

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 22/04/2016	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 10/07/2017	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data

Plain English Summary

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 hypothesis

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

Condition

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

Overall study end date

31/07/2016

Eligibility

Participant 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 unilateral shoulder pain of musculoskeletal origin

Participant 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

Recruitment start date

21/04/2016

Recruitment end date

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