

LEAPS

(Locomotor Experience Appplied Post-Stroke)



Home Exercise Program (HEP)

Therapist Intervention Manual

INTRODUCTION

This manual describes a non-specific low intensity home exercise program for patients following stroke. This is a **standardized** intervention that has been developed specifically for the purposes of the LEAPS clinical trial.

The patients assigned to the home exercise group will be visited by a physical therapist 3 times per week for 12 weeks (36 sessions). To keep session length comparable to those receiving the locomotor intervention, the duration of each visit is to be one to one and a half hours. The content of the home exercise program is outlined in the following sections.

All patients will be required to come to the clinic or research laboratory for assessment after the 12th, 24th, and 36th session. An independent examiner will conduct these assessments. The examiner will be blinded to group assignment. Maintaining blindness is imperative to the design of this study, and as the intervention therapist, you will be involved in educating the patient about the importance of not exposing their group assignment to the examiner during these assessments.

The patients will be aware that they have been assigned to either a home exercise group or a group that uses the treadmill for exercise. It is imperative that time spent with the patient, attention to the patient and enthusiasm for the intervention be equitable for both groups of participants.

It is essential that the training not deviate from that specified in this manual. Exercises may be progressed according to the specified guidelines in the relevant sections. The decision to implement a progression is at the discretion of the intervention therapist, but additional activities and progressions, outside of the standardized protocol must not be prescribed.

The program includes three 4-week phases. The manual will provide specific progressions and protocols for each phase. At the end of each phase, the participant's assistive device and orthosis should be evaluated for safety and comfort. The LEAPS trial does not provide funds for new or modifications to existing assistive or orthotic devices.

All patients participating in this study will have access to customary and usual care as well as the intervention they are receiving as part of the LEAPS trial.

Vital signs (heart rate, blood pressure and O₂ saturation rate) will be monitored throughout each exercise session. Specific instructions and guidelines regarding monitoring vital signs prior to exercise and the response to exercise are provided in the Medical Issues section of this manual.

WARM UP

The warm up is to be performed at the beginning of every session.

1. Baseline vital signs

Refer to Medical Issues for full details concerning guidelines for beginning exercise, continuing exercise, and terminating exercise based on vital signs and participant response. Measure resting heart rate (HR) and blood pressure (BP) and O₂ saturation rate before commencement of each exercise session.

2. Gentle passive range of motion exercise and stretching

- a. Upper extremity (UE) range of motion (perform bilaterally, 5 repetitions)

Scapular mobilization is best performed in sidelying on the nonparetic side. Shoulder ROM exercises of the paretic UE can be performed in supine or sidelying, providing adequate support to the scapula, especially if the shoulder girdle complex is mal-aligned and/or the UE is flaccid. Distal UE ROM can be provided in supine or sitting.

- Scapular mobilization (protraction and retraction)
- Shoulder abduction
- Shoulder flexion
- Shoulder internal rotation
- Shoulder external rotation
- Shoulder shrugging (active, in sitting)
- Elbow flexion/extension
- Forearm pronation/supination
- Wrist flexion/extension
- Finger flexion/extension

- b. Lower extremity (LE) range of motion (perform bilaterally, 5 repetitions)

- Hamstring stretch (30 second hold, straight leg raise, supine)
- Gastrocnemius stretch (30 second hold, in standing)
- Soleus stretch (30 second hold) (in standing)

- c. Trunk rotation (sitting, 5 repetitions each direction)

- d. Additional stretching as required

- If additional joints have soft tissue limitations, perform assisted stretching

3. Monitor vital signs at the end of the warm-up phase

Record vital signs (HR or Borg Perceived Exertion Scale, BP, and O₂ saturation rate on standardized documentation sheet).

PHASE 1 (12 sessions)

Warm up Exercises (see Page 2)

A. Sitting Balance

Progression:

1. Sitting with equal weight on ischial tuberosities for 30 seconds
Repeat up to 5X.
2. Sitting with upright posture, shift weight laterally to nonparetic hip, lift paretic leg from chair by flexing paretic hip. Hold 5 seconds. Then shift weight laterally to paretic hip, lift nonparetic leg from chair by flexing nonparetic hip. Hold 5 seconds
Can alternate up to 10X



Sitting with equal weight



Weight shift to nonparetic side



Weight shift to paretic side

Reaching with paretic and nonparetic UE

Place object just beyond arm's length

Reach for object (can pick up or touch, depending on ability, return to upright posture)

Repeat up to 5X each direction

3. Ipsilateral anterior diagonal reaching/nonparetic UE
4. Ipsilateral posterior diagonal reaching/nonparetic UE
5. Contralateral anterior diagonal reaching/paretic UE
6. Contralateral posterior diagonal reaching/paretic UE



Ipsilateral anterior
(nonparetic)



Ipsilateral posterior
(nonparetic)



Contralateral anterior
(paretic)



Contralateral posterior
(paretic)

7. Contralateral anterior diagonal reaching/nonparetic UE
8. Contralateral posterior diagonal reaching/nonparetic UE
9. Ipsilateral anterior diagonal reaching/paretic UE
10. Ipsilateral posterior diagonal reaching/paretic UE



Contralateral anterior
(nonparetic)



Contralateral posterior
(nonparetic)



Ipsilateral anterior
(paretic)



Ipsilateral posterior
(paretic)

B. Upper Extremity Strengthening

For each exercise below, begin within the progression such that participant is able to perform the movement without substitutions. If the participant has no volitional movement, passively move the limb through the movement, encouraging participant to assist as able. From active assistive movements, progress to active with gravity eliminated and then to active movement against gravity. If patient is able to perform movement against gravity without substitution, progress to Theraband®. Once the participant can perform 2 sets of 10 exercises (all repetitions through available range of motion), the resistance of the Theraband® is increased. All exercises are to be conducted within a pain-free range.

NB: Refer to figures for positioning

1. Shoulder flexors (limit to 90°)

Progression:

1. Gravity eliminated, active assistive
2. Gravity eliminated, active
3. Against gravity, no Theraband
4. Against gravity, yellow Theraband
5. Against gravity, red Theraband
6. Against gravity, green Theraband
7. Against gravity, blue Theraband
8. Against gravity, black Theraband
9. Against gravity, silver Theraband

2. Shoulder extensors

Progression:

1. Gravity eliminated, active assistive
2. Gravity eliminated, active
3. Against gravity, no Theraband
4. Against gravity, yellow Theraband
5. Against gravity, red Theraband
6. Against gravity, green Theraband
7. Against gravity, blue Theraband
8. Against gravity, black Theraband
9. Against gravity, silver Theraband

3. Shoulder external rotators

Progression:

1. Gravity eliminated, active assistive
2. Gravity eliminated, active
3. Against gravity, no Theraband
4. Against gravity, yellow Theraband
5. Against gravity, red Theraband
6. Against gravity, green Theraband
7. Against gravity, blue Theraband
8. Against gravity, black Theraband
9. Against gravity, silver Theraband

4. Shoulder abductors

Progression:

1. Gravity eliminated, active assistive
2. Gravity eliminated, active
3. Against gravity, no Theraband
4. Against gravity, yellow Theraband
5. Against gravity, red Theraband
6. Against gravity, green Theraband
7. Against gravity, blue Theraband
8. Against gravity, black Theraband
9. Against gravity, silver Theraband

5. Elbow flexors

Progression:

1. Gravity eliminated, active assistive
2. Gravity eliminated, active
3. Against gravity, no Theraband
4. Against gravity, yellow Theraband
5. Against gravity, red Theraband
6. Against gravity, green Theraband
7. Against gravity, blue Theraband
8. Against gravity, black Theraband
9. Against gravity, silver Theraband

6. Elbow extensors

Progression:

1. Gravity eliminated, active assistive
2. Gravity eliminated, active
3. Against gravity, no Theraband
4. Against gravity, yellow Theraband
5. Against gravity, red Theraband
6. Against gravity, green Theraband
7. Against gravity, blue Theraband
8. Against gravity, black Theraband
9. Against gravity, silver Theraband

7. Wrist extensors

Progression:

1. Gravity eliminated, active assistive
2. Gravity eliminated, active
3. Against gravity, no Theraband
4. Against gravity, yellow Theraband
5. Against gravity, red Theraband
6. Against gravity, green Theraband
7. Against gravity, blue Theraband
8. Against gravity, black Theraband
9. Against gravity, silver Theraband

8. Wrist flexors

Progression:

1. Gravity eliminated, active assistive
2. Gravity eliminated, active
3. Against gravity, no Theraband
4. Against gravity, yellow Theraband
5. Against gravity, red Theraband
6. Against gravity, green Theraband
7. Against gravity, blue Theraband

8. Against gravity, black Theraband
9. Against gravity, silver Theraband

9. Mass finger extension

Progression:

1. Gravity eliminated, active assistive
2. Gravity eliminated, active
3. Against gravity, no resistance
4. Against gravity, yellow Theraband
5. Against gravity, red Theraband
6. Against gravity, green Theraband
7. Against gravity, blue Theraband
8. Against gravity, black Theraband
9. Against gravity, silver Theraband

10. Mass finger flexion

Progression:

1. Gravity eliminated, active assistive
2. Gravity eliminated, active, enclose hand around tennis ball

If the participant cannot grasp the TheraBand secondary to hand weakness, the therapist can assist the participant in doing so. For shoulder flexion, elbow flexion and wrist extension, the TheraBand is stabilized by the participant's foot, for shoulder external rotation, shoulder extension and elbow extension, the TheraBand is stabilized by a closed door.



Shoulder flexion,
gravity eliminated



Shoulder flexion,
with Theraband



Shoulder extension,
gravity eliminated



Shoulder extension,
with Theraband



Shoulder abduction,
gravity eliminated



Elbow flexion,
gravity eliminated



Elbow flexion, with Theraband



Elbow extension,
gravity eliminated



Elbow extension,
with Theraband



Wrist extension, gravity eliminated



Wrist extension, against gravity



Finger extension,
gravity eliminated



Finger extension,
w/Theraband - begin



Finger extension
w/Theraband - end



Finger flexion with
tennis ball

C. Lower extremity Strengthening

1. Hip abductors

Progression:

1. Gravity eliminated, active assistive
2. Gravity eliminated, active
3. Against gravity, no resistance (standing)
4. Against gravity, no resistance (sidelying)

2. Hip flexors

Progression:

1. Supine: knee to chest, active assistive
2. Supine: knee to chest, active
3. Standing: hip flexion to 90 degrees
4. Supine: straight leg raise

3. Hip extensors

Progression:

1. Supine: bilateral bridge
2. Supine: unilateral bridge, active assistive
3. Supine: unilateral bridge, active

4. Knee Flexors

Progression:

1. Supine heel slide, active assistive
2. Supine heel slide, active

5. Knee Extensors

Progression:

1. Supine, knee over bolster, active assistive
2. Supine, knee over bolster, active
3. Sitting, knee extension

6. Ankle Dorsiflexors

Progression:

1. Sitting, heel on floor active assistive
2. Sitting, heel on floor, active

7. Ankle Plantarflexors

1. Sitting, plantarflexion active assistive
2. Sitting, plantarflexion, active



Hip Abduction,
gravity eliminated



Hip Abduction,
against gravity



Hip Flexion, knee to
chest, active assistive



Standing Hip Flexion
to 90 degrees



Hip Extension,
bilateral bridge



Hip Extension,
unilateral bridge



Knee flexion, supine heel slide, active assistive



Knee flexion, supine heel slide, active



Knee extension, supine over bolster, against gravity



Knee extension, sitting, against gravity



Ankle dorsiflexion, active assistive



Ankle plantarflexion, active assistive

Remember to monitor vital signs after every 5 minutes of activity.

D. Encourage walking

At the end of each session, remind the participant to go for a walk every day.

E. Gait device evaluation

At the end of week 4, evaluate the participant's gait device and orthosis for fit and comfort.

F. Record activities completed in intervention log after each session.

PHASE 2 (12 sessions)

Warm up Exercises (see Page 2)

Remember to monitor vital signs after every 5 minutes of activity.

A. Sitting Balance

(If the participant has not yet progressed through the entire range of sitting balance exercises commenced in Phase 1, continue throughout Phase 2. If they have, progress to standing balance exercises.)

Progression:

1. Sitting with equal weight on ischial tuberosities for 30 seconds
Repeat up to 5X.
2. Sitting with upright posture, shift weight laterally to nonparetic hip, lift paretic leg from chair by flexing paretic hip. Hold 5 seconds. Then shift weight laterally to paretic hip, lift nonparetic leg from chair by flexing nonparetic hip. Hold 5 seconds
Repeat up to 10X.

Reaching with paretic and nonparetic UE

Place object just beyond arm's length.

Reach for object (can pick up or touch, depending on ability), return to upright posture

Repeat up to 5X each direction

3. Ipsilateral anterior diagonal reaching/nonparetic UE
4. Ipsilateral posterior diagonal reaching/nonparetic UE
5. Contralateral anterior diagonal reaching/paretic UE
6. Contralateral posterior diagonal reaching/paretic UE
7. Contralateral anterior diagonal reaching/nonparetic UE
8. Contralateral posterior diagonal reaching/nonparetic UE
9. Ipsilateral anterior diagonal reaching/paretic UE
10. Ipsilateral posterior diagonal reaching/paretic UE

B. Standing balance

Progression:

1. Shoulder-width stance for 30 seconds, weight evenly distributed with eyes open
2. Shoulder-width stance for 30 seconds, weight evenly distributed with eyes closed

3. Feet together for 30 seconds, weight evenly distributed with eyes open
4. Feet together for 30 seconds, weight evenly distributed with eyes closed



Standing, shoulder width stance



Standing, feet together

C. Upper Extremity Strengthening

Continue with the Upper Extremity Strengthening Exercises as outlined in Phase I.

For each exercise below, begin within the progression such that participant is able to perform the movement without substitutions. If the participant has no volitional movement, passively move the limb through the movement, encouraging participant to assist as able. From active assistive movements, progress to active with gravity eliminated and then to active movement against gravity. If patient is able to perform active movement against gravity without substitution, progress to Theraband®. Once the participant can perform 2 sets of 10 exercises (all repetitions through available range of motion), the resistance of the Theraband® is increased. All exercises are to be conducted within a pain-free range.

1. Shoulder flexors (limit to 90°)

Progression:

1. Gravity eliminated, active assistive
2. Gravity eliminated, active
3. Against gravity, no Theraband
4. Against gravity, yellow Theraband
5. Against gravity, red Theraband
6. Against gravity, green Theraband
7. Against gravity, blue Theraband
8. Against gravity, black Theraband

9. Against gravity, silver Theraband

2. Shoulder extensors

Progression:

1. Gravity eliminated, active assistive
2. Gravity eliminated, active
3. Against gravity, no Theraband
4. Against gravity, yellow Theraband
5. Against gravity, red Theraband
6. Against gravity, green Theraband
7. Against gravity, blue Theraband
8. Against gravity, black Theraband
9. Against gravity, silver Theraband

3. Shoulder external rotators

Progression:

1. Gravity eliminated, active assistive
2. Gravity eliminated, active
3. Against gravity, no Theraband
4. Against gravity, yellow Theraband
5. Against gravity, red Theraband
6. Against gravity, green Theraband
7. Against gravity, blue Theraband
8. Against gravity, black Theraband
9. Against gravity, silver Theraband

4. Shoulder abductors

Progression:

1. Gravity eliminated, active assistive
2. Gravity eliminated, active
3. Against gravity, no Theraband
4. Against gravity, yellow Theraband
5. Against gravity, red Theraband
6. Against gravity, green Theraband
7. Against gravity, blue Theraband
8. Against gravity, black Theraband
9. Against gravity, silver Theraband

5. Elbow flexors

Progression:

1. Gravity eliminated, active assistive
2. Gravity eliminated, active
3. Against gravity, no Theraband
4. Against gravity, yellow Theraband
5. Against gravity, red Theraband
6. Against gravity, green Theraband

7. Against gravity, blue Theraband
8. Against gravity, black Theraband
9. Against gravity, silver Theraband

6. Elbow extensors

Progression:

1. Gravity eliminated, active assistive
2. Gravity eliminated, active
3. Against gravity, no Theraband
4. Against gravity, yellow Theraband
5. Against gravity, red Theraband
6. Against gravity, green Theraband
7. Against gravity, blue Theraband
8. Against gravity, black Theraband
9. Against gravity, silver Theraband

7. Wrist extensors

Progression:

1. Gravity eliminated, active assistive
2. Gravity eliminated, active
3. Against gravity, no Theraband
4. Against gravity, yellow Theraband
5. Against gravity, red Theraband
6. Against gravity, green Theraband
7. Against gravity, blue Theraband
8. Against gravity, black Theraband
9. Against gravity, silver Theraband

8. Wrist flexors

Progression:

1. Gravity eliminated, active assistive
2. Gravity eliminated, active
3. Against gravity, no Theraband
4. Against gravity, yellow Theraband
5. Against gravity, red Theraband
6. Against gravity, green Theraband
7. Against gravity, blue Theraband
8. Against gravity, black Theraband
9. Against gravity, silver Theraband

9. Mass finger extension

Progression:

1. Gravity eliminated, active assistive
2. Gravity eliminated, active
3. Against gravity, no resistance
4. Against gravity, yellow Theraband

5. Against gravity, red Theraband
6. Against gravity, green Theraband
7. Against gravity, blue Theraband
8. Against gravity, black Theraband
9. Against gravity, silver Theraband

10. Mass finger flexion

Progression:

1. Gravity eliminated, active assistive
2. Gravity eliminated, active, enclose hand around tennis ball

If the participant cannot grasp the TheraBand secondary to hand weakness, the therapist can assist the participant in doing so. For shoulder flexion, elbow flexion and wrist extension, the TheraBand is stabilized by the participant's foot, for shoulder external rotation, shoulder extension and elbow extension, the TheraBand is stabilized by a closed door.

D. Lower Extremity Strengthening

1. Hip abductors

Progression:

1. Gravity eliminated, active assistive
2. Gravity eliminated, active
3. Against gravity, no resistance (standing)
3. Against gravity, no resistance (sidelying)
4. Standing, yellow Theraband
5. Standing, red Theraband
6. Standing, green Theraband

2. Hip flexors

Progression:

1. Supine: knee to chest, active assistive
2. Supine: knee to chest, active
3. Standing: hip flexion to 90 degrees
4. Supine: straight leg raise, no Theraband
5. Supine: straight leg raise, yellow Theraband
6. Supine: straight leg raise, red Theraband
7. Supine: straight leg raise, green Theraband

3. Hip extensors

Progression:

1. Supine: bilateral bridge
2. Supine: unilateral bridge, active assistive

9. Against gravity, silver Theraband

2. Shoulder extensors

Progression:

1. Gravity eliminated, active assistive
2. Gravity eliminated, active
3. Against gravity, no Theraband
4. Against gravity, yellow Theraband
5. Against gravity, red Theraband
6. Against gravity, green Theraband
7. Against gravity, blue Theraband
8. Against gravity, black Theraband
9. Against gravity, silver Theraband

3. Shoulder external rotators

Progression:

1. Gravity eliminated, active assistive
2. Gravity eliminated, active
3. Against gravity, no Theraband
4. Against gravity, yellow Theraband
5. Against gravity, red Theraband
6. Against gravity, green Theraband
7. Against gravity, blue Theraband
8. Against gravity, black Theraband
9. Against gravity, silver Theraband

4. Shoulder abductors

Progression:

1. Gravity eliminated, active assistive
2. Gravity eliminated, active
3. Against gravity, no Theraband
4. Against gravity, yellow Theraband
5. Against gravity, red Theraband
6. Against gravity, green Theraband
7. Against gravity, blue Theraband
8. Against gravity, black Theraband
9. Against gravity, silver Theraband

5. Elbow flexors

Progression:

1. Gravity eliminated, active assistive
2. Gravity eliminated, active
3. Against gravity, no Theraband
4. Against gravity, yellow Theraband
5. Against gravity, red Theraband
6. Against gravity, green Theraband

feet, hold position for 3 seconds

5. Standing: Without holding on, raise up on toes of both feet, hold position for 3 seconds

For ankle plantarflexors, at each session, begin at one level below highest level participant achieved at previous visit. Complete that level five times, then progress to level at which participant is not able to maintain 3 seconds. Record highest level participant was able to maintain for 3 seconds. Repeat exercise at this level up to 10 times.



Hip abduction, active assistive



Hip abduction with Theraband



Hip flexion, active assistive



Hip flexion, active



Hip flexion with Theraband



Hip extension, double leg bridge



Hip extension, single leg bridge



Hip extension, with Theraband



Knee flexion, active assistive



Knee flexion, active



Knee flexion with Theraband



Knee extension, over bolster



Knee extension, sitting, active



Dorsiflexion, active assistive



Dorsiflexion with TheraBand



Plantarflexion, active assistive



Plantarflexion, standing, both legs

For hip extension, hip abduction knee flexion and knee extension, TheraBand can be stabilized in a closed door. For hip flexion, TheraBand can be stabilized underneath the leg of bed or couch or can be stabilized by the therapist. For ankle dorsiflexion, the therapist can stabilize TheraBand.

E. Co-ordination

1. Lower extremity: Supine, ask the participant to slide the affected heel on the shin of the opposite leg, from ankle to knee and return. Continue as fast as possible for 20 seconds.

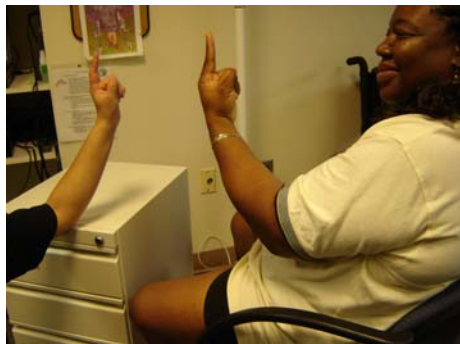
Progression: number of repetitions completed in 20 seconds



Heel on shin, reciprocal movement, knee to ankle

2. Upper extremity: Sitting, ask the participant to reach with their affected arm to touch the therapist's finger held out in front of them and then touch their nose. Repeat as fast as possible for 20 seconds.

Progression: number of repetitions completed in 20 seconds



Assistance may be provided if the participant cannot achieve these tasks independently.

F. Encourage walking

At the end of each session, remind the participant to try and go for a walk every day.

G. Gait device evaluation

At the end of Session 24, evaluate the participant's assistive device and orthosis for comfort and safety.

H. Record activities completed in intervention log after each session.

PHASE 3 (12 sessions)

Warm up Exercises (see page 2)

Remember to monitor vital signs after every 5 minutes of activity.

A. Static Standing balance

Progression:

1. Shoulder-width stance for 30 seconds, weight evenly distributed with eyes open
2. Shoulder-width stance for 30 seconds, weight evenly distributed with eyes closed
3. Feet together for 30 seconds, weight evenly distributed with eyes open
4. Staggered stance for 30 seconds, paretic leg in front, weight evenly distributed with eyes open
5. Staggered stance for 30 seconds, paretic leg in front, weight evenly distributed with eyes closed
6. Feet together for 30 seconds, weight evenly distributed with eyes closed
7. Staggered stance for 30 seconds, paretic leg behind, weight evenly distributed with eyes open
8. Staggered stance for 30 seconds, paretic leg behind, weight evenly distributed with eyes closed
9. Staggered stance for 30 seconds, paretic leg in front on step, weight evenly distributed with eyes open
10. Staggered stance for 30 seconds, paretic leg in front on step, weight evenly distributed with eyes closed
11. Staggered stance for 30 seconds, nonparetic leg in front on step, weight evenly distributed with eyes open
12. Staggered stance for 30 seconds, nonparetic leg in front on step, weight evenly distributed with eyes closed

At each session, begin at one level below highest level participant achieved at previous visit. Complete that level one time, then progress to level at which participant is not able to maintain position for 30 seconds. Record highest level participant was able to maintain for 30 seconds. Use 6-inch step for #9-#12.



Staggered stance, paretic in front



Staggered stance, paretic in front

Staggered stance, paretic
leg on stepStaggered stance,
nonparetic leg on step

B. Dynamic Standing Balance

Progression:

1. Catching ball straight on
2. Catching ball thrown towards nonparetic side
3. Catching ball thrown towards paretic side
4. Turning towards paretic side
5. Turning towards nonparetic side

At each session, begin at one level below highest level participant achieved at previous visit (able to perform without loss of balance). Complete that level 5 times, then progress to level at which participant is able to complete safely without loss of balance. Record that level. Repeat up to 10 repetitions. Ball to be used for #1 - #3 is standard lightweight playground ball.



Catching ball in front



Catching ball towards nonparetic side



Catching ball towards paretic side



Turning towards paretic



Turning towards nonparetic

C. Upper Extremity Strengthening

Continue upper extremity exercise programs outlined in Phase 1 and 2.

D. Lower Extremity Strengthening

Continue lower extremity exercise programs outlined in Phase 2.

As in Phase 2, do not progress participant beyond green TheraBand.

Ankle Plantarflexion can be progressed in Phase 3 as follows:

Progression:

1. Sitting, plantarflexion active assistive
2. Sitting, plantarflexion, active
3. Standing: Hold on with both UE's, raise up on toes of both feet, hold position for 3 seconds
4. Standing: Hold on with one UE, raise up on toes of both feet, hold position for 3 seconds
5. Standing: Without holding on, raise up on toes of both feet, hold position for 3 seconds
6. Standing: Hold on with both upper extremities, raise up on toes of involved LE (single toe raise), hold position for 3 seconds
7. Standing: Hold on with one UE, raise up on toes of involved LE (single toe raise), hold position for 3 seconds
8. Standing: Without holding on, raise up on toes of involved LE (single toe raise), hold position for 3 seconds

At each session, begin at one level below highest level participant achieved at previous visit. Complete that level five times, then progress to level at which participant is not able to maintain 3 seconds. Record highest level participant was able to maintain for 3 seconds. Repeat exercise at this level up to 10 times.



Standing, holding, up on both feet

E. Sit-to-stand

This activity involves standing up from a seated position and returning to a seated position with weight evenly distributed on both lower extremities. Complete 3 sets of 5 repetitions before progressing to the next level. This is the maximum number of repetitions to be performed at any given level.

Progression:

1. Move to edge of chair, lean forward, push up with arms, stand up.
2. Move to edge of chair, lean forward, put arms out, stand up.
3. Move to edge of chair, lean forward, fold arms across chest, stand up.
4. Sit back in chair, push with arms, stand up.
5. Sit back in chair, put arms out, stand up.
6. Sit back in chair, fold arms across chest, stand up.



Sit to stand, back in chair, push with arms



Sit to stand, edge of chair, arms out



Sit to stand, back in chair, arms folded

F. Encourage walking

At the end of each session, remind the participant to try and go for a walk every day.

G. Gait Device evaluation

At the end of Session 36, evaluate the participant's assistive device and orthotic device for comfort and safety.

H. Record activities completed in intervention log after each session.

DOCUMENTATION

Documentation of the training session must be completed using the home exercise documentation forms (D1, D2, D3). The data from the hard copy is transferred into the web-based data entry system. This is necessary to ensure that an accurate record of participants' progression and participant's vital signs is maintained.

MEDICAL ISSUES

The safety and well being of the patient is of primary concern during all exercise sessions.

Medical approval

Before participating in the LEAPS trial, each participant has undergone screening of his/her medical history for adherence to specific inclusion/exclusion criteria and has been provided medical approval from their physician for participation in the trial. Medical issues that may require specific attention in participants post-stroke: altered exercise tolerance, risk for angina, risk for congestive heart failure, orthostatic hypotension, high blood pressure, deconditioning, musculoskeletal changes, and skin abrasions.

Exercise tolerance and monitoring response to exercise during training session

Because individuals post-stroke typically have vascular disease and altered exercise tolerance secondary to neurologic impairment and deconditioning, specific guidelines for monitoring vital signs (heart rate and blood pressure) will be followed.

Monitoring vital signs

Blood pressure (BP) and heart rate (HR) will be monitored, prior to an exercise session, during a session, and at the completion of each session.

Initiation of training session:

- BP and HR must be within normal range for the subject prior to initiating each session. HR must be less than 100 bpm to begin the training session. Subjects' resting diastolic BP must be less than 100 and systolic BP less than 180 and HR less than 100 to begin the exercise session.
- If the participant's BP/HR exceeds these values, identify any issues that might be the source of the problem (e.g. stress) and try to address those issues and allow period of time to pass for the person's BP/HR to drop to normal levels. If after a period of rest/waiting, vitals do come to within acceptable training values, record these acceptable values in 1a. of the D form.
- If, after a period of rest and alleviation of external stressors, the participant's BP/HR exceeds the values listed above the intervention session should not be conducted, but will be counted

towards participant's total number of training sessions. If the training session does not occur due to BP/HR, a minor adverse event will need to be reported. On the minor adverse event form, note the BP/HR values.

- Exercise guidelines for *minimum* blood pressure to commence an exercise session have not been clearly established. If blood pressure on a given session is significantly lower than participant's typical readings the LEAPS team should use their clinical judgment, considering patients affect, subjective report, activity prior to session and consult with Site Medical Director and or CRC if possible. If the training session does not occur, a minor adverse event should be reported.
- If vitals are out of range to commence a session on consecutive visits, a new Minor Adverse Event form does not need to be completed, but rather this subsequent occurrence can be appended to the existing Minor Adverse Event form

Monitoring during a training session:

- During the exercise sessions, BP and HR, O₂ saturation rate and Borg rate of perceived exertion will be monitored after every 5 minutes of exercise initially to establish exercise tolerance to assure that they remain within acceptable limits. When an exercise is progressed to a more difficult level (i.e. an increase in Theraband resistance) vital signs should be taken
- The American College of Sports Medicine criteria for stopping an exercise session will be followed, as well as exercise monitoring guidelines shown to be effective for participants post-stroke with multiple comorbidities
- The criteria for stopping training include
 - complaints of light-headedness or moderate or severe dysnea, or the development of paleness and excessive sweating or confusion
 - complaints of feeling ill
 - onset of angina
 - pressure changes (systolic greater than 200mm Hg, diastolic greater than 110mm Hg)

- drop in systolic BP greater than 20mm Hg and inappropriate bradycardia (drop in heart rate greater than 10 bpm)
- HR exceeding 80% of the predicted maximum HR (220-age) or the participant reports a Borg exertion rate of greater than 13

Should the exercise session be halted, the subject will be asked to rest while BP and HR are monitored and will resume only when BP and HR returned to an acceptable range and excessive dyspnea or chest pain have resolved. If any of these conditions persist after rest, the patient's primary physician will be called and the patient referred for evaluation. A minor adverse event form should be filled out. Include HR/BP values on the form. If the patient complains of angina at rest, loss of consciousness occurs, or cardiac arrest, emergency medical services through 911 will be called immediately. Track patient to determine appropriate adverse event forms to complete.

All therapists will be CPR certified and aware of signs of cardiac complications.

Signs of myocardial infarction or angina include:

- pain in the chest, often radiating to the arm, neck, or jaw
- difficulty breathing
- nausea
- sweating

Signs of congestive heart failure include:

- dyspnea at relatively low levels of activity
- heart rate response may be exaggerated
- signs of fatigue disproportionate to activity
- breathing that worsens with positional changes, eg. when moving to supine

Cardiovascular medications that affect exercise tolerance include:

- Beta blockers
- Alpha-1 noradrenergic antagonists (eg. doxazocin, terazocin) (potentiate hypotension)
- Alpha-2 noradrenergic agonists (eg. clonidine) (potentiate hypotension)

Musculoskeletal system

Four common problems in persons post-stroke are spasticity, decreased range of motion, shoulder pain, and susceptibility to strains/sprains.

Spasticity

To help control spasticity make sure the warm-up exercises are included at the beginning of each session. Key areas to stretch on all patients include the, hamstrings, gastrocnemius, and soleus muscles.

Range of Motion

Maintaining a good range of motion (ROM) is necessary for normal joint kinematics during exercise. Make sure the warm-up exercises are included at the beginning of each session.

Shoulder Pain

Although the exception rather than the rule, the susceptibility of developing shoulder pain for participants in the LEAPS trial needs to be recognized. During shoulder exercises, ensure proper scapular-humeral alignment.

Strains

There is a risk of causing a muscle strain or ligament sprain during exercise because of reduced sensation and strength in the patient, particularly if the patient has not engaged in resistive exercise. Closely monitor the patient and encourage the patient to report any discomfort.

Counting Visits

Upon arrival at participant's home if participant is unable to participate in HEP secondary to a medical reason, complete Section A and B of the D form, recording participant's vitals. This session will be counted towards participant's total number of sessions.

Upon arrival at participant's home and participant is unable to participate in HEP for non-medical reasons (i.e. not home, not expecting you so engaged in another activity, sleeping) complete Section A of the D form. This session will be counted towards participant's total number of sessions.

TRAINING STANDARDIZATION

Overview

Standardization of the home exercise program (HEP) intervention across all sites entails a two-step process: initial training of the trainers, and on-going review and quality control for implementation of the standardized intervention throughout the trial.

Objectives

To know:

Standardized procedures for home exercise program intervention

Requirements for new trainers.

Process for maintaining standardization throughout the trial.

Home Exercise Training Guidelines

Guideline 1: Progression through a series of upper extremity strengthening exercises

Guideline 2: Progression through a series of lower extremity strengthening exercises

Guideline 3: Progression through a series of balance exercises.

Guideline 4: Provide 1.25 - 1.5 hours of individualized attention though the duration of the exercise program.

Standardization procedures for the HEP intervention

The Clinical Research Coordinators and co-PIs will be responsible for evaluating standardization and assessing competency throughout the trial. The HEP intervention will be standardized to achieve consistent implementation of the intervention across clinical sites. Standardization will assure that the intervention therapists successfully implement a common intervention through knowledge and application of six critical elements:

- 1) the HEP protocol including the division of the protocol into three discrete phases
- 2) progression
- 3) patient safety and monitoring;
- 4) equipment use
- 5) hands-on training skills; and
- 6) documentation of session

Documentation procedures will be standardized across sites requiring the trainers to record in a computerized database:

- The amount of time spent with the participant
- The exercises performed on a given session
- The number of repetitions or number of seconds engaged in a given