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Abstract

Background. Spinal cord injury (SCI) survivors with tetraplegia have great difficulty performing activities of daily living (ADLs). Functional electrical stimulation (FES) combined with exercise therapy (ET) can improve hand function, but delivering the treatment is problematic. **Objective.** To compare 2 ET treatments delivered by in-home tele-therapy (IHT). **Methods.** Each treatment involved ET, tele-supervised 1 h/d, 5 d/wk for 6 weeks. Treatment 1: “conventional ET” comprised strength training, computer games played with a trackball, and therapeutic electrical stimulation (TES). Treatment 2: “ReJoyce ET” comprised FES-ET on a workstation, the Rehabilitation Joystick for Computerized Exercise (ReJoyce) with which participants played computer games associated with ADLs. Participants were block-randomized into group 1 receiving conventional ET first, followed by 1-month washout, and then ReJoyce ET and group 2 in reverse order. In all, 13 participants took part, 5 completing the study with both hands, such that both groups had a sample size of 9. Primary outcome measure: Action Research Arm Test (ARAT). Secondary outcome measures: grasp and pinch forces and the ReJoyce automated hand function test (RAHFT). **Results.** ARAT scores improved more after ReJoyce ET ($13.0\% \pm 9.8\%$) than after conventional ET ($4.0\% \pm 9.6\%$; $F = 10.6$, $P < .01$). RAHFT scores also improved more after ReJoyce ET ($16.9\% \pm 8.6\%$) than conventional ET ($3.3\% \pm 10.2\%$; $F = 20.4$, $P < .01$). **Conclusions.** FES-ET on a workstation, supervised over the Internet, is feasible and may be effective for patients who can meet the residual motor function requirements of our study.

Keywords

tetraplegia, tele-rehabilitation, exercise, tele-therapy, functional electrical stimulation

An estimated 2.5 million people live with spinal cord injury (SCI) worldwide (<http://www.campaignforcure.org/iccp/>). People with tetraplegia often depend on caregivers to perform the simplest manual tasks. Recovery of upper extremity function is their top priority, over all other disabilities.¹ A rigorous program of exercise therapy (ET) can improve upper extremity function,² and small improvements can make a large difference.^{3,4} However, ensuring regular ET after clients leave rehabilitation facilities is problematic. Clients are given lists of exercises they should perform, but the exercises tend to be boring, resulting in poor compliance over time.⁵ Health care systems may not pay for home visits by therapists to supervise ET. This situation is giving rise to innovative methods of delivering rehabilitation, including home-based constraint-induced movement therapy (CIMT),⁶ ET with robotic devices,^{7,8} the use of joysticks and computer games,⁹ and in-home tele-therapy (IHT)^{10,11} (studies by Reinkensmeyer et al,⁹ Bowman and Speier,¹⁰ and Kowalczewski et al¹¹ were not

sufficiently powered for conclusions to be drawn regarding their efficacy). Therapeutic electrical stimulation (TES) and functional electrical stimulation (FES) are used to strengthen muscles and assist in functional tasks.¹²⁻¹⁴

In this study, we explored 2 IHT treatments, one involving conventional approaches and the other involving FES-assisted game playing on a novel workstation. The treatments were designed to be affordable in today's health care environment. One aim of the study was to explore the feasibility of providing IHT-ET over the Internet. Another was to compare 2 levels of treatment. To our knowledge,

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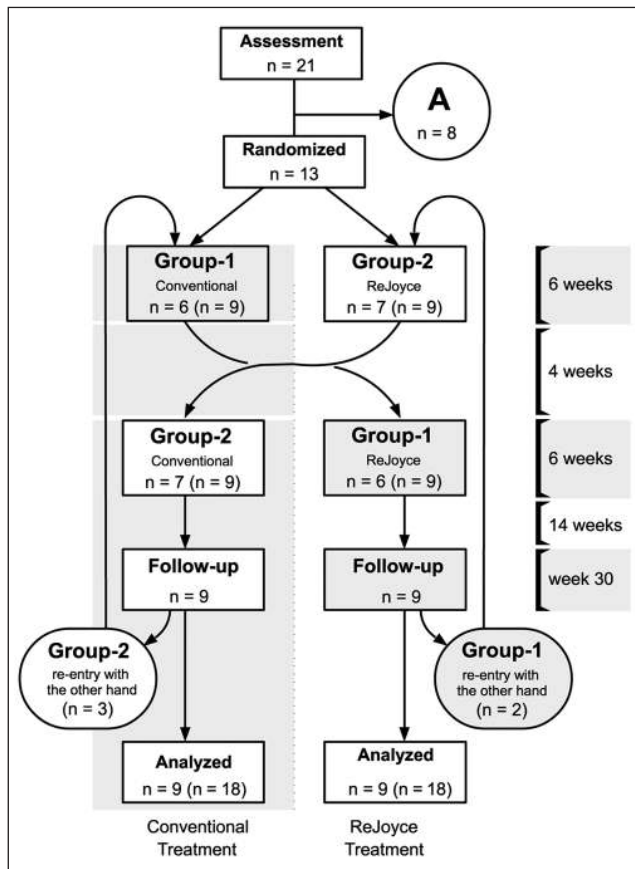


Figure 1. Modified CONSORT flowchart (see text for details)

this is the first concerted effort to provide daily, tele-supervised ET for people with a motor disorder.

Methods

Study Design

The study was a blindly evaluated, randomized controlled trial (RCT) comparing 2 treatments in a crossover design. Participants performed IHT-ET 1 h/d for 6 weeks. Conventional ET consisted of ET with conventional rehabilitation equipment, including TES. ReJoyce ET consisted of ET on the ReJoyce workstation, with an FES garment assisting grasp and release.

Participants

Written, informed consent was obtained from 21 potential subjects (Figure 1). The study was approved by the Health Research Ethics Board of the University of Alberta and registered with the National Institutes of Health (NCT00656149, <http://www.clinicaltrials.gov>). The inclusion criteria were C5-C7 tetraplegia of at least 9 months,

ability to lift and place the hand onto a table surface, and to enhance grasp and release with FES. Participants were excluded if they had inadequate proximal muscle control, if their hand muscles were unresponsive to FES, if they had severe contractures or tendon transfers, or if they were unable to commit to 5 h/wk of ET and test sessions at the host laboratory. Eight subjects were excluded: 3 had denervated muscles, 3 were unable to commit, 1 had a high risk of seizures, and 1 did not require FES to perform activities of daily living (ADLs). Of the 13 recruited subjects, 6 were randomly assigned to group 1, which received 6 weeks of conventional ET, 1-month washout, and then 6 weeks of ReJoyce ET. The remaining 7 subjects were assigned to group 2, which received 6 weeks of ReJoyce ET, 1-month washout, and then 6 weeks of conventional ET. After completing the full 16-week protocol with one hand, subjects were asked whether they wished to repeat the protocol with their other hand. Nine subjects declared themselves willing. Of these, we selected 5 subjects on the basis of the inclusion criteria and their track record of cooperation. Accordingly, 2 of the 6 subjects originally in group 1 re-entered the study and were assigned to group 2. Three of the 7 subjects originally in group 2 re-entered the study and were assigned to group 1. Thus, each group of hands studied had a sample size of 18. There were no dropouts at the 30-week follow-ups and all data were analyzed. ET took place at home except for sessions in the host laboratory at the end of weeks 2, 4, 6, 10, 12, 14, and 16 during which functional, electrophysiological, and sensory tests were also performed. The electrophysiological results are reported elsewhere.¹⁵ In 2009, 3 subjects were recruited at a second site (Royal Talbot Rehabilitation Hospital, Melbourne, Australia). One subject was assigned to group 1 (conventional ET first) and 2 subjects were assigned to group 2 (ReJoyce ET first). Because the timing and number of assessments at this site differed somewhat from those in the Canadian study, the data were not combined. The results from these subjects are reported anecdotally.

Treatments

Both treatments involved IHT. Participants were provided with a laptop computer, a Web cam, and an Internet connection. The computer had the following software: Microsoft Windows XP; virtual network computing (VNC) allowing remote control of the computer; and Skype, an Internet protocol with 2-way verbal and video communication allowing supervision of participants performing ET. The ReJoyce ET treatment involved the playing of custom computer games described below. In most cases, the laptop was connected to the Internet through a local wireless network. The tele-supervisors also had a laptop and Web cam. They remotely supervised ET sessions from the host

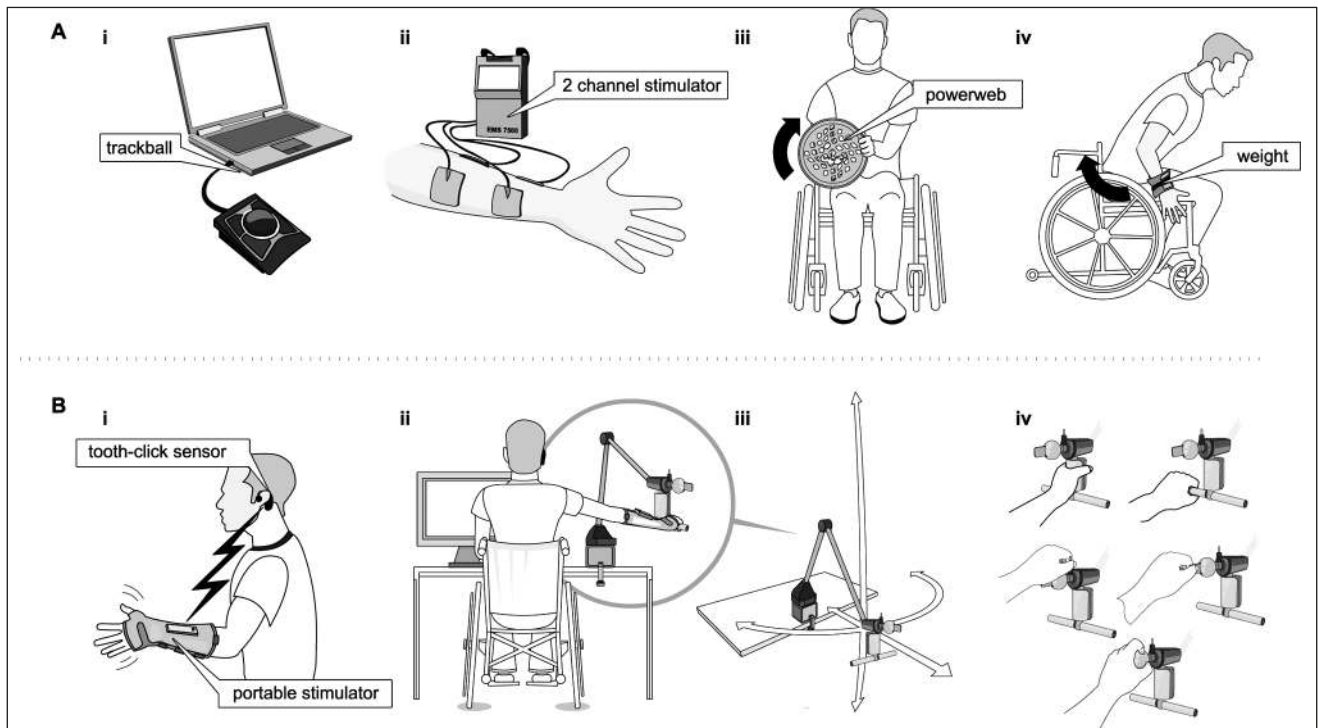


Figure 2. Exercise therapy (ET)

A, Conventional ET: (A-i) 20 minutes daily of accuracy training using a trackball to play commercially available computer games; (A-ii) 20 minutes of cyclical therapeutic electrical stimulation (TES); (A-iii, A-iv) resistance training using a Powerweb and wrist weights, respectively. B, ReJoyce ET: 1 h/d functional electrical stimulation (FES)-ET on the ReJoyce workstation: (B-i) tooth-click activated FES garment; (B-ii) participant using workstation to play computer game and interact with tele-supervisor; (B-iii) range of motion of manipulandum assembly; (B-iv) tasks performed on the manipulanda.

laboratory, or from their residences. Sessions were agreed upon in advance to suit participants' and supervisors' schedules. Supervisors were trained by a physical therapist and instructed to maintain the same standard of care throughout.

Conventional Exercise Therapy

Physical therapist SC prescribed individualized exercises based on each participant's abilities. Sessions were divided into three 20-minute segments, one for strength training, the second for accuracy training, and the third for TES. The equipment used (Figure 2A) was chosen for its low cost, ready availability, and standard usage in physical and occupational therapy. Strength training was performed with weighted wristlets and/or a "Powerweb." Accuracy training consisted of playing computer games with a large computer mouse (Kensington "Trackball"). This required movements of the arm and hand as well as mouse-clicks with the fingers. The games and their difficulty settings were chosen according to the participants' abilities and preferences. TES was delivered with a 2-channel stimulator (EMS 7500) through self-adhesive surface electrodes located over the motor points of extensor digitorum (ED)

and extensor pollicis longus (EPL) to elicit hand opening and the motor points of flexor digitorum superficialis (FDS) to elicit flexion, alternating between the 2 states every 5 seconds.

ReJoyce Exercise Therapy

IHT-ET on the ReJoyce workstation, with FES delivered to muscles ED and EPL for hand opening and FDS and flexor pollicis brevis (FPB) for grasp by a 3-channel stimulator built into a fingerless glove with a thumb loop (Figure 2B-i).¹⁶ The stimulator was wirelessly triggered with tooth-clicks. These were detected by an earpiece containing an accelerometer that sensed bone-conducted vibrations anterior to the ear.¹⁷ The earpiece sent radio frequency signals to the stimulator, advancing it through a 3-state sequence: hand opening, grasp, no stimulation. A given state could be skipped with a double click.

The ReJoyce workstation consisted of a segmented, jointed, spring-loaded arm whose base was clamped to a table or desk (Figure 2B-ii). Movie clips of the device being used by the subjects in this study are available on request. At its free end the arm supported an assembly of 6 manipulanda representing ADLs. The assembly could be moved

to any location within a 3-dimensional volume enclosing the physiological workspace of an able-bodied person 2 m in height (Figure 2B-iii). The ReJoyce was instrumented with potentiometers and switches, signals from which were sampled at 40 per second and transmitted to the computer. The arm provided between 10 and 20 N/rad elastic stiffness to manipulandum movement in any direction and returned to the rest position when released. It also provided partial weight support when loaded. The manipulanda (Figure 2B-iv) comprised a pair of horizontal handles, a vertical spring-loaded peg, the “gripper,” a spring-loaded split cylinder the size of a soda can with a stiffness of 2 N/mm, and a spring-loaded doorknob with an exposable key, either of which could be gripped and rotated (stiffness 0.16 N m/radian). The handles were situated at the bottom of the manipulandum assembly and in the rest position they were at the level of the table surface, about 45 cm from the table edge.

During ReJoyce ET sessions, participants played custom computer games on the ReJoyce workstation. The tele-supervisor remotely controlled the participant’s computer, selected games and the manipulanda controlling them, and adjusted the difficulty of the games by setting the initial speed and the range of motion (ROM) required. Six games were provided, each game configurable providing a variety of different movements and a choice of manipulanda. The software automatically increased the difficulty and speed of the games over the course of play. The games involved (a) driving a car on a winding road and avoiding other cars and obstacles, (b) catching falling objects with different grasps and twists, (c) shooting targets of different shapes and sizes, (d) weeding a garden, (e) pouring drinks, and (f) boxing. The movements required to play varied within a game and between games. For example, the virtual car could be driven either by grasping a handle or the gripper and moving the manipulandum assembly back and forth horizontally, or by grasping the doorknob and twisting it by pronating and supinating the hand. Weeding involved either holding the peg in a pinch grip and lifting it or grasping the gripper to select, move, and drop virtual weeds. Pouring a drink involved first holding the gripper loosely, moving it upward toward a specific virtual bottle on a shelf, grasping the bottle, lowering it, pronating for a specified period of time to fill but not overflow a glass, and finally supinating and then releasing the gripper to release the bottle. The catching game required a range of grasps and movements of manipulanda initially selected by the tele-supervisor.

Primary Outcome Measure

We considered using the grasp–release test,¹⁸ which was specifically designed to evaluate FES in tetraplegia, but

it takes more than 30 minutes to administer and does not provide numeric scores. In a previous study, we found that the grasp–release test caused significant muscle fatigue and so we decided against using it in the present study. Instead we chose the Action Research Arm Test (ARAT),^{19,20} which takes about 15 minutes, is validated for hemiplegia and is highly correlated with several other common hand function tests used in SCI studies.^{21,22} The ARAT was videotaped from a fixed vantage point, video clips of each component then being randomized onto digital video disks for blind assessment by a second physical therapist who had no contact with the participants.

Secondary Outcome Measures

The ReJoyce automated hand function test (RAHFT) is a test that was performed on the ReJoyce workstation with audiovisual prompts and reminders generated by interactive software.²³ The workstation sensors provided signals that allowed quantitative scoring. The RAHFT consisted of 3 parts: functional ranges of motion (fROM), functional tasks, and placement tasks. It took about 5 minutes to perform. The fROM was measured in 3 directions: left–right, up–down, and in–out. The left–right component consisted of grasping one of the horizontal handles of the ReJoyce and moving it as far to the left and then as far to the right as possible. The fROM was scored as a percentage of the full range of horizontal motion of the device. Similar fROM scores were obtained for up–down and in–out movements. Functional tasks included grasping (squeezing the gripper, which was the size of a soda can, 3 times), grasping with pronation and supination (rotating a doorknob), and key grip with pronation and supination (rotating a key). These tasks were also scored as percentages of the maximal values possible. Finally, the placement tasks involved picking up a virtual soda can displayed on the computer screen by holding the gripper loosely, moving it so as to position crosshairs onto the screen image of the can, squeezing the gripper to hold the can, and move it to a position over 1 of 2 virtual “garbage bins” located on each side of the screen. The can was then dropped into the bin by releasing the gripper. A new can then appeared in the middle of the screen, requiring the subject to grasp, move, and drop it into the other bin. The second placement task was similar, in that it required a peg located at the top of the assembly to be grasped, lifted, moved and released. A corresponding virtual peg was displayed on the subject’s screen. The task was to move it over 1 of 2 virtual “holes” and release it. As in the case of the soda can task, a second virtual peg then appeared and this had to be dropped into the second virtual “hole.” Each placement task comprised 2 components: a grasp, movement to the left and release, and a grasp, movement to the right and release. Each

Table 1. Clinical and Demographic Features of Participants^a

Age (years)	35.92 ± 11.96	n = 13
Gender	7 male/6 female (54% male)	n = 13
Time post SCI (years)	3.62 ± 2.12	n = 13
Affected ASIA level of the cervical spinal cord		n = 13
C5	5 (38% affected)	
C6	4 (31% affected)	
C7	4 (31% affected)	
Completeness of injury	4 (31% complete)	n = 13
Hand dominance	12 right/1 left (92% right hand dominant)	n = 13
Hand most functional postinjury	8 right/5 left (62% right hand)	n = 13
Treated hands (18 hands treated)	10 right/8 left (56% right hand treated)	n = 18
Distance from testing site (km)	212 ± 262	n = 13
Wireless network used	9 (69% of connection were wireless)	n = 13

Abbreviations: SCI, spinal cord injury; ASIA, American Spinal Cord Injury Association.

^aA total of 13 participants entered the trial, of whom 5 reentered with their other hand (Figure 1). The number of participants was therefore 13 and the number of hands per treatment was 18. In some participants, the spinal cord injury spanned more than one segment (eg, C5 and C6).

component was scored in terms of the time t in seconds to completion according to the equation:

$$\text{score} = 50 - (5 \times t/6)$$

For example, $t = 6$, score = 45; $t = 60$, score = 0. For $t > 60$, the score was set to zero. The scores from the 2 components were then summed to give a score of 100 for $t = 0$. Able-bodied people typically performed each component of the placement tasks in about 2 seconds, thus scoring a total of 95. The next secondary outcome measure was pinch force between thumb and fingers measured with a pinch gauge (B&L Engineering, Santa Ana, CA). A JAMAR dynamometer was first used to measure grasp force, but because it lacked calibration below 10 N, we used grasp force measurements from the RAHFT instead.

Statistical Methods

The study was a crossover RCT comparing protocols and treatments. Hand function test scores and pinch and grasp force data were obtained prior to treatment, biweekly during treatment, and at the 30-week follow-ups. ARAT scores were expressed as percentage improvements of the full range (0 to 57):

$$\text{percentage improvement} = 100 \times (\text{raw score} - \text{mean baseline score})/57$$

RAHFT scores were expressed as percentages of the mean score of a cohort of able-bodied participants.²³ Improvements in RAHFT scores were obtained by subtracting each participant's mean baseline scores from their treatment scores. Improvements in grasp and pinch force

were similarly obtained by subtracting baseline values from treatment values.

The data were analyzed with PASW Statistics 17.0 for Windows software (SPSS, Chicago, IL). Descriptive statistics, including means and standard deviations (SD), were calculated for all dependent variables. Normality of data sets was tested with the Shapiro–Wilks W test. A repeated measures analysis of variance (ANOVA) was used to test for significant differences in outcome measures between protocols and treatments. A multivariate regression analysis was also included.²⁴ This involves performing polynomial regressions on the data from each group separately and one on the combined data. The variance around the combined regression curve is then compared with the mean variance around the separate regression curves, the null hypothesis being no difference, that is, the separate regressions do not result in better fits than the combined regression.

Clinical significance was assessed on the basis of the minimal clinically important difference (MCID) defined as an improvement of 10% of the full range, based on studies after stroke.²⁵ We also computed Cohen's effect size d .²⁶ Values of 0.2, 0.5, and 0.8 represent small, medium, and large treatment effects, respectively. A post hoc power analysis was performed to verify that the sample size was sufficient for 80% power ($\alpha = .05$).

Results

Table 1 lists the participants' characteristics and demographics. Participants had a large range of functional impairment at the onset of the trial, as evidenced by the large SDs in baseline ARAT and RAHFT scores prior to each protocol. Table 2 shows the mean baseline scores at the start of each treatment. Baseline scores were well matched: comparing

Table 2. Baseline Data for ARAT, RAHFT, Pinch, and Grasp^a

Outcome Measures	Protocols (\pm SD)			Treatments (\pm SD)		
	Group 1	Group 2	Mean	Conventional ET	ReJoyce ET	Mean
ARAT	25.5 \pm 12.8	26.0 \pm 12.5	25.8 \pm 12.4	29.4 \pm 12.3	27.3 \pm 12.2	28.4 \pm 12.2
RAHFT (%)	22.8 \pm 14.7	20.7 \pm 12.1	21.8 \pm 13.1	31.2 \pm 18.0	24.0 \pm 14.2	27.6 \pm 16.4
Pinch (N)	1.6 \pm 1.8	1.9 \pm 1.1	1.7 \pm 1.5	2.0 \pm 2.0	1.8 \pm 1.3	1.9 \pm 1.7
Grasp(ReJoyce) (N)	3.9 \pm 3.3	3.6 \pm 3.7	3.7 \pm 3.6	5.4 \pm 4.1	4.3 \pm 4.3	4.9 \pm 4.2

Abbreviations: ET, exercise therapy; ARAT, Action Research Arm Test; RAHFT, ReJoyce automated hand function test; SD, standard deviation.

^aFour sets of baseline measurements per participant, 2 prior to the onset of each protocol (week 0) and 2 just prior to crossover (week 10). In the case of the combined treatment data, the baseline values are the means of all 4 of these measurements.

groups, ARAT scores differed by 0.5 and RAHFT scores differed by 2.1%. Comparing baselines prior to conventional and ReJoyce ET treatments, ARAT scores differed by 2.1 and RAHFT scores differed by 7.2%. None of these differences were significant (Student's *t* test, $P > .05$). The mean baseline grasp force prior to conventional ET (5.4 N) was significantly larger than that prior to ReJoyce ET (4.3 N), yet as will be seen, grasp force increased more after ReJoyce ET than after conventional ET.

Comparing the 2 Groups

The mean improvements in ARAT at week 16, that is, at the completion of both treatments, were 14.3% \pm 9.9% for group 1 and 13.6% \pm 10.7% for group 2 (expressed as percentages of the full 57-point range of the ARAT; Figure 3). At the 30-week follow-up, they were 11.2% \pm 6.8% and 17.3% \pm 6.8%, respectively. Similarly, at week 16, RAHFT scores had improved by 16.1% \pm 10.3% in group 1 and by 19.4% \pm 8.7% in group 2, and at follow-up they were 15.0% \pm 12.0% and 21.4% \pm 8.5%, respectively (percentages of the mean score of a cohort of able-bodied participants).

Repeated measures ANOVAs were performed for each of the outcome measures. The group was entered as the between-subjects factor and time of testing was entered as the within-subjects factor (Table 3). The between-subjects tests showed significant differences between the 2 groups in ARAT and RAHFT scores. Likewise, the within-subjects test showed a significant time of testing effect in both ARAT and RAHFT. The interaction of time of testing and group was significant for the RAHFT but not the ARAT ($P = .106$). These tests indicate that both groups showed significant functional improvements over time, but that there was a difference between the time courses of improvement. The multivariate regression analyses supported these conclusions. The between-groups tests of grasp and pinch forces did not show significant differences though there was a significant time of testing effect in grasp and near-significance in pinch ($P = .07$). The interaction of time of testing and group was significant in both pinch and grasp.

Comparing Conventional ET and ReJoyce ET

Conventional ET data from group 1, baseline to week 6 were combined with conventional ET data from group 2, weeks 10 to 16. Likewise, ReJoyce data from group 2, baseline to week 6 were combined with ReJoyce data from group 1, weeks 10 to 16. This provided sample sizes of 18 hands per ET treatment. At week 6 the improvements in the ARAT were 4.0% \pm 9.6% (conventional ET) and 13.0% \pm 9.8% (ReJoyce ET). Corresponding improvements in the RAHFT were 3.3% \pm 10.2% and 16.9% \pm 8.6%; in grasp force 1.5 N \pm 2.3 N and 4.1 N \pm 3.8 N and in pinch force -0.3 N \pm 1.2 N and 1.2 N \pm 3.0 N, respectively (Figure 4). Repeated measures ANOVAs were performed with treatment as the between-subjects factor and time of testing the within-subjects factor (Table 3). The tests showed significant differences between the 2 treatments in both ARAT and RAHFT, with significant time effects in both cases. The interaction of treatments and time were also significant. These tests indicate that both ET treatments resulted in improvements over time, that there was a difference between the treatments, and that the time courses of improvements differed. For grasp, the ANOVAs showed significant differences between treatments, a time effect, and a time-treatment interaction. Pinch force showed only a time-treatment interaction.

Effect Size and Minimal Clinically Important Difference

Cohen's *d* values for conventional ET were 0.43 for the ARAT, 0.32 for the RAHFT, 0.64 for grasp force, and 0.26 for pinch force. For ReJoyce ET, the *d* values were 1.32 for the ARAT, 1.95 for the RAHFT, 1.09 for grasp force, and 0.41 for pinch force. From Figure 3, the improvements in the ARAT exceeded the 10% MCID²⁵ in both groups (after both treatments) at 16 weeks and at the 30-week follow-up. From Figure 4, the MCID was exceeded in the ARAT (13.0%) and RAHFT (16.9%) in ReJoyce ET but not in conventional ET (ARAT 4.2%, RAHFT 3.3%).

Table 3. Results of Statistical Tests^a

		Repeated Measures ANOVA						Multivariate Regression Analysis		Comparing Baselines (t Test)
		Group		Time		Group × Time		F	P	P
		F	P	F	P	F	P			
Groups 1 and 2 (n = 9 in each)	ARAT	10.5	.01*	5.4	.03*	1.7	.11	10.6	<.01*	.932
	RAHFT	16.6	<.01*	8.2	.01*	4.0	<.01*	20.4	<.01*	.742
	Grasp force (N)	2.3	.15	5.3	<.01*	1.5	.18	5.3	.01*	.785
Conventional and Rejoyce ET (n = 18 in each)	Pinch force (N)	0.1	.76	1.9	.07	2.2	.032*	0.2	1.00	.626
	ARAT	13.9	<.01*	7.7	.01*	3.6	.017*	12.1	<.01*	.610
	RAHFT	19.3	<.01*	14.6	<.01*	10.3	<.01*	24.6	<.01*	.187
	Grasp force (N)	4.6	.04*	11.0	<.01*	2.7	.047*	7.5	<.01*	.276
	Pinch force (N)	1.4	.24	3.4	.07	4.1	.009*	4.8	.01*	.672

Abbreviations: ET, exercise therapy; ARAT, Action Research Arm Test; RAHFT, Rejoyce automated hand function test.

^aAsterisks mark significant differences ($P < .05$).

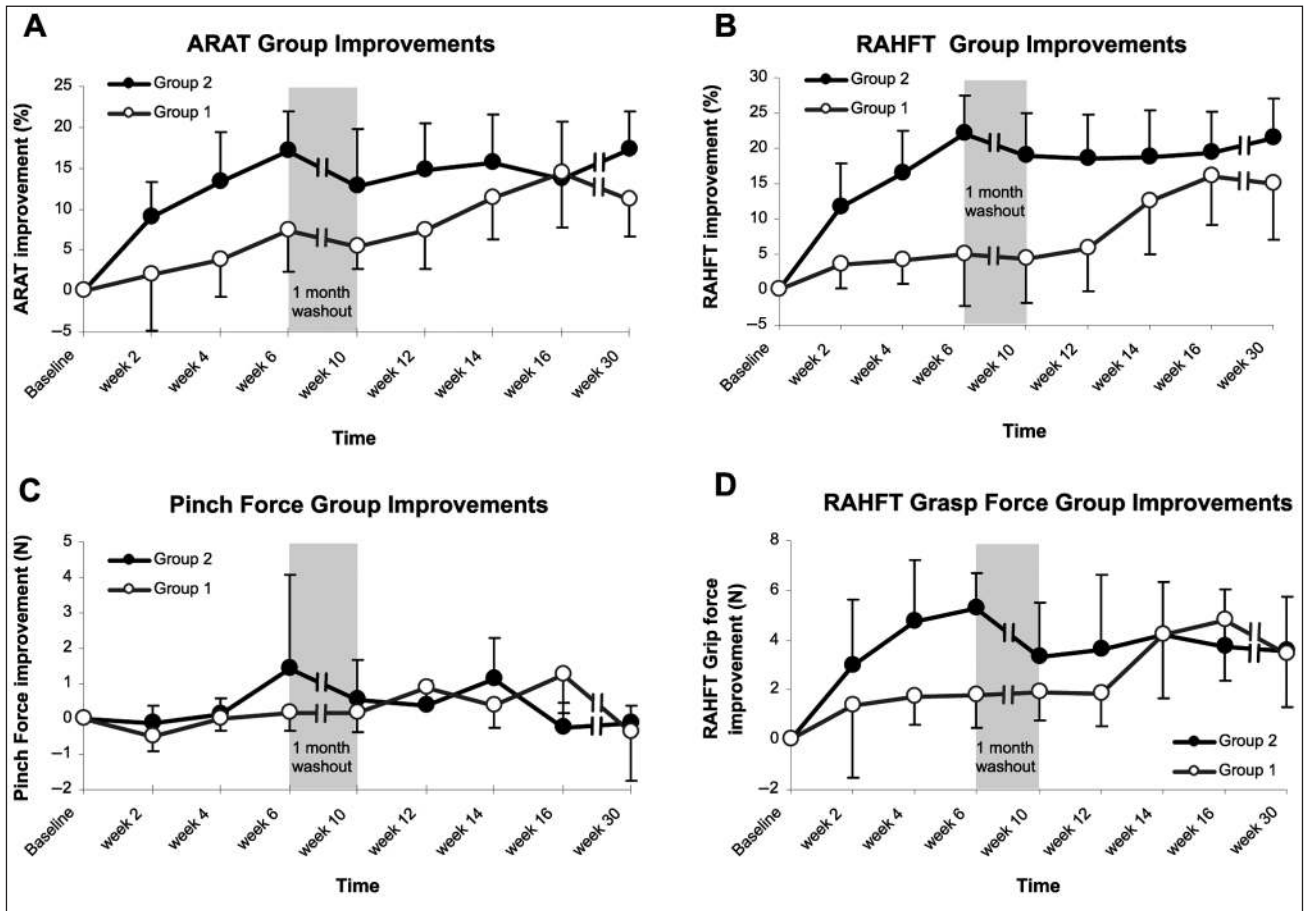


Figure 3. Improvements during the 2 protocols

Group 1: Weeks 0 to 6 conventional exercise therapy (ET), weeks 7 to 9 washout, weeks 10 to 16 Rejoyce ET, week 30 follow-up. Group 2: Reverse order of treatments. A, Action Research Arm Test (ARAT). B, Rejoyce automated hand function test (RAHFT). C, Pinch force. D, Grasp force. n = 9 in each case, each protocol lasting 16 weeks; means ± 2 standard errors (SE).

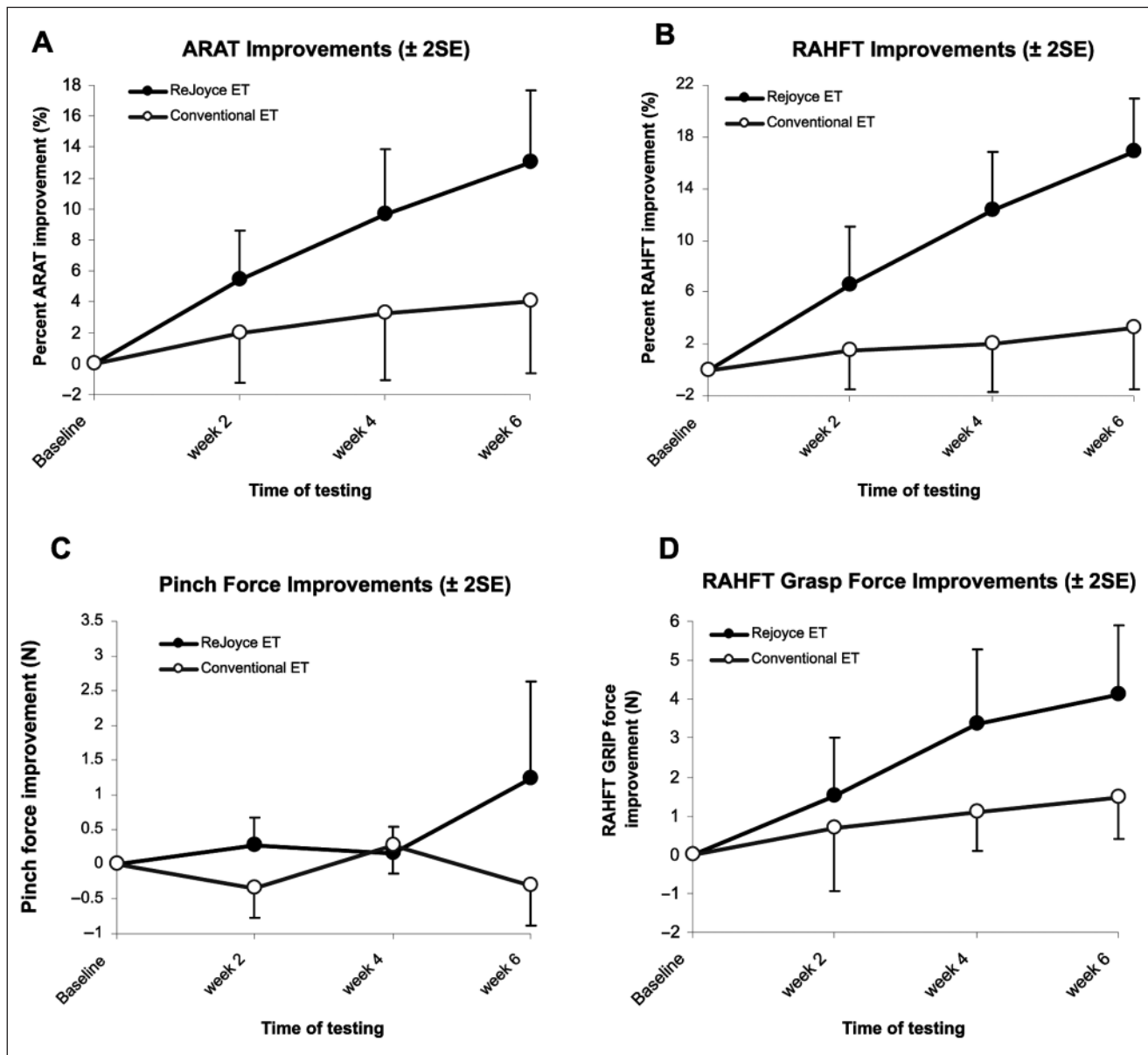


Figure 4. Combined pre- and postcrossover improvements from baselines in conventional exercise therapy (ET) and ReJoyce ET. A, Action Research Arm Test (ARAT). B, ReJoyce automated hand function test (RAHFT). C, Pinch force. D, Grasp force. $n = 18$ in each case, each treatment lasting 6 weeks. means ± 2 standard errors (SE).

Statistical Power

N , the sample size required for 80% power ($\alpha = .05$) in detecting the significance of a difference in means δ between 2 groups is as follows²⁷: $N = 2 \times 7.84 \times SD^2/\delta^2$. Comparing treatments, for the ARAT, $\delta = 9.0\%$, $SD = 9.7\%$, so $N = 18$. In the RAHFT, $\delta = 13.6\%$, $SD = 9\%$, so $N = 8$. The actual sample size of 18 therefore just met the minimum criterion for the ARAT and exceeded it for the RAHFT.

The ARAT tests performed in Melbourne were rated from video clips by the same blinded therapist as above. The 2 subjects who had 6 weeks of ReJoyce ET showed improvements of 5% and 26%, respectively, whereas the subject

who performed 6 weeks of conventional ET showed a 2% decline. These results, though anecdotal, are consistent with the findings presented above.

Discussion

To our knowledge, this is the first RCT demonstrating the feasibility and effectiveness of 2 different kinds of upper extremity IHT for people with C5-C7 tetraplegia. The benefits were clinically relevant and maintained for 3 months.

The primary outcome measure (ARAT), and the secondary outcome measures (RAHFT, grasp and pinch forces) showed statistically significant and clinically important

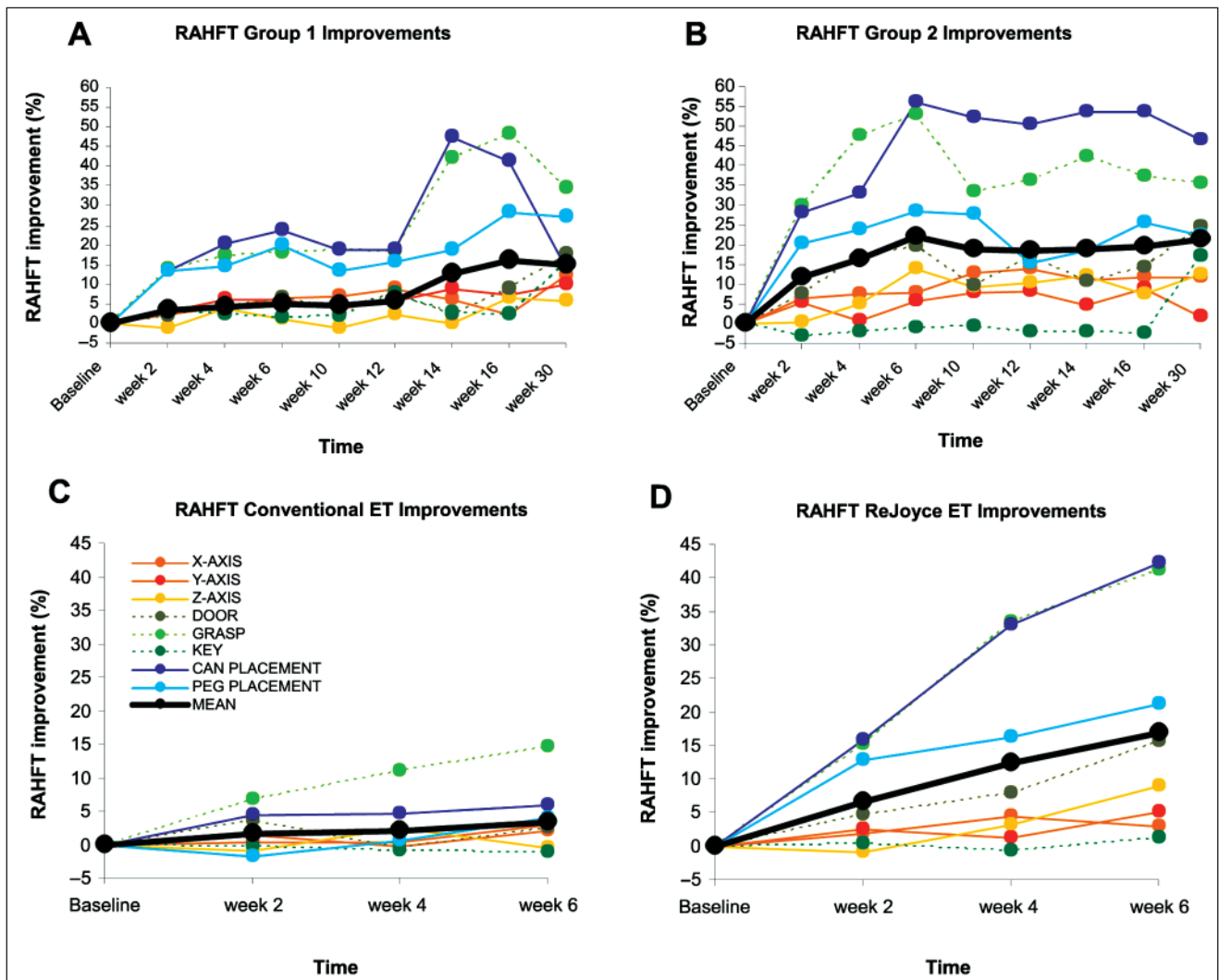


Figure 5. Improvements in individual ReJoyce automated hand function test (RAHFT) tasks

A, Group 1, $n = 9$. B, Group 2, $n = 9$. C, Conventional exercise therapy (ET), $n = 18$. D, ReJoyce ET, $n = 18$. Thick black lines show means as in Figures 3 and 4.

improvements in ReJoyce ET (FES-assisted ET on the ReJoyce workstation). The individual components of the RAHFT are shown in Figure 5. Interestingly, the largest contributors to improvements in RAHFT scores were the grasp test and the 2 placement tests. The grasp test involved squeezing the gripper 3 times, the largest force being registered. The placement test involved moving the gripper sideways to position a virtual “hand” over a virtual “soda can,” squeezing the gripper to “hold” the can, moving the can laterally over a virtual “garbage bin,” and releasing the gripper to drop the can. This was repeated twice. A timing algorithm was used to generate the score.²³ The peg placement test was similar to the gripper placement test, with a virtual peg and pegboard. The doorknob and key tasks, both of which required the subject to grasp the manipulanda and twist them clockwise and anticlockwise

did not improve significantly. Participants reported these to be the most challenging of the tests.

Most participants had weak tenodesis grasp at the onset of the trial. Improvements in grasp forces correlated with improvements in the ARAT and RAHFT. Improvements in pinch force were also observed but they failed to reach statistical significance. This may be because it was easier to elicit firm grasp with surface FES than accurate key or pinch grip and therapists tended to place more emphasis on games involving grasp. Another possibility is that C6 neuronal networks may have been in the rostral fringe of the injury in some subjects, with more scope for plasticity and adaptation. Regarding the disparity between the improvements in the RAHFT peg placement task and pinch force, it is known that some dexterous ADLs, such as writing, are more dependent on overall speed and accuracy than on force.²⁸

We were told by all participants that their level of independence and their ability to perform a variety of ADLs had improved during and after the 2 treatments, but this information was not gathered systematically. In this regard it is worth noting that both the ARAT and RAHFT were specifically designed to represent a wide range of ADLs. Regarding subject satisfaction, the clearest indicator was that 9 of the 13 participants, on completing the 16-week trial with one hand, were willing to reenter the trial with their second hand.

An important factor that determined the choice of treatments in this study was their eventual cost to the health care system should they be adopted. Both treatments involved IHT, which we believe will be an important component of rehabilitation in the future. Where the treatments differed was in the cost of the equipment provided for ET and in the type of electrical stimulation (FES vs TES). As ReJoyce ET + FES was more effective than conventional ET + TES, the question naturally arises, which factors were the more important? The treatment results support evidence in the literature that task-oriented training is more effective than nonfunctional exercise^{11,29} and that FES is a useful adjunct to ET.^{3,11} The neuronal mechanisms favoring task-oriented training are largely unknown, though recent studies suggest that sensory stimulation may play a role.^{3,4} The ReJoyce ET treatment involved intense, repetitive training under the guise of computer games. Participants were challenged to perform faster and more complex movements in the games, which increased incrementally in difficulty with each successfully completed phase. Intensity was therefore another likely factor in the effectiveness of ReJoyce ET.

The number of SCI participants available for clinical trials, even in large cities, is often limited, and this is a major problem for adequately powering RCTs.³⁰ In this study, we chose a crossover design to power the statistical comparisons. The disadvantage of this approach was that for a given treatment, after crossover, baseline functional scores were higher than those measured at week 0 and this evidently reduced the room for further improvement. Thus, in group 1 conventional ET came first and the ARAT improved, but in group 2 where conventional ET came second, the ARAT did not improve (Figure 3). Thus, when the pre- and postcrossover data for conventional ET were combined (Figure 4), at week 6 the mean ARAT improvement was reduced to 4%, from 7.5% at week 6 in group 1. An even larger dilution occurred in ReJoyce ET (13.3% at week 6 in Figure 4 compared with 17.5% at week 6 in Figure 3). Though this does not change our main conclusions, it is worth noting that the improvements shown in Figure 4 were less than those when the treatments were applied alone. Furthermore, the 1-month rest period we chose as the washout was clearly too short to allow hand function to return to the first baseline. In fact, even at the 30-week follow-ups the ARAT and RAHFT scores had

only slightly decreased for group 1 and they had even *increased* for group 2. The fact that a plateau had not been reached at 6 weeks in either treatment suggests that a longer period, for example, 8 or 10 weeks of FES-ET might have produced even larger improvements. This also raises the question of whether cross-education of strength and motor skills were transferred from one hand to the other in the 5 participants who reentered and completed both treatments with their second hand. We are unaware of studies showing cross-education after unimanual training in tetraplegia; however, a small, short-term increase in strength from a trained to an untrained upper extremity has been demonstrated in able-bodied individuals, and spinal and cortical mechanisms were proposed.³¹ The 5 participants reentered our study several months after completing the treatments with their first hand. It is not known whether cross-training endures this long, but it cannot be ruled out.

Conclusion

This study demonstrated the feasibility of delivering tele-supervised ET over the Internet. Statistically and clinically significant improvements with strong effect sizes were produced by FES-assisted IHT-ET on a workstation and a trend for improvement was observed for IHT-ET with conventional equipment.

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Declaration of Conflicting Interests

The author(s) declared a potential conflict of interest (e.g., a financial relationship with the commercial organizations or products discussed in this article) as follows: Jan Kowalczewski and Arthur Prochazka hold a US patent on the ReJoyce system. Arthur Prochazka is a stakeholder in Rehabtronics Inc (<http://www.hometelemed.com>) a university spin-off company that holds the rights to the system.

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