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An alternative group physiotherapy programme for the management of chronic low back pain

Submission date
29/01/2014

Recruitment status
No longer recruiting

Registration date
17/02/2014

Overall study status
Completed

Last Edited
19/01/2017

Condition category
Musculoskeletal Diseases

[X] Prospectively registered

[_] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims

Low back pain is very common (estimated lifetime prevalence of up to 80% and one year prevalence rates of between 50% and 76%) and the economic and social impact is substantial. Low back pain is also one of the main causes of work absenteeism with many lost working days per year. Chronic low back pain (CLBP) is defined as pain and discomfort localised below the costal margin and above the inferior gluteal folds, with or without referred leg pain which has persisted for at least 12 weeks. CLBP is a disabling condition with many patients developing psychological distress and illness behaviours.

There has been no established standard management for CLBP. Several conservative therapies such as supervised exercise and manual therapy have demonstrated some benefit. Many studies investigating group exercise for the management of CLBP have used single mode exercise types such as Pilates, core stability, aerobic or strengthening without being individualised. Effective exercises for managing CLBP are those that are specific, individualised and regularly supervised. Patients with CLBP tend to avoid physical activity due to pain and fear avoidance behaviour. They become de-conditioned due to their low activity levels which results in decreased muscle power and cardiac capacity. CLBP patients may benefit from a programme that consists of combined exercise types such as strengthening, mobility and aerobic exercise. Manual therapy combined with exercise therapy has been found to work better than manual therapy alone for the treatment of CLBP. An alternative group physiotherapy programme proposed plans to combine multimodal individualised exercises and manual therapy. There is no evidence for this type of group physiotherapy programme. The overall aim of this project is to evaluate an alternative group physiotherapy programme for the management of non-specific CLBP. This original model may change the way CLBP is managed and provide a better alternative to existing group exercise programmes such as the back school or the back to fitness programme.

What does the study involve?

The study will have two phases. In the first phase (March 2014 to May 2016), participants will be randomly allocated to one of two groups: an alternative group physiotherapy programme or a standard group physiotherapy exercise programme which will act as the control. Participants will not know whether they have been assigned to an alternative treatment or standard group. The second phase will use focus groups to explore patients views regarding their treatment in the two group programmes.

What are the possible benefits and risks of participating?
There are minimum risks to patients in this study. Patients may experience some post-exercise muscle soreness post session or slight discomfort following their hands on treatment. We will take this into account and adjust your treatment accordingly. Patients will be also given advice on how to manage their pain at home as well as relief from any post-treatment discomfort. Pregnant women in their first trimester are advised not to undertake any new physiotherapy exercises as part of their standard care and therefore they will be excluded from taking part in the study. Pregnant women must not therefore take part in this study and neither should women who plan to become pregnant during the study. Any woman who finds that she has become pregnant while taking part in the study should immediately inform the researcher and her GP. It is possible that patients may not benefit from physiotherapy but there are minimal risks to the treatment as they would have been screened thoroughly prior to their inclusion into the study.

Where is the study run from?
Ealing Hospital NHS Trust in the Ealing Community Musculoskeletal Service (UK)

When is the study starting and how long is it expected to run for?
March 2014 to June 2016

Who is funding the study?
Middlesex University (UK)

Who is the main contact?
Alex Daulat
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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
N/A

Study information

Scientific Title
An alternative group physiotherapy programme for the management of non-specific chronic low back pain in Primary Care

Study objectives
The alternative group physiotherapy programme is more effective than a standard group programme in the management of non-specific chronic low back pain (CLBP) for improving function and quality of life in the long-term.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Riverside Ethics Committee, London, 16/12/2013, ref: 13/LO/1776

Study design
Mixed methods sequential exploratory design consisting of a randomised controlled trial (RCT) and focus group interviews

Primary study design
Interventional

Secondary study design
Randomised controlled 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 low back pain in musculoskeletal medicine

Interventions
1. Spinal Rehabilitation Programme (SRP)
The content of the SRP has been developed following previous research, review of the literature and collaboration with service providers. Service users have not been involved in the development of this programme. The SRP consists of group multimodal exercise therapy and

one to one sessions consisting of manual therapy and education. In the first session, participants will be required complete their outcome measures. All participants in the group will complete a warm-up lasting 5 minutes for general stretches and a warm-down at the end of the programme for 5 minutes also. Following the warm-up participants will then start their individual exercises by selecting the appropriate exercise station and then move on the next station when completed. There will be no time limit at the exercise stations and all patients will be supervised by the assistant physiotherapist. There will be seven stations: One to one, core stability on mats, upper limb strengthening, lower limb strengthening, functional exercises, stretches/spinal mobility and cardiovascular. During the group exercise session, participants will be called to attend the one to one station. Patients will have up to six one hour treatment sessions but not consecutive. The SRP will be run by a physiotherapist and assistant physiotherapist. Both group programme sessions will have a maximum of 10 patients attending. Patients will have the opportunity to choose when they attend and have up to three months to complete the programme. Each patient will be given a specific individualised exercise programme which they are required to do at home during the course of their treatment. Patients will also be encouraged to continue with their prescribed exercises after their treatment and increase their physical activity levels in accordance with the physical activity guidelines set by the Chief Medical Officer and NICE guidelines. There is no evidence of this alternative programme in the literature.

Exercises within the SRP:
Individualised exercises will be prescribed by the referring therapist prior to the programme Each participant referred to the SRP will be given 8-10 exercises. Referring physiotherapists are required to select at least one exercise for the following five categories: Core stability, lumbar mobility/stretches, functional, upper limb strengthening and lower limb strengthening. These exercises will be supervised and progressed by the programme physiotherapist. It is hypothesised that CLBP would benefit more from a multimodal exercise programme. This type of physical exercise programme has been used as part of a multidisciplinary rehabilitation programme for patients with CLBP previously

Participants will also be advised to maintain during the programme and thereafter moderate-intensity aerobic physical activity for a minimum of 30 minutes on 5 days each week or 20 minutes of vigorous-intensity aerobic exercise on 3 days a week. These are the physical activity guidelines set by the Chief Medical Officer for adults between 19 and 65 years and the NICE guidelines. Activities performed as part of daily life such as brisk walking, gardening with a shovel performed in bouts of 10 minutes or more can be counted towards the recommendation.

One to one therapist sessions within the SRP:
Manual therapy and advice sessions specific to the participants are to be provided for every patient each session. Education regarding back pain management will be delivered on an individual basis based on the programme goal/objectives. Individual patient education can be defined as an experience in a one-to one situation which consists of one or more methods such as the provision of information or advice that may influence patients health behaviour and coping strategies for their pain. All participants will be provided with the Arthritis Research UK, Back Pain Booklet. This is a published information booklet and is a comprehensive up to date guide for back pain and how it can be managed. The education material in this booklet is very similar to that provided in previous Back School research. Written information for back pain can be considered as long as it is evidence-based and up to date. The referring physiotherapist will indicate on the checklist form whether manual therapy is indicated and what has been done previously. Manual therapy if appropriate could be applied during the one to one session by the programme therapist.

2. Standard Group Programme
The standard group programme is based on the model designed by Klaber-Moffat and Frost (2000). It consists of six one hour general exercise sessions using a circuit based exercise format and is run by a physiotherapist. There will be weekly group exercise education sessions at the end of the exercise period. All participants will be provided with the Arthritis Research UK, Back Pain Booklet. Patients will also be advised to maintain during this programme and thereafter their prescribed home exercises and moderate-intensity aerobic physical activity for a minimum of 30 minutes on 5 days each week or 20 minutes of vigorous-intensity aerobic exercise on 3 days a week as group A.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Measured pre-treatment, post-treatment (3 and 6 months) and at one year follow-up:
1. Function, measured by the Functional Rating Index (FRI) which is a valid and reliable measure used to monitor change in spinal conditions. The FRI has ten items with a 5-point Likert scale (i.e. 0 none to 4 severe) for each item. Scores for each item (maximum of 4) are totalled to give an index score. There are ten items. This index score out of 40 is multiplied by 100 to give a percentage. Higher percentage scores indicate higher perceived dysfunction and pain. If only 9 items are completed then an index score out of 36 can be multiplied by 100 to give a percentage score. This may be applicable as one item relates to work. Some patients do not work and therefore would not be able to answer this question. However, the FRI would be invalid if less than 9 items were completed. The FRI scale also estimates disability. 0-20% is classified as minimal disability, 21-40% moderate disability, 41-60% severe disability and greater than 61% very severe disability.
2.1. Quality of life, measured using the EQ-5D-5L. This is a new version of the EQ-5D which includes five levels of severity in the existing five dimensions in order to reduce ceiling effects. The EQ-5D-5L is a standardised instrument for use as a measure of health outcome. It is applicable to a wide range of health conditions and treatments.

Added 17/01/2017:
2.2. Quality of life, measured using the EQ-VAS. The EQ-VAS is part of the EQ-5D-5L and is a self-rating scale which records the respondent’s own assessment of their health status that day.
3. Pain, measured using the Numerical Pain Rating Scale (NPRS), an 11-point pain rating scale ranging from 0 (no pain) to 10 (worse pain imaginable). The NPRS was used to assess the participant’s current pain intensity as well as the best and worst level of pain during the last 24 hours. These three levels were averaged to give the participant’s pain score.
All outcomes measured pre-treatment, post-treatment (3 months) and at 6-months follow-up. (NB there was no one year follow-up)

Secondary outcome measures
Secondary outcome measures will evaluate patients perceptions and experiences of the treatments they received. These measures will be administered post-treatment.

As of 23/02/2016:
1. Patient satisfaction - Patients' perception of their treatment will be measured using a modified version of the Participant Satisfaction Reporting Scale (PSRS). The PSRS is a 5-item

report questionnaire (total score out of 25) which allows patients to rate their satisfaction with their treatment but also to rate their satisfaction with improvement. For example, this instrument rates a patients attitude toward their treatment they received from completely satisfied to completely dissatisfied. The higher the score the more satisfied they are.
2. Participants' perceptions of the group programmes will be explored qualitatively by the use of focus group interviews once the recruitment process has finished and all participants have completed their group programme sessions. All participants will be invited to take part by letter. It is expected to have two focus groups (one for each group programme) consisting of 6-8 participants based on response rates and attendance with similar studies. Participants in these focus groups will have the opportunity to discuss their experiences with aim of exploring the impact of the programme on them as individuals.

Previous:
1. Patient satisfaction - Patients' perception of their treatment will be measured using a modified version of the Participant Satisfaction Reporting Scale (PSRS). The PSRS is a 5-item report questionnaire (total score out of 25) which allows patients to rate their satisfaction with their treatment but also to rate their satisfaction with improvement. For example, this instrument rates a patients attitude toward their treatment they received from completely satisfied to completely dissatisfied. The higher the score the more satisfied they are.
2. Community Patient Experience Survey (CPES) - a questionnaire based on a version used at the trust for audit purposes will be used to explore patients experience of their treatment within the group programmes. This survey will give service users the opportunity to express their views which can be integrated into improving healthcare delivery. This questionnaire will be a mixture of open as well as closed questions on a 5-point Likert scale.
3. Participants' perceptions of the group programmes will be explored qualitatively by the use of focus group interviews once the recruitment process has finished and all participants have completed their group programme sessions. All participants will be invited to take part by letter. It is expected to have two focus groups (one for each group programme) consisting of 6-8 participants based on response rates and attendance with similar studies. Participants in these focus groups will have the opportunity to discuss their experiences with aim of exploring the impact of the programme on them as individuals.

Overall study start date
01/06/2014

Completion date
31/01/2016

Eligibility

Key inclusion criteria
1. Male and female subjects between ages of 20-65 years. This is a standard adult age range used in CLBP studies investigating the effect of exercise and /or manual therapy
2. CLBP for >3 months
3. Motivated and willing to attend both the physiotherapy programmes

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
80

Key exclusion criteria
1. Cardiac, respiratory, kidney, blood pressure or blood circulatory problems which may prevent participation in any strenuous exercise programme
2. Recent spinal surgery within one year which may affect the ability to participate in group exercise programmes. These patients are usually excluded from CLBP studies
3. Acute fracture or recent trauma require specialist management and would not be suitable for group rehabilitation programmes
4. Inflammatory or infectious diseases of the spine
5. Metabolic or bone disease such as osteoporosis
Both 4 and 5 conditions are a contraindication to physiotherapy and would require further investigation and onward referral
6. Neurological signs or symptoms such as sensation loss in a specific dermatome, myotomal muscle weakness or abnormal reflexes. These neurological deficits may require further investigation or monitoring and would not be appropriate for an extensive exercise programme or manual therapy
7. Advanced rheumatoid arthritis or uncontrolled diabetes. These conditions are contraindicated to manual therapy and exercise programmes. These conditions would also require specialist review
8. Subjects who were pregnant or attempting to become pregnant
9. Chronic pain syndrome patients with severe physical or psychological impairment. This includes the group of patients presenting with widespread sensory hypersensitivity mediated by central pain mechanisms. These patients are unlikely to respond to exercise and/or manual therapy and may need to be referred for multimodal pain management programmes or pain clinic
10. Participated in a regular exercise programme or had previous physiotherapy or any other treatment within the last six months
11. Any spinal condition requiring further investigation or on-ward referral and not likely to respond to conservative treatment

Date of first enrolment
01/06/2014

Date of final enrolment
31/05/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Ealing Community Musculoskeletal Service
London
United Kingdom
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Sponsor information

Organisation
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Sponsor type
University/education

ROR
https://ror.org/01rv4p989

Funder(s)

Funder type
University/education

Funder Name
Middlesex University (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Alex Daulat (alex.daulat@nhs.net)

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/10/2016		Yes	No
Basic results		17/01/2017	19/01/2017	No	No
HRA research summary			28/06/2023	No	No