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Management of osteoarthritis in consultations study: the development of a complex intervention in primary care

Submission date
04/07/2011

Recruitment status
No longer recruiting

Registration date
04/07/2011

Overall study status
Completed

Last Edited
27/07/2018

Condition category
Musculoskeletal Diseases

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims

Osteoarthritis (OA) is the most common type of arthritis, affecting millions of people worldwide. It occurs when the protective cartilage on the end of bones wears away. The bones then rub against one another, causing stiffness, pain and a reduction in the range of movement. One of the most effective ways to treat long-term illnesses is by giving the sufferer the tools and skills to manage their conditions day-to-day. NICE provides extensive guidelines for self-management of OA however it has been found that they are not always used in standard care. Generally, people are willing to participate in self-management of their condition, however many people feel that they need more support from healthcare professionals to do this. It is thought that by providing GP's with the necessary tools to support self-management of OA could help more people to manage their condition effectively. Using a special template the consultations given to people suffering from OA could make consultations more consistent (model OA consultation, MOAC); ensuring that self-management of the disease is successfully promoted by healthcare professionals. The aim of this study is to find out whether the MOAC is a practical way of promoting self-management of OA.

Who can participate?

GP surgeries which are members of West Midlands North PCRN or a Keele Research Network Practice, and adults with a diagnosis of OA who attend these practices.

What does the study involve?

The study is made up of two parts. In the first part of the study, the existing care that is given to OA sufferers is monitored in all participating GP surgeries by reviewing patient records and completing questionnaires with patients and healthcare professionals. In the second part of the study the participating GP surgeries are randomly allocated into two groups. For those in the first group (intervention group), healthcare professionals receive additional training to help them to better implement the OA treatment recommendations. Patients at these practices are also given an information book to help them manage their condition. Surgeries in the second

group (control group) do not receive any additional training and provide only usual care to patients. At the end of the study period, patient notes are reviewed in both groups to assess the standard of care being given.

What are the possible benefits and risks of participating?
Although no direct benefit from taking part in this study can be guaranteed, what we learn from the study should help us to treat people with osteoarthritis in the future. People with joint problems do occasionally feel that even filling in a brief questionnaire can cause some discomfort, although this should be short-lasting and does not indicate any underlying change in their condition. If an interview topic brings back unhappy memories or distressing thoughts that participants do not wish to discuss, the topic will not be followed up again during the interview.

Where is the study run from?
Keele University (UK)

When is the study starting and how long is it expected to run for?
May 2011 to February 2014

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

Who is the main contact?
Miss Jacqueline Gray
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Study website
https://www.keele.ac.uk/pchs/keelectu/studies/mosaics/

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
10104

Study information

Scientific Title
Management of Osteoarthritis in Consultations Study: the development of a complex intervention in primary care (MOSAICS): a pilot cluster randomised controlled trial

Acronym
MOSAICS

Study objectives
The MOSAICS Study is a mixed methods study which investigates the feasibility, acceptability and impact of implementing a new approach to supporting self management for osteoarthritis (OA) in primary care.
1. To develop and pilot a new model of supported self management [i.e. a Model OA Consultation (MOAC) and guidebook] in primary care
2. Carry out a cross sectional survey of the local population to establish current uptake of NICE core recommendations in people aged 45 years and over with joint pain
3. Carry out anonymised medical record reviews to describe the current patterns of management of OA in primary care, and to describe any change in management following introduction of a structure template to support a model OA consultation.
4. Carry out an evaluation of the new approach using qualitative interviews and structured observations with patients and the primary healthcare team.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North West 1 Research Ethics Committee-Cheshire, First MREC approval date 14/10/2010, ref: 10 /H1017/76

Study design
Both; Interventional and Observational; Design type: Diagnosis, Process of Care, Screening, Treatment, Qualitative

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
Not available in web format, please contact s.hill@cphc.keele.ac.uk to request a patient information sheet

Health condition(s) or problem(s) studied
Topic: Primary Care Research Network for England, Musculoskeletal; Subtopic: Not Assigned, Musculoskeletal (all Subtopics); Disease: Musculoskeletal, All Diseases

Interventions
A Joint Pain/OA Consult Temp: Template developed to record Quality Indicators for OA. To be used as part of routine consultations for patients presenting with a working diagnosis of OA (knee, hip, hand and foot) in primary care; A Model OA Consultation, a three pronged 'Model OA Consultation' has been developed and will be implemented in the four intervention practices.

The model includes consultation with the GP, consultation with the practice nurse, (educational intervention and self management support) and an opportunistic consultation with other health care professionals. An osteoarthritis guidebook, developed using national guidelines and experiential knowledge by a multi disciplinary group in collaboration with patients living with OA. The patient guidebook will be used as a resource for self care management of their OA, and to act as a reinforcement of verbal information given by health care professionals during the model consultation sessions.

Training packages for health care professionals (HCPs) in the intervention practices will receive training developed from
1. The results of two previously conducted consensus exercises on the consent and style of a model OA consultation and
2. Theoretical models to guide self management of OA.

Follow Up Length: 12 month(s)

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Test the feasibility of using quality indicators for OA as the primary outcome measure; Timepoint (s): At 21 months

Secondary outcome measures
1. A trial of paracetamol at up to 4 g/day prior to treatment with oral non steroidal anti-inflammtory drugs (NSAIDs) or opiate analgesics; Timepoint(s): At 15 and 21 months
2. Advice about weight loss; Timepoint(s): At 15 and 21 months
3. Cost utility analysis compare template & model plus template; Timepoint(s): At 3,6 and 12 and 21 months
4. Does training change HCP behaviour; Timepoint(s): Immediately after training and 6 months after training

5. Practice Level outcome measures: Frequency and pattern of Read coding of OA and joint pain; Timepoint(s): At 15 and 21 months
6. Practice Level outcome measures: Frequency of OA consultations with other health professionals; Timepoint(s): At 15 and 21 months
7. Practice Level outcome measures: Medication use for OA and joint pain; Timepoint(s): At 15 and 21 months
8. Prescription of a proton pump inhibitor (PPI) during NSAID therapy; Timepoint(s): At 15 and 21 months
9. Records of being offered information on exercise or activity; Timepoint(s): At 15 and 21 months
10. Records of being offered information on referral to a physiotherapist; Timepoint(s): At 15 and 21 months
11. Records of being offered information on referral to an exercise programme; Timepoint(s): At 15 and 21 months
12. Records of being offered information on the condition (OA); Timepoint(s): At 15 and 21 months
13. Topical NSAIDs prior to treatment with oral NSAIDs or opiate analges; Timepoint(s): At 15 and 21 months

Overall study start date
11/05/2011

Completion date
13/02/2014

Eligibility

Key inclusion criteria
General Practitioners (GP) practices
1. Member of West Midlands North PCRN or a Keele Research Network Practice
2. At least two GPs willing to undertake the study as per protocol i.e. act as a control or intervention practice
3. Willing, and able, to allow one (or for preference two - to allow for cross cover) of their practice nurses to be trained to deliver MOAC 2 and then deliver it in the practice
4. Willing, and able, to allow a PCRN employed nurse trained to deliver MOAC 2 working in their practice
5. Uses the EMIS GO computerised consultation system
6. For the implementation study and evaluation studies additional inclusion criteria are:
As above plus
6.1. GP who has received training and has delivered MOAC 1
6.2. Nurse who has received training and has delivered MOAC 2
6.3. Nurse consenting to observation and audio recording of the MOAC 2 consultation
6.4. Members of the multidisciplinary team who have delivered the MOAC 3 intervention
6.5. Practice Manager in intervention practices
6.6. Administrators in intervention practices

Patients
1. Males and females
2. 45 years and over
3. Registered with a MOSAICS study practice
4. Consenting to further contact from the study team and medical record review from their

response in the Population Survey
5. For the evaluation studies additional criteria are:
5.1. Patients from the intervention practices who have consulted a GP, been given a diagnosis of OA and received the model OA consultation (MOAC)
5.2. To be invited to take part in an individual or group interview participants must have completed the MOSAICS Consultations Questionnaires
5.3. Audio recording and observation of MOAC 2 consultations will only be carried out if a patient has given prior consent to do so

Target Gender: Male & Female ; Lower Age Limit 45 years

Participant type(s)
Mixed

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 15000; UK Sample Size: 15000

Key exclusion criteria
GP Practices
1. Single handed GP practices
2. Single handed practice nurse
3. Unable to physically accommodate MOAC 2 consultations

Patients
Excluded via GP screen of practice list.
1. Unable to give fully informed consent e.g. learning difficulties or dementia
2. Resident in a care or nursing home
3. History of serious disease e.g. malignancy, terminal illness
4. Unable to consult in the general practice surgery
6. Inflammatory arthritis (e.g. rheumatoid arthritis, psoriatic arthritis)
7. Pregnancy

Date of first enrolment
11/05/2012

Date of final enrolment
11/01/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Keele University
Newcastle-Under-Lyme
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
Government

Funder Name
Programme Grants for Applied Research (Grant Codes: RP-PG-0407-10386)

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
Protocol published in 2014. Population survey, trial, template and qualitative publications scheduled for submission in 2016 and 2017.

Intention to publish date
31/12/2017

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	27/08/2014		Yes	No
Results article	results	01/05/2015		Yes	No
Results article	results	21/12/2016		Yes	No
Results article	results	01/10/2017		Yes	No
Results article	results	29/12/2017		Yes	No
Results article	results	01/01/2018		Yes	No
Results article	results	01/07/2018		Yes	No