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A self-managed exercise programme versus usual physiotherapy for chronic rotator cuff disorders

Submission date
23/02/2012

Recruitment status
No longer recruiting

Registration date
23/02/2012

Overall study status
Completed

Last Edited
19/11/2018

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
Shoulder pain is the third most common reason for consultation with a physiotherapist and up to half of the population might be expected to experience at least one episode of shoulder pain per year. Disorders of the shoulder muscles and tendons (rotator cuff) are thought to be the most common cause of this pain. The long-term outcome is frequently poor despite treatment. This means that many patients are exposed to more invasive treatment, e.g. surgery, and/ or long term pain and disability. Patients with this disorder typically receive a course of physiotherapy which might include a range of treatments. Specifically the value of exercise against gravity or resistance (loaded exercise) in the treatment of tendon disorders is promising but appears to be under-used. Loaded exercise in other areas of the body has been favourably evaluated but further investigation is needed to evaluate the impact of these exercises in the shoulder and particularly the role of home-based or supervised exercise versus usual treatment requiring clinic attendance. The purpose of this study is to evaluate whether a self-managed exercise programme is more effective than usual physiotherapy in reducing pain and improving shoulder function in people with rotator cuff disorders.

Who can participate?
Patients over 18 years old, referred for physiotherapy with a primary complaint of shoulder pain with or without referral into the upper limb for more than 3 months with no/minimal resting shoulder pain. Disorder attributable to the rotator cuff will be confirmed prior to entry into the study.

What does the study involve?
Potential participants will be invited to attend the physiotherapy department to undergo a physical examination by a chartered physiotherapist to assess eligibility. This examination will last up to 30 minutes and will involve an examination of the shoulder and neck to determine whether the shoulder complaint is caused by the rotator cuff. Once eligibility has been confirmed a range of questionnaires will be completed to help us understand how the shoulder problem affects the participant now. This will take about 20 minutes. Once the questionnaires have been completed the participants will be randomly assigned to receive a self-managed

exercise programme under the guidance of a NHS physiotherapist or usual physiotherapy, which might include a range of treatments, e.g. exercise, stretches, massage, ultrasound treatment. Those participants allocated to receive self-managed exercise will also complete an exercise diary to enable an assessment of adherence with the programme. The end of treatment will be determined by the physiotherapist in consultation with the participant. Treatment is expected to have been completed by three months but further questionnaires will be sent by post after 3, 6 and 12 months as well as one further questionnaire to determine the resources needed to treat your shoulder problem. This will take about 15 minutes each time. During the study up to 20 participants will be invited to attend an individual interview to discuss their experience of the treatment received.

What are the possible benefits and risks of participating?
It is expected that participants will gain benefit from the treatment that is prescribed. Furthermore, the information that is gained from this study will help inform future research. Apart from the time taken to complete the questionnaires on four separate occasions, there are no disadvantages or risks to taking part in this research.

Where is the study run from?
The study is organised by a research team led by the chief investigator, Chris Littlewood, who is a chartered physiotherapist currently working as a Research Fellow in the School of Health & Related Research, University of Sheffield. The intervention will be delivered via the physiotherapy department of Doncaster & Bassetlaw NHS Foundation Trust (UK).

When is the study starting and how long is it expected to run for?
Recruitment runs from April 2012 to March 2013. Follow-up outcome measurements will last for up to 12 months after this date.

Who is funding the study?
The National Institute for Health Research (NIHR).

Who is the main contact?
Mr Chris Littlewood, Research Fellow
c.littlewood@sheffield.ac.uk

Contact information

Type(s)
Scientific

Contact name
Mr Chris Littlewood

Contact details
Health Services Research
School of Health & Related Research (ScHARR)
Regents Court
30 Regent Street
Sheffield
United Kingdom

S1 4DA
+44 (0)114 222 0888
c.littlewood@sheffield.ac.uk

Additional identifiers

Protocol serial number
11741

Study information

Scientific Title
A mixed methods study to evaluate the clinical and cost-effectiveness of a self-managed exercise programme versus usual physiotherapy for chronic rotator cuff disorders

Acronym
SELF

Study objectives
Is a self-managed exercise programme more effective than usual physiotherapy for chronic rotator cuff disorders?

Please note that as of 19/12/2012, the following changes were made to the record:
1. The overall trial end date was updated from 31/03/2013 to 30/09/2013.
2. The target number of participants was updated from 210 to 78.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee Yorkshire & the Humber - Leeds West, 06/01/2012 ref: 11/YH/0443. Amendment approved 12/11/2012.

Study design
Mixed methods: randomised controlled economic evaluation qualitative study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Musculoskeletal Disease

Interventions
The intervention is self-managed loaded (against gravity or resistance) exercise. The exercise, prescribed by the physiotherapist but completed by the patient independently, involves exercising the affected shoulder against gravity, a resistive therapeutic band or hand weight over 3 sets of 10 to 15 repetitions completed twice per day. This exercise can be uncomfortable

for the patient but is prescribed to ensure that the discomfort is manageable. Exercise prescription is guided by symptomatic response requiring that pain is produced during exercise that remains no worse upon cessation of that exercise.
The comparator, usual physiotherapy, might include a range of interventions including advice, stretching, exercise, manual therapy, massage, strapping, acupuncture, electrotherapy, corticosteroid injection at the discretion of the treating physiotherapist.

Intervention Type
Behavioural

Primary outcome(s)
Shoulder pain and disability index measured at 3, 6 and 12 months

Key secondary outcome(s))
Short-Form 36 measured at 3, 6 and 12 months

Completion date
30/09/2013

Eligibility

Key inclusion criteria
1. Age > 18 years
2. Willing and able to participate
3. Primary complaint of shoulder pain with or without referral into the upper limb for > 3 months
4. No/minimal resting shoulder pain
5. Range of shoulder movement largely preserved
6. Shoulder pain provoked consistently with resisted muscle tests, usually abduction or lateral rotation
7. Male and female participants
8. Lower age limit 18 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria

1. Shoulder surgery within last 6 months,
2. Reasons to suspect systemic pathology including inflammatory disorders,
3. Cervical repeated movement testing affects shoulder pain and/ or range of movement.

Date of first enrolment
01/04/2012

Date of final enrolment
01/03/2013

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Health Services Research
Sheffield
United Kingdom
S1 4DA

Sponsor information

Organisation
NHS Doncaster (UK)

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research [NIHR] (UK)

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?
Results article	results	01/03/2014		Yes	No
Results article	results	01/07/2016		Yes	No
Protocol article	protocol	30/04/2012		Yes	No
Protocol article	protocol	01/12/2013		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes