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# 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

**Registration date**
06/04/2016

**Overall study status**
Completed

**Last Edited**
18/11/2021

**Condition category**
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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

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Scientific

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# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
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

## Secondary study design
Non randomised study

## Study setting(s)
GP practice

## Study type(s)
Treatment

## Participant information sheet

## 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 measure
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.

## Secondary outcome measures
1. Anxiety, assessed using the General Anxiety Disorder Assessment (GAD7)
2. Patients impression of change in condition, assesed 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.

## Overall study start date
30/03/2016

## 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

### Age group
All

### Sex
Both

### Target number of participants
For the qualitative aspect approximately 60 participants. For the quantitative component it is difficult to project the total throughput of patients during the time frame of the evaluation. However, it is anticipated that this will be greater than 1000 participants.

### 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
England

United Kingdom

### 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
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## Sponsor information

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### Sponsor type
University/education

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**ROR**
https://ror.org/03z28gk75

# Funder(s)

**Funder type**
Charity

**Funder Name**
The Health Foundation

# Results and Publications

**Publication and dissemination plan**
1. To publish one paper on the quantitative findings within six months of completion of the evaluation.
2. To publish two papers on the qualitative findings within six months of completion of the evaluation.

**Intention to publish date**
31/07/2018

**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 |