

eAddenda

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Pesi H Katrak and Stephanie Potts (2010)

Treadmill walking with body weight support in subacute non-ambulatory stroke improves walking capacity more than overground walking:
a randomised trial

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Appendix 1

**The MOBILISE Trial
Subject Eligibility Checklist**

Patient name : _____

Date of stroke : _____

Inclusion Criteria

1. First stroke (can be a subsequent stroke if previous stroke did not result in residual disability in walking) yes / no
 2. Within 28 days post stroke yes / no
 3. Aged between 50 and 85 years yes / no
 4. Unilateral hemiplegia/hemiparesis yes / no
 5. Score for Item 5 of MAS <2 (ie, 0 or 1) yes / no
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Exclusion Criteria

1. Any barriers to taking part in a physical rehabilitation program yes/no
 2. Insufficient cognition/language yes / no
 3. Unstable cardiac status yes / no
 4. Neuro-surgery yes / no
 5. Pre-morbid history of orthopaedic problems or any other problems that would preclude patient from the walking yes / no
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Eligible for study **yes / no**

If yes for all inclusion criteria but no for first 3 exclusion criteria, check again within 28 days of stroke.

If still no: File sheet in back of folder under no

If yes: Information sheet to subject

Gain consent

Contact uni for randomisation (with name, MAS, site)

Start intervention ASAP Date: _____

Organise for weekly measurement starting Date: _____

The MOBILISE Trial
Subject Information on Admission to Study

Addressograph :

Name :

Address :

Telephone :

Next of kin : _____ Tel :

First language :

DOB / Age : _____ Gender :

Date of stroke :

Side of hemiplegia :

CT scan report:

Weight :

Height :

Score Item 3 MAS :

Sensation :

Spasticity :

Neglect :

Date of Day 1 of training:

Date 6 months later:

Address of discharge :

The MOBILISE Trial

Procedures for assessment of Spasticity, Sensation, and Neglect

Spasticity

- In lying with knee extended, check amount of passive dorsiflexion.
- Within available range, move ankle from full plantarflexion into dorsiflexion at a moderate speed.
- Grade muscle response according to the Ashworth Scale:
 - Grade 0 = no increase in tone
 - Grade 1 = slight increase in tone giving a 'catch' when the limb is moved in flexion or extension
 - Grade 2 = more marked increase in tone but limb easily flexed
 - Grade 3 = considerable increase in tone - passive movement difficult
 - Grade 4 = limb rigid in flexion or extension

Sensory loss

- In lying with knee extended, get subject to close eyes
- Move affected foot to new position and ask subject to touch affected toe with intact toe.
- Touch foot lightly and ask subject to report when foot is touched.
- Grade sensory loss according to the following:
 - 0 = none
 - 1 = some
 - 2 = complete

Neglect

- Sit subject at table
- Put A4 page with 10-cm line directly in front of subject
- Ask subject to put a mark in the middle of the line
- Grade neglect by measuring distance from the true middle and categorising:
 - Grade 0 = Normal = within 5 mm
 - Grade 1 = Slight neglect = between 5-20 mm
 - Grade 2 = Severe neglect = > 20 mm

The MOBILISE Trial Intervention – both groups

Experimental group

- 30 min treadmill walking with BWS and assistance of one + \leq 60 min lower limb exercise/training

Control group

- 30 min overground walking and assistance of one + \leq 60 min lower limb exercise/training

Both groups

Subjects in this study are not allowed to:

1. walk more than 2-3 consecutive steps as part of remaining therapy/training
2. do more than 60 min of supervised or semisupervised exercise/training of the lower limbs

The MOBILISE Trial

Intervention – experimental group

30 min treadmill walking with BWS + ≤ 60 min lower limb exercise/training

Procedure

1. Start on Day 1 after recruitment (within 28 days after stroke)
2. Notify measurer to start weekly YES/NO measures
3. Bring subject to gym
4. Carry out 30 min walking with BWS on treadmill and overground walking - 30 minutes from beginning (from when subject is in wheelchair in gym) to end (when subject is back in wheelchair or on plinth), ie, includes transferring time, putting on harness etc.
5. Two acclimatisation sessions (with a helper)
6. After the 2 acclimatisation sessions, trainer may get help only to transfer subject, put harness on and wheel subject onto treadmill and into standing
7. Push subject but not beyond the bounds of safety, take rests as needed, session may last less than 30 minutes but no more than 30 minutes
8. When patient can walk with harness for safety only and at a speed of 0.4 m/s, start to introduce 10 min of overground walking.
9. When finished training, return subject to wheelchair and fill in recording sheet
10. When measurer records walking as independent, measurer to take 10 m measures

30-minute session (maximum)

- If very disabled, put harness on in lying and use automatic lifter on system to stand subject
- If less disabled, put harness on partially in sitting and get subject to stand and then put groin straps on
- Get subject to rest hands on the bar – bandage on if necessary
- Put light shoes and foot bandage on affected foot
- If patient is too disabled to walk on treadmill (after 2 acclimatisation sessions), get them to walk on the spot and practice lifting feet rhythmically
- Support body weight – enough that the patient can attempt to help during stance phase, be guided by the knee being reasonably extended in mid-stance
- Run treadmill slowly enough that patient can attempt to help
- If need to lift leg through, sit on stool with trunk support. During stance, get patient to try and straighten knee. During swing, move hip hand to behind knee to flex knee and knee hand to foot bandage to lift foot through.
- Concentrate on normal step length – keep leg on ground till hip in extension
- When patient can contribute, start speeding up treadmill. Systematically, increase speed of treadmill to 0.4m/s, then decrease BWS, then start overground walking.
- Overground walking may be done with help (physical or standby) from one therapist.
- Once walking overground is introduced, this should be carried out in bare feet.

Equipment

- Timer
- Harness
- Foot bandage for lifting foot through

The MOBILISE Trial

Intervention – control group

30 min overground walking + ≤ 60 min lower limb exercise/training

Procedure

1. Start on Day 1 after recruitment (within 28 days after stroke)
2. Notify measurer to start weekly YES/NO measures
3. Bring subject to gym
4. Carry out 30 min overground walking - 30 minutes from beginning (from when subject is in gym) to end (when subject is back in wheelchair or on plinth), ie, includes transferring time, putting on splint, AFO etc.
5. Two acclimatisation sessions (with a helper)
6. After the 2 acclimatisation sessions, trainer may get help only to transfer subject, put on splint and stand subject
7. Push subject but not beyond the bounds of safety, take rests as needed, session may last less than 30 minutes but no more
8. When patient can walk with assistance of one person, may be given stick
9. Return subject to wheelchair
10. Fill in recording sheet
11. When measurer records walking as independent, measurer to take 10 m measures

30-minute session (maximum)

- Practice should be carried out in bare feet.
- If very disabled, put knee splint on in sitting and get help to stand subject
- If patient is too disabled to walk with the help of one person (after 2 acclimatisation sessions), get them to step forwards and backwards
- If subject is too disabled to step, practise standing and shifting weight side to side and walking on the spot practising lifting intact foot
- May use walking aids (knee splint, AFO, parallel bars, forearm support frame)
- May only give stick when subject can walk with standby assistance of one person or when subject is about to be discharged.
- Concentrate on decreasing assistance

Equipment

- Timer
- Splints
- Walking aids

Name: _____

Group: _____

The MOBILISE Trial
Record of intervention
Control group: = 30 min overground walking

Date of Day 1 of training: _____

Date of stroke: _____

Weight: _____

Height: _____

Details of overground walking session:

Day in training	Date	Distance walked (m)	# of steps	Amount of assistance	Aid Y / N	Comments (including adverse events for both therapist and patient)
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						

Name: _____

Group: _____

The MOBILISE Trial
Record of intervention
Experimental group: = 30 min treadmill walking

Date of Day 1 of training: _____

Date of stroke: _____

Weight: _____

Height: _____

Details of treadmill walking session:

Day in training	Date	% load weightbearing	Speed of treadmill	Distance walked (m)	# of steps	Amount of assistance	Aid Y / N	Comments (including adverse events for both therapist and patient)
1								
2								
3								
4								
5								
6								
7								
8								
9								
10								

Name: _____

Date: _____

Side of hemiplegia: _____

The MOBILISE Trial Outcome measures

Date of Day 1 of training: _____ **Date of stroke:** _____

Able to walk 15 metres independently? ie, *able to walk 15 m continuously in bare feet with no assistance meaning no aids or help from therapist (15 m is roughly the length of the gym)*

Date: _____

Yes / No

Date: _____

Yes / No

Date: _____

Yes / No

Date: _____

Yes / No

Date: _____

Yes / No

Date: _____

Yes / No

Date: _____

Yes / No

Date: _____

Yes / No

Date of Measure 1 (on independent walking): _____

10 m time : _____ s

No. steps in 10m: _____ steps

Date of Measure 2 (6 months after admission to study): _____

Independent walking : Yes / No

10 m time : _____ s No. steps in 10 m: _____ steps

6 min distance : _____ m

6 min aids : Yes / No 6 min rests : _____ #

6 month questionnaire: Yes/No Falls since discharge _____

Adelaide Activities Profile: Yes/No

Name: _____

Date: _____

Side of hemiplegia: _____

The MOBILISE Trial
Outcome Measures Checklist

10 m walk test – comfortable	
Time to walk 10 m (sec)	
Number of steps in 10m	
Comments	
6 min walk test	
Distance (in metres to nearest cm)	
Use of aids	
No of rests	
Comments	
6 month questionnaire	
Adelaide Activities Profile - score	
Falls since discharge	

Name: _____

Date: _____

Side of hemiplegia: _____

**The MOBILISE Trial
6 month questionnaire**

1. After being discharged from the hospital rehabilitation unit, did you receive walking therapy from a physiotherapist as an outpatient?

YES / NO

If YES, give details:

How many times a week _____

For how long _____

2. After being discharged from the hospital rehabilitation unit, have you attended a gym or community exercise program?

YES / NO

If YES, give details:

What type of exercise _____

How many times a week _____

For how long _____

3. On a scale of 1-10, how do you rate your walking compared with before you had your stroke? _____

4. How far do you think you could walk? _____

5. How often do you go out?

At least 1 x day / 1 x week / 1x fortnight / 1 x month / less than 1 x month

6. Any other comments about your walking? _____

Name: _____

Date: _____

Side of hemiplegia: _____

The MOBILISE Trial

6 month measurement: mobility status and living arrangements

1. Have you had any falls since discharge from the hospital rehabilitation unit?

YES /NO

If yes, give details: How many ? _____

2. After discharge from the hospital rehabilitation unit, where did you go to live?

HOME INDEPENDENT LIVING UNIT HOSTEL NURSING HOME

3. What type of residence are you living now?

HOME INDEPENDENT LIVING UNIT HOSTEL NURSING HOME

4. If at home or in an independent living unit, do you:

Live with a spouse or significant other? YES /NO

Receive regular domestic cleaning? YES /NO

Receive meals on wheels? YES /NO

Require a community nurse? YES /NO

Require community transport? YES /NO

Name: _____

Date: _____

Side of hemiplegia: _____

The MOBILISE Trial Adelaide Activities Profile Questionnaire

Instructions

I am going to ask you some questions about a number of activities in which you may participate. I want you to tell me how often you participate in each activity in a typical 3 month period. If you like, you could think about the past 3 months.

1. How often have you prepared a main meal?

Never Less than once a week 1 to 2 times a week Most days _____

2. How often have you washed the dishes?

Less than once a week 1 or 2 days a week Most days Every day _____

3. How often have you washed clothes?

Never About once a month About once a fortnight Once a week _____

4. How often have you done light housework?

Never Once a fortnight or less About once a week Several days a week _____

5. How often have you done heavy housework?

Never About once a month About once a fortnight Once a week or more _____

6. How many hours of voluntary or paid employment have you done?

None Up to 10 hours a week 10 to 30 hours a week More than 30 hours a week _____

7. How often have you cared for other family members?

Never About once a month About once a fortnight Once a week or more _____

8. How often have you done household shopping?

Never About once a month About once a fortnight Once a week or more _____

9. How often have you done personal shopping?

Never Once in 3 months About once a month Once a fortnight or more _____

10. How often have you done light gardening?

Never About once a month About once a fortnight Once a week or more _____

11. How often have you done heavy gardening?

Never About once a month About once a fortnight Once a week or more _____

Name: _____

Date: _____

Side of hemiplegia: _____

The MOBILISE Trial

Adelaide Activities Profile Questionnaire continued

12. How often have you done household and/or car maintenance?

Never Once in 3 months About once a month Once a fortnight or more _____

13. How often have you needed to drive a car or organise your own transport?

Never Up to once a month Up to once a fortnight Once a week or more _____

14. How often have you spent some time on a hobby?

Never About once a month About once a week More than once a week _____

15. How many telephone calls have you made to friends and family?

None Up to 3 calls a week 4 to 10 calls a week Over 10 calls a week _____

16. How often have you invited people to your home?

Less than a fortnight About once a fortnight About once a week More than once a week _____

17. How often have you participated in social activities at a centre such as a club, a church, or a community centre?

Less than once a month About once a month About once a week More than once a week _____

18. How often have you attended religious services or meetings?

Never About once a month About once a fortnight Once a week or more _____

19. How often have you participated in an outdoor social activity?

Never About once a month About once a fortnight Once a week or more _____

20. How often have you spent some time outdoors participating in a recreational or sporting activity?

Never About once a month About once a week More than once a week _____

21. How often have you walked outdoors for 15 minutes or more?

About once a month or less About once a fortnight About once a week Most days _____

Total _____