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Complete List of Authors:	Hurley, Deirdre; University College Dublin, School of Public Health, Physiotherapy and Sports Science Hall, Amanda; Oxford University, George Institute for Global Health, Oxford Martin School Currie-Murphy, Laura; Trinity College Dublin, Breast-Predict Collaborative Cancer Research Centre, Pharmacology and Therapeutics Pincus, Tamar; Royal Hollaway University of London, Psychology Kamper, Steve; The George Institute for Global Health, University of Sydney, Musculoskeletal Division; EMGO+ Institute, VU Medical Centre, EMGO+ Institute Maher, Chris; The George Institute for Global Health, University of Sydney, Musculoskeletal Division McDonough, Suzanne; Ulster University, Institute of Nursing and Health Research Walsh, Nicola; University of the West of England, Faculty of Health and Applied Sciences, Glenside Campus Guerin, Suzanne; University College Dublin, School of Psychology Segurado, Ricardo; University College Dublin, CSTAR, School of Public Health, Physiotherapy and Sports Science Matthews, James; University College Dublin, Institute for Sport and Health, School of Public Health, Physiotherapy and Sports Science
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Title page

A theory-driven group-based complex intervention to support self-management of osteoarthritis and low back pain in primary care physiotherapy: protocol for a cluster randomised controlled feasibility trial (SOLAS)

Deirdre A Hurley[1*], Amanda M Hall AM[2], Laura Currie-Murphy[3],Tamar Pincus[4], Steve Kamper[5], Chris Maher[6], Suzanne M McDonough[7], Nicola E Walsh N[8], Suzanne Guerin S[9], Ricardo Segurado[10], James Matthews[11], SOLAS Trial team

1. Institute for Sport and Health and UCD School of Public Health, Physiotherapy and Sports Science, University College Dublin, Dublin 4, Ireland
2. The George Institute for Global Health, Oxford Martin School, Oxford University, Oxford, United Kingdom.
3. Breast-Predict - Collaborative Cancer Research Centre, Pharmacology and Therapeutics, Trinity College Dublin, St James's Hospital, Dublin 8, Ireland.
4. Department of Psychology, University of London, Royal Holloway, Egham, TW20 OEX, Surrey, UK.
5. The George Institute for Global Health, Sydney Medical School, University of Sydney, Level 13, 321 Kent St, Sydney, NSW 2000, Australia.
6. The George Institute for Global Health, Sydney Medical School, University of Sydney, Level 13, 321 Kent St, Sydney, NSW 2000, Australia.
7. Institute of Nursing and Health Research, Ulster University, Jordanstown Campus, Antrim, BT37 0QB, Northern Ireland.
8. Faculty of Health and Applied Sciences, University of the West of England, Glenside Campus, Bristol, BS16 1DD, United Kingdom.
9. UCD School of Psychology, University College Dublin, Dublin 4, Ireland.
10. CSTAR and UCD School of Public Health, Physiotherapy and Sports Science, University College Dublin, Dublin 4, Ireland.
11. Institute for Sport and Health and UCD School of Public Health, Physiotherapy and Sports Science, University College Dublin, Dublin 4, Ireland.

Corresponding author: Dr Deirdre Hurley, Room A302, Health Sciences Centre, School of Public Health, Physiotherapy and Sports Science, University College Dublin, Belfield, Dublin 4, Ireland. Tel: 353 1 7166523; Email: deirdre.hurleyosing@ucd.ie

ABSTRACT

Introduction: International clinical guidelines consistently endorse the promotion of self-management (SM), including physical activity for patients with chronic low back pain (CLBP) and osteoarthritis (OA). Patients frequently receive individual treatment and advice to self-manage from physiotherapists in primary care, but the successful implementation of a clinical and cost-effective group SM programme is a key priority for health service managers in Ireland to maximise long-term outcomes and efficient use of limited and costly resources.

Methods/analysis: This protocol describes an assessor-blinded cluster randomised controlled feasibility trial of a group-based education and exercise intervention underpinned by self-determination theory designed to support an increase in SM behaviour in patients with CLBP and OA in primary care physiotherapy. The primary care clinic will be the unit of randomisation (cluster), with each clinic randomised to 1 of 2 groups providing the Self-management of Osteoarthritis and Low back pain through Activity and Skills (SOLAS) intervention or usual individual physiotherapy. Patients are followed up at 6 weeks, 2 and 6 months. The primary outcomes are the (1) acceptability and demand of the intervention to patients and physiotherapists, (2) feasibility and optimal study design/procedures and sample size for a definitive trial. Secondary outcomes include exploratory analyses of: point estimates, 95% confidence intervals, change scores and effect sizes in physical function, pain and disability outcomes; process of change in target SM behaviours and selected mediators; and the cost of the intervention to inform a definitive trial.

Ethics/dissemination: This feasibility trial protocol was approved by the UCD Human Research Ethics – Sciences Committee [LS-13-54 Currie-Hurley] and research access has been granted by the Health Services Executive Primary Care Research Committee in January 2014. The study findings will be disseminated to the research, clinical and health service communities through publication in peer-reviewed journals, presentation at national and international academic and clinical conferences.

Trial registration number: ISRCTN 49875385

Keywords: back pain, rheumatology, clinical trials, pain management, primary care, rehabilitation medicine

Word count: 4902

Strengths and limitations

This protocol describes a cluster randomised controlled feasibility trial of a theory-driven group-based intervention for primary care patients with low back pain and osteoarthritis.

This study will explore the acceptability and demand of the group-based intervention to patients and physiotherapists compared to usual individual physiotherapy.

The exclusion of patients who are unwilling or unavailable to attend a six week group programme will limit the study's generalisability.

INTRODUCTION

Chronic musculoskeletal pain conditions are the leading cause of disability globally, notably low back pain (LBP) ranked first[1], and hip and knee osteoarthritis (OA) ranked 11th in the Global Burden of Disease 2010 study[2]. The global point prevalence of LBP was estimated at 9.4%, with OA hip and knee combined at 3.8%[3]; Ireland has slightly higher rates of 12% and 4.2% respectively[4, 5]. In the over 50s, OA is the leading cause of disability worldwide, including Ireland (prevalence rate 12.9%),[6] and is predicted to increase due to rising ageing populations and obesity levels[7]. Both conditions place substantial demand on health systems accounting for 10-18% of consultations in primary care[8], and between 5.4% and 12.6% of total health expenditure[9]. In Ireland, 35.5% of primary care consulters experience chronic non-cancer pain at a cost of €5.34 billion per year[10]. The disability associated with LBP and OA also places significant burden on families, carers, economies and society through absenteeism, presenteeism, work disability, and the need for additional social supports[11,12].

International clinical practice guidelines consistently endorse the promotion of self-management (SM) for people with OA [13-15] and chronic LBP[16, 17] as an integral component of care, with important elements being education about the individual's chronic condition, its consequences, and its management and the uptake of evidence-based SM behaviours by participants; including physical activity, specific exercise, and pharmacological and non-pharmacological approaches[15, 16].

While SM is advocated by policy makers for chronic health conditions[7, 18-20], health service commissioners require robust evidence of its clinical and cost effectiveness prior to widespread implementation. Recent reviews suggest only small or equivocal effects for SM compared to other approaches for these conditions[21, 22], while group-based SM programmes with healthcare professional input showed some beneficial effects, further evidence of their clinical and cost effectiveness is needed [23]. Within Ireland's primary care health system the majority of patients with OA and CLBP referred for physiotherapy (PT) are treated individually[24, 25] in a diverse range of health settings by staff with varying degrees of expertise[26]. Our recent rapid review found equivocal effectiveness for individual and group-based SM programmes with limited cost-effectiveness studies and failed to identify a group-based intervention for both OA hip/knee and CLBP[27]. These conditions often present concurrently in those aged over 45 years [28, 29], and could be treated together in order to maximise outcomes and minimise inefficiencies [30]. The successful implementation of an evidence-based group SM programme for CLBP and OA is a key priority for Ireland's PT managers in current resource constrained times [19].

The multifaceted nature of SM interventions with several interacting components that need to be tailored to the individual, and underpinned by a collaborative relationship between the patient and healthcare professional within the local health service constitutes a complex intervention[31], notwithstanding the additional challenges of consistent delivery in a group format, across a diverse range of health settings with varying resources and facilities[32, 33]. It has been argued that the policy for group interventions to encourage SM in primary care has raced ahead of the evidence and there are many unanswered questions for practitioners and policy makers aiming to establish client groups in terms of their feasibility, effectiveness and costs[32, 33]. Therefore, following the Medical Research Council (MRC) framework[31, 34] we developed the Self-management of OA and LBP

through Activity and Skills (SOLAS) intervention that was acceptable and met the needs of Ireland's primary care service stakeholders and the current evidence which will be reported in detail in a separate paper. Applying the MRC framework it is necessary to establish the feasibility of delivering the SOLAS intervention to PTs and patients with OA and CLBP to determine "can it work?", does it work?" and "will it work?" [35] in primary care centres in Ireland compared to usual individual PT care, considered the most appropriate comparison. Hence, a cluster randomised controlled trial design was chosen to avoid contamination of the control group [36]. This feasibility trial will also determine the most efficient and effective design and sample size for a main effectiveness trial and provide an estimate of the cost of delivering the intervention compared to usual PT.

Consistent with the recommendations of trial reporting guidelines[37], we used theory to guide the design of the SOLAS intervention, its delivery and the training of PTs in the feasibility trial. The current lack of theory driven interventions in chronic pain populations [38-40] may partly explain the poor uptake and continuation of SM behaviours, such as physical activity, while conversely, the application of theory to an intervention enables theoretically identified mechanisms of action (i.e., mediators) to be investigated allowing greater understanding of how an intervention works and how it can be enhanced to improve outcomes[41-43]. The SOLAS intervention is underpinned by self-determination theory [44, 45], which aims to increase patients' autonomous motivation and perceived competence to self-manage through the needs supportive environment created by the PT as we have previously demonstrated in individual PT[25, 46]. The intervention is also designed to target specific determinants of SM behaviour (knowledge, skills, self-efficacy/perceived competence, fear, catastrophizing, motivation, behaviour regulation) in order to increase physical activity and the use of specific evidence-based SM behaviours [i.e. pain management using pharmacological and non-pharmacological approaches, pain coping strategies, healthy eating for lifestyle and weight management and specific exercise] leading to changed health outcomes as outlined in figure 1. As the potential for the SOLAS intervention to result in a change in the target SM behaviours is uncertain the contributing assumptions of this underlying theoretical model of behaviour change will be explored within the feasibility trial[47] and will further inform the design of a future effectiveness trial.

Aims and objectives

The aim of this cluster randomised controlled feasibility trial is to evaluate the feasibility and costs of providing the SOLAS intervention [experimental group] to promote self-management for patients with OA hip/ knee and/or CLBP compared to usual PT, which will serve as the pragmatic control group in order to determine the feasibility of moving to a full scale trial by following the MRC guidelines [31, 48].

Our primary objectives are: (1) To assess the acceptability and demand of the SOLAS intervention to patients and physiotherapists compared to usual PT in order to optimise its design, uptake and delivery. (2) To determine the feasibility of trial procedures and the most efficient and effective study design for a definitive RCT, including its sample size. See table 1 below for details of feasibility aspects. The secondary objectives are: (3) To assess medium-term changes in physical function, pain, emotional and global wellbeing. (4) To evaluate contributing assumptions of the underlying theoretical model of behaviour change of the SOLAS intervention compared to usual PT. (5) To

determine the costs of the SOLAS intervention compared to usual PT from the health service and societal perspectives.

Table 1 Operational Definitions of Feasibility Aspects related to SOLAS Intervention and Trial [adapted from Bowen et al 2009] [35]

Feasibility	Operational Definitions			
	SOLAS Intervention		Trial Procedures	
	Participants	Physiotherapists	Participants	Physiotherapists
Acceptability	The extent to which participants who have received the SOLAS intervention consider the content, mode of delivery and support materials acceptable, appropriate, and satisfactory in meeting their needs	The extent to which physiotherapists who have delivered the SOLAS intervention consider the training, content, mode of delivery and support materials acceptable and appropriate in meeting their needs and those of their patients within their service context	The extent to which participants consider taking part in the trial, and follow-ups, outcome measure completion, and fidelity procedures [direct observation of PTs delivering intervention] acceptable and appropriate	The extent to which physiotherapists who have participated in the trial consider trial recruitment and fidelity procedures acceptable and appropriate
Demand	The extent to which participants adhere to and perceive the burden of SOLAS intervention weekly class attendance and target behaviours	The extent to which physiotherapists perceive the demand and positive/negative effects of participating in training, studying intervention materials, preparing class venue and delivering the SOLAS intervention, using specified behaviour change strategies	The extent to which participants perceive the burden of participating in follow-up and completing specific outcome measures within the trial	The extent to which physiotherapists perceive the demand of completing their required tasks for participating in the trial, including fidelity procedures [self-report forms]

Implementation		The quality and extent to which the SOLAS intervention will be delivered as planned by physiotherapists who have completed training		
Practicality		The factors influencing the implementation of the SOLAS intervention in a range of HSE settings by a range of physiotherapists taking into account variations in staffing, facilities, equipment and class size		
Adaptation	The extent to which the SOLAS intervention content, mode of delivery and support materials will need to be modified to enhance its acceptability and implementation for a future definitive trial	The extent to which the SOLAS intervention training, programme content, mode of delivery and support materials will need to be modified during/at end of the trial to enhance its acceptability and implementation for a future definitive trial	The extent to which trial recruitment, follow-up and fidelity procedures and the number and range of outcome measures will need to be modified during/at end of the trial to enhance their acceptability and implementation for a future definitive trial	The extent to which trial recruitment and fidelity procedures, including physiotherapists tasks, will need to be modified during/at end of the trial to enhance acceptability and implementation for a future definitive trial
Integration		The perceived sustainability and level of system change that will be needed to integrate the SOLAS		

		intervention PT training and programme into existing HSE community physiotherapy services		

METHODOLOGY

Design and setting An assessor-blinded multi-centre two-arm non-inferiority cluster randomised controlled feasibility trial [allocation ratio 1:1] has been designed to assess the methodology proposed for use in a definitive RCT. Managers of nine publicly-funded Health Service Executive (HSE) outpatient primary care PT areas in the greater Dublin, Ireland area (population 1.25 million) have agreed to participate. Centres include 18 HSE primary community and continuing care clinics (hereafter referred to as PCCC clinics) with appropriate facilities, equipment and staffing. A full list of study sites is available from the principal investigator (PI). Eligible PTs will be purposively selected by PT managers based on affiliation with suitable study sites, interest, experience and caseload. Prior to randomisation, all identified PTs will receive a PT participant information leaflet, and invitation to provide written consent to confirm their interest by the project manager, which will involve completing training (intervention arm) and treatment of patients in the relevant trial arm. PTs will be invited to contact the project manager with any questions (see figure 2) and written informed consent will be obtained prior to their participation. PTs will not be blinded to treatment allocation, as they are implementing the intervention with HSE patients.

Participants

The following eligibility criteria will be applied to patients referred for PT to one of the participating PCCC clinics:

Inclusion: patients will: have chronic (≥3 months), *Osteoarthritis* [NICE (2014)[15] working diagnosis of OA hip/knee joint: age 45 years old or over, activity related joint pain and no morning joint-related stiffness or morning stiffness that lasts ≤30 minutes] and/or *Low Back Pain* [age ≥ 30 years old and have non-specific LBP of mechanical origin with or without radiation to the lower limb]; be able to read/understand and speak English without assistance; access to a telephone for screening and available to attend a 6 week group class of 1.5hrs per week.

Exclusion: patients will be excluded if: they have serious spinal pathology or previous spinal surgery, nerve root compromise, lower limb arthroplasty, systemic/inflammatory or cardiac disease, are scheduled for major surgery, confounding conditions (neurological, intellectual or unstable psychiatric condition), bladder/bowel incontinence, are assessed to be high risk of falls, had PT in preceding 6 months, are unable/unwilling to attend or ongoing litigation related to their pain condition.

Identification, invitation, screening and recruitment

Identifying eligible participants will be a multi-level process which has been established during the development phase of this project in agreement with participating PCCC areas. It will involve the research team providing referring general practitioners' (GPs) with information about the trial, and intervention arms, PTs raising awareness of the trial at PCCC level, reviewing waiting lists for suitable referrals and sending potentially suitable patients an invitation letter, and the research team undertaking telephone and face-to-face screening and assessment of consenting participants as outlined in figure 2.

All referrals to participating PCCC clinics will be reviewed for any potentially eligible patients with hip, knee or back pain by PTs (age, diagnosis, duration of symptoms), who will be sent standardised letters inviting them to contact the research team for information about the study by phoning [landline or trial mobile], texting or emailing as preferred. Those who make contact will be provided with information about the study, an opportunity to ask questions and if in agreement will be provisionally screened by the researcher [Chartered PT] via telephone using a standardised questionnaire (eligibility criteria, Physical Activity Readiness Questionnaire to confirm medical fitness to participate in the exercise class[49]) taking no longer than 10 minutes. Interested and potentially eligible patients will be invited to attend their local PCCC clinic for face-to-face screening and assessment by the researcher. If indicated the GP will be contacted after screening or assessment to confirm the patient is suitable to participate. Patients will receive a letter containing the participant information leaflet, study website, confirmation of their appointment date/time/location, directions and contact details for queries and a reminder text 24 hours in advance. The researcher will not be blinded to the allocation of each site but will not inform the patient of their randomisation allocation until completion of baseline assessment. A second blinded researcher will review the reasons for inclusion/exclusion of each patient to confirm lack of bias of the un-blinded researcher.

At the face-to-face assessment, the participant information leaflet will be reviewed with the researcher and an opportunity provided to ask questions about the study and what participation involves, before providing written informed consent. Consenting participants will then proceed with screening and assessment, which will follow a standardised PT subjective and objective assessment for the relevant joint area , and balance testing if indicated as in other similar trials[50]**.** If eligibility is confirmed, baseline data including the outcome measures will be completed with support from the researcher, who will read the questions to each participant unless he/she prefers to complete independently.

Participants will then be informed of their allocation by the researcher (based on the random allocation of PCCC clinic), the aim of the trial will be reiterated, and an appointment for commencement will be provided. The researcher will notify PTs which patients have given informed consent and are eligible to participate. All other patients will be informed of the reason(s) for ineligiblity (if appropriate), will remain on the waiting list and advised that they will receive routine PT as soon as an appointment is available as per usual practice. Participants will be advised that they are free to withdraw from treatment and the study at any stage.

Interventions

The interventions are described below in accordance with current guidelines (SPIRIT [51], TIDIER [37] and Borek [52]). Participants in both groups will be advised to continue their normal daily routines and medication, but will be requested to avoid any other treatment for their back, hip or knee pain during the study period.

SOLAS intervention

The overarching aim of the SOLAS intervention is to promote patient SM behaviour, i.e. physical activity and specific SM strategies, through a group exercise and education class and accompanying support materials. See table 2 for details. The intervention is structured and multi-component involving (i) *Education* to increase knowledge about the individual's chronic condition, its consequences, and its SM including the role of a healthy lifestyle and available community resources and (ii) *Training* to impart increased SM behaviours at the end of the intervention and to enable participants to deploy these enhanced skills in their lives beyond the intervention. Participants randomised to this arm will receive six consecutive sessions in a group of up to 6 participants led by a PT within a PCCC clinic or nearby community facility. The overall aim of the programme and the importance of weekly attendance will be explained throughout to improve adherence. To support the promotion of participant SM behaviour, its' determinants have been mapped to each session and relevant behaviour change techniques incorporated within sessions. In line with SDT and the importance of social agents in facilitating autonomous motivation and perceived competence for long term behaviour change, the PT plays a crucial role by being needs supportive and enabling participants to SM by seeking their input, avoiding controlling language such as "should" and "must"; and trying to understand their perspective. The content and dose of each class [including attendance record, rates and reasons for non-attendance or early withdrawal of each participant] will be recorded by the treating therapist in a weekly treatment record form.

Table 2 SOLAS summary intervention map

Session	**Self-management behaviors targeted within the session**	**Intervention content and participant materials**	**Behavior change techniques embedded *within sessions* (as per Michie et al., 2013) [53]**
1	i.Physical activity iia. Specific exercise for pain condition	**Education:** Aims of programme, back pain and OA causes, cycle of change, exercise recommendations, physical activity levels in Ireland, benefits of	1.1; 1.2; 1.3; 1.4; 1.5; 1.6; 1.7; 2.2; 2.3; 2.7; 3.1; 3.2; 3.3; 4.1; 4.2; 5.1; 5.6; 6.1; 8.1; 8.6; 8.7; 9.1; 10.4; 11.2; 13.2; 12.5; 12.6; 15.1

		exercise/physical activity, review of SOLAS exercise programme, physical activity diary and goal setting. **Exercise:** explanation and demonstration of all exercise stations, practice of sample of exercises. **Materials:** Participant Programme Handbook	
2	i.Physical activity iia. Specific exercise for pain condition	**Education:** Activity-rest cycle and pacing activities, use of pedometer, walking technique, understanding pain, physical activity diary, goal setting and action plan. **Exercise:** supervised group exercise class **Materials:** Yamax SW-200 Pedometer	1.1; 1.2; 1.3; 1.4; 1.5; 1.6; 1.7; 1.8; 2.2; 2.3; 2.7; 3.1; 3.2; 3.3; 4.1; 4.2; 5.1; 5.6; 6.1; 8.1; 8.6; 8.7; 9.1; 10.4; 11.1; 11.2; 13.2; 12.5; 12.6; 15.1
3	i.Physical activity iia. Specific exercise for pain condition iib. Healthy eating for lifestyle and balanced weight	**Education:** Balanced weight, obesity levels in Ireland, healthy eating, measuring waist circumference, physical activity diary, goal setting and action plan, food and drink diary. **Exercise:** supervised group exercise class **Materials:** Tape measure, Your Guide to Healthy Eating using the Food Pyramid, 101+ Square Meals cookbook	1.1; 1.2; 1.3; 1.4; 1.5; 1.6; 1.7; 1.8; 2.2; 2.3; 2.7; 3.1; 3.2; 3.3; 4.1; 4.2; 5.1; 5.6; 6.1; 8.1; 8.6; 8.7; 9.1; 10.4; 11,2; 13.2; 12.5; 12.6; 15.1
4	i.Physical activity iia. Specific exercise for pain condition iic. Use	**Education:** Mid-way review, evidence-based pain management with ice/heat, medication, TENS, acupuncture, physical activity diary, goal setting and action plan.	1.1; 1.2; 1.3; 1.4; 1.5; 1.6; 1.7; 1.8; 2.2; 2.3; 2.7; 3.1; 3.2; 3.3; 4.1; 4.2; 5.1; 5.6; 6.1; 8.1; 8.6; 8.7; 9.1; 10.4; 11.1; 11,2; 13.2; 12.5; 12.6; 15.1

	evidence-based pain management approaches to self-manage pain condition	**Exercise**: supervised group exercise class **Materials:**	
5	i.Physical Activity iia. Specific exercise for pain condition iid. Use of pain coping strategies	**Education:** Anxiety, mood and pain, managing flare-ups, pain coping strategies, relaxation techniques and practice, physical activity diary, goal setting and action plan. **Exercise:** supervised group exercise class **Relaxation skills:** practical group session of contract-relax relaxation technique led by PT **Materials**: Relaxation CD	1.1; 1.2; 1.3; 1.4; 1.5; 1.6; 1.7; 1.8; 2.2; 2.3; 2.7; 3.1; 3.2; 3.3; 4.1; 4.2; 5.1; 5.6; 6.1; 8.1; 8.6; 8.7; 9.1; 10.4; 11.1; 11,2; 13.2; 12.5; 12.6; 15.1
6	i.Physical activity iia. Specific exercise for pain condition	**Education:** Discharge planning, maintaining a good exercise routine in the long-term, local resources and activity information, long-term physical activity diary, goal setting and action plan, programme feedback. **Exercise:** supervised group exercise class **Materials:** Local resources to support physical activity leaflet, graduation certificate	1.1; 1.2; 1.3; 1.4; 1.5; 1.6; 1.7; 1.8; 2.2; 2.3; 2.7; 3.1; 3.2; 3.3; 4.1; 4.2; 5.1; 5.6; 6.1; 8.1; 8.6; 8.7; 9.1; 10.4; 11.1; 11,2; 13.2; 12.5; 12.6; 15.1

Structure: once weekly, 90 minute group class involving 45 minutes education/group discussion in an informal lecture format using powerpoint and 45 minutes of supervised exercise in a gym setting. *Exercise*: range of general aerobic (n=8: step ups, stationary cycling) and joint specific mobility and strengthening exercises for the lumbar spine (n=4), hip (n=6) and knee (n=4) designed to increase participants' participation in exercise and physical activity. The frequency and number of exercise stations completed is determined by each participant with support from the PT if needed.

Physiotherapist Training in SOLAS Intervention rationale, content and delivery

Prior to implementation, PTs will complete a two-day [i.e., 12 hours] small group training course [up to 8 PTs], designed and co-facilitated by the intervention developers; a Physiotherapist and Senior researcher (DAH) who holds an MSc in Musculoskeletal PT and a PhD in back pain research, and a registered Psychologist and researcher (JM) who holds an MA in Organisational and Social Psychology and a PhD in Sport and Exercise Psychology. The course aims to introduce PTs to the SOLAS intervention structure, content, support materials and delivery using a needs supportive interpersonal style. Training incorporates active participation, collaboration, and experiential learning[54], using multiple learning methods; brief PowerPoint presentations, videos of 'good ' and 'poor' intervention delivery, troubleshooting intervention implementation, and case based role-plays and micro-teaching activities to practice intervention delivery. Each PT will receive pre-course materials [i.e. intervention handbook, slides, and selected research papers] and following training additional intervention materials and individualised feedback from one of the course facilitators based on audio recordings during the course.

Usual individual PT

Participants in the Control arm will receive usual individualised PT management, defined as usual PT treatment in primary care, which is generally in accordance with international evidence-based guidelines for OA and CLBP[15, 55]; advice on prescribed exercise, manual therapy and exercise therapeutic approaches, with advice and education regarding general lifestyle-related factors including physical activity and healthy diet less common[56]. The content and dose [frequency and duration] of treatment provided to each participant will be at the discretion of the treating PT and explained to participants to promote adherence. The rate and reasons for non-attendance and/or early withdrawal will be documented by the treating PT in a standardised treatment record form. Recruitment will be from the top of the waiting list to minimise delay in commencing treatment and to allow comparability at follow-up points with the experimental arm. PTs will not be permitted to refer participants to a group-based programme for pain management during the trial.

Treatment fidelity

A range of quantitative methods [i.e. direct observation and audio-recording by researcher, PT self-report] at the level of treating PTs in both study arms will be used on at least 30% of the treatment delivery data to assess treatment fidelity during the trial, in addition to qualitative interviews with intervention PTs to assess the feasibility of implementation and its practicality [57]. Fidelity will be assessed and reported by separate evaluators from the outcome evaluators. The PI will be the integration point between the process and outcome evaluation teams [48].

Randomisation and blinding

The PCCC clinics will be the unit of randomisation (cluster) and each clinic will be randomised to the experimental (SOLAS intervention) or control (usual individual PT) arm on a 1:1 basis. In total, 18 suitable PCCC clinics initially identified as suitable for participation were randomised. Following review of geographical proximity of adjacent clinics, current availability of PT staff to participate and withdrawal of clinics, 14 randomised clinics were agreed with PT managers as available at the start of the trial. 12 clinics will proceed with recruitment (6 experimental and 6 control) and 2 clinics (1 experimental and 1 control) be will held as contingency in case recruitment targets are not met. Randomisation will be conducted using a computerized random number generator algorithm by a statistician blinded to the purpose of the study. A researcher will contact all PT managers to inform them of their allocation arm.

Participant and clinician blinding is not possible due to the nature of the intervention, and it is also not possible to blind the researcher at baseline due to the cluster nature of the study. All follow-up outcome assessments will be conducted by a blinded assessor member of the research team. The investigators responsible for data analysis will use a coded dataset to ensure blinding. Semi-structured interviews, which include treatment-specific questions, will be conducted with intervention PTs at the end of delivery, and with participants after the end of outcome measure data collection by un-blinded researchers.

Outcomes and measures

Primary outcomes

The primary outcomes are related to the feasibility of the SOLAS intervention and trial design and procedures. For participants, this will be assessed by questionnaires (see table 3 below) of treatment expectation, satisfaction, acceptability and demand of treatment and trial participation, as well as attendance rates and individual qualitative interviews described below. For physiotherapists, a range of feasibility aspects will be assessed by expectation of treatment questionnaires, individual and focus group qualitative studies. Additionally, the feasibility of trial design and procedures will be assessed by piloting the methodological procedures, monitoring the recruitment and retention rates and procedures, number and reasons for withdrawal during the treatment process, feasibility of outcome measurement, follow-up and fidelity procedures, refining the training programme and calculating the sample size for a definitive trial by estimating the effect sizes and intra-cluster correlation coefficients of secondary outcomes.

Table 3 Feasibility and Process of Behaviour Change Outcomes and Measures

Variable	Measure and Items	Details	Reliability where available	Administration point, trial arms
Expectation of treatment	Expectation of treatment scale[58] 4-items	Patients and PTs rate how helpful they believe both individual and group treatment will be for OA and CLBP. Measured with 10 point numeric rating scales ranging from not at all helpful to extremely helpful.	Internal consistency : 0.84[58]	Baseline only
Client satisfaction with outcome and care	Satisfaction questionnaire[59] 2-items	Patients rate their satisfaction with PT care and their feelings on hypothetically living the rest of their life with current symptoms. Measured using 5-point numeric rating scales.	Internal consistency : 0.87-0.90[60]	2 months, 6 months
Acceptability of treatment and trial participation	Brief questionnaire developed for this trial 11-items	Patients rate their acceptability of treatment received and trial participation, including the burden of outcome measure completion. Measured using 5-point numeric rating scales and yes/no responses.	No reliability data available	6 months
Physical activity	International Physical Activity Questionnaire[61] 7-items	Patients provide time spent undertaking vigorous/moderate physical activity, walking and being sedentary in the last 7 days.	Test-retest reliability range: 0.46-0.96[61]	Baseline, Week 6, 2 months, 6 months
SOLAS self-management behaviours	Brief questionnaire developed for this trial 6-items	Patients describe adherence to target self-management behaviours in the past week on yes/no and number of day scales.	No reliability data available	Baseline, Week 6, 2 months, 6 months
Pain catastrophizing	Pain catastrophizing scale[62] 13-items	Patients indicate their agreement with items following the question 'when in pain' such as I anxiously want the pain to go away' on 5-point scales ranging from 'not	Internal consistency : 0.95[63]	Baseline, Week 6, 2 months, 6 months

		at all' to 'all of the time'.		
Fear	Tampa Scale of Kinesiophobia [64] 11-items	Patient rate beliefs about their pain on a 4-point scale ranging from strongly disagree to strongly agree.	Internal consistency : 0.91[65]	Baseline, Week 6, 2 months, 6 months
Self-efficacy	Pain Self-Efficacy Questionnaire[66] 10-items	Patients rate confidence in performing various activities with their pain on a 7-point scale ranging from not at all confident to completely confident.	Internal consistency : 0.92[66]	Baseline, Week 6, 2 months, 6 months
Autonomy support from PT	Health Care Climate Questionnaire[67] 15-items	Patients rate aspects of their interaction with their PT during treatment, such as 'I feel understood by my physiotherapist' on a 7-point scale ranging from strongly disagree to strongly agree.	Internal consistency : 0.96[67]	Week 1, Week 6
Autonomous and controlled motivation (to follow PTs advice to self-manage)	Treatment Self-Regulation Questionnaire[68] 9-items	Patients rate their agreement with statements on why they follow their PT's advice on a 7-point scale ranging from not true for me to very true for me.	Internal consistency : 0.76[68]	Baseline, Week 6, 2 months, 6 months
Autonomous and controlled motivation (to participate in physical exercise)	Exercise Behaviour Regulation Questionnaire[69] 10-items	Patients answer items related to their motivation to engage in physical exercise on a 5-point scale ranging from not true for me to very true for me.	Internal consistency : 0.89[70]	Baseline, Week 6, 2 months, 6 months
Perceived competence (for self-management)	Perceived Competence Questionnaire[71] 4-items	Patients rate their perceived ability to manage their pain regularly and in the long term on a 7-point scale ranging from not at all true to very true	Internal consistency range: 0.80-0.94[71]	Baseline, Week 6, 2 months, 6 months
Perceived competence (to engage in physical activity or exercise)	Perceived Competence Questionnaire[71] 4-items	Patients rate their perceived ability to exercise and/or engage in physical activity regularly and in the long term on a 7-point scale ranging from not at all true to very true	Internal consistency range: 0.80-0.94[71]	Baseline, Week 6, 2 months, 6 months

Secondary Measures

At baseline demographic data including age, gender, occupational status, and clinical presentation will be documented as well as specific factors that could influence the treatment effect; i.e. therapists' personality (causality orientations), motivation to participate, and treatment expectations; participants' level of risk of chronicity (CLBP participants only). The selected secondary outcome measures are core outcomes for chronic pain trials including: physical functioning, pain intensity, pain bothersomeness, emotional functioning, quality of life, and global ratings of improvement[72-74], as well as recommended economic outcomes[75]. The process of change in selected mediators (pain catastrophizing, fear, self-efficacy/ perceived competence and motivation) and engagement in SM behaviours (physical activity and specific SM strategies) will be assessed using a range of measures. The cost of the SOLAS intervention compared to individual PT will be evaluated using several resource utilisation and health state measures. See table 3 and supplementary file for details of all measures.

Data collection

Secondary outcomes will be collected at baseline, 2 and 6 months from baseline/start of treatment, and, there will be an additional 6 week follow-up time point for collection of process of behaviour change outcomes using the same data collection methods. This will involve a face-to-face interview with a researcher at baseline, and completion at all follow-up points with a blinded researcher by telephone to minimise participant data entry errors. The time for completion will be documented. Participants will receive an information letter and questionnaire pack one week prior to each follow-up point, and telephone contact to arrange a convenient time for completion with the researcher. Participants will have the option to complete outcome assessment by post if preferred. Non-respondents will be contacted by phone/text message on three occasions within a three day period to invite completion of outcomes, and if no response is obtained will be posted the outcome measure pack [minimum data set] and pre-paid envelope, and receive a text reminder inviting completion at their convenience. All researchers will receive training in interview skills and outcome measure administration by the PI prior to commencement.

Qualitative Studies

Individual qualitative semi-structured telephone interviews will be conducted with a purposive sample of consenting participants who received the SOLAS intervention or usual PT (2:1 ratio) on completion of the 6 month follow-up to explore in depth their experience of treatment and trial participation, necessary adaptations to optimise acceptability and uptake, and their use of target SM behaviours. Individual qualitative semi-structured telephone interviews will be conducted with all PTs' following delivery of the SOLAS intervention to establish their views on the acceptability and demand of the training course, SOLAS intervention, trial recruitment and fidelity procedures and necessary adaptations to optimise acceptability and implementation. On completion of the trial a focus group with PT Managers and a purposive sample of PTs will assess views on the practicality

and potential future integration of the SOLAS intervention into existing PCCC services to further inform a definitive trial.

Sample size

We plan to recruit between 12 - 14 clusters (PCCC sites) to ensure the intervention is feasible across a range of settings with variable staffing, facilities, equipment and clientele. There will be a minimum of 6 clusters in each arm, participating in two waves of recruitment with the aim to recruit 6 participants in each cluster per wave, resulting in 144 participants (72 per arm). Additional clusters (n=2), will only be included as a contingency if recruitment targets are not met and added to the final study waves. Recommendations for feasibility studies suggest that the data set for analysis include at least 30 participants per arm in order to estimate parameters for future sample size calculations[76-78]. Accounting for the cluster design effect and assuming an ICC coefficient of 0.03[79], an effective sample size of 30 would require 36 participants per arm. Allowing for 25% loss to follow up, we would need to recruit 48 participants per arm [96 in total]. Therefore, this study size will be sufficiently large to allow a precise estimate of the ICC coefficient; the greater the number of clusters the more precise the estimate of the ICC coefficient [80]. This study design and sample size should therefore satisfy the dual aims of 1) feasibility and 2) estimation of statistics to enable a future sample size calculation for a definitive trial.

Data integrity

All hard copy and audio-recorded data will be kept confidential and stored in a locked filing cabinet in the research group office and in softcopy in a password protected database only accessible to the PI, data manager and statistician. The research team will monitor the integrity of trial data. All participant, group allocation, treatment record and sociodemographic data will be coded, and outcome questionnaires scored, and all data will be double entered into the Statistical Package for the Social Sciences package to detect and correct input errors, and range checks will be undertaken prior to data analysis. A research investigator un-blinded to treatment allocation will perform regular data checks during data entry and provide feedback to PTs regarding data omissions where necessary.

Planned analyses

Since this is a feasibility study extensive exploratory and descriptive analysis of the data will be undertaken. A combination of quantitative and qualitative methods will be used to answer the primary research objectives related to the feasibility of the intervention and trial procedures to participants and PTs to determine the feasibility and most efficient and effective study design for a definitive trial. Statistical analysis will be by intention to treat according to participants' assigned arm of the study, regardless of whether they attend for treatment or not. The data analysis plan for treatment fidelity will be reported separately.

Analysis of the feasibility aspects will be undertaken after each study wave and used to inform minor protocol refinements for subsequent waves. Qualitative data will be analysed using inductive thematic analysis, based on Braun and Clarke's[81] method. Coding frames will be developed from a review of provisional themes, which will then be re-examined and refined. The reliability of the identified themes will be established by a second researcher who will independently code a random sample of 25% of each dataset using the coding frame, with 70% agreement taken as the minimum cut-off rate of agreement[82]**.** The recruitment rate overall, and according to study arm and PCCC clinic will be calculated in addition to the ratio of number screened: number enrolled. The conversion rate and reasons for exclusion/refusal/withdrawal at each stage in the recruitment process and the attrition rate during the treatment period will be evaluated. The feasibility of outcome measurement procedures will be assessed by the time to complete measures, the number of missing items according to outcome measure, and the follow-up rates and methods of completion [phone, post] at each time point and participants' reported burden of completion.

Analysis of the secondary outcome measure data will be undertaken at the end of the trial and performed by the statistician who will remain blinded to group identification until analysis is complete. A linear mixed model will be used to examine change over time in participant outcomes between treatment groups, while adjusting for study waves and clinics, and potentially individual PTs. Treatment effects will be reported with 95% confidence intervals and ICCs for the clusters. The results will guide a sample size calculation and the form of the primary analysis for a definitive trial. The relationships between the SOLAS intervention and the physical activity/ SM behaviour measures, via potential mediators (pain catastrophizing, fear, self-efficacy/perceived competence and motivation) will be explored, contingent on adequate sample size, with a series of linear models[83], and by applying the test of Sobel[84], and structural equation models, and extended to examine impact on secondary outcomes. Finally, the cost of the SOLAS intervention compared to usual PT will be calculated from the health service and societal perspectives using data from resource utilisation measures, alongside exploratory analysis of quality adjusted life years (EQ-5D) and disease specific measures[85].

Adverse effects or events

No adverse events, apart from minor musculoskeletal complaints in the SOLAS intervention arm due to unaccustomed exercise, are anticipated. Participants and PTs will be informed that any adverse events should be reported immediately to the PI and will be documented by the research team by type, length of time, and frequency should they occur.

Trial governance

The Trial Management Committee (TMC), comprising the PI and local co-investigators provides overall management of the feasibility trial including PCCC clinic set-up, PT training, recruitment and screening procedures, trial promotion, data collection, analysis and interpretation. Trial conduct will be audited on a weekly basis using a standardised proforma during each recruitment wave, and biannually at the end of each recruitment wave. Members of the international scientific team

provide independent and scientific oversight of the progress of the study through the Data Monitoring Committee on behalf of the funder [Health Research Board].

ETHICS AND DISSEMINATION

All patients and physiotherapists will be provided with detailed written information and have an opportunity to discuss participation before providing written consent and will be advised they can withdraw at any point. Patients will be invited to give their consent to participate in a telephone interview following completion of all follow-ups. The feasibility results will be published in peer-reviewed journals and presented at national and international academic, clinical and health service conferences. Any protocol amendments including changes to eligibility criteria, outcomes or analyses will be communicated to the UCD Human Research Ethics – Sciences Committee and the HSE Primary Care Research Committee, and noted on the Current Controlled Trials trial registration page and reported in the trial results papers.

DISCUSSION

The provision of self-management healthcare interventions with robust evidence of clinical and cost effectiveness for chronic conditions, including LBP and OA, are becoming increasingly important due to their rising prevalence and significant impact on the individual, their family and carers, employers and wider society. The complex multifaceted nature of supporting patients to engage in SM behaviours requires an underlying model of behaviour change to enhance the likelihood of long-term adherence and to understand the underlying processes of change. Group-based interventions that are first designed, adapted and tested for feasibility and cost implications in partnership with patients' and healthcare providers within local health service settings before robust evaluation in an effectiveness trial have the potential to address this second translational gap. The feasibility of the SOLAS theory-driven, group-based complex intervention will be evaluated from the patient, practitioner and health service manager levels, and if achieved the trial design will be refined based on the findings of this study before moving to a definitive trial.

RERERENCES

1. Vos T, Barber RM, Bell B, et al. Global, regional, and national incidence, prevalence, and years lived with disability for 301 acute and chronic diseases and injuries in 188 countries, 1990–2013: a systematic analysis for the Global Burden of Disease Study 2013. *Lancet* 2015;386:743-800 doi: 10.1016/S0140-6736(15)60692-4 [published Online First: 7 June 2015].
2. Cross M, Smith E, Hoy D, et al. The global burden of hip and knee osteoarthritis: estimates from the global burden of disease 2010 study. *Ann Rheum Dis* 2014;73:1323-30 doi: 10.1136/annrheumdis-2013-204763 [published Online First: 19 February 2014].
3. March L, Smith EUR, Hoy DG, et al. Burden of disability due to musculoskeletal (MSK) disorders. *Best Pract Res Clin Rheumatol* 2014;28:353-66 doi: 10.1016/j.berh.2014.08.002 [published Online First: 18 November 2014].
4. Healthy Ireland Survey, The Stationey Office, Dublin, 2015.
5. Institute of Public Health. Musculoskeletal conditions briefing, Dublin, 2012.
6. French HP, Galvin R, Horgan NF, et al. Prevalence and burden of osteoarthritis amongs older people in Ireland: findings from the Irish LongituDinal Study on Ageing (TILDA). *Eur J Public Health* pii: ckv109 [published Online First: 23 June 2015].
7. Speerin R, Slater H, Li L, et al. Moving from evidence to practice: Models of care for the prevention and management of musculoskeletal conditions. *Best Pract Res Clin Rheumatol* 2014;28:479-515 doi: 10.1016/j.berh.2014.07.001 [published Online First: 16 August 2014].
8. EUMUSC. *Musculoskeletal briefing*. 2012
9. Slobbe L, Kommer G, Smit J, et al. Costs of illness in the Netherlands 2003. *Bilthoven: Rijksinstituut voor Volksgezondheid en Milieu* 2006.
10. Raftery MN, Ryan P, Normand C, et al. The economic cost of chronic noncancer pain in Ireland: results from the PRIME study, part 2. *Pain* 2012;13:139-45 doi: 10.1016/j.jpain.2011.10.004.
11. Wilkie R, Hay EM, Croft P, et al. Exploring how pain leads to productivity loss in primary care consulters for osteoarthritis: A prospective cohort study. *Plos One* 2015 doi: 10.1371/journal.pone.0120042 [published Online First: 7 April 2015].
12. Buchbinder R, Blyth FM, March LM, et al. Placing the global burden of low back pain in context. *Best Pract Res Clin Rheumatol* 2013;27:575-89 doi: 10.1016/j.berh.2013.10.007 [published Online First: 12 October 2013].
13. Fernandes L, Hagen KB, Bijlsma JW, et al. EULAR recommendations for the non-pharmacological core management of hip and knee osteoarthritis. *Ann Rheum Dis* 2013;72:1125-35 doi: 10.1136/annrheumdis-2012-202745 [published Online First: 17 April 2013].
14. McAlindon T, Bannuru R, Sullivan M, et al. OARSI guidelines for the non-surgical management of knee osteoarthritis. *Osteoarthritis Cartilage* 2014;22:363-88 doi: 10.1016/j.joca.2014.01.003 [published Online First: 24 January 2014].
15. Excellence NIFHAC. *Osteoarthritis. Care and management in adults*. Clinical Guideline 177. London:Nice,2014.
16. Delitto A, George SZ, Van Dillen LR, et al. Low back pain. *J Orthop Sports Phys Ther* 2012;42:A1-57 doi: 10.2519/jospt.2012.0301 [published Online First: 30 March 2012].
17. Savigny P, Watson P, Underwood M. Early management of persistent non-specific low back pain: summary of NICE guidance. *BMJ* 2009;338;b1805 doi: 10.1136/bmj.b1805.
18. Health Do. *Supporting people with long term conditions: an NHS and social care model to support local innovation and integration*: Department of Health, Leeds, 2005.
19. HSE. *Framework for self-management support, long-term health conditions: HSE National Advocacy Unit. Secondary framework for self-management support, long-term health conditions*: HSE National Advocacy Unit, Dublin, 2012.
20. Imison C, Naylor C, Buck D, et al. Transforming our healthcare system. *London: The King's Fund* 2011.

21. Kroon FP, van der Burg LR, Buchbinder R, et al. Self-management education programmes for osteoarthritis. *Cochrane Database Syst Rev* 2014;1:Cd008963 doi: 10.1002/14651858.CD008963.pub2.
22. Taylor SJ, Pinnock H, Epiphaniou E, et al. A rapid synthesis of the evidence on interventions supporting self-management for people with long-term conditions: PRISMS–practical systematic review of self-management support for long-term conditions. NIHR Journals Library Southampton, 2014.
23. Carnes D, Homer K, Miles C, et al. Effective delivery styles and content for self-management interventions for chronic musculoskeletal pain: A systematic literature review. *Clin J Pain* 2012;28:344-54 doi: 10.1097/AJP.0b013e31822ed2f3.
24. French HP, Cusack T, Brennan A, et al. Exercise and manual physiotherapy arthritis research trial (EMPART) for osteoarthritis of the hip: a multicenter randomized controlled trial. *Arch Phys Med Rehab* 2013;94:302-14 doi: 10.1016/j.apmr.2012.09.030 [published Online First: 16 October 2012].
25. Murray A, Hall A, Williams G, et al. Effect of a self-determination theory-based communication skills training program on physiotherapists psychological support for their patients with chronic low back pain: A randomized controlled trial. *Arch Phys Med Rehab* 2015;96:809-16 doi: 10.1016/j.apmr.2014.11.007 [published Online First: 26 November 2014].
26. McMahon S, Cusack T, O'Donoghue G. Barriers and facilitators to providing undergraduate physiotherapy clinical education in the primary care setting: a three-round Delphi study. *Physiotherapy* 2014;100:14-19 doi: 10.1016/j.physio.2013.04.006 [published Online First: 15 August 2013].
27. Toomey EC, Currie-Murphy L, Matthews J, et al. The effectiveness of physiotherapist-delivered group education and exercise interventions to promote self-management for people with oesteoarthritis and chronic low back pain: A rapid review Part I. *Man Ther* 2015;20:365-86 doi: 10.1016/j.math.2014.10.013 [published Online First: 1 November 2014].
28. O'Farrell S, Smart K, Caffrey A, et al. Orthopaedic triage at a physiotherapist-led 'Musculoskeletal Assessment Clinic': a seven-month service evaluation of outcomes. *Ir J Med Sci* 2014;183:565-71 doi: 10.1007/s11845-013-1052-5 [published Online First: 12 December 2013].
29. Roddy E, Zwierska I, Jordan KP, et al. Musculoskeletal clinical assessment and treatment services at the primary-secondary care interface: an observational study. *Brit J Gen Pract* 2013;63:e141-e48 doi: 10.3399/bjgp13X663109.
30. Pasquale MK, Dufour R, Joshi AV, et al. Inefficiencies in osteoarthritis and chronic low back pain management. *Am J Manag Care* 2013;19:816-23.
31. Craig P, Dieppe P, Macintyre S, et al. Developing and evaluating complex interventions: the new Medical Research Council guidance. *BMJ* 2008;337:a1655 doi: 10.1136/bmj.a1655.
32. Greaves CJ, Campbell JL. Supporting self-care in general practice. *Brit J Gen Pract* 2007;57:814-21.
33. Hoddinott P, Allan K, Avenell A, et al. Group interventions to improve health outcomes: a framework for their design and delivery. *BMC Public Health* 2010;10:800 doi: 10.1186/1471-2458-10-800.
34. Craig P, Petticrew M. Developing and evaluating complex interventions: Reflections on the 2008 MRC guidance. *Int J Nurs Stud* 2013;50:585-87 doi: 10.1016/j.ijnurstu.2012.09.009 [published Online First: 16 November 2012].
35. Bowen D, Kreuter M, Spring B, et al. How we design feasibility studies. *Am J Prev Med* 2009;36:452-57 doi: 10.1016/j.amepre.2009.02.002.
36. Campbell M, Fitzpatrick R, Haines A, et al. Framework for design and evaluation of complex interventions to improve health. *BMJ* 2000;321:694-96.

37. Hoffmann TC, Glasziou PP, Boutron I, et al. Better reporting of interventions: template for intervention description and replication TIDieR checklist and guide. *BMJ* 2014;348:g1687 doi: 10.1136/bmj.g1687.
38. Williams A, Eccleston C, Morley S. Psychological therapies for the management of chronic pain (excluding headache) in adults. *Cochrane Database Syst Rev* 2012; 11 CD007407 doi: 10.1002/14651858.CD007407.pub3.
39. Keogh A, Tully MA, Matthews J, et al. A review of behaviour change theories and techniques used in group based self-management programmes for chronic low back pain and arthritis. *Man Ther* Published Online First: 30th March 2015. doi: 10.1016/j.math.2015.03.014.
40. Marley J, Tully M, Poter-Armstrong A, et al. A systematic review of interventions aimed at increasing physical activity in adults with chronic musculoskeletal pain - protocol. *Syst Rev* 2014;3:106 doi: 10.1186/2046-4053-3-106.
41. Michie S, Abraham C. Identifying techniques that promote health behaviour change: Evidence based or evidence inspired? Psychological Health 2004;19:29-49.
42. Rothman R. Is there nothing more practical than a good theory?: Why innovations and advances in health behavior change will arise if interventions are used to test and refine theory. *Int J Behav Nutr Phys Act* 2004;1:11.
43. Rothman AJ. Capitalizing on opportunities to refine health behavior theories. *Health Educ Behav* 2009;36:150S-5S; discussion 67S-71S.
44. Ryan D, Deci E. Self-determination theory and the facilitation of intrinsic motivation, social development and well being. *Am Psychol* 2000;55:68-78.
45. Ng JY, Ntoumanis N, Thøgersen-Ntoumani C, et al. Self-determination theory applied to health contexts a meta-analysis. *Perspect Psychol Sci* 2012;7:325-40 doi: 10.1177/1745691612447309.
46. Matthews J, Hall AM, Hernon M, et al. A brief report on the development of a theoretically-grounded intervention to promote patient autonomy and self-management of physiotherapy patients: face validity and feasibility of implementation. *BMC Health Serv Res* 2015;15:260 doi: 10.1186/s12913-015-0921-1.
47. Courneya KS. Efficacy, effectiveness, and behavior change trials in exercise research. *Int J Behav Nutr Phys Act* 2010;7:81 doi: 10.1186/1479-5868-7-81.
48. Moore GF, Audrey S, Barker M, et al. Process evaluation of complex interventions: Medical Research Council guidance. *BMJ* 2015;350:h1258 doi: 10.1136/bmj.h1258.
49. Adams R. Revised physical activity readiness questionnaire. *Can Fam Physician* 1999;45:1004-5.
50. Walsh N, Cramp F, Palmer S, et al. Exercise and self-management for people with chronic knee, hip or lower back pain: a cluster randomised controlled trial of clinical and cost-effectiveness. Study protocol. *Physiotherapy* 2013;99:352-57 doi: 10.1016/j.physio.2012.09.002 [published Online First: 30 November 2012].
51. Chan AW, Tetzlaff JM, Gotzsche PC, et al. SPIRIT 2013 explanation and elaboration: guidance for protocols of clinical trials. *BMJ* 2013;346:e7586 doi: 10.1136/bmj.e7586.
52. Borek AJ, Abraham C, Smith JR, et al. A checklist to improve reporting of group-based behaviour-change interventions. *BMC Public Health* 2015;15:963 doi: 10.1186/s12889-015-2300-6.
53. Michie S, Richardson M, Johnston M, et al. The behavior change technique taxonomy (v1) of 93 hierarchically clustered techniques: building an international consensus for the reporting of behavior change interventions. *Ann Behav Med* 2013 46:81-95 doi: 10.1007/s12160-013-9486-6.
54. Aelterman N, Vansteenkiste M, Keer HV, et al. Development and evaluation of a training on needs-supportive teaching in physical education: qualitative and quantitative findings. Journal of Teacher Education 2013;29:64-75.
55. Koes BW, van Tulder M, Lin C-WC, et al. An updated overview of clinical guidelines for the management of non-specific low back pain in primary care. *Eur Spine J* 2010;19:2075-94 doi: 10.1007/s00586-010-1502-y [published Online First: 3 July 2010].

56. O'Donoghue G, Cunningham C, Murphy F, et al. Assessment and management of risk factors for the prevention of lifestyle-related disease: a cross-sectional survey of current activities, barriers and perceived training needs of primary care physiotherapists in the Republic of Ireland. *Physiotherapy* 2014;100:116-22 doi: 10.1016/j.physio.2013.10.004 [published Online First: 8 January 2014].
57. Borelli B. The assessment, monitoring and enhancement of treatment fidelity in public health clinical trials. *J Public Health Dent* 2011;71:S52-S63.
58. Smeets RJ, Beelen S, Goossens ME, et al. Treatment expectancy and credibility are associated with the outcome of both physical and cognitive-behavioral treatment in chronic low back pain. *Clin J Pain* 2008;24:305-15 doi: 10.1097/AJP.0b013e318164aa75.
59. Hurley DA, Tully MA, Lonsdale C, et al. Supervised walking in comparison with fitness training for chronic back pain in physiotherapy: results of the SWIFT single-blinded randomized controlled trial (ISRCTN17592092). *Pain* 2015;156:131-47 doi: 10.1016/j.pain.0000000000000013.
60. Fischer D, Stewart AL, Bloch DA, et al. Capturing the patient's view of change as a clinical outcome measure. *Jama* 1999;282:1157-62.
61. Craig CL, Marshall AL, Sjostrom M, et al. International physical activity questionnaire: 12-country reliability and validity. *Med Sci Sports Exerc* 2003;35:1381-95.
62. Sullivan MJ, Bishop SR, Pivik J. The pain catastrophizing scale: development and validation. Psychological Assessment 1995;7:524.
63. Osman A, Barrios FX, Gutierrez PM, et al. The pain catastrophizing scale: further psychometric evaluation with adult samples. *J Behav Med* 2000;23:351-65.
64. Kori SH, Miller RP, Todd DD. Kinesophobia: A new view of chronic pain behavior. Pain Management 1990:35-43.
65. Lundberg MK, Styf J, Carlsson SG. A psychometric evaluation of the Tampa Scale for Kinesiophobia—from a physiotherapeutic perspective. Physiotherapy Theory and Practice 2004;20:121-33.
66. Nicholas MK. The pain self-efficacy questionnaire: Taking pain into account. *Eur J Pain* 2007;11:153-63.
67. Williams GC, Freedman ZR, Deci EL. Supporting autonomy to motivate glucose control in patients with diabetes. *Diabetes Care* 1998,21:1644–1651.
68. Levesque CS, Williams GC, Elliot D, et al. Validating the theoretical structure of the treatment self-regulation questionnaire (TSRQ) across three different health behaviors. *Health Educ Res* 2007;22:691-702.
69. Mullan E, Markland D, Ingledew DK. A graded conceptualisation of self-determination in the regulation of exercise behaviour: Development of a measure using confirmatory factor analytic procedures. Personality and Individual Differences 1997;23:745-52.
70. Murcia JA, Gimeno EC, Camacho AM. Measuring self-determination motivation in a physical fitness setting: validation of the Behavioral Regulation in Exercise Questionnaire-2 (BREQ-2) in a Spanish sample. The Journal of Sports Medicine and Physical Fitness 2007;47:366-74.
71. Williams GC, Deci EL. Internalization of biopsychosocial values by medical students: a test of self-determination theory. *J Pers Soc Psychol* 1996;70:767-79.
72. Chiarotto A, Deyo RA, Terwee CB, et al. Core outcome domains for clinical trials in non-specific low back pain. *Eur J Spine* 2015;24:1127-42 doi: 10.1007/s00586-015-3984-0 [published Online First: 8 May 2015].
73. Deyo RA, Dworkin SF, Amtmann D, et al. Report of the NIH Task Force on research standards for chronic low back pain. *Pain Med* 2014;15:1249-67 doi: 10.1111/pme.12538.
74. Dworkin RH, Turk DC, Farrar JT, et al. Core outcome measures for chronic pain clinical trials: IMMPACT recommendations. *Pain* 2005;113:9-19.

75. HIQA. Guidelines for the economic evaluation of health technologies in Ireland, 2014. http://www.hiqa.ie/publication/guidelines-economic-evaluation-healthtechnologiesireland. accessed 27th November 2015.
76. Browne RH. On the use of a pilot sample for sample-size determination. *Stat Med* 1995;14:1933-40.
77. Lancaster GA, Dodd S, Williamson PR. Design and analysis of pilot studies: recommendations for good practice. *J Eval Clin Pract* 2004;10:307-12.
78. Shih WJ, Ohman- Strickland PA, Lin Y. Analysis of pilot and early phase studies with small sample sizes. *Stat Med* 2004;23:1827-42.
79. Lonsdale C, Hall AM, Williams GC, et al. Communication style and exercise compliance in physiotherapy (CONNECT). A cluster randomized controlled trial to test a theory-based intervention to increase chronic low back pain patients' adherence to physiotherapists' recommendations: study rationale, design, and methods. *BMC Musculoskelet Disord* 2012;13:104 doi: 10.1186/1471-2474-13-104.
80. Kerry SM, Bland JM. Statistics notes - The intracluster correlation coefficient in cluster randomisation. *BMJ* 1998;316:1455-55.
81. Braun V, Clarke V. Using thematic analysis in psychology. *Qual Res Psychol* 2006;3:77-101.
82. Guerin S, Hennessy E. Pupils' definitions of bullying. European Journal of Psychology of Education 2002;17:249-61.
83. Baron RM, Kenny DA. The moderator mediator variable distinction in social psychological-research - conceptual, strategic, and statistical considerations. *J Pers Soc Psychol* 1986;51:1173-82.
84. Sobel M. Asymptotic intervals for indirect effects in structural equations models. Sociological Methodology 1982:290-312.
85. Ramsey SD, Willke RJ, Glick H, et al. Cost-effectiveness analysis alongside clinical trials II-an ISPOR good research practices task force report. *Value Health* 2015;18:161-72 doi: 10.1016/j.jval.2015.02.001.

Authors' contributions

DAH and AH conceived the idea for the study and with input from TP, CM and SK secured funding. DAH and JM developed the SOLAS intervention and training programme with input from LM, AH, SG and NW. DH and LM designed the trial with input from JM, AH, RS, NW, SG, SMcD, SK, CM, and TP. RS, DAH and SG devised the planned analysis. DAH drafted the manuscript with critical input from all authors.

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Competing interests None declared

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Illustrations and figures

Figure 1 Process map of behaviour change in SOLAS intervention

Figure 2: Study recruitment, allocation and follow up

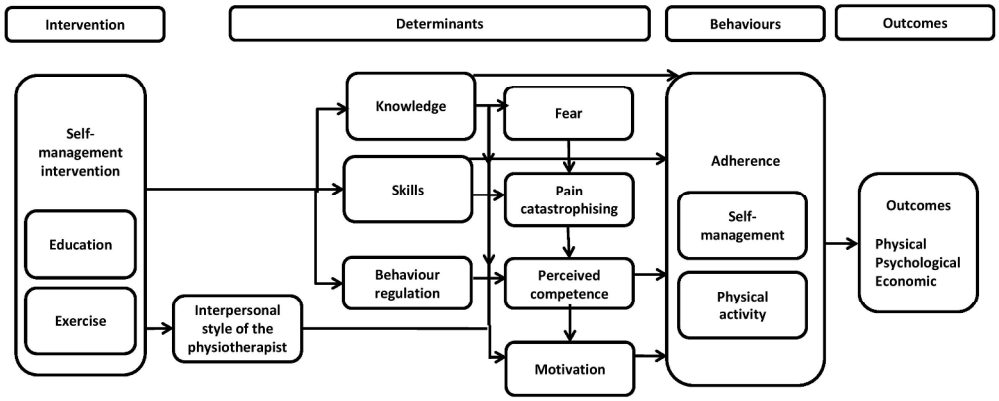

Figure 1 Process map of behaviour change in SOLAS intervention
254x190mm (300 x 300 DPI)

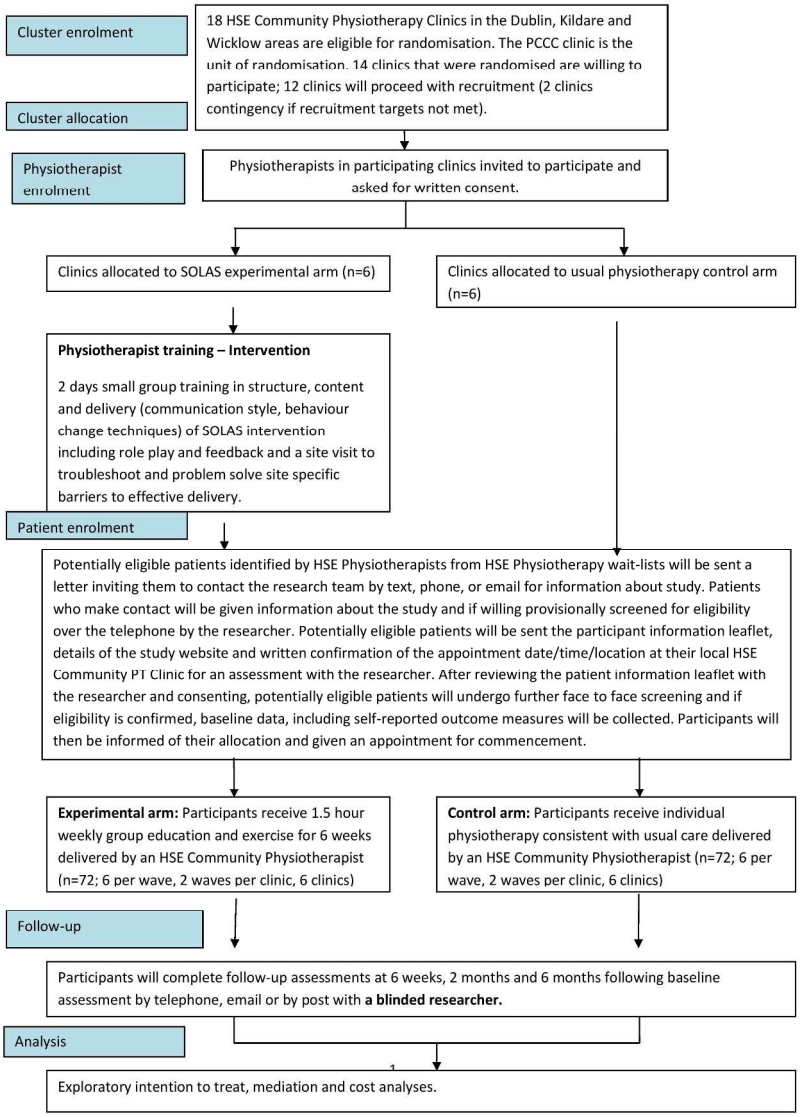

Figure 2: Study recruitment, allocation and follow up
210x297mm (300 x 300 DPI)

Supplementary file Secondary Outcomes and Measures

Variable	Measure and items	Details	Reliability where available	Administration point, trial arms
LBP patients risk of chronicity	StarT Back Screening Tool [1] 9-items	Patients rate agreement/ disagreement with a range (8) of modifiable prognostic indicators including bothersomeness, disability and mood over the past 2 weeks.	Internal consistency: 0.74l[1, 2]	Baseline only
Physiotherapists General Causality Orientations	General Causality Orientation Scale[3] 36-items	PTs rate their likely behaviour in a range of vignettes evaluating autonomous, controlling and impersonal responses on a 7-point scale ranging from very unlikely to very likely.	Internal consistency for 3 subscales range: 0.69-0.74[3]	Pre-training
Physiotherapists autonomous and controlled motivation to participate in training	Motivation to Participate Questionnaire[4] 8-items	PTs rate their reasons for participating in training on a 7-point Likert scale ranging from not at all true to very true.	No reliability data available	Pre-training
Osteoarthritis specific-functional disability	WOMAC Function Daily Living Subscale Hip or Knee[5] 17-items	Patients rate difficulty with hip and/or knee in performing various everyday activities.	Internal consistency for the subscales range: 0.83-0.96[6]	Baseline, 2 months, 6 months
Low back pain-specific functional disability	Roland-Morris Disability Questionnaire[7] 24-items	Patients respond to statements which match their experience of low back pain on the day of completion on a dichotomous scale.	Internal consistency: 0.91[7]	Baseline, 2 months, 6 months
Physical component of functional disability	Short Form-12[8] 12-items	Patients rate health and the limitations caused by physical problems on 5 point Likert scales ranging from all of the time to none of the time.	Internal consistency: 0.77[9]	Baseline, 2 months, 6 months
Pain intensity	Pain Rating	Patients rate their level	Inter-rater	Baseline,

	Scale[10] 1-item	of pain in the past week on an 11-point numeric scale.	reliability: 0.56[11]	2 months, 6 months
Pain bothersomeness	Single item on a numeric rating scale[1, 12] 1-item	Patients rate how bothered they've been by their pain in the last week on a 5-point scale ranging from not at all to extremely.	Internal consistency: 0.79[1, 12]	Baseline, 2 months, 6 months
Quality of life [Health state]	EuroQol Weighted Health Index[13] 5-items	Patients describe their current health state under five domains: mobility, self-care, usual activities, pain/discomfort, anxiety/depression.	Test-retest reliability range for the subscales range: 0.70-0.85[14]	Baseline, 2 months, 6 months
Mood	Hospital Anxiety and Depression Scale[15] 14-items	Patients rate agreement with items related to anxiety or depression, such as "I feel tense or 'wound up'" on a 4-point scale.	Internal consistency for the subscales range: 0.78-0.86[16]	Baseline, 2 months, 6 months
Global impression of change	Global Perceived Effect Scale[17] 1-item	Patients rate on an 11-point scale the level of change (positive or negative) in their hip, knee and/or back pain between now and when the pain episode started ranging from vastly worse to vastly recovered.	Test-retest reliability excellent: intraclass correlation coefficient: 0.90-0.99[18]	2 months, 6 months
Resource utilisation costs related to the patient	Client Services Receipt Inventory[19] 20-items	Patients recall costs related to their condition and its treatment: healthcare, labour productivity changes, costs borne by patients and their families and state benefits received.	Concordance correlation: 0.756[20]	Baseline, 6 months
Resource utilisation costs related to providing treatment	Brief questionnaire developed for this trial 10-items Purchase	Treating PTs record staff time, facilities, equipment used to provide treatment. Overheads will be estimated. Actual costs of	No reliability data available	End of treatment

	invoices	producing, printing or purchasing intervention materials will be documented.		

1. Hill JC, Dunn KM, Lewis M, et al. A primary care back pain screening tool: identifying patient subgroups for initial treatment. *Arthritis Rheum* 2008;59:632-41. doi: 10.1002/art.23563.
2. Bruyère O, Demoulin M, Beaudart C, et al. Validity and reliability of the French version of the STarT Back Screening Tool for patients with low back pain. *Spine* 2014;39:E123-E28. doi: 10.1097/BRS.0000000000000062
3. Williams GC, Grow VM, Freedman ZR, et al. Motivational predictors of weight loss and weight-loss maintenance. *J Pers Soc Psychol* 1996;70:115-26.
4. Black AE, Deci EL. The effects of instructors' autonomy support and students' autonomous motivation on learning organic chemistry: A self-determination theory perspective. *Sci Ed* 1989;84:740-56.
5. Bellamy N, Buchanan WW, Goldsmith CH, et al. Validation study of WOMAC: a health status instrument for measuring clinically important patient relevant outcomes to anti-rheumatic drug therapy in patients with osteoarthritis of the hip or knee. *J Rheumatol* 1988;15:1833-40.
6. Roos EM, Klassbo M, Lohmander LS. WOMAC osteoarthritis index. Reliability, validity, and responsiveness in patients with arthroscopically assessed osteoarthritis. Western Ontario and MacMaster Universities. *Scand J Rheumatol* 1999;28:210-5.
7. Roland M, Morris R. A study of the natural history of back pain. Part I: development of a reliable and sensitive measure of disability in low-back pain. *Spine (Phila Pa 1976)* 1983;8:141-4.
8. Ware Jr JE, Kosinski M, Keller SD. A 12-Item Short-Form Health Survey: construction of scales and preliminary tests of reliability and validity. *Med Care* 1996;34:220-233.
9. Luo X, George ML, Kakouras I , et al. Reliability, validity, and responsiveness of the short form 12-item survey (SF-12) in patients with back pain. *Spine (Phila Pa 1976*) 2003;28:1739-1745.
10. McCaffery M, & Beebe A. *Pain: Clinical Manual for Nursing Practice*. Baltimore: V.V. Mosby Company, 1989.
11. van Tubergen A, Debats I, Ryser L, et al. Use of a numerical rating scale as an answer modality in ankylosing spondylitis–specific questionnaires. *Arthritis Rheum* 2002;47:242-8.
12. Dunn KM, Croft PR. Classification of low back pain in primary care: using "bothersomeness" to identify the most severe cases. *Spine* 2005;30:1887-92.
13. Group TE. EuroQol-a new facility for the measurement of health-related quality of life. *Health Policy* 1990;16:199-208.
14. Hurst NP, Kind P, Ruta D, et al. Measuring health-related quality of life in rheumatoid arthritis: validity, responsiveness and reliability of EuroQol (EQ-5D). *Brit J Rheumatol* 1997;36:551-9.
15. Zigmond AS, Snaith RP. The hospital anxiety and depression scale. *Acta Psychiatr Scand* 1983;67:361-70.
16. Montazeri A, Vahdaninia M, Ebrahimi M, et al. The hospital anxiety and depression scale (HADS): translation and validation study of the Iranian version. *Health Qual Life Outcomes* 2003;1:14.
17. Fischer D, Stewart AL, Bloch DA, et al. Capturing the patient's view of change as a clinical outcome measure. *Jama* 1999;282:1157-62.
18. Kamper SJ, Ostelo RW, Knol DL, et al. Global perceived effect scales provided reliable assessments of health transition in people with musculoskeletal disorders, but ratings are strongly influenced by current status. *J Clin Epidemiol* 2010;63:760-766.e1 doi: 10.1016/j.jclinepi.2009.09.009 [published Online First: 8 January 2010].
19. Chisholm D, Knapp MR, Knudsen HC, et al. Client socio-demographic and service receipt inventory-European Version: development of an instrument for international research.

EPSILON Study 5. European Psychiatric Services: Inputs Linked to Outcome Domains and Needs. *Brit J Psychiatry Suppl* 2000(39):s28-33.

20. Patel A, Rendu A, Moran P, et al. A comparison of two methods of collecting economic data in primary care. *Fam Pract* 2005;22:323-7.

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

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	2
	2b	All items from the World Health Organization Trial Registration Data Set	2
Protocol version	3	Date and version identifier	2
Funding	4	Sources and types of financial, material, and other support	24
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	24
	5b	Name and contact information for the trial sponsor	2, 24
	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	24
	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)	18-19

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	___3 - 4_____
	6b	Explanation for choice of comparators	_____4_____
Objectives	7	Specific objectives or hypotheses	_____4_____
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	_____4_____
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, 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 (eg, surgeons, psychotherapists)	_____7_____
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	____9-12_____
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	_____8_____
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	___9, 12_____
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	_____9_____
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	__13-16_____
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)	__8, figure 2_____

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_____
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	___7-8_____
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	____13_____
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	_____8_____
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	___13, 8_____
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	__13,17-18_____
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	_____17-18____
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 (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, 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	_8, 13-16, Table 3, supplementary file_____
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	_____16_____

Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	17
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	17-18
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	18
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	17
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	19
	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	18
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	18
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	18
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	19, 24
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	19

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	16
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	17
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	24
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	17
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	12
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	19
	31b	Authorship eligibility guidelines and any intended use of professional writers	24
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	no plans
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Appendix 1
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	not applicable

*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" license.

BMJ Open

A theory-driven group-based complex intervention to support self-management of osteoarthritis and low back pain in primary care physiotherapy: protocol for a cluster randomised controlled feasibility trial (SOLAS)

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Complete List of Authors:	Hurley, Deirdre; University College Dublin, School of Public Health, Physiotherapy and Sports Science Hall, Amanda; Oxford University, George Institute for Global Health, Oxford Martin School Currie-Murphy, Laura; Trinity College Dublin, Breast-Predict Collaborative Cancer Research Centre, Pharmacology and Therapeutics Pincus, Tamar; Royal Hollaway University of London, Psychology Kamper, Steve; The George Institute for Global Health, University of Sydney, Musculoskeletal Division; EMGO+ Institute, VU Medical Centre, EMGO+ Institute Maher, Chris; The George Institute for Global Health, University of Sydney, Musculoskeletal Division McDonough, Suzanne; Ulster University, Institute of Nursing and Health Research Walsh, Nicola; University of the West of England, Faculty of Health and Applied Sciences, Glenside Campus Guerin, Suzanne; University College Dublin, School of Psychology Segurado, Ricardo; University College Dublin, CSTAR, School of Public Health, Physiotherapy and Sports Science Matthews, James; University College Dublin, Institute for Sport and Health, School of Public Health, Physiotherapy and Sports Science
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Title page

A theory-driven group-based complex intervention to support self-management of osteoarthritis and low back pain in primary care physiotherapy: protocol for a cluster randomised controlled feasibility trial (SOLAS)

Deirdre A Hurley[1*], Amanda M Hall AM[2], Laura Currie-Murphy[3],Tamar Pincus[4], Steve Kamper[5], Chris Maher[6], Suzanne M McDonough[7], Nicola E Walsh[8], Suzanne Guerin[9], Ricardo Segurado[10], James Matthews[11], SOLAS Trial team

1. Institute for Sport and Health and UCD School of Public Health, Physiotherapy and Sports Science, University College Dublin, Dublin 4, Ireland
2. The George Institute for Global Health, Oxford Martin School, Oxford University, Oxford, United Kingdom.
3. Breast-Predict - Collaborative Cancer Research Centre, Pharmacology and Therapeutics, Trinity College Dublin, St James's Hospital, Dublin 8, Ireland.
4. Department of Psychology, University of London, Royal Holloway, Egham, TW20 OEX, Surrey, UK.
5. The George Institute for Global Health, Sydney Medical School, University of Sydney, Level 13, 321 Kent St, Sydney, NSW 2000, Australia.
6. The George Institute for Global Health, Sydney Medical School, University of Sydney, Level 13, 321 Kent St, Sydney, NSW 2000, Australia.
7. Institute of Nursing and Health Research, Ulster University, Jordanstown Campus, Antrim, BT37 0QB, Northern Ireland.
8. Faculty of Health and Applied Sciences, University of the West of England, Glenside Campus, Bristol, BS16 1DD, United Kingdom.
9. UCD School of Psychology, University College Dublin, Dublin 4, Ireland.
10. CSTAR and UCD School of Public Health, Physiotherapy and Sports Science, University College Dublin, Dublin 4, Ireland.
11. Institute for Sport and Health and UCD School of Public Health, Physiotherapy and Sports Science, University College Dublin, Dublin 4, Ireland.

Corresponding author: Dr Deirdre Hurley, Room A302, Health Sciences Centre, School of Public Health, Physiotherapy and Sports Science, University College Dublin, Belfield, Dublin 4, Ireland. Tel: 353 1 7166523; Email: deirdre.hurleyosing@ucd.ie

ABSTRACT

Introduction: International clinical guidelines consistently endorse the promotion of self-management (SM), including physical activity for patients with chronic low back pain (CLBP) and osteoarthritis (OA). Patients frequently receive individual treatment and advice to self-manage from physiotherapists in primary care, but the successful implementation of a clinical and cost-effective group SM programme is a key priority for health service managers in Ireland to maximise long-term outcomes and efficient use of limited and costly resources.

Methods/analysis: This protocol describes an assessor-blinded cluster randomised controlled feasibility trial of a group-based education and exercise intervention underpinned by self-determination theory designed to support an increase in SM behaviour in patients with CLBP and OA in primary care physiotherapy. The primary care clinic will be the unit of randomisation (cluster), with each clinic randomised to 1 of 2 groups providing the Self-management of Osteoarthritis and Low back pain through Activity and Skills (SOLAS) intervention or usual individual physiotherapy. Patients are followed up at 6 weeks, 2 and 6 months. The primary outcomes are the (1) acceptability and demand of the intervention to patients and physiotherapists, (2) feasibility and optimal study design/procedures and sample size for a definitive trial. Secondary outcomes include exploratory analyses of: point estimates, 95% confidence intervals, change scores and effect sizes in physical function, pain and disability outcomes; process of change in target SM behaviours and selected mediators; and the cost of the intervention to inform a definitive trial.

Ethics/dissemination: This feasibility trial protocol was approved by the UCD Human Research Ethics – Sciences Committee [LS-13-54 Currie-Hurley] and research access has been granted by the Health Services Executive Primary Care Research Committee in January 2014. The study findings will be disseminated to the research, clinical and health service communities through publication in peer-reviewed journals, presentation at national and international academic and clinical conferences.

Trial registration number: ISRCTN 49875385 [supplementary file1]

Keywords: back pain, rheumatology, clinical trials, pain management, primary care, rehabilitation medicine

Word count: 4902

Strengths and limitations

This protocol describes a cluster randomised controlled feasibility trial of a theory-driven group-based intervention for primary care patients with low back pain and osteoarthritis.

This study will explore the acceptability and demand of the group-based intervention to patients and physiotherapists compared to usual individual physiotherapy.

The exclusion of patients who are unwilling or unavailable to attend a six week group programme will limit the study's generalisability.

INTRODUCTION

Chronic musculoskeletal pain conditions are the leading cause of disability globally, notably low back pain (LBP) ranked first[1], and hip and knee osteoarthritis (OA) ranked 11th in the Global Burden of Disease 2010 study[2]. The global point prevalence of LBP was estimated at 9.4%, with OA hip and knee combined at 3.8%[3]; Ireland has slightly higher rates of 12% and 4.2% respectively[4, 5]. In the over 50s, OA is the leading cause of disability worldwide, including Ireland (prevalence rate 12.9%),[6] and is predicted to increase due to rising ageing populations and obesity levels[7]. Both conditions place substantial demand on health systems accounting for 10-18% of consultations in primary care[8], and between 5.4% and 12.6% of total health expenditure[9]. In Ireland, 35.5% of primary care consulters experience chronic non-cancer pain at a cost of €5.34 billion per year[10]. The disability associated with LBP and OA also places significant burden on families, carers, economies and society through absenteeism, presenteeism, work disability, and the need for additional social supports[11,12].

International clinical practice guidelines consistently endorse the promotion of self-management (SM) for people with OA [13-15] and chronic LBP[16, 17] as an integral component of care, with important elements being education about the individual's chronic condition, its consequences, and its management and the uptake of evidence-based SM behaviours by participants; including physical activity, specific exercise, and pharmacological and non-pharmacological approaches[15, 16].

While SM is advocated by policy makers for chronic health conditions[7, 18-20], health service commissioners require robust evidence of its clinical and cost effectiveness prior to widespread implementation. Recent reviews suggest only small or equivocal effects for SM compared to other approaches for these conditions[21, 22], while group-based SM programmes with healthcare professional input showed some beneficial effects, further evidence of their clinical and cost effectiveness is needed [23]. Within Ireland's primary care health system the majority of patients with OA and CLBP referred for physiotherapy (PT) are treated individually[24, 25] in a diverse range of health settings by staff with varying degrees of expertise[26]. Our recent rapid review found equivocal effectiveness for individual and group-based SM programmes with limited cost-effectiveness studies and failed to identify a group-based intervention for both OA hip/knee and CLBP[27]. These conditions often present concurrently in those aged over 45 years [28, 29], and could be treated together in order to maximise outcomes and minimise inefficiencies [30]. The successful implementation of an evidence-based group SM programme for CLBP and OA is a key priority for Ireland's PT managers in current resource constrained times [19].

The multifaceted nature of SM interventions with several interacting components that need to be tailored to the individual, and underpinned by a collaborative relationship between the patient and healthcare professional within the local health service constitutes a complex intervention[31], notwithstanding the additional challenges of consistent delivery in a group format, across a diverse range of health settings with varying resources and facilities[32, 33]. It has been argued that the policy for group interventions to encourage SM in primary care has raced ahead of the evidence and there are many unanswered questions for practitioners and policy makers aiming to establish client groups in terms of their feasibility, effectiveness and costs[32, 33]. Therefore, following the Medical Research Council (MRC) framework[31, 34] we developed the Self-management of OA and LBP

through Activity and Skills (SOLAS) intervention that was acceptable and met the needs of Ireland's primary care service stakeholders and the current evidence which will be reported in detail in a separate paper. Applying the MRC framework it is necessary to establish the feasibility of delivering the SOLAS intervention to PTs and patients with OA and CLBP to determine "can it work?", does it work?" and "will it work?" [35] in primary care centres in Ireland compared to usual individual PT care, considered the most appropriate comparison. Hence, a cluster randomised controlled trial design was chosen to avoid contamination of the control group [36]. This feasibility trial will also determine the most efficient and effective design and sample size for a main effectiveness trial and provide an estimate of the cost of delivering the intervention compared to usual PT.

Consistent with the recommendations of trial reporting guidelines[37], we used theory to guide the design of the SOLAS intervention, its delivery and the training of PTs in the feasibility trial. The current lack of theory driven interventions in chronic pain populations [38-40] may partly explain the poor uptake and continuation of SM behaviours, such as physical activity, while conversely, the application of theory to an intervention enables theoretically identified mechanisms of action (i.e., mediators) to be investigated allowing greater understanding of how an intervention works and how it can be enhanced to improve outcomes[41-43]. The SOLAS intervention is underpinned by self-determination theory [44, 45], which aims to increase patients' autonomous motivation and perceived competence to self-manage through the needs supportive environment created by the PT as we have previously demonstrated in individual PT[25, 46]. The intervention is also designed to target specific determinants of SM behaviour (knowledge, skills, self-efficacy/perceived competence, fear, catastrophizing, motivation, behaviour regulation) in order to increase physical activity and the use of specific evidence-based SM behaviours [i.e. pain management using pharmacological and non-pharmacological approaches, pain coping strategies, healthy eating for lifestyle and weight management and specific exercise] leading to changed health outcomes as outlined in figure 1. As the potential for the SOLAS intervention to result in a change in the target SM behaviours is uncertain the contributing assumptions of this underlying theoretical model of behaviour change will be explored within the feasibility trial[47] and will further inform the design of a future effectiveness trial.

Aims and objectives

The aim of this cluster randomised controlled feasibility trial is to evaluate the feasibility and costs of providing the SOLAS intervention [experimental group] to promote self-management for patients with OA hip/ knee and/or CLBP compared to usual PT, which will serve as the pragmatic control group in order to determine the feasibility of moving to a full scale trial by following the MRC guidelines [31, 48].

Our primary objectives are: (1) To assess the acceptability and demand of the SOLAS intervention to patients and physiotherapists compared to usual PT in order to optimise its design, uptake and delivery. (2) To determine the feasibility of trial procedures and the most efficient and effective study design for a definitive RCT, including its sample size. See table 1 below for details of feasibility aspects. The secondary objectives are: (3) To assess medium-term changes in physical function, pain, emotional and global wellbeing. (4) To evaluate contributing assumptions of the underlying theoretical model of behaviour change of the SOLAS intervention compared to usual PT. (5) To

determine the costs of the SOLAS intervention compared to usual PT from the health service and societal perspectives.

Table 1 Operational Definitions of Feasibility Aspects related to SOLAS Intervention and Trial [adapted from Bowen et al 2009] [35]

Feasibility	Operational Definitions			
	SOLAS Intervention		Trial Procedures	
	Participants	Physiotherapists	Participants	Physiotherapists
Acceptability	The extent to which participants who have received the SOLAS intervention consider the content, mode of delivery and support materials acceptable, appropriate, and satisfactory in meeting their needs	The extent to which physiotherapists who have delivered the SOLAS intervention consider the training, content, mode of delivery and support materials acceptable and appropriate in meeting their needs and those of their patients within their service context	The extent to which participants consider taking part in the trial, and follow-ups, outcome measure completion, and fidelity procedures [direct observation of PTs delivering intervention] acceptable and appropriate	The extent to which physiotherapists who have participated in the trial consider trial recruitment and fidelity procedures acceptable and appropriate
Demand	The extent to which participants adhere to and perceive the burden of SOLAS intervention weekly class attendance and target behaviours	The extent to which physiotherapists perceive the demand and positive/negative effects of participating in training, studying intervention materials, preparing class venue and delivering the SOLAS intervention, using specified behaviour change strategies	The extent to which participants perceive the burden of participating in follow-up and completing specific outcome measures within the trial	The extent to which physiotherapists perceive the demand of completing their required tasks for participating in the trial, including fidelity procedures [self-report forms]

Implementation		The quality and extent to which the SOLAS intervention will be delivered as planned by physiotherapists who have completed training		
Practicality		The factors influencing the implementation of the SOLAS intervention in a range of HSE settings by a range of physiotherapists taking into account variations in staffing, facilities, equipment and class size		
Adaptation	The extent to which the SOLAS intervention content, mode of delivery and support materials will need to be modified to enhance its acceptability and implementation for a future definitive trial	The extent to which the SOLAS intervention training, programme content, mode of delivery and support materials will need to be modified during/at end of the trial to enhance its acceptability and implementation for a future definitive trial	The extent to which trial recruitment, follow-up and fidelity procedures and the number and range of outcome measures will need to be modified during/at end of the trial to enhance their acceptability and implementation for a future definitive trial	The extent to which trial recruitment and fidelity procedures, including physiotherapists tasks, will need to be modified during/at end of the trial to enhance acceptability and implementation for a future definitive trial
Integration		The perceived sustainability and level of system change that will be needed to integrate the SOLAS		

		intervention PT training and programme into existing HSE community physiotherapy services		

METHODOLOGY

Design and setting An assessor-blinded multi-centre two-arm non-inferiority cluster randomised controlled feasibility trial [allocation ratio 1:1] has been designed to assess the methodology proposed for use in a definitive RCT. Managers of nine publicly-funded Health Service Executive (HSE) outpatient primary care PT areas in the greater Dublin, Ireland area (population 1.25 million) have agreed to participate. Centres include 18 HSE primary community and continuing care clinics (hereafter referred to as PCCC clinics) with appropriate facilities, equipment and staffing. A full list of study sites is available from the principal investigator (PI). Eligible PTs will be purposively selected by PT managers based on affiliation with suitable study sites, interest, experience and caseload. Prior to randomisation, all identified PTs will receive a PT participant information leaflet, and invitation to provide written consent to confirm their interest by the project manager, which will involve completing training (intervention arm) and treatment of patients in the relevant trial arm. PTs will be invited to contact the project manager with any questions (see figure 2) and written informed consent will be obtained prior to their participation. PTs will not be blinded to treatment allocation, as they are implementing the intervention with HSE patients.

Participants

The following eligibility criteria will be applied to patients referred for PT to one of the participating PCCC clinics:

Inclusion: patients will: have chronic (≥3 months), *Osteoarthritis* [NICE (2014)[15] working diagnosis of OA hip/knee joint: age 45 years old or over, activity related joint pain and no morning joint-related stiffness or morning stiffness that lasts ≤30 minutes] and/or *Low Back Pain* [age ≥ 30 years old and have non-specific LBP of mechanical origin with or without radiation to the lower limb]; be able to read/understand and speak English without assistance; access to a telephone for screening and available to attend a 6 week group class of 1.5hrs per week.

Exclusion: patients will be excluded if: they have serious spinal pathology or previous spinal surgery, nerve root compromise, lower limb arthroplasty, systemic/inflammatory or cardiac disease, are scheduled for major surgery, confounding conditions (neurological, intellectual or unstable psychiatric condition), bladder/bowel incontinence, are assessed to be high risk of falls, had PT in preceding 6 months, are unable/unwilling to attend or ongoing litigation related to their pain condition.

Identification, invitation, screening and recruitment

Identifying eligible participants will be a multi-level process which has been established during the development phase of this project in agreement with participating PCCC areas. It will involve the research team providing referring general practitioners' (GPs) with information about the trial, and intervention arms, PTs raising awareness of the trial at PCCC level, reviewing waiting lists for suitable referrals and sending potentially suitable patients an invitation letter, and the research team undertaking telephone and face-to-face screening and assessment of consenting participants as outlined in figure 2.

All referrals to participating PCCC clinics will be reviewed for any potentially eligible patients with hip, knee or back pain by PTs (age, diagnosis, duration of symptoms), who will be sent standardised letters inviting them to contact the research team for information about the study by phoning [landline or trial mobile], texting or emailing as preferred. Those who make contact will be provided with information about the study, an opportunity to ask questions and if in agreement will be provisionally screened by the researcher [Chartered PT] via telephone using a standardised questionnaire (eligibility criteria, Physical Activity Readiness Questionnaire to confirm medical fitness to participate in the exercise class[49]) taking no longer than 10 minutes. Interested and potentially eligible patients will be invited to attend their local PCCC clinic for face-to-face screening and assessment by the researcher. If indicated the GP will be contacted after screening or assessment to confirm the patient is suitable to participate. Patients will receive a letter containing the participant information leaflet, study website, confirmation of their appointment date/time/location, directions and contact details for queries and a reminder text 24 hours in advance. The researcher will not be blinded to the allocation of each site but will not inform the patient of their randomisation allocation until completion of baseline assessment. A second blinded researcher will review the reasons for inclusion/exclusion of each patient to confirm lack of bias of the un-blinded researcher.

At the face-to-face assessment, the participant information leaflet will be reviewed with the researcher and an opportunity provided to ask questions about the study and what participation involves, before providing written informed consent. Consenting participants will then proceed with screening and assessment, which will follow a standardised PT subjective and objective assessment for the relevant joint area , and balance testing if indicated as in other similar trials[50]**.** If eligibility is confirmed, baseline data including the outcome measures will be completed with support from the researcher, who will read the questions to each participant unless he/she prefers to complete independently.

Participants will then be informed of their allocation by the researcher (based on the random allocation of PCCC clinic), the aim of the trial will be reiterated, and an appointment for commencement will be provided. The researcher will notify PTs which patients have given informed consent and are eligible to participate. All other patients will be informed of the reason(s) for ineligiblity (if appropriate), will remain on the waiting list and advised that they will receive routine PT as soon as an appointment is available as per usual practice. Participants will be advised that they are free to withdraw from treatment and the study at any stage.

Interventions

The interventions are described below in accordance with current guidelines (SPIRIT [51], TIDIER [37] and Borek [52]). Participants in both groups will be advised to continue their normal daily routines and medication, but will be requested to avoid any other treatment for their back, hip or knee pain during the study period.

SOLAS intervention

The overarching aim of the SOLAS intervention is to promote patient SM behaviour, i.e. physical activity and specific SM strategies, through a group exercise and education class and accompanying support materials. See table 2 for details. The intervention is structured and multi-component involving (i) *Education* to increase knowledge about the individual's chronic condition, its consequences, and its SM including the role of a healthy lifestyle and available community resources and (ii) *Training* to impart increased SM behaviours at the end of the intervention and to enable participants to deploy these enhanced skills in their lives beyond the intervention. Participants randomised to this arm will receive six consecutive sessions in a group of up to 6 participants led by a PT within a PCCC clinic or nearby community facility. The overall aim of the programme and the importance of weekly attendance will be explained throughout to improve adherence. To support the promotion of participant SM behaviour, its' determinants have been mapped to each session and relevant behaviour change techniques incorporated within sessions. In line with SDT and the importance of social agents in facilitating autonomous motivation and perceived competence for long term behaviour change, the PT plays a crucial role by being needs supportive and enabling participants to SM by seeking their input, avoiding controlling language such as "should" and "must"; and trying to understand their perspective. The content and dose of each class [including attendance record, rates and reasons for non-attendance or early withdrawal of each participant] will be recorded by the treating therapist in a weekly treatment record form.

Table 2 SOLAS summary intervention map

Session	**Self-management behaviors targeted within the session**	**Intervention content and participant materials**	**Behavior change techniques embedded *within sessions* (as per Michie et al., 2013) [53]**
1	i.Physical activity iia. Specific exercise for pain condition	**Education:** Aims of programme, back pain and OA causes, cycle of change, exercise recommendations, physical activity levels in Ireland, benefits of	1.1; 1.2; 1.3; 1.4; 1.5; 1.6; 1.7; 2.2; 2.3; 2.7; 3.1; 3.2; 3.3; 4.1; 4.2; 5.1; 5.6; 6.1; 8.1; 8.6; 8.7; 9.1; 10.4; 11.2; 13.2; 12.5; 12.6; 15.1

		exercise/physical activity, review of SOLAS exercise programme, physical activity diary and goal setting. **Exercise:** explanation and demonstration of all exercise stations, practice of sample of exercises. **Materials:** Participant Programme Handbook	
2	i.Physical activity iia. Specific exercise for pain condition	**Education:** Activity-rest cycle and pacing activities, use of pedometer, walking technique, understanding pain, physical activity diary, goal setting and action plan. **Exercise:** supervised group exercise class **Materials:** Yamax SW-200 Pedometer	1.1; 1.2; 1.3; 1.4; 1.5; 1.6; 1.7; 1.8; 2.2; 2.3; 2.7; 3.1; 3.2; 3.3; 4.1; 4.2; 5.1; 5.6; 6.1; 8.1; 8.6; 8.7; 9.1; 10.4; 11.1; 11.2; 13.2; 12.5; 12.6; 15.1
3	i.Physical activity iia. Specific exercise for pain condition iib. Healthy eating for lifestyle and balanced weight	**Education:** Balanced weight, obesity levels in Ireland, healthy eating, measuring waist circumference, physical activity diary, goal setting and action plan, food and drink diary. **Exercise:** supervised group exercise class **Materials:** Tape measure, Your Guide to Healthy Eating using the Food Pyramid, 101+ Square Meals cookbook	1.1; 1.2; 1.3; 1.4; 1.5; 1.6; 1.7; 1.8; 2.2; 2.3; 2.7; 3.1; 3.2; 3.3; 4.1; 4.2; 5.1; 5.6; 6.1; 8.1; 8.6; 8.7; 9.1; 10.4; 11,2; 13.2; 12.5; 12.6; 15.1
4	i.Physical activity iia. Specific exercise for pain condition iic. Use	**Education:** Mid-way review, evidence-based pain management with ice/heat, medication, TENS, acupuncture, physical activity diary, goal setting and action plan.	1.1; 1.2; 1.3; 1.4; 1.5; 1.6; 1.7; 1.8; 2.2; 2.3; 2.7; 3.1; 3.2; 3.3; 4.1; 4.2; 5.1; 5.6; 6.1; 8.1; 8.6; 8.7; 9.1; 10.4; 11.1; 11,2; 13.2; 12.5; 12.6; 15.1

	evidence-based pain management approaches to self-manage pain condition	**Exercise**: supervised group exercise class **Materials:**	
5	i.Physical Activity iia. Specific exercise for pain condition iid. Use of pain coping strategies	**Education:** Anxiety, mood and pain, managing flare-ups, pain coping strategies, relaxation techniques and practice, physical activity diary, goal setting and action plan. **Exercise:** supervised group exercise class **Relaxation skills:** practical group session of contract-relax relaxation technique led by PT **Materials**: Relaxation CD	1.1; 1.2; 1.3; 1.4; 1.5; 1.6; 1.7; 1.8; 2.2; 2.3; 2.7; 3.1; 3.2; 3.3; 4.1; 4.2; 5.1; 5.6; 6.1; 8.1; 8.6; 8.7; 9.1; 10.4; 11.1; 11,2; 13.2; 12.5; 12.6; 15.1
6	i.Physical activity iia. Specific exercise for pain condition	**Education:** Discharge planning, maintaining a good exercise routine in the long-term, local resources and activity information, long-term physical activity diary, goal setting and action plan, programme feedback. **Exercise:** supervised group exercise class **Materials:** Local resources to support physical activity leaflet, graduation certificate	1.1; 1.2; 1.3; 1.4; 1.5; 1.6; 1.7; 1.8; 2.2; 2.3; 2.7; 3.1; 3.2; 3.3; 4.1; 4.2; 5.1; 5.6; 6.1; 8.1; 8.6; 8.7; 9.1; 10.4; 11.1; 11,2; 13.2; 12.5; 12.6; 15.1

Structure: once weekly, 90 minute group class involving 45 minutes education/group discussion in an informal lecture format using powerpoint and 45 minutes of supervised exercise in a gym setting. *Exercise*: range of general aerobic (n=8: step ups, stationary cycling) and joint specific mobility and strengthening exercises for the lumbar spine (n=4), hip (n=6) and knee (n=4) designed to increase participants' participation in exercise and physical activity. The frequency and number of exercise stations completed is determined by each participant with support from the PT if needed.

Physiotherapist Training in SOLAS Intervention rationale, content and delivery

Prior to implementation, PTs will complete a two-day [i.e., 12 hours] small group training course [up to 8 PTs], designed and co-facilitated by the intervention developers; a Physiotherapist and Senior researcher (DAH) who holds an MSc in Musculoskeletal PT and a PhD in back pain research, and a registered Psychologist and researcher (JM) who holds an MA in Organisational and Social Psychology and a PhD in Sport and Exercise Psychology. The course aims to introduce PTs to the SOLAS intervention structure, content, support materials and delivery using a needs supportive interpersonal style. Training incorporates active participation, collaboration, and experiential learning[54], using multiple learning methods; brief PowerPoint presentations, videos of 'good ' and 'poor' intervention delivery, troubleshooting intervention implementation, and case based role-plays and micro-teaching activities to practice intervention delivery. Each PT will receive pre-course materials [i.e. intervention handbook, slides, and selected research papers] and following training additional intervention materials and individualised feedback from one of the course facilitators based on audio recordings during the course.

Usual individual PT

Participants in the Control arm will receive usual individualised PT management, defined as usual PT treatment in primary care, which is generally in accordance with international evidence-based guidelines for OA and CLBP[15, 55]; advice on prescribed exercise, manual therapy and exercise therapeutic approaches, with advice and education regarding general lifestyle-related factors including physical activity and healthy diet less common[56]. The content and dose [frequency and duration] of treatment provided to each participant will be at the discretion of the treating PT and explained to participants to promote adherence. The rate and reasons for non-attendance and/or early withdrawal will be documented by the treating PT in a standardised treatment record form. Recruitment will be from the top of the waiting list to minimise delay in commencing treatment and to allow comparability at follow-up points with the experimental arm. PTs will not be permitted to refer participants to a group-based programme for pain management during the trial.

Treatment fidelity

A range of quantitative methods [i.e. direct observation and audio-recording by researcher, PT self-report] at the level of treating PTs in both study arms will be used on at least 30% of the treatment delivery data to assess treatment fidelity during the trial, in addition to qualitative interviews with intervention PTs to assess the feasibility of implementation and its practicality [57]. Fidelity will be assessed and reported by separate evaluators from the outcome evaluators. The PI will be the integration point between the process and outcome evaluation teams [48].

Randomisation and blinding

The PCCC clinics will be the unit of randomisation (cluster) and each clinic will be randomised to the experimental (SOLAS intervention) or control (usual individual PT) arm on a 1:1 basis. In total, 18 suitable PCCC clinics initially identified as suitable for participation were randomised. Following review of geographical proximity of adjacent clinics, current availability of PT staff to participate and withdrawal of clinics, 14 randomised clinics were agreed with PT managers as available at the start of the trial. 12 clinics will proceed with recruitment (6 experimental and 6 control) and 2 clinics (1 experimental and 1 control) be will held as contingency in case recruitment targets are not met. Randomisation will be conducted using a computerized random number generator algorithm by a statistician blinded to the purpose of the study. A researcher will contact all PT managers to inform them of their allocation arm.

Participant and clinician blinding is not possible due to the nature of the intervention, and it is also not possible to blind the researcher at baseline due to the cluster nature of the study. All follow-up outcome assessments will be conducted by a blinded assessor member of the research team. The investigators responsible for data analysis will use a coded dataset to ensure blinding. Semi-structured interviews, which include treatment-specific questions, will be conducted with intervention PTs at the end of delivery, and with participants after the end of outcome measure data collection by un-blinded researchers.

Outcomes and measures

Primary outcomes

The primary outcomes are related to the feasibility of the SOLAS intervention and trial design and procedures. For participants, this will be assessed by questionnaires (see table 3 below) of treatment expectation, satisfaction, acceptability and demand of treatment and trial participation, as well as attendance rates and individual qualitative interviews described below. For physiotherapists, a range of feasibility aspects will be assessed by expectation of treatment questionnaires, individual and focus group qualitative studies. Additionally, the feasibility of trial design and procedures will be assessed by piloting the methodological procedures, monitoring the recruitment and retention rates and procedures, number and reasons for withdrawal during the treatment process, feasibility of outcome measurement, follow-up and fidelity procedures, refining the training programme and calculating the sample size for a definitive trial by estimating the effect sizes and intra-cluster correlation coefficients of secondary outcomes.

Table 3 Feasibility and Process of Behaviour Change Outcomes and Measures

Variable	Measure and Items	Details	Reliability where available	Administration point, trial arms
Expectation of treatment	Expectation of treatment scale[58] 4-items	Patients and PTs rate how helpful they believe both individual and group treatment will be for OA and CLBP. Measured with 10 point numeric rating scales ranging from not at all helpful to extremely helpful.	Internal consistency : 0.84[58]	Baseline only
Client satisfaction with outcome and care	Satisfaction questionnaire*[59] 2-items	Patients rate their satisfaction with PT care and their feelings on hypothetically living the rest of their life with current symptoms. Measured using 5-point numeric rating scales.	Internal consistency : 0.87-0.90[60]	2 months, 6 months
Acceptability of treatment and trial participation	Brief questionnaire developed for this trial* 11-items	Patients rate their acceptability of treatment received and trial participation, including the burden of outcome measure completion. Measured using 5-point numeric rating scales and yes/no responses.	No reliability data available	6 months
Physical activity	International Physical Activity Questionnaire*[61] 7-items	Patients provide time spent undertaking vigorous/moderate physical activity, walking and being sedentary in the last 7 days.	Test-retest reliability range: 0.46-0.96[61]	Baseline, Week 6, 2 months, 6 months
SOLAS self-management behaviours	Brief questionnaire developed for this trial* 6-items	Patients describe adherence to target self-management behaviours in the past week on yes/no and number of day scales.	No reliability data available	Baseline, Week 6, 2 months, 6 months
Pain catastrophizing	Pain catastrophizing scale[62] 13-items	Patients indicate their agreement with items following the question 'when in pain' such as I anxiously want the pain to go away' on 5-point scales ranging from 'not	Internal consistency : 0.95[63]	Baseline, Week 6, 2 months, 6 months

		at all' to 'all of the time'.		
Fear	Tampa Scale of Kinesiophobia [64] 11-items	Patient rate beliefs about their pain on a 4-point scale ranging from strongly disagree to strongly agree.	Internal consistency : 0.91[65]	Baseline, Week 6, 2 months, 6 months
Self-efficacy	Pain Self-Efficacy Questionnaire[66] 10-items	Patients rate confidence in performing various activities with their pain on a 7-point scale ranging from not at all confident to completely confident.	Internal consistency : 0.92[66]	Baseline, Week 6, 2 months, 6 months
Autonomy support from PT	Health Care Climate Questionnaire[67] 15-items	Patients rate aspects of their interaction with their PT during treatment, such as 'I feel understood by my physiotherapist' on a 7-point scale ranging from strongly disagree to strongly agree.	Internal consistency : 0.96[67]	Week 1, Week 6
Autonomous and controlled motivation (to follow PTs advice to self-manage)	Treatment Self-Regulation Questionnaire[68] 9-items	Patients rate their agreement with statements on why they follow their PT's advice on a 7-point scale ranging from not true for me to very true for me.	Internal consistency : 0.76[68]	Baseline, Week 6, 2 months, 6 months
Autonomous and controlled motivation (to participate in physical exercise)	Exercise Behaviour Regulation Questionnaire[69] 10-items	Patients answer items related to their motivation to engage in physical exercise on a 5-point scale ranging from not true for me to very true for me.	Internal consistency : 0.89[70]	Baseline, Week 6, 2 months, 6 months
Perceived competence (for self-management)	Perceived Competence Questionnaire[71] 4-items	Patients rate their perceived ability to manage their pain regularly and in the long term on a 7-point scale ranging from not at all true to very true	Internal consistency range: 0.80-0.94[71]	Baseline, Week 6, 2 months, 6 months
Perceived competence (to engage in physical activity or exercise)	Perceived Competence Questionnaire[71] 4-items	Patients rate their perceived ability to exercise and/or engage in physical activity regularly and in the long term on a 7-point scale ranging from not at all true to very true	Internal consistency range: 0.80-0.94[71]	Baseline, Week 6, 2 months 6 months

*Minimum Data Set

- Secondary Measures

At baseline demographic data including age, gender, occupational status, and clinical presentation will be documented as well as specific factors that could influence the treatment effect; i.e. therapists' personality (causality orientations), motivation to participate, and treatment expectations; participants' level of risk of chronicity (CLBP participants only). The selected secondary outcome measures are core outcomes for chronic pain trials including: physical functioning, pain intensity, pain bothersomeness, emotional functioning, quality of life, and global ratings of improvement[72-74], as well as recommended economic outcomes[75]. The process of change in selected mediators (pain catastrophizing, fear, self-efficacy/ perceived competence and motivation) and engagement in SM behaviours (physical activity and specific SM strategies) will be assessed using a range of measures. The cost of the SOLAS intervention compared to individual PT will be evaluated using several resource utilisation and health state measures. See table 3 and supplementary file 2 for details of all measures.

Data collection

Secondary outcomes will be collected at baseline, 2 and 6 months from baseline/start of treatment, and, there will be an additional 6 week follow-up time point for collection of process of behaviour change outcomes using the same data collection methods. This will involve a face-to-face interview with a researcher at baseline, and completion at all follow-up points with a blinded researcher by telephone to minimise participant data entry errors. The time for completion will be documented. Participants will receive an information letter and questionnaire pack one week prior to each follow-up point, and telephone contact to arrange a convenient time for completion with the researcher. Participants will have the option to complete outcome assessment by post if preferred. Non-respondents will be contacted by phone/text message on three occasions within a three day period to invite completion of outcomes, and if no response is obtained will be posted the outcome measure pack [minimum data set] and pre-paid envelope, and receive a text reminder inviting completion at their convenience. All researchers will receive training in interview skills and outcome measure administration by the PI prior to commencement.

Qualitative Studies

Individual qualitative semi-structured telephone interviews will be conducted with a purposive sample of consenting participants who received the SOLAS intervention or usual PT (2:1 ratio) on completion of the 6 month follow-up to explore in depth their experience of treatment and trial participation, necessary adaptations to optimise acceptability and uptake, and their use of target SM behaviours. Individual qualitative semi-structured telephone interviews will be conducted with all PTs' following delivery of the SOLAS intervention to establish their views on the acceptability and demand of the training course, SOLAS intervention, trial recruitment and fidelity procedures and necessary adaptations to optimise acceptability and implementation. On completion of the trial a focus group with PT Managers and a purposive sample of PTs will assess views on the practicality

and potential future integration of the SOLAS intervention into existing PCCC services to further inform a definitive trial.

Sample size

We plan to recruit between 12 - 14 clusters (PCCC sites) to ensure the intervention is feasible across a range of settings with variable staffing, facilities, equipment and clientele. There will be a minimum of 6 clusters in each arm, participating in two waves of recruitment with the aim to recruit 6 participants in each cluster per wave, resulting in 144 participants (72 per arm). Additional clusters (n=2), will only be included as a contingency if recruitment targets are not met and added to the final study waves. Recommendations for feasibility studies suggest that the data set for analysis include at least 30 participants per arm in order to estimate parameters for future sample size calculations[76-78]. Accounting for the cluster design effect and assuming an ICC coefficient of 0.03[79], an effective sample size of 30 would require 36 participants per arm. Allowing for 25% loss to follow up, we would need to recruit 48 participants per arm [96 in total]. Therefore, this study size will be sufficiently large to allow a precise estimate of the ICC coefficient; the greater the number of clusters the more precise the estimate of the ICC coefficient [80]. This study design and sample size should therefore satisfy the dual aims of 1) feasibility and 2) estimation of statistics to enable a future sample size calculation for a definitive trial.

Data integrity

All hard copy and audio-recorded data will be kept confidential and stored in a locked filing cabinet in the research group office and in softcopy in a password protected database only accessible to the PI, data manager and statistician. The research team will monitor the integrity of trial data. All participant, group allocation, treatment record and sociodemographic data will be coded, and outcome questionnaires scored, and all data will be double entered into the Statistical Package for the Social Sciences package to detect and correct input errors, and range checks will be undertaken prior to data analysis. A research investigator un-blinded to treatment allocation will perform regular data checks during data entry and provide feedback to PTs regarding data omissions where necessary.

Planned analyses

Since this is a feasibility study extensive exploratory and descriptive analysis of the data will be undertaken. A combination of quantitative and qualitative methods will be used to answer the primary research objectives related to the feasibility of the intervention and trial procedures to participants and PTs to determine the feasibility and most efficient and effective study design for a definitive trial. Statistical analysis will be by intention to treat according to participants' assigned arm of the study, regardless of whether they attend for treatment or not. The data analysis plan for treatment fidelity will be reported separately.

Analysis of the feasibility aspects will be undertaken on an interim basis after each study wave by the UCD study team and used to inform minor protocol refinements for subsequent waves. Qualitative data will be analysed using inductive thematic analysis, based on Braun and Clarke's[81] method. Coding frames will be developed from a review of provisional themes, which will then be re-examined and refined. The reliability of the identified themes will be established by a second researcher who will independently code a random sample of 25% of each dataset using the coding frame, with 70% agreement taken as the minimum cut-off rate of agreement[82]**.** The recruitment rate overall, and according to study arm and PCCC clinic will be calculated in addition to the ratio of number screened: number enrolled. The conversion rate and reasons for exclusion/refusal/withdrawal at each stage in the recruitment process and the attrition rate during the treatment period will be evaluated. The feasibility of outcome measurement procedures will be assessed by the time to complete measures, the number of missing items according to outcome measure, and the follow-up rates and methods of completion [phone, post] at each time point and participants' reported burden of completion.

Analysis of the secondary outcome measure data will be undertaken at the end of the trial and performed by the statistician who will remain blinded to group identification until analysis is complete. A linear mixed model will be used to examine change over time in participant outcomes between treatment groups, while adjusting for study waves and clinics, and potentially individual PTs. Treatment effects will be reported with 95% confidence intervals and ICCs for the clusters. The results will guide a sample size calculation and the form of the primary analysis for a definitive trial. The relationships between the SOLAS intervention and the physical activity/ SM behaviour measures, via potential mediators (pain catastrophizing, fear, self-efficacy/perceived competence and motivation) will be explored, contingent on adequate sample size, with a series of linear models[83], and by applying the test of Sobel[84], and structural equation models, and extended to examine impact on secondary outcomes. Finally, the cost of the SOLAS intervention compared to usual PT will be calculated from the health service and societal perspectives using data from resource utilisation measures, alongside exploratory analysis of quality adjusted life years (EQ-5D) and disease specific measures[85].

Adverse effects or events

No adverse events, apart from minor musculoskeletal complaints in the SOLAS intervention arm due to unaccustomed exercise, are anticipated. Treatment will be modified or discontinued if necessary due to an increase in symptoms. Participants and PTs will be informed that any adverse events should be reported immediately to the PI and will be documented by the research team by type, length of time, and frequency should they occur.

Trial governance

The Trial Management Committee (TMC), comprising the PI and local co-investigators provides overall management of the feasibility trial including PCCC clinic set-up, PT training, recruitment and screening procedures, trial promotion, data collection, analysis and interpretation. Trial conduct will

be audited on a weekly basis using a standardised proforma during each recruitment wave, and biannually at the end of each recruitment wave. Members of the international scientific team provide independent and scientific oversight of the progress of the study through the Data Monitoring Committee on behalf of the funder [Health Research Board].

ETHICS AND DISSEMINATION

All patients and physiotherapists will be provided with detailed written information and have an opportunity to discuss participation before providing written consent and will be advised they can withdraw at any point. Patients will be invited to give their consent to participate in a telephone interview following completion of all follow-ups. The feasibility results will be published in peer-reviewed journals and presented at national and international academic, clinical and health service conferences. Any protocol amendments including changes to eligibility criteria, outcomes or analyses will be communicated to the UCD Human Research Ethics – Sciences Committee and the HSE Primary Care Research Committee, and noted on the Current Controlled Trials trial registration page and reported in the trial results papers.

DISCUSSION

The provision of self-management healthcare interventions with robust evidence of clinical and cost effectiveness for chronic conditions, including LBP and OA, are becoming increasingly important due to their rising prevalence and significant impact on the individual, their family and carers, employers and wider society. The complex multifaceted nature of supporting patients to engage in SM behaviours requires an underlying model of behaviour change to enhance the likelihood of long-term adherence and to understand the underlying processes of change. Group-based interventions that are first designed, adapted and tested for feasibility and cost implications in partnership with patients' and healthcare providers within local health service settings before robust evaluation in an effectiveness trial have the potential to address this second translational gap. The feasibility of the SOLAS theory-driven, group-based complex intervention will be evaluated from the patient, practitioner and health service manager levels, and if achieved the trial design will be refined based on the findings of this study before moving to a definitive trial.

RERERENCES

1. Vos T, Barber RM, Bell B, et al. Global, regional, and national incidence, prevalence, and years lived with disability for 301 acute and chronic diseases and injuries in 188 countries, 1990–2013: a systematic analysis for the Global Burden of Disease Study 2013. *Lancet* 2015;386:743-800 doi: 10.1016/S0140-6736(15)60692-4 [published Online First: 7 June 2015].
2. Cross M, Smith E, Hoy D, et al. The global burden of hip and knee osteoarthritis: estimates from the global burden of disease 2010 study. *Ann Rheum Dis* 2014;73:1323-30 doi: 10.1136/annrheumdis-2013-204763 [published Online First: 19 February 2014].
3. March L, Smith EUR, Hoy DG, et al. Burden of disability due to musculoskeletal (MSK) disorders. *Best Pract Res Clin Rheumatol* 2014;28:353-66 doi: 10.1016/j.berh.2014.08.002 [published Online First: 18 November 2014].
4. Healthy Ireland Survey, The Stationey Office, Dublin, 2015.
5. Institute of Public Health. Musculoskeletal conditions briefing, Dublin, 2012.
6. French HP, Galvin R, Horgan NF, et al. Prevalence and burden of osteoarthritis amongs older people in Ireland: findings from the Irish LongituDinal Study on Ageing (TILDA). *Eur J Public Health* pii: ckv109 [published Online First: 23 June 2015].
7. Speerin R, Slater H, Li L, et al. Moving from evidence to practice: Models of care for the prevention and management of musculoskeletal conditions. *Best Pract Res Clin Rheumatol* 2014;28:479-515 doi: 10.1016/j.berh.2014.07.001 [published Online First: 16 August 2014].
8. EUMUSC. *Musculoskeletal briefing*. 2012
9. Slobbe L, Kommer G, Smit J, et al. Costs of illness in the Netherlands 2003. *Bilthoven: Rijksinstituut voor Volksgezondheid en Milieu* 2006.
10. Raftery MN, Ryan P, Normand C, et al. The economic cost of chronic noncancer pain in Ireland: results from the PRIME study, part 2. *Pain* 2012;13:139-45 doi: 10.1016/j.jpain.2011.10.004.
11. Wilkie R, Hay EM, Croft P, et al. Exploring how pain leads to productivity loss in primary care consulters for osteoarthritis: A prospective cohort study. *Plos One* 2015 doi: 10.1371/journal.pone.0120042 [published Online First: 7 April 2015].
12. Buchbinder R, Blyth FM, March LM, et al. Placing the global burden of low back pain in context. *Best Pract Res Clin Rheumatol* 2013;27:575-89 doi: 10.1016/j.berh.2013.10.007 [published Online First: 12 October 2013].
13. Fernandes L, Hagen KB, Bijlsma JW, et al. EULAR recommendations for the non-pharmacological core management of hip and knee osteoarthritis. *Ann Rheum Dis* 2013;72:1125-35 doi: 10.1136/annrheumdis-2012-202745 [published Online First: 17 April 2013].
14. McAlindon T, Bannuru R, Sullivan M, et al. OARSI guidelines for the non-surgical management of knee osteoarthritis. *Osteoarthritis Cartilage* 2014;22:363-88 doi: 10.1016/j.joca.2014.01.003 [published Online First: 24 January 2014].
15. Excellence NIFHAC. *Osteoarthritis. Care and management in adults*. Clinical Guideline 177. London:Nice,2014.
16. Delitto A, George SZ, Van Dillen LR, et al. Low back pain. *J Orthop Sports Phys Ther* 2012;42:A1-57 doi: 10.2519/jospt.2012.0301 [published Online First: 30 March 2012].
17. Savigny P, Watson P, Underwood M. Early management of persistent non-specific low back pain: summary of NICE guidance. *BMJ* 2009;338;b1805 doi: 10.1136/bmj.b1805.
18. Health Do. *Supporting people with long term conditions: an NHS and social care model to support local innovation and integration*: Department of Health, Leeds, 2005.
19. HSE. *Framework for self-management support, long-term health conditions: HSE National Advocacy Unit. Secondary framework for self-management support, long-term health conditions*: HSE National Advocacy Unit, Dublin, 2012.
20. Imison C, Naylor C, Buck D, et al. Transforming our healthcare system. *London: The King's Fund* 2011.

21. Kroon FP, van der Burg LR, Buchbinder R, et al. Self-management education programmes for osteoarthritis. *Cochrane Database Syst Rev* 2014;1:Cd008963 doi: 10.1002/14651858.CD008963.pub2.
22. Taylor SJ, Pinnock H, Epiphaniou E, et al. A rapid synthesis of the evidence on interventions supporting self-management for people with long-term conditions: PRISMS–practical systematic review of self-management support for long-term conditions. NIHR Journals Library Southampton, 2014.
23. Carnes D, Homer K, Miles C, et al. Effective delivery styles and content for self-management interventions for chronic musculoskeletal pain: A systematic literature review. *Clin J Pain* 2012;28:344-54 doi: 10.1097/AJP.0b013e31822ed2f3.
24. French HP, Cusack T, Brennan A, et al. Exercise and manual physiotherapy arthritis research trial (EMPART) for osteoarthritis of the hip: a multicenter randomized controlled trial. *Arch Phys Med Rehab* 2013;94:302-14 doi: 10.1016/j.apmr.2012.09.030 [published Online First: 16 October 2012].
25. Murray A, Hall A, Williams G, et al. Effect of a self-determination theory-based communication skills training program on physiotherapists psychological support for their patients with chronic low back pain: A randomized controlled trial. *Arch Phys Med Rehab* 2015;96:809-16 doi: 10.1016/j.apmr.2014.11.007 [published Online First: 26 November 2014].
26. McMahon S, Cusack T, O'Donoghue G. Barriers and facilitators to providing undergraduate physiotherapy clinical education in the primary care setting: a three-round Delphi study. *Physiotherapy* 2014;100:14-19 doi: 10.1016/j.physio.2013.04.006 [published Online First: 15 August 2013].
27. Toomey EC, Currie-Murphy L, Matthews J, et al. The effectiveness of physiotherapist-delivered group education and exercise interventions to promote self-management for people with oesteoarthritis and chronic low back pain: A rapid review Part I. *Man Ther* 2015;20:365-86 doi: 10.1016/j.math.2014.10.013 [published Online First: 1 November 2014].
28. O'Farrell S, Smart K, Caffrey A, et al. Orthopaedic triage at a physiotherapist-led 'Musculoskeletal Assessment Clinic': a seven-month service evaluation of outcomes. *Ir J Med Sci* 2014;183:565-71 doi: 10.1007/s11845-013-1052-5 [published Online First: 12 December 2013].
29. Roddy E, Zwierska I, Jordan KP, et al. Musculoskeletal clinical assessment and treatment services at the primary-secondary care interface: an observational study. *Brit J Gen Pract* 2013;63:e141-e48 doi: 10.3399/bjgp13X663109.
30. Pasquale MK, Dufour R, Joshi AV, et al. Inefficiencies in osteoarthritis and chronic low back pain management. *Am J Manag Care* 2013;19:816-23.
31. Craig P, Dieppe P, Macintyre S, et al. Developing and evaluating complex interventions: the new Medical Research Council guidance. *BMJ* 2008;337:a1655 doi: 10.1136/bmj.a1655.
32. Greaves CJ, Campbell JL. Supporting self-care in general practice. *Brit J Gen Pract* 2007;57:814-21.
33. Hoddinott P, Allan K, Avenell A, et al. Group interventions to improve health outcomes: a framework for their design and delivery. *BMC Public Health* 2010;10:800 doi: 10.1186/1471-2458-10-800.
34. Craig P, Petticrew M. Developing and evaluating complex interventions: Reflections on the 2008 MRC guidance. *Int J Nurs Stud* 2013;50:585-87 doi: 10.1016/j.ijnurstu.2012.09.009 [published Online First: 16 November 2012].
35. Bowen D, Kreuter M, Spring B, et al. How we design feasibility studies. *Am J Prev Med* 2009;36:452-57 doi: 10.1016/j.amepre.2009.02.002.
36. Campbell M, Fitzpatrick R, Haines A, et al. Framework for design and evaluation of complex interventions to improve health. *BMJ* 2000;321:694-96.

37. Hoffmann TC, Glasziou PP, Boutron I, et al. Better reporting of interventions: template for intervention description and replication TIDieR checklist and guide. *BMJ* 2014;348:g1687 doi: 10.1136/bmj.g1687.
38. Williams A, Eccleston C, Morley S. Psychological therapies for the management of chronic pain (excluding headache) in adults. *Cochrane Database Syst Rev* 2012; 11 CD007407 doi: 10.1002/14651858.CD007407.pub3.
39. Keogh A, Tully MA, Matthews J, et al. A review of behaviour change theories and techniques used in group based self-management programmes for chronic low back pain and arthritis. *Man Ther* Published Online First: 30th March 2015. doi: 10.1016/j.math.2015.03.014.
40. Marley J, Tully M, Poter-Armstrong A, et al. A systematic review of interventions aimed at increasing physical activity in adults with chronic musculoskeletal pain - protocol. *Syst Rev* 2014;3:106 doi: 10.1186/2046-4053-3-106.
41. Michie S, Abraham C. Identifying techniques that promote health behaviour change: Evidence based or evidence inspired? Psychological Health 2004;19:29-49.
42. Rothman R. Is there nothing more practical than a good theory?: Why innovations and advances in health behavior change will arise if interventions are used to test and refine theory. *Int J Behav Nutr Phys Act* 2004;1:11.
43. Rothman AJ. Capitalizing on opportunities to refine health behavior theories. *Health Educ Behav* 2009;36:150S-5S; discussion 67S-71S.
44. Ryan D, Deci E. Self-determination theory and the facilitation of intrinsic motivation, social development and well being. *Am Psychol* 2000;55:68-78.
45. Ng JY, Ntoumanis N, Thøgersen-Ntoumani C, et al. Self-determination theory applied to health contexts a meta-analysis. *Perspect Psychol Sci* 2012;7:325-40 doi: 10.1177/1745691612447309.
46. Matthews J, Hall AM, Hernon M, et al. A brief report on the development of a theoretically-grounded intervention to promote patient autonomy and self-management of physiotherapy patients: face validity and feasibility of implementation. *BMC Health Serv Res* 2015;15:260 doi: 10.1186/s12913-015-0921-1.
47. Courneya KS. Efficacy, effectiveness, and behavior change trials in exercise research. *Int J Behav Nutr Phys Act* 2010;7:81 doi: 10.1186/1479-5868-7-81.
48. Moore GF, Audrey S, Barker M, et al. Process evaluation of complex interventions: Medical Research Council guidance. *BMJ* 2015;350:h1258 doi: 10.1136/bmj.h1258.
49. Adams R. Revised physical activity readiness questionnaire. *Can Fam Physician* 1999;45:1004-5.
50. Walsh N, Cramp F, Palmer S, et al. Exercise and self-management for people with chronic knee, hip or lower back pain: a cluster randomised controlled trial of clinical and cost-effectiveness. Study protocol. *Physiotherapy* 2013;99:352-57 doi: 10.1016/j.physio.2012.09.002 [published Online First: 30 November 2012].
51. Chan AW, Tetzlaff JM, Gotzsche PC, et al. SPIRIT 2013 explanation and elaboration: guidance for protocols of clinical trials. *BMJ* 2013;346:e7586 doi: 10.1136/bmj.e7586.
52. Borek AJ, Abraham C, Smith JR, et al. A checklist to improve reporting of group-based behaviour-change interventions. *BMC Public Health* 2015;15:963 doi: 10.1186/s12889-015-2300-6.
53. Michie S, Richardson M, Johnston M, et al. The behavior change technique taxonomy (v1) of 93 hierarchically clustered techniques: building an international consensus for the reporting of behavior change interventions. *Ann Behav Med* 2013 46:81-95 doi: 10.1007/s12160-013-9486-6.
54. Aelterman N, Vansteenkiste M, Keer HV, et al. Development and evaluation of a training on needs-supportive teaching in physical education: qualitative and quantitative findings. Journal of Teacher Education 2013;29:64-75.
55. Koes BW, van Tulder M, Lin C-WC, et al. An updated overview of clinical guidelines for the management of non-specific low back pain in primary care. *Eur Spine J* 2010;19:2075-94 doi: 10.1007/s00586-010-1502-y [published Online First: 3 July 2010].

56. O'Donoghue G, Cunningham C, Murphy F, et al. Assessment and management of risk factors for the prevention of lifestyle-related disease: a cross-sectional survey of current activities, barriers and perceived training needs of primary care physiotherapists in the Republic of Ireland. *Physiotherapy* 2014;100:116-22 doi: 10.1016/j.physio.2013.10.004 [published Online First: 8 January 2014].
57. Borelli B. The assessment, monitoring and enhancement of treatment fidelity in public health clinical trials. *J Public Health Dent* 2011;71:S52-S63.
58. Smeets RJ, Beelen S, Goossens ME, et al. Treatment expectancy and credibility are associated with the outcome of both physical and cognitive-behavioral treatment in chronic low back pain. *Clin J Pain* 2008;24:305-15 doi: 10.1097/AJP.0b013e318164aa75.
59. Hurley DA, Tully MA, Lonsdale C, et al. Supervised walking in comparison with fitness training for chronic back pain in physiotherapy: results of the SWIFT single-blinded randomized controlled trial (ISRCTN17592092). *Pain* 2015;156:131-47 doi: 10.1016/j.pain.0000000000000013.
60. Fischer D, Stewart AL, Bloch DA, et al. Capturing the patient's view of change as a clinical outcome measure. *Jama* 1999;282:1157-62.
61. Craig CL, Marshall AL, Sjostrom M, et al. International physical activity questionnaire: 12-country reliability and validity. *Med Sci Sports Exerc* 2003;35:1381-95.
62. Sullivan MJ, Bishop SR, Pivik J. The pain catastrophizing scale: development and validation. Psychological Assessment 1995;7:524.
63. Osman A, Barrios FX, Gutierrez PM, et al. The pain catastrophizing scale: further psychometric evaluation with adult samples. *J Behav Med* 2000;23:351-65.
64. Kori SH, Miller RP, Todd DD. Kinesophobia: A new view of chronic pain behavior. Pain Management 1990:35-43.
65. Lundberg MK, Styf J, Carlsson SG. A psychometric evaluation of the Tampa Scale for Kinesiophobia—from a physiotherapeutic perspective. Physiotherapy Theory and Practice 2004;20:121-33.
66. Nicholas MK. The pain self-efficacy questionnaire: Taking pain into account. *Eur J Pain* 2007;11:153-63.
67. Williams GC, Freedman ZR, Deci EL. Supporting autonomy to motivate glucose control in patients with diabetes. *Diabetes Care* 1998,21:1644–1651.
68. Levesque CS, Williams GC, Elliot D, et al. Validating the theoretical structure of the treatment self-regulation questionnaire (TSRQ) across three different health behaviors. *Health Educ Res* 2007;22:691-702.
69. Mullan E, Markland D, Ingledew DK. A graded conceptualisation of self-determination in the regulation of exercise behaviour: Development of a measure using confirmatory factor analytic procedures. Personality and Individual Differences 1997;23:745-52.
70. Murcia JA, Gimeno EC, Camacho AM. Measuring self-determination motivation in a physical fitness setting: validation of the Behavioral Regulation in Exercise Questionnaire-2 (BREQ-2) in a Spanish sample. The Journal of Sports Medicine and Physical Fitness 2007;47:366-74.
71. Williams GC, Deci EL. Internalization of biopsychosocial values by medical students: a test of self-determination theory. *J Pers Soc Psychol* 1996;70:767-79.
72. Chiarotto A, Deyo RA, Terwee CB, et al. Core outcome domains for clinical trials in non-specific low back pain. *Eur J Spine* 2015;24:1127-42 doi: 10.1007/s00586-015-3984-0 [published Online First: 8 May 2015].
73. Deyo RA, Dworkin SF, Amtmann D, et al. Report of the NIH Task Force on research standards for chronic low back pain. *Pain Med* 2014;15:1249-67 doi: 10.1111/pme.12538.
74. Dworkin RH, Turk DC, Farrar JT, et al. Core outcome measures for chronic pain clinical trials: IMMPACT recommendations. *Pain* 2005;113:9-19.

75. HIQA. Guidelines for the economic evaluation of health technologies in Ireland, 2014. http://www.hiqa.ie/publication/guidelines-economic-evaluation-healthtechnologiesireland. accessed 27th November 2015.
76. Browne RH. On the use of a pilot sample for sample-size determination. *Stat Med* 1995;14:1933-40.
77. Lancaster GA, Dodd S, Williamson PR. Design and analysis of pilot studies: recommendations for good practice. *J Eval Clin Pract* 2004;10:307-12.
78. Shih WJ, Ohman- Strickland PA, Lin Y. Analysis of pilot and early phase studies with small sample sizes. *Stat Med* 2004;23:1827-42.
79. Lonsdale C, Hall AM, Williams GC, et al. Communication style and exercise compliance in physiotherapy (CONNECT). A cluster randomized controlled trial to test a theory-based intervention to increase chronic low back pain patients' adherence to physiotherapists' recommendations: study rationale, design, and methods. *BMC Musculoskelet Disord* 2012;13:104 doi: 10.1186/1471-2474-13-104.
80. Kerry SM, Bland JM. Statistics notes - The intracluster correlation coefficient in cluster randomisation. *BMJ* 1998;316:1455-55.
81. Braun V, Clarke V. Using thematic analysis in psychology. *Qual Res Psychol* 2006;3:77-101.
82. Guerin S, Hennessy E. Pupils' definitions of bullying. European Journal of Psychology of Education 2002;17:249-61.
83. Baron RM, Kenny DA. The moderator mediator variable distinction in social psychological-research - conceptual, strategic, and statistical considerations. *J Pers Soc Psychol* 1986;51:1173-82.
84. Sobel M. Asymptotic intervals for indirect effects in structural equations models. Sociological Methodology 1982:290-312.
85. Ramsey SD, Willke RJ, Glick H, et al. Cost-effectiveness analysis alongside clinical trials II-an ISPOR good research practices task force report. *Value Health* 2015;18:161-72 doi: 10.1016/j.jval.2015.02.001.

Authors' contributions

DAH and AH conceived the idea for the study and with input from TP, CM and SK secured funding. DAH and JM developed the SOLAS intervention and training programme with input from LM, AH, SG and NW. DH and LM designed the trial with input from JM, AH, RS, NW, SG, SMcD, SK, CM, and TP. RS, DAH and SG devised the planned analysis. DAH drafted the manuscript with critical input from all authors.

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Competing interests None declared

Ethics approval UCD Human Research Ethics – Sciences Committee, REC Reference: LS-13-54 Currie-Hurley. Research access: HSE Primary Care Research Committee.

Illustrations and figures

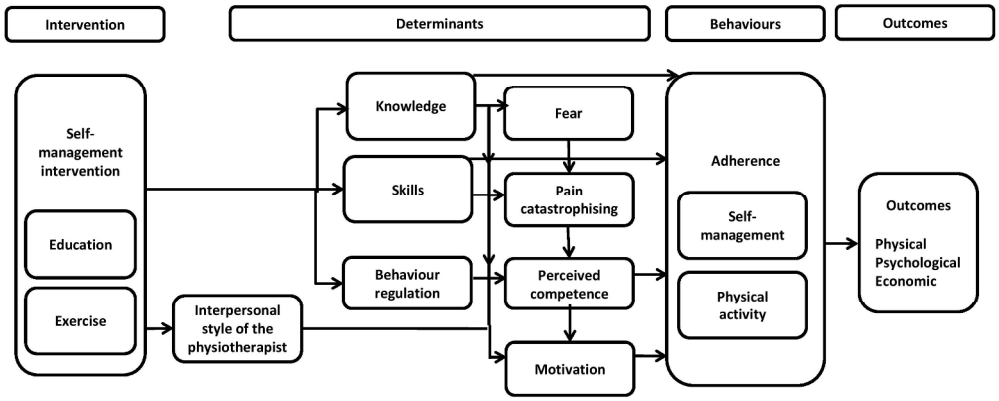

Figure 1 Process map of behaviour change in SOLAS intervention
254x190mm (300 x 300 DPI)

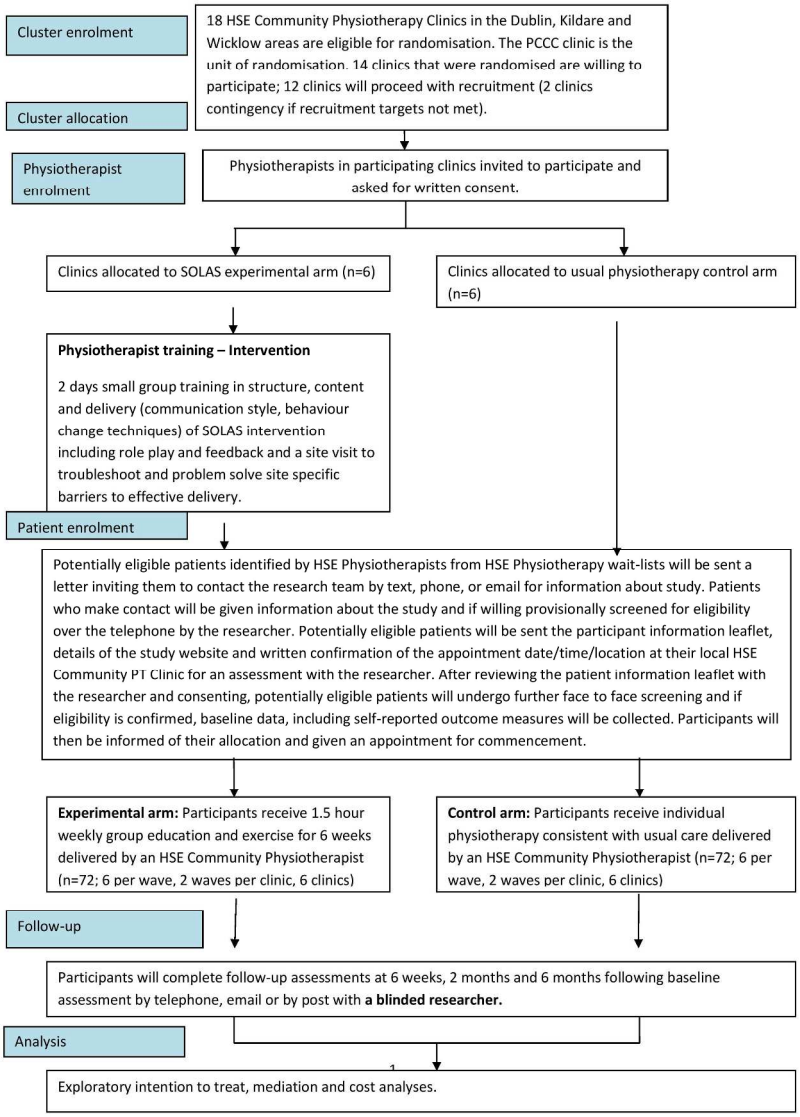

Figure 2: Study recruitment, allocation and follow up
210x297mm (300 x 300 DPI)

Supplementary file 1 Trial Registration Data

Data category	Information
Primary registry and trial identifying number	controlled-trials.com ISRCTN 49875385
Date of registration in primary registry	26th March, 2014
Secondary identifying numbers	N/A
Sources of monetary or material support	Health Research Board, Ireland
Primary sponsor	Health Research Board, Ireland
Contact for public queries	Principal Investigator Dr Deirdre Hurley [email: deirdre.hurleyosing@ucd.ie)
Contact for scientific queries	Principal Investigator Dr Deirdre Hurley [email: deirdre.hurleyosing@ucd.ie)

Protocol version

Issue date: 26th March, 2014

Protocol amendment 01: 2nd October, 2014

Primary reason for amendment: minor change in inclusion criteria[i.e. age of low back pain patients lowered from ≥45 years to ≥30 years] following a pilot study.

Supplementary file 2 Secondary Outcomes and Measures

Variable	Measure and items	Details	Reliability where available	Administration point, trial arms
LBP patients risk of chronicity	StarT Back Screening Tool [1] 9-items	Patients rate agreement/ disagreement with a range (8) of modifiable prognostic indicators including bothersomeness, disability and mood over the past 2 weeks.	Internal consistency: 0.74l[1, 2]	Baseline only
Physiotherapists General Causality Orientations	General Causality Orientation Scale[3] 36-items	PTs rate their likely behaviour in a range of vignettes evaluating autonomous, controlling and impersonal responses on a 7-point scale ranging from very unlikely to very likely.	Internal consistency for 3 subscales range: 0.69-0.74[3]	Pre-training
Physiotherapists autonomous and controlled motivation to participate in training	Motivation to Participate Questionnaire[4] 8-items	PTs rate their reasons for participating in training on a 7-point Likert scale ranging from not at all true to very true.	No reliability data available	Pre-training
Osteoarthritis specific-functional disability	WOMAC Function Daily Living Subscale Hip or Knee*[5] 17-items	Patients rate difficulty with hip and/or knee in performing various everyday activities.	Internal consistency for the subscales range: 0.83-0.96[6]	Baseline, 2 months, 6 months
Low back pain-specific functional disability	Roland-Morris Disability Questionnaire* [7] 24-items	Patients respond to statements which match their experience of low back pain on the day of completion on a dichotomous scale.	Internal consistency: 0.91[7]	Baseline, 2 months, 6 months
Physical component of functional disability	Short Form-12*[8] 12-items	Patients rate health and the limitations caused by physical problems on 5 point Likert scales ranging from all of the time to none of the time.	Internal consistency: 0.77[9]	Baseline, 2 months, 6 months
Pain intensity	Pain Rating	Patients rate their level	Inter-rater	Baseline,

	Scale*[10] 1-item	of pain in the past week on an 11-point numeric scale.	reliability: 0.56[11]	2 months, 6 months
Pain bothersomeness	Single item on a numeric rating scale*[1, 12] 1-item	Patients rate how bothered they've been by their pain in the last week on a 5-point scale ranging from not at all to extremely.	Internal consistency: 0.79[1, 12]	Baseline, 2 months, 6 months
Quality of life [Health state]	EuroQol Weighted Health Index[13] 5-items	Patients describe their current health state under five domains: mobility, self-care, usual activities, pain/discomfort, anxiety/depression.	Test-retest reliability range for the subscales range: 0.70-0.85[14]	Baseline, 2 months, 6 months
Mood	Hospital Anxiety and Depression Scale[15] 14-items	Patients rate agreement with items related to anxiety or depression, such as "I feel tense or 'wound up'" on a 4-point scale.	Internal consistency for the subscales range: 0.78-0.86[16]	Baseline, 2 months, 6 months
Global impression of change	Global Perceived Effect Scale*[17] 1-item	Patients rate on an 11-point scale the level of change (positive or negative) in their hip, knee and/or back pain between now and when the pain episode started ranging from vastly worse to vastly recovered.	Test-retest reliability excellent: intraclass correlation coefficient: 0.90-0.99[18]	2 months, 6 months
Resource utilisation costs related to the patient	Client Services Receipt Inventory[19] 20-items	Patients recall costs related to their condition and its treatment: healthcare, labour productivity changes, costs borne by patients and their families and state benefits received.	Concordance correlation: 0.756[20]	Baseline, 6 months
Resource utilisation costs related to providing treatment	Brief questionnaire developed for this trial 10-items Purchase	Treating PTs record staff time, facilities, equipment used to provide treatment. Overheads will be estimated. Actual costs of	No reliability data available	End of treatment

	invoices	producing, printing or purchasing intervention materials will be documented.		

*Minimum Data Set

1. Hill JC, Dunn KM, Lewis M, et al. A primary care back pain screening tool: identifying patient subgroups for initial treatment. *Arthritis Rheum* 2008;59:632-41. doi: 10.1002/art.23563.
2. Bruyère O, Demoulin M, Beaudart C, et al. Validity and reliability of the French version of the STarT Back Screening Tool for patients with low back pain. *Spine* 2014;39:E123-E28. doi: 10.1097/BRS.0000000000000062
3. Williams GC, Grow VM, Freedman ZR, et al. Motivational predictors of weight loss and weight-loss maintenance. *J Pers Soc Psychol* 1996;70:115-26.
4. Black AE, Deci EL. The effects of instructors' autonomy support and students' autonomous motivation on learning organic chemistry: A self-determination theory perspective. *Sci Ed* 1989;84:740-56.
5. Bellamy N, Buchanan WW, Goldsmith CH, et al. Validation study of WOMAC: a health status instrument for measuring clinically important patient relevant outcomes to anti-rheumatic drug therapy in patients with osteoarthritis of the hip or knee. *J Rheumatol* 1988;15:1833-40.
6. Roos EM, Klassbo M, Lohmander LS. WOMAC osteoarthritis index. Reliability, validity, and responsiveness in patients with arthroscopically assessed osteoarthritis. Western Ontario and MacMaster Universities. *Scand J Rheumatol* 1999;28:210-5.
7. Roland M, Morris R. A study of the natural history of back pain. Part I: development of a reliable and sensitive measure of disability in low-back pain. *Spine (Phila Pa 1976)* 1983;8:141-4.
8. Ware Jr JE, Kosinski M, Keller SD. A 12-Item Short-Form Health Survey: construction of scales and preliminary tests of reliability and validity. *Med Care* 1996;34:220-233.
9. Luo X, George ML, Kakouras I , et al. Reliability, validity, and responsiveness of the short form 12-item survey (SF-12) in patients with back pain. *Spine (Phila Pa 1976*) 2003;28:1739-1745.
10. McCaffery M, & Beebe A. *Pain: Clinical Manual for Nursing Practice*. Baltimore: V.V. Mosby Company, 1989.
11. van Tubergen A, Debats I, Ryser L, et al. Use of a numerical rating scale as an answer modality in ankylosing spondylitis–specific questionnaires. *Arthritis Rheum* 2002;47:242-8.
12. Dunn KM, Croft PR. Classification of low back pain in primary care: using "bothersomeness" to identify the most severe cases. *Spine* 2005;30:1887-92.
13. Group TE. EuroQol-a new facility for the measurement of health-related quality of life. *Health Policy* 1990;16:199-208.
14. Hurst NP, Kind P, Ruta D, et al. Measuring health-related quality of life in rheumatoid arthritis: validity, responsiveness and reliability of EuroQol (EQ-5D). *Brit J Rheumatol* 1997;36:551-9.
15. Zigmond AS, Snaith RP. The hospital anxiety and depression scale. *Acta Psychiatr Scand* 1983;67:361-70.
16. Montazeri A, Vahdaninia M, Ebrahimi M, et al. The hospital anxiety and depression scale (HADS): translation and validation study of the Iranian version. *Health Qual Life Outcomes* 2003;1:14.
17. Fischer D, Stewart AL, Bloch DA, et al. Capturing the patient's view of change as a clinical outcome measure. *Jama* 1999;282:1157-62.
18. Kamper SJ, Ostelo RW, Knol DL, et al. Global perceived effect scales provided reliable assessments of health transition in people with musculoskeletal disorders, but ratings are strongly influenced by current status. *J Clin Epidemiol* 2010;63:760-766.e1 doi: 10.1016/j.jclinepi.2009.09.009 [published Online First: 8 January 2010].

19. Chisholm D, Knapp MR, Knudsen HC, et al. Client socio-demographic and service receipt inventory-European Version: development of an instrument for international research. EPSILON Study 5. European Psychiatric Services: Inputs Linked to Outcome Domains and Needs. *Brit J Psychiatry Suppl* 2000(39):s28-33.
20. Patel A, Rendu A, Moran P, et al. A comparison of two methods of collecting economic data in primary care. *Fam Pract* 2005;22:323-7.

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

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	_____2_____
	2b	All items from the World Health Organization Trial Registration Data Set	Supplementary file 1
Protocol version	3	Date and version identifier	Supplementary file 1
Funding	4	Sources and types of financial, material, and other support	_____24_____
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	_____24_____
	5b	Name and contact information for the trial sponsor	_____24____
	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	_____24_____

	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)	___18-19_____
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	___3 - 4_____
	6b	Explanation for choice of comparators	_____4_____
Objectives	7	Specific objectives or hypotheses	_____4_____
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	_____4_____
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, 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 (eg, surgeons, psychotherapists)	_____7_____
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	____9-12_____
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	__8, 18_____
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	___9, 12_____
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	_____9_____

Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	__13-16_____
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)	__8, figure 2_____
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_____
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	___7-8_____
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	____13_____
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	_____8_____
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	___13, 8_____
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	__13,17-18_____
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	_____17-18____
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 (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, 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	_8, 13-16, Table 3, supplementary file 2_____
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	16, Table 3, Supplementary file 2_____
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	____17_____
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	_17-18_____
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	___18_____
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	___17_____
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	___19_____
	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	_____18_____
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	____18_____
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	____18_____

Ethics and dissemination

Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	__19, 24_____
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	_____19_____
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	_____16_____
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	_____17_____
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	_____24_____
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	_____17_____
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	_____12_____
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	_____19_____
	31b	Authorship eligibility guidelines and any intended use of professional writers	_____24_____
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	_no plans_____

Appendices

Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	_Appendix_____
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	__not applicable_____

*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" license.