ISRCTN49875385 https://doi.org/10.1186/ISRCTN49875385

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

Submission date
04/03/2014

Recruitment status
No longer recruiting

Registration date
26/03/2014

Overall study status
Completed

Last Edited
25/09/2020

Condition category
Musculoskeletal Diseases

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] 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
deirdre.hurleyosing@ucd.ie

Contact information

Type(s)
Scientific

Contact name
Dr Deirdre Hurley

Contact details
School of Public Health, Physiotherapy and Population Science
Health Science Centre
University College Dublin
Belfield
Dublin
Ireland
D4
+353 (0) 1 7166524
deirdre.hurleyosing@ucd.ie

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Quality of life

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

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

Secondary outcome measures
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

Overall study start date
31/03/2014

Completion date
31/12/2016

Eligibility

Key inclusion criteria
Current inclusion criteria as of 02/10/2014:
1. Age ≥ 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 ≥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. ≥ 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 ≥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

Age group
Adult

Sex
Both

Target number of participants
144

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)

Sponsor details
73 Lower Baggot Street
Dublin
Ireland
D2

Sponsor type
Government

Website
http://www.hrb.ie

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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?
Protocol article	protocol	21/01/2016		Yes	No
Results article	results	23/09/2020	25/09/2020	Yes	No