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RESEARCH ARTICLE

The feasibility and acceptability of a physical activity intervention for older people with chronic musculoskeletal pain: The iPOPP pilot trial protocol*

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Abstract

Introduction: This pilot trial will inform the design and methods of a future full-scale randomized controlled trial (RCT) and examine the feasibility, acceptability and fidelity of the Increasing Physical activity in Older People with chronic Pain (iPOPP) intervention, a healthcare assistant (HCA)-supported intervention to promote walking in older adults with chronic musculoskeletal pain in a primary care setting.

Methods and analysis: The iPOPP study is an individually randomized, multicentre, three-parallel-arm pilot RCT. A total of 150 participants aged ≥65 years with chronic pain in one or more index sites will be recruited and randomized using random permuted blocks, stratified by general practice, to: (i) usual care plus written information; (ii) pedometer plus usual care and written information; or (iii) the iPOPP intervention. A theoretically informed mixed-methods approach will be employed using semi-structured interviews, audio recordings of the HCA consultations, self-reported questionnaires, case report forms and objective physical activity data collection (accelerometry). Follow-up will be conducted 12 weeks post-randomization. Collection of the quantitative data and statistical analysis will be performed blinded to treatment allocation, and analysis will be exploratory to inform the design and methods of a future RCT. Analysis of the HCA consultation recordings will focus on the use of a checklist to determine the fidelity of the iPOPP intervention delivery, and the interview data will be analysed using a constant comparison approach in order to generate conceptual themes focused around the acceptability and feasibility of the trial, and then mapped to the Theoretical Domains Framework to understand barriers and facilitators to behaviour change. A triangulation protocol will be used to integrate quantitative and qualitative data and findings.

KEYWORDS

chronic pain, older people, osteoarthritis, physical activity, primary care, walking

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1 | INTRODUCTION

Musculoskeletal (MSK) pain is reported by 66% of older adults (Thomas, Peat, Harris, Wilkie, & Croft, 2004). Patients with chronic MSK pain have reduced physical activity (van den Berg-Emons, Schasfoort, Vos, Bussmann, & Stam, 2007) and pain is an important predictor of physical inactivity (Plooij, van der Spek, & Scherder, 2012).

Physical activity reduces pain, improves quality of life and reduces the risk of chronic illness in those with MSK pain (Der Ananian et al., 2006). In older people, walking reduces pain and the risk of joint replacement (Ageberg et al., 2012). Interventions to support increased walking in older people with chronic MSK pain are appropriate, although the mechanisms to achieve this remain unclear. Developing such interventions is challenging, as they need to address pain-related factors such as fear of injury (Cook, Brawer, & Vowles, 2006) and fear of falling (Hubscher, Vogt, Schmidt, Fink, & Banzer, 2010). A recent systematic review concluded that walking-based exercise can be recommended for individuals with chronic MSK pain, but further, robustly designed research with longer-term follow-up is required (O'Connor et al., 2015).

Whether these review findings are transferable to the older population is unclear. In older people, restricted mobility, limited time, transportation and finance are barriers to participating in physical activity interventions. Alternative methods of delivering support to these individuals (e.g. telephone, email, text) could encourage them to take part and adhere to an intervention. A recent walking intervention for older adults with knee osteoarthritis demonstrated increased adherence when supported according to preference (Loew et al., 2017); therefore, it appears that choice is of importance to this population. Interventions that also emphasize the evidence-based, dose–response nature of increasing individual physical activity (i.e. "some is good, more is better", irrespective of an individual's starting point) may be beneficial (Ambrose & Golightly, 2015).

The National Institute for Health and Care Excellence (NICE) concluded in their behaviour change guideline that interventions should incorporate a range of behavioural strategies, including goal setting, self-monitoring, self-efficacy, support and relapse prevention (National Institute for Health and Care Excellence, 2007). In order to maximize physical activity behaviour change, it is important that physical activity interventions are successful at promoting self-regulatory and volitional skills (drawing on intentions as a vehicle to change) as well as traditional motivational components, such as self-efficacy (Sniehotta, Scholz, & Schwarzer, 2006).

To facilitate roll-out in primary care, interventions should be acceptable and feasible to patients, intervention deliverers and the setting in which they will be undertaken. Interventions also need to be cost-effective; selection of the intervention deliverer is vital. In primary care, healthcare assistants (HCAs) are increasingly expected to provide brief behaviour change advice on physical activity, weight management, alcohol consumption and smoking cessation during NHS health checks, and therefore may be suitable deliverers of a walking intervention for older adults with chronic MSK pain, given appropriate training.

2 | AIMS AND OBJECTIVES

The aims of the pilot trial are to test the design and methods of a future full-scale randomized controlled trial (RCT) and examine the feasibility, acceptability and fidelity – the degree to which the intervention is delivered as intended (Gearing et al., 2011) – of the HCA-supported Increasing Physical activity in Older People with chronic Pain (iPOPP) intervention to promote walking in older adults with chronic MSK pain in a primary care setting.

The objectives of the pilot trial are:

1. To determine the response rate of general practices to participate in the pilot trial.
2. To assess the feasibility and acceptability of the HCA-supported iPOPP intervention, with a particular focus on the HCAs' experiences of *delivering* the intervention, and participants' experiences of *receiving* the intervention.
3. To determine whether HCAs can be recruited, trained and retained to deliver the iPOPP intervention for the pilot trial.
4. To assess fidelity of the HCA-supported iPOPP intervention delivery.
5. To estimate overall participant recruitment to the trial.
6. To estimate the short-term follow-up rate at 12 weeks across trial arms and per treatment arm.
7. To examine the completion rates of the self-reported outcome measures (for primary and secondary outcome measures).
8. To estimate the parameters needed for a realistic sample size calculation for a larger RCT.
9. To assess the feasibility and quality of collecting and analysing objective physical activity data as the primary outcome data for a future full-scale trial, using accelerometers.
10. To integrate data analysis and findings from the quantitative and qualitative evaluations, in order to identify changes required to the trial design and intervention components ahead of a full-scale trial.

3 | METHODS

3.1 | Trial design and setting

The Standard Protocol Items for Randomized Trials (SPIRIT) recommendations were followed in preparing this protocol (see Appendix 1) (Chan et al., 2013). This is an individually randomized, multicentre, three-parallel-arm pilot RCT recruiting 150 participants from four general practices across Cheshire and the West Midlands, UK.

General practitioner (GP) practices are eligible to take part if they use the clinical operating system EMIS Web (a clinical electronic computer system for delivering healthcare which allows healthcare professionals to record, share and use vital patient information), and are willing to allow their employed HCAs to be trained and to deliver the HCA-supported intervention. General practice participation will be formalized through written service level agreements.

3.2 | Trial population

Adults aged 65 years and over who have consulted at their general practice in the last 12 months for MSK pain in one or more of the index

sites (foot, knee, hip, back, shoulder or neck) and have had their pain for ≥3 months will be recruited to the trial. The full pilot trial eligibility criteria are listed in Box 1.

3.3 | Identification and screening of potentially eligible participants

Members of the Clinical Research Network (CRN) Informatics Team who are contracted to work in the participating general practices, or the general practice staff will conduct a search of the computerized consultation records, for adults aged 65 years and over who have consulted with pain in at least one of the index sites in the last 12 months. The computerized record screen will identify patients using Read codes (these are the standard clinical terminology coding system used in general practice in the UK) that have been informed by our previous research (Study of Work and Pain [SWAP] trial ISRCTN 52269669 (Bishop et al., 2014); Management of OsteoArthritis In Consultations [MOSAICS] trial ISRCTN: 06984617 (Dziedzic et al., 2014)). In addition, the computerized record screening protocol will take into account aspects of the exclusion criteria where possible (e.g. those in residential or nursing home accommodation or those with congestive heart failure). From each practice, a GP will be given the opportunity to review the list generated and exclude those patients whom they consider inappropriate to be invited into the trial, according to the trial exclusion criteria. CRN staff will then administer an initial mailing phase in the form of a brief chronic pain screening survey, to identify and screen potentially eligible participants.

The screening survey will assess the eligibility criteria, enquire about pain location and duration, determine the patient's Chronic Pain Grade classification (von Korff et al., 1992) and confirm access to a telephone (to enable further eligibility checking by a research nurse and facilitate consent). Patients will be eligible to participate in the trial if they have a Chronic Pain Grade classification of between 2 and 4 (i.e. clinically significant mean levels of pain and functional difficulty) (Foster et al., 2014).

Patients will return their screening survey to the Arthritis Research UK Primary Care Centre and only those who are eligible and consent to further contact will form the sample that are sent information about the iPOPP trial.

Box 1. Eligibility criteria for the physical activity in older people with chronic pain (iPOPP) pilot trial

Inclusion criteria

- Aged 65 years and over
- Registered with one of the participating general practices during the specified trial period for that practice
- Consulted at their general practice for a musculoskeletal disorder in one or more index sites (foot, knee, hip, back, shoulder or neck) in the last 12 months
- Pain that has lasted ≥3 months
- A chronic pain grade (von Korff, Ormel, Keefe, & Dworkin, 1992) score of between 2 and 4, determined through a brief postal chronic pain screening survey
- Able to provide full, informed, written consent

Exclusion criteria

- Traumatic injury-related pain (recent sports injury, fall or accident) to rule out traumatic fractures
- 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 (within the last 3 months), active and severe synovitis)

3.4 | Approach and recruitment to the iPOPP trial

Those who meet the eligibility criteria and who agree to further contact will be posted an iPOPP trial pack (a cover letter, a patient information sheet, a baseline questionnaire and a freepost return envelope). Patients will then be contacted by a CRN nurse by telephone to confirm eligibility and willingness to participant within 10 working days. Those who wish to take part in the trial will be asked to sign and date the written consent form (see Appendix 2) and return it, along with the completed baseline questionnaire, to the study team in a pre-paid envelope. On receipt of the written informed consent form and baseline questionnaire, each participant will be sent an accelerometer in the post for baseline data collection. Once accelerometry data collection is complete (7 days) and the accelerometer is returned to the research centre, participants will be randomized. Figure 1 summarizes the participant recruitment for the iPOPP trial.

3.5 | Randomization

Participants will be randomized to one of the three interventions using third-party computerized randomization supported by Keele Clinical Trials Unit (CTU). To ensure that participants at each general practice have an equal chance of receiving any of the interventions, participants will be individually randomized using random permuted blocks, stratified by general practice.

The GP of each participant will be sent a letter to confirm that their patient is taking part in the trial, unless the participant does not provide consent for this.

3.6 | Allocation concealment, blinding and selection bias

A CRN nurse blind to subsequent treatment allocation will obtain informed consent. Selection bias at recruitment will be avoided by separating the processes of determining patient eligibility and intervention allocation. The trial database will be password protected,

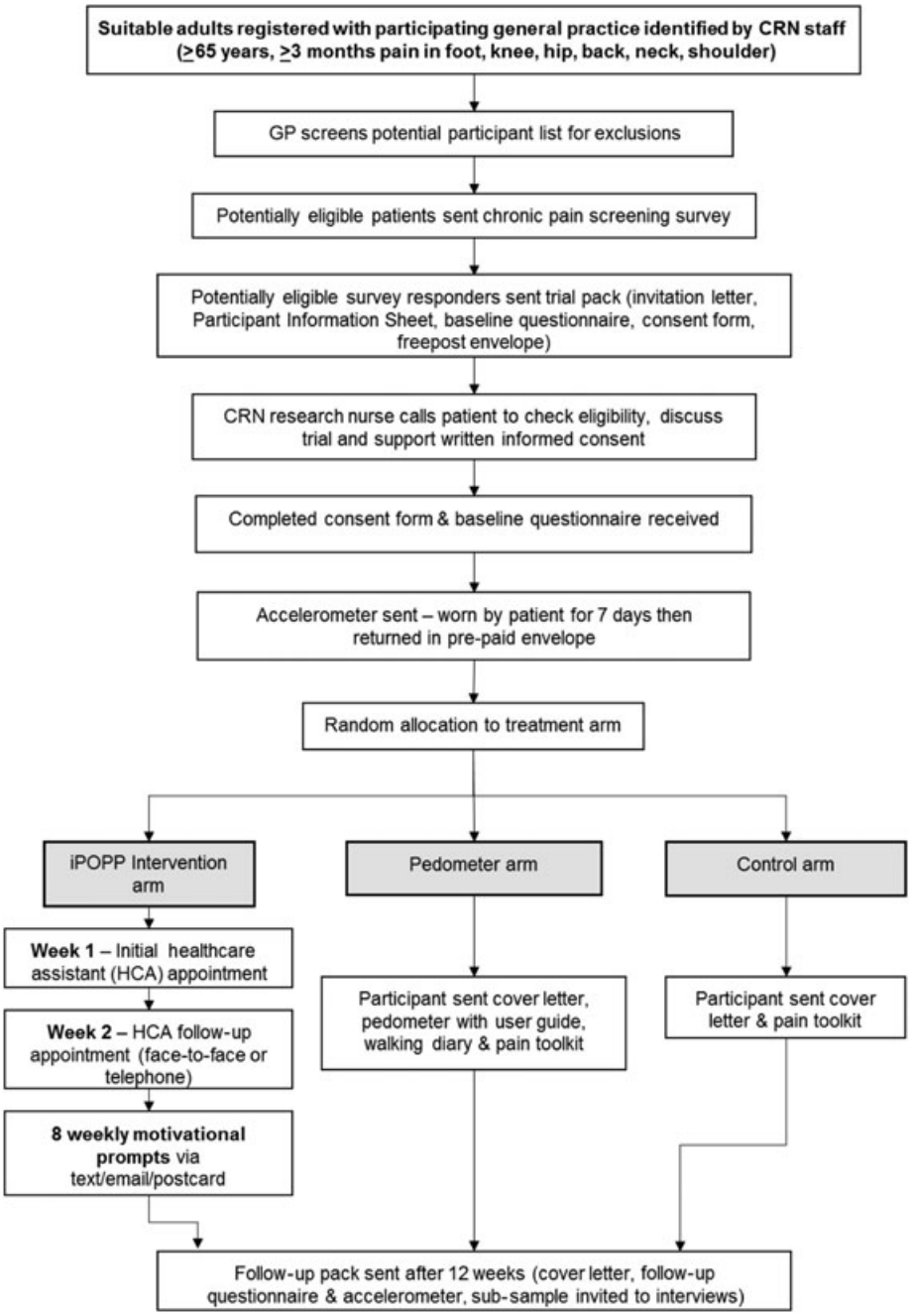

FIGURE 1 Flow chart demonstrating recruitment of participants into the iPOPP trial

to ensure that the trial statistician and study personnel involved in the questionnaire and accelerometry data collection remain blind to treatment allocation. Allocation concealment and blinding is not possible for the participants or HCAs; however, the HCAs will deliver only one of the three trial interventions. Data entry, coding, security, storage and management will follow the standard operating procedures at Keele CTU.

3.7 | The interventions

Each of the three interventions are detailed below:

1. **Usual care:** Participants randomized to this intervention will be sent some high-quality written information in the form of the pain toolkit (http://www.paintoolkit.org) in the post by the study team, and will continue to be managed via usual care. The pain toolkit is a simple booklet that provides participants with tips and advice to support them in managing their 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, such as physiotherapy, podiatry or occupational therapy.
2. **Usual care plus pedometer:** Participants randomized to this intervention will continue with their usual care, and in addition will receive in the post a pedometer, a pedometer user guide based on the NICE guidance on promoting walking (National

Institute for Health and Care Excellence, 2012), a walking diary and the pain toolkit.

3. **iPOPP walking intervention:** When a participant is randomized to this intervention, the trial coordinator will pass on contact details to the relevant trained HCA. The HCA will then contact the participant to arrange their first consultation. The aim of this intervention is to initiate and support adherence to a walking plan. In brief, 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. At this first consultation, participants will receive a pedometer, the user guide and a walking diary plus a copy of the pain toolkit. The consultation (approximately 30 min) will include two components. The motivational stage will draw on motivational interviewing techniques, to prompt the patient to make self-motivating statements about walking behaviour. Then, in the action planning stage, volitional techniques will be used to facilitate realistic walking goals, to help to translate intentions into practice (e.g. setting specific, measurable, achievable, realistic, time-related [SMART] goals and drawing on the use of the pedometer). Participants will be encouraged to identify places (e.g. the local park, their home) where they can accumulate steps over the course of a day. Important barriers to walking specific to the individual, such as pain-related fear of movement, will be addressed. Participants will receive a second consultation about 2 weeks later (approximately 30 min) either face to face or via telephone (depending on participant preference), consisting of a review of progress since the first consultation, positive feedback in relation to effort and achievement, possible revision of goals set, and relapse prevention strategies (e.g. support from friends/family, identifying a walking "buddy"). Participants will then receive eight weekly motivational prompts, which will be in the form of a postcard, email or text (dependent on patient preference). Participants allocated to this intervention arm will also continue to access usual care (as described above). Each HCA will use a case report form (CRF) to record what happened during the two intervention consultations, how they were delivered (face to face or telephone), the dates of the consultations and the agreed method for the eight weekly motivational prompts (postcard, text or email). This information will be sent by the HCA back to the study team and logged on the trial database. The start of the weekly prompts will be initiated by the trial database.

4 | DEVELOPMENT OF THE HCA TRAINING

The development and content of the HCA-supported iPOPP intervention training will be reported elsewhere. In brief, the development of the HCA training programme will, in line with previous research, consist of four phases (French, Stevenson, & Michie, 2012; Healey et al., 2015; Porcheret et al., 2014): (i) defining the content; (ii) selecting the behaviour change techniques; (iii) deciding on the style of delivery; and (iv) addressing local practicalities. It is anticipated that at least one HCA will be trained to deliver the HCA-supported iPOPP intervention per practice and that the training will take place in a group setting over 2 days, 1 week apart, to allow the HCAs to absorb and reflect on what they have learnt, re-read intervention materials and complete "homework" before further review training. All HCA time taken to attend the training and deliver the intervention will be reimbursed to the general practice that employs them. All HCAs that attend the training will be asked to complete a pre- and post-training evaluation questionnaire, focused on assessing knowledge and confidence to deliver the iPOPP intervention.

5 | OUTCOMES

In order to achieve the aims and objectives set out for this pilot trial, a theoretically informed mixed-methods approach, including semi-structured interviews, audio recordings of the HCA consultations, participant self-reported questionnaires, CRFs, and accelerometry data collection, will be undertaken. These methods of data collection will help to inform the design and methods of a future full-scale RCT and examine the feasibility, acceptability and fidelity of the HCA-supported intervention (iPOPP) in a primary care setting.

5.1 | Qualitative data collection

Audio recordings of a sample of HCA consultations (including both first and second consultations) and semi-structured interviews with all HCAs and a sample of participants will form the basis of the qualitative data collection.

5.1.1 | Audio-recording of the HCA-supported iPOPP intervention consultations

A sample of the first and second HCA consultations will be digitally audio-recorded, with HCA and participant consent. These audio recordings will focus on the fidelity of the iPOPP intervention delivery – for example, which elements of this intervention the HCAs used, whether the training was reflected in HCA behaviour and whether there are any gaps in intervention delivery.

Each HCA trained ($n = 6$) to deliver the iPOPP intervention will be asked to record a total of six consultations, with three participants (ideally three first and three second consultations). The team will therefore have a minimum of 36 recorded consultations. A digital recorder will be used, and switched on by the HCA at the start of the consultation. Fully informed consent from the participant for the recording of both consultations with the HCA will be obtained by a member of the study team.

5.1.2 | Semi-structured interviews

Semi-structured interviews will be conducted with a sample of participants (pedometer and iPOPP interventions only) and all trained HCAs. The interviews with participants will explore the acceptability and credibility of the pedometer and iPOPP interventions, whether walking has been continued, barriers and facilitators to maintaining or increasing walking, and prior experience of consulting with HCAs (iPOPP intervention only).

The interviews with the HCAs will explore how the training developed their knowledge and skills to enable them to deliver the intervention, how the training could be improved and the factors that helped or hindered the implementation and delivery of the intervention to the target population.

HCAs

All of the HCAs ($n = 6$) trained to deliver the iPOPP intervention will be invited to participate in individual telephone or face-to-face semi-structured interviews at the end of the intervention period. A topic guide will stimulate dialogue in the interview and allow an exploration of the acceptability and operationalizing of the training and the iPOPP intervention.

Trial participants

A sample of participants across the four practices, from the pedometer and iPOPP interventions only, will be invited to participate in a semi-structured interview after the 12-week follow-up data collection is complete. We will specifically sample participants who completed and dropped out of the iPOPP intervention, to explore reasons for completion and drop-out. A sample will be selected from the pedometer intervention purposively, based on practice, age and gender, to ensure a broad range of participants. Approximately 10–15 participants per intervention will be interviewed; data collection will be continued until category saturation is achieved in each group.

All interviews and audio recordings of the iPOPP intervention will be digitally recorded, with consent, and will be professionally transcribed verbatim. This will form the data for analysis.

5.2 | Quantitative data collection

Accelerometry data, self-reported questionnaires, and individual CRFs (iPOPP intervention only) will form the basis of the qualitative data collection.

5.2.1 | Accelerometers

This trial will primarily use these objective physical activity monitors to estimate levels of physical activity via average daily step count. Number of counts per minute, time spent sedentary, time spent in light, moderate and vigorous physical activity, and proportions of people who meet guideline levels of physical activity will also be estimated (Department of Health., 2011; Foster et al., 2014; Lee et al., 2015). This pilot trial is not powered to detect clinically relevant differences between the interventions in walking, and these data will not be used as criteria for progression to a full trial. However, we will collect data on the feasibility of using accelerometers as the primary outcome in our target population for a full-scale trial. The waist-worn triaxial accelerometer units (wGT3X-BT monitor, Actigraph, Pensacola, FL, USA) will be pre-programmed and posted out to the participants with full instructions, once consent to the trial is received but prior to randomization, and again at the 12-week follow-up. Participants will be asked to wear the unit for 7 consecutive days on their waist during waking hours, and then to post the unit back to the research centre, where the data collected will be downloaded and analysed if participants have worn the accelerometer on at least 5 days, for 10 h or more each day (assuming that consecutive runs of zero count for 60 min or more are "non-wear") (Foster et al., 2014). To maximize response rates, participants will receive up to two reminder telephone calls and a reminder postcard, asking them to return the units if they are not returned within 4 weeks after the end of data collection.

5.2.2 | Self-reported questionnaires

All participants will be asked to complete a self-report questionnaire at two time points: at baseline and at 12 weeks post-randomization. Participants will return the questionnaires to the research centre in pre-paid envelopes. To maximize response rates to the follow-up questionnaire, participants will receive a reminder telephone call and then sent a reminder postcard if it is not returned within 2 weeks. If the follow-up questionnaire is not received following these reminders, participants will receive a telephone call to ask them to provide a minimum dataset over the telephone (see Table 1).

The baseline questionnaire will collect information on participant characteristics (e.g. gender, age, pain sites, co-morbidity, employment status). Questionnaire measures (at baseline and 12-week follow-up) of physical functioning and mental health (The EQ-5D-5L) (Herdman et al., 2011), pain intensity (Numerical Rating Scale) (Ostelo & de Vet, 2005), pain location (pain manikin) (Lacey et al., 2014), physical activity (International Physical Activity Questionnaire for the Elderly (Hurtig-Wennlo, Hagströmer, & Olsson, 2010) and the Self-Efficacy for Exercise Scale (Resnick & Jenkins, 2000) will be collected.

The 12-week follow-up questionnaire will also collect information on any adverse events experienced during the trial, and include a modified version of the treatment acceptability and credibility measure developed by Borkovec and Nau (1972), with four items each measured using a 10-point scale. This measure will help us to investigate the acceptability and credibility of the HCA-supported iPOPP intervention to older people with chronic MSK pain, by assessing how logical it seems to participants, how confident participants are that it will be successful in managing chronic pain, how confident participants would be in recommending it to a friend and how successful participants feel it would be for another pain problem. Table 1 summarizes all data collection methods and their respective time points.

5.2.3 | Individual CRFs

The CRFs will be audited by the study team during the intervention delivery phase, to ensure that the HCA-supported iPOPP intervention is being delivered per protocol and to identify any further training requirements. The CRFs will also be examined at the end of the pilot trial, to help to assess the fidelity of the iPOPP intervention delivery.

6 | PILOT TRIAL SUCCESS CRITERIA

The following criteria will be used to judge the success of the pilot trial, in order to make decisions about a future full-scale trial:

TABLE 1 Types and timing of data collection for the physical activity in older people with chronic pain (iPOPP) pilot trial

	Time points					
iPOPP pilot trial data collection	**Screening phase**	**Baseline (all)**	**Week 1 (HCA-supported intervention only)**	**Week 2 (HCA-supported intervention only)**	**12-week follow-up**	**Post-12 weeks**
Participant demographics						
Gender	✓	✓				
Age	✓	✓				
Employment status	✓					
Pain sites	✓					
Pain duration	✓					
Chronic pain grade (von Korff et al., 1992)	✓					
Co-morbidity		✓				
Primary outcome measure						
Physical activity level – 7-day accelerometer data		✓			✓	
Secondary outcome measures						
Modified version of treatment acceptability and credibility measure (Borkovec & Nau, 1972)					✓	✓ (MDC)
Physical functioning and mental health (EQ-5D-5 L) (Herdman, Gudex, & Lloyd, 2011)		✓			✓	
Pain intensity Numerical Rating Scale (Ostelo & de Vet, 2005)		✓			✓	
Pain location (body manikin) (Lacey et al., 2014)		✓				
International physical activity questionnaire for the Elderly (Hurtig-Wennlo et al., 2010)		✓			✓	✓ (MDC)
Self-efficacy for exercise Scale (Resnick & Jenkins, 2000)		✓			✓	
Process measures						
HCA-supported intervention case report form			✓	✓		
Sample of consultation audio recordings			✓	✓		
Semi-structured interviews – HCA						✓
Sample of semi-structured interviews – Participant						✓

EQ-5D-5 L, 5-level European Quality of Life–5 Dimensions; HCA, healthcare assistant; MDC, minimum data collection.

1. Satisfactory treatment acceptability and credibility scores at follow-up, whereby the mean score for participants randomized to the HCA-supported intervention should be at least 5 to progress to a full trial.
2. Recruitment rates of at least 70% predicted (n = 150).
3. Follow-up rates of at least 70% of those randomized at the 12-week follow-up.
4. An acceptable intervention adherence rate (at least 50% of those receiving the HCA-supported iPOPP intervention will complete the two consultations).

7 | SAMPLE SIZE

This is a pilot trial, and a formal sample size calculation is not appropriate. However, for pilot studies it has been recommended that the dataset should comprise a minimum of 30 participants in each arm (Shih, Ohman-Strickland, & Lin, 2004). We anticipate that the combined total loss to follow-up and non-adherence to the iPOPP intervention will be no more than 30% at the 12-week follow-up (i.e. 20% due to loss to follow-up and 10% due to non-compliance) and therefore aim to recruit 50 participants in each arm, to account for potential missing data. Part of the rationale of a pilot is to gather data to inform the design of a full trial; therefore, more robust estimates for non-compliance and loss to follow-up rates in this patient group will be generated by the end of the pilot study and will inform power calculations for a potential full trial.

To determine the number of persons to be mailed the chronic pain screening survey, to identify the 150 participants for this pilot trial, as a guide, we have used data from previous RCTs and observational studies with older adults with MSK pain (e.g. the Self-Management in OA of the Hand [SMOOTH] trial (Dziedzic et al., 2011), benefits of effective exercise for knee pain (BEEP) trial (Foster et al., 2014)). To obtain at least 150 eligible adult participants aged 65 and over, we will target at least 800 adults aged 65 and over who have consulted their GP for MSK pain in the index sites in the last 12 months. Based on previous trials, we anticipate that approximately 400 will respond with a completed questionnaire, of whom 150 will fulfil eligibility criteria and consent to participate in the trial, and approximately 105 will provide 12-week follow-up data. Four typical general practice sizes in excess of 7,000 should provide a sufficient sampling frame from which to ascertain the required numbers for this pilot trial.

8 | MONITORING AND SAFETY CONSIDERATIONS

The iPOPP pilot trial will be monitored in line with the protocol and Keele CTU standard operating procedures. An independent trial steering committee will monitor the progress of the trial and a data monitoring committee will be convened to monitor the safety of participants and data integrity. Monitoring will also be undertaken by the research ethics committee and the funder (Arthritis Research UK) in the format of annual progress reports.

All HCAs at participating general practices must report any significant events that they become aware of that occur during the 12-week period over which a patient is participating in the trial (i.e. 12 weeks from the date of randomization). All participants will also be provided with the contact details of the trial coordinator and asked to self-report any such events to the trial team as soon as possible. Participants randomized to the HCA-supported iPOPP intervention will see or speak to an HCA at the first and second consultation. HCAs will ask participants about, record and report any significant events that they become aware of to the trial team. As the risk of related unexpected serious adverse events (SAEs) is low in this study, HCAs will not be trained in SAE definitions. They should instead report significant events – for example, a participant needing to be admitted to hospital, a fall or any problem which needed medical treatment to prevent the participant being admitted to hospital. Safety reporting procedures will be covered during HCA training sessions, and a copy of the procedure will be filed in the site file. We will also ask participants in their 12-week follow-up questionnaire if they perceive that they have experienced any adverse events during the trial period.

If a potential SAE is reported to a member of the trial team, this information will be passed to the study coordinator at Keele CTU, who will ensure that the necessary paperwork is completed and inform the trial chief investigator and trial GP immediately. The trial GP will assess whether any reported SAEs were related to the trial intervention, according to the process laid out in Keele CTU's standard operating procedure. Any unexpected SAEs considered to be related to the trial procedures will be reported to the research ethics committee by the chief investigator within 15 days of becoming aware of the event. In addition, all related unexpected SAEs will be reported to Keele University (as the trial sponsor), the trial steering committee and the data monitoring committee.

9 | ANALYSIS

9.1 | Qualitative data

Researchers from the qualitative team will examine the audio recordings of the iPOPP intervention consultations and use an intervention fidelity checklist specifically developed for the trial to assess whether components of the consultation intended to be included, and focused on during training, were demonstrated by the HCA.

The interviews with HCAs and trial participants will be transcribed and the data analysed by members of the study team, adopting a constant comparison approach (Glaser, 1965; Hallberg, 2006), with initial coding of text segments, followed by re-coding and memo writing in order to generate conceptual themes. The study team will then discuss and agree on overarching thematic interpretations. A framework approach will then be used to facilitate interpretation of the data (Richie & Spencer, 1994). Analysis will be conducted by researchers from different professional backgrounds, to improve the trustworthiness of the analysis (Henwood & Pigeon, 1992). Following initial inductive analysis, themes will be mapped to behavioural theory by using the Theoretical Domains Framework (Atkins et al., 2017; Michie et al., 2005) to identify influences on behaviour that have an impact on implementation of the iPOPP intervention.

9.2 | Quantitative data

The analysis of the quantitative data will be exploratory and provide further data on the feasibility and acceptability of the HCA-supported intervention, and the design and methods of a full-scale RCT. For example, findings from the pilot trial might inform required changes in the trial recruitment processes, data collection processes and outcome measures Participant characteristics (e.g. gender, age, pain sites, co-morbidity, employment status), self-reported at baseline, will be compared by intervention arm and by general practice to explore the balance of patient characteristics. These data will also allow any evidence of selection bias to be assessed by comparing consenting and non-consenting individuals, withdrawals, drop-outs and completers. The percentage of participants consenting to take part in the trial and follow-up rates for the post-intervention follow-up questionnaire per intervention group will also be examined. Completion rates of the self-reported outcome measures will be reported, to identify any that are poorly completed. The content of the self-reported questionnaire for a full RCT will be adapted accordingly.

Data from the pilot study will also be used to help to inform a sample size calculation for the full-scale trial, for the primary outcome of interest (step counts measured using accelerometry). This estimate will be viewed cautiously, however, given that there are only four practices included in the pilot trial. Participants will only be included in this analysis if they have worn the monitor for at least 5 days, for 10 h or more each day. Valid time will be calculated assuming that any consecutive runs of zero count lasting for 60 min or more are counted as "non-wear" (Foster et al., 2014). For each participant, we will generate the following: average daily step count, and the proportion of time spent sedentary and in light, moderate and vigorous physical activity, using the cut-offs from Lee et al. (2015) and Freedson, Melanson, and Sirard (1998), and the proportions of people who meet guideline levels of physical activity for older adults will also be calculated (Department of Health, 2011).

9.3 | Integrating quantitative and qualitative data and findings

When the analysis of the quantitative and qualitative data is complete, a triangulation protocol (O'Cathain, Murphy, & Nicholl, 2010; Tonkin-Crine et al., 2016) will be used. This technique enables integration of data in order to investigate the completeness, convergence

and dissonance of key themes across datasets (Farmer, Robinson, Elliott, & Eyles, 2006). Methods include following a thread and development of a convergence coding matrix. The matrix allows findings from different study components to be displayed side by side. Integration will aid interpretation of findings and inform decisions about changes to trial processes or intervention components ahead of a full-scale trial.

10 | PATIENT AND PUBLIC INVOLVEMENT AND ENGAGEMENT (PPIE)

The pilot trial design and processes have been informed by patient and public involvement, in line with our centre's strong commitment to involving the public in research (Jinks, Carter, et al., 2016), following INVOLVE's recommendations (http://www.invo.org.uk/resource-centre/resource-for-researchers/).

A lay co-applicant helped with the iPOPP pilot trial funding application. For the development phase of the iPOPP pilot trial (intervention and training development), two members of the public attended a stakeholder workshop in January 2015 and 11 members of the public attended a nominal group technique meeting held in February 2015 (Jinks, Healey, et al., 2016). These individuals were selected as they were aged 65 years and over and reported having chronic pain, and were recruited from local third-sector groups such as Age UK and The Beth Johnson Foundation, which are charities working towards a positive impact on the lives of older people. We have also involved our PPIE group at the Arthritis Research UK Primary Care Centre, which is made up of patients and members of the public with different MSK conditions, in the assessment our participant information (letters of invitation, participant information sheets, questionnaires), and their feedback will be incorporated into the final versions. Two members of the iPOPP pilot trial steering committee will be lay members. All research users are supported by a user support worker and a PPIE coordinator through regular meetings and an annual conference at Keele University.

11 | ETHICS AND DISSEMINATION

The pilot trial has been approved by the West Midlands – Solihull Research Ethics Committee (REC reference: 15/WM/0329).

All participating general practices will receive a poster at the end of the study, which they can display in order to inform participants of the pilot trial results. In addition, all participants will be informed of the results personally by post. The results of this study will be reported to the trial steering committee, data monitoring committee and our funder, published in relevant high-quality peer-reviewed journals and presented at national and international conferences.

12 | TRIAL MONITORING

The trial steering committee met prior to ethics application in order to agree the final protocol, and at agreed time intervals over the course of the pilot trial. The data monitoring committee also reviewed the study protocol and receive reports at agreed intervals. All data collection, database design, data input and cleaning, as well as trial oversight procedures, will be in line with the standard operating procedures of the Keele CTU and the conditions of the grant.

13 | DATA CONFIDENTIALITY AND ARCHIVING

All pilot trial-related information will be stored securely at the Arthritis Research UK Primary Care Centre at Keele University. Data will be anonymized using coded identification numbers, with the housing of the data and the linking code in separate locations, under password protection. Access to the data will be restricted to individuals involved in audit and analysis. The data from the pilot trial will be archived and made available for future, secondary analysis and data pooling purposes from the Arthritis Research UK Primary Care Centre at Keele University.

ACKNOWLEDGEMENTS

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AUTHOR CONTRIBUTIONS

E.L.H., J.M., C.J., N.E.F., C.C.G., E.M.H., T.P. and S.D. conceived the trial, developed the trial design and secured funding. E.L.H., T.P., C.C.G. and C.J. developed and delivered the HCA training. J.M. and C.J. are co-chief investigators. E.L.H. is the principal investigator and leads the trial management team and produced the first draft of the iPOPP pilot trial protocol. E.N. provided statistical expertise and developed the statistical analysis plan. K.C. and L.H. provide trial coordination support. C.J., C.C.G. and J.P. contributed to the development of the qualitative data collection and analysis plan. S.W. developed the EMIS CRF data template. All authors contributed to the refinement of the pilot trial protocol and approval of the final manuscript.

REFERENCES

Ageberg, E., Engstrom, G., Gerhardsson de Verdier, M., Rollof, J., Roos, E. M., & Lohmander, L. S. (2012). Effect of leisure time physical activity on severe knee or hip osteoarthritis leading to total joint replacement: A population-based prospective cohort study. *BMC Musculoskeletal Disorders*, *13*, 73. https://doi.org/10.1186/1471-2474-13-73

Ambrose, K. R., & Golightly, Y. M. (2015). Physical exercise as non-pharmacological treatment of chronic pain: Why and when? *Best Practice & Research. Clinical Rheumatology*, *29*(1), 120–130. https://doi.org/10.1016/j.berh.2015.04.022

Atkins, L., Francis, J., Islam, R., O'Connor, D., Patey, A., Ivers, N., … Michie, S. (2017). A guide to using the Theoretical Domains Framework of behaviour change to investigate implementation problems. *Implementation Science*, *12*(1), 77. https://doi.org/10.1186/s13012-017-0605-9

Bishop, A., Wynne-Jones, G., Lawton, S. A., Windt, van der D., Main, C., Sowden, G., … SWAP study team. (2014). Rationale, design and methods of the study of work and pain (SWAP): A cluster randomised controlled trial testing the addition of a vocational advice service to best current primary care for patients with musculoskeletal pain. *BMC Musculoskeletal Disorders*, *15*, 232. https://doi.org/10.1186/1471-2474-15-232

Borkovec, T. D., & Nau, S. D. (1972). Credibility of analogue therapy rationales. *Journal of Behavior Therapy and Experimental Psychiatry*, *3*(4), 257–260. https://doi.org/10.1016/0005-7916(72)90045-6

Chan, A. W., Tetzlaff, J. M., Altman, D. G., Laupacis, A., Gøtzsche, P. C., Krleža-Jerić, K., … Moher, D. (2013). SPIRIT statement: Defining standard protocol items for clinical trials. *Annals of Internal Medicine*, *158*(3), 200–207. https://doi.org/10.7326/0003-4819-158-3-201302050-00583

Cook, A. J., Brawer, P. A., & Vowles, K. E. (2006). The fear-avoidance model of chronic pain: Validation and age analysis using structural equation modelling. *Pain*, *121*(3), 195–206. https://doi.org/10.1016/j.pain.2005.11.018

Department of Health. (2011). Guidance: UK physical activity guidelines. Factsheet 5: Physical activity guidelines for older Adults (65+ years). Retrieved from https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/213741/dh_128146.pdf

Der Ananian, C. A., Wilcox, S., Abbott, K., Vrazel, J., Ramsey, C., Sharpe, P., & Brady, T. (2006). The exercise experience in adults with arthritis: A qualitative approach. *American Journal of Health Behaviour*, *30*(6), 731–744.

Dziedzic, K. S., Healey, E. L., Porcheret, M., Ong, B. N., Main, C. J., Jordan, K. P., … Hay, E. M. (2014). Implementing the NICE osteoarthritis guidelines: A mixed methods study and cluster randomised trial of a model osteoarthritis consultation in primary care – The Management of OsteoArthritis In Consultations (MOSAICS) study protocol. *Implementation Science*, *9*, 95. https://doi.org/10.1186/s13012-014-0095-y

Dziedzic, K. S., Hill, S., Nicholls, E., Hammond, A., Myers, H., Whitehurst, T., … Hay, E. M. (2011). Self management, joint protection and exercises in hand osteoarthritis: A randomised controlled trial with cost effectiveness analyses. *BMC Musculoskeletal Disorders*, *12*, 156. https://doi.org/10.1186/1471-2474-12-156

Farmer, T., Robinson, K., Elliott, S. J., & Eyles, J. (2006). Developing and implementing a triangulation protocol for qualitative health research. *Qualitative Health Research*, *16*(3), 377–394. http://doi.org/10.1177/1049732305285708

Foster, N. E., Healey, E. L., Holden, M. A., Nicholls, E., Whitehurst, D. G., Jowett, S., … BEEP trial team (2014). Improving the effectiveness of exercise for knee pain in older adults in primary care: The BEEP trial protocol. *BMC Musculoskeletal Disorders*, *15*, 254. https://doi.org/10.1186/1471-2474-15-254

Freedson, P. S., Melanson, E., & Sirard, J. (1998). Calibration of the computer science and applications, Inc. accelerometer. *Medicine and Science in Sports and Exercise*, *30*(5), 777–781

French, D. P., Stevenson, A., & Michie, S. (2012). An intervention to increase walking requires both motivational and volitional components: A replication and extension. *Psychology, Health & Medicine*, *17*(2), 127–135. https://doi.org/10.1080/13548506.2011.592843

Gearing, R. E., El-Bassel, N., Ghesquiere, A., Baldwin, S., Gillies, J., & Ngeow, E. (2011). Major ingredients of fidelity: A review and scientific guide to improving quality of intervention research implementation. *Clinical Psychology Review*, *31*(1), 79–88. https://doi.org/10.1016/j.cpr.2010.09.007

Glaser, B. G. (1965). The constant comparative method of qualitative analysis. *Social Problems*, *12*(4), 436–445. http://doi.org/10.1525/sp.1965.12.4.03a00070

Hallberg, L. R. M. (2006). The "core category" of grounded theory: Making constant comparisons. *International Journal of Qualitative Studies on Health and Well-being*, *1*(3), 141–148. https://doi.org/10.1080/17482620600858399

Healey, E. L., Jinks, C., Tan, V. A., Chew-Graham, C. A., Lawton, S. A., Nicholls, E., … Mallen, C. D. (2015). Improving the care of people with long-term conditions in primary care: protocol for the ENHANCE pilot trial. *Journal of Comorbidity*, *5*(1), 135–149. https://doi.org/10.15256/joc.2015.5.60

Henwood, K., & Pigeon, N. (1992). Qualitative research and psychological theorizing. *British Journal of Psychology*, *83*(Pt 1), 97–111. https://doi.org/10.1111/j.2044-8295.1992.tb02426.x

Herdman, M., Gudex, C., & Lloyd, A. (2011). Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). *Quality of Life Research*, *20*(10), 1727–1736. https://doi.org/10.1007/s11136-011-9903-x

Hubscher, M., Vogt, L., Schmidt, K., Fink, M., & Banzer, W. (2010). Perceived pain, fear of falling and physical function in women with osteoporosis. *Gait Posture*, *3I2*(3), 383–385. https://doi.org/10.1016/j.gaitpost.2010.06.018

Hurtig-Wennlo, A., Hagströmer, M., & Olsson, L. A. (2010). The international physical activity questionnaire modified for the elderly: Aspects of validity and feasibility. *Public Health Nutrition*, *13*(11), 1847–1854. https://doi.org/10.1017/S1368980010000157

Jinks, C., Carter, P., Rhodes, C., Taylor, R., Beech, R., Dziedzic, K., … Ong, B. N. (2016). Patient and public involvement in primary care research – An example of ensuring its sustainability. *Research Involvement and Engagement*, *2*, 1. https://doi.org/10.1186/s40900-016-0015-1

Jinks, C., Healey, E. L., Chew-Graham, C., McLachlan, S., Pincus, T., McBeth, J., & iPOPP team (2016). Increasing physical activity in older people with pain: Development of a brief and simple intervention to promote walking. *Rheumatology*, *55*(Suppl. 1), i81–i82. https://doi.org/10.1093/rheumatology/kew140.014

Lacey, R. J., Belcher, J., Rathod, T., Wilkie, R., Thomas, E., & McBeth, J. (2014). Pain at multiple body sites and health-related quality of life in older adults: Results from the north Staffordshire osteoarthritis project. *Rheumatology*, *53*(11), 2071–2079. https://doi.org/10.1093/rheumatology/keu240

Lee, J., Chang, R. W., Ehrlich-Jones, L., Kwoh, C. K., Nevitt, M., Semanik, P. A., … Dunlop, D. D. (2015). Sedentary behavior and physical function: Objective evidence from the Osteoarthritis Initiative. *Arthritis Care & Research*, *67*(3), 366–373. https://doi.org/10.1002/acr.22432

Loew, L., Brosseau, L., Kenny, G. P., Durand-Bush, N., Poitras, S., De Angelis, G., & Wells, G. A. (2017). An evidence-based walking program among older people with knee osteoarthritis: The PEP (participant exercise preference) pilot randomized controlled trial. *Clinical Rheumatology*, *36*(7), 1607–1616. https://doi.org/10.1007/s10067-017-3606-9

Michie, S., Johnston, M., Abraham, C., Lawton, R., Parker, D., Walker, A., & on behalf of the "Psychological Theory" Group (2005). Making psychological theory useful for implementing evidence based practice: A consensus approach. *Quality and Safety in Health Care*, *14*, 26–33. https://doi.org/10.1136/qshc.2004.011155

National Institute for Health and Care Excellence. (2007). Behaviour change: General approaches. Public health guideline [PH6]. Retrieved from https://www.nice.org.uk/guidance/ph6

National Institute for Health and Care Excellence. (2012). Physical activity: Walking and cycling. Public health guideline [PH41]. Retrieved from http://www.nice.org.uk/guidance/ph41

O'Cathain, A., Murphy, E., & Nicholl, J. (2010). Three techniques for integrating data in mixed methods studies. *British Medical Journal*, *341*, c4587. https://doi.org/10.1136/bmj.c4587

O'Connor, S. R., Tully, M. A., Ryan, B., Bleakley, C. M., Baxter, G. D., Bradley, J. M., & McDonough, S. M. (2015). Walking exercise for chronic

musculoskeletal pain: Systematic review and meta-analysis. *Archives of Physical Medicine and Rehabilitation*, *96*(4), 724–734. https://doi.org/10.1016/j.apmr.2014.12.003

Ostelo, R. W. J. G., & de Vet, H. C. W. (2005). Clinically important outcomes in low back pain. *Best Practice and Research in. Rheumatology*, *19*(4), 593–607. https://doi.org/10.1016/j.berh.2005.03.003

Plooij, B., van der Spek, K., & Scherder, E. J. (2012). Pain medication and global cognitive function in dementia patients with painful conditions. *Drugs & Aging*, *29*(5), 377–384. https://doi.org/10.2165/11630850-000000000-00000

Porcheret, M., Main, C., Croft, P., McKinley, R., Hassell, A., & Dziedzic, K. (2014). Development of a behaviour change intervention: A case study on the practical application of theory. *Implementation Science*, *9*(1), 42. https://doi.org/10.1186/1748-5908-9-42

Resnick, B., & Jenkins, L. S. (2000). Testing the reliability and validity of the self-efficacy for exercise scale. *Nursing Research*, *49*(3), 154–159. https://doi.org/10.1097/00006199-200005000-00007

Richie, J., & Spencer, L. (1994). Qualitative Data Analysis for Applied Policy Research. In A. Bryman, & R. Burgess (Eds.), *Analysing Qualitative Data* (pp. 173–194). London: Routledge.

Shih, W. H., Ohman-Strickland, P. A., & Lin, Y. (2004). Analysis of pilot and early phase studies with small sample sizes. *Statistics in Medicine*, *23*(12), 1827–1842.

Sniehotta, F. F., Scholz, U., & Schwarzer, R. (2006). Action plans and coping plans for physical exercise: A longitudinal intervention study in cardiac rehabilitation. *British Journal of Health Psychology*, *11*(1), 23–37. https://doi.org/10.1348/135910705X43804

Thomas, E., Peat, G., Harris, L., Wilkie, R., & Croft, P. R. (2004). The prevalence of pain and pain interference in a general population of older adults: Cross sectional findings from the North Staffordshire Osteoarthritis Project (NorStOP). *Pain*, *110*(1–2), 361–368. http://doi.org/10.1016/j.pain.2004.04.017

Tonkin-Crine, S., Anthierens, S., Hood, K., Yardley, L., Cals, J. W., Francis, N. A., … on behalf of the GRACE INTRO/CHAMP consortium (2016). Discrepancies between qualitative and quantitative evaluation of randomised controlled trial results: Achieving clarity through mixed methods triangulation. *Implementation Science*, *11*, 66. https://doi.org/10.1186/s13012-016-0436-0

van den Berg-Emons, R. J., Schasfoort, F. C., de Vos, L. A., Bussmann, J. B., & Stam, H. J. (2007). Impact of chronic pain on everyday physical activity. *European Journal of Pain*, *11*(5), 587–593. https://doi.org/10.1016/j.ejpain.2006.09.003

von Korff, M., Ormel, J., Keefe, F. J., & Dworkin, S. F. (1992). Grading the severity of chronic pain. *Pain*, *50*(2), 133–149. https://doi.org/10.1016/0304-3959(92)90154-4

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APPENDIX 1

SPIRIT

STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

THE STANDARD PROTOCOL ITEMS FOR RANDOMIZED TRIALS (SPIRIT) CHECKLIST

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents[a].			
Section/item	**Item no**	**Description**	**Addressed on page number**
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions and, if applicable, trial acronym	1_____
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	4_____
	2b	All items from the World Health Organization trial registration data set	4_____
Protocol version	3	Date and version identifier	4_____
Funding	4	Sources and types of financial, material and other support	25_____
Roles and responsibilities	5a	Names, affiliations and roles of protocol contributors	1 & 24_____
	5b	Name and contact information for the trial sponsor	19_____
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	22_____
	5d	Composition, roles and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team and other individuals or groups overseeing the trial, if applicable (see item 21a for data monitoring committee)	23_____

(Continues)

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SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents[a].			
Section/item	**Item no**	**Description**	**Addressed on page number**
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4-5_____
	6b	Explanation for choice of comparators	4-5_____
Objectives	7	Specific objectives or hypotheses	5_____
Trial design	8	Description of trial design, including type of trial (e.g. parallel group, crossover, factorial, single group), allocation ratio and framework (e.g. superiority, equivalence, noninferiority, exploratory)	5_____
Methods: Participants, interventions and outcomes			
Study setting	9	Description of study settings (e.g. community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	7_____
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (e.g. surgeons, psychotherapists)	7_____
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	10-11_____
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (e.g. drug dose change in response to harms, participant request or improving/worsening disease)	N/A_____
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (e.g. drug tablet return, laboratory tests)	10-11_____
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	N/A_____
Outcomes	12	Primary, secondary and other outcomes, including the specific measurement variable (e.g. systolic blood pressure), analysis metric (e.g. change from baseline, final value, time to event), method of aggregation (e.g. median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	12-17_____
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure 1)	Figure 1____
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	17-18_____
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	8-9_____
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (e.g. computer-generated random numbers), and list of any factors for stratification. To reduce the predictability of a random sequence, details of any planned restriction (e.g. blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	9_____
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (e.g. central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	9_____
Implementation	16c	Who will generate the allocation sequence, who will enrol participants and who will assign participants to interventions	9_____

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SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents[a].			
Section/item	**Item no**	**Description**	**Addressed on page number**
Blinding (masking)	17a	Who will be blinded after assignment to interventions (e.g. trial participants, care providers, outcome assessors, data analysts), and how	9_____
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/A_____
Methods: Data collection, management and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline and other trial data, including any related processes to promote data quality (e.g. duplicate measurements, training of assessors) and a description of study instruments (e.g. questionnaires, laboratory tests), along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	12-17_____
	18b	Plans to promote participant retention and complete follow-up, including a list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	14-17_____
Data management	19	Plans for data entry, coding, security and storage, including any related processes to promote data quality (e.g. double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	20-23_____
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	20-23_____
	20b	Methods for any additional analyses (e.g. subgroup and adjusted analyses)	N/A_____
	20c	Definition of analysis population relating to protocol non-adherence (e.g. as randomized analysis), and any statistical methods to handle missing data (e.g. multiple imputation)	N/A_____
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	23_____
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	N/A_____
Harms	22	Plans for collecting, assessing, reporting and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	16,19_____
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	N/A_____
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	23_____
Protocol amendments	25	Plans for communicating important protocol modifications (e.g. changes to eligibility criteria, outcomes, analyses) to relevant parties (e.g. investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	N/A_____
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see item 32)	8_____
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A_____

(Continues)

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SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents[a].			
Section/item	**Item no**	**Description**	**Addressed on page number**
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared and maintained in order to protect confidentiality before, during and after the trial	23-24_____
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	25_____
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	24_____
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A_____
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (e.g. via publication, reporting in results databases or other data sharing arrangements), including any publication restrictions	23_____
	31b	Authorship eligibility guidelines and any intended use of professional writers	N/A_____
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset and statistical code	N/A_____
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorized surrogates	Appendix 2____
Biological specimens	33	Plans for collection, laboratory evaluation and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A_____

[a]It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" licence.

APPENDIX 2

CONSENT FORM

The iPOPP study - increasing Physical activity in Older People with chronic Pain

CONSENT FORM

Please INITIAL each statement you agree to

1. I confirm that I have read and understood the iPOPP RCT Patient Information Sheet (version 2.1 dated 04/02/2016) and have had the opportunity to ask questions..... ☐
2. I understand that I will be allocated to one of three groups, either the Control Group, the Pedometer Group or the iPOPP Intervention Group..... ☐
3. I agree to complete the two questionnaires provided, one at the beginning of the study and one approximately 12 weeks later..... ☐
4. I agree to wear a physical activity monitor (accelerometer) on two occasions for a 7 day period, once at the beginning of the study and once approximately 12 weeks later..... ☐
5. I understand that study data will be stored securely for a minimum of 5 years after funding has ended, and after this time will be destroyed..... ☐
6. I agree for relevant information be obtained from my medical records... ☐
7. I understand that relevant sections of my medical notes may be looked at by individuals from regulatory authorities or from the NHS trust where it is relevant to my taking part in research..... ☐
8. I understand that I may be invited to interview to talk about my experiences of the study..... ☐
9. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason..... ☐
10. I agree that my GP may be informed of my participation in this study.... ☐
11. I agree to participate in the above study..... ☐

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Name of participant (please print) Date Signature

Please note: all information held about you as part of this study will be held in confidence by the iPOPP study team.

Office use only
Study ID