

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

<b>Submission date</b> 04/03/2014	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 26/03/2014	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 25/09/2020	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data

## 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**  
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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

Ireland

D4

## 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	Date created	Date added	Peer reviewed?	Patient-facing?
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<a href="#">Results article</a>	results	23/09/2020	25/09/2020	Yes	No
<a href="#">Protocol article</a>	protocol	21/01/2016		Yes	No