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GRASP - Getting it right: addressing shoulder pain

Submission date	Recruitment status	[X] Prospectively registered
13/07/2016	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[X] Statistical analysis plan
14/07/2016	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
06/08/2024	Musculoskeletal Diseases	

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 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 find out 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 know 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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Study website
grasp.octru.ox.ac.uk

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
2016-002991-28

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
GRASP:
Multi-centre phase 3 2x2 factorial randomised controlled trial

PROMPTS (embedded retention trial):
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

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 measure
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.

Secondary outcome measures
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
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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

Overall study start date
01/06/2016

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
704

Total final enrolment

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
England

United Kingdom

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
2
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
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ST16 3AG

Sponsor information

Organisation
University of Oxford

Sponsor details
Joint Research Office
Block 60
Churchill Hospital
Old Road
Headington
Oxford
England
United Kingdom
OX3 7LE

Sponsor type
University/education

Website
www.admin.ox.ac.uk/researchsupport/ctrg/

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type

Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
31/08/2021

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?
Statistical Analysis Plan	statistical analysis plan	07/09/2020	09/09/2020	No	No
Results article		12/07/2021	16/07/2021	Yes	No
Funder report results		01/08/2021	13/08/2021	No	No
Other publications	Intervention development	09/07/2019	10/10/2022	Yes	No
Protocol article		17/07/2017	10/10/2022	Yes	No
HRA research summary			28/06/2023	No	No
Other publications	Study within a trial	28/07/2021	06/08/2024	Yes	No