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EFFECT OF PERONEAL ELECTRICAL SIMULATION VERSUS AN ANKLE FOOT ORTHOSIS ON OBSTACLE AVOIDANCE ABILITY IN PATIENTS WITH STROKE RELATED FOOT DROP

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AIM AND OBJECTIVE

The study is aim to identify the potential benefits of peroneal Electrical Stimulation (ES) over on Ankle Foot Orthosis (AFO) with respect to the ability to negotiate a sudden obstacle.To find out the effectiveness of peroneal Electrical Stimulation (ES)in the improvement of Foot Drop in stroke patients. To find out the effectiveness of Ankle Foot Orthosis (AFO) in the improvement of Foot Drop in stroke patients. To evaluate the effectiveness of either peroneal Electrical Stimulation (ES) or Ankle Foot Orthosis (AFO) is useful in the improvement of Foot Drop in stroke patients.

Study design: Pre test Post test experimental study design, Simple random sampling, 30 subjects are randomly selected and are assigned into two equal groups.

Group A: Experimental group 15 members.

Group B: Control group 15 members.

Inclusion Criteria

- ✓ Subject with stoke with age of 45-65 years
- ✓ Subjects with stoke should be able to walk independently for at least 10 minutes.
- ✓ Subject with lower extremity involvement.
- ✓ Should be under rehabilitation program (Training) for balance and gait problems.

Exclusion Criteria

- Subject with insufficient ankle mobility i.e. Ankle passive range of movement(PROM) <30^0.
- Or inability to reach a plantigrade foot position when standing with an extended knee.
- Subjects with skin lisions at the electrode sides.
- Subject with Foot drop not related to stoke.
- Subject with psychological disorders, pace makers implant, cognitive impairments etc.

HYPOTHESIS

Null Hypothesis (H0)

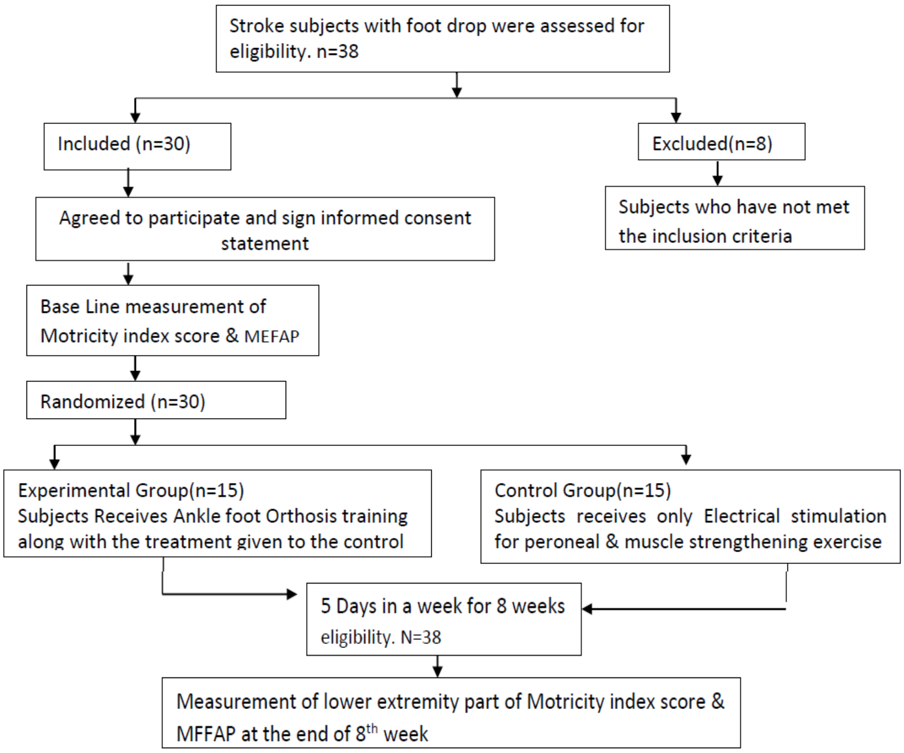
There is no significant effect of peroneal electrical stimulation on obstacle avoidance ability in stroke patients with Foot Drop. There is no significant effect of Ankle Foot Orthosis on obstacle avoidance ability in stroke patients with Foot Drop. There is no significant difference between either peroneal Electrical Stimulation or an Ankle Foot Orthosis on obstacle avoidance in people with stroke related foot drop.

Alternate Hypothesis (H1)

There is significant effect of electrical stimulation on obstacle avoidance ability in stroke patients with Foot Drop.

There is significant effect of Ankle Foot Orthosis on obstacle avoidance ability in stroke patients with Foot Drop. There is significant difference between either peroneal Electrical Stimulation or an Ankle Foot Orthosis on obstacle avoidance in people with stroke related foot drop. The subjects are randomly divided into two groups. Control Group and experimental group. The written informed consent was taken from successive patients/patient attendants whom cannot give a written consent.

MATERIALS AND METHODOLOGY



Intervention methodologyExperimental Group

1. Subjects receives **Ankle Foot Orthosis(AFO)** training about 40 to 50 minutes per day and while performing ADLs.
2. Receives Electrical Stimulation

Stimulation applied to the peroneal muscle of effected lower extremity.Placement of electrode:
Inactive at the head of the fibula. (lateral aspect of leg).
Active electrode at the motor point of the dorsiflexors muscles.

Using the parameters: Faradic stimulation 30 contraction each set for 3 setsAmplitude : 60 mA
Pulse width: 300 u s Frequency 25 – 50 Hz

3. Muscle Strengthening Exercises for Drop Foot:

Ankle rolls
Toe to heel rocks Foot stretch Isometric dorsiflexion
Toe curls
Foot band
Note: Above all exercises to be repeated for 10 times comprises of 3 sets each.

Control Group
Subject receives the Experimental group protocol except the training of AFO.

OUTCOME MEASURE
Lower extremity part of the motircity index score and modified Emory Functional Ambulation Profile(EFAP)
1. Motricity Index is a more feasible measure that can demonstrate the overall patients' impairment. It is a simple, brief measure of general motor function that can predict the mobility outcomes post-stroke.[20]

The Motricity Index can be used to assess the motor impairment in a patient who has had a stroke.
In upper extremity the movements were shoulder abduction, elbow flexion and pinch grip. In lower limb the three movements were hip flexion, knee extension and ankle dorsiflexion.[21]
In order to grade muscle force, they used the ordinal six point's scale of Medical Research Council.[21]

The MRC grades were converted into modified weighted scores according to patients' difficulty in progressing from one grade to the next. The three scores were summed and added by one, and total score was ranged from 0 (complete paresis) to 100 (normal strength) APPENDIX II

Tests for Each Leg

(1) Ankle dorsiflexion with foot in a plantar flexed position
- 14 points are given if there is less than a full range of dorsiflexion

(2) Knee extension with the foot unsupported and the knee at 90°
- 14 points are given for less than 50% of full extension
- 19 points are given for full extension yet it can be easily pushed down

(3) Hip flexion with the hip bent at 90° moving the knee towards the chin
- 14 points are given if there is less than a full range of passive motion
- 19 points are given if the hip is fully flexed yet it can be easily pushed down

2. Emory Functional Ambulation Profile

The Functional Ambulation Profile (FAP) is a timed walking test that was specifically designed to track down the progress of patients with neurological impairments throughout their participation in a comprehensive outpatient rehabilitation programme.[23]

In its most recent form, this test (**The Emory Functional Ambulation Profile OR EFAP**) require an individual to negotiate 5 common environmental challenges, and it incorporates the use of orthotics or assistive devices (AD) 23

The modified Emory Functional Ambulation Profile (mEFAP) is an easily administered test that measures the time to ambulate through 5 common environmental terrains with or without an assistive device or manual assistance.[12] APPENDIX III (IV)

STATISTICAL ANALYSIS

Formulae

(Student t test) paired 't' test

$$t = \frac{\sum x/n}{S/\sqrt{n}}$$

$$s = \sqrt{\frac{\sum(x-\bar{x})^2}{n-1}}$$

S = standard deviation (sample)
n= number of subjects in the sample X = Difference between the pre and post test values. (n-1)= degree of freedom

(Ficher's 't' test) Unpaired 'T' test

$$\bar{x}_1 - \bar{x}_2.$$

- $$s_p = \sqrt{\frac{(n_1-1)s_1^2 + (n_2-1)s_2^2}{n_1+n_2-2}}$$
- $$SE(\bar{x}_1 - \bar{x}_2) = s_p\sqrt{\frac{1}{n_1} + \frac{1}{n_2}}$$
- $$T = \frac{\bar{x}_1 - \bar{x}_2}{SE(\bar{x}_1 - \bar{x}_2)}.$$

S_p = Pooled Standard deviation
SE: Standard error of difference Degree of freedom n1+n2 -2

STATISTICAL ANALYSIS AND RESULT

Data was entered into Microsoft excel spread sheet, tabulated and subjected to statistical analysis. Of the 30 subjects, 15 were randomised into experimental group and 15 were randomized into control group. All the subjects completed the entire study protocol as defined, by 6 weeks in the training sessions.

Pretest – post test values of lower extremity part of motorcity index score and modified emory functional ambulation profile.

The compare the pre and post treatment effect within the group paired sample t-test was used and to compare the pre and post treatment effect between the groups, unpaired t-test was used.

Table: Analysis of Control Group with pre and post intervention.

Parameter		N	Mean	't' value	df	t value*
Lower extremity part of Motricity index score	Pre	15	57.866	10.974	14	2.15
	post	15	70.6			

*Table of 't'. Probability of large value of 't'

To test the significance of the pre and post intervention of the parameter the paired 't' test has been used. Since the corresponding 't' value of parameter is <2.15 at 14 degree of freedom, there is notable significance. It is observed that the post intervention has shown significant impact on the subjects.

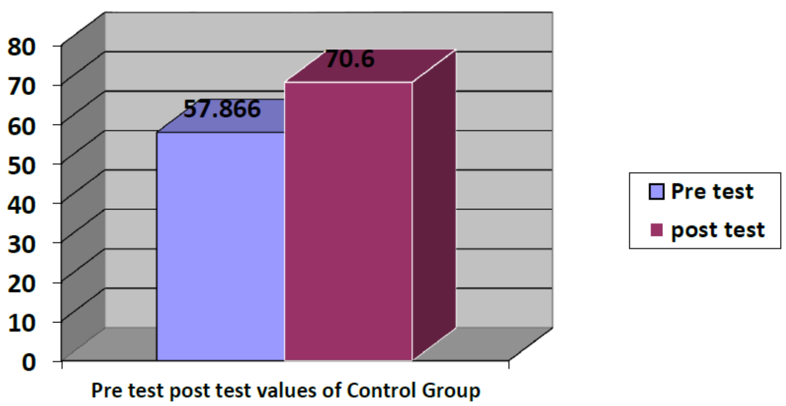


Table: Analysis of Experimental group with pre and post intervention.

Parameter		N	Mean	't' value	df	t value*
Lower extremity part of Motricityindex score	Pre	15	53.26	8.857	14	2.15
	post	15	65.66			

*Table of 't'. Probability of large value of 't'

To test the significance of the pre and post intervention of the parameter the paired 't' test has been used. Since the corresponding 't' value of parameter is <2.15 at 14 degree of freedom, there is notable significance. It is observed that the post intervention has shown significant impact on the subjects.

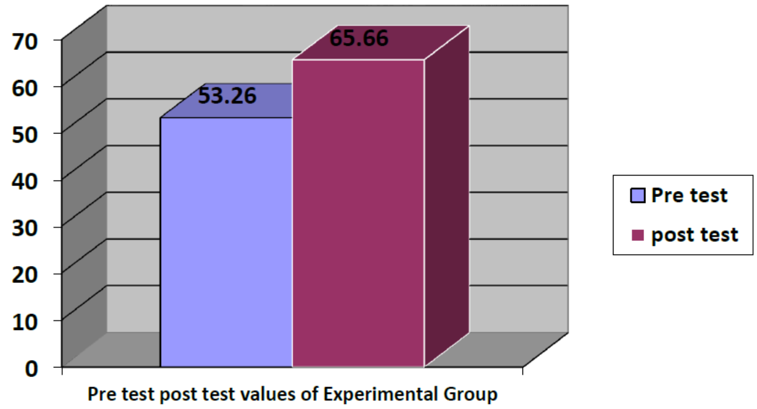


Table: Comparison of post test values between the groups.

Parameter		N	Mean	SD	't' value	df	't' value*
Lower extremity part of Motricity index score	Exp Post	15	68.26	5.42	1.81	28	2.05
	Cont post	15	70.6	4.52			

*Table of 't'. Probability of large value of 't'

To test the significance of the post intervention mean values between the groups, the **unpaired 't'** test has been used. Since the corresponding 't' value of parameter is <2.05 at 28 degree of freedom, there is no significant difference. It is observed that the post intervention has not shown significant impact on the subjects.

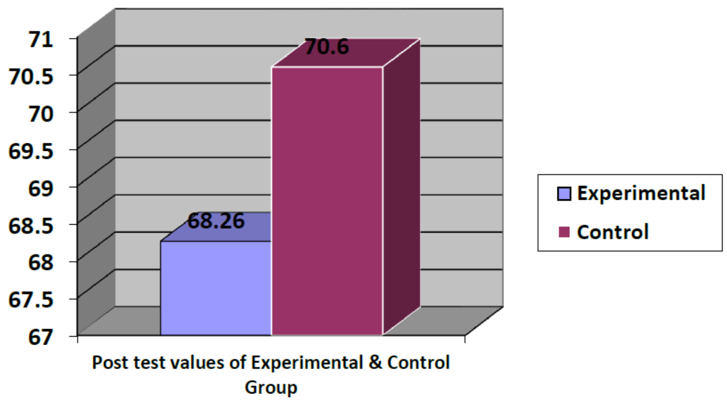


Table: Analysis of Control Group with pre and post intervention

Parameter		N	Mean	't' value	df	t value*
Modified Emory Functional Ambulation Profile	Pre	15	612.12	22.56	14	2.15
	Post	15	230.23			

*Table of 't'. Probability of large value of 't'

To test the significance of the pre and post intervention of the parameter the paired 't' test has been used. Since the corresponding 't' value of parameter is <2.15 at 14 degree of freedom, there is notable significance. It is observed that the post intervention has shown significant impact on the subjects.

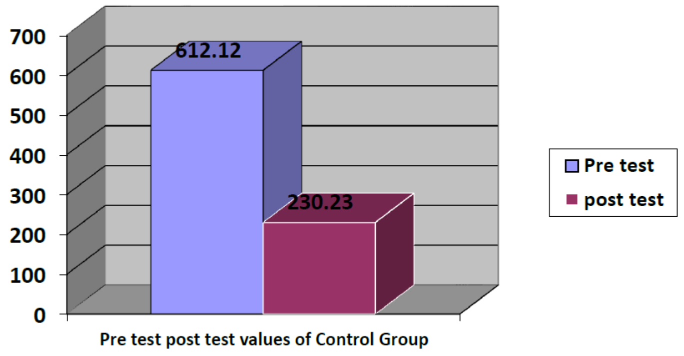


Table: Analysis of Experimental Group with pre and post intervention

Parameter		N	Mean	't' value	df	t value*
Modified Emory Functional Ambulation Profile:	Pre	15	536.658	26.009	14	2.15
	Post	15	261.091			

*Table of't'. Probability of large value of't'

To test the significance of the pre and post intervention of the parameter the paired 't' test has been used. Since the corresponding 't' value of parameter is <2.15 at 14 degree of freedom, there is notable significance. It is observed that the post intervention has shown significant impact on the subjects.

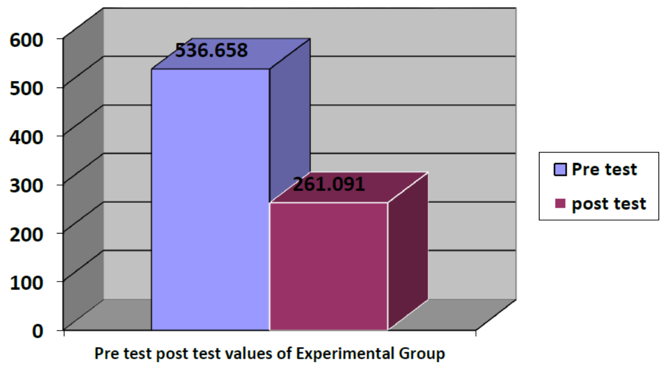
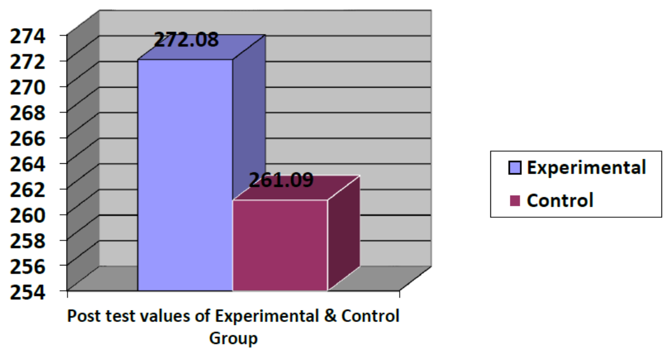


Table: Comparison of post test values between the groups.

Parameter		N	Mean	SD	't' value	df	't' value*
Modified Emory Functional Ambulation Profile:	Exp Post	15	272.080	41.10	14.85	28	2.05
	Cont post	15	261.091	40.14			

*Table of 't'. Probability of large value of 't'

To test the significance of the post intervention mean values between the groups, the **unpaired 't'** test has been used. Since the corresponding 't' value of parameter is <2.05 at 28 degree of freedom, there is significant difference. It is observed that the post intervention has shown significant impact on the subjects.



TOOLS USED FOR TESTING OBSTACLE AVOIDANCE ABILITY USING STABILISATION

MEFAP

ELECTRICAL STIMULATOR

AFO

ASSESSING MOTRICITY INDEX SCORE

ASSESSING MEFAP INDEX SCORE

RESULTS

After a 8 week treatment period, the subjects in control group(Electrical stimulation & muscle strengthening) and experimental group(Electrical stimulation, muscle strengthening & AFO) had shown improvement with the out come measures; but on comparing experimental group with control group, experimental group had not shown statistically significant improvement at 0.05 level with the out come measure of Motricity Index Score. Null hypothesis is accepted. The obtained table value is less than referred table value in this study, so there isno significant difference between both the groups.

In the second outcome measure, i.e. Modified Emory Functional Ambulation Profile (MEFAP), the subjects in control group and experimental group had shown improvement with the out come measure; but on comparing experimental group with control group, experimental group had shown a statistically significant improvement at 0.05 level of significance. Hence in this study null hypothesis is rejected. The obtained table value is greater than referred table value in this study, so there is significant difference between both the groups.

DISCUSSION

The present study aimed to identify whether, in a group of community-dwelling people in the chronic phase after stroke, peroneal ES was superior to an AFO regarding time-critical obstacle avoidance performance. The included participants had relatively good balance skills and walking speeds These people demonstrated no significant difference with ES than with their AFO, although the overall increase in success rate was small. The mean of the lower extremity Motricity index score of the experimental group post test value is 68.26 and where as for control group post test value is 70.6 at 5% confidence intervals, it is observed that additional use of AFO has not shown significant impact on subjects. An increase in the Motricity index score, however was associated with greater benefits of electrical stimulation of the peroneals; therefore, the gain with Motricity index score with ES might be clinically relevant, particularly in this patient group.

The present study we found that low leg muscle strength has increased with peroneal ES concerning obstacle avoidance ability.

Better obstacle avoidance ability has previously been reported to be associated with a lower fall risk in elderly people who were healthy. Although similar evidence of the construct validity of this test is not available for people in the chronic phase after stroke, the present results suggest that peroneal ES may enhance the safety of ambulation in community-dwelling people with stroke. Both gait variables have been related to a reduced risk of falling. However, at this time, there is no direct evidence that peroneal nerve ES is superior to an AFO in reducing fall incidence.

On average, the observed improvement in success rates with ES, compared with an AFO, was relatively small, raising the question of whether this result is clinically important. There was, however, large between-subject variability, indicating that ES worked very well for some participants but not for others. Therefore, we suggest that, although the improvements with ES were statistically significant for the group at large, in clinical practice, ES may only outweigh an AFO for a particular subset of people.

The mEFAP was evaluated for its interrater reliability, test-retest reliability, sensitivity to change, and concurrent validity in the assessment of a heterogeneous group of subjects undergoing outpatient rehabilitation for post stroke gait dysfunction.

The mEFAP provides clear and specific functional information, has no apparent ceiling effect, and looks at an activity (walking) that is often a high priority for the patient. Clinical scales that are currently in use, such as the FIM, Barthel, and Rankin scales, may not provide appropriately detailed task specific information and may be limited by ceiling effects in the assessment of functional ambulation for individuals after stroke.

The mEFAP experimental group post test mean of 15 subjects is 272.080 while for the control group is 261.091,This shows significance difference between two groups hence showing significant impact on obstacle avoidance ability in the subjects.

The present finding shows that there is an overall decrease in the time taken for obstacle avoidance ability with experimental group. Yet this is the firtst study to show that obstacle avoidance ability with peroneal electrical stimulation also was better compare with using an AFO, the standard of care for people with foot drop due to stroke.

SUMMARY

To summarise, electrical stimulation of peroneal muscle improves lower leg muscle strength and obstacle avoidance ability in subjects with stroke related foot drop. In order to investigate this randomized study using Motricity index score and Emory functional ambulation profile were performed over a period of one year.

30 patients are randomly selected and assigned to experimental group and control group, each consisting of 15 patients. The experimental group received electrical stimulation of peroneal muscle, strengthening of dorsiflexors muscle and training of AFO and control group received the same except AFO. The study design was pre-test post test experimental design. The collected data was analysed and interpreted using 't' test which has shown a significant difference in obstacle avoidance ability between two groups when using mEFAP. However, the use of AFO does not shown any significant difference in between the two groups using Motricity index score.

LIMITATIONS

This study had some limitations. First, the applied between the subject line was optimal, given the limited number of participant. Second, This study compared electrical stimulation with ES & AFO, the current standard of care in many counties, which limits the generality to other, more specialised, typed of AFOs. Third, The current study focused on obstacle avoidance ability with the affected leg. It would be interesting to investigate obstacle avoidance with the non affected as well. However, an AFO is not active during the test procedure, we expect it to have less pronounced effects in this situation. Further more the present protocol was already very strenuous for our patients and adding another condition would have been too strenuous for most of them. Fourth, Although blinding patients to the use of AFO is not possible in practice, the fact that they were aware of the test condition was a limitation and might have influenced their performance. Lastly the present study included only community ambulators with relatively good balance and walking abilities because we expected these people to profit most from peroneal ES, which limits generalizablity to people with lesser ambulation capacity. Direct comparison of the mEFAP to a well-validated test of gait velocity (such as the timed 10-meter walk) may have strengthened the establishment of concurrent (as well as construct) validity. Previous comparison of the EFAP, the predecessor of the mEFAP, to the timed 10-meter walk revealed a strong association between the measures in the performance characteristics of both post stroke subjects and healthy controls.

FUTURE RECOMMENDATIONS

Future studies on the added value of ES over AFOs with regard to obstacle avoidance ability should be conducted with larger samples of people with stroke, including indoor and limited outdoor ambulators, to investigate whether the results of this study can be generalized to other types of patients. In addition, the value of low leg muscle strength as a predictor of good response to peroneal ES should be confirmed in other groups of people with stroke. In larger samples, it also may be possible to identify other (and combinations of) characteristics of people with stroke that are associated with a good response to peroneal ES. Furthermore, additional research, outside the controlled setting of the laboratory, on the effects of ES with regard to community ambulation is recommended. The mEFAP is sensitive to changes in time taken to complete challenging ambulation tasks. Comparison of subject performance on the mEFAP and on measures of community and household ambulation is now needed to investigate the relationship between improved speed on the mEFAP and functional ambulation in a real-world setting. Age matched normal values, as well as the minimal mEFAP values associated with successful household and community ambulation, can be established to focus treatment efforts, predict caregiver burden, and plan for appropriate discharge disposition.

Further research will be required to determine whether the mEFAP will be sufficiently sensitive and specific as an outcome measure for defined therapeutic interventions. Ambulation status after intensive rehabilitation may greatly affect a stroke survivor's sense of self, ease of community reentry, and vocational prospects. Future trials should look at the relationship between mEFAP score changes and measures of stroke-specific quality of life, such as the Stroke Impact Scale. Future investigations should also address the possible added benefit of serial measurements with this tool during rehabilitation. Performing repeated measurements might allow treatment planning to be altered when the patient does not follow an expected course of functional recovery.

APPENDIX I MASTER CHART

MOTRICITY INDEX SCORE: EXPERIMENTAL GROUP

S.NO	AGE	SEX	PRE	POST
1	48	M	53	76
2	45	M	59	70
3	56	M	53	65
4	52	M	54	70
5	45	M	43	53
6	49	F	43	59
7	52	F	38	53
8	56	M	59	64
9	62	M	59	76
10	57	F	70	70
11	55	M	53	70
12	49	M	59	70
13	47	M	53	64
14	53	F	59	70
15	55	F	59	70

MOTRICITY INDEX SCORE : CONTROL GROUP

S.NO	AGE	SEX	PRE	POST
1	55	M	53	70
2	49	M	64	76
3	47	M	53	70
4	62	M	58	76
5	57	F	59	70
6	55	M	59	70
7	49	M	53	64
8	49	F	70	76
9	47	M	53	64
10	53	F	64	70
11	55	M	58	76
12	49	M	58	70
13	47	F	53	70
14	53	F	58	76
15	55	M	70	76

MEFAP: EXPERIMENTAL GROUP

S.NO	AGE	SEX	PRE	POST
1	48	M	537.76	241.73
2	45	M	517.22	267.73
3	56	M	512.3	300.35
4	52	M	567.33	202.13
5	45	M	525.42	253.08
6	49	F	479.24	304.22
7	52	F	545.3	287.52
8	56	M	532.21	295.97
9	62	M	554.21	265.52
10	57	F	578.15	197.22
11	55	M	526.22	304.25
12	49	M	552.55	260.57
13	47	M	539.48	297.53
14	53	F	534.48	234.4
15	55	F	539	204.15

MEFAP: CONTROL GROUP

S.NO	AGE	SEX	PRE	POST
1	55	M	517.72	231.73
2	49	M	547.28	277.73
3	47	M	532.3	320.35
4	62	M	547.35	242.13
5	57	F	575.42	213.08
6	55	M	419.24	334.22
7	49	M	525.36	297.52
8	49	F	562.21	255.97
9	47	M	524.29	285.52
10	53	F	558.17	197.22
11	55	M	546.23	314.25
12	49	M	582.55	280.57
13	47	F	519.48	297.53
14	53	F	524.48	254.4
15	55	M	535.54	214.15

APPENDIX II

Table: MRC Grading & Motricity.

MRC Grade	MRC Score	Points for Pinch Grip	Points for Other Tests
no movement	0	0	0
palpable flicker but no movement	1	11	9
movement but not against gravity	2	19	14
movement against gravity	3	22	19
movement against resistance	4	26	25
normal	5	33	33

Arm score for each side = SUM (points for the 3 arm tests) + 1 Leg score for each side = SUM (points for the 3 leg tests) + 1

Side score for each side = ((arm score for side) + (leg score for side)) / 2

Interpretation: • Minimum score: 0

- Maximum score:

MEFAP Data Sheet						
Time, s Time, s	Floor	Carpet	Up & Go	Obstacles	Stairs	Total
Initial						
Final						
AD/Orthotic (I/F)						
AFO						
KAFO						
Straight cane						
NBQC						
LBQC						
Hemiwalker						
Walker						
Assistance (I/F)						
Independent						
Modified independent						
Supervision						
Contact guard						
Minimal assist						
Moderate assist						

I indicates initial; F, final; AFO, ankle-foot orthotic; KAFO, knee-ankle-foot orthotic; NBQC, Narrow-based quad cane; LBQC, large-based quad cane; Independent, completely independent; Modified independent, requires extra time or devices; Supervision, requires cueing or prompting; Contact guard, requires close contact support; Minimal assist, performs at least 75% of task; and Moderate assist,

APPENDIX IV

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