

# A Comparison Between Two Physical Therapy Treatment Programs for Subjects with Lumbar Spinal Stenosis (LSS): A Randomized Clinical Trial

<b>Submission date</b> 11/10/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 25/10/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 16/05/2013	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

### Secondary identifying numbers

FWH20010030H

# Study information

## Scientific Title

### Study objectives

Subjects receiving a program that includes manual physical therapy, exercise, and a body weight supported ambulation program will achieve superior outcomes compared to the subjects receiving flexion based exercise, sub-therapeutic ultrasound, and a treadmill walking program without body weight support.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Not provided at time of registration

### Study design

Randomised controlled trial

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

### Study setting(s)

Not specified

### Study type(s)

Treatment

## Participant information sheet

### Health condition(s) or problem(s) studied

Lumbar Spinal Stenosis

### Interventions

Individualized Rehabilitation Group: Manual physical therapy, exercise, body weight supported treadmill ambulation

Traditional Rehabilitation Group: Flexion exercises, level treadmill ambulation, and placebo ultrasound

### Intervention Type

Other

### Phase

Not Specified

**Primary outcome measure**

Global Rating of Change

**Secondary outcome measures**

Modified Oswestry, Treadmill Test, Swiss Spinal Stenosis Scale, NPRS, Patient Specific Functional Scale

**Overall study start date**

01/06/2001

**Completion date**

30/01/2005

## **Eligibility**

**Key inclusion criteria**

1. Age greater than or equal to 50 years and eligible for military health care
2. Magnetic resonance imaging (MRI) findings consistent with LSS (evidence of compression of lumbar spinal nerve root(s) by degenerative lesions of the facet joint, disc, and/or ligamentum flavum)
3. Chief complaint of pain in the low back, buttock and/or lower extremity(s)
4. Rates sitting as a better position with respect to symptom severity than standing or walking
5. Lives within one hour of either Brooke Army Medical Center or Wilford Hall Medical Center
6. Can attend regular physical therapy appointments for six weeks (2 appointments per week) and three examination appointments (baseline, end of treatment, and 1 year after completion of treatment)
7. Sufficient English reading and language skills and mental capability to complete pain and functional assessment questionnaires

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

60

**Key exclusion criteria**

1. Severe vascular, pulmonary or coronary artery disease which limits ambulation (as determined by the referring physician, the specialist, or the therapist)
2. Other orthopedic conditions or physical impairments of unrelated nature which would limit ambulation or prevent the subject from fully participating in any other aspect of the rehabilitation exercises (as determined by the referring physician, the specialist, or the therapist)
3. Previous spinal surgery
4. History of spinal tumors, spinal infection, or lumbar vertebral fractures other than spondylolysis or spondylolisthesis

5. Inability to have an MRI scan of the lumbar spine. As with any standard MRI scan, the MRI clinic staff will determine if a subject may or may not complete the test. The following conditions may exclude a patient from being able to have the MRI scan: pacemaker, biomedical implants, a history of metal work or hobbies including metal work, cochlear implants, metal in the eye, claustrophobia, obesity (over 440 lbs).

**Date of first enrolment**

01/06/2001

**Date of final enrolment**

30/01/2005

## Locations

**Countries of recruitment**

United States of America

**Study participating centre**

3485 W 115th Ave

Westminster

United States of America

80031

## Sponsor information

**Organisation**

Wilford Hall Medical Center (USA)

**Sponsor details**

59 CRES

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**Sponsor type**

Hospital/treatment centre

**ROR**

<https://ror.org/025m0q735>

# Funder(s)

## Funder type

Charity

## Funder Name

Orthopaedic Section of the American Physical Therapy Association (\$10,000); US Air Force Surgeons General (\$10,000)

# Results and Publications

## Publication and dissemination plan

Not provided at time of registration

## Intention to publish date

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	15/10/2006		Yes	No
<a href="#">Results article</a>	results	01/10/2012		Yes	No