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SWAP - Study of Work And Pain

Submission date	Recruitment status	[_] Prospectively registered
25/10/2012	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
26/10/2012	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
10/07/2018	Musculoskeletal Diseases	

Plain English summary of protocol

Background and study aims
Recent government reviews highlighted that primary care is a key arena to address work-related issues in patients who experience pain. However, such a service has not been implemented in primary care before. The aim of this study is to test the clinical and cost-effectiveness of introducing a vocational advisor into GP practices to provide a structured approach to managing work-related issues in primary care patients with musculoskeletal pain problems.

Who can participate?
Adults aged 18 to 70 struggling with work or off sick from work due to musculoskeletal pain

What does the study involve?
Participating GP practices are randomly allocated to either the control group or the intervention group. Practices in the control group provide the best current care while the intervention practices provide the best current care and also access to the vocational advisory service. All participants are followed up at 4 and 12 months. Interviews are conducted with about 20 patients who have accessed the vocational advisory service.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Four GP practices in the Primary Care Research West Midlands North area of South Staffordshire (UK)

When is the study starting and how long is it expected to run for?
July 2012 to January 2014

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

Who is the main contact?
Sarah Lawton, Study Coordinator
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
13183

Study information

Scientific Title
Primary care management of work related issues in patients with musculoskeletal conditions

Acronym
SWAP

Study objectives
This study is a pilot randomised controlled cluster trial that will include up to 6 GP practices within Primary Care Research West Midlands North. We aim to recruit 360 patients aged between 18 and 70, 180 patients in each group. Information about the characteristics (pain, disability, psychological factors, employment, other health conditions) of these patients will be collected on postal questionnaires at baseline, and during one-year follow-up.

This pilot trial will inform us about the feasibility and acceptability of running a full-scale randomised trial, including information about the recruitment and response rates. In addition, the pilot involves interviewing GPs, Nurse Practitioners, patients and vocational advisors to assess their feedback and an early assessment of the costs of the vocational advice service and issuing GPs a brief questionnaire to explore experiences of the sickness certification process.

More details can be found at: https://www.ukctg.nihr.ac.uk/trials/trial-details/trial-details?trialId=3230

Ethics approval required
Old ethics approval format

Ethics approval(s)
Staffordshire Research Ethics Committee, First MREC approval date 18/04/2012, ref: 12/WM/0020

Study design
Randomised; Interventional; Design type: Treatment

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
Musculoskeletal pain

Interventions
Vocational Advice Service.
Intervention Practices will consist of best current care as determined by the GP practice. In addition, a vocational advice service will be provided at each GP practice allocated to the intervention arm. GPs and Nurse Practitioners will be able to refer patients to the vocational advisor.

All patients (in both arms) will receive the same information about the research evaluation indicating that this consists of completing questionnaires at baseline, four months and twelve months from the date of identification."

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Work absence at baseline, 4 months and 12 months follow up

Secondary outcome measures
Measures of pain at baseline, 4 months and 12 months follow up

Overall study start date
03/07/2012

Completion date
31/01/2014

Eligibility

Key inclusion criteria
1. Primary care consulters with musculoskeletal pain
2. Adults 18 to 70 years of age
3. Currently employed (paid)
4. Current sickness absence of less than 6 months duration, (either GP or self-certified absence) due to musculoskeletal pain OR
5. Patients assessed by the GP (or a nurse practitioner), during the consultation, as struggling with work due to musculoskeletal pain

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 360; UK Sample Size: 360

Key exclusion criteria
1. Patients with symptoms of possible serious pathology, requiring urgent medical attention
2. Patients unable to read and speak English (Information sheets, cover letters and questionnaires are in English). The postal questionnaires will have a contact name and telephone number that participants can call to discuss any difficulties or help required with completion of the consent form or the questionnaire. Potential participants will need to be able to understand the cover letter and information sheet which explains the study to them, before they can consent to take part. People who can speak English but not write English will however be included and their questionnaires will be completed by telephone. In addition, all interviews will be conducted in English.
3. Patients with serious mental health problems who are vulnerable and for whom participation in the study would be detrimental (at the GP's discretion)
4. Current pregnancy or those patients on maternity leave

Date of first enrolment
03/07/2012

Date of final enrolment
31/01/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Arthritis Research UK Primary Care Centre
Newcastle-Under-Lyme
United Kingdom
ST5 5BG

Sponsor information

Organisation
Keele University (UK)

Sponsor details
Arthritis Research UK Primary Care Centre
Newcastle-Under-Lyme
England
United Kingdom
ST5 5BG

Sponsor type
University/education

ROR
https://ror.org/00340yn33

Funder(s)

Funder type
Government

Funder Name
Programme Grants for Applied Research

Alternative Name(s)
NIHR Programme Grants for Applied Research, PGfAR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Publications are planned for Spring 2017.

Intention to publish date
30/06/2017

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	10/07/2014		Yes	No
Results article	results	01/01/2018		Yes	No
Other publications	development and content of the intervention and training package	01/06/2019		Yes	No