ISRCTN16795883 https://doi.org/10.1186/ISRCTN16795883

Explaining osteoarthritis: development of a patient explanation package (PEP-OA)

Submission date 25/09/2019	**Recruitment status** No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 02/10/2019	**Overall study status** Completed	☐ Statistical analysis plan ☐ Results
Last Edited 24/03/2021	**Condition category** Musculoskeletal Diseases	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol

Background and study aims
Osteoarthritis is common, but healthcare professionals often do not have the right words to help patients understand the condition. This can result in patients feeling that their condition is being trivialised or negative beliefs about osteoarthritis, even before they have been diagnosed with it. Because osteoarthritis can cause pain upon moving the affected joint, patients often worry about, or may avoid, doing exercise (which is recommended to help joint pain) and patients can also doubt whether they can improve their symptoms. The aim of this study is to improve osteoarthritis explanations for patients to help their understanding of their condition and make sense of the management approaches suggested to them.

Who can participate?
Work packages 1 and 2: patients aged 47 or older who have consulted at their GP practice over the last 2 years with osteoarthritis
Work package 3:
Patients - responding to work packages 1 and 2 who give consent to future contact
Lay people - people aged 45 and older who have not had a diagnosis of osteoarthritis (potential patients in the future)
Healthcare professionals - those providing care to patients with osteoarthritis

What does the study involve?
The researchers will create a Patient Explanation Package for OsteoArthritis (PEP-OA) and the supporting package in four steps. Possible statements for an osteoarthritis explanation will be identified by professionals and patients. Patients will be asked which are the most important for all people with osteoarthritis. The most important statements will be tested to find out which have the most positive impact for patients. Draft explanations (made from the most important statements) will be developed and then tested among people with and without osteoarthritis and among healthcare professionals who would explain OA in their day-to-day role. The researchers will develop and test written and cartoon versions of a core explanation which will be relevant to all patients with osteoarthritis, and additional written statements that can be used to tailor the core information to individual patients. Once tested, the feedback and

learning will allow the researchers to finalise PEP-OA. A package will be developed and evaluated to support healthcare professionals to find out about the content and importance of PEP-OA and to make use of PEP-OA.

What are the possible benefits and risks of participating?
There may be no direct benefits from taking part. However, participants may get a better understanding of osteoarthritis and will be contributing to the development of improved explanations for patients with osteoarthritis. This will help to deliver better care and reduce uncertainty among patients with osteoarthritis in the future. It is not expected that there will be any risks from taking part in the study. Participants are free to decline to take part in sections of the discussions and/or to answer questions if they feel uncomfortable.

Where is the study run from?
NHS North Staffordshire via Keele University (UK)

When is the study starting and how long is it expected to run for?
April 2019 to March 2022

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

Who is the main contact?
Clare Jinks
c.jinks@keele.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Elizabeth Cottrell

ORCID ID
http://orcid.org/0000-0002-5757-1854

Contact details
School of Primary, Community and Social Care
Primary Care Centre Versus Arthritis
Keele University
Keele
United Kingdom
ST5 5BG
+44 (0)1782 734870
e.cottrell@keele.ac.uk

Type(s)
Scientific

Contact name
Prof Clare Jinks

ORCID ID
http://orcid.org/0000-0002-3407-2446

Contact details
School of Medicine
Keele University
Keele
United Kingdom
ST5 5BG
-
c.jinks@keele.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
RG-0291-19 IPCHS; CPMS: 42528

Study information

Scientific Title
Explaining osteoarthritis: development and implementation of a multimedia Patient Explanation Package

Acronym
PEP-OA

Study objectives
To improve osteoarthritis explanations for patients to:
1. Help their understanding of their condition
2. Make sense of the management approaches suggested to them

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 22/08/2019, East of England - Cambridge East Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; Tel: +44 (0)207 104 8101; Email: NRESCommittee.EastofEngland-CambridgeEast@nhs.net), REC ref: 19/EE/0221, IRAS Project ID: 252365

Study design

A variety of observational approaches will be used: adapted nominal group technique, conjoint survey questionnaire and think aloud interviews to develop the patient education package for osteoarthritis

Primary study design
Observational

Secondary study design
Qualitative research

Study setting(s)
GP practice

Study type(s)
Other

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Osteoarthritis

Interventions
WP1: A stakeholder co-design workshop with ongoing individual feedback will develop potential explanation statements within domains of the underpinning conceptual framework. Through a patient adapted nominal group technique consensus on priority explanation statements within each domain will be reached.
WP2: A partial-profile conjoint analysis patient study will estimate the extent to which new, prioritised, explanation statements are preferred over currently used/available statements.
WP3: Using the results of WP1 and WP2, the patient advisory group (PAG) will develop draft core (written and animated) and important additional (written) explanation statements. Think-aloud qualitative interviews will establish the comprehension and acceptability of the draft explanations. The core and important additional explanation statements will be finalised through co-design with the PAG.
WP4: Communities of practice approach will be used to develop knowledge mobilisation materials to support dissemination and implementation of the explanations. Early usage, acceptability and self-report impact data will be collected.

Intervention Type
Other

Primary outcome measure
WP1 - Adapted nominal group technique to collect 11 prioritised explanation statements to be taken forward for testing in the conjoint analysis.

WP2 - Partial-profile conjoint analysis questionnaire survey to ascertain the extent to which new, prioritised explanation statements are preferred over currently used/available statements for explaining OA

WP3 - Think-aloud interviews to identify the necessary refinements required to develop the final core OA explanation and important additional statements

WP4 - The early utility, acceptability and impact of PEP-OA measured using an on-line questionnaire and usage metrics gathered from the multimedia knowledge mobilisation package app

Secondary outcome measures
n/a

Overall study start date
01/04/2019

Completion date
31/03/2022

Eligibility

Key inclusion criteria
Work package 1 & 2:
1. Patients aged ≥47
2. Have consulted in their general practice in the last two years
3. Have a recorded consultation coded relating to osteoarthritis

Work package 3:
1. Patients who responded with consent-to-future contact in earlier stages of the research will be eligible for inclusion. In this way we are ensuring that the patients have recently consulted with a problem pertaining to osteoarthritis
2. Lay people aged 45 years or older who do not have a diagnosis of osteoarthritis (and thus are potential future patients)
3. Healthcare professionals who, in their usual clinical roles, give diagnoses to patients with osteoarthritis. These are likely to include, but may not exclusively be, General Practitioners, Primary Care Nurses and Physiotherapists

Participant type(s)
Mixed

Age group
Adult

Sex
Both

Target number of participants
Work package 1: 9; Work package 2: 300-400; Work package 3: 30

Key exclusion criteria
Work package 1 & 2: patients with
1. Severe mental illness
2. Rheumatoid arthritis

3. Psoriatic arthritis
4. Ankylosing spondylitis
5. Gout
6. Polymyalgia rheumatica
7. Moderate to severe learning disabilities
8. Dementia
9. Record that they lack capacity
10. Record that they are on the palliative care register
11. Recorded dissent to share their data
12. Inability to speak English

Work package 3:
1. Patients will only be excluded if they indicate they no longer wish to participate or if they have developed any of the exclusion conditions since the original search
2. Lay people will excluded if they report that they have previously been diagnosed with osteoarthritis
3. Healthcare professionals will be excluded if, in their clinical role, they have not provided a diagnosis of osteoarthritis to a patient in the last 6 months

Date of first enrolment
07/10/2019

Date of final enrolment
31/12/2021

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Keele University
School of Medicine
David Weatherall Building
Keele
United Kingdom
ST5 5BG

Sponsor information

Organisation
Keele University

Sponsor details

Directorate of Research, Innovation and Engagement
Keele
England
United Kingdom
ST5 5BG
+44 (0)1782732975
research.governance@keele.ac.uk

Sponsor type
University/education

Website
https://www.keele.ac.uk/admin/directorateofresearchinnovationengagement/

ROR
https://ror.org/00340yn33

Funder(s)

Funder type
Government

Funder Name
Research for Patient Benefit Programme

Alternative Name(s)
NIHR Research for Patient Benefit Programme, RfPB

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Patient and public involvement and engagement (PPIE): Patients with osteoarthritis confirmed this study's importance and strongly influenced the design of the first two stages. The PPIE co-applicant and regular patient advisory groups will ensure the study remains patient-focussed.

Dissemination: PEP-OA will be ready for use after two years. The researchers will write scientific articles, present the work at conferences and develop interactive cards to be given to patients. Circulation and use of PEP-OA will be supported through their existing links which include: the local implementation team, university educators, an NHS social media expert, healthcare and national arthritis and patient organisations.

Scientific papers planned are:
1. Paper describing the findings from work-packages 1 and 2 aiming for submission August 2020
2. Paper describing findings from work-package 3, including the final explanation

The researchers will submit the findings to scientific conferences:
1. Abstract describing the findings from work-packages 1 and 2 aiming for submission to national primary care conference February 2020
2. Abstract describing findings from WP3 and the complete explanation package to be submitted to international osteoarthritis conference likely submission deadline November 2020

The researchers are using pre-existing platforms for dissemination wherever possible:
1. Faculty Vimeo account to host the animations means no additional costs are attached. Other websites/dissemination documents can signpost people to the animations held here
2. Using an existing augmented reality technology app, for which the IP is held by our own institute, means no additional costs are required to enable this technology to be developed or licenced. The only new design work required for the augmented technology is for the appearance of the cards themselves and integration of these into the app
3. Networks associated with the team mean that there are immediate, easily accessible and low-cost routes into local, national and international routes to the dissemination of, implementation of and education about PEP-OA

Intention to publish date
01/05/2022

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during this current study will be available upon request from primarycare.datasharing@keele.ac.uk. Core data will be available immediately after main publication. A data request form is required to be completed and must outline the type of data to be obtained, the reason for obtaining this data (research question/objective), the timing for when the data is required to be available (start date/end date). Checks will be performed by a Data Custodian and Academic Proposals (DCAP) committee at Keele to ensure that the data set requested is appropriately suited to answer the research question/objective and that the request fits with the original ethical approval and participant consent and adheres to funder and legal restrictions. Only de-identified data are available for request in aggregated format or at the level of the individual participant.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			26/07/2023	No	No