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Increasing physical activity in older people with ch

Submission date	Recruitment status	[_] Prospectively registered
20/01/2016	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
20/01/2016	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
28/06/2021	Signs and Symptoms	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Chronic (long-term) pain is any pain that has lasted for more than 12 weeks. As we get older, it is particularly common to experience pain in muscles and joints (musculoskeletal pain), especially in the over 65s age group. Studies have shown that when a person is in pain, they are likely to avoid movement and physical activity which could make their pain worse. This has led to many people over the age of 65 becoming very inactive. The benefits of exercise on the body are well documented, and so it is important to encourage older people to be more active. An acceptable form of exercise which does not put too much strain on the body is walking. iPOPP (increasing physical activity in older people) is a new programme which has been developed to encourage older people to walk more. It involves face-to-face appointments with specially trained health care assistants (HCAs) as well as the delivery of motivational messages to encourage people to continue with the programme. The aim of this study is to find out whether the iPOPP programme is an effective way of improving physical activity in older people suffering from chronic pain.

Who can participate?
Adults aged 65 or over who have seen their GP about musculoskeletal pain in the last 12 months.

What does the study involve?
Participants are randomly allocated to one of three groups. Participants in the first group (control group) continue to receive usual care, such as seeing their GP, taking medication and receiving treatment (i.e. physiotherapy) and are also posted a copy of the pain toolkit (a simple booklet which provides tips and skills to help people to manage their chronic pain). Participants in the second group continue to receive their usual care, but are also given two appointments with a trained HCA. At the first appointment, they are given a pedometer and user guide, a walking diary (to record how much they are walking) and a copy of the pain toolkit and at the second appointment (by telephone) they are asked for feedback about how much they are walking. Participants also receive motivational messages every week for 8 weeks in the form of a postcard, email or text, to encourage them to maintain their walking plan. Participants in the third group receive the pedometer, user guide, walking diary and pain toolkit in the post, as well as continuing to receive their usual care.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Arthritis Research UK Primary Care Centre (UK)

When is the study starting and how long is it expected to run for?
December 2015 to May 2016

Who is funding the study?
Arthritis Research UK (UK)

Who is the main contact?
Ms Jacqueline Gray

Study website
https://www.keele.ac.uk/pchs/keelectu/studies/ipopp/

Contact information

Type(s)
Public

Contact name
Ms Jacqueline Gray

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
20117

Study information

Scientific Title
Increasing Physical activity in Older People with chronic musculoskeletal Pain: A brief and simple in

Acronym
iPOPP

Study objectives
The aim of this study is to find out whether a brief and simple intervention to promote walking can be delivered by Health Care Assistants (HCAs) and is acceptable to patients suffering with chronic musculoskeletal pain.

Ethics approval required
Old ethics approval format

Ethics approval(s)
15/WM/0329

Study design
Randomised; Interventional; Design type: Treatment

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Topic: Primary Care, Musculoskeletal disorders, Ageing; Subtopic: Musculoskeletal (all Subtopics), Ageing, Primary care; Disease: Musculoskeletal, All Diseases, All Ageing

Interventions
Participants are randomly allocated to one of three study arms.

Control arm: Participants will continue to be managed via usual care but will be posted a copy of the pain toolkit, which is a simple information booklet that provides patients with tips and skills to support them to manage their chronic pain. Usual primary care management normally consists of a patient consulting their GP or practice nurse for their pain and may include advice and education, the prescription of medication and referrals to other appropriate services i.e. physiotherapy, podiatry, occupational therapy.

iPOPP arm: Participants will be offered an initial appointment for a face-to-face consultation at their general practice with a trained HCA. At this initial consultation patients will receive a pedometer, the user guide and walking diary (as above) plus a copy of the pain toolkit. Participants will receive a second consultation either face-to-face or via telephone (depending on participant preference) consisting of a review of progress since session one, 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,

email or text. The type of prompt will be based on individual patient preference. Patients allocated to this intervention arm will also continue to be able to access usual care.

Pedometer arm: Participants will receive a pedometer, a pedometer user guide, a walking diary and the pain toolkit in the post. In addition, these patients will continue to be able to access usual care.

Intervention Type
Other

Primary outcome measure
Acceptability and feasibility of training the HCAs and delivery of the iPOPP intervention.

Secondary outcome measures
Not provided at time of registration.

Overall study start date
08/12/2015

Completion date
05/01/2017

Eligibility

Key inclusion criteria
1. Adults aged 65 years and over
2. Consulted at their general practice for musculoskeletal pain in one or more index sites (foot, knee, hip, back, shoulder or neck) in the last 12 months
3. Registered with one of the participating GP practices during the specified trial period for that practice
4. Chronic Pain Grade score of between 2 to 4, determined through a brief postal chronic pain screening survey
5. Able to provide full, informed, written consent

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 150; UK Sample Size: 150

Total final enrolment
160

Key exclusion criteria

1. Traumatic injury related pain (recent sports injury, fall or accident) to rule out traumatic fractures
2. Patients with complex medical conditions deemed at risk of exercise-related complications by their GP (e.g. chest pain on exertion, severe hypertension, congestive heart failure, syncope, uncontrolled epilepsy, recent fracture, active and severe synovitis)
3. Vulnerable patients (i.e. patients with significant cognitive impairment (e.g. dementia), or in palliative stage of care)
4. Patients who reside in a residential or nursing home

Date of first enrolment
08/12/2015

Date of final enrolment
30/05/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Arthritis Research UK Primary Care Centre
Primary Care Sciences
Keele University
Newcastle-Under-Lyme
United Kingdom
ST5 5BG

Sponsor information

Organisation
University of Keele

Sponsor details
Keele
Newcastle
England
United Kingdom
ST5 5BG

Sponsor type
University/education

ROR

https://ror.org/00340yn33

Funder(s)

Funder type
Charity

Funder Name
Arthritis Research UK

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
31/12/2021

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		01/03/2018	14/05/2021	Yes	No
HRA research summary			28/06/2023	No	No