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Primary care Osteoarthritis Screening Trial (POST): a cluster randomised trial of an electronic prompt for comorbidity screening in clinical osteoarthritis consultations in primary care

Submission date
21/06/2011

Recruitment status
No longer recruiting

Registration date
21/06/2011

Overall study status
Completed

Last Edited
23/07/2019

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
10334

Study information

Scientific Title
Primary care Osteoarthritis Screening Trial (POST): a cluster randomised trial of an electronic prompt for comorbidity screening in clinical osteoarthritis consultations in primary care

Acronym
POST

Study objectives
POST is a cluster randomised clinical trial that will compare pain intensity and interference outcomes over a 12-month period in osteoarthritis (OA)/joint pain patients screened for depression and anxiety (intervention arm) to those who receive usual care (control arm; screened only for pain intensity).

As a cluster randomised trial the GP practices will be randomised (to one of the 2 arms) rather than the patients. We aim to recruit 44 GP practices in total in order to screen and contact 1745 patients. Recruitment of patients from GP practices will take place over 12 months. It is anticipated that patients will be contacted within 1-2 weeks of their index consultation with a baseline questionnaire and those who consent will be followed-up with further postal questionnaires 3, 6 and 12 months following their baseline. These questionnaires contain detailed questions on pain intensity and interference (our primary outcomes) and further questions on anxiety, depression, pain catastrophising, health economics and demographics. A medical record review of treatments, diagnoses and referrals will be conducted for patients who consent

Ethics approval required
Old ethics approval format

Ethics approval(s)
11/WM/0093; First MREC approval date 04/04/2011

Study design
Randomised; Interventional; Design type: Screening

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Screening

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
Osteoarthritis

Interventions
Generalised Anxiety Disorder-2 (GAD-2)
1. Eligible patients in the intervention arm consulting their GP for osteoarthritis or joint pain will be asked these 4 questions on depressive and anxiety symptoms during their consultation:
1.1. Modified Patient Hlth Quest
1.2. Modified Patient Health Questionnaire (PHQ-2)
2. Eligible patients in the intervention arm consulting their GP for osteoarthritis or joint pain will be asked these 4 questions on depressive and anxiety symptoms during their consultation
3. Follow-up length: 12 months

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Self report measure of current pain intensity measured at baseline, 3 months, 6 months and 12 months

Secondary outcome measures
1. Anxiety (GAD-7 (5)) at baseline, 3 months, 6 months and 12 months
2. Body mass index (from self reported height and weight) at baseline, 3 months, 6 months and 12 months
3. Characteristic Pain Intensity and Disability Score at baseline, 3 months, 6 months and 12 months
4. Demographics (marital status and occupation/employment details) at baseline, 3 months, 6 months and 12 months
5. Depression (PHQ-8 (4)) at baseline, 3 months, 6 months and 12 months
6. Detailed questions about pain at baseline, 3 months, 6 months and 12 months
7. Medication and health care use at baseline, 3 months, 6 months and 12 months
8. Overall quality of life (EQ5D (2) and SF-36 (3)) at baseline, 3 months, 6 months and 12 months
9. Pain Catastrophising Scale (6) at baseline, 3 months, 6 months and 12 months
10. Pain interference with daily activities at baseline, 3 months, 6 months and 12 months
11. Social support (questions taken from previous postal surveys) at baseline, 3 months, 6 months and 12 months

Overall study start date
29/07/2011

Completion date
30/09/2012

Eligibility

Key inclusion criteria
1. Aged 45 years and over
2. Registered with the participating GP practices during the specified study period of that practice
3. Read-coded peripheral joint pain or OA consultation within the specified study period (termed the index consultation)
4. May be first, new episode, or ongoing consultation)
5. Provided full written informed consent to study participation and to further contact
6. Male & female

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 1309; UK Sample Size: 1309

Key exclusion criteria
1. Patients who are under active care for or who have a diagnosis of depression and/or an anxiety disorder in the past 12 months
2. Vulnerable patients, including any patients on the Quality and Outcomes Framework mental health register, or those who have a diagnosis of dementia or a terminal illness
3. Patients who reside in a nursing home
4. Red flag pathology
5. Recent trauma associated with significant injury
6. Acute, red, hot swollen joint
7. Inflammatory arthropathy, crystal disease, spondyloarthropathy and polymyalgia rheumatic

Date of first enrolment
29/07/2011

Date of final enrolment
30/09/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Keele University
Newcastle under Lyme
United Kingdom
ST5 5BG

Sponsor information

Organisation
Keele University

Sponsor details
Keele
Newcastle under Lyme
England
United Kingdom
ST5 5BG

Sponsor type
University/education

Website
http://www.keele.ac.uk/

ROR
https://ror.org/00340yn33

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research, ref: RP-PG-0407-10386 (United Kingdom)

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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?
Results article	results	11/04/2017		Yes	No
Results article	results	01/07/2018		Yes	No
Other publications	cost-utility analysis	01/12/2018	23/07/2019	Yes	No