

Evaluation of the introduction of a new regional back pain process of care in the North East of England

Submission date 29/03/2016	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 06/04/2016	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 18/11/2021	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Low back pain is a major cause of disability and is one of the most costly conditions in the UK. Patient knowledge of the condition is poor which causes unrealistic expectations and demands on the NHS. These demands are met by a variation in back pain management which often results in expensive investigations and unsuccessful care leading to poor results and patients being unsatisfied. A new process (pathway) of managing back pain is being introduced in the north east of England. The main reason for this new pathway is to introduce a structured way of managing low back pain to reduce the current variation in the way low back pain patients are dealt with.

Who can participate?

Patients presenting with back pain in the north east of England.

What does the study involve?

Each participant is first assessed by their GP (or other first contact) using a back pain questionnaire. This determines whether they are sent to see a specialist Triage and Treat Practitioner (TTP) who then manage their treatment. The TTP decides on the next step of the treatment pathway the patient should attend. This may involve, for example, being referred to therapies such as exercises or acupuncture, attending an Intensive Combined Physical and Psychological Programme (a programme that includes intensive exercise, education and help with long-term self-management of the patients back pain), pain management services and possible surgical options. Data is collected through the use of a variety of clinically validated questionnaires and interviews with both patients and staff.

What are the possible benefits and risks of participating?

Not provided at time of registration

Where is the study run from?

The pathway will be introduced in four Clinical Commissioning Group regional areas, South Tees, Darlington, Hartlepool and Stockton on Tees, and Newcastle/Gateshead.

When is the study starting and how long is it expected to run for?
March 2016 to January 2018

Who is funding the study?
The Health Foundation (UK)

Who is the main contact?
Mr Shaun Wellburn
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Contact information

Type(s)

Public

Contact name

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Type(s)

Scientific

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Additional identifiers

Protocol serial number

N/A

Study information

Scientific Title

Implementation of the North East regional back pain pathway: an evaluation protocol

Study objectives

The key evaluation question is; following the implementation of an integrated pathway of care for people with low back pain and acute radiculopathy, what changes are seen in patient outcomes and experiences, and in the performance of the health service? This overarching question can be broken down into six evaluation objectives:

1. To measure and explain changes in the following clinical and social outcomes for patients:
 - 1.1. Pain
 - 1.2. Function
 - 1.3. Employment status
 - 1.4. Quality of life
 - 1.5. Overall improvement
2. To measure and explain changes in the following health service performance indicators:
 - 2.1. Frequency and nature of patient contacts with health professionals
 - 2.2. Frequency and nature of medical investigations (e.g. X-Rays, MRI)
 - 2.3. Waiting times
 - 2.4. Referral patterns
3. To examine the cost effectiveness of the pathway.
4. To gain an understanding of patient experiences and perceptions of the implementation.
5. To gain an understanding of clinicians' and strategic leaders' experiences and perceptions of the implementation
6. To assess the sustainability and the scalability of the back pain pathway

Ethics approval required

Old ethics approval format

Ethics approval(s)

Teesside University Ethics Committee, 18/09/2015, ref. 115/15 and R179/15

Study design

Mixed methods multi-centre interventional evaluation

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Back pain

Interventions

A new clinical pathway of care which operationalises NICE guidelines. Key aspects of the pathway are the use of the STarT Back tool to guide pathway route, and case management of patients through Triage and Treat practitioners (specialist allied health professionals and nurses).

Individuals attending the GP practice or first contact provider (e.g. physiotherapist) will complete a STarT Back questionnaire. The score of the STarT Back will determine whether the patient is discharged, with advice, to self-management or follows the new back pain pathway.

Once referred into the pathway the patient will attend with the Triage and Treat Practitioner (TTP). Triage and Manage Practitioner will then refer, as appropriate, to one of the following options:

1. Core therapies (manual therapy, exercises, acupuncture)
2. Intensive Combined Physical and Psychological Programme (CPPP)
3. Pain services
4. Specialist spinal surgical opinion

Intervention Type

Mixed

Primary outcome(s)

1. Health status, assessed with the EuroQol (EQ5D) questionnaire, at base
2. Pain, assessed using a Pain Numerical Rating Scale
3. Disability caused by back pain, assessed using the Oswestry Disability Index

A qualitative analysis will also be conducted utilising Normalisation Process Theory. Data is collected at baseline, and then again after 5 months and 12 months.

Key secondary outcome(s)

1. Anxiety, assessed using the General Anxiety Disorder Assessment (GAD7)
2. Patients impression of change in condition, assessed using the Global Subjective Outcome Scale (GSOS)
3. Quality of service, assessed using the Friends and Family Test (FFT)
4. Depression, assessed using The Patient Health Questionnaire (PHQ9)
5. Self-management
6. Work status
7. Work loss
8. Health-care usage
9. Cost-effectiveness analysis

Data is collected at baseline, and then again after 5 months and 12 months.

Completion date

31/01/2018

Eligibility

Key inclusion criteria

1. Patients: Individuals who have presented with low back pain in the North East of England
2. Non-patients: Individuals who are involved in the implementation and delivery of the Regional Back Pain Pathway

Participant type(s)

Mixed

Healthy volunteers allowed

No

Age group

All

Sex

All

Total final enrolment

136

Key exclusion criteria

There are no specific exclusion criteria

Date of first enrolment

30/03/2016

Date of final enrolment

01/06/2017

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Hartlepool and Stockton on Tees Clinical Commissioning Group

Billingham Health Centre

Queensway

Billingham

United Kingdom

TS23 2LA

Study participating centre

Darlington Clinical Commissioning Group

Dr Piper House

King Street

Darlington

United Kingdom

DL3 6JL

Study participating centre

Newcastle Gateshead Clinical Commissioning Group

Goldcrest Way

Newburn Riverside (Business Park)

Newcastle Upon Tyne

United Kingdom
NE15 8NY

Study participating centre
South Tees Clinical Commissioning Group
14 Trinity Mews
Middlesbrough
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TS3 6AL

Sponsor information

Organisation
Teesside University

ROR
<https://ror.org/03z28gk75>

Funder(s)

Funder type
Charity

Funder Name
The Health Foundation

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/05/2021	18/11/2021	Yes	No