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Developing better care for the elderly patients with walking disability due to degenerative lumbar spine stenosis

Submission date	Recruitment status	[ ] Prospectively registered
29/09/2006	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
29/09/2006	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
06/01/2021	Musculoskeletal Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0626176966

Study information

Scientific Title
Developing better care for the elderly patients with walking disability due to degenerative lumbar spine stenosis

Study objectives
Not provided at time of registration

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)
Quality of life

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Musculoskeletal Diseases: Degenerative lumbar spine stenosis

Interventions
Walking tolerance will be measured with and without a stick.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure

Shuttle walking crossover test: difference in walking tolerance (measured in metres) between SWT with walking stick and SWT without walking stick. Each shuttle is 10 metres, thus the number of completed shuttles counted by the investigator will be multiplied by 10 to provide an outcome measure in metres.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/2006

Completion date
01/09/2008

Eligibility

Key inclusion criteria
1. Patients 65 and over
2. Unilateral or bilateral neurogenic claudication (NC), ie exercise induced leg pain on walking, relieved in sitting
3. Patient reported limitation of walking tolerance due to symptoms of NC

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
20

Key exclusion criteria
1. Cognitive impairment preventing full understanding or participation in the study
2. Evidence of medical conditions such as hip/leg pathology or peripheral vascular disease, which may mimic NC or prevent participation in a shuttle walking test
3. Severe or worsening neurological status
4. Signs/symptoms of cauda equina compression, inflammatory joint disease, signs/symptoms of sinister pathology (unexplained weight loss, unremitting/night-time pain, history of cancer), which may require urgent surgical opinion. This will be determined through subjective and objective examination of patients by the recruiting researcher at the point of screening
5. Exclusion criterion for Home Trial Pilot phase only: previous use of walking aid

Date of first enrolment
01/01/2006

Date of final enrolment

01/09/2008

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Wharfedale Hospital
Otley
United Kingdom
LS21 2LY

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2006 Update - Department of Health

Sponsor details
The Department of Health, Richmond House, 79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
Bradford South and West Primary Care Trust (UK), NHS R&D Support Funding

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?
Results article	results	30/09/2013	06/01/2021	Yes	No