ISRCTN75449581 https://doi.org/10.1186/ISRCTN75449581

Stratified care for patients with sciatica in primary care

Submission date
31/10/2014

Recruitment status
No longer recruiting

Registration date
20/11/2014

Overall study status
Completed

Last Edited
13/10/2020

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
"Sciatica" describes patients who have back-related leg pain, often felt below the knee, or other leg symptoms such as pins and needles or muscle weakness. It has a significant impact on patients' lives, which can lead to problems doing everyday activities, time off work, and financial burdens for the patient and their family and health and social services. Whilst many patients have mild problems, up to 30% of sufferers have pain for a year or more and incur considerable costs. In primary care (for example, in a GP setting) our research shows that up to 70% of patients with back-related leg pain either have sciatica or are suspected of suffering from the condition. Patients with sciatica tend to be managed with a 'wait and-see' approach, with some eventually being referred to other healthcare professionals. This could include physiotherapists for help with pain and function, or spinal specialists including pain specialists and orthopaedic surgeons. Current treatments range widely from information and advice, medications, exercise and manual therapy, and more invasive treatments such as spinal injections and surgery. One particular problem for patients is the current delay in treatment. The wide variation in the management of patients throughout the UK means that some patients are offered unnecessary treatments whilst others have to wait a long time to get treatments that will work. The recently published NHS Spinal Taskforce (January 2013) made some recommendations based largely on the opinion of experts rather than research evidence, highlighting the urgent need for good quality trial evidence about treatments for sciatica. Given that the responsibility for early treatment decisions for patients with sciatica is in primary care, high quality research in this setting is particularly needed. Here, we want to improve primary care management of patients with sciatica through a new approach called stratified care. Stratified care is a model of care with two components; clearer identification and subgrouping of patients with different characteristics and ii) matching of patient subgroups to different treatments. lt includes early identification of patients who are most likely to benefit from referral to spinal specialists. Our stratified care approach combines systematic information about individual patients' likelihood of recovery (prognostic information) with information from their clinical history and physical examination (clinical indicators of the severity of sciatica) in order to ensure that the right patient gets the right treatment at the right time. Using a systematic, step-by-step procedure that combines information about each patient's likelihood of a poor outcome (for example, not respond well to treatment) and the presence of important clinical indicators, patients with sciatica will be grouped into one of three subgroups (referred to as low, medium and high risk)

and matched to appropriate and timely treatments. Patients will be grouped into those likely to get better who can be given good advice and self-help support in up to two treatment visits, those with more troublesome problems who should be referred for a course of physiotherapy treatments and those with more significantly troublesome problems who need to be seen early by spinal specialists for assessment and treatment.

Who can participate?
Adults aged at least 18, who are going to their GP with sciatica or suspected sciatica. They must also have a mobile phone that can receive and send SMS texts or have access to a land line telephone.

What does the study involve?
Participants are randomly allocated into one of two groups. Those in group 1 receive the usual care. Those in group 2 receive stratified care. Participants in group 2 are placed into a subgroup according to predicted outcome. Those placed in the low risk subgroup are given a brief treatment package by physiotherapists in up to two treatment visits. Those in the medium risk subgroup receive an average of 6 treatment sessions over an average of 3 months tailored to their needs. Those in the high risk subgroup are fast tracked to spinal specialists for assessment of their suitability for other treatments such as spinal injections or surgery. All participants report on their symptoms via a weekly SMS text message for the first 4 months and then monthly from months 4 to 12 or until the participant reports on two consecutive months that they have recovered.

What are the possible benefits and risks of participating?
There are no direct risks of taking part in the trial. The care participants receive from their doctor will not be affected. This is a randomised trial therefore participants cannot choose which treatment (care) pathway they receive. This helps us to make a fairer comparison between the two different types of care provided in the study. However, the treatments in the care pathways we are testing in this study are currently used in the care of sciatica.

Where is the study run from?
Research Institute for Primary Care and Health Sciences at Keele University (UK)

When is the study starting and how long is it expected to run for?
May 2015 to August 2018

Who is funding the study?
National Institute for Health Research (NIHR) Health Technology Assessment programme (UK)

Who is the main contact?
Professor Nadine Foster

Contact information

Type(s)
Scientific

Contact name
Prof Nadine Foster

Contact details

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Keele University
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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Stratified care for patients with sciatica and suspected sciatica in primary care: a randomised trial (the SCOPiC trial - SCiatica Outcomes in Primary Care)

Acronym
SCOPiC

Study objectives
The management of primary care patients with sciatica and suspected sciatica can be improved through stratified care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee West Midlands - Solihull, 17/03/2015, ref: 15/WM/0078

Study design
Multi-centre pragmatic assessor-blind two-arm randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
1. Usual non-stratified care. Participants randomised to this arm will receive usual, non-stratified care. They will be seen by a physiotherapist for one off assessment and treatment including education and advice, with onwards referral to further treatment if necessary.
2. Stratified care. Participants randomised to this arm will receive treatment according to their risk subgroup (referred as low, medium, high):
2.1. Low risk subgroup: participants will receive a brief treatment package delivered by trial

physiotherapists, in up to two treatment visits.
2.2. Medium risk subgroup: participants will receive a course of physiotherapy treatment delivered in an average number of six sessions over an average of three months and tailored to their individual needs.
2.3. High risk subgroup: participants will be fast-tracked to spinal specialists for assessment and opinion about suitability for other treatments, such as spinal injections or surgery

Intervention Type
Mixed

Primary outcome(s)
Time to resolution of sciatica symptoms measured on a 6-point ordered categorical scale. Data will be collected by weekly SMS text messages for the first 4 months, then from months 4 to 12 the SMS data collection will change to monthly, or until patients report on two consecutive occasions that they have recovered.

Key secondary outcome(s))
1. Leg and back usual pain severity is measured using pain intensity of back and leg pain at baseline, 4 and 12 months
2. Disability is measured using Roland Morris Disability Questionnaire at baseline, 4 and 12 months
3. Overall impact of sciatica symptoms is measured using Sciatica Bothersomeness Index at baseline, 4 and 12 months
4. Sleep disturbance is measured using Jenkins sleep questionnaire at baseline, 4 and 12 months
5. Fear of movement is measured using Tampa Scale of Kinesiophobia at baseline, 4 and 12 months
6. Anxiety and depression is measured using Hospital Anxiety and Depression Scale at baseline, 4 and 12 months
7. Risk of poor outcome is measured using STarT Back Tool at baseline, 4 and 12 months
8. Quality of life is measured using EQ5D-5L at baseline, 4 and 12 months
9. General health is measured using SF-1 at baseline, 4 and 12 months
10. Neuropathic pain scales is measured using S-LANSS at baseline, 4 and 12 months
11. Days lost from work and productivity loss due to sciatica is measured using Questions on employment status and work absence (days) at 0, 4 & 12 months
12. Pain medication is measured using Patient Questionnaires at baseline, 4 and 12 months
13. Adverse events are measured using clinicians and Patient Questionnaires at baseline, 4 and 12 months
14. Patient satisfaction with care is measured using 5-point scale at baseline, 4 and 12 months
15. Health economic measures and health utilisation is measured using EQ-5D-5L at baseline, 4 and 12 months

Completion date
31/01/2019

Eligibility

Key inclusion criteria
1. Aged 18 years and over
2. Consulting in general practice with back and/or leg symptoms, and GP suspects sciatica
3. Following clinical assessment in research clinics, have a clinical diagnosis of sciatica
4. Have a mobile phone that can receive and send SMS texts or have access to a land-line

telephone
5. Able to read and communicate in English (to give full informed consent and to complete the baseline and outcome assessments)
6. Willing to participate

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
476

Key exclusion criteria
1. Have suspected serious spinal pathology or red-flags (eg. cauda equina syndrome, suspicion of spinal tumours, infection, fractures, inflammatory spondyloarthopathy)
2. Have had any previous lumbar spine surgery
3. Are currently receiving ongoing care from or have been in consultation with a secondary care doctor or physiotherapist for the same problem in the last 3 months
4. Have serious co-morbidity preventing them from attending the research clinic and/or been able to undergo assessment and potentially interventions
5. Have severe enduring mental health condition
6. Are currently pregnant
7. Are currently participating in any other research study because they have symptoms of back and leg pain or sciatica

Date of first enrolment
04/05/2015

Date of final enrolment
20/07/2017

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Keele University
Keele
United Kingdom
ST5 5BG

Sponsor information

Organisation
Keele University (UK)

ROR
https://ror.org/00340yn33

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and analysed during the current study will be available upon request from the Chief investigator. Requests should be emailed to: primarycare.datasharing@keele.ac.uk in which an external data request process will be initiated and considered. Consent was gained from participants for anonymised data to be used in future research and will be available for 5 years after the study has ended.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	25/06/2020	06/07/2020	Yes	No
Results article	results	01/10/2020	13/10/2020	Yes	No
Protocol article	protocol	26/04/2017		Yes	No
HRA research summary			28/06/2023	No	No