# Physiotherapy for Sciatica: Is Earlier Better?

Submission date	Recruitment status  No longer recruiting	[X] Prospectively registered		
10/12/2015		[X] Protocol		
Registration date 10/12/2015	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited	Condition category	Individual participant data		
25/04/2019	Musculoskeletal Diseases			

## Plain English summary of protocol

Background and study aims

Sciatica is the name given to pain in the lower back or legs, caused by the compression (squeezing) or irritation of the sciatic nerve. The sciatic nerve is the longest nerve in the body, running from the spine at the level of the lower back through the hips and buttocks and down each leg. One of the most common causes causes of sciatica occurs when the sciatic nerve is compressed (squashed) or irritated by one of the discs which separate the bones in the spine (vertebrae) sticking out (herniating). Typically, most people only experience sciatica on one side of the body, and the pain can range from mild to so severe that it is physically disabling. In most people, the condition can improve on its own however physiotherapy is widely used in order to speed up recovery. A Physiotherapist is able to help devise a management programme with the patient in order to improve function, help pain management and optimise the bodys' natural healing response. The length of time between referral from the GP and physiotherapy can vary greatly in different parts of the UK however this is thought to be because of local clinical commissioning group decisions rather than medical recommendations. The aim of this study is to compare the benefits of early physiotherapy (within 2 weeks of referral) to the standard wait time (of around 6 weeks) in the treatment of patients with sciatica. The study also aims to find out whether it would be possible to conduct a larger trial in the future.

## Who can participate?

Adults between 18 and 70 years old with sciatica in one leg.

## What does the study involve?

Participants are randomly allocated to one of two groups. Participants in the first group are referred to see a physiotherapist within 2 weeks of seeing their GP. Each participant is interviewed by the physiotherapist and their physiotherapy regimen is tailored to their individual needs. Participants in the second group a referred to see a physiotherapist around 6 weeks after seeing their GP, as is usual practice. After 6 months, participants in both groups are interviewed in order to find out whether they feel that they have reached the goals that they set in the initial meeting with the physiotherapist. The amount of participants that took part and how many continued to the end of the study is then recorded, so that the investigators can decide whether a larger study would be appropriate.

What are the possible benefits and risks of participating? Not provided at time of registration Where is the study run from? Northern General Hospital (UK)

When is the study starting and how long is it expected to run for? February 2016 to August 2017

Who is funding the study? National Institute for Health Research (UK)

Who is the main contact? Mr Michael Reddington

## Contact information

## Type(s)

Public

#### Contact name

Mr Michael Reddington

#### **ORCID ID**

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#### Contact details

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# Additional identifiers

EudraCT/CTIS number

**IRAS** number

ClinicalTrials.gov number

NCT02618278

Secondary identifying numbers

19794

# Study information

### Scientific Title

Physiotherapy management Of LumbAr Radicular syndrome: does early intervention improve outco

#### Acronym

## **Study objectives**

The aim of this study to investigate the effects of early intervention physiotherapy for people with sciatica, and to determine the feasibility of performing a full-scale trial.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

East of Scotland Research Ethics Service, 20/08/2015, ref: 15/ES/0130

## Study design

Mixed methods randomised controlled trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

### Study setting(s)

Other

## Study type(s)

Treatment

## Participant information sheet

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

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

Topic: Musculoskeletal disorders; Subtopic: Musculoskeletal (all Subtopics); Disease: Musculoskeletal

#### Interventions

Participants are randomly allocated to one of two groups.

Group 1: Participants receive an individual, goal-orientated physiotherapy management package within 2 weeks G.P referral for physiotherapy.

Group 2: Participants receive the same individual, goal-orientated physiotherapy management as the intervention arm but at 6 weeks post G.P referral, as is usual care.

Participants in both groups are followed up at 6 months post-randomisation.

#### Intervention Type

Other

#### Primary outcome measure

- 1. Recruitment rate is determined at 26 weeks
- 2. Attrition rate is determined at 26 weeks

#### Secondary outcome measures

- 1. Feasibility measures for a future, full-scale trial include attrition rates, recruitment rate, acceptability of the intervention to patient and clinician, patient adherence to the intervention and will be measured with monthly report and analysis
- 2. Oswestry Disability Index will be used to assess self-rated disability at baseline, 6 weeks, 12 weeks and 26 weeks
- 3. Pain will be measured using the VAS pain scale for back and leg pain at baseline, 6 weeks, 12 weeks and 26 weeks
- 4. General health status will be measured using the EQ5D-5L tool at baseline, 6 weeks, 12 weeks and 26 weeks

## Overall study start date

01/02/2016

#### Completion date

01/02/2018

# **Eligibility**

#### Key inclusion criteria

- 1. Aged between 18 and 70 years of age
- 2. Presence of unilateral lumbar radicular syndrome (defined as pain and or sensory disturbance and or weakness in a dermatomal and/or myotmal distribution)

## Participant type(s)

Patient

## Age group

Adult

#### Lower age limit

18 Years

#### Sex

Both

## Target number of participants

Planned Sample Size: 80; UK Sample Size: 80; Description: 80 patients will be recruited from primary care G.P practices and randomised into 2 groups.

#### Total final enrolment

80

#### Key exclusion criteria

- 1. Bilateral lumbar radicular syndrome (LRS)
- 2. Patients with 'red flag' signs and symptoms of potential serious pathology

- 3. Cancer at the time of the study
- 4. Proven vascular claudication
- 5. Cauda Equina Syndrome (CES)
- 6. Spinal fracture within the last 3 months
- 7. Chronic regional pain syndromes
- 8. Recent lower limb fracture
- 9. CVA with physical and/or psychiatric disability
- 10. Poor English skills (necessitating the use of an interpreter and invalidating outcomes measures--ODI as well as increasing costs)
- 11. Other significant co-morbidities preventing regular attendance at physiotherapy clinics
- 12. Patients with significant mental health problems for which treatment adherence may be difficult or psychologically disabling (at the discretion of the referring G.P)

### Date of first enrolment

01/02/2016

#### Date of final enrolment

06/11/2016

## Locations

### Countries of recruitment

England

**United Kingdom** 

## Study participating centre Northern General Hospital

South Yorkshire Cardiothoracic Unit Sheffield Teaching Hospitals NHS Trust Herries Road Sheffield United Kingdom S5 7AU

# Sponsor information

#### Organisation

Northern General Hospital

#### Sponsor details

South Yorkshire Cardiothoracic Unit Sheffield Teaching Hospitals NHS Trust Herries Road Sheffield England United Kingdom S5 7AU

## Sponsor type

Hospital/treatment centre

#### **ROR**

https://ror.org/05r409z22

# Funder(s)

## Funder type

Government

#### **Funder Name**

National Institute for Health Research

#### Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

## **Funding Body Type**

Government organisation

## **Funding Body Subtype**

National government

#### Location

**United Kingdom** 

## **Results and Publications**

## Publication and dissemination plan

Planned publication of study results in a peer reviewed journal, as well as presentation at relevant conferences.

## Intention to publish date

31/07/2017

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?
<u>Protocol article</u>	protocol	03/03/2017		Yes	No
Results article	results	28/07/2018	25/04/2019	Yes	No
HRA research summary			26/07/2023	No	No