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.

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.

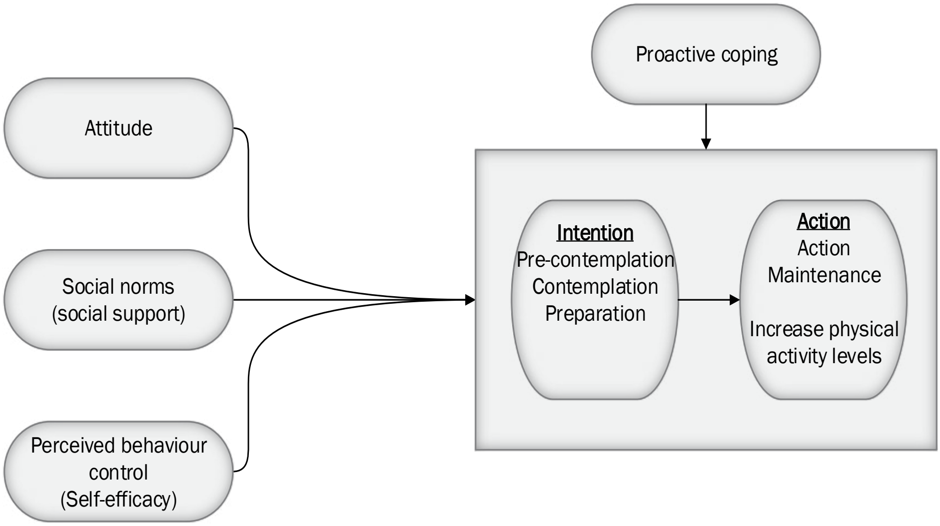

Figure 1 The combined theoretical model used as a basis for these studies

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.

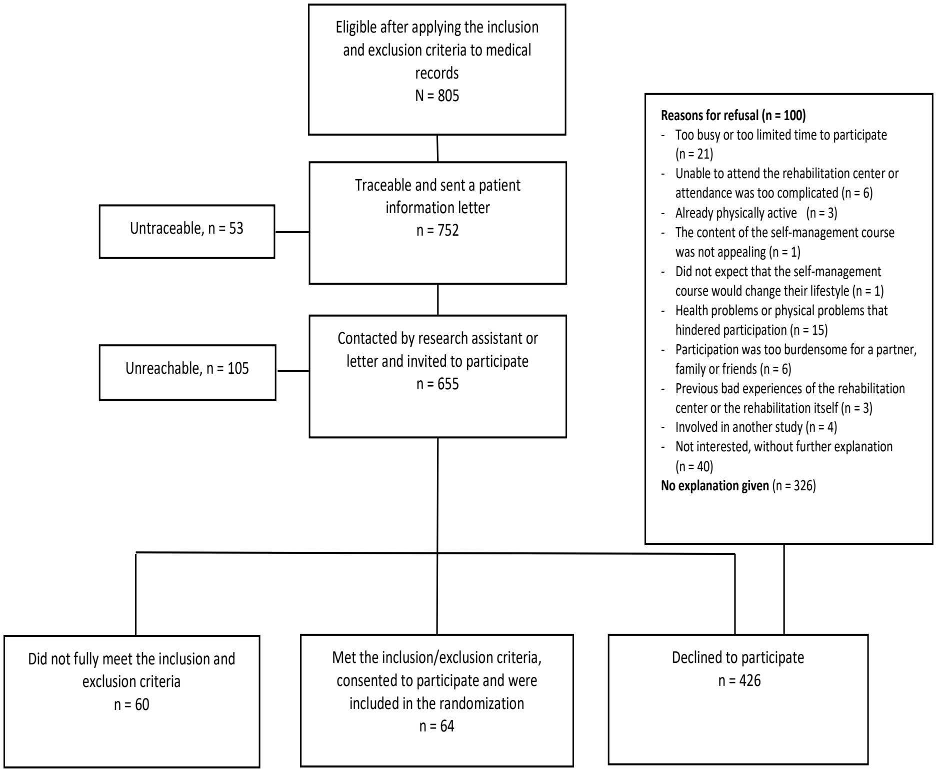

Figure 2 Enrolment flowchart of the participants in the HABITS RCT.

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]

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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