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Facilitating Activity and Self management in Arthritis (FASA)

Submission date
26/10/2011

Recruitment status
No longer recruiting

Registration date
24/11/2011

Overall study status
Completed

Last Edited
16/11/2016

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims

As the population increases and people live longer, diseases associated with older age pose a considerable public health issue. Demands on already compromised health services are likely to grow as individuals seek medical assistance to retain independence and quality of life. The pressure on the older individual to remain healthy will intensify in association with the expectations to continue working into the seventh decade. Chronic joint pain including osteoarthritis (OA) can significantly limit the functional independence of individuals, and given that 25% of the population experience these problems, the impact is immense. These conditions are not life-threatening, but the effects of pain, immobility and reduced function can contribute to the development and progression of other serious conditions common in the older population. Furthermore associated anxiety and depression is recognisably higher in this group; reducing the impact of these conditions is key to maintaining a healthy older population.
Although chronic musculoskeletal pain and OA can present in any joint, the hip, knee and back are mainly affected. There is good evidence that exercise reduces pain and improves function in patients with chronic joint pain, but in order to encourage exercise participation, patients require appropriate advice, instruction and facilities. Approximately 70% of GPs reportedly recommend exercise for these conditions, whilst one third of those affected are reportedly referred for physiotherapy.
Adherence to exercise like any healthcare intervention is generally poor, most patients stop exercising once formal programmes cease as a result of loss of interest, time commitment, minimal change in function and availability of facilities. Symptoms often return and re-referral for further treatment is common at considerable cost to health services.
However, previous work from our group has demonstrated that for chronic knee pain/OA, a six-week exercise and self-management intervention (called ESCAPE) facilitated by a physiotherapist resulted in significant improvements in function and pain six-months after rehabilitation ceased; furthermore, participants still showed improvements 2½ years later. In addition, this intervention was cost-effective compared to usual GP care.
Most studies tailor interventions for specific joints e.g. hip or knee. In order to deliver evidence-based treatments this therefore requires clinicians to either manage patients on an individual basis or refer to joint specific group interventions. Neither option is ideal the first results in significant time and financial cost, whilst the second often requires patients to wait for appropriate numbers of people to be referred to allow groups to run. Additionally, many older

people with degenerative joint problems experience pain and functional difficulty in other joints, seeking further healthcare input when these present.
This research will help us to determine whether an exercise and self-management intervention delivered to groups of patients with chronic knee, hip or lower back pain can improve function six months after completion of the intervention; whether this works better than continued GP care.

Who can participate?
Participants will be recruited from GP practices in Wiltshire Primary Care Trust (UK). Individuals ages 50 years or older who have consulted their GP for ongoing joint pain of the lower back, hip or knee of at least 6 months duration.

What does the study involve?
GP practices will be randomly allocated to one of two groups: the GP practices' participants receive exercise and SM or remain on continued GP care (control arm). On completion of the exercise class, and six months later we will measure any changes in pain, function, willingness to exercise, confidence and anxiety and depression, to see whether the classes have benefited people.

What are the possible benefits and risks of participating?
Patients will be provided with providing general self-management skills that can be used for managing problems in lower limb joints or the lower back through exercise. This could potentially reduce the need for repeat visits to healthcare professionals as advice is frequently the same for many presentations. In addition, widening therapy to cover patients with more than one joint affected would attract more patients and enable classes to run more frequently, thus reducing waiting times. Encouraging individuals to pursue regular exercise and activity has the added potential to improve general health status in addition to joint function. Improving weight and blood pressure can reduce the risk of developing other conditions which are prevalent in this age group.

Where is the study run from?
GP practices in Wiltshire Primary Care Trust (UK)

When is the study starting and how long is it expected to run for?
December 2011 to November 2014

Who is funding the study?
This study is funded by the Charitable Trust of the Chartered Society of Physiotherapy and sponsored by the University of the West of England, Bristol (UK).

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
UWE CE10/0817

Study information

Scientific Title
Exercise and self-management for people with chronic knee, hip or lower back pain: a study of clinical and cost effectiveness

Acronym
FASA

Study objectives
1. To determine whether a generic exercise and self-management intervention delivered to groups of patients with chronic knee, hip or lower back pain can improve function six months post-completion of the intervention
2. To evaluate the acceptability and adherence to the intervention and determine professionals perspectives regarding the intervention
3. To determine the cost-effectiveness of the intervention compared to continued general practitioner (GP) care at six months post-completion of the intervention

Ethics approval required
Old ethics approval format

Ethics approval(s)
National Research Ethics Service, South West - Southmead, 07/07/2011, ref: 11/SW/0053

Study design
Cluster randomised controlled trial

Primary study design

Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
GP practice

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Chronic musculoskeletal pain and osteoarhritis

Interventions
Participants allocated to the intervention arm will receive 6-weeks (twice weekly) group exercise (approximately 8 participants) and self-management based on the ESCAPE programme. In brief, each session lasts for 60-minutes and includes 15-20 minutes of physiotherapist led group discussion and problem-solving session (with supporting handouts) regarding issues of self-management. Topics include activity-rest cycling, use of ice and heat for pain relief, goal-setting and action plans, exercise recommendations and healthy eating and managing changes in pain. After each discussion, participants undertake 35-40 minutes of exercise, based on a circuit of strengthening, aerobic and co-ordination activities. Further to the exercise circuit, in collaboration with the physiotherapist each individual completes an action plan regarding exercise/activities they want to achieve over the following week. This is reviewed after each week, to determine adherence to plan, problem-solving if the goal has proved unachievable, or progressed if achieved. All interventions will be conducted in physiotherapy departments of community/primary care hospitals in Wiltshire. Participants allocated to the continued GP care (control) arm are permitted to continue any current pharmacological or non-pharmacological treatment strategies; furthermore they can be referred for any treatments in primary or secondary care.

Participants will be assessed at baseline, post-intervention and six months later (primary end point)

Intervention Type
Behavioural

Primary outcome measure
Short musculoskeletal functional assessment

Secondary outcome measures
1. Self-efficacy and exercise health beliefs questionnaire
2. Hospital Anxiety and Depression scale
3. Short Form McGill Pain questionnaire
4. Aggregated Functional Performance Time (AFPT) a combined measure of walking, stair ascent and descent

5. Blood pressure
6. Weight and hip to waist ratio
7. EuroQol EQ-5D self-report generic health status measure (for health related quality of life, and to allow estimation of Quality Adjusted Life Years)
8. Self-reported resource use, (using the framework of the Client Services Receipts Inventory (CSRI) which collects self-reported data across a wide range of items including primary care, hospital care, use of rehabilitation facilities and patient costs)

Overall study start date
01/12/2011

Completion date
30/11/2014

Eligibility

Key inclusion criteria
1. Aged over 50 years with joint dysfunction
2. Those who have consulted a primary care physician for chronic musculoskeletal degenerative pain of the lower back, hip or knee of at least 6 months duration

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
352

Key exclusion criteria
1. Lower limb arthroplasty
2. Physiotherapy for associated condition in the preceding 12 months
3. Unstable medical conditions
4. Inability/unwillingness to exercise
5. Wheelchair dependence
6. Non-English speaking (due to pragmatic reasons of cost and engagement with the group intervention)

Date of first enrolment
01/12/2011

Date of final enrolment
30/11/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Faculty of Health and Life Sciences (HLS)
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Sponsor information

Organisation
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University/education

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ROR
https://ror.org/02nwg5t34

Funder(s)

Funder type
Charity

Funder Name
Chartered Society of Physiotherapy Charitable Trust (UK) (ref: PEP-2010)

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