Spinal Cord (2006) 44, 287–296

www.nature.com/sc

Original Article

Body weight-supported treadmill training in chronic incomplete spinal cord injury: a pilot study evaluating functional health status and quality of life

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Study design: A controlled single-case design: A1 (baseline: 6 weeks), B (intervention**:** 12 weeks of treadmill training (TT), maximally five times a week/30 min a day), A2 (wash-out: 6 weeks), follow-up measurement: 6 months.
Objective: To investigate the effects of TT on functional health status (FHS) and quality of life (QoL) in subjects with a chronic incomplete spinal cord injury (ISCI).
Setting: Rehabilitation Department, University Medical Centre Utrecht, The Netherlands.
Methods: Three male subjects with a stable ($>$48 months postinjury) ISCI, American Spinal Injury Association (ASIA) class C ($n=2$) and D ($n=1$). Performance-based walking, subject's perception concerning quality of life (SEIQoL) and activities of daily living Canadian Occupational Performance Measure (COPM).
Results: The results of the three subjects were variable. Changes in QoL were relatively small and diverse. After 6 months' follow-up, QoL was unchanged in subjects 1 and 2, and improved in subject 3. In subject 2, performance of activities of daily living (ADL) was significantly improved, consistent with his perception of improvement ($P<0.05$), and this improvement was sustained throughout the follow-up period. Walking ability improved in subject 3 ($P<0.05$) but performance of other activities remained stable. Performance of ADL decreased slightly in subject 1 whereas his walking speed and Get up and Go performance improved ($P<0.05$).
Conclusions: This study demonstrates positive effects of TT on FHS. A randomised clinical trial should be executed before definite conclusions about the effect of TT on FHS and QoL can be drawn.
Sponsorship: KF Hein Foundation and Rehabilitation Centre De Hoogstraat Scientific Foundation.
Spinal Cord (2006) **44,** 287–296. doi:10.1038/sj.sc.3101841; published online 27 September 2005

Keywords: spinal cord injury; walking; treadmill training; quality of life; ADL

Introduction

Spinal cord injury (SCI) may result in incomplete or complete paralysis of the lower limbs, making walking difficult or impossible. Several rehabilitation strategies have been developed to reduce these dramatic consequences, some of which have proved quite successful.[1,2] Recent studies suggest that, with an adequate treadmill training (TT) regimen, certain patients with an incomplete spinal cord injury (ISCI) can regain a limited ability to walk over ground. This has prompted further studies of TT during rehabilitation or long thereafter, be it in quasi- or pre-experimental designs.[3–8] In most cases, the patient walks/steps on a treadmill while being suspended in a harness that provides a certain amount of body weight support (BWS). Most studies have reported restoration of patient's ability to walk (on the treadmill) and a gradual reduction of the need for BWS.[3–8] These encouraging results are generally attributed to the plasticity and adaptive capacity of the spinal cord below the lesion, in which the so-called 'Central Pattern Generator' plays a pivotal role.[9]

Up to now, the effectiveness of TT combined with BWS in patients with an ISCI has been almost exclusively evaluated at the level of body functions,[10]

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mostly by electromyography or measuring speed and BWS on the treadmill.[3–8,11,12] A couple of studies have also measured walking over ground,[3,4,7,13] but only a few have measured walking-related activities.[3,13] While results are generally positive,[3,4,7,13] little is known about the effect of TT on the functional health status (FHS) and quality of life (QoL) of patients with an ISCI, even though changes of FHS are considered an important aspect of rehabilitation.[14,15] For this reason, we investigated the changes in FHS and QoL in individual patients with an ISCI during and after TT combined with BWS, using a controlled single-case experimental design.[16] Besides measuring body functions and walking-related activities, we asked the subjects to evaluate their QoL and how they performed their most important problematic activities of daily living (ADL).

Methods

Subjects

Three male subjects with chronic ISCI, American Spinal Injury Association class C (subjects 1 and 2) and D injury (subject 3),[17] aged 45, 51, and 49 years, respectively, participated in the study (see Table 1). All subjects had sustained a traumatic incomplete spinal cord lesion to the cervical spine. At the time of inclusion, the subjects were medically stable, had been discharged from rehabilitation for more than 12 months (duration of the lesion ranged from 29 to 168 months), and had no severe muscle shortening and no skin ulceration. Two of the subjects (1 and 3) were able to execute their transfers without any help and could walk over ground with the use of a reciprocal frame.

Design and procedure

A controlled, single-case design with an A1-B-A2 strategy was used. Phase A1 consisted of a baseline period of 6 weeks, phase B was the treatment phase of 12 weeks, and phase A2 was the wash-out period of 6 weeks, in which no more treatment was given. This wash-out phase was added, so the possible changes in parameters, direct after the stop of the intervention, could be measured. Follow-up measurements were completed at 6 months.

Before inclusion, the subjects were informed about the aim of the study and were asked to give informed consent. The local ethics committee of the University Medical Centre Utrecht approved the study. After inclusion, the subjects underwent complete medical and neurological check-up. Subsequently, a movement scientist collected baseline data. All measurements were repeated every week of the 24-week study to determine changes in the health status of the subjects. The following outcome measurements were used.

Quality of life

Schedule for the Evaluation of Individual Quality of Life (SEIQoL).[18]

Activities

1. *Self-rated:* perceived problematic skills (Canadian Occupational Performance Measure (COPM)),[19–21] and a semistructured interview of subjects and their partners (TE).
2. *Performance-based:* quality of walking (Walking Capability Scale (WCS)),[3,4] balance (Berg Balance Scale (BBS)),[22–25] walking speed (7-metre walking test),[26–29] and balance and mobility (Get up and Go test).[30,31]

Body functions

Spasms (Modified Ashworth Scale (MAS))[32–37] and muscle strength (MicroFet).[38–40]

Experimental intervention

TT was given five times a week for 12 weeks and was adapted to the subject's physical abilities (maximum of five times a week, 30 min a session). The subjects trained on a motor-driven treadmill with a BWS system (Woodway, LOKO S 55). Within the used BWS system, a static or dynamic system could be chosen. Both systems supported the weight of a patient by a parachute harness (REHA-harness, Woodway), which allowed the patients to move on the treadmill with free arm and leg movements. Whereas in the static system the weight plates were fixed, so no vertical movement of the central body point of the patient was possible, in the dynamic system, the weight plates were not fixed, which allowed the vertical movement of the central body point of the patient.

Table 1 Characteristics of the three included subjects at the time of inclusion

	Subject 1	*Subject 2*	*Subject 3*
Level of incomplete lesion	Motority C7 Sensibility C7	Motority C5 Sensibility C7	Motority C7 Sensibility C5
ASIA score	C	C	D
Sex	Male	Male	Male
Age (years)	45	51	49
Chronicity of lesion (months)	198	29	60
Employment	Not	Full-time	Part-time
Possibility to make a transfer without help	+	−	+
Possibility to walk with walking aids	+	−	+

At the start of the training, the static system was used for all subjects. As soon as the subject was able to control the position of his upper body without arm support, the static BWS system was changed for the dynamic BWS system. The subject's body weight was supported by 50% at the start of the training, but the support was reduced as rapidly as possible during the intervention phase. In the beginning, the subjects were also stabilised with dynabands (Thera-Band) to limit horizontal movement. The dynabands were attached around the subject's hips to the horizontal supports of the treadmill and were released as soon as the subject felt safe and able to walk in the same place during training.

Treadmill speed could be adjusted from $0.0\,km \times h^{-1}$ to $20\,km \times h^{-1}$ (in steps of $0.1\,km \times h^{-1}$). During the training sessions, treadmill speed was kept between $0.1\,km \times h^{-1}$ and the subject's maximal possible walking speed during that training session. The duration of TT was gradually increased depending on the subject's condition, spasms of the legs, and the condition of the skin underneath the parachute harness.

Initially, the subjects were helped by at least one movement scientist and two physiotherapy students. When necessary, they helped with the stepping movements of the legs, especially in the first weeks of the intervention phase. A mirror in front of the treadmill was used to reinforce the upright posture. Parameters recorded were walking distance, duration of the training, number of assistants, velocity, and percentage of BWS.

Outcome measures

Quality of life

Individual QoL was evaluated with the SEIQoL. In contrast to other QoL measures, the SEIQoL allows a subject to describe his/her life in terms of those factors that he/she considers important. Five items that had the greatest impact on the subject's QoL were chosen. The subject's level of satisfaction with these five items was indicated on a Visual Analogue Scale. Finally, judgement analyses were performed by the subjects to weigh each of the five items. According to the literature, this method has a satisfactory validity and reliability.[18] No information about responsiveness was found in the literature.

Activities: self-rated

The COPM, a client-centred assessment, is based on a model of human occupational performance.[19] It was used to measure a subject's perceived performance in the areas of self-care, productivity, and leisure.[19] In a semistructured interview, during which the questionnaire was administered (by TE), subjects selected the five most important problematic skills of daily life. The possibility to perform these skills (0 = major problems; 10 = superior) and satisfaction with performance (0 = major regrets; 10 = extremely satisfied) were scored.[20] The performance and satisfaction scores were the average of the scores for the five skills. The reliability and validity of the instrument have been demonstrated in several disease populations.[19,21] No information about responsiveness was found in the literature.

In week 24, in a semistructured interview, the subjects and their partners were asked (by TE) about changes in daily life during and after TT.

Activities: performance based

The WCS was developed by Wernig.[3,4] Walking capability was classified into six classes (0–5), based on the personal and instrumental support needed to help the subject stand or walk (Table 2). As in other treadmill experiments,[3,4] the WCS was used to roughly quantify the subject's standing and walking over ground. The validity, reliability, and responsiveness of the WCS have not been reported.

Balance, which is critical for optimal function of the locomotor system and the performance of many ADL, was measured with the BBS.[22] The BBS was designed for use in elderly and neurologically impaired individuals.[22] The scale consists of 14 items, which range in difficulty and include the ability to maintain a sitting posture, to transfer between positions, to reach forward while standing, and to alter positions.[22] Each item is graded on a 5-point ordinal scale (0–4) based on time or distance requirements, supervision required, need for external support, or need for assistance from the observer.[23] Validity in subjects with stroke has been proved.[24] The intrarater reliability of the scale is satisfactory[25] and correlates well with other clinical balance scales.[24] No information about responsiveness was found in the literature.

Gait velocity is straightforward to measure and can be used to quantify deficit and change.[26] Subjects were asked to walk 7 m at a comfortable speed and using the walking aids they preferred to use in their domestic surroundings. Time taken and number of steps taken were recorded. A distance of 7 m was chosen because of limited space. Measurement of gait velocity has satisfactory validity in subjects with stroke.[27] The intrareliability of gait speed is very satisfactory,[28] and the

Table 2 The Walking Capability Scale of Wernig

Wheel-chair bound	
0	Lower limbs cannot support body weight for standing or walking even with moderate help by two therapists
1	Capable of standing and walking only with the help of two therapists
2	Walking at the railing with the help of one therapist
Not wheel-chair bound	
3	Walking with the rollator/walker or reciprocal frame
4	Walking with two regular canes or four-point canes
5	Walking without devices (free walking) for more than five steps

responsiveness of gait speed has been demonstrated in subjects with stroke.[26,29]

Balance and mobility were measured using the Get up and Go test.[30] Subjects were asked to stand up from a chair, walk 3 m, turn around, return, and sit down again. The time taken was measured. The validity and intrarater reliability are reported as very satisfactory.[31] No information was found about responsiveness in the literature.

Body functions
Spasticity is considered a significant factor affecting motor performance.[32,33] The MAS is often used to provide subjective grading of muscle tone (0, no increase in muscle tone; 5, rigid joint) in subjects with an ISCI.[34] During this study, the MAS was used to test the muscle tone of the hip adductors and the knee flexors in standard positions.[35] The validity[35] and intrarater reliability[36,37] of the MAS have been ascertained earlier. No information about the responsiveness of the MAS was found in the literature.

Voluntary muscle activity was evaluated with a hand-held dynamometer, the MicroFet. The strength that could be evoked from defined resting positions (lying and sitting) on verbal command was measured. The flexors and abductors of the hip and the flexors and extensors of the knee were tested. The validity of this test is satisfactory in the lower force ranges.[38] The intrarater reliability and responsiveness are, according to the literature,[39,40] satisfactory.

Statistical analysis
In the baseline and intervention phase, all subjects were measured each week. However, in the wash-out phase only subject 1 was measured all the 6 weeks, whereas subjects 2 and 3 could only be measured, respectively, five and four times. Data of the measurements were plotted in graphs, separate for each individual subject (Figure 1).

For every graph (Figure 1), a baseline was constructed. Therefore, all data of the 6-week baseline phase within each graph were used. If these 6-week data had all the same value, a baseline could be constructed through this value immediately. However, when the data varied over the 6-week period, medians were calculated over different periods within the baseline-phase: A: median over weeks 1–3; B: median over weeks 1–4; C: median over weeks 1–5; and D: median over weeks 1–6. Subsequently, the percentage change between the medians A and B, B and C, and C and D were calculated. If these changes were less than 2.5% in all three comparisons, a baseline was constructed through the calculated median of the medians of the periods A, B, C, and D. However, if one of the changes in median between the periods A–B, B–C, and C–D was more than 2.5%, the measurement of week 1 was omitted. Subsequently, the medians were calculated over the periods as follows: A′: weeks 2–4; B′: weeks 2–5; and C′: weeks 2–6. Again, the change in median between A′–B′ and B′–C′ was calculated. If the difference between these medians was less than 2.5%, the median of the medians of A′, B′, and C′ was determined and a baseline was drawn through this value. However, if the difference between the calculated medians was more than 2.5%, it was concluded, that a baseline could not be drawn.

All baselines were extended through other phases (Figure 1) to facilitate visual identification of clinically relevant positive or negative changes. These clinically relevant changes were 5 points for the SEIQoL, 0.5 points for the COPM (performance and satisfaction score), 1 point for the WCS, 5 s and three steps for the 7-m walking test, 2 points for the BBS, 3 s for the Get up and Go test, 1 point for the MAS, and 10 points for the muscle strength test. According to Wagenaar,[41] both visual inspection and statistical analysis are needed to analyse data from studies with a single-subject design. In this study, statistical analyses were only used if a trend was detected by visual analyses. Differences between the different phases were analysed with the help of the Kruskall–Wallis test ($\alpha = 0.05$/SPSS 10.0 for windows). The Mann–Whitney *U*-test[42] was used to specify between which phases there were significant differences ($\alpha = 0.05$/SPSS 10.0 for windows) (Table 4). If it was not possible to construct a baseline, statistical analyses were only allowed if trends were very clear (simple to detect by eye and certainly clinically relevant (see above)). Data for the follow-up measurements were analysed visually and by using the criteria for clinical relevance mentioned above.

Results

Training parameters during the treadmill intervention
During the intervention phase, all subjects increased the distance walked and their walking speed, and required less assistance and a smaller quantity of BWS (expressed as a percentage of the subject's bodyweight) (Table 3). At the end of the intervention phase, all subjects were able to walk on the treadmill without assistance (median weeks 9–12; Table 3). Subjects 1 and 3 no longer required BWS, whereas subject 2 required support equal to 10.5% his body weight (mean BWS weeks 9–12; Table 3). These training parameters were not measured during the wash-out phase or at follow-up. The results for each subject are given below. The reader is referred to Figure 1 and Table 4.

Subject 1
Subject 1 judged his QoL as improved during the intervention phase. This improvement was statistically significant ($P < 0.05$; Table 4). Perceived QoL did not change significantly between the baseline and the wash-out phase ($P > 0.05$; Table 4) or after the follow-up.

The subject perceived his performance to be fairly stable, but he was less satisfied about his performance

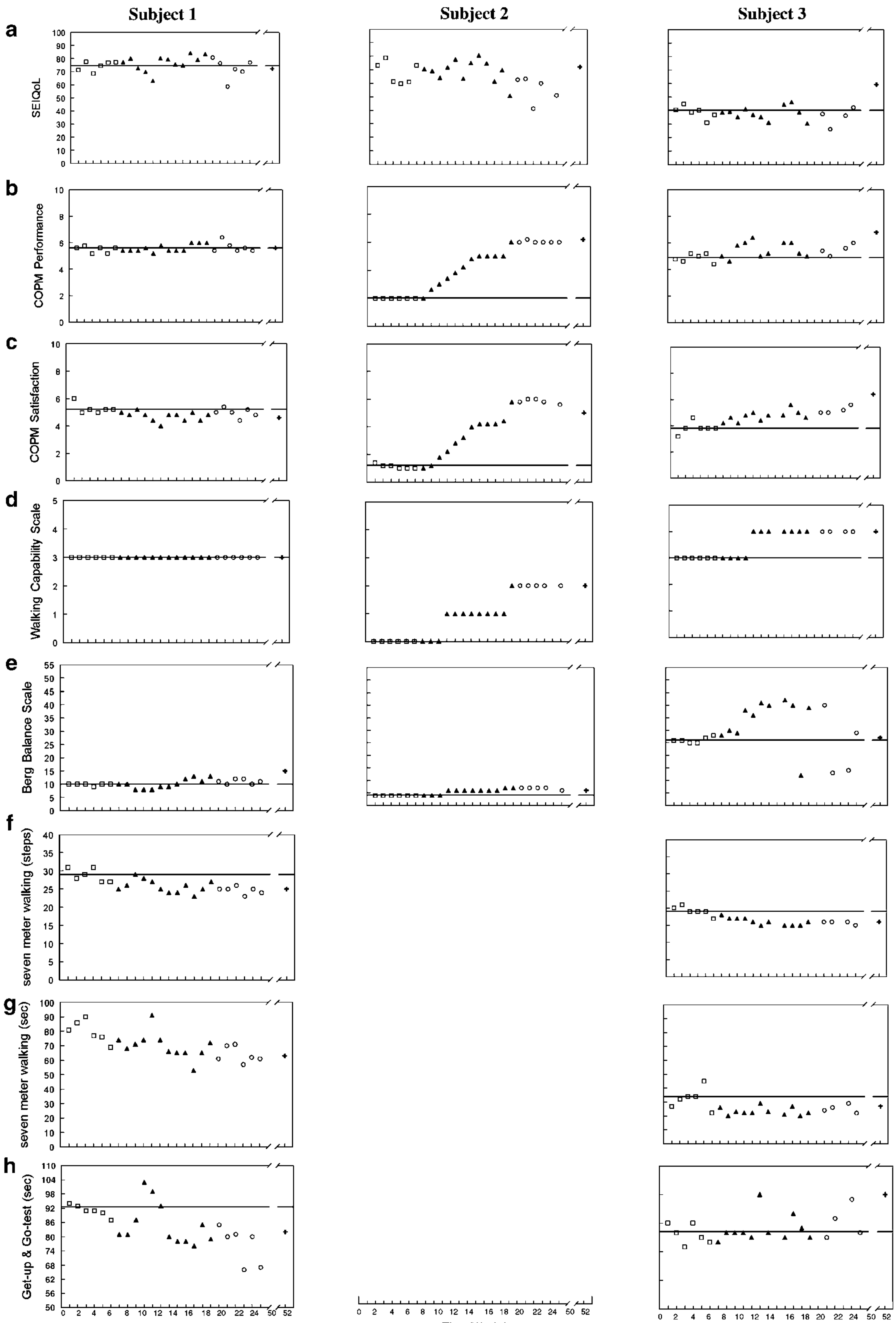

Figure 1 Measurements of QoL (**a**), self-rated activities (**b**, **c**) and performance-based activities (**d**–**h**) during the baseline (□), intervention (▲) and wash-out phase (○), and after the follow-up phase of 6 months (+) in the three included subjects. The horizontal line represents the baseline

Table 3 Training parameters during the 12-week intervention phase

Period (weeks)	*Total of training sessions*	*Mean walking distance (m)*	*Mean duration of the training (min/s)*	*Mean velocity (km/h^{-1})*	*Number of assistants (median)*	*Mean BWS (% of body weight)*
Subject 1						
1–4	19	132.8	22.14	0.36	2.0	35.5
5–8	16	189.5	18.44	0.61	2.0	16.2
9–12	14	242.7	21.06	0.69	1.0	7.9
Subject 2						
1–4	20	86.2	15.36	0.34	2.0	35.1
5–8	22	121.3	14.00	0.52	1.0	19.0
9–12	10	131.0	14.08	0.56	0.0	17.6
Subject 3						
1–4	16	206.8	22.15	0.56	1.0	20.2
5–8	13	405.0	24.55	0.98	0.0	0.75
9–12	11	510.0	26.34	1.15	0.0	0.70

of these tasks during the intervention phase (COPM-satisfaction; $P<0.01$; Table 4). No changes were found after the follow-up phase.

During a semistructured interview at the end of the wash-out phase, subject 1 explicitly stated that he could walk further without rest (30 m instead of 10 m), that he could walk around easier inside his caravan by leaning on cupboards instead of stumbling and using a small stool, and that he generally felt better. These changes were sustained during the follow-up period.

With regard to performance-based activity scales, during the intervention, the subject could walk more quickly and with a fewer number of steps in the 7-m walking test ($P<0.05$ for both scores; Table 4) and had a faster Get up and Go performance ($P<0.01$; Table 4). These improvements were sustained during the wash-out phase ($P>0.05$) and follow-up. His balance, measured between the baseline and the wash-out phase, was improved (BBS; $P<0.05$; Table 4), and was still improved at the end of the follow-up (Figure 1). His quality of walking did not change (WCS; Figure 1).

Muscle tone – as measured with the MAS – did not change (Table 4). Left hip abductors and left knee flexors showed a significant increase in voluntary muscle activity between the baseline and wash-out phase ($P<0.05$; Table 4). At the end of the follow-up, the muscle strength of the right hip flexors and right knee extensors had increased (Figure 1).

Subject 2

Subject 2 judged his QoL as unchanged during the intervention phase ($P>0.05$; Table 4), and diminished during the wash-out phase ($P<0.05$; Table 4). At the end of the follow-up, the subject's perception of his QoL had improved, reaching the baseline level.

Subject's opinion about activities mentioned in the COPM (performance and satisfaction) improved significantly ($P<0.01$; Table 4) during the intervention phase and stayed stable during the wash-out phase (Table 4). After the follow-up, the subject's perception of his performance of his activities had not changed, whereas his satisfaction with his performance was slightly diminished (Figure 1).

During a semistructured interview at the end of the wash-out phase, the subject explicitly stated that he could now make a transfer independently, he had decreased his medication for pain and spasms (100 mg/day → 50 mg/day baclofen), and he felt generally better. These changes were sustained during the follow-up.

The subject's walking performance (WCS) and functional balance (BBS) improved ($P<0.01$; Table 4). These improvements were still present at the end of the follow-up. The subject was not able to perform the 7-m walking test and the Get up and Go test.

Muscle tone did not change (Table 4). The voluntary muscle activity of the right hip flexors increased significantly between the baseline and wash-out phase ($P<0.05$; Table 4), whereas the voluntary muscle activity of the left hip abductors decreased. After the follow-up, the voluntary muscle activity of the left hip abductors and left and right knee flexors had deteriorated and those of the right hip flexors had increased.

Subject 3

During the baseline, intervention, and wash-out phases, subject 3 judged his QoL as not changed ($P>0.05$; Table 4), but as improved after the follow-up (Figure 1).

The subject considered that his performance of COPM activities had improved ($P<0.05$; Table 4), with the exception of the COPM performance in the intervention phase compared with those of the baseline phase ($P>0.05$; Table 4). He still considered his performance of COPM activities improved after the follow-up phase and was more satisfied with his performance.

During a semistructured interview at the end of the wash-out phase, the subject explicitly stated that he could sit in the wheelchair for a longer period, he had a

Table 4 Comprehensive overview of the results of each individual subject ($n=3$) organised by the type of outcome variables: QoL, activities (both performance based as well as self-rated), and body functions

Outcome variables	*Subject 1*					*Subject 2*					*Subject 3*				
	Overall change	*B–I*	*I–W*	*B–W*	*W–F*	*Overall change*	*B–I*	*I–W*	*B–W*	*W–F*	*Overall change*	*B–I*	*I–W*	*B–W*	*W–F*
	+/–/=	*P*-value			+/–/=	+/–/=	*P*-value			+/–/=	+/–/=	*P*-value			+/–/=
QoL															
SEIQoL	+	0.018*	0.059	0.749	=	–	0.640	0.011*	0.144	+	–	0.688	0.602	0.394	+
COPM-performance	–	0.700	0.688	0.621	=	+	0.001†	0.001†	0.001†	=	+	0.052	0.894	0.042*	+
COPM-satisfaction	–	0.003†	0.111	0.213	=	+	0.005†	0.002†	0.004†	–	+	0.003†	0.029*	0.008†	+
Activities (self-rated)															
Individual COPM activities		Moving around in other people's house Going to a public toilet Making a transfer to the car Walking from the car to the house Walking on the campsite					Transfer to a toilet chair Possibility to walk small distances Reaching for objects higher stored Standing for short moments Making a transfer easily					Feeling fit Sitting in the wheelchair for a long time Having a good body balance Concentration during work Starting up in the morning			
Activities (performance based)															
WCS	=				=	+	0.004†	0.002†	0.002†	=	+	0.013*	0.174	0.003†	=
BBS	+	0.961	0.215	0.020*	+	+	0.005†	0.019*	0.002†	=	+	0.008†	0.213	1.000	=
7 m – steps	+	0.007†	0.212	0.004†	=	NM	NM	NM	NM	NM	+	0.002†	0.629	0.009†	=
Walking test – seconds	+	0.018*	0.066	0.010*	=	NM	NM	NM	NM	NM	+	0.011*	0.209	0.108	=
Get up and go test	+	0.002†	0.593	0.004†	=	NM	NM	NM	NM	NM	=				–
Body functions															
MAS	=				=	=				=	=				=
Muscle Strength l. hip flex.	=				=	=				=	=				=
l. hip abd.	+	0.082	0.048*	0.009†	=	+	0.005†	0.637	0.013*(–)	–	=				=
l. knee flex.	+	0.062	0.120	0.012*	=	=				=	=				=
l. knee ext.	=				=	+	0.008†	0.222	0.233	=	=				=
r. hip flex.	+	0.003†	0.006†(–)	0.629	+	+	0.100	0.080	0.028*	+	=				+
r. hip abd.	=				=	=				=	=				=
r. knee flex.	=				=	=				=	=				=
r. knee ext.	=				+	+	0.004†	0.113	0.582	=	=				=

Visual analyses (defined by increase: '+'; decrease: '–'; no change: '='), and statistical analyses with the help of Mann–Whitney statistics (exact *P*-values; significance accentuated with * in case of $P<0.01$ and † in case of $P<0.05$; nm = not measurable) over the baseline–intervention phase (B–I), intervention–wash-out phase (I–W), baseline–wash-out phase (B–W), and wash-out follow-up phase (W–F) better stability of the right leg, he could catheterisise himself in a standing, rather than in a sitting position, he could walk with canes through the garden instead of using a walker, he had fewer ulcers on his legs, and that he felt generally better. After the follow-up, the subject stated that the greater part of these changes were still present, although the stability of his right leg and his walking ability had diminished.

With regard to the activity scales, performance of walking-related activities ($P<0.05$; Table 4) improved significantly and remained stable after the follow-up (Figure 1). An apparent exception was the subject's performance on the Get up and Go test, which did not change significantly during the intervention and wash-out phase ($P>0.05$; Table 4). His performance deteriorated during the follow-up phase. Subject's functional balance had improved during the intervention phase (BBS; $P<0.01$; Table 4) and stayed stable during the wash-out phase ($P>0.05$; Table 4), it had returned to the baseline level at follow-up (Figure 1).

Muscle tone and voluntary muscle strength did not change (Table 4). At follow-up, the voluntary muscle strength of the abductors of his right hip had increased.

Discussion

In this study, we took a broader view of the results of TT in subjects with an ISCI, including FHS and QoL. As in other studies,[3–8] all patients improved their walking capabilities on the treadmill during the 12-week period of TT. Positive changes were reported in the majority of the most important problematic activities in daily life (COPM scores). Furthermore, positive trends were seen in performance-based outcome measures, although these changes were quite variable between and within the patients. Changes in QoL were relatively small and diverse.

The question whether or not TT improves FHS and QoL in patients with ISCI remains unanswered. In our study, positive trends could be seen, but there was no consistency. A randomised clinical trial (RCT) should be performed before concrete conclusions can be drawn. The outcome measures to evaluate changes in FHS and QoL in our study were chosen after intense consideration. Nevertheless, it is a fact that, in general, more attention should be given to the psychometric characteristics of the clinimetric tools used in subjects with ISCI. It is possible that some of the currently used outcome measures are too blunt to be discriminatory in patients with ISCI.

Based on recommendations in the literature,[7] in this study a training frequency of five sessions per week was chosen. The duration of the training, number of assistants, velocity, and percentage of BWS were gradually changed according to the subject's ability. However, subjects 1 and 2 developed slight, transient symptoms (eg pain-like sensations) indicative of temporary overuse in their knees and ulcers in their groins. These problems were resolved when we applied a more gradual build-up of the training program and introduced sheepskin to reduce the pressure and friction caused by the BWS system. It is plausible that the injuries mentioned above affected the patient's measures of QoL and even the rate of progress on the activities measured (self-rated and performance based). It is more than likely that the degree of experience with TT determines, for example, the chance on injuries, and will influence the efficiency of TT.

Furthermore, in our study, solely TT was given. To reach larger improvements in specific motor functions (eg walking over ground and making transfers), exercise training of these types of activities is necessary. Possibly, TT should be imbedded in a more complete physical therapy program. In this way, TT is used to improve patient's exercise capacity as well as his task performance and efficiency.

Reported changes in QoL are relatively small and different in the three subjects. However, one should keep in mind that QoL is not closely linked to one's ability to walk (on the treadmill). Improvement in the ability to walk will only affect a small aspect of a patient's existence that relates to QoL. Subsequently, an extensive change in walking ability would probably lead to a small change in QoL. Additionally, one should also keep in mind that QoL measures are actually developed to describe changes of QoL in populations. The SEIQoL is one of the only QoL measures, which was used at an individual level before.[18] No information about responsiveness was found in the literature. So, one can conclude that it is not surprising that no obvious changes in QoL were measured in this study. However, limitations of QoL measurements as described above are less obvious in an RCT. In our opinion, QoL is of such an interest, that it should be measured in a future RCT.

The three subjects had been discharged from rehabilitation for more than 12 months, and it was expected that their FHS would be stable. This stability is a condition for single-subject designs, because subjects are their own controls, and so a stable baseline is needed as a reference. For most parameters, it was possible to create a stable baseline with the data from the 6-week baseline phase. In two cases, a trend was detected (Figure 1: graph A, subject 2; graph G, subject 1), which resulted in a less appropriate visual analysis. Conceivable explanations for these trends are changes in motivation because of the prospect of starting the TT, and secondly habituation to measurements due to frequent repetition. These possible time-related effects and dependency of the measurements make it advisable to include time-series analyses in single-subject study designs.[43] However, for this kind of analyses, more than 30 measurements are needed, which was not feasible. In this study, we chose for a second best option, namely, visual analyses in combination with randomisation tests.

Symptoms indicative of overuse in knees and ulcers, as mentioned before, suggest that in the beginning of the intervention phase the training was too demanding. During this period (Figure 1; weeks 9–11), subject 1 judged his QoL and performance of several activities as deteriorated. We decided to omit these data from the statistical analyses, because they confuse the overall results of the study. However, it is important, in future studies, to take notice of the possibility of adverse events and to gradually increase the frequency and duration of training to prevent problems associated with overuse of the limbs.

TT with BWS is strenuous and tiring, and requires motivation on the part of the subject and therapist. All three subjects indicated that they would not have completed the training if they had not experienced some kind of improvement.

Conclusions

This study demonstrates positive effects of TT on training parameters, but also positive trends in FHS (balance, over-ground walking, and walking-related activities). It is therefore stressed that effectiveness of TT in patients with ISCI should be evaluated not merely on the base of impairments of body functions, but also on the level of FHS. QoL should only be evaluated on population level. A future RCT should be executed before concrete conclusions about the effect of TT on FHS and QoL can be drawn.

Acknowledgements

This study was supported by the KF Hein foundation and Rehabilitation Centre De Hoogstraat Scientific Foundation. We thank Eduard Blanken (MSc/PT) for his assistance with the training and measuring and Joop Faber (PhD/biostatistician) and Cas Kruitwagen (MSc/biostatistician) for their help with the statistical analyses.

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