Efficacy Study of the LARA Wheelchair System for Subacute Stroke Patients

NCT 02830893

Standard Operating Procedures

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Background

We will recruit 44 individuals with an acute or subacute stroke (3 days to 30 days post stroke) to participate in this randomized controlled trial at UCI ARU and Rancho Los Amigos National Rehabilitation Center. These individuals will have an acute or subacute stroke with arm/ hand weakness defined as a score of less than 50 (out of 66) on the arm motor scale of the Fugl-Meyer Assessment.

Inclusion Criteria:

1. History of stroke affecting the arm, at least 3 days to 30 days prior to enrollment
2. Age 18 to 80 years of age
3. Upper extremity weakness, defined as a score of less than 50 (out of 66) on the arm motor scale of the Fugl-Meyer Assessment

Exclusion Criteria:

1. Moderate to severe pain in the stroke-affected upper extremity (score >6 on 10-point visual analog pain scale), at rest or increased when attempting to use LARA
2. Severe tone at the affected upper extremity (score >4 on the Ashworth Spasticity Scale)
3. Severe aphasia (score of 2 or higher on the NIH stroke scale – question 9)
4. Deficits in vision, language, attention, or other cognitive functions severe enough to interfere with using LARA
5. Currently pregnant
6. Difficulty in understanding or complying with instructions given by the experimenter
7. Inability to perform the experimental task that will be studied

Methods:

The primary outcome measure will be the Upper Extremity Fugl-Meyer Score to assess motor impairment in the affected arm. Secondary outcome measures will be Box and Blocks Test, Modified Ashworth Scale of Spasticity to measure spasticity of the shoulder, elbow, wrist and hand, Visual Analog Pain scale to assess pain, NIH Stroke Scale, mini mental state exam to assess cognitive function and the Borg scale to access their perceived exertion levels. We will perform testing at three separate evaluations: At the initial baseline visit, 3-weeks post therapy or the day before discharge if sooner, and 3-month follow up. The end point of the study will be the 3-month after baseline evaluation.

After the baseline evaluation, all participants will be randomized into 2 groups: LARA group versus conventional hand and arm exercise program. Randomization will be done through a web-based program.

For LARA group: participants will be fitted for a LARA chair, they will receive a demonstration by a research therapist and be instructed on how to get in/out of the LARA chair, how to propel LARA in a straight line, turns, figure 8 if possible. Participants will also receive training on how to perform arm exercises using a video gaming program. Participants will receive 2 sessions lasting 30 mins each for these training exercises. Participants will begin his/her exercise routine starting the third session. A research therapist will be available to assist but study participants are expected to perform exercise routines by themselves as much as possible. The research therapist will record and keep a log of time spent assisting study participants every day.

If supervising therapists believe LARA participants are skilled enough to drive LARA, participants will begin using LARA to go to therapy appointments and move around ARU by themselves throughout the study.

For control group: participants will receive a demonstration by a research therapist and instructions on how to perform arm/hand exercise programs using towel and table. Towels, tables and an exercise log will be provided. Participants will receive 2 sessions lasting 30 minutes for each training. Participants will begin his/her exercise routine starting the third session. A research therapist will be available to assist but study participants are expected to perform exercise routines by themselves as much as possible. The research therapist will record and keep a log of time spent assisting study participants every day.

Study participants will be compensated with a cash stipend of $100 for each evaluation. Study participants will receive a maximum total of $300 from the study.

Time Line of the Study

Visit #	Week	Evaluation Session #	Evaluation content	Exercise session #	Training Content (order to be randomized)
1	1		Screen		
2	1	1	All clinical outcomes		
3	1			1	A: LARA or B: Tabletop exercise program
4	1			2	A: LARA or B: Tabletop exercise program
5	1			3	A: LARA or B: Tabletop exercise program
6	1			4	A: LARA or B: Tabletop exercise program
7	1			5	A: LARA or B: Tabletop exercise program
8	2			6	A: LARA or B: Tabletop exercise program
9	2			7	A: LARA or B: Tabletop exercise program
10	2			8	A: LARA or B: Tabletop exercise program
11	2			9	A: LARA or B: Tabletop exercise program
12	2			10	A: LARA or B: Tabletop exercise program
13	3			11	A: LARA or B: Tabletop exercise program
14	3			12	A: LARA or B: Tabletop exercise program
15	3			13	A: LARA or B: Tabletop exercise program
16	3			14	A: LARA or B: Tabletop exercise program
17	3			15	A: LARA or B: Tabletop exercise program
18	3	2	All clinical outcomes		
19	13	3	All clinical outcomes: Follow-up		

Table of Clinical Testing

	Screen	Evaluation #1 (Baseline)	Evaluation #2 (Post therapy)	Evaluation #3 (3-month follow up)
Consent Form	X			
HIPAA wavier form	X			
Photography consent	X			
Medical History/ Health Status Questionnaire/ Rehab History overall	X			
NIHSS	X	X	X	X
Box and Blocks Test		X	X	X
Mini Mental State Exam		X	X	X
Modified Rankin Scale		X	X	X
Motor sections of Fugl-Meyer	X	X	X	X
Action Research Arm Test		X	X	X
Motor Activity Log		X	X	X
10-meter walk		X	X	X
Grip Strength		X	X	X
AROM & PROM at shoulder and elbow		X	X	X
Geriatric Depression Scale		X	X	X
Modified Ashworth Scale of Spasticity (Shoulder, Elbow, Wrist, Finger)	X	X	X	X
Visual Analog of Pain Scale	X	X	X	X
IMI	X	X	X	X
Stipend	X	X	X	X

List of Clinical Tests

1. Upper Extremity Fugl-Meyer Motor Score – study primary outcome measure
2. Box and Blocks Test
3. Motor Activity Log
4. Action Research Arm Test
5. Active and passive range of motion at the shoulder and elbow
6. Modified Ashworth Spasticity Scale
7. Visual Analog Pain Scale
8. 10-meter walk test
9. NIH stroke scale
10. Mini-Mental State Examination
11. Geriatric Depression Scale
12. Modified Rankin Scale Score
13. Grip Strength

Total Score _____/66
Proximal _____/36
Wrist/Hand _____/24
Coordination/Speed _____/6

Affected side (R or L) ____

Subject ID _____
Date _____
Visit # _____

FUGL-MEYER ARM MOTOR ASSESSMENT

Remember to score best, not first, patient performance

Proximal

I Reflexes

1. Biceps or finger flexor reflex	☐ 0 [no reflex]	☐ 2 [reflex elicitable]
2. Triceps reflex	☐ 0 [no reflex]	☐ 2 [reflex elicitable]

II Flexor Synergy

Seated patient is instructed to voluntarily bring affected forearm fully supinated to ear of the affected side, elbow fully flexed, shoulder abducted 90°/externally rotated/retracted/elevated.

3. Shoulder girdle retraction	☐ 0 [not done at all]	☐ 1 [partly done]	☐ 2 [faultless]
4. Shoulder girdle elevation	☐ 0 [not done at all]	☐ 1 [partly done]	☐ 2 [faultless]
5. Shoulder abduction	☐ 0 [not done at all]	☐ 1 [partly done]	☐ 2 [faultless]
6. Shoulder external rotation	☐ 0 [not done at all]	☐ 1 [partly done]	☐ 2 [faultless]
7. Elbow flexion	☐ 0 [not done at all]	☐ 1 [partly done]	☐ 2 [faultless]
8. Forearm supination	☐ 0 [not done at all]	☐ 1 [partly done]	☐ 2 [faultless]

III Extensor Synergy

Starting with full flexor synergy position (passively placed, if necessary), seated patient is instructed to adduct/ internally rotate shoulder & extend elbow towards opposite knee, forearm pronated.
Can support elbow to avoid passive movement due to gravity.

9. Shoulder adduction/ internal rotation	☐ 0 [not done at all]	☐ 1 [partly done]	☐ 2 [faultless]
10. Elbow extension	☐ 0 [not done at all]	☐ 1 [partly done]	☐ 2 [faultless]
11. Forearm pronation	☐ 0 [not done at all]	☐ 1 [partly done]	☐ 2 [faultless]

Subject ID _____
Date _____
Visit # _____

IV Movement Combining Synergies

Seated patient is instructed to perform 3 separate actions:

12. Actively position affected hand on the lumbar spine.

☐ 0 [not done at all] ☐ 1 [actively passes the anterior superior iliac spine] ☐ 2 [faultless]

13. Pure shoulder flexion, 0-90°, elbow fully extended throughout. forearm in midposition between supination/ pronation.

☐ 0 [not done at all or at start of motion, shoulder abduction or elbow flexion occurs] ☐ 1 [partly done or shoulder abduction or elbow flexion occurs during motion] ☐ 2 [faultless]

14. Pronation/supination of forearm, elbow actively flexed ≈90°, shoulder at 0°

☐ 0 [not done at all or shoulder & elbow can't achieve proper position] ☐ 1 [any pronation or supination in correct position] ☐ 2 [faultless]

V Movement Out of Synergy

Seated patient is instructed to perform 3 separate actions:

15. Abduct shoulder to 90° (pure abduction), elbow fully extended throughout, forearm pronated.

☐ 0 [not done at all or at start of motion, elbow flexion or supination occurs] ☐ 1 [partly done or elbow flexion or forearm supination occurs during motion] ☐ 2 [faultless]

16. Pure shoulder flexion, 90°-180°, elbow fully extended throughout, forearm midposition between supination/ pronation.

☐ 0 [not done at all or at start of motion, shoulder abduction or elbow flexion occurs] ☐ 1 [partly done or shoulder abduction or elbow flexion occurs during motion] ☐ 2 [faultless]

17. Pronate/supinate forearm, elbow kept fully extended, shoulder kept between 30° - 90° flexion

☐ 0 [not done at all or shoulder & elbow can't get to proper position] ☐ 1 [any pronation or supination in correct position ☐ 2 [faultless]

VI Normal Reflex Activity

18. If above 3 tests, Questions 15-17, are faultless, evaluate biceps, triceps and finger flexor deep tendon reflexes as below. Otherwise do not complete this deep tendon reflex test and record a score of 0.

☐ 0 [≥2 deep tendon reflex's are markedly hyperactive] ☐ 1 [1 deep tendon reflex markedly hyperactive or >2 deep tendon reflex lively] ☐ 2 [all 3 reflexes present, none hyperactive]

PROXIMAL SUBSCORE TOTAL _____

Subject ID _____
Date _____
Visit # _____

Wrist/Hand

VII Wrist

Seated patient is instructed to perform the following tasks with shoulder in 0°, elbow 90°, forearm pronated; can assist patient to achieve this position.

19. Dorsiflex wrist

☐ 0 [can't dorsiflex wrist to 15°]
☐ 1 [can dorsiflex but not against resistance, or elbow flexes/ forearm supinates during resistance]
☐ 2 [can dorsiflex against slight resistance]

20. Now repeat alternate wrist movement, dorsiflex/volarflex, with fingers somewhat flexed

☐ 0 [no volitional movements]
☐ 1 [active range of motion is less than passive range of motion]
☐ 2 [faultless & smooth]

Seated patient is instructed to perform the following tasks with shoulder somewhat flexed and/or abducted, elbow extended to 0, forearm pronated. Can assist patient to achieve this position.

21. Dorsiflex wrist

☐ 0 [can't dorsiflex wrist to 15°]
☐ 1 [can dorsiflex but not against resistance, or elbow flexes/ forearm supinates during resistance]
☐ 2 [can dorsiflex against slight resistance]

22. Now repeat alternate wrist movement, dorsiflex/volarflex, with fingers somewhat flexed

☐ 0 [no volitional movements]
☐ 1 [active range of motion is less than passive range of motion, or elbow flexes during motion]
☐ 2 [faultless & smooth]

23. Circumduct wrist

☐ 0 [can't do]
☐ 1 [jerky or incomplete circumduction]
☐ 2 [faultless]

Subject ID _____
Date _____
Visit # _____

VIII Hand

Patient is instructed to perform the following tasks with elbow at 90° (support elbow if necessary, but don't support wrist).

24. Flex (all) fingers

☐ 0 [no flexion] ☐ 1 [some but not full active flexion] ☐ 2 [full as compared with unaffected side]

25. Extend all fingers, starting from position of active (passive if necessary) full flexion

☐ 0 [no extension] ☐ 1 [partial or can release active mass flexion grasp] ☐ 2 [full active extension]

26. Grasp while extending metacarpophalangeal joints II-V and flexing proximal and distal interphalangeal joints

☐ 0 [can not reach posistion] ☐ 1 [weak grasp] ☐ 2 [grasp maintained against great resistance]

27. Grasp 1 sheet of paper with pure thumb adduction (requires full extension of carpometacarpal, all metacarpalphalangeal and interphalangeal joints in all fingers)

☐ 0 [can not do this] ☐ 1 [paper kept in place between thumb and 2nd MC, but not against a slight tug] ☐ 2 [paper held well against a tug]

28. Oppose thumb pad against pad of index finger with a pencil interposed

☐ 0 [can not do this] ☐ 1 [pencil kept in place between thumb pad and index finger, but not against a slight tug] ☐ 2 [pencil held well against a tug]

29. Grasp cylinder-shaped object, eg small can, with volar surface of thumb and index finger wrapped around can

☐ 0 [can not do this] ☐ 1 [cylinder/can kept in place between thumb and index finger, but not against a slight tug] ☐ 2 [cylinder/can held well against a tug]

30. Grasp a tennis ball with all 5 fingers

☐ 0 [can not do this] ☐ 1 [ball kept in place between all fingers, but not against a slight tug] ☐ 2 [ball held well against a tug]

WRIST/HAND SUBSCORE TOTAL _____

Subject ID _____
Date _____
Visit # _____

IX Coordination/Speed

While patient is blind-folded, place tip of index finger from knee to nose, 5 times, in as rapid a succession as possible.

31. Tremor:

☐ 0 [marked tremor] ☐ 1 [slight tremor] ☐ 2 [no tremor]

32. Dysmetria:

☐ 0 [pronounced or unsystematic dysmetria] ☐ 1 [slight or systematic dysmetria] ☐ 2 [no dysmetria]

33. Speed:

☐ 0 [affected hand is 6 or more seconds slower than the unaffected hand] ☐ 1 [affected hand is 2-5 seconds slower than the unaffected hand] ☐ 2 [less than 2 seconds difference between the affected and unaffected hands]

COORDINATION/SPEED SUBSCORE TOTAL_____

Subject ID: _____

Date: _____

Exam#: _____

Box & Blocks

Right	Left

Box and Blocks Test

- Open test box and place the divider between the two compartments
- Position the box lengthwise along the edge of a standard height table with compartment with cubes on same side as the subject's dominant hand
- Seat the subject in a standard height chair facing the box
- The examiner sits facing the subject to view blocks being transported and note discrepancies in technique
- ***"I want to see how quickly you can pick up one block at a time with your right/left hand (point to hand), carry it to the other side of the box and drop it. Make sure your fingertips cross the partition. Watch me while I show you how."***
- Examiner transports three cubes over partition
- ***"If you pick up two blocks at a time, they will count as one. If you drop one on the floor or table after you have carried it across, it will still be counted, so do not waste time picking it up. If you toss the blocks without your fingers crossing the partition, they will not be counted. Before you start, you will have a chance to practice for 15 seconds. Do you have any questions? Place your hands on the sides of the box. When it is time to start, I will say 'READY' and then 'GO.'"***
- Perform a 15 second practice. If mistakes are made, correct them.
- ***"This will be the actual test. The instructions are the same. Work as quickly as you can. READY… (wait 3 seconds) GO."***
- After one-minute STOP
- Count the number of blocks transported and record. Subtract blocks transported more than one at a time or if the fingertips did not cross over
- Turn the box so all the blocks are on the same side as the next hand to be tested
- ***"Now you are to do the same thing with your left hand. First you can practice. Put your hands on the sides of the box as before. Pick up one block at a time with your hand and drop it on the other side of the box. READY… (wait 3 seconds) GO."***

MOTOR ACTIVITY LOG

Task	Use?	AS	HW	If no, why?
1. Turn on light switch				
2. Open drawer				
3. Remove clothing from drawer				
4. Pick up phone				
5. Wipe off counter				
6. Get out of car				
7. Open refrigerator				
8. Open door with doorknob				
9. Use TV remote				
10. Wash your hands				
11. Turn on/off water faucet				
12. Dry your hands				
13. Put on socks				
14. Take off socks				
15. Put on shoes				
16. Take off shoes				
17. Get up from chair with armrests				
18. Pull chair away from table				
19. Pull chair towards table				
20. Pick up glass/bottle/cup/can				
21. Brush your teeth				
22. Put makeup/lotion/cream on face				
23. Use key to unlock door				
24. Write on paper				
25. Carry object in hand				
26. Use fork or spoon				
27. Comb your hair				
28. Pick up cup by handle				
29. Button a shirt				
30. Eat half sandwich or finger food				
MEAN SCORE				

1. Did you perform this activity during the past week? Yes or No (if yes, continue)
2. How much did your affected arm participate in this activity (AOU-Amount of Use)?
   0 (Never/ Not at All) 5 (Always During/All the Time)
3. How well did your affected arm help during this activity? (QOM – Quality of Movement)
4. 0 (Inability to use the affected arm for this activity)
   5 (Ability to use the affected arm just as well as before the stroke)

Subject ID: _____

Date: _____

Exam #: _____

Subject ID_____

Date_____

ACTION RESEARCH ARM TEST

Grasp subscale	***Left***	***Right***
Grasp and lift blocks, a cricket ball and a sharpening		
stone from one shelf of a table to another (lift over 37 cm)		
1. Block, 10 cm (*if score=3, total=18 and goto grip subscale)*	0 1 2 3	0 1 2 3
2. Block, 2.5 cm (*if score=0, total=0 and goto grip subscale)*	0 1 2 3	0 1 2 3
3. Block, 5 cm	0 1 2 3	0 1 2 3
4. Block, 7.5 cm	0 1 2 3	0 1 2 3
5. Cricket ball	0 1 2 3	0 1 2 3
6. Sharpening stone	0 1 2 3	0 1 2 3
Subtotal	____/18	____/18
Grip subscale		
7. Pour water from one glass to another	0 1 2 3	0 1 2 3
(if score=3, total=12 and goto pinch subscale)		
8. Displace an alloy tube (diameter 2.25 cm) from one side of the	0 1 2 3	0 1 2 3
table to the other *(if score=0, total=0 and goto pinch subscale)*		
9. Displace an alloy tube (diameter 1 cm) from one side of the	0 1 2 3	0 1 2 3
table to the other		
10. Put washer over a bolt	0 1 2 3	0 1 2 3
Subtotal	____/12	____/12
Pinch subscale		
Pinch and lift the ball bearing, marble from one shelf		
of a table to another (lift over 37 cm)		
11. Ball bearing of 6 mm, 3rd finger and thumb	0 1 2 3	0 1 2 3
(if score=3, total=18 and goto gross movement subscale)		
12. Marble, 1st finger and thumb	0 1 2 3	0 1 2 3
(if score=0, total=0 and goto gross movement subscale)		
13. Ball bearing of 6 mm, 2nd finger and thumb	0 1 2 3	0 1 2 3
14. Ball bearing of 6 mm, 1st finger and thumb	0 1 2 3	0 1 2 3
15. Marble, 3rd finger and thumb	0 1 2 3	0 1 2 3
16. Marble, 2nd finger and thumb	0 1 2 3	0 1 2 3
Subtotal	____/18	____/18
Gross movement subscale		
17. Hand behind head *(if score=3, total=9 or if score=0, total=0)*	0 1 2 3	0 1 2 3
18. Hand on top of head	0 1 2 3	0 1 2 3
19. Hand to mouth	0 1 2 3	0 1 2 3
Subtotal	____/9	____/9
TOTAL	____/57	____/57

Subject ID: _____

Date: _____

Exam#: _____

Range of Motion - Shoulder				
ROM	Active	Passive	Active	Passive
	Left	Left	Right	Right
Flexion				
Abduction				
Internal Rotation				
External Rotation				

Range of Motion - Elbow				
ROM	Active	Passive	Active	Passive
	Left	Left	Right	Right
Flexion				
Extension				

RANGE OF MOTION MEASUREMENTS:

Shoulder Flexion:
Measurement Tool: Universal Goniometer
Testing Position: Supine with hips and knees bent and lumbar spine flat. Arm is at the side with the palm in and the thumb up
Stabilization: Body weight should stabilize scapula but manual stabilization may be required to prevent excessive scapular rising and tipping posteriorly
Goniometer Axis: Lateral aspect of the center of the humeral head approximately 1" below the acromion process
Stationary Arm: Parallel to midaxillary line of the trunk
Expected ROM: 120° of pure GH flexion; 150° with GH, AC, SC, and scapulothoracic contribution; 180° if lumbar hyperextension permitted

Shoulder Abduction:
Measurement Tool: Universal Goniometer
Testing Position: Supine with the hips and knees bent. Arm is in the anatomical position with the shoulder externally rotated
Stabilization: Stabilize the thorax
Goniometer Axis: Anterior aspect of the shoulder just inferior and lateral to the coracoid process
Stationary Arm: Parallel to midaxillary line of the trunk
Moving Arm: Anterior aspect of the upper arm parallel to longitudinal axis of the humerus
Expected ROM: 90° of pure GH abduction; 150° with GH, AC, SC, and scapulothoracic contribution; 180° if lumbar lateral flexion is allowed

Shoulder Internal/External Rotation
Measurement Tool: Universal Goniometer
Testing Position: Supine with the shoulder and elbow abducted 90°. The forearm is midway between pronation/supination with the entire humerus is supported by the table.
Stabilization: Stabilize the distal humerus through the full ROM and stabilize the thorax/scapula at the end ROM
Goniometer Axis: The olecranon process of the ulna projecting through the humeral shaft toward the humeral head
Stationary Arm: Parallel to the supporting surface or perpendicular to the floor
Moving Arm: Parallel to the longitudinal axis of the ulna pointing toward the styloid process
Expected ROM: 70° internal rotation; 90° external rotation

Elbow Flexion:
Measurement Tool: Universal Goniometer
Testing Position: Supine or sitting with the arm parallel to the midline and the forearm in the anatomical position
Stabilization: Examiner manually stabilizes the humerus
Goniometer Axis: Over the lateral epicondyle of the humerus
Stationary Arm: Parallel to the longitudinal axis of the humerus pointing towards the tip of the acromion
Moving Arm: Parallel to longitudinal axis of the radius pointing toward the styloid process of the radius
Expected ROM: 150°

Elbow Extension:
Measurement Tool: Universal Goniometer
Testing Position: Supine or sitting with the arm parallel to the midline and the forearm in the anatomical position
Stabilization: Examiner manually stabilizes the humerus
Goniometer Axis: Over the lateral epicondyle of the humerus
Stationary Arm: Parallel to the longitudinal axis of the humerus pointing towards the tip of the acromion
Moving Arm: Parallel to the longitudinal axis of the radius pointing towards the styloid process of the radius
Expected ROM: 0° in males; 10-15° in females is common.

Subject ID: _____

Date: _____

Exam#: _____

Modified Ashworth Scale of Spasticity

After Katz et al, Arch PMR 73:339-347, 1992

Shoulder	Elbow	Wrist	Finger

0 **No increase in muscle tone.**

1 **Slight increase in tone, manifested by a catch and release or by minimal resistance at the end of the range of motion when the affected part(s) is moved in flexion or extension.**

1+ **Slight increase in muscle tone, manifested by a catch, followed by minimal resistance throughout the remainder (less than half) of the ROM, but affected part(s) easily moved.**

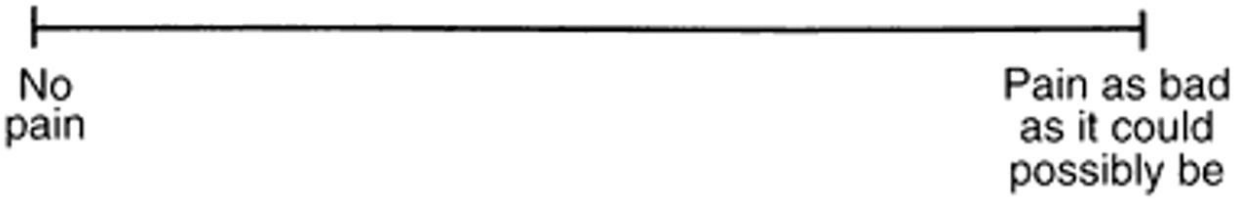
2 **More marked increase in muscle tone through most of the ROM, but affected part(s) easily moved.**

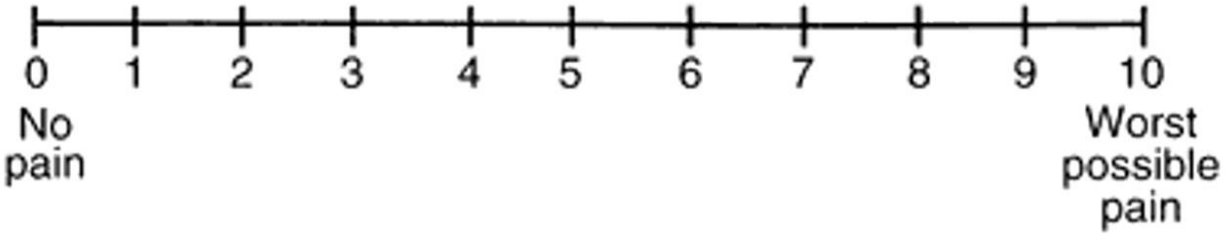
3 **Considerable increase in muscle tone, passive movement difficult.**

4 **Affected part(s) rigid in flexion or extension.**

For elbow, go from full flexion to full extension in 1 second with patient supine and arm stop a pad (per Bohannon and Smith, Phys Ther 1987).

Visual Analogue Scales





No Movement: _____

With Movement: _____

Subject ID_____
Date_____
Visit # _____
Name of person doing exam_____

Gait velocity testing – 10m Walk

Record time (to the nearest hundredth of a second) for the subject to complete the 10 meter walk. Record score separately for each of the two trials.

Timed 10meter walk	
Trial #1 (# seconds)	
Trial #2 (# seconds)	

Was an attempt made to evaluate gait velocity testing?
Yes or No
If no, enter 999 in both of the above boxes for "# seconds" and state the reason why gait velocity testing could not be attempted:_____

Was an attempt made to evaluate gait velocity but the subject was not able to initiate even a single step?
Yes or No
If yes, enter 300 in both of the above boxes for "# seconds".

Did subject use any assistive device or orthotic device (e.g., AFO, cane, or walker)?
Yes or No
If yes, state the device: _____

Did study site personnel provide any physical support during gait velocity testing?
Yes or No
If yes, describe this support:_____

Subject ID: _____

Date: _____

Exam #: _____

TOTAL SCORE

NIH Stroke Scale--*Score first response. No prompting.*

*Indicates option to score X (e.g., joint fusion/amputation); provide explanation.

Test	Scale Definition	Score
1a. Level of Consciousness--Must choose a response.	0=Alert; keenly responsive 1=Not alert; but arousable by minor stimulation 2=Requires repeated or painful stimuli to attend 3=Reflex motor, flaccid, or areflexic	
1b. LOC Questions--Ask pt his age & the month; must be correct. Tube, dysarthria, foreign lang. barrier=1.	0=Both correct 1=One correct 2=Neither correct; aphasia or stupor=2	
1c. LOC Commands--Ask pt to open & close eyes, then grip & release non-paretic hand. Can use different 1-step command or pantomime instructions.	0=Both correct; full credit if incomplete 2° weak 1=One correct 2=Neither correct	
2. Best Gaze--Horizontal EOM only, voluntary or Doll's. Conjugate deviation which can be overcome=1. Isolated CN palsy=1.	0=Normal 1=Partial gaze palsy; abnl gaze in 1 or both eyes 2=Forced deviation or total gaze paresis not overcome by Doll's	
3. Visual Field--Use visual threat if nec. If monocular, score per field of remaining eye. Quadrantanopia=1.	0=No visual loss 1=Partial hemianopia, quadrantanopia, or extinction. 2=Complete hemianopia 3=Bilateral hemianopia or any blindness, incl/ctxcl	
4. Facial Palsy--If stuporous, check symmetry of grimace to pain.	0=Normal 1=Minor paralysis, flattened NLF, asym smile 2=Partial paralysis (paralysis of lower face) 3=Complete paralysis (upper & lower face)	
5. Motor Arm*--extend pt's arm 90 deg (sitting) or 45 deg (supine); watch for 10 sec. Use pantomime or voice urgency but not pain. Begin w/stronger arm. Circle paretic arm in score box.	0=No drift for 10 sec 1=Drifts before 10 sec but does not hit bed 2=Some effort vs. gravity, can't maintain postn 3=No effort vs. gravity 4=No movement (score 3 if any mvmt in extremity)	Paretic arm is L R
Other Arm*--For brainstem stroke.	0-4, use same scale as above. Circle L & R.	
6. Motor Leg*--Place leg at 30 deg (always supine); watch for 5 sec.	0-4, use same scale as above Circle paretic leg in score box.	L R
Other Leg*--For brainstem stroke.	0-4, use same scale as above. Circle L & R.	
7. Limb Ataxia*--OU open, in good vis field. Only score if o/o proportion to any weakness. Score 0 if pt can't understand or is hemiplegic. If blind, pt to touch nose after extending arm.	0=No ataxia 1=Ataxia in 1 limb (upper ext or lower ext;; specify limb in score box) 2=Ataxia in upper ext and lower ext	
8. Sensory--Use pin; only score losses related to the stroke. Can assess by grimace or withdrawal if pt obtunded. Score 2 only if pt clearly comprehends thus aphasics/stupor usually=1.	0=Normal 1=Mild-mod sensory loss, less sharp on affected side, pt aware of being touched 2=Severe total sensory loss, unaware of touch; unresponsive=2, bilat sens loss(brnstem)=2	
9. Best Language--Describe cookie thief, name pictures, read sentences; can use stereognosis, repetition, or writing. Score=3 only if pt mute & follows no 1 step commands.	0=Normal 1=Mild-mod aphasia 2=Severe aphasia; great need for guessing & inference by examiner; lim'd info exchanged. Examiner carries burden of communication. 3=Mute, global aphasia, coma	
10. Dysarthria*--Have patient read from list of words; can rate speech w/severe aphasia. Score=X only if patient intubated or has other barrier.	0=Normal 1=Mild-mod; pt slurs but can be understood 2=Severe; unintelligible. Mute/anarthric=2	
11. Extinction & Inattention--severe vis loss + normal sens=0; aphasia but attending well bilat'ly=0. Vis neglect or anosognosia =abnl.	0=Normal or none detectable 1=Inattention or extinction on DSS in any of vis, auditory, sens, spatial, or personal 2=Profound in > 1 modality	

SCC 2/99

Subject ID: _____

Date: _____

Exam # _____

Mini-Mental State Examination CMMSE)

ORIENTATION-onepointforeachanswer

"Whatisthedatetoday?(year)(date)(month)(day)(season)?"(5) _
"Where are we? (state)(county)(town)(hospital)(floor)?" (5)

REGISTRATION – score 1,2,3 points according to how many are repeated on first try (Apple, piano, green)

Name three objects: Give the patient one second to say each.

Ask the patient to: repeat all three after you have said them. Repeat them until the patient learns all three. (3)

ATTENTION AND CALCULATION - one point for each correct subtraction

Ask the patient to: begin from 100 and count backwards by 7. Stop after 5 answers. (93, 86, 79, 72, 65) or Spell WORLD
backwards (5)

RECALL–onepointforeachcorrectanswer

Ask the patient to: name the three objects from above. (3)

LANGUAGE

Ask the patient to: identify and name a pencil and a watch. (2) _____

Ask the patient to: repeat the phrase "No ifs, ands, or buts." (1) _____

Ask the patient to: "Take a paper in your right hand, fold it in half, and put it on the floor" (1 point for each task completed properly)(3) _____

Ask the patient to: read and obey the following: (1) _____

Close your eyes

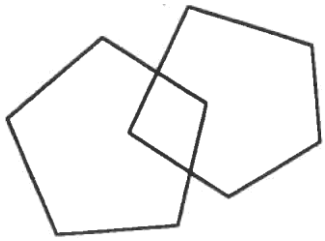
Ask the patient to: write a sentence. (1) _____

_____

_____

Ask the patient to: copy a complex diagram of two interlocking pentagons. (1)

_____



TOTAL:_____/30

MODIFIED RANKIN SCALE (MRS)

Patient Name: _____
Rater Name: _____
Date: _____

Score	Description
0	No symptoms at all
1	No significant disability despite symptoms; able to carry out all usual duties and activities
2	Slight disability; unable to carry out all previous activities, but able to look after own affairs without assistance
3	Moderate disability; requiring some help, but able to walk without assistance
4	Moderately severe disability; unable to walk without assistance and unable to attend to own bodily needs without assistance
5	Severe disability; bedridden, incontinent and requiring constant nursing care and attention
6	Dead

TOTAL (0–6): _____

References

Rankin J. "Cerebral vascular accidents in patients over the age of 60."
Scott Med J 1957;2:200-15

Bonita R, Beaglehole R. "Modification of Rankin Scale: Recovery of motor function after stroke."
***Stroke* 1988 Dec;19(12):1497-1500**

Van Swieten JC, Koudstaal PJ, Visser MC, Schouten HJ, van Gijn J. "Interobserver agreement for the assessment of handicap in stroke patients."
***Stroke* 1988;19(5):604-7**

Subject ID: _____

Date: _____

Exam#: _____

Geriatric Depression Scale

15 Question Version ("Short Form")

Choose the best answer for how you have felt over the past week:

Question	Y/N	Score
1. Are you basically satisfied with your life?	Yes **No**	
2. Have you dropped many of your activities and interests?	**Yes** No	
3. Do you feel that your life is empty?	**Yes** No	
4. Do you often get bored?	**Yes** No	
5. Are you in good spirits most of the time?	Yes **No**	
6. Are you afraid that something bad is going to happen to you?	**Yes** No	
7. Do you feel happy most of the time?	Yes **No**	
8. Do you often feel helpless?	**Yes** No	
9. Do you prefer to stay at home, rather than going out and doing new things?	**Yes** No	
10. Do you feel you have more problems with memory than most?	**Yes** No	
11. Do you think it is wonderful to be alive now?	Yes **No**	
12. Do you feel pretty worthless the way you are now?	**Yes** No	
13. Do you feel full of energy?	Yes **No**	
14. Do you feel that your situation is hopeless?	**Yes** No	
15. Do you think that most people are better off than you are?	**Yes** No	

Answers in **bold** and underlined indicate depression. Although differing sensitivities and specificities have been obtained across studies, for clinical purposes a score > 5 points is suggestive of depression and should warrant a follow-up interview. Scores > 10 are almost always depression.

Subject ID: _____

Date: _____

Exam#: _____

Power Grasp Test

	Trial 1	Trial 2	Trial 3	Average
Grasp (kg) Right				
Grasp (kg) Left				

Grasp

- Displays grip force in pounds (0-200) and kilograms (0-90).
- Isometric; accommodates variable size hands, adjusts to five grip positions (1 ⅜" to 3 ⅜").
- Set adjustable handle to the desired spacing.
- Rotate the peak hold needle counter-clockwise to 0.
- The patient should be seated with shoulder adducted and neutrally rotated, elbow flexed at 90 degrees, and the forearm in neutral position and wrist between 0-30 degrees dorsiflexion and 0-15 degrees ulnar deviation.
- Let the patient comfortably arrange the instrument in hand. Lightly hold around the readout dial to prevent inadvertent dropping
- Have the patient squeeze with maximum strength.
- 3 trials with 2-3 min. rest period between trials.
- The average of the three trials is recorded.
- Compare the other hand and the normative data. Scores within 2 standard deviations of the mean are considered within normal limits.

Subject ID: _____

Date: _____

Exam#: _____

Pinch Strength Test

Test	Trial 1	Trial 2	Trial 3	Average
Lateral Pinch (kg) **Right**				
Lateral Pinch (kg) **Left**				

Pinch

- Measures key (Lateral Pinch) strength.

-Measures in pounds (0-45) or kilograms (0-20).

-ASHT recommends the following test position: patient should be seated, shoulders adducted and neutrally rotated, elbow flexed at 90 degrees, forearm and wrist in neutral position.

-Key or lateral pinch: pad of thumb and lateral surface of index finger

Daily Procedures:

1. Stroke patients admitted to ARU.

2. Screen will be done upon admission (within 1-2 days).

3. Baseline evaluation will be performed within 1-3 days after the screening visit. The therapist will see patients in a separate room right outside ARU.

4. Randomization occurs after baseline evaluation – same day if possible. We will use the web-based formula to randomize patients from both study sites.

5. Study participants will be assigned to groups the day after randomization and begin their assigned intervention.

6. We will measure patient's heart rate and blood pressure in sitting position before and after each training session and record the data in the vital signs log.

7. For LARA group: participants will be fitted for LARA chair, will receive a demonstration by a research therapist and will be instructed on how to get in/out of LARA chair, how to propel LARA in a straight line, turns, figure 8 if possible (please see below for more details). Participants will receive 2 sessions lasting 30 minutes each for these trainings. If time permits, participants will perform video games using LARA in the common area at ARU. Instruction for all these trainings will be played through a pre-programmed computer. All data will be recorded to the same computer. Starting the third session, a research therapist will be available to assist but study participants are expected to perform exercise routines by themselves as much as possible. The research therapist will record and keep a log of time spent assisting study participants every day.

Study participants will perform the following exercise routines for 15 minutes, 5 days a week:

a. Spin LARA with unimpaired arm (wheel on impaired side is locked) for 30 sec.
b. Spin LARA with impaired arm (wheel on unimpaired side is locked) for 30 sec.
c. Go straight (put these two skills to use) for 2 mins.
d. Turn test unconstrained (turn towards the impaired side) for 30 sec.
e. Turn test unconstrained (turn towards the unimpaired side) for 30 sec.
f. Functional Task (Figure 8 track) for 2 mins.

Study participants will then play the video games: balloon and rocket driving for another 15 minutes, 5 days a week.

8. For control group: participants will receive a demonstration by a research therapist and will be instructed on how to perform arm/hand exercises using towel and table (please see appendix A for details). Towels, tables and an exercise logs will be provided. Participants will receive 2 sessions lasting 30 minutes each for these trainings. Starting the third session, a research therapist will be available to assist but study participants are expected to perform exercise routines by themselves as much as

possible. The research therapist will record and keep a log of time spent assisting study participants every day.

9. If supervising therapists at ARU and research therapist believe LARA participants are skilled enough to drive LARA, participants will begin using LARA to go to therapy appointments and move around ARU by themselves.

10. 3 clinical evaluations: baseline, 3-week post therapy or the day before discharge if sooner, 3-month follow up. All clinical evaluations must be completed within 2 days of scheduled dates.

11. 3-month follow up is 3 months after baseline evaluation.

Statistical Considerations

Data will be analyzed using modified intention-to-treat analysis. That is, all participants will be included in the analysis if data from the last follow-up assessment is available, regardless of treatment they receive or deviations from protocol. For missing data, we will carry forward the last available value. The effect of treatment on each outcome measure will be assessed using a repeated-measures ANOVA. Follow up analysis will be done using t-tests with Bonferroni corrections, or Wilcoxon rank sum tests if the distributions fail the Lilliefors test for normality. We hypothesize that the participants in the LARA therapy group will have significantly greater reductions in motor impairment measured by FM score than participants in the conventional therapy group. We expect this will be due to the increased dose of therapy LARA provides, and we will include total arm activity (as measured by the wrist-mounted actigraphy) and baseline function as covariates in the analysis. We will compare changes in MAL score, ARAT score, range of motion at the shoulder and elbow, Visual Analog Pain scores, Ashworth Spasticity, and 10 min walk scores using student's t-test or Wilcoxon rank sum tests for non-parametric data. We expect improvements in functional use of the impaired limb (MAL and ARAT) and range of motion but expect no significant differences in pain, spasticity, wheelchair odometer reading, or walking speed. All analyses will be reviewed by our statistical consultant.

Appendix A

Part 1: Arm Strengthening Exercises with Tabletop Support

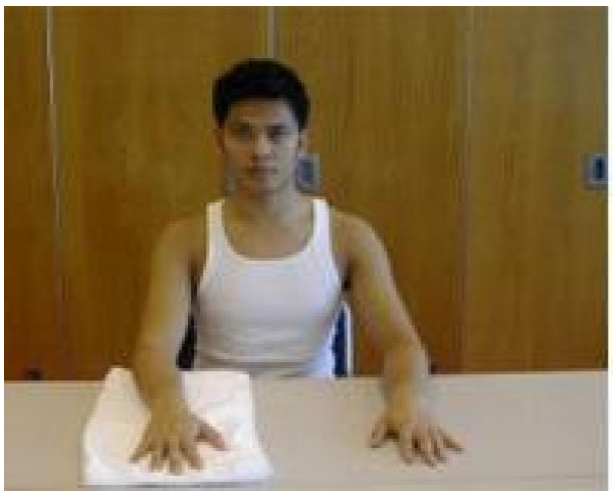
These exercises for the joints of the arm can help strengthen weak arm muscles, improve range of motion, and minimize stiffness and pain.

Instructions

- Use the muscles of your weak arm as much as possible.
- Use the stronger arm to help guide the weaker arm only as needed.
- Move slowly.
- The movements should not cause pain, but you may feel your muscles stretch.
- Repeat each exercise ten times.
- Perform exercises_____times per day.

Exercises

(1) Shoulder and Elbow Flexion/Extension

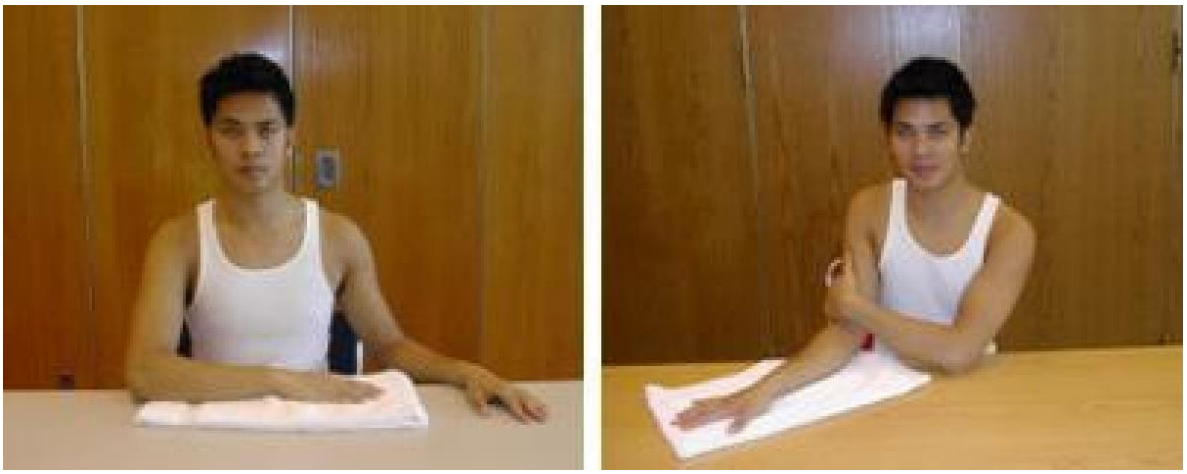


1. Place towel on the table
2. Place weaker arm on top of towel.
3. Using the strength of your shoulder and elbow, stretch your arm out in front of you
4. Try to keep arm as straight as possible.
5. Using the strength of your weaker arm, bend your elbow.
6. Pull arm back towards you.

(2) Shoulder Abduction/Adduction

1. Using the strength of your shoulder, slide arm out away from you.
2. Try to keep elbow straight and move only at the shoulder.
3. Slide arm in and around toward the opposite side of your body.
4. Try to keep elbow straight and move only at the shoulder.

(3) ShoulderInternal/ExternalRotation



1. Bend arm at elbow and tuck elbow in at your side.
2. Pull your arm in, toward your body.
3. Now slide hand out away from your body.
4. Keep elbow tucked in as much as possible. (You may need to use stronger hand to hold the weaker elbow in during this movement).

(4) Forearm Supination/Pronation


1. Place weaker elbow on the table.
2. Allow weaker forearm to rest in the palm of the stronger hand.
3. Using the strength of your weaker arm, turn palm toward you.
4. Keep hands in the same position.
5. Using the strength of your weaker arm, turn your palm away from you.

(5) Wrist Flexion/Extension


1. Hold weaker arm behind the wrist with your stronger hand, and lift the weaker arm slightly off the table. This will help your weaker hand to move without rubbing on the table.
2. Using the strength of your weaker arm, bend wrist forward.
3. Using the strength of your weaker arm, bend wrist backward.

(6) Finger and Thumb Flexion/Extension

1. Hold weaker arm behind the wrist with your stronger hand, and lift the weaker arm slightly off the table. This will help your weaker hand to move without rubbing on the table.
2. Using the strength of your weaker hand, close fingers into a fist.
3. Using the strength of your weaker hand, open all of your fingers and straighten thumb.

Part 2: Weight Bearing Exercises for the Arm

These exercises can help maintain range of movement and minimize stiffness and pain in the arm joints.

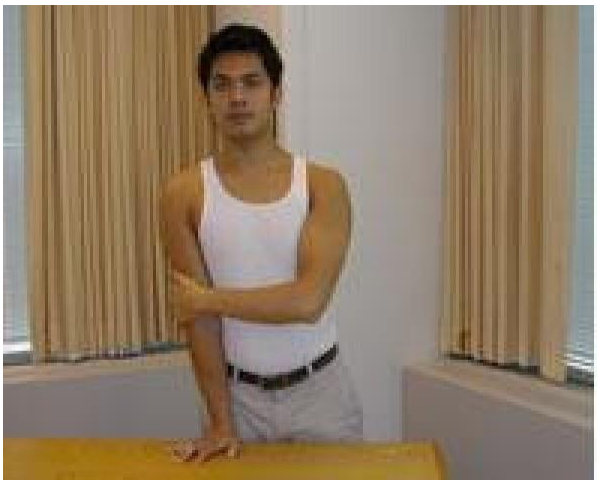
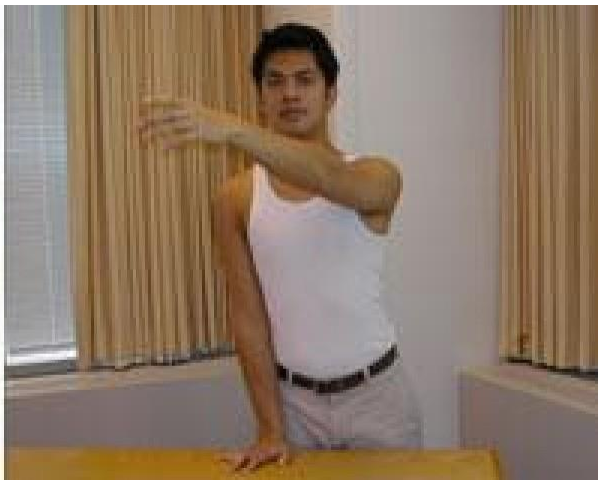
Instructions

- Move slowly and carefully. Stretches should not cause pain.
- Hold each position for at least 20 to 60 seconds.
- Perform exercises five times.
- If unable to stand easily, do only the first exercise

(1) SittingWeightBearing-*Elbow/Wrist/FingerExtension*


1. Place two stable chairs (of the same height) next to each other.
2. Place weaker hand on the seat next to you, as close to your body as possible.
3. Try to open weaker hand and place palm flat.
4. If unable to open hand, try placing only the heel of hand on the chair.
5. Use stronger hand to help straighten weaker elbow by placing hand behind elbow and pulling forward. Keep weaker arm as straight as possible.
6. Push down through the heel.
7. Hold position for 20-60 seconds.
8. To increase the stretch if desired, keep weaker hand on chair with elbow straight while stronger arm reaches forward and up.
9. Hold position for 20-60 seconds.

(2) StandingWeightBearing- *Elbow/Wrist/FingerExtension*

1. Stand facing a table. Place weaker hand on top of table, as close to your body as possible.
2. Try to open weaker hand and place palm flat.
3. If unable to open hand, try placing only the heel of hand on the table.
4. Use stronger hand to help straighten weaker elbow by placing hand behind elbow and pulling forward.
5. Keep weaker arm as straight as possible and push down through the heel of hand.
6. Hold position for 20-60 seconds.
7. To increase stretch if desired, keep weaker hand on chair and elbow straight while stronger arm reaches forward and up.
8. Hold position for 20-60 seconds.