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ORIGINAL ARTICLE

Effects of hybrid cycling versus handcycling on wheelchair-specific fitness and physical activity in people with long-term spinal cord injury: a 16-week randomized controlled trial

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Study design: This is an open randomized controlled trial.

Objective: The objective of this study was to investigate the effects of a 16-week hybrid cycle versus handcycle exercise program on fitness and physical activity in inactive people with long-term spinal cord injury (SCI).

Setting: The study was conducted in two rehabilitation centers with a specialized SCI unit.

Methods: Twenty individuals (SCI $\geqslant$ 8 years) were randomly assigned to a hybrid cycle (voluntary arm exercise combined with functional electrical stimulation (FES)-induced leg exercise) or a handcycle group. During 16 weeks, both groups trained twice a week for 30 min at 65–75% heart rate reserve. Outcome measures obtained before, during and after the program were fitness (peak power output, peak oxygen consumption), submaximal VO_2 and heart rate (HR), resting HR, wheelchair skill performance time score) and physical activity (distance travelled in wheelchair and Physical Activity Scale for Individuals with Physical Disabilities (PASIPD) score). Changes were examined using a two-factor mixed-measures analysis of variance.

Results: For all fitness parameters, except for submaximal VO_2, no interaction effects were found. The hybrid cycle group showed a decrease in VO_2 over time in contrast to the handcycle group ($P = 0.045$). An overall reduction in HR_{rest} (5 ± 2 b.p.m.; $P = 0.03$) and overall increase in PASIPD score (6.5 ± 2.1; $P = 0.002$) were found after 16 weeks of training. No overall training effects were found for the other fitness and activity outcome measures.

Conclusion: In the current study, hybrid cycling and handcycling showed similar effects on fitness and physical activity, indicating that there seem to be no additional benefits of the FES-induced leg exercise over handcycle training alone.

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INTRODUCTION

Many people with long-term spinal cord injury (SCI) show an inactive lifestyle, which is associated with decreased fitness levels and several health complications.[1,2] Exercise has an important role in improving fitness, and subsequently physical activity and health, in this population.[3]

Typically, exercise in people with SCI involves upper-body activities owing to the paralysis of the lower body. Although several upper-body exercise (that is, handcycle) intervention studies showed positive effects on fitness,[4,5] this approach may limit successful health outcome, as the dynamics of arm exercise are not conducive to the development and maintenance of the superior levels of fitness that can be achieved with leg exercise.[6] Important limitations of arm exercise are the relatively small muscle mass available, inactivity of the venous muscle pump of the legs and deficient cardiovascular reflex responses.[6]

The use of the paralyzed lower-limb musculature, accomplished through functional electrical stimulation (FES), could alleviate some of the above-mentioned problems. A major advantage of FES-induced leg exercise over voluntary arm exercise is that it can use a large muscle mass that otherwise would be inactive. This can potentially augment the circulation by activating the skeletal muscle pump of the legs, and elicit relatively large exercise responses for better aerobic training capability.

To further activate more muscle mass and subsequently provide greater exercise responses to enhance aerobic fitness training capability, a hybrid mode of exercise, consisting of FES-induced leg exercise combined with voluntary arm exercise, can be used. Several training studies conducted on hybrid exercise suggest benefits on fitness and health parameters.[7,8] However, a limitation of these studies was the absence of a control group. From previous research, it is known that both hybrid cycle[8,9] and handcycle[4] training lead to

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improvements in fitness (that is, peak power output (PO_{peak}) and peak oxygen consumption (VO_{2peak})) if specific (that is, hybrid cycle or handcycle) exercise testing is used to evaluate these outcome measures. However, in daily life, many people with SCI are dependent on a wheelchair for mobility and will specifically benefit from an increased wheelchair-specific fitness.

Therefore, the purpose of this study was to investigate the effects of a 16-week hybrid cycle versus handcycle exercise program on wheelchair-specific fitness and physical activity in inactive people with long-term SCI.

MATERIALS AND METHODS

Design

The current study is part of a larger study whose design was previously described by Bakkum *et al.*[10] Briefly, this study was a 16-week open randomized controlled trial performed in two Dutch rehabilitation centers with a specialized SCI unit. Within each center, participants were randomly assigned to either the hybrid cycle or the handcycle group. Outcome measures in the current study were obtained in the week before the training program (pre), after 8 weeks of training (mid) and in the week after (post) the training (in the larger study, the outcome measures were also obtained 26 weeks after the training program).

Participants

The sample size calculation of this study was performed a priori on the main outcome measure (PO_{peak}) , and it revealed a group size of 18 participants.[10] Participants were recruited from the databases of two Dutch rehabilitation centers. Inclusion criteria were as follows: spastic SCI $\geqslant$10 years; age 28–65 years; age at onset SCI$\geqslant$18 years; physically inactive (Physical Activities Scale for Individuals with Physical Disabilities (PASIPD)[11] score$<$30); and wheelchair dependent. Exclusion criteria were as follows: contraindications for physical training and testing; psychiatric problems; plans to alter another healthy lifestyle behavior (for example, diet changes); and insufficient knowledge of the Dutch language.

Training devices

The hybrid cycle (BerkelBike Pro, BerkelBike BV, St Michielsgestel, the Netherlands; Figure 1a) combines synchronous voluntary handcycling with asynchronous FES-induced leg cycling. A six-channel stimulator (Impuls, BerkelBike BV, St Michielsgestel, the Netherlands; Figures 1a and I) provided electrical stimulation via self-adhesive 50$\times$90 mm surface electrodes placed bilaterally over the quadriceps, hamstrings and gluteus muscles. During cycling, the stimulator received information from the crank angle encoder (Figures 1a and II) about pedal position and velocity to control the cyclic stimulation pattern.

The handcycle (Speedy-Bike, Reha-Technik GmbH, Delbruck, Germany; Figure 1b) was equipped with a wide synchronous bull-horn crank. Both cycles were equipped with eight gears that could be changed manually, and with quad grips for the participants who needed them. The front wheel of both devices was mounted on an ergotrainer (Tacx Flow, Technische Industrie Tacx BV, Wassenaar, the Netherlands; Figures 1a and III and b–III) adapted to the wheel size of the cycles.

Training protocol

During 16 weeks, participants trained twice a week for 18–32 min (duration of the sessions increased during the program) at an intensity of 65–75% heart rate reserve.[10] As the use of heart rate (HR) as an indicator for training intensity can be unreliable in some individuals with tetraplegia, rating of perceived exertion served as a supplementary measure of training intensity; a target score of 4–7 on a 10-point rating of perceived exertion scale was required during training.[12] Exercise intensity was controlled by the participant making adjustments in cycle velocity or by the trainer adjusting the gear of the cycle or the resistance of the ergotrainer. In addition, during hybrid cycling, the current amplitude of the stimulation was adjusted manually by the trainer to control the degree of muscle activation. The trainer tried to induce strong lower-body muscle contractions during training by using an as high as possible current amplitude (range 0–150 mA). However, the current amplitude was decreased if the participant indicated that the stimulation was too intense, or if the trainer visually noted that the legs were moving too fiercely owing to the stimulation. HR was recorded constantly during each training session using radiotelemetry (Polar, Polar Electro Inc., Woodbury, NY, USA), and rating of perceived exertion was assessed after each training block.

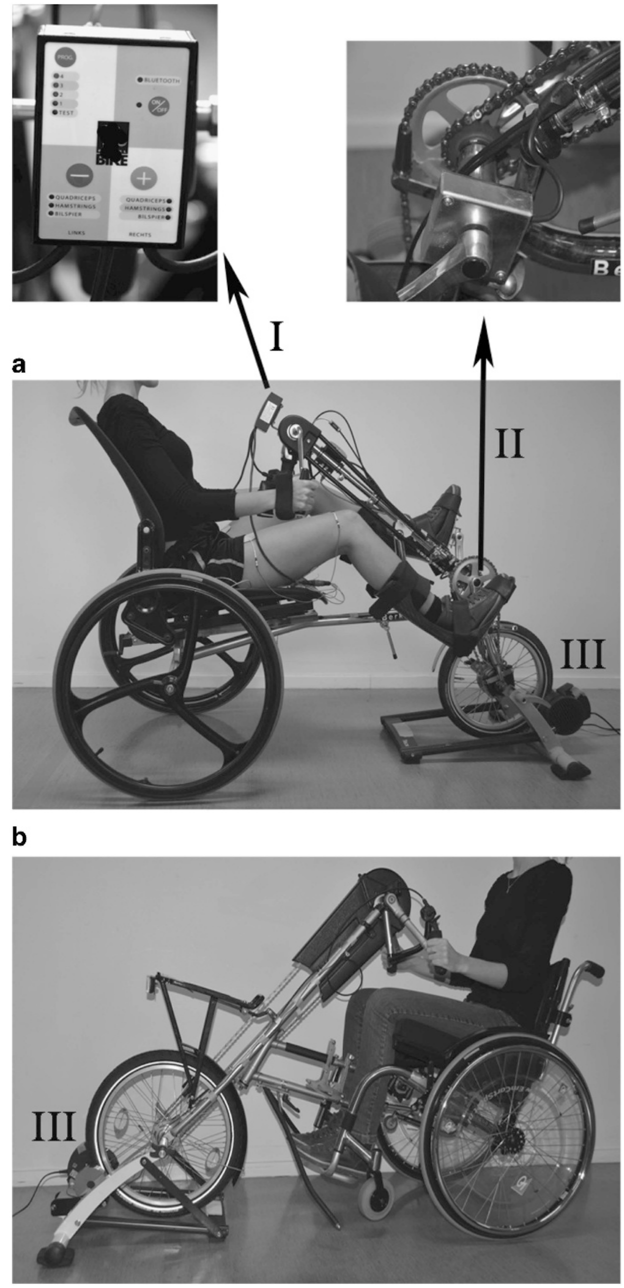

Figure 1 The hybrid cycle (**a**) with the stimulator (I) and crank angle encoder (II), and the handcycle (**b**), mounted on an ergotrainer (III).

Outcome measures

Wheelchair-specific fitness. Wheelchair exercise capacity, expressed as the PO_{peak} and VO_{2peak}, was assessed during a graded exercise test in the participant's own handrim-propelled wheelchair (within participants, tire pressure, seating position and so on were kept constant over time) on a motor-driven treadmill, using the protocol of Dallmeijer *et al.*[13] This protocol consisted of a 3-min warm-up session, a 5-min rest interval, two 3-min submaximal exercise blocks and an incremental test in which the incline of the treadmill belt was increased by 0.36° every minute. The velocity of the belt was kept constant during testing, and it was dependent on the participant's physical capability. The test was ended when the participant could no longer maintain the velocity owing to fatigue, or when the participant indicated that he/she wanted to stop. Directly after the warm-up session, a drag test was performed to determine the drag force (F_{drag}), and subsequently the power output of the wheelchair-user system on different treadmill inclines, using custom-made software (Technical Department Faculty of Human Movement Sciences, VU University Amsterdam).[14] During testing, respiratory gas exchange was measured using open circuit spirometry ($K4b^2$, COSMED, Rome, Italy), and HR was measured using radiotelemetry (Polar, Polar Electro Inc.). PO_{peak} and VO_{2peak} were defined as the highest power output maintained for at least 30 s and the highest VO_2 (averaged over 30 s) attained during the test, respectively. Submaximal VO_2 and HR were defined as the mean value over the last 30 s of the submaximal exercise blocks. Resting HR (HR_{rest}) was defined as the lowest HR (averaged over 30 s) of the 5-min rest.

For indirect determination of fitness, wheelchair skill performance was assessed with the performance time score (total time needed for a 15- m sprint and figure-of-8).[15] Furthermore, at the end of the training program, subjectively experienced fitness level was measured using one multiple-choice question in which participants were asked whether they thought that their fitness level had changed because of the training sessions (answers ranged from 'very much reduced' to 'very much improved').

Physical activity. Physical activity was measured objectively with an odometer, as well as subjectively with the Dutch PASIPD.[11] The odometer was mounted on the wheel of the participant's daily-use wheelchair to record every forward and backward revolution of the large wheels during 7 consecutive days before and after the training program.[16] Participants were asked to keep a diary in which they registered the number of wheel revolutions on a daily basis. The distance covered was calculated by multiplying the number of wheel revolutions by the wheel circumference. The PASIPD is a 12-item questionnaire that requests the number of days a week and hours a day of participation in leisure (six items), household (five items) and occupational (one item) activities over the past 7 days. Participants were asked to digitally fill out this questionnaire at home.

Statistical analysis

The assumption of normality of the data within groups was checked by visual inspection of the q-q plot and box plot; in addition, a Shapiro-Wilks test was performed. Homogeneity of variance was checked using the Levene's test. In case of violations of these assumptions, the statistical analyses were performed on the log-transformed data. Normal distribution and homogeneity of error variance were confirmed for all variables except for PO_{peak}, performance time score, distance travelled in the wheelchair (WC_{dist}) and PASIPD scores. Independent *t*-tests were used to determine possible baseline differences in the outcome measures between groups. Differences between pre-, mid- and post-outcome measures were examined using a two-factor (timexgroup) mixed-measures analysis of variance and three-factor (blockxtimexgroup) mixed-measures analysis of variance for the submaximal VO_2 and HR. Paired *t*-tests with Bonferroni correction were used to identify where the specific differences occurred between the three time points. One-way within-subjects analysis of variances with Bonferroni correction were used to examine the interaction effect if significant. Partial eta-squared (n_p^2) was calculated to determine the effect size. Significance was set a priori at $P<0.05$.

Statement of ethics

All participants provided written informed consent indicating voluntary participation in this study, approved by the Medical Ethics Committee of the VU University Medical Center Amsterdam. We certify that all applicable institutional and governmental regulations concerning the ethical use of human volunteers were followed during the course of this research.

RESULTS

Figure 2 shows the flow diagram of the process through the phases of the randomized controlled trial. Between November 2011 (start recruitment) and August 2013 (end recruitment), 36 participants

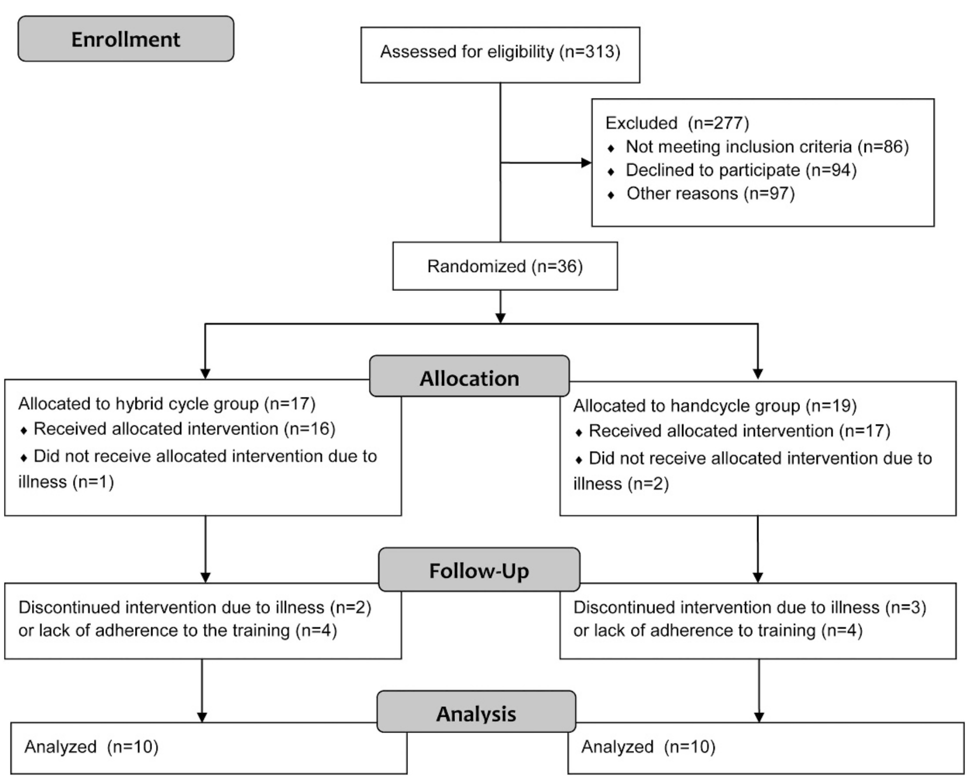

Figure 2 Flow diagram of the process through the phases of the randomized controlled trial.

were included (17 hybrid cycle, 19 handcycle), of whom 20 individuals (10 hybrid cycle, 10 handcycle) completed the study and were analyzed for all outcome measures (Table 1). The reasons for dropout were illness (three hybrid cycle, five handcycle) and lack of motivation to complete the training program (four hybrid cycle, four handcycle). All 20 participants who completed the study recorded 100% compliance to the program and trained at the target exercise intensity during the program. No significant baseline differences were present for any outcome measure or personal and lesion characteristics between the two training groups, and between participants who dropped out and participants who completed the training program. Owing to limited hand function, one participant was not able to

Table 1 Participants' characteristics

Participant	*Sex*	*Age (years)*	*TSI (years)*	*Lesion level*	*AIS*	*Height (cm)*	*Body mass (kg)*	*BMI (kg m^{-2})*
HYB								
1	M	55	34	C3	C	178	90.7	28.5
2	M	40	12	C5	A	177	65.2	20.9
3	M	39	13	C6	B	184	84.4	24.9
4	M	49	31	C7	A	174	55.5	18.3
5	M	53	10	C7	C	182	63.4	19.1
6	M	49	27	T1	A	186	67.2	19.4
7	M	40	18	T6	A	188	66.6	18.9
8	M	58	24	T8	A	172	83.0	28.1
9	M	64	18	T9	A	174	80.2	26.5
10	M	31	14	T10	A	173	73.5	24.6
Mean (s.d.)		48 (10)	20 (8)			179 (6)	73.0 (11.2)	22.9 (4.0)
HC								
1	M	63	10	C2	D	180	73.6	22.9
2	M	48	30	C6	C	171	91.6	31.3
3	M	47	12	C6	C	174	80.2	26.5
4	M	51	21	T3	A	181	72.6	22.2
5	M	30	11	T4	A	174	73.8	24.4
6	M	49	16	T5	A	174	75.0	24.8
7	M	47	18	T7	A	185	82.0	24.0
8	M	38	9	T9	A	173	60.5	20.2
9	M	49	15	T11	A	187	58.8	16.8
10	F	50	14	L2	A	166	67.2	24.5
Mean (s.d.)		47 (9)	16 (6)			177 (7)	73.5 (9.8)	23.8 (3.8)

Abbreviations: AIS, ASIA (American Spinal Injury Association) Impairment Scale; BMI, body mass index; F, female; HC, handcycle group; HYB, hybrid cycle group; M, male; TSI, time since injury.

Table 2 Effects of the 16-week hybrid cycle versus handcycle training program on fitness and physical activity

N = 10 HYB, 10 HC	*Whole group*			*HYB*			*HC*			*Main effect time*		*Interaction (time × group)*	
Fitness	*Pre*	*Mid*	*Post*	*Pre*	*Mid*	*Post*	*Pre*	*Mid*	*Post*	P-*value*	n_p^2	P-*value*	n_p^2
PO_{peak} (W)[a]	45.4 (6.1)	50.3 (5.7)	49.2 (5.5)	39.5 (9.5)	44.5 (9.5)	45.4 (8.5)	50.7 (7.9)	55.6 (6.9)	52.5 (7.3)	0.11	0.14	0.39	0.05
VO_{2peak} (l min^{-1})[b]	1.32 (0.12)	1.43 (0.13)	1.41 (0.12)	1.19 (0.20)	1.25 (0.24)	1.33 (0.21)	1.43 (0.16)	1.57 (0.12)	1.48 (0.14)	0.14	0.11	0.33	0.07
$VO_{2\ block1}$ (l min^{-1})[b]	0.63 (0.08)	0.60 (0.15)	0.64 (0.13)	0.61 (0.08)	0.57 (0.10)	0.60 (0.13)	0.65 (0.08)	0.63 (0.18)	0.67 (0.13)	0.59	0.03	0.05	0.19
$VO_{2\ block2}$ (l min^{-1})[b]	0.64 (0.14)	0.66 (0.14)	0.66 (0.14)	0.68 (0.15)	0.57 (0.11)	0.60 (0.13)	0.63 (0.13)	0.72 (0.14)	0.70 (0.14)				
HR_{block1} (b.p.m.)	93 (11)	87 (16)	88 (15)	89 (15)	82 (16)	83 (12)	96 (7)	90 (16)	93 (17)	0.11	0.15	0.78	0.02
HR_{block2} (b.p.m.)	95 (12)	88 (14)	91 (16)	92 (17)	84 (14)	84 (11)	98 (7)	91 (14)	96 (17)				
HR_{rest} (b.p.m.)	76 (2)	70 (3)	71 (2)	73 (4)	68 (4)	70 (3)	78 (2)	71 (3)	72 (4)	0.03	0.17	0.82	0.01
PTS (s)	18.9 (3.1)	18.6 (2.8)	18.1 (2.6)	22.2 (5.9)	21.9 (5.3)	20.9 (4.9)	15.5 (1.6)	15.2 (1.2)	15.3 (1.3)	0.41	0.04	0.41	0.04
Physical activity													
WC_{dist} (km)[c]	27.8 (6.9)	NA	34.3 (7.1)	27.1 (12.1)	NA	30.0 (6.9)	28.7 (6.7)	NA	39 (13.5)	0.30	0.08	0.78	0.006
PASIPD score	8.0 (1.5)	15.1 (2.7)	14.5 (2.5)	6.3 (1.9)	16.6 (3.9)	15.5 (3.3)	9.7 (2.4)	13.6 (3.8)	13.5 (4.0)	0.002	0.37	0.10	0.13

Abbreviations: HC, handcycle group; HRrest, resting heart rate; HYB, hybrid cycle group; NA, not applicable (not measured at the mid-test); np^2, partial eta-squared; PASIPD, Physical Activity Scale for Individuals with Physical Disabilities; PO_{peak}, peak power output; PTS, performance time score; VO_{2peak}, peak oxygen consumption; WC_{dist}, distance travelled in the wheelchair.
[a]N = 9 HYB, 10 HC.
[b]N = 8 HYB, 10 HC.
[c]N = 8 HYB, 7 HC.
Values are mean ± s.e. For all outcome measures, except for VO_{2block}, no significant differences over time between the hybrid cycle and handcycle training group were found (no significant time × group interactions were found).

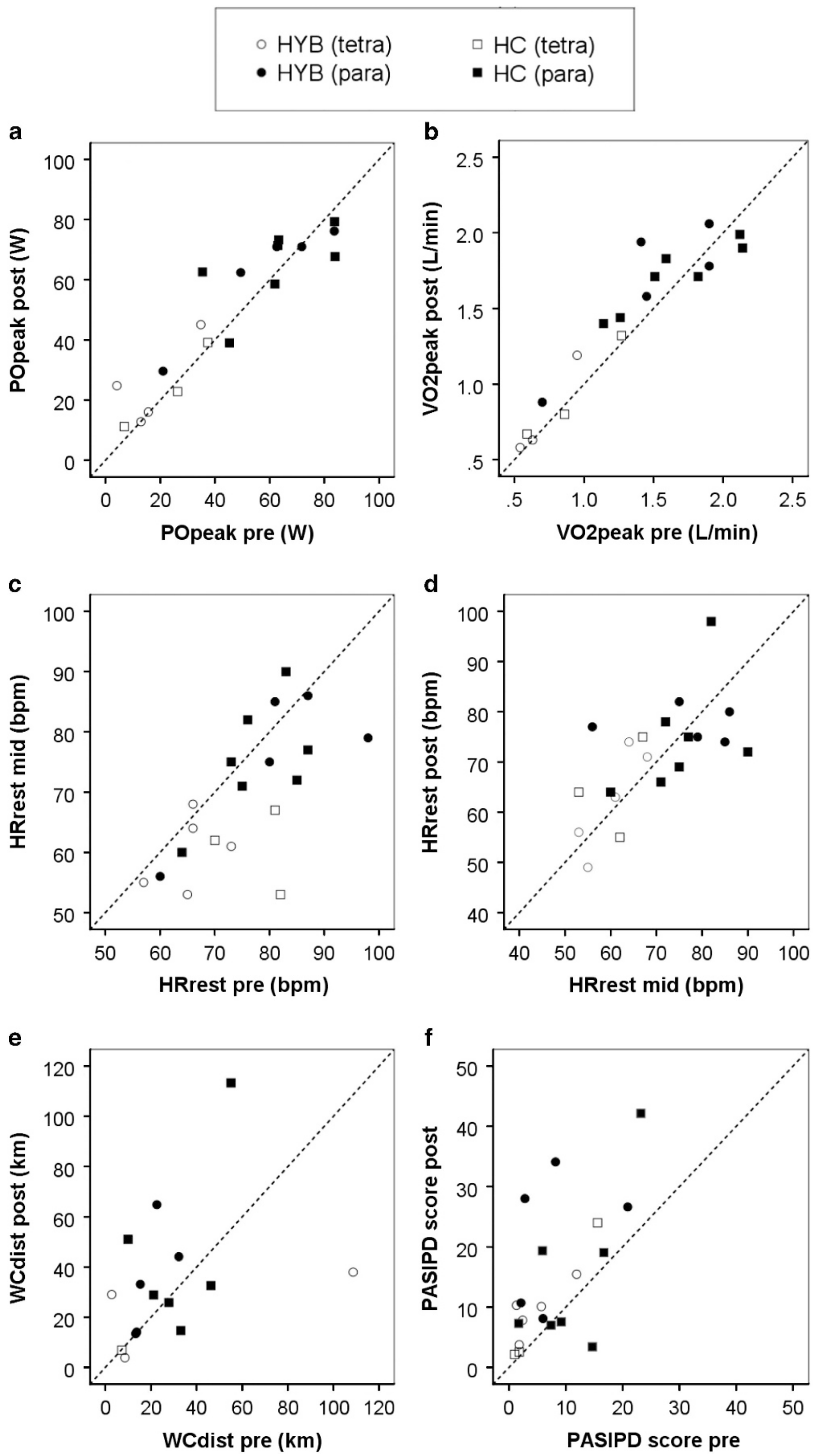

Figure 3 Individual values for fitness and physical activity components in the week before the 16-week training program (pre), after 8 weeks of training (mid) and in the week after the training program (post). For PO_{peak} (**a**), VO_{2peak} (**b**), WC_{dist} (**e**) and PASIPD score (**f**), each data point represents the pre- and post-value of one participant. For HR_{rest} (**c** and **d**), each point represents the pre-value and mid-value (**c**), and mid- value and post-value (**d**) of one participant. The dotted line is the line of identity. For example, if for PO_{peak}, a data point lies above the line of identity, this means that the PO_{peak} for this participant was increased following the 16-week training program. HC, handcycle; HR_{rest}, resting heart rate; HYB, hybrid cycle; para, paraplegia; PASIPD, Physical Activity Scale for Individuals with Physical Disabilities; PO_{peak}, peak power output; tetra, tetraplegia; VO_{2peak}, peak oxygen consumption; WC_{dist}, distance travelled in the wheelchair.

perform the graded wheelchair exercise test. Furthermore, for one participant, pre- and post-VO_{2peak} values were missing. For the WC_{dist} analysis, five participants were excluded owing to missing samples.

Owing to the missing samples, we also performed multilevel regression analyses with the participants who had at least two test occasions. As these results were similar to the analysis of variances, only the latter results are shown.

Wheelchair-specific fitness

For all fitness parameters, except for submaximal VO_2, no interaction effects were found (Table 2). The hybrid cycle group showed a decrease in VO_2 over time, whereas the handcycle group showed an increase ($P=0.045$).

There were no significant main effects for time for PO_{peak}, VO_{2peak} and submaximal VO_2 and HR, and performance time score (Table 2, Figures 3a and b). For HR_{rest}, there was a significant main effect for time (Table 2). *Post hoc* analysis revealed a significant reduction ($P=0.03$) of 6 ± 2 b.p.m. (8%) between the pre- and mid-test, and no further reduction ($P=1.0$) between the mid- and post-test (Figures 3c and 2d). Almost 90% of the participants indicated that their subjectively experienced fitness level was ‘slightly’ (50%) to ‘very much’ (40%) improved after 16 weeks of training; only 10% of the participants reported no change in subjectively experienced fitness level.

Physical activity

For both WC_{dist} and PASIPD score, no significant interaction effects were found (Table 2). Overall WC_{dist} increased by 23% following the exercise program; however, this increase was not significant (Table 2, Figure 3e). In contrast, there was a significant main effect for time for PASIPD score (Table 2, Figure 3f). *Post hoc* analysis revealed a significant increase of 88% ($P=0.002$) between the pre- and mid-test, and no further improvement ($P=1.0$) between the mid- and post-test.

DISCUSSION

Except for submaximal VO2, hybrid cycling training showed no favorable effects on wheelchair-specific fitness and physical activity compared with handcycle training. Both training modalities showed a reduction in HR_{rest} and an increase in the PASIPD score.

FES cycling has a low efficiency,[17] but the decrease in submaximal VO_2 in the hybrid cycling group might indicate that it can improve because of training. The reduction in HR_{rest} for both training groups, suggesting an improved cardiorespiratory fitness,[18] and the increased subjectively experienced fitness observed, support previously reported findings regarding the positive effects of hybrid cycle and handcycle training on fitness. However, PO_{peak} and VO_{2peak} were not significantly improved, suggesting that it is better to train more specifically (that is, wheelchair training) than with hybrid cycling or handcyling to achieve desirable effects in wheelchair-specific fitness. On the basis of normative values for PO_{peak} and VO_{2peak} in people with long-term SCI,[19] at baseline, our participants were classified as ‘average’ and ‘fair’, respectively. It might be possible that significant training effects would have been found if we were able to include people with the poorest levels of fitness. Another explanation for the lack of clear training effects might be the low training frequency. Our training program was largely based on the guidelines of the American College of Sports Medicine for training in people with disabilities (that is, frequency 3×30 min, duration 8–12 weeks, intensity 70% heart rate reserve).[20] Initially, our intention was to train three times a week. However, to increase the chance of including a sufficient number of participants and to decrease the chance of dropouts and noncompliance, eventually a training frequency of two times a week was considered to be more feasible in this physically inactive population. Afterward, looking at the difficulties with the inclusion and the high dropout rate in the current randomized controlled trial, we hypothesize that this was a good choice. The small sample size owing to the large dropout rate might also explain the lack of significant results.

Although there was no significant change over time in wheelchair activity measured with an odometer, the overall increased PASIPD score indicates an improved physical activity level. Moreover, participants subjectively indicated that various activities of daily living (for example, transfers, transportation, housework) became easier owing to an improved fitness level. The discrepancy between the activity outcomes might be explained by the different concepts that are measured by the odometer (WC_{dist}) and the PASIPD (also including, for example, strength training and gardening, in which you are physically active but do not have to move the wheelchair).

Future studies should focus on how to make this type of training more feasible and attractive for the SCI population so that they would like to start training, do not drop out and are able to train three times a week. Better facilitation of the training equipment might be a way to make these programs more feasible; if people have the possibility to exercise at home, for example, they do not have to come to a rehabilitation center, which would save travel time. The fact that eight individuals (22%) dropped out owing to health problems (for example, urinary tract infections and kidney stones) indicates that inactive people with chronic SCI are vulnerable for illness, and that interventions aiming to increase fitness and health are important in this population.

In conclusion, in the current study, hybrid cycling and handcycling showed similar effects on fitness and physical activity, indicating that there seem to be no additional benefits of the FES-induced leg exercise over handcycle training alone.

DATA ARCHIVING

There were no data to deposit.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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