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Increasing physical activity in older people with persistent musculoskeletal pain

Submission date
22/01/2019

Recruitment status
No longer recruiting

Registration date
26/02/2019

Overall study status
Completed

Last Edited
22/01/2024

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Updated 06/07/2021: The ongoing COVID-19 situation means that the study recruitment and analysis were not completed as planned. However, the study team have the opportunity to look into a slightly different question, using the information provided by study participants – how has the COVID-19 pandemic affected physical activity in older people with joint pain?
Below is the summary of the study as completed by study participants:

Background and study aims
Previous research has shown that chronic pain is very common in people aged 65 years and over, and usually occurs in more than one place on the body. The more pain a person has, the less likely they are to be physically active. Being physically active is good for you. Walking has been shown to be an acceptable and accessible form of physical activity for people aged 65 years and over. The aim of this study is to see if patients find the iPOPP walking intervention or receiving a pedometer in the post helpful in increasing or maintaining their activity levels, in comparison to usual care.

Who can participate?
Patients aged over 65 who have consulted at their GP practice with chronic musculoskeletal pain in the last 12 months. GP practices within the West Midlands must have signed up to the study in order for their patients to take part.

What does the study involve?
Patients are invited to provide information about their pain by filling in a brief screening survey. As part of the survey, the research team asks patients if they wish to be contacted again about the next stage of the research. Participants who consent to be contacted and who meet the eligibility criteria are sent a pack including a questionnaire and consent form for the main trial. A study administrator telephones each patient to confirm eligibility and consent to the trial. Those who confirm are sent a small physical activity monitor (accelerometer) to wear on their waist for 7 days. Once data from the accelerometer is received back at Keele CTU, patients are randomly allocated to one of three groups. All groups continue to receive health care from their GP as normal. The usual care group are provided with an information booklet about ways to manage joint pain. The pedometer group are provided with the pain information booklet, a pedometer user guide and an activity diary. The iPOPP Intervention Group are provided with the pain

information booklet, a pedometer, a pedometer user guide and an activity diary, and are offered two appointments with a trained Health Care Assistant to discuss and plan ways in which participants might be able to increase the amount of walking that they do. The first of these sessions will be held in their GP surgery, the second can be held in the surgery or over the telephone. They also receive weekly motivational messages over eight weeks (via postcard through the post or text message). Participants from all groups may also be invited to take part in an interview to explore their experiences of being involved in the study. Over 12 months, participants are asked to complete four questionnaires (start, 3,6 and 12 months later) and are asked to wear the accelerometer on four occasions (start, 3, 6 and 12 months later).

What are the possible benefits and risks of participating?
There may not be any direct benefit of participating in the study, however, patient involvement will help us learn more about physical activity in older people with joint pain. The results of the study will inform further research into the effectiveness of joint pain management in older people. Participation will impact on patient's time and will vary according to which group they are allocated to. All participants are asked to complete four questionnaires and wear a physical activity monitor for 7 days on four occasions. Each questionnaire will take approximately 20 minutes to complete. A small number of participants will be invited to take part in an interview about their experiences in the study. This could take up to 45 minutes.

Where is the study run from?
Participating GP practices within the West Midlands Clinical Research Network (CRN) (UK)

When is the study starting and how long is it expected to run for?
July 2018 to December 2021

Who is funding the study?
Versus Arthritis (UK)

Who is the main contact?
Sarah Lawton, Keele CTU Head of Operations

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
RG-0191-17

Study information

Scientific Title
The iPOPP study: a pragmatic, three-parallel-arm, individually randomised controlled trial with parallel health economic and process evaluation

Acronym
iPOPP

Study objectives
Current study hypothesis as of 06/07/2021:
Due to the COVID-19 pandemic, the original objectives cannot be achieved. Revised objectives are to describe levels of walking and physical activity and to understand the perspectives and experiences of older adults with chronic musculoskeletal pain during ongoing COVID-19 restrictions.

Previous study hypothesis:
The aim of the iPOPP study is to investigate whether either the iPOPP walking intervention (a brief behavioural intervention with a health care assistant) or a pedometer intervention (pedometer and activity diary sent in the post) are superior to usual primary care in terms of increasing average daily step count at 6 months in adults aged 65 years and over with persistent musculoskeletal pain.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 01/03/2019, West Midlands - Edgbaston Research Ethics Committee (The Old Chapel Royal Standard Place, Nottingham, NG1 6FS, Health Research Authority, +44 (0)207 104 8104; NRESCommittee.WestMidlands-Edgbaston@nhs.net), ref: 19/WM/0016

Primary study design
Observational

Study design
Observational study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Persistent musculoskeltal pain

Interventions
Participants will be individually randomised to one of the three arms of the study (allocation 1:1:1 ratio), using random permuted blocks, stratified by general practice.

Usual primary care:
Participants randomised to continue with usual primary care alone will continue to be managed as per usual care and will receive the Pain Toolkit in the post. Usual primary care management normally consists of a patient consulting their GP practice or practice nurse for their pain and may include advice and education, the prescription of medication and referrals to other appropriate services for example, Physiotherapy, podiatry, occupational therapy. It may or may not include advice and support about physical activity and walking.

Pedometer intervention:
Participants randomised to this group will continue with their usual care and in addition will receive a pedometer, a pedometer user guide, an activity diary and the Pain Toolkit in the post. Participants will be asked to keep the pedometer as a motivator and to use it as they see fit over the 10 week intervention period.

iPOPP walking intervention:
Participants randomised to this group will receive two consultations with a health care assistant (HCA) within a two week period where participants will receive a pedometer, a pedometer user guide, an activity diary and the Pain Toolkit and then 8 weekly motivational prompts. Participants allocated to this intervention arm will be offered an initial appointment for a face-to-face consultation at their general practice with a trained HCA to discuss and agree a walking plan. Participants will receive a second consultation either face-to-face or via telephone consisting of a review of progress since the first consultation, positive feedback in relation to effort and achievement, and possible revision of goals set. Participants will then receive the 8 weekly motivational prompts which will be in the form of a postcard or text designed to increase physical activity. Participants allocated to this intervention arm will also continue to be able to access usual care.

Consented participants and HCAs may be invited to take part in an interview to share perceptions and experiences of the interventions. Over 12 months, participants will be asked to complete four questionnaires (baseline, 3,6 and 12 months post randomisation) and asked to wear the accelerometer on four occasions (baseline, 3, 6 and 12 months post randomisation).

Intervention Type
Behavioural

Primary outcome(s)
Average daily step count per day over 7 days measured via accelerometry on four occasions (baseline, 3, 6 and 12 months post randomisation)

Key secondary outcome(s)
Measured at baseline, 3, 6 and at least 12 months follow up, except where specified differently:
1. Pain intensity and location, measured using the Numeric Pain Intensity Scale, pain manikin
2. Physical function, measured using the PF-10 from the SF-36
3. Physical activity, measured using IPAQ-E
4. Sedentary time, measured using accelerometry
5. Health-related quality of life, measured using EQ-5D-5L
6. Non-health aspects of quality of life, measured using ICECAP-O
7. Self-efficacy, measured using Self-Efficacy for Exercise Scale
8. Anxiety, measured using GAD-7
9. Depression, measured using PHQ 8
10. Healthcare resource use, measured using patient self -reported questionnaires at 6 and 12 months follow-up
11. Adverse events, measured using patient self -reported questionnaires at 3,6 and 12 months follow-up
12. Pedometer use, measured using patient self -reported questionnaires at 3,6 and 12 months follow-up
13. Consultation experience (iPOPP intervention only), measured using patient self -reported questionnaires at 3 month follow-up

Completion date
31/12/2021

Eligibility

Key inclusion criteria
1. Aged 65 years and over
2. Consulted at general practice for musculoskeletal pain in one or more index sites (foot, knee, hip, back, shoulder, neck) in the last 12 months
3. Registered with one of the participating GP practices during the specified trial period for that practice
4. Pain that has lasted for > 3 months and a current Chronic Pain Grade (Von Korff et al., 1992) score of between 2 to 4, determined through a brief postal chronic pain screening survey

Participant type(s)
Patient

Healthy volunteers allowed

No

Age group
Senior

Sex
All

Total final enrolment
386

Key exclusion criteria
1. Patients with complex medical conditions deemed at risk of walking-related complications (e. g. new onset chest pain (within the last 3 months, chest pain on exercise, severe hypertension, syncope (within the last 12 months), recent lower limb fracture (within the last three months), active and severe synovitis
2. Vulnerable patients (i.e. patients with significant cognitive impairment (e.g. dementia; psychotic illness), or in palliative stage of care)
3. Patients who reside in a residential or nursing homes
4. Unable to provide full, informed, written consent

Date of first enrolment
04/06/2019

Date of final enrolment
13/03/2020

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
GP practices within the West Midlands Clinical Research Network
United Kingdom
TF1 5QX

Sponsor information

Organisation
Keele University

ROR

https://ror.org/00340yn33

Funder(s)

Funder type
Charity

Funder Name
Versus Arthritis

Alternative Name(s)
Arthritis UK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/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?
Protocol article		08/12/2017	12/01/2023	Yes	No
HRA research summary			26/07/2023	No	No
Other unpublished results			22/01/2024	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes