Research protocol (Human subject study)

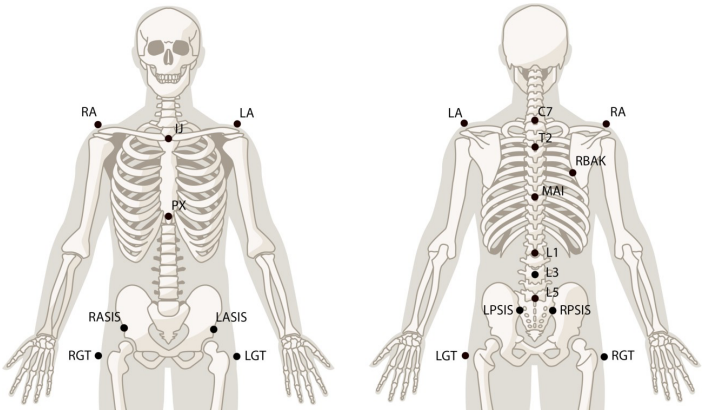
Research project title

The Effects of Reaching Task Following Selective Trunk Stability Exercise in Chronic Stroke Survivors

Methodology and Design

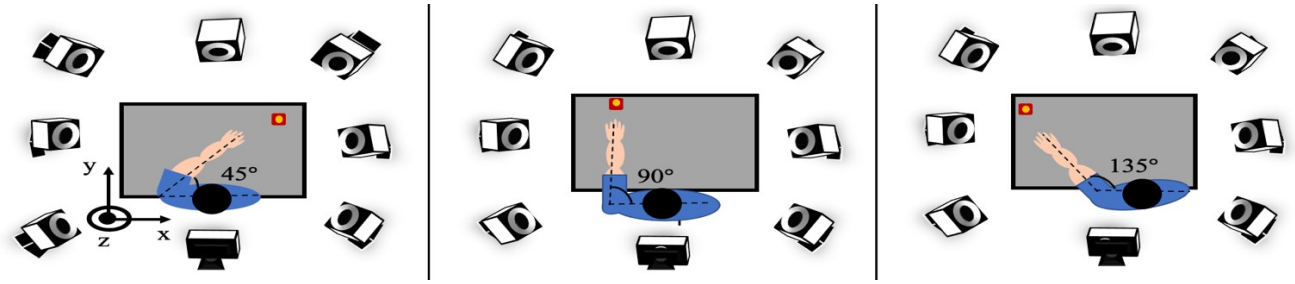
- This study used a two-period crossover design to compare the effectiveness of Abdominal Drawing-In Maneuver (ADIM) exercise and TENS for individual with chronic stroke.
- Stroke was diagnosed based on the following criteria: physician-confirmed chronic hemiplegia (≥ 6 months onset), Mini-mental State Examination score ≥ 25, ability to sit on a chair independently, and < 60 Fugl-Meyer Assessment (FMA) in the upper extremities.
- The exclusion criteria were muscle flaccidity, neglect syndrome, orthopaedic diseases, and poor coordination.

* The specific placement of markers



- Sternum, xyphoid process, Both acromion, C7, T4, elbow(lateral and medial epicondyle), wrist (lateral and medial styloid process), finger 3rd MCP

The seated reaching task posture is as follows:



- The participant attempts to reach the target using the affected upper limb
- The seated height is adjusted to 100% of the participant's lower limb length, with the feet flat on the floor and the knees bent at a 90 degree angle. A chair with adjustable height is used to achieve this.
- Reaching movements are categorized into three directions: forward, ipsilateral and contralateral direction.
- The task is performed five times in a comfortable speed for each direction, and for analysis purposes, three out of the five trials are selected to calculate the average time.

1. Clinical assessment

1-1. Fugl-Meyer motor Assessment of the Lower Extremity (FMA-UE) Assessment of sensorimotor function:

A. UPPER EXTREMITY, sitting position					
I. Reflex activity			**none**	**can be elicited**	
Flexors: biceps and finger flexors (at least one) **Extensors**: triceps			0 0	2 2	
Subtotal I (max 4)					
II. Volitional movement within synergies, without gravitational help			**none**	**partial**	**full**
Flexor synergy: Hand from contralateral knee to ipsilateral ear. From extensor synergy (shoulder adduction/ internal rotation, elbow extension, forearm pronation) to flexor synergy (shoulder abduction/ external rotation, elbow flexion, forearm supination). **Extensor synergy:** Hand from ipsilateral ear to the contralateral knee	Shoulder Elbow Forearm	retraction elevation abduction (90°) external rotation flexion supination	0 0 0 0 0 0	1 1 1 1 1 1	2 2 2 2 2 2
	Shoulder Elbow Forearm	adduction/internal rotation extension pronation	0 0 0	1 1 1	2 2 2
Subtotal II (max 18)					
III. Volitional movement mixing synergies, without compensation			**none**	**partial**	**full**
Hand to lumbar spine hand on lap	cannot perform or hand in front of ant-sup iliac spine hand behind ant-sup iliac spine (without compensation) hand to lumbar spine (without compensation)		0	1	2
Shoulder flexion 0°- 90° elbow at 0° pronation-supination 0°	immediate abduction or elbow flexion abduction or elbow flexion during movement flexion 90°, no shoulder abduction or elbow flexion		0	1	2
Pronation-supination elbow at 90° shoulder at 0°	no pronation/supination, starting position impossible limited pronation/supination, maintains starting position full pronation/supination, maintains starting position		0	1	2
Subtotal III (max 6)					
IV. Volitional movement with little or no synergy			**none**	**partial**	**full**
Shoulder abduction 0 - 90° elbow at 0° forearm neutral	immediate supination or elbow flexion supination or elbow flexion during movement abduction 90°, maintains extension and pronation		0	1	2
Shoulder flexion 90° - 180° elbow at 0° pronation-supination 0°	immediate abduction or elbow flexion abduction or elbow flexion during movement flexion 180°, no shoulder abduction or elbow flexion		0	1	2
Pronation/supination elbow at 0° shoulder at 30°- 90° flexion	no pronation/supination, starting position impossible limited pronation/supination, maintains start position full pronation/supination, maintains starting position		0	1	2
Subtotal IV (max 6)					
V. Normal reflex activity assessed only if full score of 6 points is achieved in part IV; compare with the unaffected side			**hyper**	**lively**	**normal**
Biceps, triceps, finger flexors	2 of 3 reflexes markedly hyperactive 1 reflex markedly hyperactive or at least 2 reflexes lively maximum of 1 reflex lively, none hyperactive		0	1	2
Subtotal V (max 2)					
Total A (max 36)					

B. WRIST support may be provided at the elbow to take or hold the starting position, no support at wrist, check the passive range of motion prior testing		**none**	**partial**	**full**
Stability at 15° dorsiflexion elbow at 90°, forearm pronated shoulder at 0°	less than 15° active dorsiflexion dorsiflexion 15°, no resistance tolerated maintains dorsiflexion against resistance	0	1	2
Repeated dorsifexion / volar flexion elbow at 90°, forearm pronated shoulder at 0°, slight finger flexion	cannot perform volitionally limited active range of motion full active range of motion, smoothly	0	1	2
Stability at 15° dorsiflexion elbow at 0°, forearm pronated slight shoulder flexion/abduction	less than 15° active dorsiflexion dorsiflexion 15°, no resistance tolerated maintains dorsiflexion against resistance	0	1	2
Repeated dorsifexion / volar flexion elbow at 0°, forearm pronated slight shoulder flexion/abduction	cannot perform volitionally limited active range of motion full active range of motion, smoothly	0	1	2
Circumduction elbow at 90°, forearm pronated shoulder at 0°	cannot perform volitionally jerky movement or incomplete complete and smooth circumduction	0	1	2
	Total B (max 10)			

C. HAND support may be provided at the elbow to keep 90° flexion, no support at the wrist, compare with unaffected hand, the objects are interposed, active grasp		**none**	**partial**	**full**
Mass flexion from full active or passive extension		0	1	2
Mass extension from full active or passive flexion		0	1	2
GRASP				
a. Hook grasp flexion in PIP and DIP (digits II-V), extension in MCP II-V	cannot be performed can hold position but weak maintains position against resistance	0	1	2
b. Thumb adduction 1-st CMC, MCP, IP at 0°, scrap of paper between thumb and 2-nd MCP joint	cannot be performed can hold paper but not against tug can hold paper against a tug	0	1	2
c. Pincer grasp, opposition pulpa of the thumb against the pulpa of 2-nd finger, pencil, tug upward	cannot be performed can hold pencil but not against tug can hold pencil against a tug	0	1	2
d. Cylinder grasp cylinder shaped object (small can) tug upward, opposition of thumb and fingers	cannot be performed can hold cylinder but not against tug can hold cylinder against a tug	0	1	2
e. Spherical grasp fingers in abduction/flexion, thumb opposed, tennis ball, tug away	cannot be performed can hold ball but not against tug can hold ball against a tug	0	1	2
	Total C (max 14)			

D. COORDINATION/SPEED, sitting, after one trial with both arms, eyes closed, tip of the index finger from knee to nose, 5 times as fast as possible		**marked**	**slight**	**none**
Tremor		0	1	2
Dysmetria	pronounced or unsystematic slight and systematic no dysmetria	0	1	2
		≥ 6s	**2 - 5s**	**< 2s**
Time start and end with the hand on the knee	6 or more seconds slower than unaffected side 2-5 seconds slower than unaffected side less than 2 seconds difference	0	1	2
	Total D (max 6)			

1-2 TIS

Item			
	Static sitting balance		
1	Starting position	Patient falls or cannot maintain starting position for 10 seconds without arm support	☐ 0
		Patient can maintain starting position for 10 seconds	☐ 2
		If score = 0, then TIS total score = 0	
2	Starting position Therapist crosses the unaffected leg over the hemiplegic leg	Patient falls or cannot maintain sitting position for 10 seconds without arm support	☐ 0
		Patient can maintain sitting position for 10 seconds	☐ 2
3	Starting position Patient crosses the unaffected leg over the hemiplegic leg	Patient falls	☐ 0
		Patient cannot cross the legs without arm support on bed or table	☐ 1
		Patient crosses the legs but displaces the trunk more than 10 cm backwards or assists crossing with the hand	☐ 2
		Patient crosses the legs without trunk displacement or assistance	☐ 3
		Total static sitting balance	/7
	Dynamic sitting balance		
1	Starting position Patient is instructed to touch the bed or table with the hemiplegic elbow (by shortening the hemiplegic side and lengthening the unaffected side) and return to the starting position	Patient falls, needs support from an upper extremity or the elbow does not touch the bed or table	☐ 0
		Patient moves actively without help, elbow touches bed or table	☐ 1
		If score = 0, then items 2 and 3 score 0	
2	Repeat item 1	Patient demonstrates no or opposite shortening/lengthening	☐ 0
		Patient demonstrates appropriate shortening/lengthening	☐ 1
		If score = 0, then item 3 scores 0	
3	Repeat item 1	Patient compensates. Possible compensations are: (1) use of upper extremity, (2) contralateral hip abduction, (3) hip flexion (if elbow touches bed or table further then proximal half of femur), (4) knee flexion, (5) sliding of the feet	☐ 0
		Patient moves without compensation	☐ 1
4	Starting position Patient is instructed to touch the bed or table with the unaffected elbow (by shortening the unaffected side and lengthening the hemiplegic side) and return to the starting position	Patient falls, needs support from an upper extremity or the elbow does not touch the bed or table	☐ 0
		Patient moves actively without help, elbow touches bed or table	☐ 1
		If score = 0, then items 5 and 6 score 0	
5	Repeat item 4	Patient demonstrates no or opposite shortening/lengthening	☐ 0
		Patient demonstrates appropriate shortening/lengthening	☐ 1
		If score = 0, then item 6 scores 0	

Item			
6	Repeat item 4	Patient compensates. Possible compensations are: (1) use of upper extremity, (2) contralateral hip abduction, (3) hip flexion (if elbow touches bed or table further then proximal half of femur), (4) knee flexion, (5) sliding of the feet	☐ 0
		Patient moves without compensation	☐ 1
7	Starting position Patient is instructed to lift pelvis from bed or table at the hemiplegic side (by shortening the hemiplegic side and lengthening the unaffected side) and return to the starting position	Patient demonstrates no or opposite shortening/lengthening	☐ 0
		Patient demonstrates appropriate shortening/lengthening If score = 0, then item 8 scores 0	☐ 1
8	Repeat item 7	Patient compensates. Possible compensations are: (1) use of upper extremity, (2) pushing off with the ipsilateral foot (heel loses contact with the floor)	☐ 0
		Patient moves without compensation	☐ 1
9	Starting position Patient is instructed to lift pelvis from bed or table at the unaffected side (by shortening the unaffected side and lengthening the hemiplegic side) and return to the starting position	Patient demonstrates no or opposite shortening/lengthening	☐ 0
		Patient demonstrates appropriate shortening/lengthening If score = 0, then item 10 scores 0	☐ 1
10	Repeat item 9	Patient compensates. Possible compensations are: (1) use of upper extremities, (2) pushing off with the ipsilateral foot (heel loses contact with the floor)	☐ 0
		Patient moves without compensation	☐ 1
		Total dynamic sitting balance	/10
	Co-ordination		
1	Starting position Patient is instructed to rotate upper trunk 6 times (every shoulder should be moved forward 3 times), first side that moves must be hemiplegic side, head should be fixated in starting position	Hemiplegic side is not moved three times	☐ 0
		Rotation is asymmetrical	☐ 1
		Rotation is symmetrical If score = 0, then item 2 scores 0	☐ 2
2	Repeat item 1 within 6 seconds	Rotation is asymmetrical	☐ 0
		Rotation is symmetrical	☐ 1
3	Starting position Patient is instructed to rotate lower trunk 6 times (every knee should be moved forward 3 times), first side that moves must be hemiplegic side, upper trunk should be fixated in starting position	Hemiplegic side is not moved three times	☐ 0
		Rotation is asymmetrical	☐ 1
		Rotation is symmetrical If score = 0, then item 4 scores 0	☐ 2
4	Repeat item 3 within 6 seconds	Rotation is asymmetrical	☐ 0
		Rotation is symmetrical	☐ 1
		Total co-ordination	/6
		Total Trunk Impairment Scale	/23

1-3 PASS

Maintaining a Posture

Give the subject instructions for each item as written below. When scoring the item, record the lowest response category that applies for each item.

1. Sitting Without Support

Examiner: Have the subject sit on a bench/mat without back support and with feet flat on the floor.

____(3) Can sit for 5 minutes without support
____(2) Can sit for more than 10 seconds without support
____(1) Can sit with slight support (for example, by 1 hand)
____(0) Cannot sit

2. Standing With Support

Examiner: Have the subject stand, providing support as needed. Evaluate only the ability to stand with or without support. Do not consider the quality of the stance.

____(3) Can stand with support of only 1 hand
____(2) Can stand with moderate support of 1 person
____(1) Can stand with strong support of 2 people
____(0) Cannot stand, even with support

3. Standing Without Support

Examiner: Have the subject stand without support. Evaluate only the ability to stand with or without support. Do not consider the quality of the stance.

____(3) Can stand without support for more than 1 minute and simultaneously perform arm movements at about shoulder level
____(2) Can stand without support for 1 minute or stands slightly asymmetrically
____(1) Can stand without support for 10 seconds or leans heavily on 1 leg
____(0) Cannot stand without support

4. Standing on Nonparetic Leg

Examiner: Have the subject stand on the nonparetic leg. Evaluate only the ability to bear weight entirely on the nonparetic leg. Do not consider how the subject accomplishes the task.

____(3) Can stand on nonparetic leg for more than 10 seconds
____(2) Can stand on nonparetic leg for more than 5 seconds
____(1) Can stand on nonparetic leg for a few seconds
____(0) Cannot stand on nonparetic leg

5. Standing on Paretic Leg

Examiner: Have the subject stand on the paretic leg. Evaluate only the ability to bear weight entirely on the paretic leg. Do not consider how the subject accomplishes the task.

____(3) Can stand on paretic leg for more than 10 seconds
____(2) Can stand on paretic leg for more than 5 seconds
____(1) Can stand on paretic leg for a few seconds
____(0) Cannot stand on paretic leg

Maintaining Posture SUBTOTAL _____

2. Intervention

2.1 ADIM exercise

The objective of this study is to enhance the strength of the deep core muscles, specifically the Transverse abdominis (TrA) muscle by using a simple device that observes pressure changes with a gauge. ADIM exercise is a functional and requiring precise motor control to engage the relevant muscle with the appropriate level of intensity for targeted muscle control. Pull the navel deeply to the lumbar region using the Stabilizer^{TM} pressure Biofeedback, which stabilizes the TrA muscle (S.-D. Park & Yu, 2013). Participants receive ADIM exercise twice a week for four weeks. Participants were asked to Move from supine to hook-lying (hip joint_ 40°; knee joint_ 80°) (S.-D. Park & Yu, 2013; Yu & Park, 2013). They focus on controlled contractions, gentle breathing, and avoid pelvic and chest movement during the exercise. Each exercise session lasts for 40 minutes, with an additional 10 minutes dedicated to trunk stretching and mobilization exercises for the upper extremities (Ko et al., 2016). Over a 4-week period, participants engaged in an exercise regimen that gradually increased the contraction of the TrA muscle to 40 mmHg, with a limited maximum increased of an additional 2 mmHg (D.-J. Park & Lee, 2013). The exercise involved 10 repetitions per set, with each contraction lasting 5 seconds. This routine was repeated for a total of 10 sets.

2.2 Transcutaneous Electrical Nerve Stimulation (TENS)

The intervention encompassed a range of pain relief techniques, including limb stretching, mobilization of the upper extremity, and targeted pelvic movements. To manage pain, a TENS (EMGFES 1000, Cyber medic, South Korea) was applied to the affected area for a duration of 20 minutes. Additionally, participants engaged in a series of movements while in a supine position, involving trunk rotations to each lateral side, each held for 5 seconds, as well as anterior and posterior pelvic movements with knees flexed at 90 degrees. This regimen comprised 10 repetitions per set, totaling 5 sets. Participants attended two sessions per week over a 4-week period, with each session lasting 40 minutes under the guidance of the same experienced physical therapist. For control of pain, the instrument was applied to pain area with TENS in 20 minutes to upper extremity pain area. And in supine position, trunk movement rotation each lateral side with holding on 5 seconds and pelvic anterior and posterior with knee 90 flexion. The intensity consisted of 10 repetitions per set in total 5 sets. They had two 40-minute sessions per week for 4 weeks. This therapy is guided by a physical therapist with over 10 years of experience.

Safety evaluation criteria and evaluation methods

Before starting the experiments, the health and physical condition of the subjects are assessed, and within 24 hours after the experiment, and signs of physical abnormalities are monitored.

Data analysis and statistical methods

To determine the sample size, the G * Power V.3.1 was utilized (Franz Paul, Kiel, Germany) (Faul F et al., 2007) incorporating an effect size of 0.44, $\alpha < 0.05$, power = 0.80, requiring total sample size of 12 participants (Dos Santos et al., 2019).

1. Statistical analysis was performed with IBM SPSS (version 28.0.1.1 (14)). Data were tested for normality using the Kolmogorov-Smirnov test. Kinematic data did not significantly deviate from a normal
2. distribution ($P > 0.05$). The Chi-square test was used to assess the sex distribution of the participants. The independent *t*-test and Mann-Whitney *U* test, as a nonparametric test, were employed to compare the two groups concerning specific demographic and clinical characteristics.

In the event of an unforeseen emergency, the participant's condition will be assessed, and immediate contact

Predicted side effects and precautions with corresponding measures

will be made with emergency medical personnel for necessary actions. Subsequently, a prompt report will be submitted to the Institutional Review Board (IRB)

Criteria for discontinuation and dropout

1. Inability to independently perform the action of sitting and extending the paralyzed arm
2. Feeling of dizziness

Risks and benefits to research participants

- Prior to the start of the experiment, participants will receive a comprehensive explanation of the entire experimental procedure and the potential risks involved through an informed consent document. They will proceed with the experiment after understanding and acknowledging these risks.

- In the event of an emergency during the experiment, participants will be provided with non-monetary measures to seek medical examination and treatment from a qualified healthcare institution, even after the conclusion of the experiment.

References

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