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Locomotor training improves daily stepping activity and gait efficiency in individuals post-stroke who have reached a "plateau" in recovery

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Abstract:

Background and Purpose: Individuals with chronic stroke often demonstrate a "plateau," or deceleration of motor recovery, which may lead to discharge from physical therapy (PT). However, numerous studies report improvements in motor function when individuals are provided intensive practice of motor tasks. We suggest that reduced task-specific walking practice during clinical PT contributes to limited gains in ambulatory function in those with a perceived plateau post-stroke, and suggest that further gains can be realized if intensive, stepping or locomotor training (LT) was provided following discharge. ***Methods:*** Twenty subjects with chronic stroke completed a repeated baseline measures, randomized crossover trial in which walking performance was assessed during the last 4 weeks of clinical PT prior to discharge secondary to reaching a plateau, followed by 4 weeks of intensive LT and 4 weeks of no intervention. Outcome measures included clinical and physiological (metabolic) measures of walking overground and on a treadmill, and measures of daily stepping activity in the home and community, including during clinical PT and subsequent LT sessions. ***Results:*** Stepping practice was over 4-fold higher during LT vs clinical PT sessions, with significant improvements in daily stepping and gait efficiency only after LT. Changes in daily stepping following clinical PT and intensive LT were correlated ($p < 0.001$) with the amount of stepping practice received during these interventions. ***Conclusions:*** Intensive LT results in improved daily stepping in individuals post-stroke who have been discharged from PT because of a perceived plateau in motor function. These improvements may be related to the amount and intensity of stepping practice.

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Introduction

Despite initial improvements in motor function in individuals early post-stroke, patients often demonstrate a "plateau," or deceleration of motor recovery in the chronic stages (i.e., > 6 mo) [1, 2] which often leads to discharge from physical therapy (PT)[3]. Current data suggest that the physiological substrates underlying motor recovery following supraspinal injury[4] are reduced in the latter stages post-insult and could contribute to this apparent "plateau". However, numerous studies have demonstrated that practice of specific motor tasks enables clinically significant improvements in function after the presumed "plateau" phase[5-7]. Several theories underlying this perceived "plateau" in the clinical setting have been articulated[8], although few studies have directly addressed this issue.

One hypothesis to explain this "plateau" in motor function post-stroke is the provision of minimal task-specific practice in the clinical setting. In animal models of cortical injury and humans with hemiparesis post-stroke, the amount of volitional motor practice can markedly influence motor recovery[4, 9]. For recovery of walking function, locomotor training (LT) performed on a treadmill with partial weight support is one intervention which can increase the amount and intensity of stepping practice. LT facilitates improvements in overground walking speed and timed walking distance[10, 11] in individuals post-stroke which may be related to improved muscle activation[12]or metabolic measures of peak aerobic capacity[11] or gait efficiency[13]. Recent estimates indicate an average of ~4000 steps performed during 1-hr LT sessions[13], which may contribute to the observed clinical and physiological benefits. Unfortunately, data from single- and multi-center studies suggest that the amount of stepping practice[14, 15] provided to patients post-stroke during actual clinical physical therapy (PT) sessions

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averages < 400 steps. Decreased practice may limit recovery of motor function and contribute to the perceived "plateau", whereas further improvements may be realized if intensive interventions were provided.

The primary goals of the present study were two-fold. The first was to quantify the changes in daily stepping and walking performance in individuals with chronic hemiparesis post-stroke with a primary goal to improve walking ability, but scheduled for discharge from clinical PT secondary to reaching a plateau in motor function. Our second goal was to determine whether those same individuals post-stroke could realize significant improvements in locomotor function when provided intensive LT following discharge from clinical services. Using a repeated measures crossover design, we quantified physiological and functional measures of locomotor function in subjects with chronic hemiparesis post-stroke during the last 4 weeks of PT, and subsequently following 4 weeks of LT. Daily stepping activity was recorded throughout the study, including during PT and LT sessions to identify the amount of stepping practice provided during these interventions. We hypothesized that the amount of stepping practice during clinical PT may contribute to the perceived "plateau" in walking ability, while higher doses provided during intensive LT would facilitate improved walking ability.

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Methods

All procedures were approved by the Institutional Review Board of Northwestern University/Rehabilitation Institute of Chicago. All subjects provided written informed consent.

Subjects. Subjects with hemiparesis of > 6 months duration who were attending PT following unilateral supratentorial stroke were recruited. All subjects were required to walk > 10 m overground without physical assistance at speeds ≤ 0.9 m/s at their self-selected velocity (SSV), and required medical clearance to participate. Two additional inclusion criteria consisted of: 1) a primary stated goal to improve walking ability; and 2) enrolled approximately 1 month prior to termination of PT services secondary to decreased gains in function, as stated by the treating clinical therapist (i.e., subjects with limited insurance coverage for PT services were not eligible). Exclusion criteria included presence of lower extremity contractures, significant osteoporosis, cardiovascular instability, previous history of peripheral or central nervous system injury, cognitive or communication impairment[10]; and inability to adhere to study requirements. Previous data using LT[10] and conventional interventions[16] provided estimates of effect sizes for improvements in SSV, where 20 subjects would provide 99% power.

Experimental protocol. A randomized crossover study design with ≥ 2 baseline measures was employed in which clinical and quantitative assessments were performed at ≥4 time points throughout subject enrollment. To examine the effects of clinical PT on walking function, assessments were performed initially at 4 weeks prior to discharge from clinical PT services (assessment 1: A_1) following which study participants continued with their conventional treatment (i.e., clinical PT). The content and intensity of treatment interventions provided during the clinical PT during these 4 weeks were determined by the treating therapist without consultation from study investigators.

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Following discharge from PT and adherence to study guidelines, quantitative assessments were repeated (assessment 2: A_2). If therapists extended PT services beyond the scheduled termination date, subjects were reassessed every 4 weeks until discharge, with A_1 considered their assessment at 4 weeks prior to discharge. Subjects were stratified into those with moderate (SSV 0.5-0.9 m/s) vs severe (< 0.5 m/s) gait limitations, and randomized to receive 4 weeks of intensive LT immediately after discharge from clinical PT (*immediate LT group*), or following 4 weeks after discharge from clinical PT (*delayed LT group*). Subjects were randomized using sealed envelopes concealed from view.

The immediate LT group was provided 4 weeks of intensive LT following discharge from clinical PT, which consisted of high-intensity, stepping practice on a motorized treadmill while wearing an overhead harness, safety system. LT was performed at the same frequency as PT (2-5 days/week) at the highest tolerable speed[6, 7] , with velocity increased in 0.5 kmph increments until subjects' heart rate reached 80-85% of age-predicted maximum or until the subjects' Rating of Perceived Exertion increased to 17 on the Borg scale[17]. Up to 40% partial body weight support using a counterweight system attached to the safety harness was provided for those subjects who walked < 0.2 m/s overground[6], and was reduced in 10% increments as tolerated. Subjects held onto the handrail for balance only, and therapists did not provide manual assistance to improve intralimb kinematics, but rather focused on increasing intensity and amount of stepping practice as tolerated. Following completion of LT, subjects were reassessed (assessment 3: A_3), and again following a delay of 4 weeks after completion of LT (assessment 4: A_4)

The delayed LT group was also assessed 4 weeks prior to and following termination from clinical PT (A_1 and A_2), but did not receive LT or any other interventions for 4 weeks following

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termination of clinical PT (i.e., delay period). Following this 4 week delay, subjects were reassessed prior to (A_3) and following (A_4) 4 weeks of intensive LT as described above. The study design is illustrated in fig 1.

Outcomes. Outcome measures included clinical measures of walking performance over short and long distances, peak treadmill velocity during a graded walking test, metabolic responses during continuous overground and treadmill walking, and stepping activity in the home and community, including during PT and LT sessions. Gait speed at SSV or fastest-possible velocity (FV) was collected using the GaitMat II ® (Equitest Inc, Chalfont, PA). Timed walking distance at SSV was determined using the 12 min walk test and recorded each minute, with cardiorespiratory/metabolic data collected simultaneously using a portable, indirect calorimetry system (K4b2, Cosmed, Inc, Chicago, IL). Following subtraction of baseline oxygen consumption (VO_2, ml/kg/min) recorded during quiet sitting, gait efficiency (or O_2cost) during continuous walking was determined by dividing the average VO_2 per minute of the 12 min walk by the average gait speed recorded during each minute of the test or until the subject required a rest break. Peak treadmill velocity and peak VO_2 (VO_2peak) were determined using a modified graded exercise testing protocol, in which subjects walked at 0.1 m/s for 2 min, with speed increased by 0.1 m/s every 2 min as tolerated. Testing was terminated with gait instability at higher speeds or when heart rate reached 85% of age predicted maximum, or RPE > 17[17], and the highest VO_2 averaged over 1 min was recorded. Additional measures included the Berg Balance Scale (BBS) and the Timed Up and Go (TUG).

Daily stepping activity in the home and community, including during PT and LT sessions, was determined using a Step Activity Monitor (StepWatch, Cyma Inc, Seattle, WA) a portable, lightweight microprocessor-based accelerometer/pedometer placed on the unimpaired leg, and

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used previously in this popoulation[18]. Subjects were required to wear the pedometer for 90% of their waking hours throughout the study and document precise times of clinical PT with a daily journal, which was later confirmed by PT documentation. Subjects who did not wear the pedometer as required were excluded from the study. Stepping activity was recorded each minute and averaged per day, with ≥ 5 days of stepping activity determined prior to and following clinical PT and intensive LT to assess changes with each intervention. Stepping activity (i.e., practice) provided during PT and LT sessions were recorded and averaged, and verified using therapists' documentation and subjects' journals.

Data and statistical analysis: Demographics and/or outcome measures at each assessment period (A_1-A_4) are presented as mean ± standard deviation (SD) in the text and tables, with mean ± standard errors in the figures. Data was assessed for normality (Kolmogorov-Smirnov) and baseline characteristics were compared between immediate and delayed LT group*s* using unpaired t-tests and Mann-Whitney U tests as appropriate. Statistical analyses focused on changes in outcome measures during PT, during LT vs delay periods, and differences in stepping activity during and following the PT and LT sessions. Differences during the last 4 weeks of clinical PT (A_1 to A_2) were analyzed using paired comparisons (t-test, Wilcoxon signed rank) as appropriate. Changes in outcome measures during the intensive LT vs delay period (A_2-A_4), were determined using a two-way, repeated measures ANOVA with main effects of group (immediate vs delayed LT) and repeated for time/assessment; effects of gait impairment were not performed due to low numbers of severely impaired subjects. Post-hoc single factor repeated measures ANOVA and Tukey-Kramer tests were performed with significant main effect of time or interaction effects. BBS data were analyzed using Friedman's tests with post-hoc Wilcoxon tests. Daily stepping was averaged over the 4 weeks of PT and LT, with separate analysis of

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stepping activity during PT and LT sessions. Daily stepping for at least 5 days in the home and community was determined prior to and following each intervention period (PT and LT). Correlation and simple regression analyses were used to determine the relationship between amount of stepping practice received during PT/LT, and the changes in daily stepping following each intervention. Significance was set at $\alpha = 0.05$.

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Results

Thirty of 68 individuals referred to the study fulfilled inclusion criteria and were enrolled, although 10 did not complete the protocol because of non-compliance with study requirements (i.e., not wearing accelerometer, n=5), early discharge from clinical PT (n=2), orthopedic injury which limited walking (n=1), or previous diagnosis of secondary neurological injuries (n=2). Seven of 20 subjects presented with severe gait impairments (4 in the immediate LT group, 3 in delayed LT group). Demographics and clinical characteristics are provided in Table 1, with no differences between groups.

Changes in outcome measures were assessed prior to and following the last 4 weeks of clinical PT in subjects with therapist-report of reduced gains in locomotor function. Daily stepping averaged 3822±2805 steps/day prior to the last 4 weeks of clinical PT, and was not different following discharge (3846±2932 steps/day, $p = 0.88$). Average daily stepping during clinical PT was 4207±2922, with a mean of 886±852 steps performed during PT sessions. Changes in other outcome measures are shown in Table 2, with improvements in clinical measures of walking performance (SSV, FV, and 12 min walk), but no change in other assessments.

During the 4 weeks of LT performed following discharge from PT (immediate and delayed groups), daily stepping averaged 5560±2801, with 3896±3906 steps performed during LT sessions; both values were significantly greater than stepping activity performed during clinical PT (both $p < 0.001$; Fig 2A-B). Daily stepping activity performed following LT sessions increased ~ 25% (3692±2557 to 4590±3027, $p < 0.001$) from pre-LT values and was significantly different from changes observed during clinical PT ($p < 0.01$; Fig. 2C). Further analysis revealed that the average stepping dosage (# steps/session) provided to subjects each PT

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or subsequent LT session was correlated with improvements in daily stepping in the home and community ($r = 0.57$, $p < 0.001$; Fig. 2D). A similar relation between stepping dosage and improvements in daily stepping was observed when average stepping practice/week during PT/LT sessions was calculated to account for differences in training frequencies across subjects ($r = 0.55$, $p < 0.001$).

Laboratory-based walking measures demonstrated variable changes following intensive LT and delay periods, with outcomes detailed in Table 3 and selected variables described in Fig 3. For example, SSV and FV improved throughout A_2-A_4 (main effect of time) despite discharge from clinical PT secondary to the presumed "plateau" with a significant time X group interaction only for FV. Post-hoc testing indicated significant increases in SSV for the delay group during the "delay" period and in FV in the immediate group during LT. For 12 min walk (Fig. 3A), total distance increased significantly throughout A_2-A_4 with no interactions, with significant improvements at each assessment.

For metabolic and treadmill-based measures, significant main and interaction effects were demonstrated for O_2cost and peak treadmill speed, but not VO_2peak (Fig 3B-D). Specifically, the former variables improved for either immediate or delayed LT groups during LT sessions only. Notably, changes in O_2cost assessed during the 12 min walk improved substantially despite non-significant changes in 12 min walk distance following LT.

Changes in BBS and TUG were observed throughout A_2-A_4, although there was no specific benefit of LT over the delay period.

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Discussion

Our results indicate that improvements in walking performance could be elicited in individuals with hemiparesis post-stroke when provided intensive LT, even after discharge from PT secondary to therapist report that subjects reached a "plateau" in motor function. Significant improvements in clinical measures of walking performance (SSV, FV and 12 min walk) were observed at each assessment, although there was no greater improvement following LT beyond changes observed during clinical PT or the delay period. Rather, O_2cost assessed during the 12 min walk improved only following LT, despite non-significant improvements in distance. Daily stepping also improved following LT with no improvement observed following clinical PT.

Gains in daily stepping and gait efficiency following intensive LT appear to be related to stepping dosage. The amount of stepping practice performed during PT in this study was over 2X greater than previous estimates during conventional PT[14, 15], but was still < 25% of stepping practice performed during subsequent LT sessions. Differences in stepping dosage appear to contribute to improvements in daily stepping, and likely contributed to changes in O_2cost following LT sessions[13]. Gait efficiency is thought to strongly influence community walking following neurological injury[19], although previous studies have not demonstrated simultaneous improvements in daily stepping and O_2cost with physical interventions.

The current and previous data revealed markedly reduced daily stepping (2500-3500 steps/day) in individuals with chronic stroke as compared to sedentary older adults (5000-6000 steps/day), with significant contributions of reduced balance and metabolic capacity and efficiency[20]. Following specific exercise regimens, changes in walking speed, balance, and VO_2peak have been observed[21] although few studies have been able to detect changes in daily stepping in chronic stroke (see [12] for subacute stroke). In the present study, daily stepping

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increased up to 4500 steps/day following LT, with significant improvements in O_2cost. Despite this improvement, daily stepping following LT was still below average stepping in elderly individuals[20] and below the threshold for "sedentary" individuals (i.e., < 5000 steps/day[22]). Daily stepping below this threshold is thought to contribute to the progression of cardiovascular disease in the general population, which is exacerbated post-stroke. Improvements in O_2cost may contribute to improved daily stepping, but was still ~25-40% worse than O_2cost observed in elderly individuals without neurological injury (estimated from [23]). Whether gait efficiency can improve further with continued LT and contribute to improve daily stepping is unclear and requires further investigation.

Limitations of the current study include lack of blinding of investigators and the small sample size. In addition, history and/or testing effects may have contributed to the study results, although the repeated measures crossover design was utilized to minimize these effects following clinical PT. However, we are uncertain whether subjects actually demonstrated a plateau in walking ability during the last 4 months of clinical PT, as significant improvements in clinical gait measures were observed. Such changes may be due to a testing effect, as O_2cost measured during 12 min walk test was slightly worse following PT. Nonetheless, the improvements observed following LT suggest that these subjects did not reach a plateau in locomotor function. Providing LT is feasible in the clinical setting, particularly when therapist assistance is not provided in subjects who are ambulatory post-stroke (similar to the present protocol). Reasons why high intensity stepping practice is not provided more often are unclear, and the barriers to delivering this type of training should be identified. Further investigation is warranted to find solutions to facilitating more intensive LT during clinical PT, as the current results indicate that the minimal stepping practice may limit improvements in locomotor performance.

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Table 1. Demographic and baseline characteristics; mean± standard deviation provided for ratio data.

Demographics/baseline characteristics	
Age (yrs)	50 ± 15
Gender (male/female)	14/6
Race (white/other)	8/12
Side of paresis (left/right)	16/4
Ischemic/hemorrhagic stroke (n)	10/10
Duration post-injury (mo)	13 ± 8
Ankle foot orthosis (n)	12
Assistive device (n)	16
Moderate/severe gait limitations (n)	13/7

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Table 2. Changes (mean ± standard deviation) in walking measures during clinical PT, determined from the 1st (A_1) to 2nd assessments (A_2).

Primary measures	A_1	A_2	p value
Self-selected velocity (m/s)	0.51 ± 0.21	0.56 ± 0.24	< 0.01
Fastest velocity (m/s)	0.70 ±0.29	0.77 ± 0.35	0.01
12 min walk (m)	340 ± 193	384 ± 225	0.03
O_2 cost (ml/kg/km)	326 ± 180	378 ± 306	0.26
peak treadmill speed (m/s)	0.97 ± 0.3	0.96 ±0.3	0.63
VO_2peak (ml/kg/min)	16± 4.5	16 ± 4.3	0.12
Berg Balance Scale	43± 13	44 ± 13	0.10
Timed Up and Go (s)	23 ±11	23 ±12	0.91

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Table 3. Changes (mean ± standard deviation) in walking measures prior to and following locomotor training (LT) and delay period per training group (immediate vs. delayed LT); outcomes at 2nd (A_2), 3rd (A_3) and 4th (A_4) assessment periods are provided with shaded areas indicating when LT was provided.

	Immediate LT			Delayed LT			Time effects	Time x group interaction
	A_2	A_3	A_4	A_2	A_3	A_4		
Self-selected velocity (m/s)	0.58±0.27	0.63±0.30	0.66±0.31	0.53±0.22	0.58±0.23	0.57±0.23	0.01	0.36
Fastest velocity (m/s)	0.80±0.40	0.91±0.44	0.92±0.46	0.74±0.32	0.77± 0.32	0.80±0.35	<0.01	0.03
12 min walk (m)	413 ± 231	452 ± 260	464 ± 263	356 ± 228	402 ± 268	417±287	<0.01	0.96
O_2 cost (ml/kg/km)	410 ± 386	291 ± 228	326 ± 231	346 ± 217	371 ± 234	293±206	0.03	0.02
peak treadmill speed (m/s)	1.0 ± 0.3	1.2 ± 0.4	1.2 ±0.4	0.9 ± 0.4	0.9 ± 0.4	1.1±0.5	<0.01	0.02
VO_2peak (ml/kg/min)	17 ± 3.2	18 ± 5.4	16 ± 6.5	16 ± 5.4	16 ± 7.1	17±7.4	0.57	0.27
Berg Balance Scale	46 ± 15	48 ± 10	46 ±14	43 ±12	46±10	47 ±10	0.01	0.08
Timed Up and Go (s)	21 ±12	20 ±12	19± 9.9	25 ± 13	24 ± 16	22 ±13	0.07	0.85

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Fig. 1. Schematic of the study design, with ≥ 2 repeated baseline measures (A_1-A_2) of walking performance during the last 4 weeks of clinical PT followed by randomization to immediate LT for 4 weeks and then a delay period (immediate LT group) or a delay period following by 4 weeks of LT (delayed LT group). Assessments were made following completion of each period (A_3-A_4) Shaded area indicates when LT occurred.

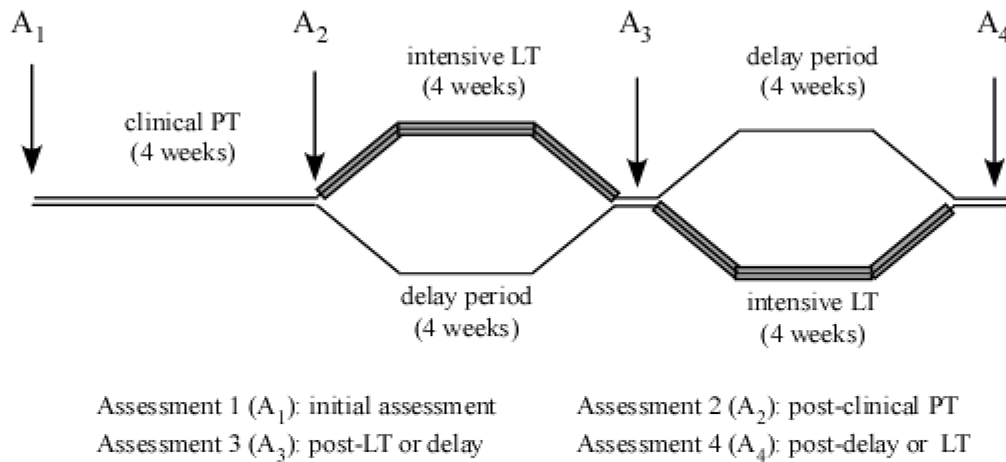

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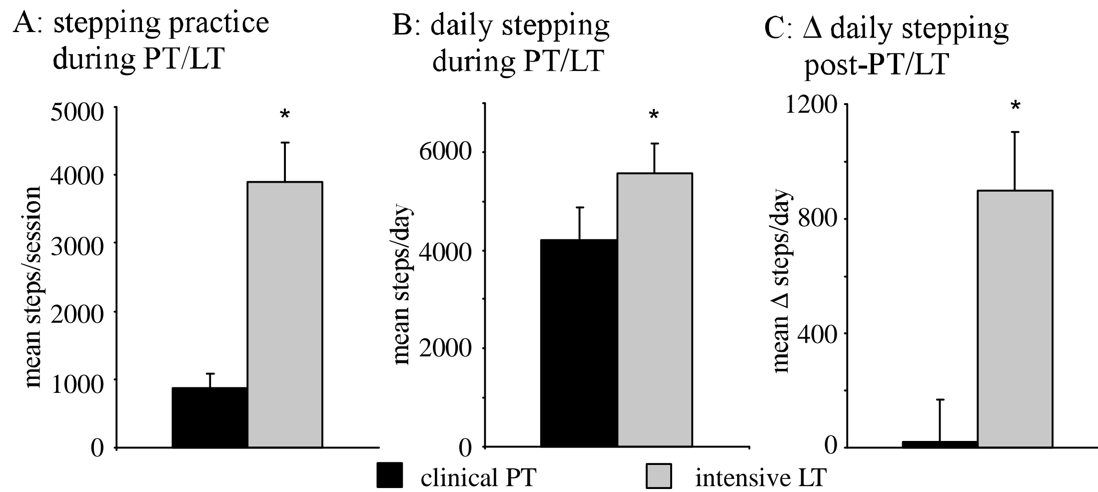
Fig. 2. Differences in mean stepping practice (steps/session) received during PT (black) vs LT (gray; 2A), differences in daily stepping (steps/day) during periods of PT and LT (2B); and, changes in daily stepping following PT vs LT (Δsteps/day; 2C) were significant (* = $p < 0.01$), with a significant correlation ($p < 0.001$) between stepping practice in PT or LT and the Δsteps/day after PT or LT was observed (2D).



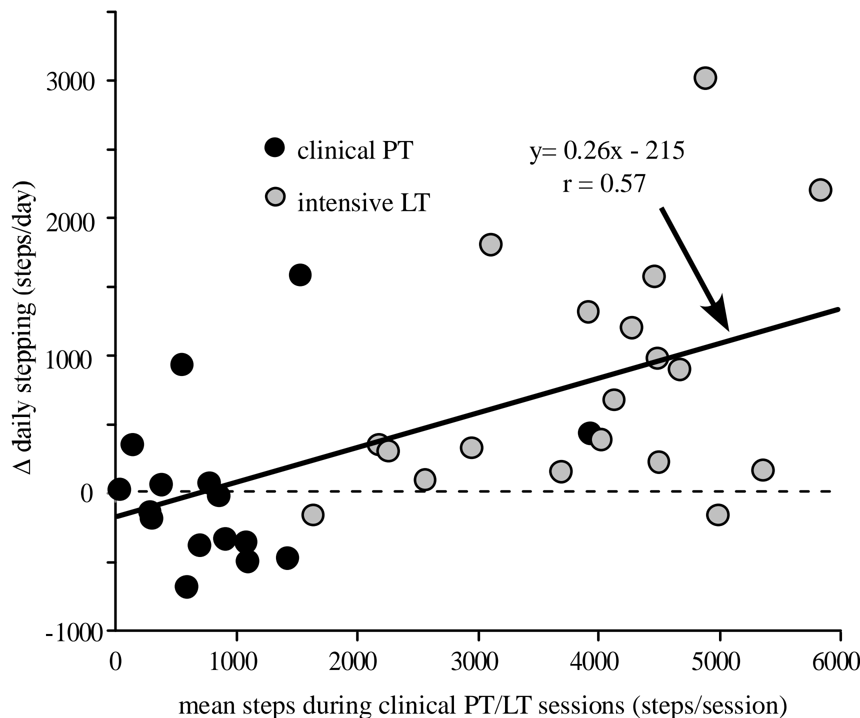


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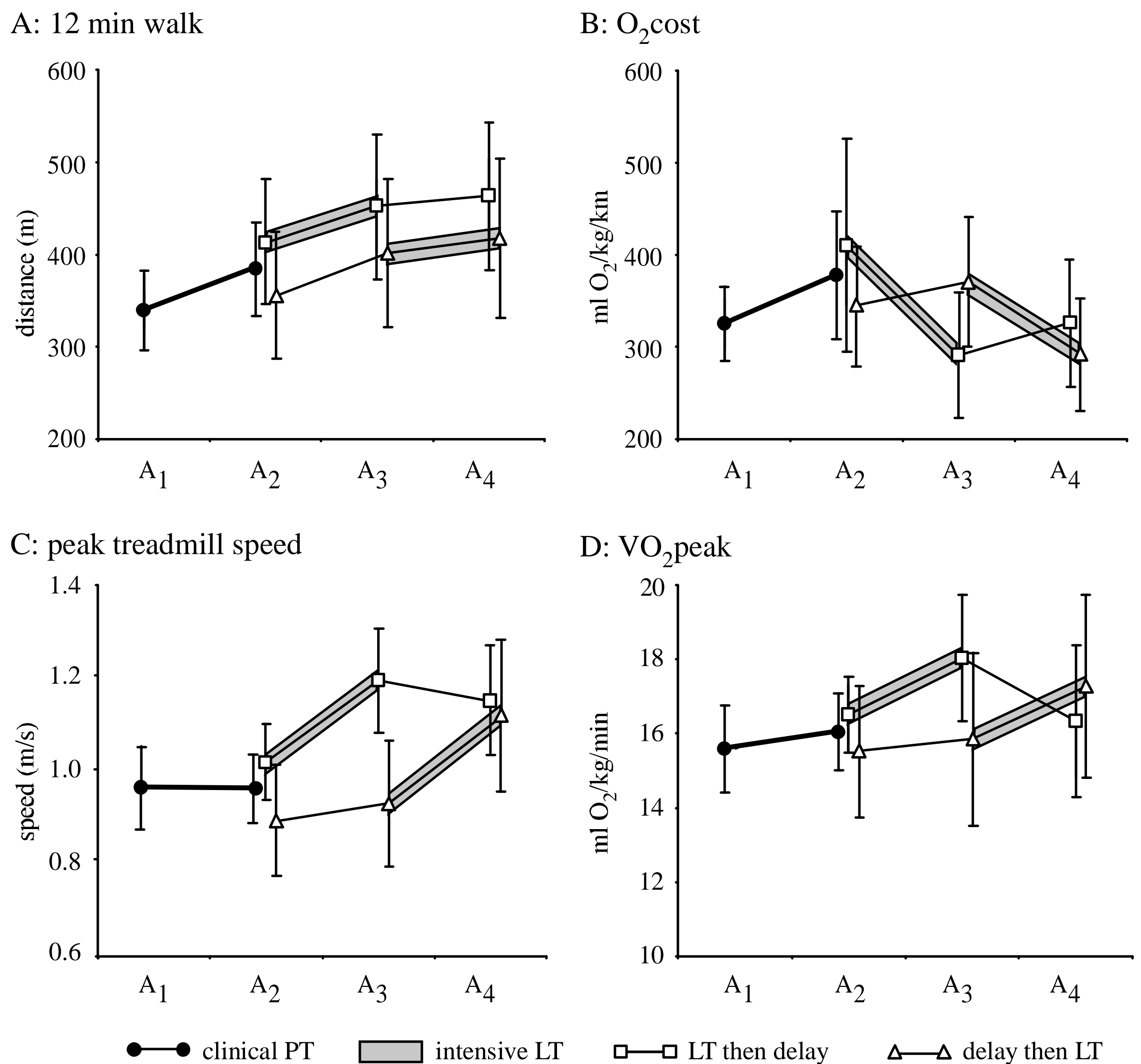
Fig. 3. Alterations in selected walking variables during clinical PT, intensive LT and the delay period, with shaded areas indicating intensive LT. Distance walked during 12 min walk test revealed no specific benefit of intensive LT (Fig. 3A). In contrast, O_2cost and peak treadmill speed (Fig. 3B-C) demonstrated significant improvements during LT only. VO_2peak (Fig. 3D) was not different throughout the protocol.



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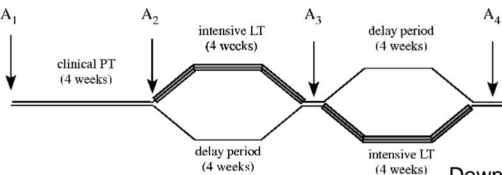

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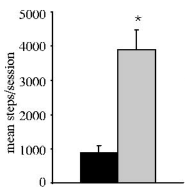
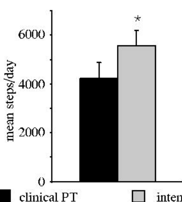
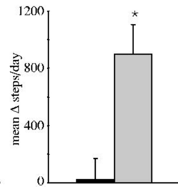
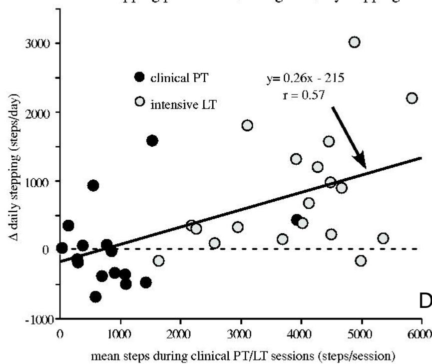
Assessment 1 (A_1): initial assessment
Assessment 2 (A_2): post-clinical PT
Assessment 3 (A_3): post-LT or delay
Assessment 4 (A_4): post-delay or LT







clinical PT   intensive LT



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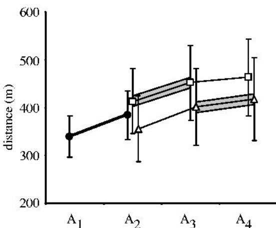
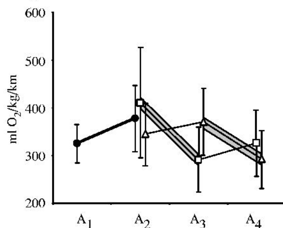
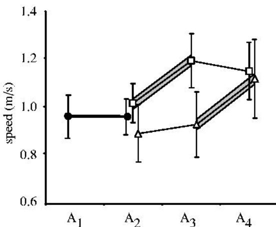
A: 12 min walk



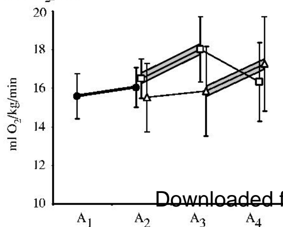
B: O_2cost



C: peak treadmill speed



D: VO_2peak



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clinical PT — intensive LT — LT then delay — delay then LT