

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

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| Submission date 25/09/2019 | Recruitment status No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered |
| | | <input type="checkbox"/> Protocol |
| Registration date 02/10/2019 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan |
| | | <input type="checkbox"/> Results |
| Last Edited 24/03/2021 | Condition category Musculoskeletal Diseases | <input type="checkbox"/> Individual participant data |
| | | <input type="checkbox"/> 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

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers**Clinical Trials Information System (CTIS)**

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

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

Study type(s)

Other

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(s)

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

Key secondary outcome(s)

n/a

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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 be 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

United Kingdom

England

Study participating centre

Keele University

School of Medicine

David Weatherall Building

Keele

United Kingdom

ST5 5BG

Sponsor information

Organisation

Keele University

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, Research for Patient Benefit (RfPB), The NIHR Research for Patient Benefit (RfPB), RfPB

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

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 |