Mental Practice–Triggered Electrical Stimulation in Chronic, Moderate, Upper-Extremity Hemiparesis After Stroke

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OBJECTIVE. To determine the feasibility and impact of home-based, mental practice–triggered electrical stimulation among stroke survivors exhibiting moderate upper-extremity (UE) impairment.

METHOD. Five participants with moderate, stable UE hemiparesis were administered the Fugl-Meyer Assessment, the Box and Block Test, and the Activities of Daily Living, Hand Function, and overall recovery domains of the Stroke Impact Scale (Version 3). They were then administered an 8-wk regimen consisting of 1 hr of mental practice–triggered electrical stimulation every weekday in their home. At the end of every 2 wk, participants attended supervised stimulation to progress therapeutic exercises and stimulation levels and monitor compliance.

RESULTS. Six instances of device noncompliance were reported. Participants exhibited reduced UE motor impairment and increased UE dexterity and participation in valued activities.

CONCLUSION. The regimen appears feasible and had a substantial impact on UE impairment, dexterity, and participation in valued activities as well as perceptions of recovery.


Stroke remains a leading cause of disability, with the number of survivors exhibiting residual deficits expected to increase over the next decade (Go et al., 2014). Motor impairments are common and profoundly undermine occupational performance and independence (Broeks, Lankhorst, Rumping, & Prevo, 1999; Mayo, Wood-Dauphinee, Côté, Durcan, & Carlton, 2002). Because functional practice integrating the paretic upper extremity (UE) appears to be critical to reduction of motor deficits (Nudo, 2006), many contemporary rehabilitative approaches emphasize repetitive, task-specific practice (RTP) integrating the paretic UE (e.g., Page, Levine, & Leonard, 2007; Wolf et al., 2006). Yet, most of these therapies are efficacious only in clients exhibiting active distal UE movement, a minority of the stroke survivor population.

Mental practice (MP) is one example of a promising UE therapy that incorporates RTP but that currently offers only limited application because of its requirement for distal UE movement. Its use in stroke rehabilitation has long been supported by evidence showing that MP triggers the same neural areas and musculature as physical practice of the same tasks (e.g., Decety, 1996; Decety & Ingvart, 1990; Weiss et al., 1994). The primary author’s laboratory was the first to show that repetitive MP use consistently reduces UE impairment (Page, 2000) and causes cortical reorganizations similar to those brought about by motor practice (Page, Szaflarski, Eliassen, Pan, & Cramer, 2009) and that addition of MP to physical practice significantly increases paretic UE use and function (e.g.,...
Page et al., 2007; Page, Dunning, Hermann, Leonard, & Levine, 2011), a finding subsequently replicated by others (for a review, see Cha, Yoo, Jung, Park, & Park, 2012). However, MP combined with RTP is also limited in that survivors must exhibit active paretic wrist and finger flexion to be eligible.

To address this challenge, an innovative electrical stimulation device was developed that is triggered by the minute muscle activations occurring during MP. The stimulation is activated only when the client’s electromyographic (EMG) activity during MP attains a preset EMG threshold level displayed on the device’s screen. When this level is reached, the client receives electrical stimulation via surface electrodes on the paretic UE musculature. Moreover, when the client is repeatedly successful at attaining a certain threshold, the threshold level can be increased, thereby increasing the level of challenge for the client. In addition to movement repetition, such progressive challenge is a prerequisite for plasticity and UE motor return (Nudo, 2006).

Use of this device—called the Mentamove (Mentamove Deutschland, Karlsfeld, Germany)—has the potential to expand MP’s use to the large number of stroke survivors exhibiting only trace UE movement—a group that is not eligible for traditional MP protocols and that cannot activate stimulation devices predicated on substantial active limb movements as a trigger. The primary study objective was to estimate the impact of Mentamove use on UE motor impairment in stroke survivors exhibiting trace movement in the distal areas of their paretic UEs. We chose a cohort of chronic stroke survivors (³6 mo postictus) because they were likely to be neurologically stable and not receiving other rehabilitative interventions that could contaminate the findings of this pilot study.

An additional, unique study facet was that the intervention was mostly home based. This aspect was consistent with other home-based electrical stimulation studies that we had conducted (e.g., Gabr, Levine, & Page, 2005; Page, Levin, Hermann, Dunning, & Levine, 2012), and we felt it was highly relevant to occupational therapy practice given the diminishing amount of clinical contact time available to intervene with the growing population of clients with poststroke UE deficits. Given that the regimen was mostly home based and that this was the first application of MP-triggered stimulation to the paretic UE poststroke, we monitored patient compliance and adverse events—important information for a pilot study that would inform, in part, whether the intervention should move forward to testing in subsequent Phase 1b and Phase 2 work.

Method

Participants

Participants were recruited through presentations provided to local stroke support groups and by distributing advertisements approved by the local institutional review board to local therapists during continuing education events or via mail. To be eligible for the study, volunteers had to meet the following inclusion criteria:

1. In the paretic UE, ³20° of active shoulder flexion, ³20° of active internal and external humeral rotation, ³20° active elbow flexion, and ³15° of passive wrist flexion and extension. The latter motor criterion was intended to ensure that participants exhibited sufficient passive range of motion without contractures or discomfort such that their fingers could be moved by the stimulation.

2. Manual muscle test of 1/5 in the paretic wrist flexors and extensors, indicative of a palpable muscle contraction. Minimal active joint movement could be exhibited in the paretic wrist or metacarpophalangeals but was not a requirement. The movement had to be <10°, which was a differentiating characteristic of this work from previous MP + RTP studies (e.g., Page, Szflarski, et al., 2009; Page et al., 2011).

3. One stroke (verified from each participant’s medical record) resulting in motor deficits, occurring ³6 mo before study enrollment.

4. Score ³24/30 on the Mini-Mental State Examination (Folstein, Folstein, & McHugh, 1975).

5. Discharged from all forms of physical rehabilitation. We also applied the following exclusion criteria:

1. Score ³5 on a 10-point visual analog scale measuring pain in the paretic UE

2. Excessive spasticity in any of the paretic UE joints, defined as a score of ³2 on the Modified Ashworth Scale (Bohannon & Smith, 1987)

3. Other conditions that, in the opinion of the investigative team, precluded safe or effective study participation.

Assessments

Because of the moderately impaired nature of our participants’ UEs, they were expected to be unsuccessful in attempting most items on distally based measures (e.g., Action Research Arm Test; Arm Motor Ability Test). Thus, we chose the UE section of the Fugl-Meyer Assessment (FM; Fugl-Meyer, Jäähkö, Leyman, Olsson, & Steglind, 1975) as the primary outcome measure in this study. We administered this measure twice before intervention to ensure a stable baseline level on this measure. FM items evaluate UE movements from proximal (e.g., shoulder...
abduction, internal rotation) to distal (e.g., mass grasp; pincer grasp). Each test item is scored on a 3-point ordinal scale (0 = cannot perform; 2 = can perform fully) and summed to provide a maximum score of 66.

We also administered the Box and Block (B&B) Test (Smith, 1961), which was used to determine whether changes occurred in UE gross manual dexterity as a result of participation in the intervention. During the test, the client is seated in front of a wooden box with a partition in the middle and is asked to move colored blocks from one side of the box over the partition to the other side. The number of blocks moved in 1 min is recorded.

To examine how changes in motor impairment and dexterity would conspire to affect participation and quality of participation in common UE activities, we collected scores on the Activities of Daily Living (ADLs), Hand Function, and Overall Perception of Recovery domains of the Stroke Impact Scale (SIS) Version 3.0 (Duncan, Bode, Min Lai, & Perera, 2003) before and after intervention. To respond to the ADLs and Hand Function items, participants used a 5-point Likert scale (0 = extremely difficult; 5 = not difficult at all) to indicate the difficulty with which they were able to carry out common ADLs and use the paretic UE for common ADLs, respectively, over the past week. For the Overall Perception of Recovery domain, participants indicated their perception of overall recovery from 0 to 100, with a higher score indicative of a higher degree of perceived recovery.

**Apparatus**

The Mentamove is a neuromuscular electrical stimulation device approved by the U.S. Food and Drug Administration for use by stroke survivors. It uses three surface electrodes (one ground; two over the motor point of the targeted muscle) to detect electrical signals sent to the targeted muscle group. A computer inside the device evaluates the amount of EMG activity present in the muscle during MP and determines whether the client’s muscle activity meets or exceeds a preset threshold. If the client attains the threshold, the Mentamove activates the muscle with its own biphasic waveform with pulse width ranging between 100 and 400 μs. The “on” signal duration can be adjusted to be between 0.5 s and 10 s, but research (Cauraugh & Kim, 2003) has suggested that 10 s is the optimal duration, and we used this duration in this study. All members of the research team had attended a 5-day intensive training program in Bad Griesbach, Germany, detailing safe, effective Mentamove use with neurological populations.

**Data Collection and Intervention Procedures**

As interested volunteers came forward, they provided informed consent using forms approved by the local institutional review board and a Health Insurance Portability and Accountability Act of 1996 (Pub. L. 104–191) consent form (to obtain medical information on each participant and screened using the aforementioned criteria). Participants passing screening were administered the outcome measures described in the preceding section on one occasion.

About 1 wk after the testing session, each participant and his or her caregiver were administered a 1-hr education session in our laboratory. The goal of this session was to provide information on safe, effective Mentamove use, and it included review of device safety, supervised practice donning and doffing electrodes over the targeted muscles, starting and terminating the stimulation protocol, and eliciting stimulation using MP. To elicit stimulation, participants were instructed to imagine themselves reaching for a large cup situated on a table in front of them and to imagine themselves waving to a friend located across the street—large UE movements intended to elicit muscle contractions during MP and that had been incorporated into the device manufacturer’s training and in clinical UE Mentamove work across Germany and India for several years with high success. Participants were instructed not to actively move the paretic UE during attempts to attain the EMG threshold, and this direction was reiterated in the written instructions. Caregivers were asked to monitor participants and practice sessions when possible to ensure that participants were not moving.

At the conclusion of the education session, participants were provided with a device, a supply of electrodes, written instructions including safety reminders, and a home use log in which they were instructed to record the time of device use, amount of use (in minutes), and muscles targeted. No difficulties were noted with activation of the targeted muscle groups, instructions not to move the paretic UE during attempts to attain the EMG threshold, and this direction was reiterated in the written instructions. Participants were instructed not to actively move the paretic UE during attempts to attain the EMG threshold, and this direction was reiterated in the written instructions. Caregivers were asked to monitor participants and practice sessions when possible to ensure that participants were not moving.

Thereafter, participants used the device every weekday over a period of 8 wk. The target was 1 hr/day of Mentamove use, with approximately 0.5 hr spent on the finger extensors and about 0.5 hr spent on the wrist flexors. The device was set to stop automatically after 30 min of stimulation had concluded. Additionally, at the end of every 2 wk, each participant and his or her caregiver returned to the laboratory. During this visit, the therapist addressed any concerns, adjusted the EMG threshold, checked the device to ensure it was in working order, and checked diaries to ensure that they were being completed.
When participants missed sessions as reported during the meetings or in their diaries, they were asked about the reason for missing the treatment, and the team member collaborated with them on strategies that could be used to prevent future noncompliance (e.g., scheduling sessions on different days or at different times). At this time, participants also demonstrated appropriate device use, and stimulation levels and electrode placements were adjusted as needed. Activities being mentally rehearsed were sometimes advanced or adjusted (e.g., to include smaller movements, such as simply flexing the paretic shoulder and extending the elbow toward a cup in front of the participant) during this time to optimally elicit MP. Advanced activities that were used later in the regimen and that still incorporated the entire paretic UE in big movements included reaching for a large object (e.g., a large bottle or appliance) on an elevated shelf or closing drapes using both hands. The therapist was available by telephone between laboratory visits to troubleshoot any issues that arose.

At the conclusion of the final compliance visit, clients returned the device and their home use diaries. The outcome measures were then readministered by the same examiner who had administered them before intervention; this examiner was blinded to the intervention that the participants had just received. We were able to attain this level of blinding because multiple poststroke UE studies were ongoing for which this individual was the tester. Thus, at the scheduled posttesting point, we laid out the case report forms for this study and asked him to test each participant but did not apprise him of the intervention that the participant had received or the time point (pre- or postintervention) at which each participant was being tested.

Study Design and Data Analyses
A primary goal of this Phase 1 work was to determine the effect associated with Mentamove use in a well-defined, small, stable cohort of stroke survivors exhibiting moderate UE impairment. Such work was expected to indicate whether to proceed with larger, controlled studies. Thus, we used a prospective, pre–post, case-series design in which we analyzed outcomes using means and standard deviations.

Results
Baseline Characteristics
The sample originally consisted of 6 participants, but 1 participant experienced a second stroke and was hospitalized before beginning the intervention. Thus, the sample consisted of 5 participants (4 women, 1 man; mean age = 43.7 yr, standard deviation [SD] = 6.43 yr; mean time poststroke = 56.5 mo, SD = 42.2 mo); 3 were White, and 2 were African-American. Four had left-sided strokes, 5 had ischemic stroke, and all strokes occurred in participants’ dominant limbs. Two had basal ganglia strokes, 2 had strokes occurring in the left middle cerebral artery, and 1 had stroke occurring in the cerebellum.

Outcomes
Device Use and Adverse Events. The mean number of days that devices were used was 39.0 (SD = 0.67 days); the mean number of minutes that devices were used was 2,340 (SD = 40.0 min). Only six instances of noncompliance were reported during the intervention period. All six instances were due to forgetting to use the device as scheduled, and three of these instances were documented by 1 particular participant. All six instances occurred during the first 2 wk of the intervention period, with no noncompliance issues occurring during the last 6 wk of the intervention period. No difficulties with electrode placement were reported. No adverse events or discomforts were reported during the course of the intervention.

During the first 2 wk, caregivers reported occasional instances of participants attempting to move during MP attempts, particularly in the proximal areas of the paretic UE. Participants were reminded not to move any part of the paretic UE during therapy sessions. To reinforce this point, activating the targeted muscles without actively moving the paretic UE was rehearsed during clinical sessions.

Response to Intervention. As shown in Table 1, after intervention, participants uniformly displayed increases on the FM (our primary study outcome), with a mean change score of +4.0 (SD = 0.6 points), and the B&B Test (mean = +4.4 blocks, SD = 1.1 blocks), with 1 participant who was unable to move any blocks before the intervention able to move three blocks after intervention. These changes translated to consistently positive increases in perception of UE recovery and ability to integrate the paretic UE into valued activities as measured by the SIS.

Discussion
The number of stroke survivors exhibiting residual deficits is increasing, with most exhibiting UE motor impairments. However, few efficacious treatments are available for the growing segment of survivors with moderately to severely impaired UEs. This study was the first of which we are aware to determine the impact of MP-triggered electrical stimulation among stroke survivors exhibiting moderate UE impairment.
Because this constituted a new area of investigation, we regularly monitored participants’ regimen compliance and integrated educational and behavioral components expected to aid in complete, safe, effective device use at home. Clients reported high compliance, with only six instances of noncompliance, even though most sessions were home based with supervised sessions occurring only once every 2 wk. This finding was somewhat unsurprising because other home-based electrical stimulation regimens conducted by our team (Gabr et al., 2005; Page, Fulk, & Boyne, 2012) have yielded similarly high compliance levels with few adverse events. Moreover, several of the strategies used in this study (e.g., home use diaries; intermittent compliance visits) had been successfully applied in our previous home-based electrical stimulation work (Page, Fulk, & Boyne, 2012) as well as in our studies of modified constraint-induced therapy (for a review, see Page, Boe, & Levine, 2013). These previous successes increased our expectations that the use of these strategies would be successful in this study.

With the positive compliance trends reported in this study and others, occupational therapists now have several accounts of home-based protocols in which patients have shown favorable compliance. Concurrently, the amount of clinical time available to work with clients is diminishing in many countries, and therapeutic programming incorporating both education and UE motor treatment is well within the traditional scope of occupational therapy practice. Such programming is likely to facilitate increased transfer of gains realized in the clinic to the home environment, which can sometimes be elusive. Taken together, these trends suggest that occupational therapists should integrate education and home monitoring programs as promising, cost-effective methods of providing adequate repetitions for restitution of UE motor function, overcoming the diminishing amount of clinical contact available to provide these repetitions.

In addition to high compliance, clients uniformly exhibited UE motor impairment reductions, indicated by a mean FM score increase of 4.0 points. These score gains were attributable to new active elbow extension, active wrist extension, active wrist flexion, and mass grasp movements exhibited by clients. Previously, our laboratory produced the first data to indicate the amount of FM score change needed to be clinically important in stroke survivors exhibiting minimal UE impairment (Page, Levin, et al., 2012). However, the FM’s minimally clinically important difference (MCID) has yet to be determined in moderately impaired stroke survivors, such as those sampled in our study. This area remains ripe for future investigation, possibly using the approach described here as the intervention on which such changes are based.

Although no MCID is currently available for the FM, FM score changes were corroborated by participants exhibiting new ability to move nearly four blocks more on the B&B Test after intervention than before intervention. These B&B Test changes were indicative of increased gross manual dexterity in the paretic UE. Participants and their caregivers corroborated FM and B&B Test changes in two ways: They informally reported that (1) participants exhibited new ability to carry out home-based occupations (e.g., using a broom; washing the kitchen counter) and leisure occupations (e.g., using a fishing rod; dining with others without the use of some adaptive equipment) after intervention and (2) participants exhibited markedly higher scores on the SIS Overall Perception of Recovery domain (mean score change = +7.9 points after intervention), the SIS Hand Function domain (mean score change = +17.5 points after intervention), and the SIS ADLs domain (mean score change = +8.8 points after intervention).

Together, these changes suggest not only that participants exhibited gross motor changes (as indicated by the FM and B&B Test score changes) but that these gross motor changes were sufficiently large to translate to ability to perform occupations better. In the absence of MCIDs for the moderately impaired population on the FM and B&B Test, the data from the SIS are useful in determining the true clinical value of this intervention. However, one should

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Note. ADL = Activities of Daily Living subscale; B&B = Box and Block Test; FM = Fugl-Meyer Assessment; Hand = Hand subscale; Post = postintervention; Pre = preintervention; SIS = Stroke Impact Scale.
also keep in mind that the SIS is self-report, based entirely on participants’ perceptions of their recoveries and UE abilities in ADLs. This facet explains why some rated their UE ability levels as very low (e.g., scores of 0) on the SIS, although more objective measures used in this study showed that their UE impairment and dexterity levels were comparable to those of other participants. Such discrepancies were a major reason for incorporating a mix of objective and subjective measures into this study, and we expect that future work will again use a mix of objective and subjective measures, preferably administered at 2-wk intervals during the clinical sessions to better gauge rate of motor skill acquisition. Likewise, recording changes in EMG activity as well as joint angles using kinematics (e.g., simple measure of joint acceleration or angle using accelerometers or electric goniometers) would provide insight into the nature of changes and how they iteratively occur during the intervention period.

It is also of interest to note that in 3 of the 6 cases, the amount of distal UE change that participants exhibited was adequate to qualify them for a more traditional MP + RTP intervention as described elsewhere (e.g., Page et al., 2011) because, although all participants were able to mentally rehearse movements, 3 of the participants exhibited sufficient active movement in their paretic wrists and fingers after intervention to participate in RTP. Previous work by our team has shown that MP + RTP can be a gateway to participation in modified constraint-induced movement therapy (Page, Levine, & Khoury, 2009); the current data suggest that, in participants exhibiting higher degrees of paretic limb impairment, MP-triggered electrical stimulation may similarly be a method of increasing active movement to subsequently participate in MP + RTP.

Given the positive and corroborating nature of our findings, there is sufficient rationale to move forward with a larger MP-triggered stimulation study, with likely next steps including incorporation of an active control group into the study design as a comparison, long-term follow-up to examine stability of the treatment effect, and examination of the optimal regimen duration to identify its optimal dosing for clinical and home use. Given the home-based nature of the protocol, combining provision of the stimulation with functional activities (e.g., attempting to grasp a glass when the finger flexors are stimulated) also seems plausible and will be explored.

In addition to its potential efficacy, this regimen offers decided advantages over other approaches currently used by occupational therapists. For instance, some clinicians have undergone training for prefabricated dynamic orthoses with outriggers (e.g., the SaeboFlex; Saebo, Inc., Charlotte, NC). These approaches have tended to use similar inclusion criteria as those described in this study. However, whereas initial results from this study were uniformly positive, the largest independent studies of these orthoses have reported negative (Barry, Ross, & Woehrle, 2012) or neutral (Butler, Blanton, Rowe, & Wolf, 2006) findings. Alternatively, electrical stimulation neuroprosthetics have shown great promise in the moderately impaired population (e.g., Page, Levin, et al., 2012); however, these devices cost more than $20,000, which is prohibitive for many clients and clinics. Data from this study suggest that MP-triggered electrical stimulation offers a safe, promising approach for increasing UE movement and ability to participate in valued occupations even years poststroke without the limitations noted in these approaches and at an appreciably lower unit cost.

Clinical Implications and Applications

In accord with the American Occupational Therapy Association’s (2007) Centennial Vision, it is important to incorporate evidence-based interventions to facilitate recovery from stroke. Occupational therapy services alone are not enough to help people recover motor function after a stroke. Creative, complementary approaches are essential to facilitate such motor recovery, including ensuring that participants fully engage in interventions as prescribed when they are not present in the clinic.

Training and supervision as used herein require minimal interaction with the occupational therapist. The practice associated with both MP and use of a triggered electrical stimulation device requires about an hour to provide. Yet, the skills practiced in this session can be transferred to successful practice attempts while at home as well as during subsequent therapy sessions. Efficacy can be maximized without a substantial number of clinical visits and to prime the brain and muscles to prepare for full participation in subsequent occupational therapy sessions. Ideally—and as with all occupational therapy sessions—the activities that are mentally rehearsed should be client chosen and complement the occupations being rehearsed during occupational therapy sessions.

In addition to increasing poststroke motor recovery, the combination of MP, EMG-triggered electrical stimulation, and traditional occupational therapy approaches described herein have the potential to reduce UE weakness and address poststroke sequelae that are common in the moderately impaired stroke survivor population (e.g., UE spasticity). The impact of MP-triggered electrical stimulation on such sequelae has yet to be tested but is ripe for future work, and it can be implemented across the continuum of care, including early after stroke, when the presence of
spontaneous neurological recovery is likely to heighten the impact of this promising regimen.

For example, clients and caregivers at inpatient rehabilitation centers could be trained during education sessions, between scheduled therapy sessions, or both by a member of the care team and could then carry out MP-triggered electrical stimulation in the evenings and in between therapy sessions. Again, the occupational therapist must exercise prudence to ensure the techniques are introduced appropriately and in a timely fashion without overwhelming or fatiguing the client. Alternatively, occupational therapists could integrate MP-triggered electrical stimulation to prescribe a home program that is functional, engaging to clients, and likely to provide adequate repetition to invoke motor changes as shown in this study. Clients who exhibit response to MP-triggered electrical stimulation can begin physically practicing the component movements needed and, ultimately, the full task without the electrical stimulation. Thus, MP-triggered electrical stimulation would ideally be used early in the rehabilitative process to engage in valued occupations and provide a primer to physical practice as the client progresses.

This combination approach may not be suitable for all clients or locations. For example, people with cognitive deficits may find it difficult to comprehend the MP components, and some clients may require additional assistance operating the device. Also, some clients may have hypersensitivity (because of either their lesion or skin sensitivity) to the electrical stimulation. As with any modality, occupational therapists must consider their clinical population, and they also need to follow state certification laws for practicing modalities before using MP-triggered electrical stimulation.

Implications for Occupational Therapy Practice
The results of this study have the following implications for occupational therapy practice:
- MP-triggered electrical stimulation appears to reduce UE motor impairment and increase gross manual dexterity, participation, and performance of valued activities.
- These effects were observed in people who were >6 mo poststroke and who exhibited moderately severe UE hemiparesis.
- Although the MP-triggered electrical stimulation was mostly home based, participants displayed favorable compliance. Behavioral strategies were used to increase compliance and comprehension of the study protocol.
- These strategies included compliance visits, a 1-hr education session, and home use diaries.

Conclusion
Poststroke UE motor recovery frequently necessitates many long hours of task-specific practice to elicit neuroplastic and motor changes. With diminishing contact time and funding available for rehabilitation, high-duration protocols and protocols requiring expensive equipment are often not feasible. MP-triggered electrical stimulation offers the possibility of repetitive, home-based practice and appears to increase gross dexterity, UE recovery, and participation in valued activities even years poststroke. The innovative integration of behavioral techniques to enhance protocol compliance and client understanding of this home-based approach appears promising and should be further investigated in future trials.

References


