

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

Submission date 11/10/2005	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 25/10/2005	Overall study status Completed	☐ Protocol
Last Edited 16/05/2013	Condition category Musculoskeletal Diseases	☐ Statistical analysis plan
		☒ Results
		☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

Global Rating of Change

Key secondary outcome(s))

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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)

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

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?
Results article	results	15/10/2006		Yes	No
Results article	results	01/10/2012		Yes	No