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Stepping up the evidence for musculoskeletal services

Submission date
05/07/2013

Recruitment status
No longer recruiting

Registration date
05/07/2013

Overall study status
Completed

Last Edited
14/03/2017

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
This study is evaluating local NHS services for patients with pain conditions. Aches and pains are very common symptoms. The study aims to find out more about patients with pain or pain-related symptoms and the services available to them.

Who can participate?
Patients aged 18 or over seeing a GP with a pain or pain-related problem and who are registered at one of the four participating GP practices will be invited to take part in the study.

What does the study involve?
It involves completion of four questionnaires in total over a period of 12 months and a medical record review, where a researcher will collect information from the patient's medical records about their pain or related symptoms over the 12 months of the study.

What are the possible benefits and risks of participating?
We do not expect any problems for patients from taking part in this study and although there is no direct benefit from taking part, what we learn from the study should help to develop better services for patients with pain and pain-related symptoms in the future.

Where is the study run from?
The study is run by a research team based at the Arthritis Research UK Primary Care Centre at Keele University, UK.

When is the study starting and how long is it expected to run for?
Recruitment began in early June 2013 and is expected to be completed by January 2014. Follow-up of participants will continue until January 2015.

Who is funding the study?
Charitable Trust of the Chartered Society of Physiotherapy (CSP) (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
14803

Study information

Scientific Title
STEMS study: STepping up the Evidence for Musculoskeletal Services: a pilot cluster randomised controlled trial

Acronym
STEMS

Study objectives
Musculoskeletal problems are common and costly, leading to 9.3 million lost working days in the UK per year. The most common presentations include low back pain, shoulder pain, neck pain, knee pain and widespread pain where many sufferers develop persistent or recurrent problems. Given our ageing population and the impact of these problems, the demand for musculoskeletal healthcare is set to rise.
For most patients in the UK, the first professional seen is the GP and access to NHS physiotherapy is controlled through GP referral. For example approximately 1.3 million of all consultations for low back pain in UK general practice are referred onwards to physiotherapists. This pilot randomised controlled cluster trial will test the addition of a self-referral to

physiotherapy pathway to usual GP-led care. Self-referral is a system of access in which patients are able to refer themselves to a physiotherapist directly without having to see anyone else first or without being told to refer themselves by a doctor. All patients in the trial (intervention and control) will receive care for their musculoskeletal condition as indicated by their clinical need and as directed by their health care professionals, but patients in the intervention practices will have the option to self-refer to physiotherapy. We aim to recruit for a 6 month period estimating that around 960 participants will be recruited. Participants will complete questionnaires at baseline, 2, 6 and 12 months providing information about their musculoskeletal condition, the care received for the condition and clinical and cost outcomes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
First MREC approval date 08/02/2013, ref: 13/NW/0053

Study design
Randomised; Interventional; Design type: Not specified

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

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: Primary Care Research Network for England; Subtopic: Not Assigned; Disease: All Diseases

Interventions
Self referral physio pathway. The intervention is the addition of a self-referral to physiotherapy pathway to usual GP-led care for patients with a musculoskeletal condition
Study Entry: Single Randomisation only

Intervention Type
Other

Phase
Phase III

Primary outcome measure

Physical function, measured by Version 2.0 of SF-36 Health Survey Scoring Demonstration (SF36v2) physical component summary at baseline, 2, 6 and 12 months follow-up

Secondary outcome measures
1. Accessibility of services; Timepoint(s): 2 and 6 months
2. Baseline risk of persistent problems; Timepoint(s): Baseline only
3. Comorbidities; Timepoint(s): Baseline only
4. Demographics; Timepoint(s): Baseline only
5. Experience of consultations; Timepoint(s): Baseline, 2 and 6 months
6. Further health care utilisation; Timepoint(s): 2 and 6 months
7. Mental health; SF36v2 Mental Component Summary; Timepoint(s): baseline, 2, 6 and 12 months
8. Overall change in condition; Global Assessment of Change one question; Timepoint(s): 2, 6 and 12 months
9. Pain duration; Timepoint(s): Baseline only
10. Pain location; Timepoint(s): Baseline only
11. Presenteeism; Timepoint(s): Baseline, 2, 6 and 12 months
12. Quality of Life; Timepoint(s): Baseline, 2, 6 and 12 months
13. Satisfaction with services; Timepoint(s): 2 and 6 months
14. Self-efficacy; Timepoint(s): Baseline, 2, 6 and 12 months
15. Understanding of condition; Timepoint(s): Baseline, 2, 6 and 12 months
16. Willingness to pay; Timepoint(s): 12 months only
17. Work absence; Timepoint(s): Baseline, 2, 6 and 12 months

Overall study start date
10/06/2013

Completion date
31/12/2013

Eligibility

Key inclusion criteria
Adults consulting participating GP practices or physiotherapy services with musculoskeletal problems (for either their first consultation for a new episode of musculoskeletal pain or a reconsultation)
Target Gender: Male & Female ; Lower Age Limit 18 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 960; UK Sample Size: 960

Key exclusion criteria
1. Under 18 years old
2. Those consulting with nonmusculoskeletal problems
3. Those unable to provide their own consent to the research evaluation
4. Those undergoing palliative care
5. Those with severe learning disabilities or are housebound or are in nursing home accommodation
6. Those unable to communicate in English

Date of first enrolment
10/06/2013

Date of final enrolment
31/12/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Keele University
Newcastle
United Kingdom
ST5 5BG

Sponsor information

Organisation
Keele University (UK)

Sponsor details
Keele
Newcastle
England
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Sponsor type
University/education

ROR
https://ror.org/00340yn33

Funder(s)

Funder type
Charity

Funder Name
Chartered Society of Physiotherapy Charitable Trust (UK)

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?
Protocol article	protocol	01/12/2015		Yes	No
Results article	results	12/03/2017		Yes	No
HRA research summary			28/06/2023	No	No