# Self-management of Osteoarthritis and Low back pain through Activity and Skills (SOLAS)

Submission date	Recruitment status	[X] Prospectively registered	
04/03/2014	No longer recruiting	[X] Protocol	
Registration date	Overall study status	Statistical analysis plan	
26/03/2014	Completed	[X] Results	
Last Edited	Condition category	Individual participant data	
25/09/2020	Musculoskeletal Diseases		

#### Plain English summary of protocol

Background and study aims

Research from other countries has shown that group physiotherapy, including education and exercise, is as effective as individual physiotherapy for people with hip and knee pain and costs less for the health service. The establishment of group education and exercise classes for clients with chronic hip, knee and back pain that promote self-management is a priority for Health Service Executive (HSE) community physiotherapy services in Ireland. But we do not know how feasible this is. This study will examine the feasibility of providing group education and exercise classes for self-management compared to individual physiotherapy treatment for people with chronic hip, knee and/or low back pain in HSE Community Physiotherapy services in Counties Dublin, Wicklow and Kildare.

#### Who can participate?

Male or female patients, 45 years old and over, diagnosed with osteoarthritis of any of the joints of the lumbar spine, hip or knee and/or low back pain.

#### What does the study involve?

At the first appointment, a research physiotherapist will ask each study participant about their pain and how they manage it, how often they exercise, their quality of life and their use of health services. Study participants will be randomly allocated to one of two groups (either group or individual physiotherapy treatment) and they will then receive the most appropriate physiotherapy care and treatment advice for their condition and how to manage it. Each study participant will then be contacted by a Researcher 2 and 6 months after the first appointment and asked the same questions to see if they have changed after their treatment. This study will help to improve future physiotherapy services for people who have hip, knee or back pain.

What are the possible risks of participating?

There are no risks involved in participating in this research.

Where is the study run from?

Health Service Executive (HSE) Primary, Community and Continuing Care Physiotherapy services of Dublin, Kildare and Wicklow (Ireland).

When is the study starting and how long is it expected to run for? March 2014 to December 2016 (duration 30 months). The study will be recruiting participants for 24 months.

Who is funding the study? Health Research Board of Ireland

Who is the main contact?
Dr Deirdre Hurley-Osing
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## Contact information

#### Type(s)

Scientific

#### Contact name

Dr Deirdre Hurley

#### Contact details

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# Additional identifiers

**Protocol serial number** N/A

# Study information

#### Scientific Title

Development of an evidence-based, theory-driven group education and exercise intervention to promote self-management for people with osteoarthritis of the lumbar spine, hip or knee and/or chronic low back pain in primary care physiotherapy: a single-blinded feasibility cluster randomized controlled trial within the MRC Framework for Complex Interventions

#### **Acronym**

**SOLAS** 

#### **Study objectives**

1. The feasibility of providing the group education and exercise intervention to promote self-management compared to individual physiotherapy for clients with osteoarthritis of the lumbar spine/hip/knee and/or chronic low back pain within HSE Community Physiotherapy Services in

Dublin, Wicklow and Kildare will be established

2. The protocol and sample size for a fully powered randomised controlled trial will be established

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

University College Dublin Human Research Ethics Committee Sciences, 17/12/2013, LS-13-54-Currie-Hurley

#### Study design

Single-blinded feasibility cluster randomized controlled trial

#### Primary study design

Interventional

#### Study type(s)

Quality of life

#### Health condition(s) or problem(s) studied

Osteoarthritis of the lumbar spine, hip and/or knee joints Chronic non-specific low back pain

#### **Interventions**

- 1. Group education and exercise class to promote self-management, once per week for 6 weeks
- 2. Individual usual physiotherapy treatment, number and frequency of treatments at the discretion of the treating physiotherapist

Total duration of follow-up is 6 months

#### Intervention Type

Other

#### **Phase**

Not Applicable

#### Primary outcome(s)

- 1. Acceptability, demand, practicality, and adaptation of the intervention to clients baseline, 2 and 6 months
- 2. Acceptability, demand, implementation, practicality, adaptation and integration of intervention to physiotherapists baseline, 1 and 2 months
- 3. Feasibility of recruitment process baseline
- 4. Feasibility of outcome measurement process baseline, 1, 2 and 6 months

## Key secondary outcome(s))

Current secondary outcome measures as of 02/10/2014:

- 1. Self-management behaviours
- 2. International Physical Activity Questionnaire
- 3. Physical Component Summary of the Medical Outcomes Study Short Form Health Survey SF-12
- 4. Average pain intensity over the last week (0-10 scale)

- 5. Disease-specific functional disability: low back pain (Roland Morris Disability Questionnaire), and/or Hip and Knee OA (WOMAC function Daily Living Hip and/or Knee Subscale)
- 6. Participants satisfaction with outcome and care received
- 7. Participants global impression of change
- 8. Hospital Anxiety and Depression Scale
- 9. Client Services Receipt Inventory
- 10. EuroQol Weighted Health Index EQ5D-5L
- 11. Average symptom bothersomeness over the last week (0-5 scale)
- 12. Pain Catastrophising Scale (PCS)
- 13. Tampa Scale of Kinesiophobia Avoidance Subscale
- 14. Pain Self-Efficacy Questionnaire
- 15. Exercise Behaviour Regulation Questionnaire
- 16. Perceived Competence for Self-Management Questionnaire
- 17. Treatment Motivation Questionnaire
- 18. Health Care Climate Questionnaire

Measured at baseline, 2 and 6 months

Previous secondary outcome measures:

- 1. Self-management behaviours
- 2. International Physical Activity Questionnaire
- 3. Physical Component Summary of the Medical Outcomes Study Short Form Health Survey SF-12
- 4. Average pain intensity over the last week (0-10 scale)
- 5. Patient-Specific Functional Scale
- 6. Participants satisfaction with outcome and care received
- 7. Participants global impression of change
- 8. Hospital Anxiety and Depression Scale
- 9. Client Services Receipt Inventory
- 10. EuroQol Weighted Health Index EQ5D-5L

Measured at baseline, 2 and 6 months

#### Completion date

31/12/2016

# **Eligibility**

#### Key inclusion criteria

Current inclusion criteria as of 02/10/2014:

- 1. Age  $\geq$  30 years for people with non-specific low back pain of mechanical origin with or without radiation to the lower limb
- 2. NICE (2014) working diagnosis of osteoarthritis of any of the joints of the lumbar spine, hip or knee defined as: age 45 years old or over, and activity-related joint pain and either no morning joint-related stiffness or morning stiffness that lasts no longer than 30 minutes or
- 3. Non-specific low back pain of mechanical origin with or without radiation to the lower limb  $\geq$ 3 months
- 4. English speaking and English literate
- 5. Access to a telephone for screening and assessment
- 6. Willing to attend 6-week group education and exercise class

#### Previous inclusion criteria:

- 1.  $\geq$  45 years of age
- 2. NICE (2014) working diagnosis of osteoarthritis of any of the joints of the lumbar spine, hip or knee defined as: age 45 years old or over, and activity-related joint pain and either no morning joint-related stiffness or morning stiffness that lasts no longer than 30 minutes or
- 3. Non-specific low back pain of mechanical origin with or without radiation to the lower limb  $\geq$ 3 months
- 4. English speaking and English literate
- 5. Access to a telephone for screening and assessment
- 6. Willing to attend 6-week group education and exercise class

#### Participant type(s)

Patient

#### Healthy volunteers allowed

No

#### Age group

Adult

#### Sex

All

#### Total final enrolment

120

#### Key exclusion criteria

- 1. Suspected or confirmed serious spinal pathology (fracture, metastatic, inflammatory or infective diseases of the spine, cauda equina syndrome/widespread neurological disorder)
- 2. Nerve root compromise (2 of strength, reflex or sensation affected for same nerve root)
- 3. Lower limb arthroplasty
- 4. Past medical history
- 5. Spinal surgery or history of systemic/inflammatory disease
- 6. Current medical status
- 7. Scheduled for major surgery during treatment
- 8. Contraindications
- 9. Unstable angina/uncontrolled cardiac dysrhythmias/severe aortic stenosis/acute systemic infection accompanied by fever

#### Other

- 10. No confounding conditions, such as a neurological disorder, intellectual disorder or unstable psychiatric condition.
- 11. Bladder or bowel incontinence
- 12. People who are assessed to be at high risk of falls
- 13. Physiotherapy in the preceding 6 months
- 14. Unable or unwilling to attend
- 15. Ongoing litigation related to the pain condition

#### Date of first enrolment

31/03/2014

#### Date of final enrolment

31/12/2016

## Locations

#### Countries of recruitment

Ireland

Study participating centre
School of Public Health, Physiotherapy and Population Science
Dublin
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# Sponsor information

#### Organisation

Health Research Board (Ireland)

#### **ROR**

https://ror.org/003hb2249

# Funder(s)

## Funder type

Government

#### Funder Name

Health Research Board of Ireland - Health Research Award HRA\_HSR/2012/24

# **Results and Publications**

Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration

## Study outputs

Output type

**Details** 

Results article	results	23/09/2020	25/09/2020 Yes	No
<u>Protocol article</u>	protocol	21/01/2016	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025 No	Yes