Can severe upper extremity hemiplegia improve with functional electrical stimulation?

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Introduction

Stroke survivors with low levels of arm and hand function, characterized by Chedoke–McMaster Stages of Motor Recovery Levels 1 and 2, or Upper Extremity Fugl-Meyer Score (UE-FM) of ≤ 19, are often considered unlikely to make significant functional gains with upper extremity (UE) intervention.[1]

Very few treatment options have been designed or tested with this population due to this assumption. Often one handed compensatory interventions are instituted early with this most severe hemiparetic group resulting in learned non-use.[2]

Effective new treatment options are required to enhance recovery for individuals with severe UE hemiparesis.

Objectives

To investigate whether treatment with MyndMove™, a novel, non-invasive, advanced functional electrical stimulation (FES) therapy improves recovery of voluntary arm function in stroke patients with severe UE deficits.

A study was designed to investigate the efficacy of MyndMove™ therapy in 3 cohorts of participants: (1) early sub-acute (< 2 months), (2) late sub-acute (2 - 6 months) and (3) chronic (> 6 months) periods of recovery. Recruitment of 25 participants within each cohort is planned. This poster describes the results for the chronic population cohort which has completed recruitment. (ClinicalTrials.gov Identifier: NCT02266836)

Methods

Design: Multi-centre, open-label, single group intervention assignment.

Subjects: Twenty-five (25) chronic stroke patients with severe upper extremity hemiparesis, who were greater than 6 months after onset of stroke.

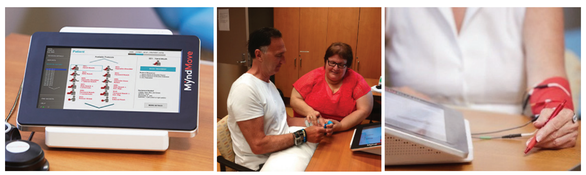
Inclusion criteria: Age 18 or older**,** ischemic or hemorrhagic stroke, greater than 6 months post stroke, severe hemiplegia as defined by an UE-FM score of less than 19, able to follow instructions, provide consent and participate in 20 one-hour sessions of treatment.

Exclusion criteria: Global aphasia, history of a previous stroke, previous neurological or musculoskeletal condition which interferes with UE function, life expectancy of less than 12 months, history of seizure disorders and on seizure medications, participant has an existing stimulation device (e.g. pacemaker), rash or open wound on arm, botulinum toxin injection in the last 3 months, enrolled in another UE study, previously enrolled in a drug or biologic study in last 6 months.

Intervention: Each participant received 20 one-hour sessions of MyndMove™ Therapy, 3-5 times a week, for 4 – 6 weeks at one of 6 outpatient clinics. Centres included 5 private clinics and 1 hospital based rehabilitation facility.

MyndMove™ devices offer 17 different MyndMove™ stimulation protocols to treat proximal and distal deficits of the UE in stroke patients. MyndMove™ protocols provide bursts of short electrical pulses using surface electrodes and proper sequencing to produce muscle contractions and achieve a range of reaching and grasping functions. During each session, a MyndMove™ trained occupational or physical therapist administered 1 to 4 protocols which matched the needs and goals of the patient during the hour session. Participants were encouraged to use their limbs to do functional tasks during the course of the therapy and were given homework to sustain gains made with the device between sessions.[3]

Figure 1: MyndMove Device and examples of activities performed during MyndMove™ Therapy



Results

Twenty-five (25) chronic stroke patients were enrolled in the study. Twenty-four (24) patients completed 19 or 20 sessions. One patient was withdrawn from the study for medical reasons unrelated to MyndMove™ Therapy.

Table 1: Summary of Baseline Patient Characteristics

Characteristics	
Age (years) (Mean (SD); min-max)	61.1 (10.3) (41 – 86)
Sex (M/F)	14/10
Type of Stroke	
Ischemic	15
Hemorrhagic	7
Missing	2
Brain Hemisphere	Right 11/ Left 13
Time post stroke (months) (Mean (SD); min-max)	49 (67) (6.1 – 264)

Figure 2: UE-FM Assessment for individual patients before (□) treatment and gain (■) after 20 sessions of MyndMove™ Therapy. (Maximum UE-FM = 66 points)

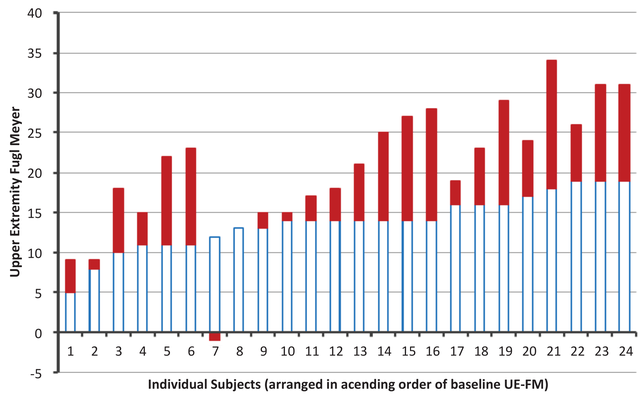


Table 2: Mean Change in Fugl-Meyer Upper Extremity Score and Subscores

Fugl-Meyer Upper Extremity Scores (N = 24)	Baseline UE-FM (Mean (SD))	Final UE-FM (Mean (SD))	Change UE-FM (Mean (SD))	P-value
Overall UE-FM	13.8 (3.5)	21.0 (7.1)	7.1 (5.0)	<0.001
Proximal	9.7 (2.8)	14.6 (5.1)	4.9 (3.2)	<0.001
Wrist/Hand	1.3 (1.6)	3.2 (3.1)	1.8 (2.6)	0.002
Coordination	2.8 (1.3)	3.2 (1.2)	0.4 (0.9)	0.059

Minimal Clinical Important Difference (MCID) (> 5 point increase)[4,5] in UE-FM was observed in 14/24 (58%) of participants.

The mean time to complete 20 sessions was 40 days (SD=6) with a range between 28 to 55 days.

Other observations reported spontaneously by patients and therapists:

- decreased spasticity
- decreased subluxation
- increased range of motion (active and passive)
- increased sensation

Safety: Treatment was well tolerated across the 478 treatment sessions administered in the 24 participants. Only one treatment session was stopped (due to intolerability).

Discussion

MyndMove™ therapy provides benefit to chronic stroke with severe hemiparesis with half of the number of treatment sessions than previously studied.[6]

Change scores on the UE-FM test and sub scores were significant suggesting that individuals in the chronic phase, when provided with the MyndMove™ intervention that facilitates/guides movement, can improve and obtain benefit.

Changes in occupation/function were not measured. However, participants reported benefits such as using their hemiparetic side as a stabilizer and using their impaired limbs in functional tasks such as putting on a glove and holding objects.

This data is only for the chronic population. An analysis of the early sub-acute and late sub-acute populations, once recruitment is complete, will further clarify the potential benefit from MyndMove™ therapy.

Conclusions

Twenty (20) 1-hour sessions of MyndMove™ therapy resulted in clinically meaningful improvements in UE usability in chronic stroke individuals with severe hemiparesis.

This study design (multicentre, open label, single group intervention) enabled therapists to become comfortable with the new technology, collaborate and problem solve in how to best implement MyndMove™ therapy.

This open-label study has guided the design of a randomized controlled trial to further support the clinical use of MyndMove™ therapy.

Future Recommendations

Documentation of MyndMove™ treatment approaches used by therapists would be valuable to learn more about therapists perceptions of the technology.

Future RCT studies should include functional assessment and how participants use their hemiparetic side throughout the day, dose response and monitoring of durability and long term effectiveness.

References

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