

# GRASP - Getting it right: addressing shoulder pain

<b>Submission date</b> 13/07/2016	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 14/07/2016	<b>Overall study status</b> Completed	<input checked="" type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 06/08/2024	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Shoulder pain is very common, with around 1% of adults in the UK consulting their GP about a new shoulder problem each year. Most new cases of shoulder pain are caused by problems with the group of muscles and tendons that surround the shoulder joint (rotator cuff). The rotator cuff can be damaged through irritation and inflammation (swelling), trapping of the tendons and/or muscle tears. The main symptom is pain, both when still and when moving the shoulder. Shoulder pain can seriously affect a person's ability to work, sleep soundly and perform daily tasks. Common treatments include advice, rest, painkillers, anti-inflammatories, physiotherapy and steroid injections. Currently, it is unclear how best to improve physiotherapy for shoulder pain, as it is not known which physiotherapy techniques work best for shoulder pain, how exactly they should be delivered, and whether patients do better if they get a steroid injection before starting an exercise programme. The aim of this study is to investigate the effectiveness of a progressive exercise programme supervised over 16 weeks by a physiotherapist compared to a single education/advice session (best practice advice). The study will also test whether getting a corticosteroid injection in the shoulder joint before starting either regime helps to relieve pain, enabling comfortable exercise and improving function.

### Who can participate?

Adults who have new (within the last six months) shoulder pain caused by a rotator cuff problem who are not currently being treated with physiotherapy or being considered for surgery.

### What does the study involve?

Participants are randomly allocated to one of four groups. Those in the first group take part in a progressive exercise programme, which involves up to six sessions with a physiotherapist over 16 weeks where the exercises become more intense as they go on. Those in the second group receive a single face-to-face session in which they are given education, reassurance and self-management exercise advice, including advice on pain management and how to change their activity so as not to cause more pain (best practice advice session). Those in the third group take part in the progressive exercise programme with the addition of an injection of a steroid and local anaesthetic (numbing injection) once before the programme starts and again afterwards. Those in the fourth group receive the same best practice advice session as group two, but receive a steroid and local anaesthetic injection before and after this session. Participants in all

groups are examined and complete a range of questionnaires at the start of the study and then 8 weeks, 6 months and 12 months later in order to see if there have been any changes to their pain levels and shoulder function.

A sample of participants taking part are also asked to take part in a sub-study. This involves being randomly allocated to receive either a standard text message or a personalised text message to remind them to complete their follow up questionnaires from the main study. The response rate to the questionnaires is then recorded.

What are the possible benefits and risks of participating?

For those participating in the trial – all will receive some physiotherapy which aims to restore functional movement and reduce pain – the only difference for participants in the trial is that the amount of physiotherapy given will differ as it is not known the best amount of physiotherapy for people to have with a rotator cuff injury. There are no notable risks involved with participating, as all treatments being tested are routinely offered within the NHS.

Where is the study run from?

Botnar Research Centre  
Windmill Road  
Headington  
Oxford  
OX3 7LD

When is the study starting and how long is it expected to run for?

June 2016 to July 2020

Who is funding the study?

NIHR Health Technology Assessment Programme (UK)

Who is the main contact?

1. Professor Sally Hopewell (scientific)  
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2. Ms Lucy Cureton (public)  
grasp@ndorms.ox.ac.uk

## Contact information

### Type(s)

Scientific

### Contact name

Prof Sally Hopewell

### Contact details

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**Type(s)**

Public

**Contact name**

Ms Lucy Cureton

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## Additional identifiers

**Clinical Trials Information System (CTIS)**

2016-002991-28

**Protocol serial number**

OCTRU0105

## Study information

**Scientific Title**

Clinical and cost effectiveness of progressive exercise compared to best practice advice, with or without corticosteroid injection, for the treatment of rotator cuff disorders: a 2x2 factorial randomised controlled trial

**Acronym**

GRASP

**Study objectives**

GRASP:

The aim of this study is to investigate:

1. Whether people with a rotator cuff problem do better after a progressive exercise programme supervised over 16 weeks by a physiotherapist or after one best-practice advice session with a physiotherapist
2. Whether getting a corticosteroid injection in the shoulder joint before starting either regime helps to relieve pain, enabling comfortable exercise and improving function

PROMPTS (embedded retention trial):

The aim of this study is to test the effectiveness of a low-cost personalised text messaging strategy (PROMPTS) to prompt the return of questionnaires, using a randomised controlled trial embedded within the GRASP trial.

**Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Berkshire B Research Ethics Committee, 20/10/2016, ref: 16/SC/0508

## **Primary study design**

Interventional

## **Study design**

GRASP:

Multi-centre phase 3 2x2 factorial randomised controlled trial

PROMPTS (embedded retention trial):

Randomised controlled trial

## **Study type(s)**

Treatment

## **Health condition(s) or problem(s) studied**

Rotator cuff problem

## **Interventions**

GRASP:

Consented participants will be randomised to intervention groups (1:1:1:1) using the centralised computer randomisation service RRAMP (<https://rramp.octru.ox.ac.uk>) provided by the Oxford Clinical Trials Research Unit (OCTRU).

Group 1: Progressive exercise programme:

The participants randomised to the progressive exercise programme will receive up to six sessions with a physiotherapist over 16 weeks. This programme consists of 3 phases:

Phase 1 – assessment and advice

Phase 2 – progressive structured resistance training

Phase 3 – patient-specific functional restoration

Group 2: Best practice advice session:

The participants randomised to the best practice advice session will receive a single face-to-face session with a physiotherapist, lasting up to 60 minutes. After a comprehensive shoulder assessment, the participants will be given education, reassurance and self-management exercise advice, including advice on pain management and activity modification. They will also be given a simple set of self-guided exercises that can be progressed and regressed depending on their capability.

Group 3: Progressive exercise programme + Methylprednisolone injection or Triamcinolone acetonide injection

Participants receive an injection of 40 mg methylprednisolone (Depo-Medrone) together with local anaesthetic in one injection at the same time, or separately, depending on local treatment protocols at sites OR

Participants receive an injection of 20-40 mg triamcinolone acetonide (Kenalog) together with local anaesthetic in one injection at the same time, or separately, depending on local treatment protocols at sites.

(The local anaesthetic will either be 1% lidocaine (up to 5 ml) or 0.5% bupivacaine hydrochloride (up to 10 ml), again depending on local treatment protocols.)

This injection will be given once before the progressive exercise intervention is delivered, then

the progressive exercise intervention is delivered.

The participants randomised to the progressive exercise programme will receive up to six sessions with a physiotherapist over 16 weeks. This programme consists of 3 phases:

Phase 1 – assessment and advice

Phase 2 – progressive structured resistance training

Phase 3 – patient-specific functional restoration

A second injection can be given after 6 weeks, but will only be administered to those patients who receive good initial benefit from their first injection and who request further pain relief to facilitate their exercises.

**Group 4: Best practice advice session + Methylprednisolone injection or Triamcinolone acetonide injection**

Participants receive an injection of 40 mg methylprednisolone (Depo-Medrone) together with local anaesthetic in one injection at the same time, or separately, depending on local treatment protocols at sites OR

Participants receive an injection of 20-40 mg triamcinolone acetonide (Kenalog) together with local anaesthetic in one injection at the same time, or separately, depending on local treatment protocols at sites.

(The local anaesthetic will either be 1% lidocaine (up to 5 ml) or 0.5% bupivacaine hydrochloride (up to 10 ml), again depending on local treatment protocols.)

This injection will be given once before the best practice advice session is delivered, then the best practice advice session is delivered.

The participants randomised to the best practice advice session will receive a single face-to-face session with a physiotherapist, lasting up to 60 minutes. After a comprehensive shoulder assessment, the participants will be given education, reassurance and self-management exercise advice, including advice on pain management and activity modification. They will also be given a simple set of self-guided exercises that can be progressed and regressed depending on their capability.

A second injection can be given after 6 weeks, but will only be administered to those patients who receive good initial benefit from their first injection and who request further pain relief to facilitate their exercises.

All participants in every group will be followed-up at baseline, 8 weeks, 6 months and 12 months after randomisation.

**PROMPTS (embedded retention trial):**

Participants will be randomised (1:1) to receive one of two interventions:

**Control group:** A standard text message

**Intervention group:** A personalised text message which includes their name

The text message will be sent to trial participants after they have been posted their trial follow-up questionnaire by the trial team, according to the first postal follow-up specified in the GRASP protocol after implementing the text message trial. The text message will be sent at the same time as they are expected to receive their postal follow-up questionnaire (i.e., normally 2-4 days after the questionnaire is sent, depending on whether first or second class postage is used). The message will be sent in addition to routine trial follow-up procedures, specifically a reminder follow up questionnaire followed by a phone call to those who do not respond to the reminder.

Each text message will contain the same core information. Recipients will be reminded about the arrival of the questionnaire, about the importance of their responses and to return the questionnaire as soon as possible. For participants in the intervention group, text messages will be customised using their name, according to how they preferred to be addressed.

## **Intervention Type**

Drug

## **Phase**

Phase III

## **Drug/device/biological/vaccine name(s)**

Methylprednisolone injection Triamcinolone acetonide

## **Primary outcome(s)**

GRASP:

Shoulder pain and function is measured using the Shoulder Pain and Disability Index (SPADI) at baseline, 8 weeks, 6 and 12 months.

PROMPTS (embedded retention trial):

Questionnaire response rate, defined as the proportion of GRASP follow up questionnaires returned by participants.

## **Key secondary outcome(s)**

Current secondary outcome measures as of 09/07/2018:

GRASP:

1. Pain is measured using the Shoulder Pain and Disability Index (SPADI) 5-item subscale at baseline, 8 weeks, 6 and 12 months
2. Function is measured using the Shoulder Pain and Disability Index (SPADI) 8-item subscale at baseline, 8 weeks, 6 and 12 months
3. Health-related quality life is measured using the EQ-5D-5L at baseline, 8 weeks, 6 and 12 months
4. Psychological factors are measured using the Fear Avoidance Belief Questionnaire – physical activity 5-item subscale and Pain Self-efficacy questionnaire (short form) at baseline, 8 weeks, 6 and 12 months
5. Sleep disturbance is measured using the Insomnia Severity Index at baseline, 8 weeks, 6 and 12 months
6. Global impression of treatment is measured using the Patient-rated Likert scale at 8 weeks, 6 and 12 months
7. Return to desired activities is measured using the Patient-reported return to desired activities including work, social life and sport activities at 0, 8 weeks, 6 and 12 months
8. Exercise adherence is measured using the Patient-reported adherence to exercise at 8 weeks, 6 and 12 months
9. Medication usage is measured using the Patient-reported prescribed and over the counter medications, additional steroid injection at 8 weeks, 6 and 12 months
10. Work disability is measured by recording the number of days of sick leave taken at 8 weeks, 6 and 12 months
11. Healthcare use is measured by collecting NHS usage data at 8 weeks, 6 and 12 months
12. Out-of-pocket expenses are measured using patient related recording of out of pocket expenses at 8 weeks, 6 and 12 months

PROMPTS (embedded retention trial):

1. Time to response, defined as the number of days which elapse between the GRASP follow up questionnaire being mailed out to participants and the questionnaire recorded as being returned to the GRASP trial team
2. The proportion of participants sent a reminder follow up questionnaire
3. The cost-effectiveness of the text message intervention

Previous secondary outcome measures:

GRASP:

1. Pain is measured using the Shoulder Pain and Disability Index (SPADI) 5-item subscale at baseline, 8 weeks, 6 and 12 months
2. Function is measured using the Shoulder Pain and Disability Index (SPADI) 8-item subscale at baseline, 8 weeks, 6 and 12 months
3. Health-related quality life is measured using the EQ-5D-5L at baseline, 8 weeks, 6 and 12 months
4. Psychological factors are measured using the Fear Avoidance Belief Questionnaire – physical activity 5-item subscale and Pain Self-efficacy questionnaire (short form) at baseline, 8 weeks, 6 and 12 months
5. Sleep disturbance is measured using the Insomnia Severity Index at baseline, 8 weeks, 6 and 12 months
6. Global impression of treatment is measured using the Patient-rated Likert scale at 8 weeks, 6 and 12 months
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PROMPTS (embedded retention trial):

1. Time to response, defined as the number of days which elapse between the GRASP follow up questionnaire being mailed out to participants and the questionnaire recorded as being returned to the GRASP trial team
2. The proportion of participants sent a reminder follow up questionnaire
3. The cost-effectiveness of the text message intervention

**Completion date**

31/08/2020

## **Eligibility**

**Key inclusion criteria**

GRASP:

1. Men and women aged 18 years and above
2. New episode of shoulder pain (i.e., within the last 6 months) attributable to a rotator cuff disorder (e.g., cuff tendonitis, impingement syndrome, tendinopathy or rotator cuff tear) using

the diagnostic criteria set out in the BESS guidelines

3. Not currently receiving physiotherapy

4. Not being considered for surgery

**PROMPTS (embedded retention trial):**

All participants in the PROMPTS study will have consented and be enrolled in the GRASP trial which will act as the host trial. In addition to meeting the inclusion criteria for the GRASP trial, the following inclusion criteria will apply for participants enrolled in the embedded PROMPTS study:

1. Participants will have the use of a mobile telephone,

2. Participants will be willing to provide this mobile telephone number and consent for contact to be made by the GRASP trial team using this number

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 Years

### **Sex**

All

### **Total final enrolment**

708

### **Key exclusion criteria**

1. Participants with a history of significant shoulder trauma (e.g., dislocation, fracture or full thickness tear requiring surgery)

2. Those with a neurological disease affecting the shoulder

3. Those with other shoulder disorders (e.g., inflammatory arthritis, frozen shoulder, glenohumeral joint or instability) or with red flags consistent with the criteria set out in the BESS guidelines

4. Those who have received corticosteroid injection or physiotherapy for shoulder pain in the last 6 months

5. Those with contra-indications to corticosteroid injection

### **Date of first enrolment**

01/02/2017

### **Date of final enrolment**

02/05/2019

## **Locations**

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

**Derby Teaching Hospitals NHS Foundation Trust**

Uttoxeter Road

Derby

United Kingdom

DE22 3DT

**Study participating centre**

**East Lancashire Hospitals NHS Trust**

Haslingden Road

Blackburn

United Kingdom

BB2 3HH

**Study participating centre**

**Gloucestershire Hospitals NHS Foundation Trust**

Great Western Road

Gloucester

United Kingdom

GL1 3NN

**Study participating centre**

**Birmingham Community Healthcare NHS Foundation Trust**

3 Priestley Wharf

Holt Street

Birmingham

United Kingdom

B7 4BN

**Study participating centre**

**Buckinghamshire MusiC Service**

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The Merlin Centre

Cressex Business Park

Lancaster Road

High Wycombe

United Kingdom  
HP12 3QL

**Study participating centre**  
**East Cheshire NHS Trust**  
United Kingdom  
SK10 3BL

**Study participating centre**  
**Bedford Hospital NHS Trust**  
Kempston Road  
Bedford  
United Kingdom  
MK42 9DJ

**Study participating centre**  
**Wirral University Teaching Hospital NHS Foundation Trust**  
Arrowe Park Road  
Birkenhead  
United Kingdom  
CH49 5PE

**Study participating centre**  
**Medway Community Healthcare**  
MCH House  
Bailey Drive  
Gillingham  
United Kingdom  
ME8 0PZ

**Study participating centre**  
**Bristol Community Health**  
South Plaza  
Marlborough Street  
Bristol  
United Kingdom  
BS1 3NX

**Study participating centre**

**Somerset Partnership NHS Foundation Trust**

Mallard Court  
Express Park  
Bristol Road  
Bridgwater  
United Kingdom  
TA6 4RN

**Study participating centre**

**Doncaster & Bassetlaw Teaching Hospitals NHS Foundation Trust**

Thorne Road  
Doncaster  
United Kingdom  
DN2 5LT

**Study participating centre**

**Northern Devon Healthcare NHS Trust**

Raleigh Park  
Barnstaple  
United Kingdom  
EX31 4JB

**Study participating centre**

**Airedale NHS Foundation Trust**

Skipton Road  
Steeton  
United Kingdom  
BD20 6TD

**Study participating centre**

**Warrington & Halton Hospitals NHS Foundation Trust**

Lovely Lane  
Warrington  
United Kingdom  
WA5 1QG

**Study participating centre**

**Sandwell & West Birmingham Hospitals NHS Trust**

Dudley Road

Birmingham  
United Kingdom  
B18 7QH

**Study participating centre**  
**Sherwood Forest Hospitals NHS Foundation Trust**  
Mansfield Road  
Sutton-in-Ashfield  
United Kingdom  
NG17 4JL

**Study participating centre**  
**Kent Community Health NHS Foundation Trust**  
United Kingdom  
N25 4AZ

**Study participating centre**  
**North West Boroughs Healthcare NHS Foundation Trust**  
Hollins Lane  
Winwick  
United Kingdom  
WA2 8WA

**Study participating centre**  
**Midlands Partnership NHS Foundation Trust**  
Stafford  
United Kingdom  
ST16 3AG

## **Sponsor information**

**Organisation**  
University of Oxford

**ROR**  
<https://ror.org/052gg0110>

# Funder(s)

## Funder type

Government

## Funder Name

Health Technology Assessment Programme

## Alternative Name(s)

NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

## Funding Body Type

Government organisation

## Funding Body Subtype

National government

## Location

United Kingdom

# Results and Publications

## Individual participant data (IPD) sharing plan

Direct access to research data will be granted to authorised representatives of the Sponsor, regulatory authorities or the host institution for monitoring and/or auditing of the study to ensure compliance with regulations. Summary results data will be included on the EudraCT database (<https://eudract.ema.europa.eu/>) within 12 months of the end of the trial. General release will be 5 years after the end of the trial, to allow the investigators sufficient time to complete and report additional analyses of the dataset. The study consent form includes that the patients have consented for anonymised information to be used to support other research.

## IPD sharing plan summary

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		12/07/2021	16/07/2021	Yes	No
<a href="#">Protocol article</a>		17/07/2017	10/10/2022	Yes	No
<a href="#">Funder report results</a>		01/08/2021	13/08/2021	No	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Other publications</a>	Intervention development	09/07/2019	10/10/2022	Yes	No
<a href="#">Other publications</a>	Study within a trial	28/07/2021	06/08/2024	Yes	No
<a href="#">Statistical Analysis Plan</a>	statistical analysis plan	07/09/2020	09/09/2020	No	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes

