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An investigation of the reliability of the Shoulder Symptom Modification Procedure in people with shoulder pain

Submission date
15/04/2016

Recruitment status
No longer recruiting

Registration date
22/04/2016

Overall study status
Completed

Last Edited
10/07/2017

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Determining the cause of symptoms for people with musculoskeletal problems of the shoulder (that is problems involving the bone and/or muscles of the shoulder) is complicated and fraught with difficulty. Many people without symptoms have tears of the tendons and have problems involving the structures (for example, the bones and connective tissues making up the shoulder joint, or the muscles) associated with the shoulder. As such many clinicians have started to use assessment techniques that change and improve the patient's symptoms as a method of determining how best to treat the person with shoulder symptoms. One such method is the Shoulder Symptom Modification Procedure. The reliability of these procedures is largely unknown. The aim of this study is to assess how reliable clinicians find the Shoulder Symptom Modification Procedure in identifying and being able to treat the cause of shoulder pain in their patients.

Who can participate?
Patients over 18 years old with diagnosed shoulder pain

What does the study involve?
Patients recruited into the study identify a movement, posture or activity that causes or reproduces their symptoms. Physiotherapists apply the procedures of the Shoulder Symptom Modification Procedure to these symptoms and the patients report the response, for example, can they carry out a procedure that is asked, or does a procedure improve their symptoms, does a procedure make their symptoms worse, or does it make no difference to them at all. The assessment that the physiotherapist makes as to what is causing a patients shoulder problems is then looked at to see whether they agree with other physiotherapists.

What are the possible benefits and risks of participating?
The possible benefit is to see whether the techniques associated with the Shoulder Symptom Modification Procedure are reliable. The techniques used are commonly used in clinical practice and as such there are no identifiable risks associated with participation for the patient participant's involvement with the investigation.

Where is the study run from?
University of Limerick

When is the study starting and how long is it expected to run for?
December 2015 to July 2016

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Jeremy Lewis

Contact information

Type(s)
Scientific

Contact name
Dr Jeremy Lewis

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
01

Study information

Scientific Title
An investigation of the reliability of the Shoulder Symptom Modification Procedure in people with shoulder pain: an observational cross-sectional study

Study objectives

The aim of this study is to assess of the reliability of the Shoulder Symptom Modification Procedure.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research Ethics Committee Ollscoil Luimnigh / University of Limerick, 06/04/2016, ref: 2015_12_13_EHS

Study design
Observational cross-sectional study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Other

Study type(s)
Diagnostic

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Shoulder pain of musculoskeletal origin

Interventions
The study involves taking videos of people with shoulder pain undergoing a clinical examination, followed by viewing and scoring of this clinical examination by a number of physiotherapists, in order to determine the inter-rater reliability.

Immediately following direct observation of the patient participant's response to the Shoulder Symptom Modification Procedure each physiotherapist participant will record on a dedicated data sheet one of the following responses:
1. No change
2. Worse
3. Partial improvement
4. Complete improvement

Inter-rater reliability will then be assessed by determining the agreement between the physiotherapist participants on each assessment procedure using Kappa statistics.

Intervention Type
Other

Primary outcome measure
Reliability of physiotherapist participants to determine the effect of a series of procedures (that comprise the Shoulder Symptom Modification Procedure) on the patient participant's shoulder symptoms. This will be achieved by independent observation of the assessment and patient participant's responses. This will be assessed on one occasion immediately after observing the response.

Secondary outcome measures
An assessment of the influence of years in practice, number of shoulder patients assessed and treated each week, and previous training (if any) in the use of the Shoulder Symptoms Modification Procedure.

Overall study start date
13/12/2015

Completion date
31/07/2016

Eligibility

Key inclusion criteria
Shoulder pain participants:
Inclusion criteria: over 18 years, shoulder pain is reproduced by one or more shoulder movements, provision of informed written consent.

Physiotherapists:
A group of up to 30 registered qualified physiotherapists will act as the raters

Participant type(s)
Mixed

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
11 to 12 people with uniliateral shoulder pain of musculoskeletal origin

Key exclusion criteria
1. People who have recent shoulder surgery or fracture
2. People with rheumatological or neurological cause for shoulder pain, or potentially serious conditions e.g. systemic disease, neurological disorders, inflammatory conditions or major trauma
3. People who have had physiotherapy treatment resulting in resolution of their pain

Date of first enrolment
21/04/2016

Date of final enrolment
31/07/2016

Locations

Countries of recruitment
Ireland

United Kingdom

Study participating centre
University of Limerick
Castletroy
Limerick
Ireland
-

Sponsor information

Organisation
University of Limerick

Sponsor details
Dept of Clinical Therapies
Castletroy
Limerick
Ireland
-

Sponsor type
University/education

ROR
https://ror.org/00a0n9e72

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan

Intention to publish date
31/07/2017

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	11/11/2016		Yes	No