

A Randomized Controlled Trial of Functional Neuromuscular Stimulation in Chronic Stroke Subjects

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Background and Purpose—Conventional therapies fail to restore normal gait to many patients after stroke. The study purpose was to test response to coordination exercise, overground gait training, and weight-supported treadmill training, both with and without functional neuromuscular stimulation (FNS) using intramuscular (IM) electrodes (FNS-IM).

Methods—In a randomized controlled trial, 32 subjects (>1 year after stroke) were assigned to 1 of 2 groups: FNS-IM or No-FNS. Inclusion criteria included ability to walk independently but inability to execute a normal swing or stance phase. All subjects were treated 4 times per week for 12 weeks. The primary outcome measure, obtained by a blinded evaluator, was gait component execution, according to the Tinetti gait scale. Secondary measures were coordination, balance, and 6-minute walking distance.

Results—Before treatment, there were no significant differences between the 2 groups for age, time since stroke, stroke severity, and each study measure. FNS-IM produced a statistically significant greater gain versus No-FNS for gait component execution ($P=0.003$; parameter estimate 2.9; 95% CI, 1.2 to 4.6) and knee flexion coordination ($P=0.049$).

Conclusion—FNS-IM can have a significant advantage versus No-FNS in improving gait components and knee flexion coordination after stroke. (*Stroke*. 2006;37:172-178.)

Key Words: exercise ■ gait ■ rehabilitation

Gait deficits that remain after conventional therapies can result in falls,¹ elevated energy cost,^{2,3} and poor endurance.⁴ Coordination impairment is an underlying cause of gait deficits after stroke⁵ that prevents normal performance of the following coordinated movements: swing phase hip, knee, ankle flexion excursion and timing; swing phase knee extension; and stance phase pelvic and knee control.⁶ However, there is a dearth of efficacious interventions that specifically target and measure restoration of coordinated gait components. In the absence of interventions targeted at coordination deficits, more general treatment is provided, with the expectation of producing gait changes according to the more general measures of endurance or speed.

There are 2 types of reported randomized controlled trials (RCTs) of gait training, none of which showed restoration of coordinated gait components: (1) comparisons of no treatment versus treadmill training (TT) or overground (OG) walking; and (2) comparisons among TT, OG, and body weight-supported TT (BWSTT). In the first category, no treatment was compared with TT or OG^{7,8} and exercise or mobility training,^{9,10} according to measures of activities of daily living, mobility, and speed. There was a significantly greater

gain for treatment versus control, according to six-minute walk test (6MWT),^{7,8} speed,⁷⁻⁹ functional independence measure (FIM) subscales, and bathing and dressing but not for walking mobility.¹⁰ Gains in coordinated gait components were either not investigated^{7,8,10} or no significant gain was obtained.⁹ In the second category, gait training methods were compared with each other, with most studies reporting no significant difference among gait training methods, according to speed. BWSTT was comparable to a variety of other gait training methods, even when 11 studies (485 participants) were combined.¹¹ BWSTT was comparable to conventional methods for middle-aged, moderately involved adults.^{12,13} TT was also comparable to conventional methods.¹⁴ BWSTT was reported superior to TT alone¹⁵ but in 2 studies only for more disabled or older adult subgroups.^{12,13} Results were mixed in these comparative studies, and also there were no gains reported in measures of coordinated gait components.¹¹⁻¹⁵

Few RCTs have studied treatment response according to the coordinated gait components comprising gait. One promising study using an animal model showed that coordination training was superior to either TT or no treatment according to coordinated leg movements during mobility tasks;¹⁶ but in

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humans, there was no significant difference in a gait coordination measure.¹⁷

The inability, to date, to restore gait components could result from deficiencies in gait practice paradigms available during TT and BWSTT. Specific practice characteristics are critical to reacquisition of coordinated, skilled movement, including: practice of close-to-normal movements, muscle activation driving practice of movement, and repetition of desired movements.^{18,19} Many stroke survivors are unable to volitionally activate muscles rapidly or in the proper timing/sequence for practicing coordinated gait components. Rather, patients continually reinforce abnormal movements during walking. Although some stance phase training opportunities were reported for BWSTT, neither TT nor BWSTT provided swing phase practice of normal movement timing, excursion,²⁰ or muscle activations.²¹ Therefore, these training methods are likely to include repetition of abnormal gait components.

Functional neuromuscular stimulation (FNS) is a promising treatment that can provide critical practice of close-to-normal movements by electrically inducing muscle contractions and coordinated movements not possible volitionally. Previous FNS gait studies had some limitations. Two RCTs using FNS with surface electrodes showed a significant advantage for FNS versus no-FNS, but in the first study, the gait speed advantage lasted only a number of weeks.²² In the second study, gait energy cost was an outcome measure,²³ but subjects did not use methods allowing attainment of steady-state during energy cost data acquisition.²⁴ There has been no documentation that surface FNS can provide a practical system for practice of coordinated movements for >1 lower limb joint.^{22,23} However, an FNS system with intramuscular (IM) electrodes (FNS-IM) demonstrated the capability to provide practice of close-to-normal gait components at hip, knee, and ankle.²⁰ For chronic stroke survivors (>12 months), case studies showed gains in volitionally executed gait components as a result of FNS-IM treatment,^{1,25} but FNS-IM alone required >6 months to produce results.

One disadvantage of previous FNS studies was that an optimally synergistic combination of modalities was not tested. FNS-IM, BWSTT, OG, and coordination training together have the potential to target the dyscoordination in persistent stance and swing phase gait components.²⁰ FNS coordination training can target the dyscoordination that prevents normal gait.²⁶ BWSTT can provide the practice of a variety of stance phase gait components.¹⁵ FNS can provide the practice of swing and stance phase muscle activations at close-to-normal timings and movement excursions.²⁰ Thus, the combination of FNS-IM+BWSTT has greater gait training practice opportunities than either modality alone.²⁰

No previous study reported significant gains in coordinated gait component movements in response to coordination training, OG gait training, BWSTT, or FNS. The purpose of the current study was to test the effect of FNS-IM according to coordinated gait component movements. The treatment for group 1 was coordination training, OG, and BWSTT. The same treatment was provided for group 2, with the exception that FNS-IM was used in all phases of treatment.

Methods

Subjects

Subjects were recruited using newspaper advertisement in an urban community and surrounding region with a population of 1.4 million. Fifty-eight candidates were screened from September 1999 to June 2004 by 1 coprincipal investigator. Sample size was limited by time constraints. Candidates were not aware of group assignment. Study criteria included: >12 months after single stroke; inability to clear the floor normally in the sagittal plane; hyperflexion or hyperextension of knee during stance; walking without human assistance; passive joint range of motion of hip, knee, and ankle equal to normal excursion needed for walking; normal corrected distance vision; and not participating in rehabilitation. Exclusion criteria included: inability to follow 2-level commands; pacemaker; peripheral neuropathy; absent proprioception; and acute diagnosis (eg, cancer). Twenty-six did not meet the inclusion criteria, and 5 declined to participate after screening. Thirty-two remaining candidates were accepted, and informed consent was obtained according to the Declaration of Helsinki (supervision by medical center internal review board).

According to principles described in the revised CONSORT statement for clinical trials,²⁷ we allocated either FNS-IM or No-FNS treatment. Two completely independent sets of information were generated by 2 independent individuals, maintaining suggested separation between enrollment and treatment allocation.²⁷ Individual 1 generated an unpredictable treatment allocation sequence and was not involved in enrollment, treatment, or assessment. Individual 2 screened and enrolled subjects, recorded enrollment date, and was not involved in treatment allocation, treatment, or assessment of treatment response. Individual 3 allocated treatment to a given subject based on a cross-matching of enrollment date with the unpredictable treatment allocation sequence (open-list method). We stratified²⁷ subjects according to moderate and severe motor involvement and used blocking²⁷ to ensure greater probability of balance between the 2 groups. As recommended,²⁸ stroke severity was determined according to Fugl-Meyer lower extremity coordination (FMLE), a 34-point scale: 0 to 19 severe; 20 to 28 moderate; and >29 mild (≥ 29 not accepted).

Treatment

All subjects were treated 1.5 hours per session, 4 sessions per week, for 12 weeks, including: 0.5 hours coordination exercises, 0.5 hours BWSTT, and 0.5 hours OG. Exercise included coordination of joint movements.²⁹ For BWSTT, we used BIODEX500 with handrails. Body weight support was decreased 30% to 0% according to ability to maintain normal, neutral alignment of torso, and stance limb. Chosen walking speed was increased to 0.894 m/s as tolerated. OG included: torso, pelvic, knee, and ankle position control during loading and weight bearing, swing hip, knee, and ankle flexion (manual guidance, as needed), and terminal swing knee extension/ankle dorsiflexion. Home exercises were coordination exercises performed for 1 hour per day.

Exercises, BWSTT, OG, and home exercise were identical for both groups except that FNS was used for all treatment aspects for the FNS-IM group but not the No-FNS group. FNS-IM targeted restoration of voluntary ankle dorsiflexion during swing, knee flexion at toe-off, knee flexion during swing, knee extension before heel strike, and knee and pelvic control during stance.^{1,20,25,30} Template FNS patterns were individualized.^{1,25} FNS parameter ranges were: amplitude 4 to 20 mA, pulse width 1 to 150 μ s, and frequency 15 to 50 Hz, within comfort. During combination BWSTT+FNS-IM, FNS activated swing phase movement. As volitional control improved, amplitude of FNS-IM was incrementally reduced. IM electrode construction, safety, performance, and insertion methods are described previously.³¹ Eight muscles were provided with electrodes: tibialis anterior; peroneus longus; lateral head, gastrocnemius; short head, biceps femoris; semimembranosus; long head, biceps femoris; vastus lateralis; and gluteus medius (except for 2 subjects who received 4 or 7, respectively) and remained in place throughout the treatment protocol. The following criteria were used: ≤ 3 strength and inability to perform coordinated movements (FMLE). Software and a research stimulator provided FNS patterns for ≤ 8 muscles in multiple combinations and timings.³²

TABLE 1. Subject Characteristics

Group	Stroke Severity Mean (SD)	Stroke Type		Years After Stroke Mean (SD)	Age Mean (SD)	Gender	
		Ischemic	Hemorrhagic			Male	Female
FNS-IM	22.9 (3.5)	11	3	3.6 (3.8)	57.7 (11.9)	11	3
No-FNS	19.7 (4.3)	12	3	3.3 (2.1)	63.6 (10.4)	11	4

Outcomes

Measures were obtained the day before and after treatment using volitional movement (no FNS or BWSTT during testing; maximum high score was normal, all measures). To date, there have been few studies reporting interventions that produced significant gains in coordinated gait components. Because the purpose of this study was to test the benefit of FNS-IM in targeting dyscoordination during walking and producing a change in the execution of coordinated gait components, it was important to use a measure of coordinated gait component execution. The primary measure was the Tinetti gait (TG³³), a 12-point scale assessing these coordinated gait components: (1) gait-initiation; (2) walking path; (3) trunk alignment; (4) swing phase limb trajectory; (5) step continuity; (6) step symmetry; and (7) swing limb floor clearance and forward swing limb excursion. In inter-rater (2 raters) and test-retest reliability testing (n=10 chronic stroke survivors), we found the following: intraclass correlation coefficient (ICC)=0.85; CI, 0.496, 0.959; $P=0.001$; and ICC=0.91; CI 0.681, 0.977; $P=0.0001$, respectively.

The secondary outcomes were: FMLE, Fugl-Meyer knee flexion coordination (FMKnFx), Tinetti balance (TB), 6MWT, and self-reported functional milestones. Coordination was assessed using FMLE as described above. FMKnFx was a 6-point, ordinal measure comprised of the 3 FMLE items that measure knee flexion coordination under the following conditions: supine/within-synergy, sitting/within-synergy, and standing/out-of-synergy. This measure was important because 1 aspect of treatment targeted the dyscoordination of knee flexion, which may be a critical factor in the stroke "stiff-legged gait."⁶ The FMKnFx (26 chronic stroke survivors; >12 months) showed good convergent validity with the FIM mobility scale ($r=0.557$; $P=0.001$) and divergent validity with FIM communication scale ($r=0.383$). In reliability testing, 2 raters independently

scored 10 chronic stroke survivors (ICC; inter-rater reliability of the FMKnFx scale=0.90 [95% CI, 0.64, 0.97]).

TB was a 16-point, ordinal scale assessing balance as follows: sitting, sit-to-stand, standing, response to challenge, eyes closed, turning-in-place, and stand-to-sit. 6MWT measured walking distance within 6 minutes. Subjects used usual assistive device (constant at pretreatment/post-treatment) and a 30.5-m walkway. 6MWT was correlated with activities of daily living, used in the stroke population, and had test/retest reliability of 0.95 for older adults.⁴ Subjects were queried bimonthly regarding functional milestones that had been achieved during the previous 2 weeks.

The primary measure, TG, was scored by a blinded examiner who viewed a video record of gait before and after treatment. Independent staff obtained the secondary outcomes, and because they worked in an adjacent clinical area, there is a chance that group allocation may have been unmasked.

Analysis

We compared the 2 groups regarding initial differences for age, years after stroke, stroke severity, and each measure (Mann-Whitney U test). Group comparisons for ordinal measures were made using an ordinal regression model (PLUM Ordinal Regression Model; SPSS) and a general linear model for 6MWT. In all analyses in the study, we used the Sidak stepdown P value adjustment for multiple comparisons.³⁴ All results are reported using adjusted P values with critical $\alpha=0.05$.

Results

Each of the 2 treatments was allocated to 16 subjects. Subject attrition was 2 (FNS-IM) and 1 (No-FNS), resulting from a compromised social support system (14 FNS-IM and 15

TABLE 2. Comparison of Pretreatment/Post-Treatment Measures for FNS-IM and No-FNS

Measure	Pretreatment Median* or Mean† (interquartile range** or SD‡)	Pretreatment Range	Post-Treatment Median* or Mean† (interquartile range** or SD‡)	Post-Treatment Range	Group Comparison [□]
Primary measure					
TG (n=14)	6.5* (3)**	3–10	9* (1)**	6–12	$P=0.0003^*$
No-FNS (n=15)	6* (4)**	3–10	7* (3)**	3–10	
Secondary measures					
FMLE					
FNS-IM	22* (5)**	16–28	28* (6)**	19–32	$P=0.182$
No-FNS	20* (4)**	11–28	23* (8)**	13–29	
FMKnFx subscale					
FNS-IM	4* (2)**	1–5	5* (0)**	2–6	$P=0.049^*$
No-FNS	3* (2)**	0–5	4* (2)**	1–5	
TB					
FNS-IM	13.5* (4)**	10–15	15* (2)**	12–16	$P=0.133$
No-FNS	10* (5)**	6–14	13* (4)**	8–16	
6MWT distance (m)					
FNS-IM	186.6† (±75.6)‡	75.6–309.7	252.2† (±101.6)‡	111.6–407.8	$P=0.184$
No-FNS	128.3† (±83.8)‡	14.6–285.9	165.9† (±98.8)‡	29.9–299.3	

□Adjusted P values reported.

*Significant P value, $P\leq 0.05$, with adjusted P values shown.

No-FNS completed treatment, according to their treatment allocation). Reported data are exclusively from those who completed the study (Table 1). There was no baseline difference between groups for the following: age ($P=0.166$), years after stroke ($P=0.701$), and stroke severity ($P=0.089$). Among 4 FNS-IM subjects, there was a total of 7 instances of erythema on the skin surface at lead exit sites. All were treated with topical antibiotic and resolved in ≤ 3 days. There was no statistically significant baseline difference between the 2 groups for TG ($P=0.533$), FMLE ($P=0.089$), FMKnFx ($P=0.291$), TB ($P=0.078$), and 6MWT ($P=0.145$).

For the primary measure, TG, FNS-IM produced a statistically significant greater gain versus No-FNS ($P=0.003$; Table 2). The statistically significant model coefficient indicated a difference in slope of 2.9 points for FNS-IM versus No-FNS (while accounting for pretreatment scores; 95% CI, 1.2 to 4.6). The difference in distribution of gain scores for the 2 groups (Figure 1) underlies the statistically significant group difference in treatment response. For FNS-IM, 64% had gains of 2 to 6 points; whereas, only 13% of No-FNS had gains of ≥ 2 . In fact, $\approx 50\%$ of No-FNS had no gains; whereas only 14% of FNS-IM subjects had no gains. Figure 2a shows an example of pretreatment abnormal swing phase using a stiff-legged pattern. Figure 2b shows the identical point in the gait cycle and restoration of volitional swing phase flexion at post-treatment after FNS-IM treatment (no FNS during video).

In secondary analysis, gains in TG items were calculated (Figure 3). FNS-IM demonstrated gains for all items, and the gain for each item was greater than that exhibited by No-FNS (except item 1). For No-FNS, there were no gains in 3 items, and for 1 item, there was a worsening.

For FMKnFx, FNS-IM had a statistically significant greater gain than No-FNS ($P=0.049$; Table 2). Figure 4a and 4b show changes in individual scores that underlie the group difference.

For the remaining measures, after accounting for pretreatment scores, there was no statistically significant difference between groups in response to treatment, according to the following: FMLE ($P=0.182$), TB ($P=0.133$), and 6MWT ($P=0.184$; Table 2).

Both groups subjectively reported gains in walking endurance and functional milestones. Figure 5 shows that functional milestones were reported in 11 instances for No-FNS



Figure 2. a. Subject, before treatment, unable to perform normal hip/knee/ankle flexion at midswing. He was treated with FNS-IM. b shows that at the identical point in the gait cycle, after treatment, his volitional limb flexion (no FNS was activated) was restored.

and 53 instances for FNS-IM. Milestones of greater motor complexity were demonstrated more frequently for FNS-IM versus No-FNS.

Discussion

This study extends the literature and adds to the totality of gait training information by showing that FNS-IM produced a statistically significant greater gain versus No-FNS in a measure of coordinated gait component execution. Restoring normal coordinated gait component execution can reduce the frequency of falls, reduce energy cost, increase endurance,

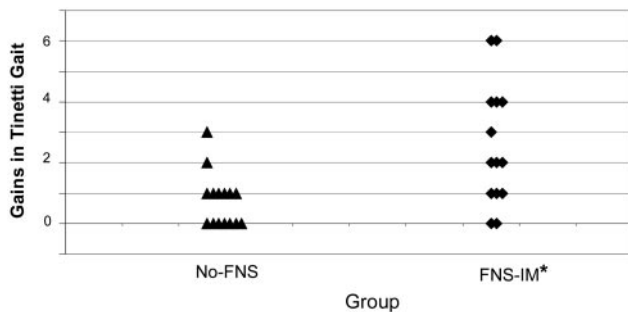


Figure 1. Pretreatment/post-treatment gain for each subject, according to TG scale, shown separately for No-FNS and FNS-IM. Thirty-six percent in FNS-IM had gains ≥ 4 , whereas no subjects in No-FNS had gains ≥ 4 . Eighty-seven percent of No-FNS had minimal to no gains (0 to 1 point), whereas 36% of FNS-IM had gains of only 0 to 1 point.

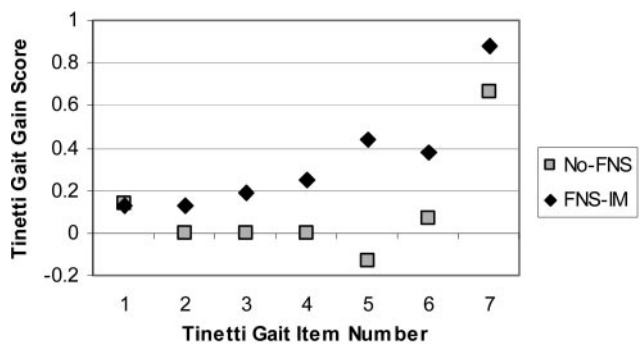


Figure 3. Item mean gain score is shown for each of 7 TG items, separately for No-FNS and FNS-IM. These item-level data underlie the results of ordinal regression model analysis, which showed statistically significant greater gain for FNS-IM vs No-FNS. No statistical analyses were performed on the individual item gains, and so individual item gain scores may be attributable to chance. For 6 of 7 items, FNS-IM produced greater absolute gains than did No-FNS.

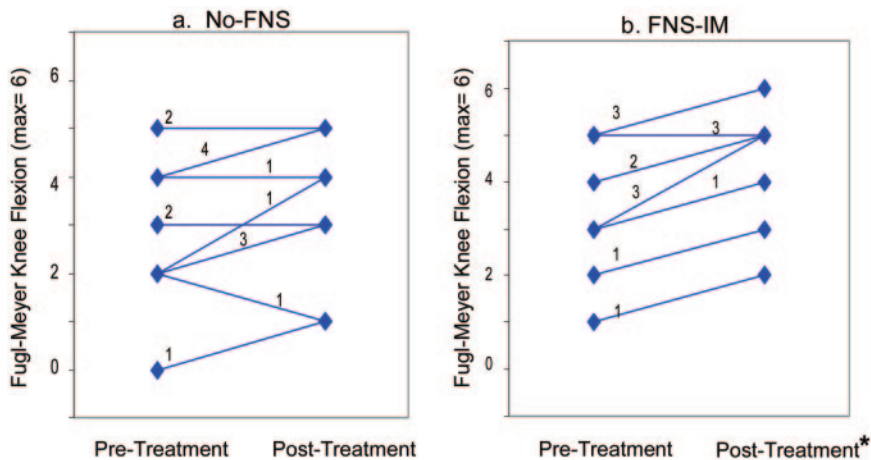


Figure 4. Individual FMKnFx scores are shown for pretreatment/post-treatment, separately for No-FNS and FNS-IM. Each line illustrates the direction of change from pretreatment to post-treatment. Numbers on each line illustrate number of subjects having a given pattern of change in pretreatment/post-treatment score. More subjects had gains in the FNS-IM group (79%) vs the No-FNS group (60%). Greater total gains were produced by FNS-IM (14 points) vs No-FNS (9 points).

and enable greater functional capability and life role participation (Figure 5). Figure 2 shows that FNS-IM produced recovery from an uncoordinated, unsafe gait to normal swing phase limb flexion (2-point gain; TG). This 2-point gain in TG can reduce frequency of falls.³⁵ Sixty-four percent of FNS-IM had gains of 2 to 6 points in TG. In contrast, only 13% of No-FNS had gains ≥ 2 points. Multiple gait deficits can elevate energy cost 1.5 to 2.0 \times normal.³⁶ For example, lack of normal movement at the knee or ankle during swing phase can reduce gait efficiency to 76% or 92% of normal, respectively.^{2,3} With improvement in each gait component, safety and energy cost can improve.^{35,36}

Greater safety and reduced gait energy cost can result in greater functional ability. FNS-IM subjects demonstrated not only greater gains in coordinated gait components but also greater gains in self-reported functional mobility (Figure 5). In contrast, 87% of No-FNS had minimal or no gain (0 to 1 points) in gait component execution and fewer demonstrated functional milestones.

FNS-IM produced a significantly greater gain in knee flexion coordination versus No-FNS. This could have occurred because FNS-IM provided the training advantage of electrically induced, coordinated muscle contractions and joint movements that closely approximated normal. Without FNS-IM assistance, practice of coordinated movements among hip, knee, and ankle were not possible. Practice and motor relearning of coordinated movements were important because isolated joint movement control and coordination among hip, knee, and ankle movements are critical to execute the movement components inherent in normal gait.³⁷

Similarly, the FNS-IM advantage in the TG measure could have occurred because FNS-IM uniquely targeted gait components including joint movement excursion, sequence, and timing of movements.²⁰ First, FNS-IM activated knee flexors and ankle dorsiflexors during swing phase at normal timing and at normal joint movement excursions so that the normal sagittal plane trajectory (TG item 4) could be practiced.²⁰ Second, FNS-IM smoothly transitioned changes in knee flexor and ankle dorsiflexor muscle activations across the phases of swing phase to enable practice of a smooth, continuous swing phase pattern closely approximating normal step continuity (TG item 5). Third, during loading and

throughout stance phase, FNS-IM activated hip abductors for pelvic control and knee flexors/extensors for knee control, assisting in weight shift and balance, and further facilitating step continuity (TG item 5). Stable support of the body in the upright position precluded abnormal compensatory trunk movement (TG item 3). As volitional control of the gait components was reacquired, FNS-IM amplitude was reduced in a finely graded manner so that volitional muscle activation was increasingly required and practiced. FNS-IM advantages, reflected in the gait component scale and knee flexion coordination, are generalizable to stroke survivors with the following characteristics: >12 months after stroke, ambulating at least short distances without human assistance, and moderate to severe coordination and gait deficits.

Limitations included small sample size and possibility of unmasking for some secondary measures. There were standard secondary measures that contained items that were not uniquely targeted by FNS-IM. First, FMLE included hip flexion/extension coordination that was treated identically in both groups. Second, TB measured balance capability during sitting, sit-to-stand, stand-to-sit, and turning in a circle, which was addressed in both treatment groups. FNS-IM uniquely targeted the more complex balance challenges during walking, but TB did not capture them. Third, 6MWT tested gait speed per 6 minutes. Given that both groups had BWSTT intervention targeting gait speed, training specificity for both groups can explain the lack of group difference in the 6MWT. In contrast, FNS-IM uniquely targeted the execution of coordinated gait components. Training specificity of FNS-IM can explain the differential response of the FNS-IM group in measures of coordinated gait components and knee flexion coordination.

Existing standard care for patients in the chronic phase consists of addressing new symptoms or diagnoses. The dyscoordination, gait deficits, and dysfunction from the index stroke are not customarily treated beyond 3 months, regardless of the extent of problems. The number of treatments provided in the study (48) is ≈ 21 visits greater than conventional therapy, assuming a best-case conventional scenario of 3 weeks of daily inpatient visits (15 visits), and 6 weeks of twice-weekly outpatient visits (12 visits; total 27). For FNS-IM, the gains in gait components and functional milestones may justify the additional

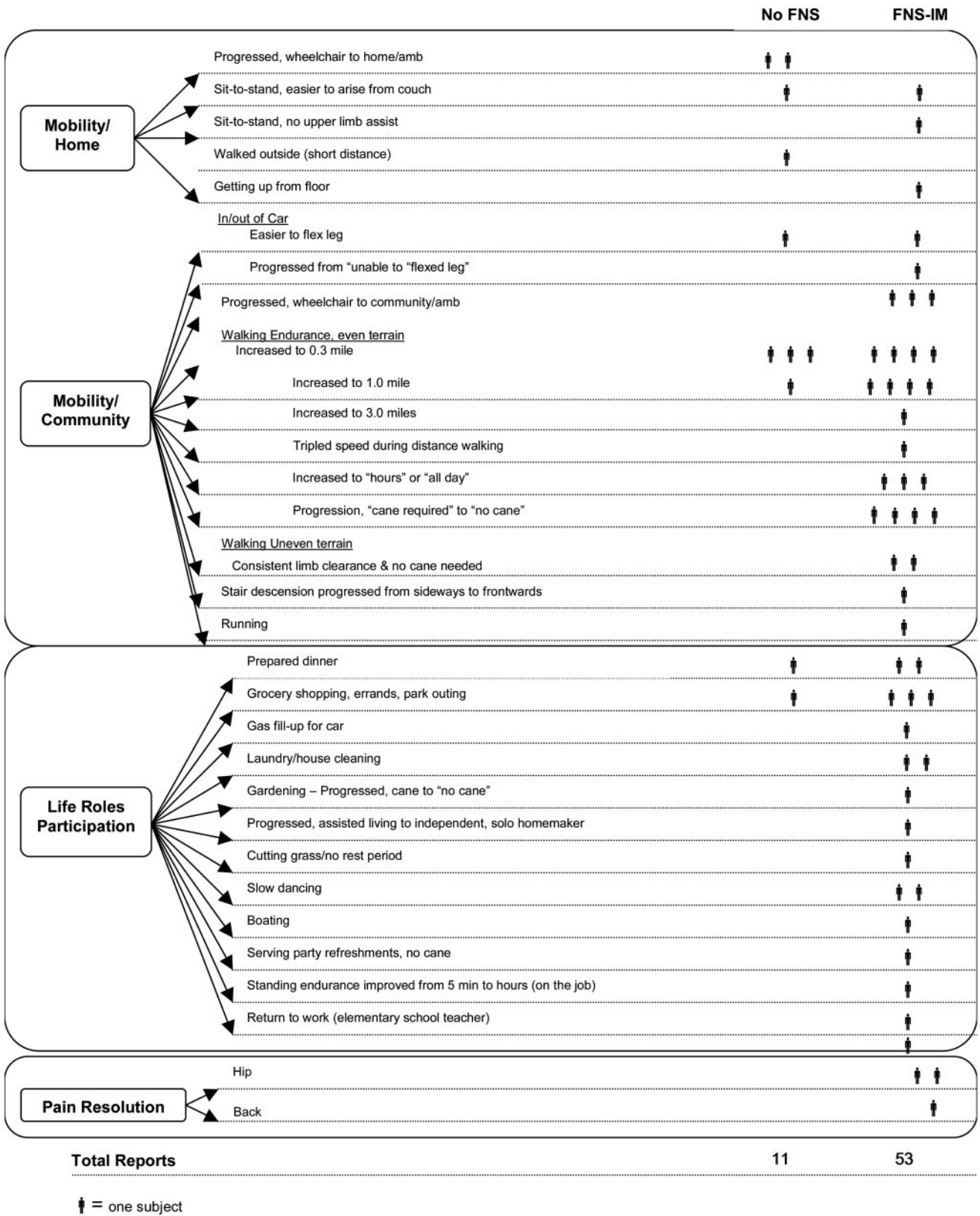


Figure 5. Functional milestones reported by study participants.

21 visits. The combined cost of the FNS-IM system and electrode placement would be ≈\$4960. Because results of this study showed that FNS-IM treatment of persistent gait deficits could produce statistically significantly greater gait improvements, the relatively small incremental cost of the FNS-IM system justifies additional investigation of the use of FNS-IM in gait training. The nature of individual functional gains in the FNS-IM group suggests a potential for improvement in quality of life. A formal cost/benefit analysis might be useful in determining whether functional changes in response to FNS-IM gait training would mitigate expenses incurred by disability across the lifespan of stroke survivors.

Summary

There was a statistically significant greater gain in gait components and in knee flexion coordination in response to FNS-IM versus No-FNS. FNS-IM gait practice advantages could explain the group differences. There was no statistically significant difference between the 2 groups in measures of overall limb coordination, balance, and 6-minute walking distance.

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References

- Daly JJ, Barnickle K, Kobetic R, Marsolais EB. Electrically induced gait changes post stroke. *J Neuro Rehabil*. 1993;37:17–25.
- Waters RL, Campbell J, Thomas L, Hugaos L, Davis P. Energy cost of walking in lower extremity casts. *J Bone Joint Surg*. 1982;64:896–899.
- Waters RL, Barnes G, Husserl T, Silver L, Liss R. Comparable energy expenditure following arthodesis of the hip and ankle. *J Bone Joint Surg*. 1988;70:1032–1037.
- Mayo NE, Wood-Dauphinee S, Ahmed S, Gordon C, Higgins J, McEwen S, Salbach N. Disablement following stroke. *Disabil Rehabil*. 1999;21:258–268.
- O'Sullivan SB, Schmitz TJ. *Physical Rehabilitation: Assessment And Treatment*. Philadelphia, Pa: F.A. Davis Company; 1999.
- Moore S, Schurr K, Wales A, Moseley A, Herbert R. Observation and analysis of hemiplegic gait: swing phase. *Aust J Physiother*. 1993;39:271–278.
- Ada L, Dean CM, Hall JM, Bampton J, Crompton S treadmill and overground walking improves walking after stroke. *Arch Phys Med Rehabil*. 2003;84:1486–1491.
- Dean CM, Richards CL, Malouin F Task-related circuit training improves locomotor tasks, chronic stroke. *Arch Phys Med Rehabil*. 2000;81:409–417.
- Wade DT, Collen FM, Robb GF, Warlow CP. Physiotherapy intervention late after stroke. *BMJ*. 1992;304:609–613.
- Werner RA, Kessler S. Effectiveness of outpatient rehabilitation for postacute stroke. *Am J Phys Med Rehabil*. 1996;75:114–120.
- Moseley AM, Stark A, Cameron ID, Pollock A. Treadmill training and weight-support for stroke. *Cochrane Database Syst Rev*. 2003; CD002840.
- Kosak MC, Reding MJ. Comparison of weight-support versus bracing. *Neurorehabil Neural Repair*. 2000;14:13–19.
- Barbeau H, Visintin M. Optimal outcomes obtained with weight-support in stroke. *Arch Phys Med Rehabil*. 2003;84:1458–1465.
- Liston R, Mickelborough J, Harris B, Hann AW, Tallis RC. Conventional physiotherapy and treadmill re-training for higher-level gait disorders in CVA. *Age Ageing*. 2000;29:311–318.
- Visintin M, Barbeau H, Korner-Bitensky N, Mato N. A new approach to retrain gait in stroke through weight-support. *Stroke*. 1998;29:1122–1128.
- Ding Y, Li J, Lai Q, Rafols JA, Luan X, Clark J, Diaz FG. Motor balance and coordination training enhances functional outcome in rat with transient middle cerebral artery occlusion. *Neuroscience*. 2004;123:667–674.
- Kwakkel G, Wagenaar RC. Effect of duration of upper- and lower-extremity rehabilitation sessions and walking speed on recovery of interlimb coordination in hemiplegia. *Phys Ther*. 2002;82:432–448.
- Nudo RJ, Wise BM, SiFuentes F, Milliken GW. Neural substrates for rehabilitation on motor recovery after infarct. *Science*. 1996;272:1791–1794.
- Butefisch C, Hummelsheim H, Mauritz K-H. Repetitive training of isolated movements. *J Neurol Sci*. 1995;130:59–68.
- Daly JJ, Ruff RL. Feasibility of combining FNS with BWSTT. *J Neurol Sci*. 2004;225:105–115.
- Harris-Love ML, Macko RF, Whittall J, Forrester LW. Improved hemiparetic muscle activation in treadmill versus overground walking. *Neurorehabil Neural Repair*. 2004;18:154–160.
- Bogataj U, Gros N, Kljajic M, Acimovic R, Malezic M. The rehabilitation of gait in hemiplegia. *Phys Ther*. 1995;75:490–502.
- Burridge JH, Taylor PN, Hagan SA, Wood DE, Swain ID. The effects of common peroneal stimulation on effort and walking speed. *Clin Rehabil*. 1997;11:201–210.
- Hood VL, Granat MH, Maxwell DJ, Hasler JP. A new method of using heart rate to represent energy expenditure. *Arch Phys Med Rehabil*. 2002;83:1266–1273.
- Daly JJ, Ruff RL. Electrically induced recovery of volitional gait in older stroke patients. *Am J Phys Med & Rehab*. 2000;79:349–360.
- Meesala SR, Daly JJ. Differential impact of lower-limb strength and coordination on gait swing phase restoration after 7 years of persistent gait deficits: an intervention case study. *Arch Phys Med Rehabil*. 2004;85:e35 (Epub ahead of print).
- Altman DG, Schulz KF, Moher D, Egger M, Davidoff F, Elbourne D, Gotzsche PC, Lang T. The revised CONSORT statement for reporting randomized trials: explanation and elaboration. *Ann Intern Med*. 2001;134:663–694.
- Duncan PW, Goldstein LB, Matchar D, Divien GW, Feussner J. Measurement of motor recovery after stroke. *Stroke*. 1992;23:1084–1089.
- Ryerson S, Levit K. *Functional Movement Reeducation: Stroke Rehabilitation*. New York, NY: Churchill Livingstone Inc.; 1997.
- Daly JJ, Ruff RL, Osman S, Bieri CL. The response of prolonged flaccid paralysis to FNS. *Dis and Rehabil*. 2000;22:565–573.
- Daly JJ, Kollar KK, Debogorski AA, Strasshofer B, Marsolais EB, Scheiner A, Snyder S, Ruff RL. Performance of intramuscular electrodes for stroke gait. *J Rehab Res Dev*. 2001;38:513–526.
- Borges G, Ferguson K, Kobetic R. Development and operation of portable and laboratory electrical stimulation systems for walking in paraplegic subjects. *IEEE Trans Biomed Eng*. 1989;36:798–801.
- Tinetti ME. Assessment of mobility. *Am J Ger Soc*. 1986;34:119–126.
- Long JS. *Regression Models for Categorical and Limited Dependent Variables*. Sage Publications; 1997.
- Tinetti ME, Williams TF, Mayewski R. A fall risk index for elderly. *Am J Med*. 1986;80:429–434.
- Gerston J, Orr W. External work of walking in hemiparetics. *Scand J Rehabil Med*. 1971;3:85–88.
- Winters DA. *Biomechanics of Motor Control of Human Gait*. Waterloo, Ontario: University of Waterloo Press; 1991.