is influenced by many factors[3] a high percentage of explained variance cannot be expected. The total amount of explained variance of the total physical activity score was 34%; in comparison, Ginis et al.[29] reported a total explained variance of only 19-25% of the total variance of leisure time physical activity in a population of people of spinal cord injury. Another explanation could be that the authors included different determinants, with the type of self-efficacy probably being the most important. Ginis et al.[29] included barrier self-efficacy, instead of exercise self-efficacy as applied in our study. Because exercise self-efficacy is theoretically more directly related to physical activity than barrier self-efficacy, a higher explained variance seems logical. Furthermore, Ginis et al.[29] only examined leisure time physical activity, whereas we included all components of physical activity.

In the present study, the total explained variance of 34% suggests that other factors might also be important in explaining physical activity levels. Behavioural change models suggest that potentially modifiable factors such as motivation, social support and attitude, are also determinants of behavioural change.[30, 31] Although we did not measure these factors, we feel that behavioural change models can support the development of interventions targeted at behavioural change towards a more physically active lifestyle.[32]

In our study sample, activity levels (mean 19.4; SD 20.6) were similar to the means of 17.8 (SD 18.6) and 19.8 (SD 19.0) found in an earlier Dutch study in people with spinal cord injury at 1 and 5 years post discharge from initial inpatient rehabilitation.[15, 20] In the Canadian study of Ginis et al. [15] an average of 27.14 (SD 49.36) min of leisure time physical activity per day was found in a sample of persons with spinal cord injury with a mean time since injury of 13.5 years (SD 10.0). They also reported that 50% of their population spent no time on leisure time physical activity. To compare our data with those of Ginis et al., we converted our MET scores of the leisure time physical activity component of the Physical Activity Scale for Individuals with Physical Disabilities. We then found that our study population spends 26.8 (SD 4.5) min per day on these activities, which is similar to the results of Ginis et al.

In the present study, given the long time since injury it is remarkable that the activity levels are not lower than those reported by others with a shorter time since injury. With a longer time since injury, a decline of activity levels is expected. [9] This expectation is supported by the significant association we found between time since injury (P=0.00) and levels of physical activity, as well as by the strong correlation (R>0.80) found between time since injury and current age. Furthermore, other studies in people with an spinal cord injury in Sweden and Canada, showed that Age was significantly, negatively associated with total leisure time physical activity. [17, 33]

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In contrast to other studies on the association between self-efficacy and physical activity, we chose an outcome measure of physical activity that includes all aspects of physical activity. Earlier studies on people with chronic diseases [34] and with early-onset spinal cord injury [35] have shown that exercise self-efficacy is related to exercise and sport engagement. The current study adds to previous evidence that exercise self-efficacy is also related to physical activity that is more broadly defined, i.e. that also includes other components of physical activity (Figure 1). For instance, our sub analyses showed that that there is still a significant association between self-efficacy and daily activities which are not sports related.

This approach broadens the target of interventions to enhance physical activity, since it proves easier to increase physical activities in daily life rather than getting individuals involved in exercise or sport programs. For example, a relatively easy way to increase physical activity is to use a self-propelled wheelchair or handbike to go to work or for shopping, rather than using a car.

Another reason to focus not only on exercise and sports is the increasing evidence for the importance of avoiding sedentary behaviour, since it is an independent risk factor for health problems. A person can meet the norms for an active lifestyle, for instance by achieved by sports and exercise, but can still be at risk for health problems due to prolonged periods of sitting with low levels of energy expenditure in daily life [36]. This emphasizes the need to include daily physical activities in both research and interventions.

Study limitations

The present cross-sectional study has some methodological limitations. First, we cannot draw valid conclusions on the causality of the associations studied. Longitudinal data would have provided important information on the course of physical activity and the influence of self-efficacy on that activity. Second, a self-reported questionnaire was used to measure physical activity even though self-reported measures are prone to bias, for example people often tend to overestimate their activity levels, and it is difficult for some individuals to recall physical activities.[37] Nevertheless, the Physical Activity Scale for Individuals with Physical Disabilities is the best self-reported questionnaire for which a validated Dutch version is available.[20] Instruments, like accelerometers, are an option to measure physical activity objectively. However, for both practical and financial reasons these types of instruments could not be used in the present study. Currently, more user-friendly and cost-effective instruments have been developed which make it easier to implement objective measures in rehabilitation research.[38]

Conclusions

This study indicates that exercise-self efficacy is an independent significant explanatory factor of the level of physical activity in people with a long-standing spinal cord injury. Longitudinal studies are required to explore the relationships and effects of exercise self-efficacy-oriented intervention programs on the amount of physical activity in persons with long-standing spinal cord injury.

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Effectiveness of a self-management intervention to promote an active lifestyle in persons with long-term spinal cord injury: the HABITS randomized clinical trial

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Abstract

Background: Most people with long-term spinal cord injury (SCI) have a very inactive lifestyle. Higher activity levels have been associated with health benefits and enhanced quality of life. Consequently, encouraging an active lifestyle is important and behavioural interventions are needed to establish durable lifestyle changes.

Objective: The Healthy Active Behavioural Intervention in SCI (HABITS) study was aimed to evaluate the effectiveness of a structured self-management intervention to promote an active lifestyle in inactive persons with long-term SCI.

Methods: This assessor-blinded randomized controlled trial was conducted at 4 specialized SCI units in the Netherlands. Sixty-four individuals with long-term SCI (>10 years), wheelchair-user and physically inactive, were included. Participants were randomized to either a 16-week self-management intervention consisting of group meetings and individual counselling and a book, or to a control-group that only received information about active lifestyle by one group meeting and a book. Measurements were performed at baseline, 16 weeks and 42 weeks. Primary outcome measures were self-reported physical activity and minutes per day spent in wheelchair-driving. Secondary outcomes included perceived behavioural control (exercise self-efficacy, proactive-coping), stages of change concerning exercise, and attitude towards exercise.

Results: Mixed models analyses adjusted for age, sex, level of SCI, time since injury, baseline body mass index, and location did not show significant differences between the intervention and control group on the primary and secondary outcomes (P =>0.05).

Conclusions: A structured 16-week self-management intervention was not effective to change behaviour towards a more active lifestyle, and to improve perceived behavioural control, stages of change, and attitude.

Introduction

An inactive lifestyle is a well-known and serious problem in the general population, and even more in people with spinal cord injury (SCI). Compared to able-bodied individuals and individuals with other chronic disorders, individuals with SCI show the lowest levels of physical activity. [1, 2] An inactive lifestyle has been associated with de-conditioning and secondary health conditions (SHCs) in persons with long-term SCI,[3-5] whereas higher activity levels have been associated with the reduction and prevention of SHCs and other physiological and psychological benefits. [4-6] Just like the prevention of pressure sores, maintaining a physically active lifestyle should therefore be considered part of the day-to-day self-management in individuals with a long-term SCI. Self-management refers to the individual's ability to manage the symptoms, treatment, physical and psychosocial consequences, and lifestyle changes inherent in living with a chronic condition. Effective self-management has been shown to be associated with more physical activity in individuals with chronic conditions other than SCI. [7,8]

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Several interventions to increase or maintain levels of physical activity in persons with SCI have been evaluated. For example, Hicks et al. reviewed exercise training interventions in SCI, which showed to improve physical capacity but were not aimed to increase into a more active lifestyle. [9] Other studies focused on providing information or education about the importance of an active lifestyle in SCI; they resulted in knowledge transfer, but did not facilitate a behavioural change towards an active lifestyle. [10, 11]

Behavioural interventions towards a more active lifestyle might therefore be needed to achieve a sustainable increase of physical activity. Several behavioural interventions aimed at enhancing physical activity have been evaluated in individuals with SCI, including telephone counselling, multi-strategy behavioural interventions, and guided and counselled home exercise programs. [12-18] These studies provided some support for these interventions to increase physical activity levels, but these studies did not include a control group,[13, 14, 16] or focused on specific intervention characteristics, such as the added value of coping planning[15] or level of support.[12] Nooijen et al.[18] showed positive results in an RCT of a behavioural intervention on physical activity levels in SCI. However, their study included people with sub-acute SCI, and the other studies were neither specifically aimed at individuals with a long-term SCI. [18-21]

Behavioural interventions are probably more effective if they incorporate different types of behavioural and active learning strategies.[21] Such multifaceted behavioural interventions have shown to be effective in preventing health problems and in modifying behaviour, in both people with recent SCI and persons with other chronic disorders, but they have not been evaluated in persons with long-term SCI. [18-21]

Therefore, the aim of the Healthy Active Behavioural Intervention in SCI (HABITS) study was to evaluate the effectiveness of a structured self-management intervention on an active and healthy lifestyle measured by physical activity, perceived behaviour control, stages of exercise change and attitude in persons with long-term SCI. It is hypothesized that this intervention will show beneficial effects on an active and healthy lifestyle. Additionally, the effects on perceived behavioural control (exercise self-efficacy, proactive coping), stages of change concerning exercise, and attitude towards exercise were assessed, as well as the effects on the more remote outcomes such as secondary health complications, social support and participation.

Methods

Design and overview

This study was a multicentre randomized-controlled trial. Details of the methods and design have been reported elsewhere. [22] Four rehabilitation centres with a specialized SCI unit across the Netherlands participated this study. The intervention group received the 16-week self-management intervention. The control group received information about the importance and maintenance of an active lifestyle only.

Setting and Participants

Adults with SCI were eligible for this study if they met the following criteria: age at injury was 18 years or above; time since injury at least 10 years; current age between 28 and 65 years; able to use a hand-rim wheelchair; physically inactive as defined by a physical activity scale for individuals with physical disabilities (PASIPD) score lower than the 75th percentile of a Dutch SCI population. [23] Potential participants were excluded from the study if they had no intention to change their exercise behaviour in the next 6 months; a progressive disease or severe co-morbidities; psychiatric problems that could interfere with the study; and insufficient knowledge of the Dutch language to understand the purpose of the study and the testing methods.

Recruitment

Physicians from the participating rehabilitation centres pre-selected former inpatients using information from medical charts. Potential participants were sent a patient information letter and, two weeks thereafter, they were contacted by the research assistant to check the inclusion and exclusion criteria and to provide further information. All participants signed the consent form after expressing their willingness to participate.

Multicentre approval was granted by the Erasmus MC Medical Ethics Committee, Rotterdam, the Netherlands. Local approval was further granted by all participating centres.

Randomization and Interventions

Randomization

In each rehabilitation centre participants were randomly allocated to the intervention group or the control group after the baseline measurements. Blocked randomization with a block size of 6 was used to ensure an even distribution of participants. The research assistants who performed the measurements for this study were not involved in the self-management intervention and were blinded for group allocation. The researchers were also blinded for group allocation until the initial data analyses of the primary and secondary outcomes were performed.

Intervention

The theoretical framework that was used to design the intervention and to select outcome measures is described in detail elsewhere. [22] In this theoretical framework we combined two well-known models of behaviour change: the Theory of Planned Behaviour (TPB) [24] and the Trans Theoretical Model of behavioural change (TTM). [25] TPB assumes that intentions to perform (new) behaviour are influenced by attitudes (e.g., the perceived benefits or importance of the new behaviour), subjective norms (e.g. social support, attitudes expressed by other people), and perceived behavioural control (e.g. confidence in one's ability to perform the new behaviour). [24] The TTM assesses an individual's readiness to act on a new healthier behaviour,[25] such as a more active lifestyle. [26] In other words, readiness is measured as one's willingness to adopt certain new behaviour within a certain time frame.

The HABITS intervention specifically targeted on two conditions for behaviour change: optimizing intentions towards a healthier lifestyle and improving perceived behavioural control. Perceived behavioural control included: 1) self-efficacy, defined as a person's confidence in one's ability to perform certain behaviour, namely a more active lifestyle;[27] and 2) proactive coping, which assumes that individuals do not only react on threatening situations, but that they can also anticipate on situations that may threat or influence their goals, a more active lifestyle, in the future. [28, 29]

The HABITS intervention consisted of one home visit, 5 individual and 5 group sessions during a total of 16 weeks. The HABITS intervention contained various elements which should facilitate an active lifestyle and the development of self-management skills: guidance of the HABITS counsellor, peer support and mastery experiences (experiencing task accomplishment strengthens self-efficacy),[21, 27] discussions on various themes related to an healthy active lifestyle, action & proactive coping planning, problem solving, activity monitoring, a self-help workbook and a booklet, "How to stay fit with SCI". [30]

The intervention was provided by counsellors who were already working in one of the participating rehabilitation centres, were experienced in the treatment of persons with SCI, e.g., physical therapist, and were trained in motivational interviewing (MI). MI is a directive client-cantered counselling style to elicit behaviour change by helping clients to explore and resolve their ambivalence towards behaviour change. [31]

Control group

The control group received information about active lifestyle in SCI including one information group meeting in the first weeks of the study. In addition, they received the same self-health workbook as the intervention group; "How to stay fit with SCI". [30] This book was published at the same time as the start of the study and resonated with the information needed for the control group.

Outcomes and follow up

Data was collected for both groups at baseline (T0); and at 16 weeks (T1) and 42 weeks (T2) after baseline. Measurements at the different time points included wearing an activity monitor, self-report questionnaires, and physical tests performed at the rehabilitation centre.

The hierarchy in the outcome measures was determined according to the research questions and the theory we used: the primary outcomes provide the direct answer on the research questions. The secondary outcomes are those that may reveal the mechanisms between behaviour change. The tertiary outcomes concern the more remote outcomes of our RCT.

Primary outcomes

Amount of self-propelled wheelchair driving

Physical activity was objectively measured as the amount of time of self-propelled wheelchair driving in seconds, using two accelerometer-based devices (ActiGraph GT3X+). [32] One accelerometer was attached at the wrist and the other to the spokes of one wheelchair wheel with special Velcro bands. Based on the data of the two accelerometers, a custom-made algorithm in MatLab (r20011b) differentiated between self-propelled wheelchair driving and other activities. This method allowed the identification of self-propelled wheelchair driving with a sensitivity of 88% and a specificity of 83%. [33] Participants were asked to wear the activity monitor directly after each test occasion continuously for 5 consecutive days, except while swimming, bathing or sleeping. They were instructed to continue their ordinary daily activities during these 5 days. Data were included in the analysis if patients wore the activity monitor for at least three days and for at least 10 hours a day. Participants received a simple diary - as reference to the data- in which they could indicate whether they have worn the activity monitor and if there were any peculiarities that could have influenced the measurement.

Self-reported physical activity

Self-reported levels of physical activity (PA) was assessed with the Physical Activity Scale for Individuals with Physical Disabilities (PASIPD). [34] The Dutch adaptation of the PASIPD consists of 11 items concerning sports, hobbies, household- and work-related activities. The questionnaire includes items on the number of days a week and the hours a day a certain activity was performed during the past 7 days. The total score of the PASIPD was computed by multiplying the average hours per day for each item by a Metabolic Equivalent value (METs) associated with the intensity of the activity, MET*hour/week. PASIPD scores ranges between 0 and 182.

Both measures provide other but sufficient information about physical activity. The objective method we have used in our study provides information on the duration of wheelchair use, expressed in e.g. minutes of active wheelchair driving. The PASIPD aims to assess energy expenditure, based on duration of activity categories of different intensities.

Secondary outcomes

Perceived behavioural control

Perceived behavioural control (consisting of self-efficacy and proactive coping) was measured with two scales:

(1) The SCI exercise self-efficacy scale [35] measures self-reported self-efficacy for various types of physical exercise in individuals with SCI. This scale includes 10 items with a 4 point scale (1: not at all true, up to 4: exactly true). The maximum range of the total score is 10-40. Internal consistency was 0.93. [35] This questionnaire was translated into Dutch and validated in a sample of individuals with SCI. [36]

(2) Pro-active coping was measured with the Utrecht Proactive Coping Competence scale [37, 38] which assesses self-reported competency with regard to proactive coping, meaning anticipating on and dealing with possible future situations. This self-report scale includes 21 items with 4-point response scales (1: not capable, up to 4: very capable). The total score is the mean of the item scores, and therefore the range is also 1-4. Internal consistency has shown to be between 0.83 and 0.95, and test-retest reliability between 0.45 and 0.82. [37, 38]

Stage of exercise change

The University of Rhode Island continuous measure (URICA-E2) [39] assesses readiness to change regards regular exercise and was based on the TTM [25] and a previous questionnaire, the URICA. [40] The URICA-E2 consists of 24 statements reflecting intentions towards exercise change. The responses are given on a Likert 1–5 scale, from 'strongly disagree' to 'strongly agree'. Internal consistency of this questionnaire was 0.80-0.93. [41]

Attitude to change behaviour

Attitude was measured using the Exercise Decisional Balance. [42] This questionnaire reflects the individual's relative weighing of the pros and cons of changing exercise behaviour. The questionnaire consists of 10 statements (5 cons', 5 pros). The importance of each pro and con is rated on a 5-point scale ranging from 1 (not at all) to 5 (extremely). Mean internal consistency of this measure was 0.8 for the pro subscale, and 0.7 for the cons subscale. Test–retest reliability of the pros and cons scales was 0.84 and 0.74, respectively. [42]

Tertiary outcomes

The tertiary outcomes concern the more remote outcomes of our RCT. Secondary health conditions (Spinal Cord Injury Secondary Conditions Scale [43]), Social support (Social Support for Exercise Behaviour Scale [44]), Aerobic capacity (VO2peak (L/min)/ POpeak (W)) measured during a wheelchair treadmill test [45, 46], Functional Independence (Spinal Cord Independence Measure III [47, 48]), Mood (Mental Health Inventory-5 [49, 50]), Fatigue (Fatigue severity scale [51-53]), Participation (The Utrecht Scale for Evaluation of Rehabilitation-Participation and quality of life [54], Quality of Life (five items from the World Health Organization quality of life assessment [55] and body mass index (BMI).

Confounders

We included age, sex, time since injury, level of SCI, rehabilitation centre and baseline BMI as confounders. Differences between the intervention and control groups with respect to these variables may distort the outcomes of the study since we supposed female gender, older age, a longer time since onset of SCI, a higher level of SCI, and a higher BMI to be associated with lower levels of physical activity. [56]

Statistical Analysis

The desired size of the study sample (N=80) was based on a power analysis with a power of 80%, alpha=0.05, and an expected increase of 30 minutes per day in the duration of self-propelled wheelchair driving as assessed with the accelerometer-based activity monitor in the intervention group compared to the control group. This estimation was based on levels of daily physical activity found in persons with SCI in previous studies of our department. [1, 57]

We performed non-response analyses with data available from medical charts including the following variables, age, sex, level of SCI, completeness of SCI and time since injury. In addition, 50 individuals who declined participation in the RCT volunteered to complete the baseline questionnaire. Group differences were tested with T-tests or χ^2 tests.

To determine the effectiveness of the self-management intervention, Linear Mixed Models analyses with a three-level structure (repeated measures, participants and rehabilitation centre) were performed. In the Linear mixed Model analyses we adjusted for the correlated observations within the participant and for the correlated observations within the rehabilitation centre by adding a random intercept on both levels to the model. Only participants who completed the baseline and at least one follow-up test occasion were included in these analyses. First, separate overall models were made for each outcome variable, including group allocation and the baseline value of the particular outcome variable to estimate the overall intervention effect over time. Secondly, we added time and an interaction between group allocation and time to these overall models to assess the between-group differences at the two follow-up moments (T1 and T2).

The regression coefficient (β), the p value and confidence intervals were computed for the unadjusted models as well as for the models that were adjusted for age, sex, time since injury, level of SCI, and baseline BMI.

For the stages of exercise change Poisson mixed model analyses were performed, including the same steps as the Linear Mixed Models analyses.

Because analyses could not be performed if baseline values were missing and because of the relatively large amount of missing data in the objectively measured physical activity, we replaced missing baseline values by the overall (intervention and control) group baseline value. This step was only performed if the two follow-up measurements were available.

IBM SPSS Statistics version 21 was used for all statistical analyses except for the Poisson mixed model analyses where STATA version 13 was used.

Results

Between January 2012 and October 2014, 64 persons with long-term SCI were included in this study. Figure 1 shows the flow diagram of the inclusion. Baseline, personal and lesion characteristics of the 64 participants are presented in Table 1. Drop-outs in the intervention group (n=7) and in the control group (n=8) did not significantly differ from the included participants in terms of personal or lesion characteristics and physical activity at baseline.

No significant differences were found between the included participants of this study (n=64) and data on the non-participants available from the medical charts (N= 394-617; P>0.05; N varies, since not all data on every characteristic were available of all non-responders). In addition, no significant differences (P> 0.05) were found between the self-reported main and secondary outcomes between the participants of this study and the non-participants who volunteered to complete the baseline questionnaire. Adherence percentages to the different parts of the intervention were 100 for the home visits, and 86 and 96 for the group sessions and telephone counselling sessions, respectively.

Of the 192 potential activity monitor data points, 98 were available (38 at T0, 29 at T1, and 24 at T2). Five measurements at T0, 3 at T1, and 5 at T2 were missing due to technical problems. Seventy-four measurements (21 at T0, 33 at T1, 38 at T2) were not available because the participant did not wear the activity monitor for at least 3 days.

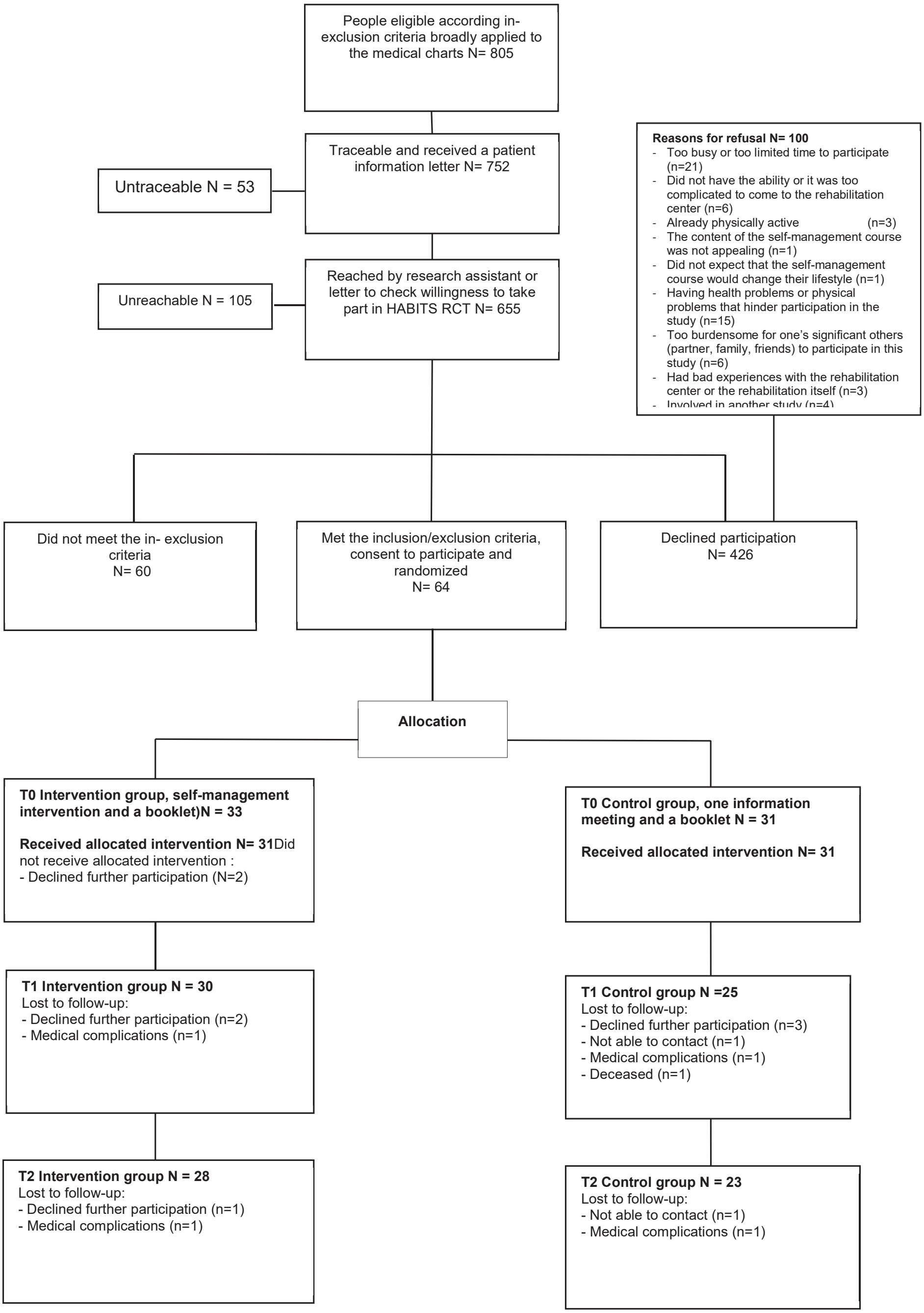

Figure 1 Flow diagram

Table 1 Characteristics of participants at baseline

	Intervention group	Control group
Age in years, mean (SD)	48 (10)	49 (11)
Sex, n (%) men	21 (64)	24 (77)
Lesion level, n (%) tetraplegia	11 (33)	10 (32)
Completeness, n (%) motor complete	24 (73)	26 (86)
Years since injury, mean (SD)	21(8)	23 (10)

Intervention effects

The observed data of the primary and secondary outcomes are presented in figure 2 and in tables 2 and 3. The modelled data are presented in table 4 and 5. In the models adjusted for confounders, no overall intervention effects were found on the primary outcomes amount of self-propelled wheelchair driving (β=4.68; P=0.19; 95% CI=-2.46 to 11.81) and self-reported physical activity (β=9.97 minutes; P=0.83; 95% CI=-93.21 to113.22) and. The same applies to the between group differences at T1 and T2. On the secondary outcomes we did not find an overall intervention effect or between group differences for perceived behavioural control. For the stages of exercise change a positive trend (p=0.08) was found for the overall intervention effect in favour of the intervention group. For exercise attitude a higher score was found for the intervention group at T1, whereas at T2 the control group had a higher score than the interventions group.

Of the tertiary outcomes, only secondary health complications showed significant difference: at T2 the intervention group experienced significantly less impact of SHCs compared to the control group.

Table 2 Observed values for primary and secondary outcomes

	Intervention group						Control group					
	T0		T1		T2		T0		T1		T2	
	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Subjectively measured physical activity (PASIPD)	23	14.3 (11.6)	25	16.7 (12.1)	21	16.8 (12.9)	26	13.2 (11.4)	20	13.0 (11.2)	16	11.3 (8.5)
Objectively measured physical activity (min/day)	21	95.4 (48.0)	10	90.9 (29.9)	9	108.78 (85.34)	17	83.4 (52.7)	17	78.3 (90.0)	15	80.7 (66.7)
Perceived behavioural control												
Self-efficacy (SCI-ESES)	25	29.7 (7.9)	24	30.3 (7.2)	19	32.4 (7.2)	24	33.2 (6.9)	19	32.2 (6.10	15	30.4 (6.9)
Proactive coping (UPPC)	26	3.1 (0.6)	23	3.1 (0.5)	19	3.0 (0.6)	24	3.2 (0.5)	19	3.2 (0.5)	14	3.1 (0.6)
	N	**%**	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**
Stages of exercise change	23		23		20		20		19		15	
Pre-contemplation (non-believers)	1	4.3	1	4.3	1	5.0	1	5.0	3	15.8	3	20.0
Pre-contemplation (believers)	3	13	2	8.7	0	0	0	0	0	0	0	0
Contemplation	9	39.1	4	17.4	4	20.0	5	25.0	6	31.6	3	20.0
Preparation	1	4.3	1	4.3	1	5.0	1	5.0	0	0	0	0
Action	2	8.7	1	4.3	1	5.0	4	20.0	0	0	1	6.7
Maintenance	7	30.4	14	61	13	65	9	45.0	10	52.6	8	53.3
	N	**Mean (SD)**	**N**	**Mean (SD)**	**N**	**Mean (SD)**	**N**	**Mean (SD)**	**N**	**Mean (SD)**	**N**	**Mean (SD)**
Attitude (DBL)	26	1.3 (0.8)	23	1.4 (1.1)	19	0.8 (0.4)	24	1.2 (1.0)	19	1.3 (0.7)	14	0.9 (0.4)

Table 3 Observed values for tertiary outcomes

	Intervention group						Control group					
	T0		T1		T2		T0		T1		T2	
	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Secondary health conditions (SCI_SCS)	26	16.4 (7.4)	25	11.8 (6.4)	19	12.05 (6.5)	24	13.63 (7.6)	20	11.0 (8.8)	14	15.4 (9.0)
Social support (SSEBS)	26		25		19		24		20		14	
Family support and involvement		16.0 (6.6)		17.1 (7.4)		17.4 (6.3)		18.6 (8.1)		18.2 (7.2)		18.3 (7.0)
Family and friend reward and punishment		4.3 (1.2)		4.6 (1.9)		5.0 (1.1)		5.1 (1.3)		4.6 (1.4)		4.8 (1.2)
Friend support		6.9 (2.8)		7.5 (4.1)		8.0 (3.3)		8.6 (3.8)		7.8 (94.3)		7.7 (4.4)
Aerobic capacity	20		18		15		17		18		15	
PO2peak		48.6 (22.9)		47.5 (23.5)		58.2 (26.0)		41.5 (20.2)		56.6 (27.3)		47.7 (25.8)
VO2max		3.5 (5.7)		2.3 (4.3)		3.0 (5.5)		3.2 (5.3)		1.3 (0.4)		2.1 (2.7)
Functional independence (SCIMIII)	32	57.2 (16.7)	25	58.4 (15.6)	23	57.9 (16.3)	30	58.3 (15.0)	25	56.6 (15.6)	20	57.1 (15.5)
Mood (MHI-5)	26	72.3 (17.8)	21	77.5 (11.2)	17	79.3 (14.1)	24	78.6 (15.0)	21	74.7 (11.2)	14	78.6 (9.4)
Fatigue (FSS)	29	31.9 (9.6)	25	29.7 (9.1)	18	25.1 (9.5)	24	27.0 (12.5)	20	28.5 (11.0)	14	29.0 (10.3)
Participation (USPERP)	26		25		19		24		20		14	
Frequency		32.7 (9.7)		32.7 (14.1)		37.7 (12.4)		36.2 (6.4)		36.9 (8.5)		32.2 (10.2)
Restriction		77.5 (14.7)		79.2 (15.4)		83.3 (16.4)		81.4 (16.3)		76.3 (15.8)		78.1 (16.7)
Satisfaction		70.1 (13.4)		75.3 (14.1)		80.8 (9.9)		77.3 (16.8)		76.0 (12.3)		75.6 (16.65)
Quality of life (WHOQOL-5)	26	17.5 (2.73)	21	18.5 (3.1)	17	19.8 (3.3)	20	18.6 (4.1)	21	19.0 (2.7)	14	18.7 (2.8)
BMI	31	25.0 (5.1)	25	24.4 (6.5)	23	23.7 (6.3)	29	23.1 (6.1)	25	23.5 (6.0)	25	23.7 (6.3)

Table 4 Mixed models for primary and secondary outcomes

		Crude ł				Adjusted †			
		B	p	95% CI		B	p	95% CI	
Subjectively measured physical activity (PASIPD)	**Overall**	3.31	0.26	-2.60	9.21	4.68	0.19	-2.46	11.81
	T1	4.66	0.25	-3.29	12.61	6.20	0.17	-2.85	15.25
	T2	2.17	0.55	-5.05	9.39	3.42	0.42	-4.99	11.84
Objectively measured physical activity (in minutes)	**Overall**	25.71	0.35	-30.72	82.15	9.97	0.83	-93.28	113.22
	T1	-1.78	0.96	-67.44	63.87	-12.27	0.80	-117.95	93.41
	T2	53.41	0.09	-10.25	117.08	52.35	0.30	-53.20	157.89
Perceived behavioural control									
Self-efficacy (SCI-ESES)	**Overall**	0.00	0.66	-0.17	0.27	-0.46	0.83	-4.93	4.01
	T1	1.81	0.47	-3.21	6.83	-1.47	0.60	-7.08	4.14
	T2	-1.50	0.51	-6.07	3.07	0.81	0.80	-5.54	7.16
Proactive coping (UPPC)	**Overall**	0.02	0.23	-0.10	0.40	0.13	0.40	-0.40	0.27
	T1	-0.06	0.73	-0.43	0.30	-0.05	0.83	-0.50	0.40
	T2	0.34	0.04	0.01	0.70	0.32	0.13	-0.10	0.70
Stages of exercise change *	**Overall**	0.46	0.16	-0.20	1.12	0.62	0.08	-0.10	1.33
	T1	1.09	0.16	-0.43	2.62	1.21	0.13	-0.35	2.78
	T2	0.02	0.97	-1.37	1.33	0.07	0.92	-1.31	1.50
Exercise attitude (DBL)	**Overall**	0.13	0.47	-0.24	0.51	0.07	0.22	-0.11	0.45
	T1	0.53	0.05	0.01	1.05	0.62	0.03	0.05	1.20
	T2	-0.46	0.09	-1.00	0.08	-0.68	0.04	-1.34	0.02

ł Adjusted for the baseline value of the outcome variable

†Adjusted for the baseline value of the outcome variable, rehabilitation centre, sex, age, level of SCI, baseline BMI, and years since injury

*Poisson mixed model analyses were performed for the stages of exercise change

T1 at the end of the intervention, T2 half year after intervention.

Table 5 Mixed models for tertiary outcomes

		Crude ł				Adjusted †			
		B	p	95% CI		B	p	95% CI	
Secondary health conditions (SCI_SCS)	**Overall**	-5.44	0.06	-11.07	0.19	0.24	0.10	-0.05	0.53
	T1	-2.51	0.19	-6.31	1.29	-0.98	0.73	-6.59	4.63
	T2	-0.53	0.83	-5.31	4.25	-6.96	0.03	-13.40	-0.52
Social support (SSEBS)									
Family support and involvement	**Overall**	0.13	0.95	-4.15	4.41	0.73	0.68	-2.83	4.29
	T1	-1.49	0.42	-5.18	2.19	0.54	0.81	-3.94	5.01
	T2	0.13	0.95	-4.15	4.41	0.98	0.70	-4.19	6.16
Family and friend reward and punishment	**Overall**	0.15	0.69	-0.62	0.93	0.15	0.74	-0.75	1.04
	T1	-0.05	0.92	-0.97	0.88	0.12	0.83	-0.94	1.17
	T2	0.46	0.39	-0.61	1.52	0.18	0.76	-1.02	1.38
Friend support	**Overall**	0.30	0.73	-1.41	2.01	0.59	0.57	-1.48	2.67
	T1	-0.31	0.79	-2.56	1.94	0.33	0.80	-2.24	2.91
	T2	1.13	0.39	-1.46	3.72	0.96	0.51	-1.97	3.89
Aerobic capacity									
PO2peak	**Overall**	-9.32	0.04	-18.22	-0.41	-2.44	0.65	-13.68	8.79
	T1	-9.03	0.05	-18.05	-0.01	-2.96	0.60	-14.53	8.60
	T2	-9.67	0.04	-18.92	-0.42	-2.09	0.70	-13.46	9.28
VO2max	**Overall**	0.12	0.89	-1.62	1.86	0.08	0.94	-2.18	2.34
	T1	0.42	0.72	-1.94	2.79	0.48	0.75	-2.57	3.53
	T2	-0.33	0.80	-2.93	2.27	-0.42	0.79	-3.64	2.80
Functional independence (SCIMIII)	**Overall**	-0.55	0.68	-3.21	2.10	-0.63	0.70	-3.99	2.73
	T1	-0.63	0.67	-3.58	2.32	-0.94	0.61	-4.66	2.77
	T2	-0.54	0.73	-3.66	2.59	-0.37	0.84	-4.19	3.44

Mood (MHI-5)	**Overall**	0.94	0.94	-5.97	7.86	3.04	0.37	-3.72	9.80
	T1	1.79	0.70	-7.45	11.03	5.19	0.23	-3.45	13.84
	T2	-0.07	0.99	-10.50	10.36	0.07	0.99	-9.83	9.98
Fatigue (FSS)	**Overall**	-1.18	0.62	-5.89	3.53	-2.24	0.43	-8.00	3.52
	T1	1.48	0.63	-4.59	7.55	0.40	0.91	-6.61	7.40
	T2	-4.96	0.17	-12.06	2.13	-5.85	0.16	-13.98	2.29

ǂ Adjusted for the baseline value of the outcome variable

†Adjusted for rehabilitation centre, sex, age, level of SCI, baseline BMI, and years since injury,

T1, the end of the intervention, T2 half year after intervention.

5

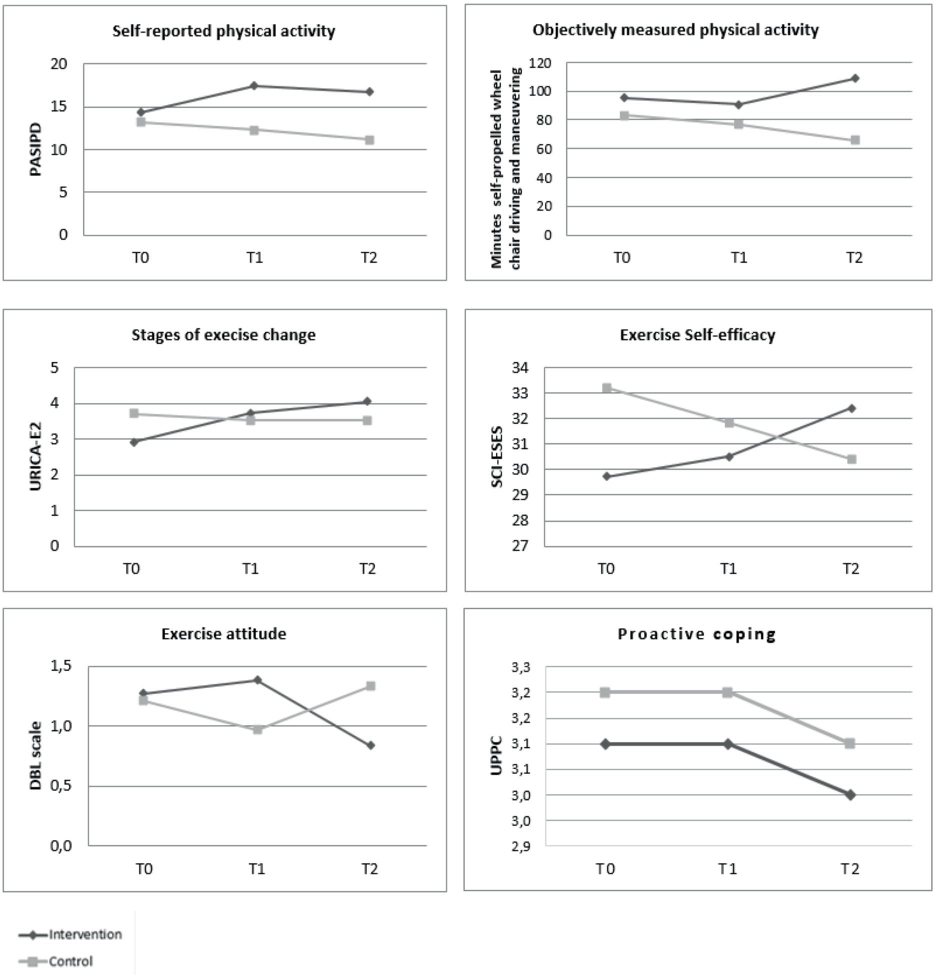

Figure 2 Observed data primary and secondary outcomes
(The measures of error are presented in table 2)

Discussion

To our knowledge this is the first RCT to examine the effectiveness of a self-management intervention on physical activity levels in individuals with long-term SCI. Overall, we did not find significant differences between the intervention and the control group on the outcome measures, and thus our study does not support the effectiveness of the self-management intervention.

This result on the lack of effectiveness is not what we hypothesized. Other studies in SCI populations provided some indication for positive effects of behavioural interventions on physical activity levels in individuals with SCI and in people with other chronic conditions (e.g. diabetes, arthritis and asthma). [19-21] The RCT of Nooijen et al [18] most strongly corresponds with our study, and in that study positive results of a behavioural intervention on level of physical activity were found. However, in that study people with a sub-acute SCI participated, instead of the chronic SCI group in our study. It might be that people in the sub-acute stage are more open to behavioural interventions Because almost everything has changed and everything needs to be done differently than in the past, people might also be more open to adapt behaviours that are taught or advised, such as an active lifestyle.

Our study-participants have lived with the condition for many years, learned to cope with their SCI and will have developed stable behaviour pattern. As a result, they don't experience a strong need to change their behaviour, with a resulting increased difficulty to change their behaviour.

Another explanation for the intervention not being effective - with respect to levels of physical activity and other outcomes - might be that we did not include the chronic SCI participants for whom the intervention could have been most effective. For example, we included individuals with a PASIPD score lower than the 75th percentile of a Dutch SCI population 5 years post-onset.[23] Our study sample showed to have an average level of physical activity of about the 70th percentile, quite close to the allowed maximum of 75. Consequently, our sample did have relatively less potential for improvement, although the mean PASIPD score in our study was still substantially lower compared to a Dutch cohort study (13.8 vs. 19.0).

Other outcomes also showed relatively high baseline scores. For example, the average baseline exercise self-efficacy score of 31.4 (SD 7.6) seems high compared to the maximum value of 40, and is similar to the results (mean 31.4, SD 7.8) of a large sample of individuals with long-standing SCI (N=268) who were not selected on activity level. [58] Similarly, the mean baseline proactive coping score in our study was 3.1 (SD 0.5), which seems to be relatively high compared to the range of 1 to 4, and comparable to the mean score of a population with a recent SCI and who were not selected on activity level (mean score: 3.2 (SD .4). [18] In addition and maybe most importantly, a large part of the participants already were in the action or maintenance phase of the stages of exercise change at baseline, which means according to themselves they were already active. This makes it difficult to further improve on this outcome, which is remarkable because the aim of the study - to improve active lifestyle - was also clarified to the participants. This cannot be logically linked to being categorized in the action and maintenance phase.

We did not see evidence for effectiveness of the intervention on the secondary outcome measures either. An intervention effect on these outcomes was expected, since previous studies in other populations showed that exercise self-efficacy [59, 60] and perceived behavioural control [61] could be improved by a behavioural intervention. However, behavioural studies with negative results on outcomes such as self-efficacy can also be found. [62, 63] Although these studies have a common target, they also differ in many aspects, making it difficult to speculate about the background of the between-study differences in effects. A specific factor that might have contributed to the absence of significant effects on the secondary outcomes might be that the participants in the intervention group may have developed a more critical look upon their behavioural control and attitude after their intervention, since they are much more aware of their (in)capabilities after the intervention. This explanation is also suggested by Maher et al. in their study with adolescents with cerebral palsy. [62]

With respect to exercise attitude, we found no overall intervention effect, but the intervention group showed a significantly more positive exercise attitude directly after the intervention compared to the control group. However, at follow-up the control group was significantly more positive compared to the intervention group. This shift in effect on attitude is difficult to explain. The observed data shows that all participants of the intervention group remained a positive exercise attitude, however it became less positive as compared to the control group.

It can be questioned whether the design and the execution of the intervention affected the effectiveness of the intervention. It takes time to change behaviours to an active lifestyle in individuals with physical disabilities,[64] and it is assumed that at least 6 months are needed.[25] An important requirement for a behavioural change is that people are aware of their own abilities (similar to perceived behavioural control) and intentions to perform physical activities.[64] For some of the participants the length of our intervention might have been too short to change behaviour, despite the fact that they have received tools to put their self-management skills into practice and tools to proceed on their goals after the determination of the intervention. Furthermore, as a result of the multi-centre character of our study, a uniform execution of the intervention cannot be guaranteed. It might also be possible that the intervention was not completely executed according to the protocol. However, we made every arrangement to ensure that the intervention was executed as intended. The counsellors received 3 training sessions in advance of the intervention, and there was a contact meeting during the intervention in which the process and the protocol of the intervention was discussed.

We already discussed the possible role of patient characteristics in the effectiveness of the intervention. One point should be added to this discussion. In our study we did not succeed in including the required number of 80 participants as indicated by our power calculation. After having invited 805 individuals with a long-term SCI to participate in this study, only 64 participants agreed to participate and were included. This may have caused selection bias, and the lack of power may have had impact on our results. However, when we compared the demographic characteristics of the participants of study and all non-participants, we did not find any significant differences. Furthermore, 50 non-participants completed a questionnaire with the main outcomes of this study and, again, no significant differences were found between participants and non-participants.

Strengths and limitations

A strength of our study was that the study was blinded, for both the assessor and the researcher, also in the phase of data analysis. Furthermore, by performing mixed model analyses, we have used the best possible statistical analyses that handles longitudinal, repeated measures in small numbers and relatively high drop-outs in the best possible way. [65]

Another strength is the application of objective assessment of levels of physical activity. The primary aim of the intervention was to increase levels of physical activity. Because it is known that in the area of physical activity outcomes from self-reported instruments differ from objectively measured outcomes, we included both types of instruments in our study.

The main limitations in our study were the small sample size, selection bias, missing values, and drop-outs. Individuals with a long-term SCI are a vulnerable group; two participants died (not related to the study) during the study and several participants dropped out of the study because of illness or secondary complications.

Future research

Firstly, future research should focus on people who have a greater potential to improve. For this, insight is needed in the determinants of the outcomes of behavioural interventions.

Second, the measurement of objective physical activity should become less burdensome to the patients to minimize missing data. The devices we used were much smaller than activity monitors used before,[57] but 5 days proved to be very long.

Third, it seems important to further decrease the burden of participation in the intervention, for example by making use of e-health to reduce transportation time and problems or to organize more intensive support in the home environment, for instance by home visits or collaborations with local gyms. However the effectiveness of such an e-health program in this kind of population needs to be studied.

Conclusion

A structured 16-week self-management intervention was not effective to change behaviour towards a more active lifestyle and to improve perceived behavioural control, stages of change and attitude in individuals with a long-term SCI.

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Determinants of physical activity in a behavioural intervention study in persons with long-standing spinal cord injury

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Abstract

Study design: Cross-sectional study

Objectives: The HABITS-trial was undertaken to test the effectiveness of a behavioural intervention to enhance physical activity (PA) in persons with long-standing spinal cord injury (SCI). This intervention was based on the transtheoretical model of behavioural change (TTM) and the theory of planned behaviour (TPB). The aim of the present study was to examine the assumed underlying mechanisms of the behavioural intervention.

Methods: Utilising pre- and post-intervention HABITS-data, three types of associations were examined using (log)linear regression analyses: (1) between baseline determinants of the TTM and TPB models (i.e. attitude, self-efficacy, social support) and baseline PA and the stages of exercise change; (2) between baseline determinants and change in PA; and (3) between change in determinants and change in PA. Inclusion criteria were: age at injury ≥ 18 years, time since injury ≥ 10 years, able to use a hand-rim wheelchair and physically inactive. Exclusion criteria were no intention to change exercise behaviour.

Results: We included 66 participants in the first analysis and 33 in the second and third analyses. Overall, no associations between the determinants and PA were found. However, at baseline, a significant relationship was detected between self-efficacy and PA.

Conclusion: The determinants of the models we tested in this study did not facilitate behavioural change in persons with long-standing SCI. Moreover, no cross-sectional relationships were found, self-efficacy excepted. Our results do not support the usefulness of the TTM and TPB models in defining and evaluating interventions.

Introduction

Many people with spinal cord injury (SCI) lead an inactive and sedentary lifestyle.[1-3] This is problematic because both are associated with deconditioning and decreased health, e.g. in terms of cardiovascular function and other secondary health conditions.[4-7] Therefore, the availability of effective behavioural interventions aiming at behavioural change is necessary. Previous studies tended to show positive effects of behavioural interventions in people with SCI,[8-10] but these studies were performed in the acute phase or in person with a recent SCI.

To our knowledge, the only behavioural intervention study undertaken to promote physical activity in people with long-standing SCI was the HABITS randomised controlled trial (RCT). [2] This study compared an intensive 16-week theory-based self-management intervention including group meetings and individual counselling to a less intensive intervention consisting of one information meeting and an instructional booklet. Results showed that the self-management intervention was no more effective than the control intervention for all study outcomes. Additional analyses, however, showed large variability in intervention effects within the self-management group, indicating that some subjects benefitted more from the intervention than others.

We based the self-management intervention on two well-known behavioural change models: the theory of planned behaviour (TPB) and the transtheoretical model (TTM). TPB assumes that intentions to perform (new) behaviours are determined by personal attitudes (e.g. the perceived benefits or importance of the new behaviour), subjective norms (e.g. social support, attitudes expressed by other people), and perceived behavioural control (e.g. confidence in one's ability to perform the new behaviour). [11] The TTM assesses an individual's readiness to act on a new healthier behaviour,[12] such as a more active lifestyle. [13] In other words, readiness is measured as one's willingness to adopt a certain new behaviour within a certain time frame. In addition, we measured proactive coping as a determinant, which should facilitate the step from intention to action. In other words, proactive coping supports individuals to overcome barriers to become more physically active.

These behavioural change models gave substance and structure to our intervention in several ways. For example, the intervention was tailored towards the participant's needs and motivations, and the tools used in the interventions were focused on improving all factors included as determinants in these models and not only on the physical activity outcomes. All these determinants were measured as secondary outcomes of the RCT. Also, the inclusion of the participants was based on these models; participants had to be motivated to perform a more active lifestyle. It can be expected that such an approach will be effective,[14] but this proved not to be the case. Nevertheless, the RCT data allow targeted examination of the assumed relationships between determinants and the primary physical activity outcomes. By examining these relationships, we will gain more insight into these presumed working mechanisms, which will give more direction to what works or does not work in persons with long-standing SCI.

Therefore, the overall goal of this study was to explore the underlying mechanisms of a behavioural intervention based on two well-known behavioural change models (TTM and TPB). The primary research question is: are determinants of the models (self-efficacy, attitude, social support) and proactive coping related to physical activity and stages of exercise change (STOEC). These relationships were examined in three types of analysis: (1) between baseline determinants and baseline physical activity and STOEC; (2) between baseline determinants and change in physical activity; and (3) between change in determinants and change in physical activity. We hypothesise that the (changes in) determinants from the behavioural change models and proactive coping are related to (changes in) physical activity and STOEC.

Methods

This study is part of the HABITS-study, a multi-centre, randomised controlled trial (RCT).[2] In each rehabilitation centre, participants were randomly allocated to the self-management intervention group or the control group after the baseline measurements. The research assistants who performed the baseline measurements were not involved in the self-management intervention and were blinded to the group allocation. The researchers were also blinded to the group allocation until the initial data analyses of the primary and secondary outcomes were performed.

Participants

Adults with SCI were eligible for this study if they met the following criteria: age at injury was 18 years or above; time since injury was at least 10 years; current age between 28 and 65 years; able to use a hand-rim wheelchair; physically inactive, as defined by a Physical Activity Scale for Individuals with Physical Disabilities (PASIPD) score lower than the 75th percentile of a Dutch SCI population.[3, 15] Potential participants were excluded from the study if they had no intention to change their exercise behaviour in the next 6 months, a progressive disease or severe co-morbidities, psychiatric problems that could interfere with the study, and insufficient knowledge of the Dutch language to understand the purpose of the study and the testing methods.

Recruitment

Physicians from the participating rehabilitation centres pre-selected former inpatients using information from medical charts. Potential participants were sent an invitation letter and two weeks thereafter they were contacted by the research assistant to check the inclusion and exclusion criteria and to provide further information. All participants signed a consent form after expressing their willingness to participate.

Multi-centre approval was granted by the Erasmus MC Medical Ethics Committee, Rotterdam, the Netherlands. Local approval was further granted by all participating centres.

Interventions

The theoretical framework (figure 1) used to design the interventions, with a focus on behavioural change, and to select outcome measures is described in detail elsewhere. [15] In this theoretical framework, we combined two well-known models of behavioural change.

Study participants received either the self-management interventions or were in the information group. Details of these intervention are described elsewhere [2, 15] and are described here only briefly.

The HABITS intervention specifically targeted two conditions for behavioural change: optimising intentions towards a healthier lifestyle and behaviour by (i) improving self-management skills (i.e. by changing perceived behavioural control) and (ii) fostering proactive coping skills. The HABITS intervention consisted of one home visit, 5 individual and 5 group sessions during a total of 16 weeks. It included: guidance from the HABITS counsellor; peer support and mastery experiences (experiencing task accomplishment strengthens self-efficacy) and discussions on various themes related to a healthy active lifestyle, e.g. discussing the benefits of social support and making plans on how the environment of the participants could support an active lifestyle, or by letting participants experience physical activities they can easily perform in their home setting, to stimulate a more positive attitude about exercising. Furthermore, the following tools were used: action & proactive coping planning, problem solving, activity monitoring, a self-help workbook and a booklet, "How to stay fit with SCI". [16]

The control group received information about an active lifestyle in SCI, which included attendance at one information group meeting in the first weeks of the study. During this meeting the same themes relating to a healthy active lifestyle as presented in the HABITS intervention were discussed. In addition, participants were instructed on how they could change their behaviour and what they would have to do to achieve these new behaviours. This group also received the self-health workbook; "How to stay fit with SCI". [16]

The HABITS intervention and the information group were provided with counsellors who were already working in one of the participating rehabilitation centres, were experienced in the treatment of persons with SCI, e.g. physical therapist, and were trained in motivational interviewing (MI). MI is a directive client-centred counselling style to elicit behavioural change by helping clients to explore and resolve their ambivalence towards behavioural change. [17]

Outcome measures

Measurements were recorded at baseline, T0 (week 0), directly after the intervention, T1 (week 16) and half a year after termination of the intervention (week 42). For the analyses in this study, we used data from T0 and T1 only.

Self-reported physical activity

Self-reported physical activity was assessed with the PASIPD instrument. [18] The Dutch adaptation [3] of the PASIPD consists of 11 items concerning sports, hobbies, household- and work-related activities. The questionnaire includes items on the number of days per week and the hours per day a certain activity was performed during the past 7 days. The total score of the PASIPD was computed by multiplying the average hours per day for each item by a Metabolic Equivalent value (MET) associated with the intensity of the activity, MET*hour/week. PASIPD scores range between 0 (no activity) and a maximum of 182. We chose this measure instead of the accelerometer data from the HABITS trial because the latter has too many missing values. [2]

Stage of exercise change (STOEC)

The University of Rhode Island continuous measure (URICA-E2) [19] assesses readiness to change in regards to regular exercise. The URICA-E2 consists of 24 statements reflecting intentions towards exercise change. The responses are given on a Likert 1–5 scale, from 'strongly disagree' to 'strongly agree'. There are six outcome stages: pre-contemplation non-believer, pre-contemplation believer, contemplation, preparation, action and maintenance. The internal consistency of this questionnaire was determined to be 0.80-0.93. [20] In our analyses here, we dichotomised the STOEC score into intention (including pre-contemplation until preparation) and action (action and maintenance).

Determinants

Self-efficacy

The SCI exercise self-efficacy scale [21] measures self-reported self-efficacy for various types of physical exercise in individuals with SCI. This scale includes 10 items, each with a 4-point scale (1: not at all true, up to 4: exactly true). The range for the total score is 10-40. Internal consistency was determined to be 0.93. This questionnaire was translated into Dutch and validated in a sample of individuals with SCI. [22]

Proactive coping

Proactive coping was measured with the Utrecht Proactive Coping Competence scale,[23, 24] which assesses self-reported competency with regard to proactive coping, meaning anticipating on and dealing with possible future situations. This self-report scale includes 21 items, each with a 4-point response scale (1: not capable, up to 4: very capable). The total score is the mean of the item scores; therefore, the range is also 1-4. Internal consistency was measured as 0.83 and 0.95, and the test-retest reliability was between 0.45 and 0.82. [23, 24]

Attitude to change behaviour

Attitude was measured using the Exercise Decisional Balance. [25] This questionnaire reflects the individual's relative weighing of the pros and cons of changing exercise behaviour. The questionnaire consists of 10 statements (5 cons, 5 pros), all rated on a 5-point scale ranging from 1 (not at all) to 5 (extremely important). A positive ratio of pros versus cons means that the respondent is positive about changing his/her exercise behaviour. The mean internal consistency of this measure was 0.80 for the pro subscale and 0.70 for the con subscale. The test–retest reliability values of the pros and cons scales were 0.84 and 0.74, respectively. [25]

Social support

Social support (Social Support for Exercise Behaviour Scale): the level of support individuals experienced in making their health-behavioural changes (exercise). The questionnaire consists of 23 statements subdivided into three categories (family support, rewards/punishments and friend support). The frequency of each item is rated on a 5-point Likert scale ranging from 1 (none) to 5 (very often). [26]

Statistical analyses

Analyses that focused on the baseline relationships were performed with all participants (N=64). The analyses which included change data (the second and third types of analysis) were performed with participants of the HABITS intervention group only (N=33), because they received the intervention aimed at exercise behavioural change whereas no significant behavioural change was expected in the control group. Further, the change analyses did not include the STOEC variable because of the high number of missing values in the post-intervention data.

Analysis began with descriptive statistics of the demographic variables, lesion characteristics and the main outcomes. As the physical activity score was positively skewed, it was log-transformed before the analyses to satisfy the assumption of normality. The change score (T1 minus T0) of physical activity showed a normal distribution and was therefore not log-transformed. For descriptive purposes, a frequency table was developed to show the change in the stages of exercise change at an individual level and showed in which intervention the participants participated. In addition, a cross table was developed to show the types and number of transitions between the STOEC during the intervention. Differences in PASIPD score between the STOEC intention and action group were tested with a t-test.

Associations between each baseline determinant and baseline PASIPD and dichotomous STOEC were first examined by univariate linear regression analyses (PASIPD) or univariate log regression analysis (STOEC), followed by multivariable regression analyses to investigate possible confounding for age, sex, time since injury, level of SCI, rehabilitation centre and baseline body mass index (BMI). Associations between each separate baseline determinant and change in physical activity during the intervention were examined by univariate regression analysis. Since we had a limited number of participants in the study, only univariate analyses were performed. In a similar way, the associations between change in each separate determinant and change in physical activity during the intervention were examined. Alpha was set at 0.05.

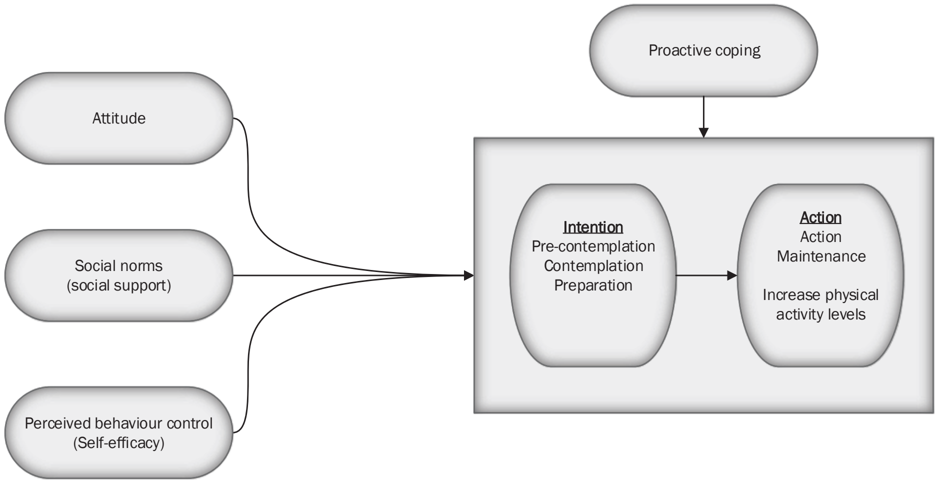

Figure 1 HABITS theoretical model

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Results

Descriptive findings

Between January 2012 and October 2014, 64 persons were included in the HABITS RCT. Table 1 shows the characteristics of all participants and those in the HABITS intervention group. The descriptive data of physical activity, STOEC and the determinants are shown in table 2. Table 3 shows the number of patients in the HABITS group for each STOEC at baseline, and their stage at T1.

Table 1 Characteristics of participants

	Intervention group (HABITS-group) N=33	**Total group N=64**
Age in years, mean (±SD)	48 (10)	49 (10)
Sex, n (%) male	21 (64)	45 (67)
Lesion level, n (%) tetraplegia	11 (33)	21 (38.2)
Completeness, n (%) motor complete	24 (73)	50 (87.1)
Years since injury, mean (±SD)	21 (8)	22 (9)
BMI, mean (±SD)	25.0 (5.1)	24.0(5.7)

Table 2 Observed data

		T0 Total group		T0 HABITS intervention group		T1 HABITS intervention group	
	min/max	**N**	**Median IQR [Q1 - Q3]**	**N**	**Median IQR [Q1 - Q3]**	**N**	**Median IQR [Q1 - Q3]**
Physical activity	0/168	64	10.2 [18]		13.0 [22]		12.0 [16]
	min/max	**N**	**%**	**N**	**%**	**N**	**%**
Stages of exercise change (categorical)	1/6	43		23		23	
Pre-contemplation (non-believer)		2	3.1	1	4.3	1	4.3
Pre-contemplation (believer)		3	4.7	3	13.0	2	8.7
Contemplation		14	21.9	9	39.1	4	17.4
Preparation		2	3.1	1	4.3	1	4.3
Action		6	9.4	2	8.7	1	4.3
Maintenance		16	25.0	7	30.4	14	61.0
Dichotomous stages of exercise change intention phase		21	23.8	13	56.3	9	34.7
	min/max	**N**	**Mean (SD)**	**N**	**Mean (SD)**	**N**	**Mean (SD)**
Self-efficacy	0/40	64	31.5 (1.4)	25	29.7 (7.9)	24	30.3 (7.2)
Attitude	1/5	64	1.3 (0.2)	26	1.3 (0.8)	23	1.4 (1.1)
Proactive coping	1/4	64	3.1 (0.1)	26	3.1 (0.6)	23	3.1 (0.5)
Social support	0/30	64		26		25	
Family support	0/23		17.7 (1.3)		16.0 (6.6)		17.1 (7.4)
Rewards and punishment	0/19		4.6 (0.4)		4.3 (1.2)		4.6 (1.9)
Friend support	0/23		4.8 (0.3)		6.9 (2.8)		7.5 (4.1)

Table 3 Cross table of the stages of exercise change at T0 and T1 in the HABITS group, for the subjects with data for both time points

	Number of participants who moved from T0 STOEC to T1à								
Number of participants at STOEC at T0	T1 Pre-contemplation non-believer	T1 Pre-contemplation believer	T1 Contemplation	T1 Preparation	T1 Action	T1 Maintenance	T1 Missing	T1 Total valid	T0 Missing
Pre-contemplation non-believer (n=1)						1	0	1	0
Pre-contemplation believer (n= 3)	1	1				1	0	3	0
Contemplation (9)			3	1		2	3	6	3
Preparation (1)						1	0	1	0
Action (2)						2	0	2	0
Maintenance (7)		1				5	1	6	1
T1 total valid									
Missing T1 (10)			1		1	2	6	4	6

Associations between STOEC and physical activity (Met score) (sub-question two)

We found a significant difference between the median PASIPD score of the intention group (6.3 METs-h/d [IQR[13]]) and the action group (14.9 METs-h/d, [IQR[7]]) of the dichotomised STOEC mean difference 7.6 [95% CI 1.5 to 13.9], p=0.02.

Baseline determinants vs. baseline STOEC and PASPID

Table 4 shows the associations between the baseline determinants and the baseline log-transformed PASIPD score. We found a significant association between self-efficacy and physical activity (B=1.04, 95%CI:1.00 to 1.08).

Table 4 Separate associations between baseline determinants and baseline physical activity (N=64)

		Univariate			Multivariable		
	N	B	95%CI	P	B	95%CI	P
Self-efficacy	64	1.22	0.99-1.05	0.25	1.04	1.00-1.08	0.03
Attitude	64	1.05	-0.78-1.42	0.72	1.02	1.34-1.37	0.91
Proactive coping	64	1.70	1.06-2.64	0.03	1.43	-0.83-2.51	0.19
Social support	64						
Family support		1.02	0.98-1.06	0.26	1.16	0.98-1.05	0.41
Rewards and punishment		1.01	0.83-1.23	0.90	0.82	0.78-1.23	0.86
Friend support		1.03	0.67-1.12	0.40	0.05	-0.97-0.01	0.23

Linear regression analysis per determinant, dependent variable log-transformed PASIPD score. Multivariable results corrected for age, sex, time since injury, level of SCI, rehabilitation centre and baseline BMI.

Table 5 shows the associations between the baseline determinants and the baseline dichotomous STOEC. Similar to the PASIPD data, we found a significant relationship with self-efficacy (B=1.23, 95% CI: 1.05 to1.45).

Table 5 Separate associations between baseline determinants and baseline dichotomous stages of exercise change (N=64)

	N	Univariate			Multivariable		
		B	95%BI	P	B	95%BI	P
Self-efficacy	64	1.21	1.06-1.38	0.01	1.23	1.05- 1.45	0.01
Attitude	64	1.23	0.65-2.36	0.53	1.51	0.28- 3.92	0.40
Proactive coping	64	3.00	0.91-9.81	0.07	4.45	0.72-27.61	0.11
Social support	64						
Family support		1.06	0.97-1.15	0.19	1.06	0.95- 1.17	0.30
Rewards and punishment		1.26	0.82-1.94	0.30	1.21	0.63- 2.23	0.59
Friend support		1.15	0.96-1.38	0.13	1.25	0.97- 1.60	0.08

Logistic regression analysis, dependent variable dichotomous stages of exercise change. Intention phase = 0, action-phase = 1.

Baseline determinants vs. change in PASIPD

Table 6 shows the associations between the baseline determinants and the change in PASIPD in the HABITS group during the intervention. One association was significant, i.e. the negative relationship between proactive coping and PASIPD (B=-8.50, 95%CI:

-14.83 to -0.83), which means that higher proactive coping skills were associated with lower PASIPD scores.

Table 6 Separate associations between the baseline determinants and change in physical activity in the HABITS group

	N	Univariate		
		B	**95%CI**	**P**
Self-efficacy	25	0.10	-0.36- 0.56	0.66
Attitude	23	2.02	-1.97- 6.02	0.31
Proactive coping	24	-8.50	-14.83- -0.83	0.01
Social support	25			
Family support		0.03	-0.49- 0.60	0.90
Rewards and punishment		0.55	-2.24- 3.33	0.69
Friend support		-0.57	-1.56- 0.43	0.26

Linear regression analysis, dependent variable delta PASIPD (physical activity) score T1 minus T0

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Change determinants vs. change in PASIPD

Table 7 shows the associations between the change in determinants and change in PASIPD in the HABITS intervention group. No significant relationships were found.

Table 7 Separate associations between the change in determinants and change in physical activity in the HABITS group

Determinant (N)		Univariate		
	N	**B**	**95%CI**	**P**
Self-efficacy	25	0.17	-0.24- 0.57	0.41
Attitude	23	-1.52	-4.82- 1.78	0.36
Proactive coping	24	4.8	-6.16-15.73	0.38
Social support	25			
Family support		0.40	-0.32- 1.11	0.27
Rewards and punishment		0.30	-2.07- 2.67	0.80
Friend support		0.20	-0.11- 1.45	0.30

Linear regression analysis, dependent variable delta PASIPD (physical activity) score T1 minus T0. Independent variables are the delta scores of the determinants (T1 minus T0).

Discussion

We performed an RCT of a behavioural intervention in patients with chronic SCI. This intervention was based on two well-known behavioural change models: the trans-theoretical model (TTM) and the theory of planned behaviour (TPB). Although the results of the RCT were negative, the study also allowed us to analyse the determinants from those models. Therefore, the overall aim of this study was to explore the working mechanisms of a behavioural intervention on physical activity and its changes, based on the TTM and TPB and the primary outcomes. Overall, we did not find a relationship between the determinants of the two models and physical activity. A significant relationship was found between self-efficacy and physical activity, but only at baseline.

The TBP model includes three determinants of behaviour: attitude, social norms and self-efficacy. From these determinants, only self-efficacy was associated with our two behavioural outcomes, i.e. STOEC and physical activity, and only at baseline. This cross-sectional relationship is in line with another cross-sectional study in another sample in which we explored the relationship between self-efficacy and physical activity. [2] In that study, we showed that exercise-self efficacy is a weak but independent predictor of the level of physical activity amongst persons with long-standing SCI. In other cross-sectional studies, similar relationships were found, e.g. that self-efficacy was related to leisure physical activity in both persons with non-acute SCI [27] and persons with acute SCI. [10]

Self-efficacy is believed to be one of the most important and modifiable behavioural change determinants [12, 28] of the TPB model. However, the results of the present study showed no relationship between change in physical activity and change in self-efficacy, nor between baseline self-efficacy and change in physical activity. Longitudinal studies regarding the relationship between self-efficacy and change in physical activity in comparable populations are scarce. One study showed that, amongst other variables, self-efficacy had a weak mediating effect on physical activity in persons with acute SCI after a behavioural intervention. [29] Another longitudinal study in a population with young healthy adults showed that self-efficacy had a significant but weak direct relationship with change in physical activity. [30] A review showed that after a behavioural intervention (e.g. self-regulation, motivation interviewing), change in self-efficacy can lead to change in physical activity in older community-dwelling people. [31] The same relationships were found in persons with chronic obstructive pulmonary disease (COPD). [32] However, our RCT study showed no effects on self-efficacy in both study groups,[2] and we found no relationship between change in physical activity and change in self-efficacy. An explanation might be that most of the participants had already started with a high self-efficacy score, so there was little room left for improvement.

In our study we included two behavioural outcomes: STOEC and physical activity. Although there is not a one-to-one relationship between these outcomes, it is assumed that higher STOEC levels mean higher levels of physical activity. [13, 33] This assumption was confirmed in the present study. The longitudinal study of Rozekranz, published in 2005, in which the number of objectively measured steps was used as a measure of physical activity, produced similar results. [34] These results imply a longitudinal relationship between the STOEC and physical activity.

Although not part of the TTM and TPB model, we also included proactive coping as a determinant of behaviour and behavioural change, because the medical literature shows that proactive coping facilitates the step from intention to action. Thus, a relationship could be expected between coping at baseline and change in behaviour, and between change in proactive coping and change in behaviour. We did find a significant relationship between baseline proactive coping and delta PASIPD score, but this was a negative relationship, i.e. persons with higher proactive coping skills at baseline decline in physical activity level after an intervention. This is a remarkable finding which we cannot explain, and might simply be due to chance.

This study focused on the relationships between determinants of behaviour derived from two models: TTM and TPB. The aim of our study was to use, and not to validate, these models; however, our results do not support the validity of these models. Especially at baseline, substantial relationships could have been expected, but only self-efficacy was found to be a significant determinant. The interpretation of the lack of associations between longitudinal (change) score is more complex. Possibly our intervention was not sufficiently strong to result in changes of the determinants and behavioural outcomes. However, it might also be the case that some of the determinants are difficult to change, regardless of the content of the intervention. Reviews focusing on behavioural change techniques showed that it is difficult to identify effective determinants of behaviour change. For instance, two review studies on this topic also failed to provide conclusive evidence for which determinants are changeable. Furthermore, relationships reported between physical activity self-efficacy, attitude and social norm are rather weak. [14, 35]

Limitations

This study has some limitations. First, the statistical power of the study might be considered low, because of the relatively small number of participants, some with missing data. For example, we had to limit ourselves to univariate or simple equations.

Secondly, certain characteristics of our group might have influenced the results. A considerable number of the participants were found to be in the contemplation phases, and may have had no or minimal intention to change their behaviour. A few participants were even in the pre-contemplation phase and therefore should not have been in this study, according to our inclusion criteria. [2] It is unclear how this happened, because all participants were asked prior to their inclusion whether they had the intention to change their exercise behaviour in the following six months. Conversely, it is also remarkable that several participants were already in the action and maintenance phases, thus making it difficult for them to become even more physically active. Possibly they already considered themselves to be physically active but had an interest in further enhancing their physical activity. This is more in line with the median activity levels of the included participants, which were low compared to a group of people with SCI for only five years. [3] We are unable to provide a satisfactory explanation for the inclusion of these anomalous participants.

Conclusion

The determinants proactive coping and attitude, social support, self-efficacy from the models TTM and TPB that we used in this study did not facilitate behavioural changes in terms of increasing the level of physical activity in persons with long-standing SCI. In addition, no cross-sectional relationships were found, except for self-efficacy. Our results do not support the usefulness of the models in defining and evaluating interventions.

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7

General discussion

Introduction

The main aims of the studies described in this thesis were to develop and evaluate the 16-week HABITS intervention, a structured self-management active lifestyle intervention for people with a long-standing SCI, and to investigate the mechanisms underlying in the results of the intervention. This intervention, which included group meetings and motivational interviewing conversations with a coach, was developed using a theoretical model that combined the Transtheoretical Model (TTM), the Theory of Planned Behaviour (TPB) and proactive coping theory. Self-efficacy was one of the components of this integrated model and of our intervention; we therefore examined the association between exercise self-efficacy and physical activity in a larger population with long-standing SCI, the ALLRISC cross-sectional study. Finally, we developed and validity tested a new objective measure of physical activity in people who are wheelchair-bound.

The most important finding of these studies was that the HABITS intervention was not effective in eliciting behavioural change to a more physically active lifestyle in the participants with a long-standing SCI. The intervention resulted in no effect on this primary outcome; in addition, it had no effects on the secondary outcome measures, namely the stages of exercise change, self-efficacy, attitude, proactive coping skills and social support. Our investigation of the underlying mechanisms produced only partial evidence in support of our theoretical model: in the cross-sectional study, only exercise self-efficacy was found to be significantly related to physical activity and stages of exercise change (chapter 6). The ALLRISC cross-sectional study also found self-efficacy to be a significant determinant of self-reported physical activity (chapter 4). The other components of our theoretical model showed no association with physical behaviour, either longitudinally or cross-sectional. In contrast, the study to establish the validity of our monitor of wheelchair use, a device used in our randomized controlled trial (RCT), produced satisfying results.

This chapter interprets and discusses the study results in the context of the scientific literature. It also discusses methodological considerations and the clinical implications of the findings, and it makes recommendations for future research.

Questions raised by the negative results

As just described, our self-management intervention showed no added effect on eliciting a behavioural change in daily physical activity in the participants with a chronic SCI, nor did it have any additional effects on the secondary outcomes. This raises several questions. For example, did we choose appropriate determinants in our theoretical model for changing physical activity? Was the design of the HABITS intervention suitable? For instance, did we use appropriate tools and was the delivery of the content sufficiently well executed? Was the intervention suitable for the study population? These questions will be addressed in the following sections.

Suitability of the theoretical model underlying the HABITS study

At the start of the study, we developed a model as the theoretical basis on which to build our intervention and choose our outcome measures (chapter 2). This model combined two well-established behavioural change models, the TTM and the TPB. In addition, we added proactive coping theory to the model because we considered this would be a facilitator for moving from the intention phase (not performing physical activity behaviour) to the action phase (performing physical activity behaviour; see Figure 1). Our theoretical model guided our choice of primary and secondary outcomes. The primary outcomes of the trial were behavioural measures, namely the stages of exercise change reached by each participant and physical activity behaviour. Physical activity behaviour was measured both objectively with the wheelchair use monitor and subjectively, using a self-reported questionnaire. The determinants of these behavioural outcomes in our theoretical model were attitude, self-efficacy, social support and proactive coping; these were measured as the secondary outcomes of the trial.

We consider our clearly defined theoretical model to be a strength of this study. Although the results of the trial were negative, we used the model to gain greater insight into the working mechanisms of our intervention by studying inter-correlations between the model elements (chapter 6). We showed that, at baseline, only self-efficacy was significantly related to the participants' final levels of physical activity and the stages of exercise change reached by the participants. Consistent with findings in other studies of physical activity behaviour [1,2], self-efficacy seems to be an explanatory factor of health behaviour. We therefore believe that self-efficacy may be an important precondition for interventions aimed at changing health behaviours. However, caution should be exercised in hypothesizing that greater self-efficacy leads to higher levels of physical activity in people with an SCI, or that changes in self-efficacy result in changes in physical activity.

The baseline values of the other determinants in our theoretical model did not show significant relationships with the behavioural outcomes. For instance, we examined the change from baseline in the determinant scores of the intervention group and the change in the outcomes of this group, but these analyses did not show any statistically significant relationships. This suggests that the baseline characteristics included in our study were not explanatory factors for change in physical activity behaviour. In addition, our results do not support the hypothesis that changes in the determinants result in changes in physical activity behaviour.

To summarize, our study results did not support a role for the determinants of TTM and TPB in changing behaviour, with the partial exception of self-efficacy. In the literature, there is much discussion about the determinants of physical activity behaviour and which should be included in interventions. Three reviews on this topic concluded that it is difficult to determine which determinants can be changed and which behavioural techniques are effective for achieving changes in physical activity behaviour in SCI [3] and other chronic disorders. [4, 5] However, a recent study did show significant relationships between the determinants we used in our study and physical activity outcomes in populations with chronic disorders. [6] Thus, care should be exercised before rejecting the validity of our theoretical model, even though it was not supported by the results from our study.

Suitability of the techniques used in the HABITS intervention

Our intervention was focused on changing the determinants in the theoretical model to achieve our main outcome, a change in physical activity behaviour. However, as described, the results were negative. This raises the question: was the design of the HABITS intervention appropriate for changing the determinants in order to achieve a change in physical activity behaviour? For example, did it involve appropriate tools and behavioural techniques and was the delivery intervention sufficiently strong?

To answer these questions, we examined the results of intervention studies that used similar behavioural techniques and tools for participants with an SCI. Many studies have shown positive effects on physical activity with behavioural interventions or techniques that were similar to ours (although the participants in those studies were patients with a relatively recent SCI compared with the participants in our study). For example, three studies including individuals with a recent SCI (one RCT including 44 participants [7], and two pre-post studies which included 32 [8] and 16 participants [9]) in which a self-reported measure of physical activity was used as feedback during a behavioural intervention, all showed positive effects on physical activity behaviour immediately after the intervention. [7, 9, 10] Telephone counselling has also been reported to be an effective intervention. [9] Furthermore, interventions that combined action and coping planning have been found to be more effective than those that use action planning alone. [7] Motivational interviewing, a conversational technique, has also proved effective in eliciting behavioural change, such as in physical activity. [11, 12] These behavioural techniques were similar to our intervention. Apart from the fact they were used in a population with a more recent SCI, this gave us good reasons to believe that we chose appropriate behavioural techniques for our intervention.

In our study, we combined different behavioural change techniques in one intervention. However, a disadvantage of this approach is that the specific effect of each technique cannot be assessed. Combined approaches have been used in previous studies. For example, two systematic reviews -including comparative studies aimed at behaviour change techniques in general (135 articles included)[5] and to increase physical activity (24 articles included) [6] underlined the need for multicomponent interventions that combine different behavioural techniques (such as action planning, motivational interviewing, proactive coping and mastery experiences) to elicit changes in health-related behaviour, such as in physical activity. However, these reviews concluded that it was difficult to examine the contribution of each component of the interventions.

A further question is whether the intervention period and level of support in the present study were sufficient for the application of the behavioural techniques. The duration of the intervention may have been too short to change the behaviour of some of the participants. A period of 6 months is often considered necessary to elicit a behavioural change. [13] Unfortunately, the intervention period for this study was restricted to 16 weeks to allow comparison with the RCT studies of the umbrella ALLRISC project [14]. A longer intervention would have been a burden for the participants; transportation to the rehabilitation centre is difficult for most people with SCI. [15] In addition, there were practical and financial reasons that required the intervention to be designed in this way. To address the shorter length of the intervention, the participants were given tools and taught enhanced skills to allow them to pursue or develop new behaviours after the end of the intervention. However, pursuing new learned behaviour without support may have been too difficult.

It is possible that the multicentre character of our study resulted in non-uniform execution of the intervention, or that the intervention was not executed entirely according to the protocol. However, we made every arrangement to ensure that the intervention was executed as intended. The counsellors received three training sessions in advance of the intervention, and there was a contact meeting during the intervention in which the protocol and process were discussed. Furthermore, the coaches underwent training in motivational interviewing and were specifically trained for the HABITS study. During the study, the coaches were able to maintain and develop their skills with refresher courses. For these reasons, we do not believe that the execution of the protocol or the multicentre nature of the study strongly influenced the results. Moreover, a multilevel analysis found no differences in results between the centres.

Suitability of the intervention for the study population

Differences in study population may be a possible explanation for the lack of positive results in our study when compared to previous studies. For example, the intervention of Nooijen et al. [11] was similar to ours, but the SCIs of the participants in that study were still in the acute phase. A study of ter Hoeve et al. [16] reported positive effects for an intervention, based on similar behavioural techniques to ours, aimed at motivating people who had recently experienced a cardiac arrest to become more physical active. In two other studies that reported the effective use of behavioural techniques to increase physical activity in participants with SCIs, the SCIs were relatively recent, from acute to 5 years post-injury. [3, 17] The main difference between our study and those studies was that we included participants with a long-standing SCI, who were therefore in a chronic phase of their disability, instead of those with a recent life-changing disability.

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This raises the question of whether the HABITS intervention may have been successful with a different study population. A recent life-changing condition (such as an SCI, stroke or heart attack) could provide a window of opportunity to change behaviour. Such dramatic events result in an individual's life being turned upside down, with the need to relearn daily activities and behaviours. It might be easier to elicit additional health-related behaviours, such as increased physical activity, at the same time as the individual develops these new learned behaviours than to change unhealthy behaviours that have become habitual for people with a long-standing SCI or other chronic condition. We assumed that agreeing to participate in our study would mean that the participants were motivated to change their behaviour, but this may have been insufficient. Several studies on behavioural interventions for people with a long-standing chronic physical disability based on similar behavioural techniques to those in the present study, such as motivational interviewing, reported no long-term effects on physical activity. [17-20] When designing an intervention, it is important to consider whether the intervention can feasibly change behaviour in the target population; in some populations, the intended behavioural change may be unachievable.

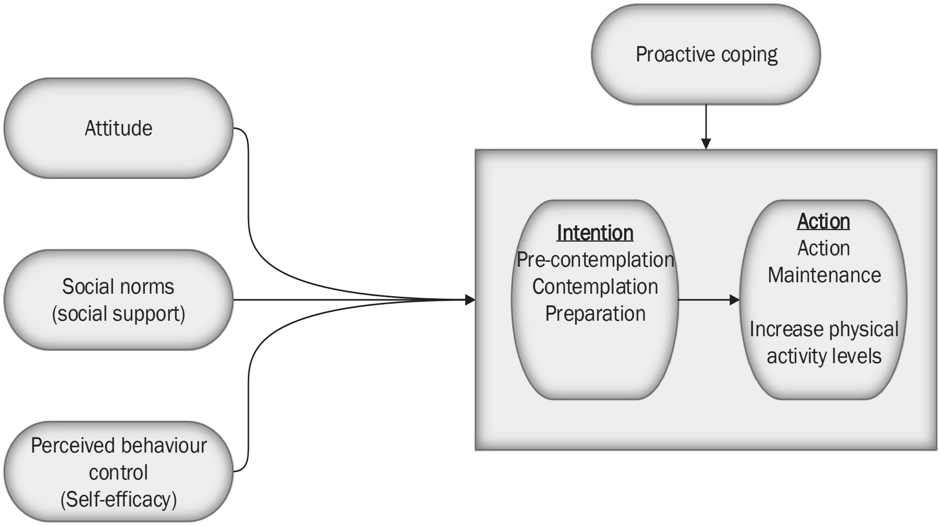

Figure 1 The combined theoretical model used as a basis for these studies

Suitability of the objective measure of physical activity

The primary aim of the intervention was to increase the participants' levels of physical activity. We therefore measured daily physical activity objectively with a new type of activity monitor that measured each participant's use of their self-propelled wheelchair (chapter 3). This was a strength of our study, because it is well established that an objective measurement of physical activity is more reliable than self-reported instruments [21], which are sensitive to recall bias and often overestimate the amount of physical activity performed in daily living. [21, 22] The monitoring system used two accelerometers (ActiGraph GT3X+) that are commonly used in research involving ambulant subjects. One accelerometer was attached at the participant's wrist, the other to the spokes of the wheelchair wheel. Based on the movement intensity of the two accelerometers, a custom-made algorithm differentiated between self-propelled wheelchair driving and other activities, such as being pushed or arm movements unrelated to wheelchair propulsion.

We conducted validity testing to assess whether self-propelled wheelchair driving could be reliably detected by the new method. This showed good validity scores: overall agreement (percentage of correct classification by the accelerometers) for the detection of self-propelled wheelchair driving was 85%, with sensitivity 88% and specificity 83%. The method was innovative; at the start of the study, there were no other devices that objectively quantified time periods of self-propelled wheelchair driving. Our method was less burdensome to wear and cheaper than instruments previously validated and used at the Department of Rehabilitation Medicine of Erasmus University Medical Centre [20], because only one small accelerometer was fixed to the participant's body; this was easily worn as a wristwatch. The previous methods included a greater number of larger devices, such as one on each wrist and one attached to the trunk [11] or even five devices, with an additional sensor attached to each upper leg. [20]

Unfortunately, we encountered some practical difficulties with the monitor during the HABITS trial. Some of the participants did not comply with wearing the activity monitor for 5 days; some did not wear the activity monitor at all and other wore it only for a limited time. This is an established issue in research that includes activity monitors [23], but it was especially significant in our study. Insight into the reasons for non-compliance were obtained from the diaries the participants were asked to keep during the measurement period, in which they could indicate when they removed the activity monitor (such as during a bath), with space for additional comments. The participants indicated that they found it bothersome to wear the activity monitor. They did not like it that the activity monitor was in sight, even though it could be worn as a watch. It is important that more user-friendly devices are developed.

The market for consumer activity trackers has increased enormously during the last decade. For example, Apple Watch has a function to detect self-propelled wheelchair driving. [24] Devices have become smaller, cheaper, better and more user-friendly. However, few devices can validly assess self-propelled wheelchair driving. Since the RCT described in this thesis, our activity monitor has undergone further development, including a change to smaller sensors, which are more user-friendly. [25] Modern devices worn on the wrist can also measure heart rate, which can be used as a measure of energy expenditure. [25] Extra funding from Rijndam Rehabilitation Centre has been provided to develop our activity monitor further into a real consumer device that provides the user with direct feedback (via a smartphone application) about his or her current level of active wheelchair use. This project is ongoing.

Devices with more feedback options, such as a measure of heart rate, walked or wheeled distance, may help to improve compliance in future interventions. To reduce the possibility of bias in our study, we did not want the participants to know what the activity monitor actually measured. However, immediate feedback on physical activity and the possibility of tracking of activity levels and sharing these with other people are important motivating factors for the use of such a device. We conclude that an activity monitor should be less burdensome that the type used in our study; for example, it should be very small and not visible to other people, it should provide instant feedback on physical activity levels, and the user should not be aware he or she is wearing it.

Methodological considerations

The need for a pilot study

Because of restrictions in time and money, as well as practical barriers, we were unable to perform a pilot study before starting the RCT. With our current knowledge, we would be highly likely to conduct a pilot study in future research. This would provide advance knowledge about practical problems, such as difficulties with recruitment, the intervention and measurements.

Study design

We attempted to avoid any form of bias in this study. A strength of the study was its double-blind, multicentre, randomized controlled trial design. However, although it was intended that the research assistants making the measurements would be blinded to group allocation, this was not always possible because they were working as therapists in the same rehabilitation centres as attended by the participants and the behavioural intervention coaches. However, we believe that this will not have strongly influenced the results, because most outcomes were measured objectively (e.g., with the activity monitor) or with self-reported questionnaires. The researcher who analysed the data was blinded for group allocation until after the analyses of the primary and secondary outcomes.

Study population

This study faced a number of practical challenges in recruitment. As with many other RCTs, it was difficult to enrol enough participants to achieve the sample size needed according to the power calculations. This practical challenge resulted in methodological consequences, which should be taken into account when interpreting the results of the study. This section describes the practical challenges and discusses their methodological consequences.

Practical challenges in recruitment

A number of general issues affected recruitment to our RCT. First, we applied strict inclusion and exclusion criteria, including time since injury, age at the onset of the SCI, current age, and wheelchair propulsion ability. These criteria excluded a large number of possible participants. In addition, HABITS was a multicentre project; recruiting by the same people at multiple locations increased the difficulty with regard to coordination, time restrictions and not overlooking participant characteristics that affected inclusion.

Figure 2 shows the enrolment flowchart for the study. Patients eligible to participate were initially selected based on applying the inclusion and exclusion criteria to their medical record data. Of the initial 805 patients, 752 were traceable and were sent an information letter. From these, 655 were contacted by a research assistant and asked if they were willing to participate; 426 declined and 60 more did not fully meet the inclusion and exclusion criteria. Finally, we included 64 participants in the study, only 8.5% of the initially eligible participants.

This small percentage might have led to bias. The type of people who declined to participate, and their reasons for non-participation, were investigated by asking them, during the recruitment conversation with the research assistant, if they would give a reason for non-participation. Of the 426 who declined to participate, 100 provided reasons. In addition, each was invited to complete a non-participation questionnaire (NPQ), which largely corresponded to the baseline questionnaire administered to the participants of the RCT; 52 agreed to do so. The main reasons for non-participation mentioned during the conversation and in the NPQ were as follows: too busy or with limited time to participate; unable to come to the rehabilitation centre; and the intervention was not applicable to them. The reasons given for non-participation are summarized in figure 2.

The NPQ responses allowed us to compare the characteristics of this group with those of the study sample. The main findings were as follows: the time since injury was significantly shorter for the non-participants; they were more highly educated; they spent more time participating in sports; and they scored higher on negative attitudes about exercising than the study participants. Compared to the study participants, more of the non-participants were in the contemplation phase, and fewer were in the preparation and action maintenance phases. These differences between the participants and the non-participants were mostly expected and could be explained; for example, people with a more recent injury had been given more tools and materials during their rehabilitation to support physical activity, such as receiving a hand-cycle and training. [11]

As well as asking their reasons for non-participation, the non-participants were asked if any changes in the protocol would have resulted in their participation. The responses indicated that more would have been motivated to participate if the intervention had been offered as an e-health programme (an intervention programme offered via the internet). Such programmes can usually be followed from home and therefore involve less time and cost, and participants do not have to attend a rehabilitation centre. These programmes are also easier to implement. However, behavioural change may need more intensive personal contact [3] and an e-health intervention may not have the intensity needed to change behaviour. We believe a blended approach combining face-to-face contact and an e-health programme might be more effective.

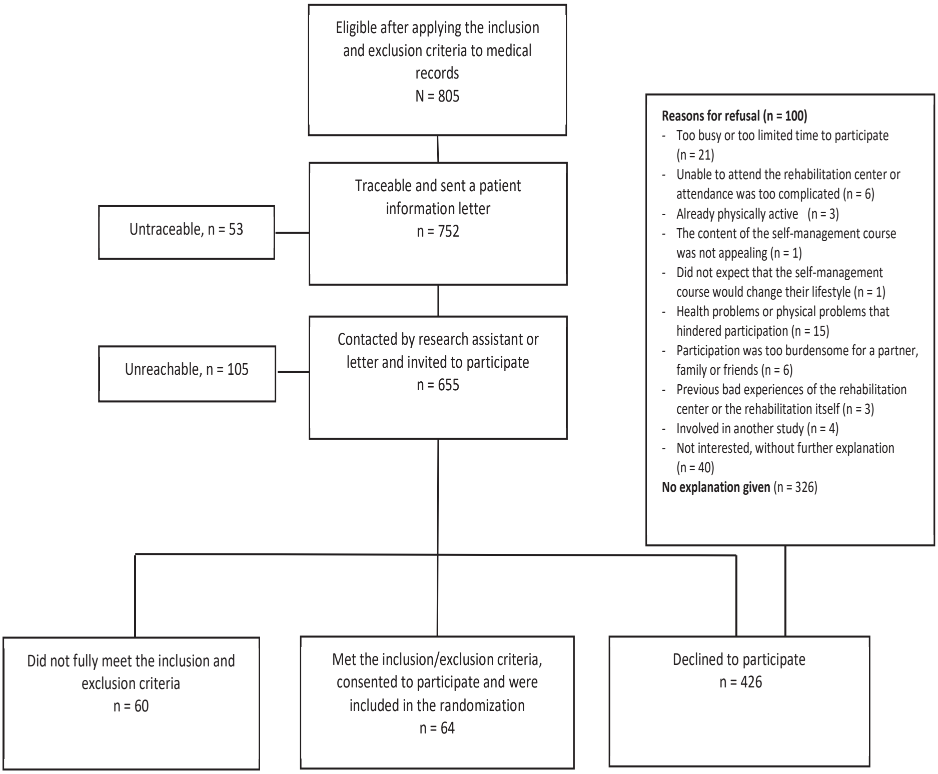

Figure 2 Enrolment flowchart of the participants in the HABITS RCT.

Methodological consequences

As described, only a small proportion of the initially eligible patients were included in the study and there were differences in characteristics between the participants and non-participants. This indicates that the study sample was not representative of the eligible population. Furthermore, data about reasons for non-participation were available only for a select group. Therefore, there should be caution with regard to the external validity of our study.

Issues related to the study population

People with a long-standing SCI can be vulnerable. Some of the study participants had to cope with several secondary health conditions (SHCs) that interfered with their compliance in our study. During the trial, several participants had to stop temporarily or end their participation in the trial because of these problems, contributing to the high level of missing data in our study. Bloemen-Vrencken et al. [26] reported that people with a long-standing SCI experience more SHCs than people with a more recent SCI. [27] Even though the aim of our study was a healthier, more active lifestyle, we were unable to retain all the participants in the study.

Another problem we encountered was that the aim of the study (increasing physical activity) was not always the most important goal for the participants. Although we did not measure this in a standardized way, we received several anecdotal indications of this during the study. For example, some participants reported problems that were more important to them than their low level of physical activity, such as losing weight. Physical activity can result in weight loss, but in this study it was not used as a tool for losing weight. Weight loss in people with an SCI is more complex than for able-bodied people because of their altered metabolism [28]; they require a special diet and additional nutritional counselling. [29]

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Implications and recommendations

Implications for the aftercare and rehabilitation of people with SCIs

Healthcare professionals understand the benefits of daily physical activity and thus the need to encourage increased levels of activity for people with SCIs. The findings of this study showed that a short intervention did not result in significant behavioural change; we therefore believe it is important to discuss levels of physical activity with this patient group during check-ups in the rehabilitation centres. Until recently, people with a long-standing SCI did not routinely attend check-ups at the specialized rehabilitation centres. [14] However, another ALLRISC project showed the need for regular check-ups to treat SHCs related to a long-standing SCI [27], offering an opportunity to engage these individuals in discussions about physical activity.

When people with SCIs are open to changing their physical activity behaviour, an activity monitor might be an effective tool to provide them with insight into their activity levels and to motivate them to become more active. As described earlier, activity monitors are increasingly easy to implement in daily care, and they are available from various providers.

In addition to low levels of physical activity, health care providers should examine which other health-related behaviours people with a long-standing SCI need to address, such as weight loss. These may be more important to the patient than increasing physical activity. When future health behavioural interventions are developed, action can be targeted at problems the patients actually experience.

An easier alternative to the HABITS intervention for eliciting behavioural change in the rehabilitation setting may be to use motivational interviewing in a one-to-one setting instead of as a tool in group sessions. In the Netherlands, increasing numbers of care providers in the rehabilitation setting are familiar with the techniques of motivational interviewing. This could be an effective way to elicit health behavioural changes in people with a long-standing SCI, and could be integrated into the rehabilitation setting.

Other clinical implications

There are several lessons that can be learned from our research for clinical practice more generally. In particular, there are implications for patients with chronic illnesses, for encouraging behavioural change, and for measuring physical activity.

First, building on the point made earlier, it is important to examine the problems that are actually experienced by patients with chronic illnesses or disabilities instead of simply offering a pre-defined intervention with an established health goal (in our case, increasing physical activity). When interventions are focused on the patients' self-selected health goals, they will probably be more driven by their intrinsic motivation and the intervention is likely to be more effective. We believe it is difficult to change long-term habits if the change is not experienced as a necessity by the patients themselves. We have to acknowledge that most people with a chronic disease are not motivated and convinced of the need to change their physical activity levels, or have other priorities. Perhaps it is better to focus only on people who have the intrinsic motivation to change their behaviour.

If people with a chronic disease are motivated to change their health behaviour, such as increasing their level of physical activity, self-efficacy should be taken in to account when offering behavioural interventions in daily practice. Our analysis showed that self-efficacy was an explanatory factor for the change in level of physical activity and the stages of exercise change reached by the participants. As reported in other behavioural studies [3, 6, 7, 9, 10, 30, 31], self-efficacy seems to be a relevant mediating determinant of health behaviour and of physical activity [1, 2, 32].

In this study, we developed a validated method for measuring the daily physical activity of wheelchair bound people. This may be a useful tool for the rehabilitation of people confined to wheelchairs for reasons other than an SCI, particularly after the device has undergone the further developments described earlier. The direct feedback about physical activity levels and energy expenditure provided by activity monitors could be an important tool in behavioural interventions and could help to increase compliance. Such a device could also be used for routine check-ups in rehabilitation, providing physicians with an objective insight into the activity levels of their patients. In addition, feedback on the activity levels could form a basis for conversations with the patients.

Future research

The ALLRISC study [14, 27] showed that people with a long-standing SCI have various health issues that need attention. Just as in the normal population, the prevention of health problems is important for people with a long-standing SCI. However, people with a chronic disorder often have a higher burden of disease, with multiple chronic conditions. [33] To be effective, preventive interventions should focus on the most important or most limiting types of problems experienced by people with long-standing SCIs. A generic self-management intervention based on self-chosen goals and tailored to an individual's intrinsic motivations to change his or her health behaviour might be effective for rehabilitation aftercare; this should be investigated in future research.

Clinicians may need to think about placing the responsibility to change behaviour on the individuals themselves, instead of imposing interventions on their patients. Provided that people with a long-standing SCI have enough information about their disorder and the additional benefits of healthy behaviour, such as physical activity, and are aware of what behavioural interventions are available, they can choose whether they wish to work on a health problem. The relevant information could be provided during check-ups. It is likely that the individual's motivation and the subsequent success rate in changing his or her behaviour would be higher when the individual has taken that decision independently. Future studies are needed to investigate this will apply on health behaviours like physical activity.

Technological developments will improve the objective measurement of physical activity by wearable devices, making these easier to use and more user-friendly in the future. It is likely these devices will increasingly combine different types of input, such as accelerometry, heart rate, location-tracking such as GPS and electronic diaries, and will provide different types of feedback, such as about sleep, stress and fatigue. An activity monitor could be an important tool in future behavioural intervention. Future research is needed to provide insight into the added value of having objective feedback about activity levels, and in how people with a long-standing SCI experience wearing such an activity monitor when used during rehabilitation.

To overcome the practical objections to participation in a behavioural intervention, other intervention designs should be examined. Limited time and having to travel to the rehabilitation centre were mentioned as main reasons for non-participation in our study. These problems can be overcome by conducting an e-health intervention or an intervention aimed at social groups such as running groups. However, the content and the effectiveness of such interventions for people with long-standing SCI requires future study.

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Summary

People who have lived with a spinal cord injury over a long period generally tend to be physical inactive. Previous research has shown that people who suffer a spinal cord injury become less physically active, and that their level of physical activity continues to decrease. Their activity levels are especially low compared to the general population and it is even lower than that of people with other chronic conditions. Conversely, a physically active lifestyle can improve the health of people with a spinal cord injury; for example, physical activity reduces the risk of cardiovascular disease, prevents secondary health disorders and increases physical fitness, as well as improving the individual's quality of life.

Previous research has shown that behavioural change to develop a healthier, more active lifestyle requires more than just information about the benefits of physical activity or physical fitness training. There have been indications that a self-management intervention would be an effective way to improve physical activity levels. Such an intervention would combine the provision of information with active learning strategies and behavioural change techniques to increase the individual's self-management skills. These skills facilitate behavioural change so that the individual develops and maintains a more active physical lifestyle. Examples of self-management skills related to physical activity are: Self-efficacy, the confidence in being able to exercise more; Attitude, the pros and cons the individual feels about physical activity; Social Support, the support for becoming more physically active received by the individual from his or her environment; and Proactive Coping, the development of strategies by the individual in advance to solve potential problems that may restrict him or her from becoming more physically active.

The main objective of the study described in this thesis was to examine the effectiveness of a 16-week self-management intervention in changing the level of physical activity of people who have lived with a spinal cord injury for a long time. We also examined whether the self-management intervention contributed to an improvement in the level of exercise behaviour of the participants and whether it resulted in an improvement in their self-management skills. In addition, the study tested the validity of a newly developed device for appropriately measuring the physical activity of the participants; this was based on an activity monitor that measured their self-propelled wheelchair driving.

The main research of this thesis was based on a theoretical model of the relationship between self-management skills and physical activity. This model was based on two behavioural change theories: the transtheoretical model of behavioural change and the theory of planned behaviour. A further aspect of the study, therefore, was to investigate the relationship between self-efficacy and physical activity, testing the hypothesis that, among people with a long-standing spinal cord injury, those who have a higher level of self-efficacy level have higher activity levels.

Chapter 1 describes the consequences of spinal cord injury, and especially the low levels of physical activity that are generally the result of a long-lasting standing injury. The chapter briefly describes self-management and behavioural interventions that promote physical activity, and it provides an overview of the Healthy Active Behavioural Intervention Spinal Cord Injury (HABITS) study, a randomized controlled trial conducted as part of the umbrella project ALLRISC. The chapter ends by outlining the goals and structure of the thesis.

Chapter 2 describes the design of the HABITS randomized controlled trial and explains the theoretical model on which the study was based, which served as a theoretical background for choosing the outcome measures and developing the intervention. The chapter lists the inclusion and exclusion criteria for potential participants, of which the most important were having a spinal cord injury for at least 10 years, being aged 28–65 years old, the ability to drive a wheelchair independently, being physically inactive, and the intention to change exercise behaviour within 6 months. The main outcome measure was physical activity level and the secondary outcome measures were the stages of behavioural change achieved by the participants and their levels of self-management skills (self-efficacy, attitude, social support and proactive coping). Finally, the chapter explains the design of the intervention. The 16-week self-management intervention combined active learning strategies with behavioural techniques to improve self-management skills, with group and individual sessions supported by a specially trained

coach. The control group received only a book about exercise and one information meeting about an active healthy lifestyle.

Chapter 3 describes the validity testing of the device (activity monitor) developed to detect and measure self-propelled wheelchair driving. Independent wheelchair driving is considered to be a measure of physical activity in people with spinal cord injury. The measuring device comprised two small sensor units, one attached to the spokes of the wheelchair and one to the wheelchair user's wrist with a strap. Movements were registered by both sensors simultaneously and were analysed by a custom-developed computer algorithm that quantified, second by second, whether or not the wheelchair was being propelled by the user. To validate the output of the activity monitors, comparisons were made with video recordings of 10 participants with spinal cord injuries. The participants wore the activity monitors and were filmed while performing various wheelchair activities. Two independent researchers scored the video images second by second according to whether or not the participant was propelling the wheelchair and the results were compared with those of the computer algorithm. This demonstrated a high degree of correspondence between the two sets of results, confirming that the activity monitor was a valid instrument for detecting propelled wheelchair driving as a measure of an individual's physical activity, with high sensitivity and specificity.

Chapter 4 discusses the relationship between exercise self-efficacy and the level of physical activity in people with a long-standing spinal cord injury, testing the hypothesis that people with higher self-efficacy levels are more physically active than those with lower self-efficacy levels. This research used a large dataset of individuals who had lived with a spinal cord injury for more than 10 years. Self-efficacy and physical activity were measured by means of questionnaires, taking account of potential confounders, such as time since injury, age, sex and the level of the spinal cord injury. A significant association was found between self-efficacy and physical activity, even when controlling for these other characteristics. This showed that self-efficacy might be an important characteristic that should be taken into account when increasing physical activity levels.

Chapter 5 describes the results of the randomized controlled trial that tested the HABITS self-management intervention. This showed that the intervention did not contribute to the participants becoming more physically active (as measured by the activity monitor and a questionnaire) than the control group that did not receive the self-management intervention. The intervention also had no effect on the secondary outcomes of the study: compared with the control group, the participants who underwent the intervention did not achieve an improved stage of exercise change and did not improve their self-management skills. We concluded that the HABITS intervention was not effective in increasing physical activity levels, improving the stage of exercise change or improving the self-management skills of people with a long-standing spinal cord injury.

Chapter 6 tested whether the theoretical model could explain the relationship between self-management skills and physical activity. The determinants in this model were based on two behavioural change theories: the transtheoretical model of behavioural change and the theory of planned behaviour. In addition, the model included elements of the proactive coping strategy. The determinants were attitude, self-effectiveness, social support and proactive coping. Two questionnaires were used to measure behaviour in terms of the level of physical activity and stage of exercise change. At baseline, a significant relationship was detected between self-efficacy and physical activity and self-efficacy and the stages of exercise change. Furthermore, no relationships were found between the behaviour at baseline (the first measurement time point, prior to the intervention) and any of the determinants. Similarly, neither the physical activity levels at the second measurement time point (after the intervention) nor the change in physical activity levels between the first and second time points showed relationships with the baseline determinants. Thus, the determinants from the models used in this study did not facilitate behavioural change in people with a long-term spinal cord injury. Although caution should be exercised with drawing conclusions, our results question the usability of these theoretical models in defining and evaluating physical activity interventions for people with a long-term spinal cord injury.

Chapter 7 presents a general discussion of this thesis. This chapter describes the most important findings and interprets of the results. In addition, it describes the strengths and weaknesses of the research design and concludes with clinical implications and recommendations for future research.

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Samenvatting

Mensen die al een lange tijd een dwarslaesie hebben, bewegen over het algemeen zeer weinig. Uit eerder onderzoek is gebleken dat na het oplopen van een dwarslaesie mensen minder lichamelijk actief zijn en dat lichamelijke activiteit verder afneemt naar een niveau dat zeer laag is vergeleken met de algemene bevolking. Ook in vergelijking met mensen met andere chronische aandoeningen is dit niveau laag. Meer bewegen bij mensen met een dwarslaesie verbetert de gezondheid. Lichamelijke activiteit vermindert bijvoorbeeld de kans op hart- en vaatziekten, voorkomt secundaire aandoeningen, en vergroot lichamelijke fitheid en kwaliteit van leven.

Uit eerder onderzoek is gebleken dat voor gedragsverandering naar een actievere leefstijl meer nodig is dan alleen het trainen van lichamelijke fitheid of alleen het geven van informatie over de voordelen van lichamelijke activiteit. Daarnaast waren er bij aanvang van de studie aanwijzingen dat een zelfmanagementinterventie een effectieve manier is om lichamelijke activiteit te verbeteren. In een dergelijke interventie worden informatie met actieve leerstrategieën en gedragsveranderingstechnieken gecombineerd, waardoor zelfmanagementvaardigheden worden vergroot. Deze zelfmanagementvaardigheden faciliteren gedragsverandering naar een actievere lichamelijke leefstijl en mogelijk zelfs het behoud hiervan. Onderdelen van zelfmanagementvaardigheden zijn (beweeg) zelf-effectiviteit, attitude, sociale support en proactieve coping. Zelf-effectiviteit betreft het vertrouwen dat het lukt om meer te gaan bewegen, attitude de houding die mensen hebben ten opzichte van bewegen, sociale support de ondersteuning die je uit je omgeving krijgt om meer te gaan bewegen, en proactieve coping het van tevoren bedenken hoe je omgaat met problemen die in de weg staan om lichamelijk actiever te worden.

De belangrijkste doelstelling van het onderzoek beschreven in dit proefschrift was het onderzoeken van de effectiviteit van een 16 weken durende zelfmanagementinterventie - genaamd HABITS - op het niveau van lichamelijke activiteit bij mensen die al een lange tijd een dwarslaesie hebben. Daarnaast hebben we onderzocht of de zelfmanagementinterventie er ook aan bijdroeg dat deelnemers veranderden op factoren die voorwaardelijk werden geacht voor verandering in fysieke activiteit, zoals de fases van beweeggedragsverandering en of zelfmanagementvaardigheden. Om lichamelijke activiteit goed te kunnen meten is er een meetinstrument ontwikkeld en is de validiteit daarvan onderzocht. Het meetinstrument behelst een activiteitenmonitor die zelfstandig rolstoel rijden - als maat van lichamelijke activiteit - kan meten.

Het primaire onderzoek van dit proefschrift was gebaseerd op een theoretisch model dat de relatie tussen zelfmanagementvaardigheden en lichamelijke activiteit beschrijft. Dit model was gebaseerd op twee gedragsveranderingstheorieën: het trans-theoretisch model van beweeggedragsverandering en de theorie van gepland gedrag. Een ander aspect van de studie was daarom het onderzoeken van de relatie tussen zelf-effectiviteit en lichamelijke activiteit. Hierbij werd de hypothese getoetst dat mensen met een langdurige dwarslaesie met een grotere zelf-effectiviteit ook meer lichamelijk actief zijn.

Hoofdstuk 1 beschrijft de gevolgen van een dwarslaesie - en met name de gevolgen van een langdurige dwarslaesie - op het niveau van lichamelijke activiteit. Kort worden zelfmanagement- en gedragsinterventies beschreven die lichamelijke activiteit bevorderen. Daarnaast wordt HABITS (Healthy Active Behavioural IntervenTion Spinal cord injury) ingeleid, en wordt het ALLRISC project beschreven waarbinnen de studies van dit proefschrift werden uitgevoerd. Het hoofdstuk sluit af met de doelen en de opzet van het proefschrift.

Hoofdstuk 2 beschrijft de opzet van het gerandomiseerde gecontroleerde onderzoek dat centraal staat in dit proefschrift (HABITS). In dit hoofdstuk wordt het theoretisch model waarop het onderzoek is gebaseerd uitgelegd. Dit theoretisch model diende als theoretische achtergrond waarmee de uitkomstmaten zijn geselecteerd en waarop de interventie is ontwikkeld. Daarnaast beschrijft dit hoofdstuk de criteria waarop potentiële deelnemers werden geïncludeerd of geëxcludeerd van de studie. De belangrijkste criteria waren: tenminste 10 jaar een dwarslaesie, tussen de 28-65 jaar oud, volledig rolstoel gebonden, in staat om zelfstandig rolstoel te rijden, lage niveaus van activiteit, en de intentie om binnen 6 maanden hun beweeggedrag te veranderen. De belangrijkste uitkomstmaten waren de mate van lichamelijke activiteit, de fase van beweeggedragsverandering; de secundaire uitkomstmaten waren de zelfmanagementvaardigheden (zelf-effectiviteit, attitude, sociale support en proactieve coping). Tot slot wordt in dit hoofdstuk de opzet van de interventie uitgelegd. De zelfmanagementinterventie was opgebouwd uit actieve leerstrategieën en gedragsveranderingstechnieken en werd gegeven door een speciaal getrainde coach. De interventie duurde 16 weken waarbij groepsbijeenkomsten onder begeleiding van de coach werden afgewisseld met 10 individuele gesprekken met de coach. De controlegroep ontving alleen informatie over lichamelijke activiteit en een dwarslaesie door middel van een informatiebijeenkomst en een boek.

Hoofdstuk 3 beschrijft het valideringsonderzoek van het meetinstrument (activiteitenmonitor) dat is ontwikkeld om zelfstandig rolstoel rijden te meten. De hoeveelheid zelfstandig rolstoel rijden kan worden gezien als een maat van lichamelijke activiteit bij mensen die een dwarslaesie hebben. De ontwikkelde en gevalideerde activiteitenmonitor bestaat uit twee kleine sensoren die zijn bevestigd aan de pols en aan de spaken van de rolstoel. Bewegingen werden door beide sensoren tegelijkertijd geregistreerd en werden geanalyseerd door een zelf ontwikkeld computeralgoritme dat per seconde kwantificeerde of er zelfstandig rolstoel werd gereden of niet. Om de output van de activiteitenmonitor te valideren, werden vergelijkingen gemaakt met video-opnames van 10 deelnemers met een dwarslaesie. De deelnemers droegen de activiteitenmonitor en werden gefilmd tijdens het uitvoeren van verschillende rolstoelactiviteiten. Twee onafhankelijke onderzoekers hebben de videobeelden per seconde gescoord of de deelnemers aan het zelfstandig rolstoel rijden waren of niet, en deze resultaten werden vergeleken met het computeralgoritme. Beide registraties kwamen grotendeels overeen (85%), dit uitte zich in een hoge specificiteit (83%) en sensitiviteit (88%). Daarmee wordt bevestigd dat de activiteitenmonitor een valide meetinstrument is om zelfstandig rolstoel rijden te meten als maat van lichamelijke activiteit.

In **Hoofdstuk 4** wordt de relatie tussen zelf-effectiviteit en het niveau van lichamelijke activiteit beschreven. De voorspelling was dat mensen met een grotere zelf-effectiviteit meer bewegen dan mensen met een lagere zelf-effectiviteit. Voor dit onderzoek is gebruik gemaakt van een grote dataset uit het ALLRISC onderzoek van mensen die al een lange tijd een dwarslaesie hebben (≥ 10 jaar). Door middel van vragenlijsten is zelf-effectiviteit en lichamelijke activiteit gemeten. In de analyses is er rekening gehouden met potentiele confounders, zoals leeftijd, geslacht, hoogte dwarslaesie en duur van de dwarslaesie. Er was een significantie relatie tussen zelf-effectiviteit en lichamelijke activiteit, ook als er rekening werd gehouden met de potentiele confounders. Deze significante relatie laat zien dat zelf-effectiviteit een mogelijke determinant is waar rekening mee kan worden gehouden bij het vergroten van lichamelijke activiteit.

Hoofdstuk 5 beschrijft de resultaten van de eerder genoemde gerandomiseerde gecontroleerde trial. De zelfmanagementinterventie HABITS droeg er niet aan bij dat mensen met een langdurige dwarslaesie lichamelijk actiever (gemeten door de activiteitenmonitor en vragenlijst) werden ten opzichte van de controlegroep die geen zelfmanagementinterventie heeft ontvangen. Daarnaast had de interventie ook geen effect op de secundaire uitkomstmaten. Vergeleken met de controlegroep zijn de deelnemers die de HABITS-interventie hebben gevolgd niet vooruitgegaan op de fases van beweeg gedragsverandering en hebben zij hun zelfmanagementvaardigheden niet verbeterd. Hieruit moeten we concluderen dat de HABITS-interventie niet effectief was in het bevorderen van lichamelijke activiteit, in het vooruitgaan in de fases van beweeg gedragsverandering en het vergroten van zelfmanagementvaardigheden bij mensen met een langdurige dwarslaesie.

In **hoofdstuk 6** werd getoetst of het theoretisch model de relaties tussen zelfmanagementvaardigheden en lichamelijke activiteit kon verklaren. De determinanten in dit model waren gebaseerd op de twee eerder genoemde gedragsveranderingstheorieën: het trans-theoretisch model en de theorie van gepland gedrag. Daarnaast bevatte het model aspecten van de proactieve copingstrategie. De determinanten van het theoretisch model waren attitude, zelf-effectiviteit en sociale support. Het gewenste gedrag - lichamelijke activiteit en de fases van beweeg gedragsverandering - werden gemeten door middel van vragenlijst. Op baseline (het meetmoment voor de start van de interventie) werd er een significante relatie gevonden tussen lichamelijke activiteit en zelf-effectiviteit, en tussen de fases van beweeggedragsverandering en zelf-effectiviteit. Op baseline werden er geen significante relaties gevonden tussen de andere determinanten en de gedragsuitkomsten. Verder werden er geen significante relaties gevonden tussen de veranderingen in gedragsuitkomsten en de baseline determinanten; ook vonden we geen relaties tussen de veranderingen in gedragsuitkomsten en de veranderingen in determinanten. Hoewel voorzichtigheid geboden is bij het trekken van conclusies, lijken we de bruikbaarheid van deze theoretische modellen in twijfel te kunnen trekken bij het ontwikkelen en evalueren van interventies gericht op het vergroten van lichamelijke activiteit bij mensen met een dwarslaesie.

Hoofdstuk 7 bevat de algemene discussie van dit proefschrift. Dit hoofdstuk beschrijft de belangrijkste bevindingen en interpretaties van de resultaten. Daarnaast worden de sterke en zwakke punten beschreven van het onderzoek. Het hoofdstuk wordt afgesloten met klinische implicaties en aanbevelingen voor toekomstig onderzoek.

A

About the author

Curriculum vitae

Hedwig Kooijmans was born in Amsterdam on the 24th of August 1985. After finishing high school, she started the study Occupational therapy at Rotterdam University of Applied Sciences. She obtained her bachelor´s degree in 2008. Because of her thirst in more knowledge and science she started her master study Health Sciences at the VU university in Amsterdam. She obtained her Bachelor's degree in 2009 and her Master in 2010, with a specialization in prevention of public health care.

In 2010 Hedwig started with her PhD research –as described in this thesis- at Rehabilitation department of the Erasmus MC under the supervision of prof. dr. Henk Stam. dr. Hans Bussmann and prof. dr. Marcel Post. During her PhD-project Hedwig worked from 2014-2015 as a scientific researcher at Rijndam Revalidation Centre. She started an international research project with the aim to measure patient reported outcome measures in people with a cerebral palsy.

In 2016 Hedwig worked at the Knowledge Institute of Medical Specialists. She advised and supported medical specialists in the development of quality policy and in particular evidence-based guideline development. She coordinated and supported (policy) projects and she gave functional leadership to a team.

Education and research held onto Hedwig's interests, therefore she started in October 2018 to work at The Hague University of Applied Science at the study Dermal Therapy. At the moment Hedwig is a college lecturer and coordinator of the graduation year. Furthermore she is involved in the design and development of the Dermal Therapy's research policy.

Dankwoord

Promoveren doe je niet alleen. Ik ben heel dankbaar voor iedereen die op welke manier dan ook betrokken was bij mijn promotie. In het bijzonder de volgende mensen.

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ALLRISC
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List of publications

Blikman, L.J., B.M. Huisstede, H. Kooijmans, H.J. Stam, J.B. Bussmann, and J. van Meeteren, *Effectiveness of energy conservation treatment in reducing fatigue in multiple sclerosis: a systematic review and meta-analysis.* Arch Phys Med Rehabil, 2013. 94(7): p. 1360-76.

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Kooijmans, H., M.W. Post, L.H. van der Woude, S. de Groot, H.J. Stam, and J.B. Bussmann, *Randomized controlled trial of a self-management intervention in persons with spinal cord injury: design of the HABITS (Healthy Active Behavioural IntervenTion in SCI) study.* Disabil Rehabil, 2013. 35(13): p. 1111 8.

Kooijmans, H., M.W.M. Post, H.J. Stam, L.H.V. van der Woude, D.C.M. Spijkerman, G.J. Snoek, H.M.H. Bongers-Janssen, C.F. van Koppenhagen, J.W. Twisk, and J.B.J. Bussmann, *Effectiveness of a Self-Management Intervention to Promote an Active Lifestyle in Persons With Long-Term Spinal Cord Injury: The HABITS Randomized Clinical Trial.* Neurorehabil Neural Repair, 2017. 31(12): p. 991-1004.

PhD Portfolio

Summary of PhD training and teaching

Name PhD student: **H. Kooijmans, MSc**	PhD period: **2010-2015**
Erasmus MC Department: **Rehabilitation Medicine & Physical Therapy**	Promotor(s): **Prof. dr. H.J. Stam**
Research School: **NIHES**	Supervisor: **Dr. J.B.J. Bussmann, Prof. dr. M.W. Post**

1. PhD training	**Year**	**Workload (Hours/ECTS)**
General courses		
- Biomedical English Writing and Communication	2013	3 ECTS
- Research Integrity	2014	1 ECTS
- Statistics		
- Biostatistics for clinicians (**NIHES**)	2012	30 hours
- Regression analysis (**NIHES**)	2016	56 hours
- Longitudinal data analysis	2013	32 hours
- BROK (‘Basiscursus Regelgeving Klinisch Onderzoek)	2011	1 ECTS
Specific courses		
- Course training program Spinal Cord Injury (Paog-Heyendael, VRA accredited)	2010	12 hours
- Motivational Interviewing	2011	1 ECTS
Seminars and workshops		
- PhD day Erasmus MC	2013	4 hours
- PhD day Erasmus MC	2012	4 hours
- Mini course methodology of patient orientated research and preparation for subsidy application	2011	8 hours
- Consulted library for review search strategies	2011	8 hours
Presentations		
- Oral presentation at “Mini-symposium spinal cord injury” about the study results	2015	8 hours
- Oral presentation VRA	2014	8 hours
- Poster presentation International conference of behavioral medicine	2014	20 hours

- Oral presentation at "Mini-symposium spinal cord injury"	2014	4 hours
- Poster presentation ISCOS Istanbul	2013	8 hours
- Oral presentation at reference meeting of the department why participants do not want to participate in intervention studies	2011	8 hours
- Oral presentation at "Mini-symposium spinal cord injury" about research progress and projects.	2012	8 hours
- Oral presentation regional reference meeting VRA	2011	4 hours
- Oral presentation at "Mini-symposium spinal cord injury" about research design.	2011	8 hours
- Oral presentation at reference meeting of the department about research design.	2011	8 hours

(Inter)national conferences

- VRA congres	2014	24 hours
- International conference of behavioral medicine Groningen	2014	28 hours
- Mini-symposium spinal cord injury	2014	4 hours
- ISCOS Istanbul	2013	28
- Mini-symposium spinal cord injury	2013	4 hours
- Mini-symposium spinal cord injury	2012	4 hours
- Spinal Cord Injury Organistion Netherlands Day. information stent ALLRISC.	2012	3 hours
- Self-management conference "Het Landelijk Actieprogramma Zelfmanagement NPCF-CBO (LAZ)"	2012	8 hours
- Spinal Cord Injury Organistion Netherlands Day. information stent ALLRISC.	2011	5 hours
- Mini-symposium spinal cord injury	2011	4 hours
- Symposium Human movement sciences	2011	8 hours
- NVDG-symposium "Centrumsuccessen"	2011	8 hours

Other

- Research report committee 2010-2013 (prof. dr. H.J. Stam)	2011-2014	18 hours

2. Teaching	**Year**	**Workload (Hours/ECTS)**
Lecturing		
- Minor rehabilitation medicine for medical students	2012	16 hours
- Minor rehabilitation medicine for medical students	2013	8 hours
- Training coaches of the HABITS interventions	2011	30 hours

Supervising practical's and excursions, Tutoring		
- Coordinator internships department	2012-2015	20 hours
- Supervisor interns motion technology	2012	12 hours
- Supervised medical students with a review assignment	2012	6 hours
- Supervised medical students with a review assignment	2011	6 hours
Supervising graduation theses		
- Supervised student Human Movement Sciences	2014	30 hours
- Supervised student movement technology	2014	30 hours
- Supervised two students movement technology	2013	60 hours
Other		
- Participation in research meeting of Rehabilitation department medicine, Erasmus MC	2010-2015	240 hours
Total workload		**1682 hours** **60 ECTS**