



Development and implementation of the physiotherapy-led exercise interventions for the treatment of rotator cuff disorders for the ‘Getting it Right: Addressing Shoulder Pain’ (GRASP) trial

David J Keene^{a,*}, Hessam Soutakbar^a, Sally Hopewell^a, Peter Heine^a,
Anju Jaggi^b, Chris Littlewood^c, Zara Hansen^a, Karen Barker^{a,d},
Willie Hamilton^e, Andrew J. Carr^a, Sarah E. Lamb^a

^a Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences, University of Oxford, Oxford, UK

^b Royal National Orthopaedic Hospital NHS Trust, Stanmore, Middlesex, UK

^c Primary Care and Health Sciences, Keele University, Keele, UK

^d Oxford University Hospitals NHS Foundation Trust, Oxford, UK

^e Institute of Health Research, University of Exeter, Exeter, UK

Abstract

Objectives The Getting it Right: Addressing Shoulder Pain (GRASP) trial is a large-scale, multicentre, 2 × 2 factorial randomised controlled trial investigating clinical and cost-effectiveness of a progressive exercise programme versus best-practice advice, with or without corticosteroid injection, for treating people with rotator cuff disorders. Here we describe the development, implementation and details of the physiotherapy-led interventions.

Methods Medical Research Council guidance for developing complex interventions were used, taking into account clinical guidelines, expert and patient opinion, research evidence, current practice variation, and deliverability. A stakeholder meeting of 26 experts, clinicians, researchers, and patient representatives was used to design key components of the interventions. Stakeholders prioritised strengthening posterior rotator cuff muscles and using practical, easy-to-do exercises. The interventions were designed to be deliverable across the UK National Health Service.

Results Progressive exercise consists of up to six sessions with a physiotherapist over 16 weeks. The best-practice advice consists of one face-to-face session with a physiotherapist with substantially greater reliance on self-management. Both interventions include self-management advice, home-exercise instruction, and behaviour-change strategies to target exercise adherence. All participants receive a Participant Information Booklet. The best-practice advice intervention is a self-guided system of progressively challenging exercises, with demonstration videos and written materials. The progressive exercise intervention has a wider range of exercise options, and greater flexibility for tailoring, progression, supervised practice and feedback.

Conclusion GRASP has recruited 708 participants and will provide high quality evidence to inform management of people with shoulder pain due to a rotator cuff disorder. Results are anticipated in 2020.

Trial registration number ISRCTN16539266; EudraCT number:2016-002991-28.

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Keywords: Shoulder Pain; Exercise; Clinical Trial

* Corresponding author at: Kadoorie Research Centre, University of Oxford, John Radcliffe Hospital, Oxford OX3 9DU, UK.

E-mail address: david.keene@ndorms.ox.ac.uk (D.J. Keene).

URL: <https://twitter.com/davidkeenePT> (D.J. Keene).

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Introduction

Shoulder pain is very common, annually around 1% of adults over 45 in primary care present with a new episode of shoulder pain [1], accounting for 2.4% of all GP consultations in the UK [2]. The most common attribution is the rotator cuff, which underlies around 70% of cases [1]. Rotator cuff disorders (e.g., tendonitis, impingement syndrome, tendinopathy or rotator cuff tear) are characterised by loss of shoulder function due to pain, weakness, and movement restriction. The aim of rotator cuff rehabilitation therefore is to strengthen the rotator cuff [3] and manage pain [4]. Despite widespread provision of physiotherapist-prescribed exercise for rotator cuff disorders, there is uncertainty about which exercise types and delivery modes are associated with the best outcomes [5–8]. Existing evidence is limited by problems in study design and treatment comparator choices [6]. There are also competing ideologies about which exercise programmes should be considered and how they are delivered.

In 2016, the National Institute for Health Research Health Technology Assessment Programme (NIHR HTA) commissioned a large-scale multicentre randomised controlled trial to investigate the clinical and cost-effectiveness of an individually tailored progressive exercise programme versus best-practice advice, with or without corticosteroid injection, to treat people with shoulder pain due to a rotator cuff disorder. Following current recommendations [9], we describe here the complex physiotherapy-led interventions used in the GRASP (Getting it Right: Addressing Shoulder Pain) trial and their development and implementation.

GRASP trial overview

GRASP is a 2×2 factorial randomised controlled trial that aims to assess whether: 1) an individually tailored progressive home exercise programme prescribed and supervised by a physiotherapist in ≤ 6 face-to-face sessions results in a greater improvement of shoulder pain and function at 12 months compared to a single best-practice advice and exercise instruction session with a physiotherapist supported by high-quality self-management materials; and 2) a sub-acromial corticosteroid injection results in greater improvement of shoulder pain and function at 12 months compared to no injection. The published GRASP protocol describes the study design in more detail [10].

We have recruited 708 participants across musculoskeletal services and related physiotherapy services in the UK. The target population is adults aged ≥ 18 years with a new (i.e. < 6 months), but not necessarily first, episode of shoulder pain attributable to a rotator cuff disorder using the British Elbow and Shoulder Society (BESS) guidelines' diagnostic criteria (Fig. 1) [11], and who are not receiving physiotherapy or being considered for surgery. Patients with a traumatic injury (e.g., dislocation, fracture or full thickness tear requiring surgery), neurological disease affecting the shoulder, other

shoulder disorder (e.g., inflammatory arthritis, frozen shoulder, glenohumeral joint instability) or a contraindication to corticosteroid injection are excluded.

Participants are randomised to intervention groups (1:1:1:1) using a centralised computer randomisation service to one of four interventions: 1) progressive exercise only (≤ 6 physiotherapy sessions); 2) best-practice advice only (1 physiotherapy session); 3) corticosteroid injection then progressive exercise (≤ 6 sessions); or 4) corticosteroid injection then best-practice advice (1 session). The primary outcome is shoulder pain and function at 12 months, measured using the Shoulder Pain and Disability Index (SPADI) total score [11,12]. We are conducting a parallel within-trial economic analysis and estimating treatment effects in secondary outcomes using a postal questionnaire at 8 weeks, 6 months, and 12 months. Secondary outcomes include sub-domains of the SPADI (pain and function); health-related quality of life (EQ-5D-5L) score [13]; Fear Avoidance Belief Questionnaire (physical activity 5-item subscale) [14]; Pain Self-efficacy questionnaire (short form) [15]; sleep disturbance (Insomnia Severity Index) [16]; patient global impression of change [17]; return to desired activities, including work, social life and sport activities; patient adherence to exercise; any serious adverse events; health resource use; additional out-of-pocket expenses; and work absence.

Developing the GRASP trial exercise interventions

The GRASP trial interventions were developed following Medical Research Council guidance for developing and evaluating complex interventions [18]. We took into account clinical guidelines, research evidence, current practice variation, deliverability in the UK NHS in terms of staffing, resources and time, expert and patient opinion, acceptability to clinicians and patients, and the need to ensure consistency in delivery, and reproducibility.

Phase 1a: Clinical guidelines

There are no recommended National Institute for Health and Care Excellence (NICE) clinical guidelines for treating rotator cuff disorders. The BESS [19] Patient Care Pathway for sub-acromial shoulder pain refers to physiotherapy and exercise, but does not specify details.

Phase 1b: Research evidence

Although research to date suggests that exercise might be a promising intervention for rotator cuff disorders [5,6], there is little evidence for long-term clinical and cost-effectiveness [20]. Supervised or home-based resistance training to improve muscular strength is a key component of exercise for rotator cuff disorders, although there is no evidence that any specific programme is superior [21,22]. Although exercises to treat rotator cuff disorders

Diagnosis of Shoulder problems in Primary Care: Guidelines on treatment and referral

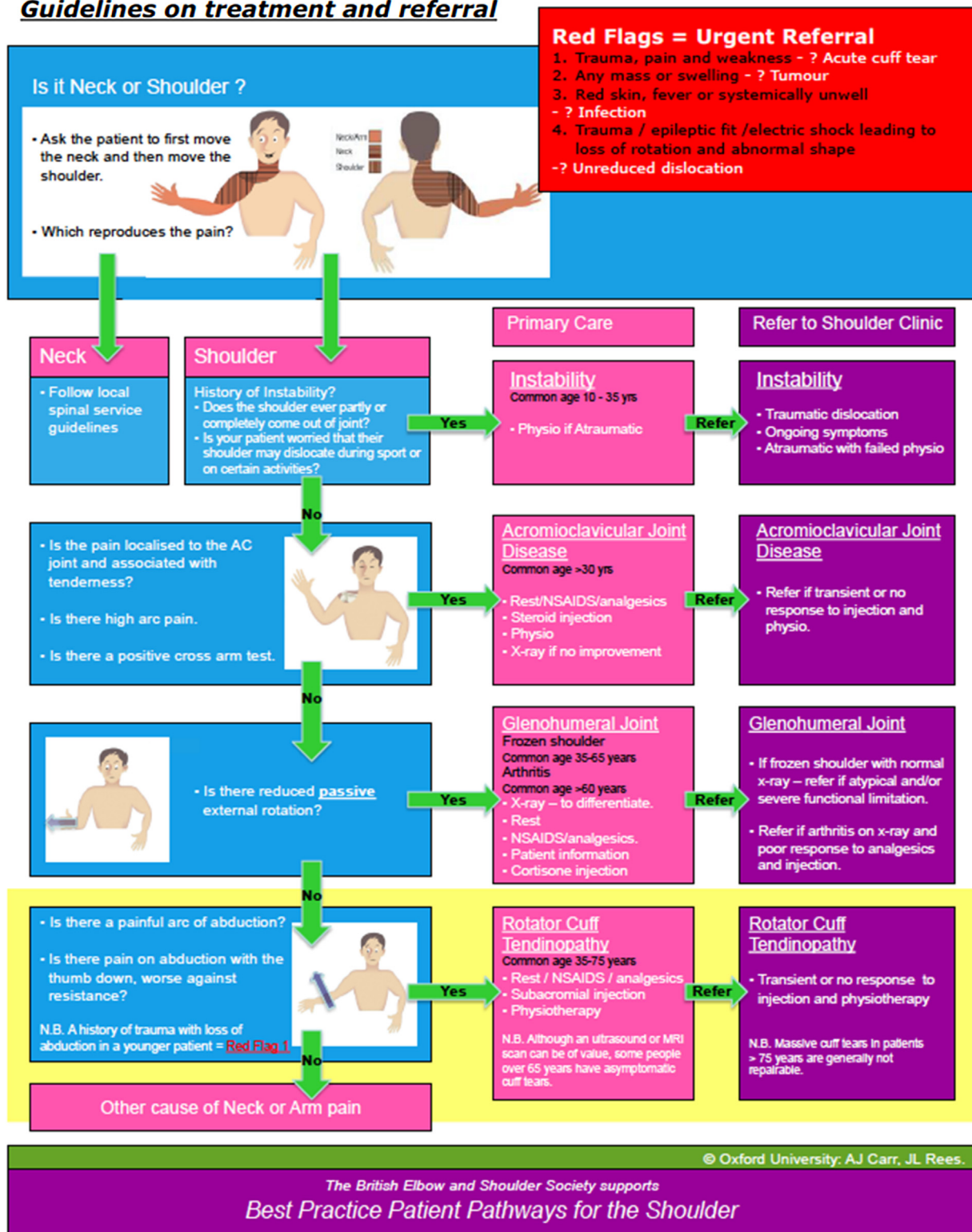


Fig. 1. British Elbow and Shoulder Society (BESS) guidelines' diagnostic criteria. Reproduced with permission, copyright Oxford University: AJ Carr, JL Rees.

are predominantly performed at home without physiotherapist supervision, little attention has been paid to behavioural frameworks to enhance exercise adherence or tackle unhelpful pain beliefs [23]. Other physiotherapy modalities, such as electrotherapy, acupuncture, soft-tissue mobilisation, and manipulation, were not included in GRASP because current research evidence does not support their efficacy when compared to exercise or in terms of adding benefit to exercise-alone approaches [24,25].

Corticosteroid injections are commonly used as a treatment for rotator cuff disorders. Systematic review evidence [26–28] has shown that corticosteroid injections may have a short-term benefit in the shoulder over placebo in terms of reduced pain and improved function. However, these findings are inconclusive and there are concerns about longer-term safety [29]. Combining injections and physiotherapy has intuitive appeal, with some evidence of an additive, but not interactive, short-term effect [28,30–32]. Unguided corticosteroid injections are included in the GRASP trial to investigate their longer-term safety. Although ultrasound is increasingly used to guide injections in primary care, the SUPPORT trial (comparing guided and unguided injection) and others have demonstrated that it is no more effective than standard injection practice [33,34].

Phase 2: Intervention development

The lack of evidence for particular exercises or treatment intensity and duration mirrors the wide variation in UK physiotherapy practice. With no clear evidence or clinical consensus, advice from clinicians, patient and public representatives, and other experts was crucial.

Twenty-six clinicians, researchers, patients, and public representatives attended a GRASP intervention development meeting (17 June 2016, see Acknowledgements). Delegates discussed and evaluated a comprehensive list of 22 exercise types commonly used in clinical practice and/or reported in trials of shoulder pain treatments (see online supplementary file). The delegates categorised the exercises into essential exercises, optional exercises, or considered not important for managing rotator cuff disorders.

The selected essential exercises generally strengthen the posterior rotator cuff muscles (supraspinatus, infraspinatus, and teres minor) and load the shoulder into an elevated position, consistent with current trial evidence [35,36]. The GRASP trial thus included these exercise types as an essential component of both the progressive exercise and best-practice advice exercise programmes. Delegates agreed that both interventions should be as practical and simple as possible. Some exercises were considered important for patients with specific presentations or in particular circumstances. These were included as optional exercises in the progressive exercise intervention. They were not incorporated into the best-practice advice intervention, which prioritised a simple progressive set of exercises likely to benefit most patients

and that could be easily understood and performed at home without supervision.

Delegates agreed that stretching was not a priority target in rotator cuff disorders and that range-of-motion could be incorporated into other active exercises. A posterior capsule/soft tissue stretch for the shoulder was included as an option in the progressive exercise intervention as we recognised that these stretches feature in many exercise programmes evaluated in other clinical trials [20]. Isolated exercises to correct posture towards a theoretical ideal were not included as there is limited evidence for this approach [37]. Experts disagree whether exercises can or should provoke symptoms or should be symptom-free. There is limited evidence for these alternatives, although evidence is building up for the acceptability of mild-to-moderate pain symptoms during exercise [38,39]. The Participant Information Booklet, included as part of the GRASP trial intervention materials, and treating physiotherapist, advise participants that some pain during the exercises is acceptable, provided they find it manageable and symptoms resolve to an acceptable level within a few hours [39].

After the meeting we developed detailed intervention manuals for therapists, which described the key components of the progressive exercise and best practice advice interventions. We also developed patient facing materials, which were reviewed by patient representatives.

Phase 3a: Internal pilot

As part of the GRASP trial we ran an internal pilot from February to June 2017 at three sites, recruiting 42 participants. The aim of the internal pilot was to test and refine the recruitment process and explore treatment acceptability. The clinicians delivering the GRASP interventions were also asked to provide feedback on delivery of the intervention. The intervention manuals and training materials were subsequently refined to clarify identified misconceptions, and were finalised. The interventions did not require significant modifications.

Phase 3b: The GRASP trial interventions

The interventions are reported following the template for intervention description and replication (TIDieR) checklist [40], Consensus on Exercise Reporting Template (CERT) [41], and Workgroup for Intervention Development and Evaluation Research (WIDER) recommendations for behaviour change interventions [42].

Sub-acromial corticosteroid injection

Participants randomised to receive a sub-acromial corticosteroid injection receive the injection before starting the physiotherapy intervention (typically within 10 days of randomisation). The injection is predominately delivered by extended-scope physiotherapists with appropriate post reg-

istration qualifications working within local patient group directives or equivalent. This delivery method is increasingly common NHS practice.

The corticosteroid (up to 40 mg methylprednisolone acetate or triamcinolone acetonide) is given with local anaesthetic (up to 5 ml 1% lidocaine or up to 10 ml 0.5% bupivacaine hydrochloride), following local treatment protocols. These two corticosteroids are the most routinely used for shoulder pain. There is no clear evidence that one is more effective than the other [28]. Participants are advised to avoid strenuous shoulder activity and heavy lifting for 24 to 48 hours post injection. A second injection can be given after 6 weeks (but within 16 weeks of randomisation), but is only administered to participants who receive good initial benefit from the first injection and request further pain relief to facilitate exercise.

GRASP exercise interventions

Table 1 summarises the key components of the GRASP physiotherapy interventions. The interventions are delivered face-to-face, one-to-one, by UK-registered physiotherapists based at physiotherapy and musculoskeletal services across England.

Research physiotherapists on the GRASP team provide one full day of face-to-face training on the progressive exercise intervention and at least half a day of face-to-face training on the best-practice advice intervention to the relevant delivering physiotherapists. Physiotherapists are trained to deliver either the progressive exercise intervention or the best practice advice intervention (not both) in order to reduce the risk of contamination. Training includes the trial background, how to deliver the intervention, the exercises permitted within the trial protocol, behavioural techniques to improve adherence, trial reporting and paperwork, and practical examples using case studies. Therapist manuals are provided detailing all aspects of the trial and interventions. GRASP trial team members are available post-training to provide support and answer queries.

Assessment and advice

Appointments are coordinated so that participants typically start their first exercise session within 14 to 28 days of randomisation. The physiotherapist carries out an initial assessment as per their usual practice in order to identify which shoulder movements, in relation to the rotator cuff, are particularly problematic in terms of pain, weakness, and restriction, and associated functional deficits. Participants receive a Participant Information Booklet containing education and advice relevant to people with a rotator cuff disorder (Table 2). Advice includes use of over-the-counter analgesia, as per BESS guidance [19]. The treating physiotherapist reinforces the education and advice aspects relevant to that participant. Participants are advised to do exercises for at least 4 months and continue longer if they are still

improving or find them helpful. Physiotherapists delivering the intervention are trained in questioning techniques based on cognitive behavioural models [43], to elicit and address unhelpful beliefs about shoulder pain or exercise that may impede exercise adherence [44]. The advice and exercise adherence strategies are described in more detail later on.

Progressive exercise intervention

Participants receive up to 6 sessions with a physiotherapist over 16 weeks. The initial session lasts ≤ 60 minutes for assessment and treatment initiation, followed by ≤ 5 follow-up sessions of 20 to 30 minutes each. The physiotherapist and participant decide how frequently to schedule the review appointments within the 16-week timeframe. Six sessions over 16 weeks allows the exercise intensity to be progressed, and is a volume of physiotherapy that is within range of feasible delivery in the UK NHS. It is sufficient time for a physiological response in the neuromuscular system to improve function and for longer-term health behaviour changes to occur. The Participant Information Booklet is provided in a file so that instructions on the progressive exercises selected can be inserted, including detailed guidance and photos for each exercise. The physiotherapist and participant jointly choose one to three exercises to address the problems identified during the assessment (Fig. 2). We anticipate participants presenting with different problems and pain irritability – the exercises are therefore categorised into three difficulty levels (Level 1, 2 and 3 exercises), with progressions within each level and different aims and guidelines to match indications for use:

Level 1 exercises – Simple shoulder movements

Level 1 exercises aim to reduce fear, encourage normal movement, improve shoulder mobility, and build confidence in exercising at home (see online supplementary file). They are appropriate for participants with irritable and/or severe shoulder pain and/or fear avoidance. The frequency and the number of sets and repetitions for each exercise are agreed jointly between the physiotherapist and participant. Depending on their symptom severity, some participants may be able to move straight to Level 2 exercises.

Level 2 exercises – Progressive structured resistance training

Level 2 exercises address the essential exercises that target strengthening of the posterior rotator cuff muscles and other optional exercises (see online supplementary file). The essential exercises focus on the movements most commonly affected by a rotator cuff disorder: resisted external rotation, flexion, and abduction of the shoulder [35]. Resisted exercises for other shoulder movements are optional. If participants are prescribed exercises at Level 2, at least one must be from the essential exercise category.

The American College of Sports Medicine (ACSM) guidance for progressive resistance training recommends two to

Table 1
Overview of GRASP trial exercise interventions, as per TIDieR Criteria³⁵.

TIDieR Items	Description	
Brief Name	GRASP (Getting it Right: Addressing Shoulder Pain)	
Why	Physiotherapy-led exercise and advice are commonly used to manage rotator cuff disorders but evidence is lacking in terms of how exactly it should be delivered, and whether patients do better if they get a corticosteroid injection before starting an exercise programme.	
	Progressive exercise	Best practice advice
What	Home exercise and advice programme overseen by physiotherapist over six sessions within 16 weeks.	Home exercise and advice programme initiated during a single face-to-face session with a physiotherapist, and then performed unsupervised by participant at home.
<u>Materials: Participants</u>	Participant Information Booklet (see Table 2) and exercise instruction sheets with photos. Action planner and exercise diary (see Table 3 and online supplementary file) Resistance bands (if applicable)	Participant Information Booklet (see Table 2) incorporating exercise instructions with photos. Action planner and exercise diary (see Table 3 and online supplementary file) Exercise instruction videos via website or DVD Resistance bands
<u>Materials: Physiotherapists</u>	Therapist manuals: detailing all aspects of the trial and the intervention and a quick reference guide for use in the clinic Training: one full day face-to-face training delivered by GRASP trial research physiotherapists.	Same as progressive exercise intervention, but training was at least half a day.
<u>Procedures</u>	Initial appointment Assess participant as per normal physiotherapy practice Issue folder containing the Progressive Exercise Participant Information Booklet Agree level of exercise that is most appropriate for the participant initially (see Figure 2 and 3) Advice should address barriers to exercise identified during assessment Provide education regarding pain during and after exercise	Single face-to-face appointment Assess participant as per normal physiotherapy practice. Issue Best Practice Advice Participant Information Booklet Explain exercise ladder (see online supplementary file) and agree with participant what level of the ladder is most appropriate initially Educate participants how to progress and regress their exercises.

Table 1 (Continued)

	Help participant to complete exercise documentation (exercise diary and action planner) Make follow-up appointment(s) Complete Treatment Log Appointments 2-6 Reassess as per normal physiotherapy practice Assist participant to progress/regress exercises Reassure the participant, reinforce key messages from the advice and education Review home exercise programme using the exercise diary Discuss return to functional activities Review action planner Complete Treatment Log (after every session)	Ensure participant knows how to access the exercise videos online, or issue DVD, or both. Advice should address barriers to exercise identified during assessment Provide education regarding pain during and after exercise Help participant to complete exercise documentation (exercise diary and action planner) Strategies to encourage adherence to exercise will be less extensive than in the progressive exercise intervention as they need to be feasible to deliver within a single session (see Table 3). Discharge participant with advice/encouragement to continue with the self-management exercise programme for at least 16 weeks. Complete Treatment Log.
Who provides	Physiotherapists already working in NHS musculoskeletal services. GRASP does not exclude physiotherapists based on number of years qualified or experience treating shoulder conditions.	Same as progressive exercise intervention.
How	Participants receive up to six sessions with a physiotherapist over 16 weeks. The initial session lasts up to 60 minutes for assessment. It is then followed by up to five sessions of 20 to 30 minutes each.	Participants receive a single face-to-face session with a physiotherapist lasting up to 60 minutes
Where	Physiotherapy sessions are in outpatient clinics based in the UK NHS. Exercise programme is performed by the participant at home.	Same as progressive exercise intervention
When and how much	Initial Appointments is coordinated within 14 to 28 days of randomisation, as per local appointment availability. Up to 5 follow-up sessions arranged within 16 weeks.	Same as progressive exercise, but without any follow-up appointments. Volume of exercise detailed in the manuscript.

Table 1 (Continued)

	Can be less than 6 session if participant has met rehabilitation goals and is self-managing condition. Volume of exercise described in Figures 2 and 3 and detailed in manuscript.	
Tailoring	Education and advice Focus of education and advice are individualised based on assessment Exercises Selection, manipulation of sets, repetitions and/or load is a joint decision-making process Range of motion and position may be modified to accommodate the patient’s comfort and preferences	Education and advice Focus of education and advice are individualised based on assessment Exercises The range of motion through which an exercise is performed, and the load and volume, may be increased or decreased
Modifications	Quick reference guides for each intervention were produced after the pilot phase, containing all key operational procedures for each intervention to supplement the comprehensive manuals.	
Intervention Fidelity		
How well: <u>Training</u>	All aspects of training delivery, content, structure, duration and therapists’ confidence to implement the intervention were evaluated using the post training feedback forms completed anonymously.	
How well: <u>Physiotherapists</u>	Intervention fidelity is monitored centrally via treatment logs, and during site monitoring and quality assurance visits. If performance is found to be below the required standard of protocol adherence, further measures (e.g. further training) will be instituted after discussion with the trial management team and the site.	
How well: <u>Participants</u>	Exercise adherence Physiotherapists review the exercise diary at each subsequent session. Participants asked to report exercise frequency in postal follow-up questionnaires at 8 weeks, 6 months, and 12 months.	Exercise adherence Participants asked to report exercise frequency in postal follow-up questionnaires at 8 weeks, 6 months, and 12 months.
How well: <u>Reporting</u>	Intervention fidelity will be reported with main trial results.	

Table 2
Contents of the GRASP trial Participant Information Booklet.

Section	Contents
Introduction	Summary of common treatments for rotator cuff disorders
What is the rotator cuff?	Description of rotator cuff muscles
What does the rotator cuff do?	Function of rotator cuff muscles
What can go wrong with the rotator cuff?	Possible mechanisms and common symptoms of rotator cuff disorders
What can I do to help my rotator cuff problem?	Introduction to role of self-management advice, includes simple pain education, pain management (including use of heat and cold, medication, and pacing)
Maintaining physical fitness	Importance of staying active
Return to usual physical activities	Fear-avoidance, deconditioning, and how to address these
Modifying activities	Modifying rather than avoiding activities
Work	Advice on returning to work activities
Sleeping	Sleep positions, pacing to lessen night-time pain
Looking after your mental wellbeing	Activities to maintain a positive mood and when to seek medical advice
Coping with flare-ups	Planning exercise and activity for times when pain is more severe
Exercise guide	Benefits of exercise and how long to continue with exercise
	Pain during and after exercise
	Guidance on doing GRASP exercises with full instructions (colour photographs and text explaining technique and modifications that can be made)
	<i>NB: details are specific to the progressive exercise or best-practice advice intervention</i>

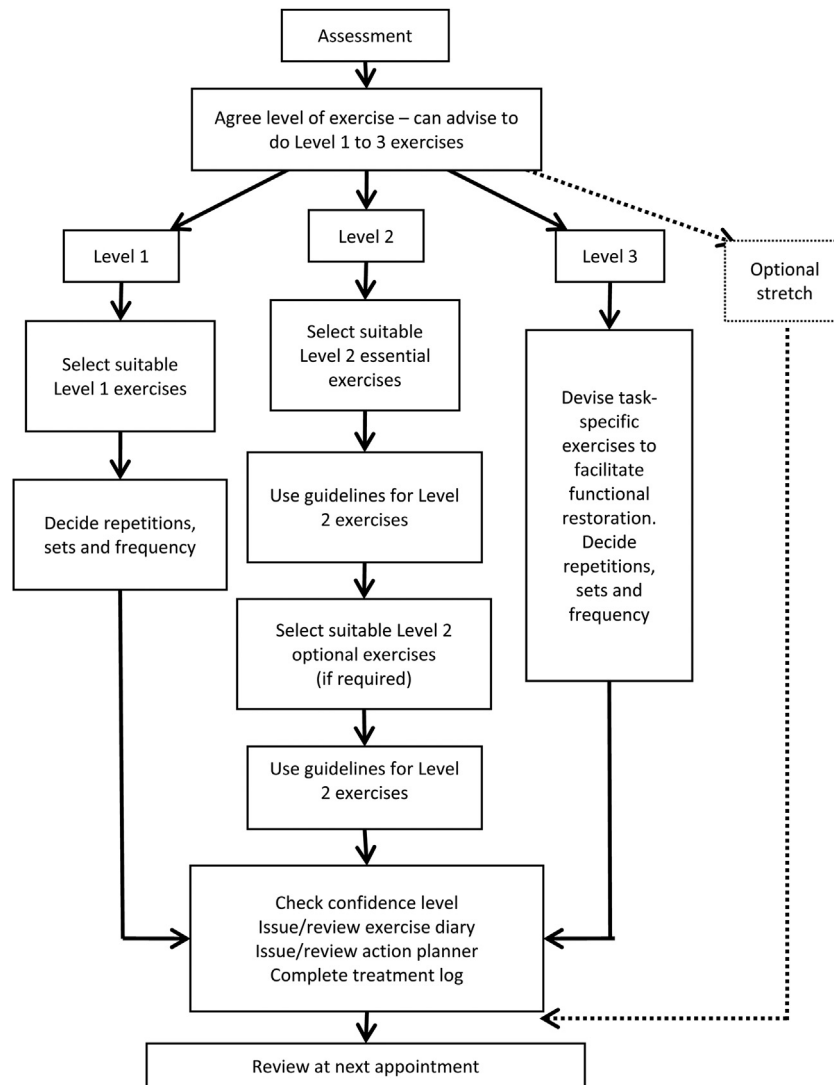


Fig. 2. Process map of the GRASP trial progressive exercise intervention.

three sessions of resistance training per week [45], whereas many studies of resistance training in patients with musculoskeletal disorders use daily exercise programmes [46,47]. We attempt to strike a balance, ensuring that the resistance training is effective, but also regular enough to address other aims such as building confidence in moving the arm and re-learning motor skills. We ask GRASP participants to do their exercises five days per week, with two non-consecutive recovery days.

We regulate the exercise intensity with the modified Borg scale of perceived exertion, an 11-point version of the Rating of Perceived Exertion (RPE) scale [48] validated for quantifying the intensity of resistance exercise [49]. Participants start at a moderate load (3 to 4 on the Borg scale) to enhance motivation and adherence and reduce the likelihood of symptom flare-up. Fig. 3 contains detailed guidance on the scale and how Level 2 exercises are initiated, progressed, and regressed. Where appropriate, resistance bands or hand weights were

incorporated into the exercise, with the level of resistance recommended being guided by the RPE scale feedback from the participant.

Level 3 Exercise – Patient-specific functional restoration

Participants can progress to Level 3 when their initial problems (e.g., weakness) begin to resolve. The physiotherapist amends the exercise programme to be more task-specific (e.g., returning to sport) by devising a new exercise in consultation with the participant. Level 3 exercises modify the essential resistance training exercises towards the specific movements required to achieve the participant's individual functional goals. The exercise may be high- or low-load, using many or few repetitions, depending on the participant's needs. Not all GRASP participants will reach or need this stage of the programme. We anticipate that Level 3 exercise instructions will be given face-to-face and reinforced with written guidance to aid recall.

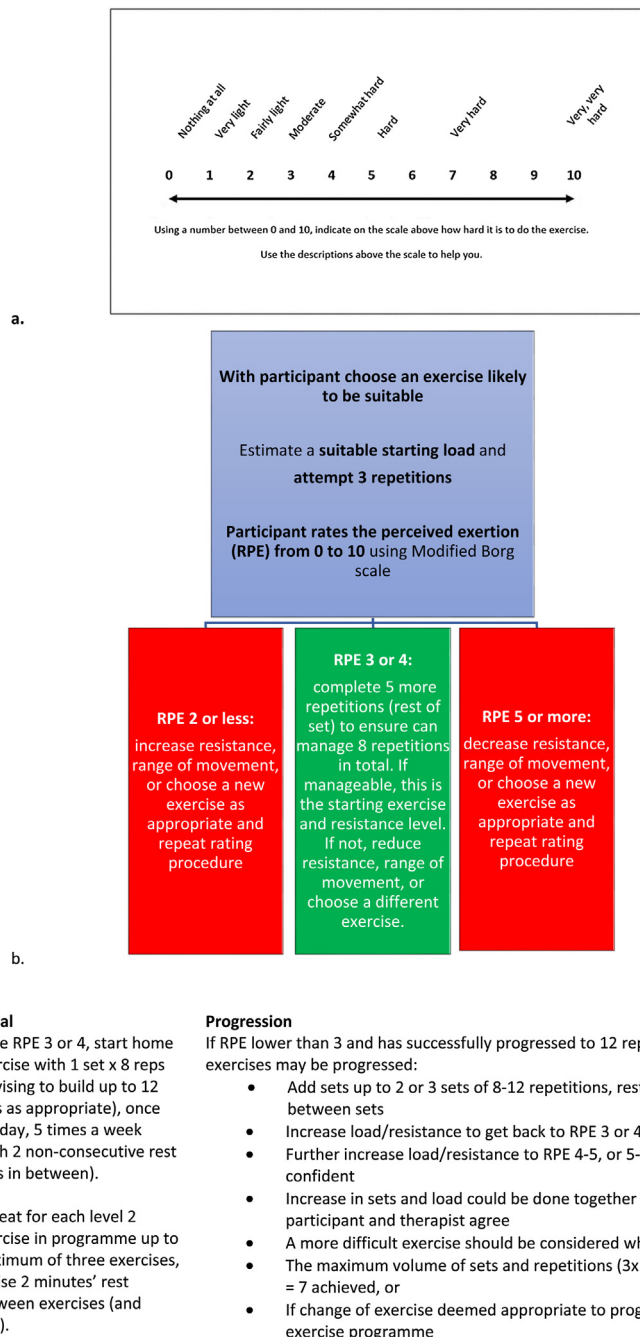


Fig. 3. Guidance for setting Level 2 resistance exercises in the GRASP trial (a) modified BORG^{43,44} scale (b) setting the initial exercise and progression and regression decision guidance.

Optional stretching exercise

Posterior capsule and/or soft tissue stretches of the shoulder (see online supplementary file) are included as optional exercises at any stage. We recommend selective use, generally for younger adults engaged in throwing or other overhead athletic or physical activities [50] who have posterior capsule tightness. We anticipate these exercises to be suitable for participants with low irritability, if they do not provoke symptoms. Although discomfort and stretching sensations may be felt during stretches, we do not anticipate provocation

of anterior shoulder pain or reproduction of the participant's specific symptoms. We advise holding stretches for 20 to 30 seconds, but the physiotherapist and participant decide the number of repetitions and frequency.

Best-practice advice intervention

The best-practice advice intervention is given as a single face-to-face session with a physiotherapist, lasting up to 60 minutes. With only one session, there is a substantially

Table 3

Behavioural strategies to address barriers to exercise.

Behaviour change technique	Progressive Exercise	Best Practice Advice
Education and persuasion	Information face-to-face and in Participant Information Booklet on benefits of exercise	Same as Progressive Exercise
Training	Exercises demonstrated; instructions provided in written form; practiced within the session and at home independently; reviewed at each appointment and feedback provided	Exercises demonstrated; instructions provided in written and video form (web and/or DVD); practiced within the session and at home independently
Graded tasks	Focus on starting with a manageable amount of exercise (up to 3 exercises). Use of modified BORG scale to set resistance exercise, initially at lower levels and then increase difficulty, volume, load (see Fig. 3)	Focus on starting with a manageable amount of exercise (1 to 2 exercises). Participants to increase volume, load according to set progression advice.
Equipment provision to enable exercise	Resistance band issued if appropriate; advice on what can be used for hand weights	All participants issued resistance band to enable exercise performance; advice on what can be used for hand weights
Problem-solving	Over the sessions therapists facilitate participant problem-solving and promote participant leading the decision-making about progression/regression of programme; review barriers to exercise (e.g. belief or practicalities) and discuss ways to overcome these; agree exercise plan collaboratively.	Therapists encourage participant problem-solving within the session; agree starting point on exercise ladder collaboratively.
Action planning	Action planner document completed (where and when exercises will be done), contingency plans, prompts/cues to do them, plan what to do if pain increases; when and where exercise diary will be completed. See also behavioural contract and confidence ruler question.	Action planner document completed (where and when exercises will be done), contingency plans, prompts/cues to do them, plan what to do if pain increases; when and where exercise diary will be completed.
Goal setting	Agree long-term and short-term goal (specific, measurable, achievable, relevant, timed) ; reinforce link between goal and exercise plan;	Agree long-term goal (specific, measurable, achievable, relevant, timed); reinforce link between goal and exercise plan
Review goals	Goals reviewed and adjusted at each session	Not applicable
Confidence ruler	Use the confidence ruler (0 to 10) to assess participants confidence in doing agreed exercise plan, if 7 or less, discuss reasons and adapt programme (see graded tasks) or address barriers (see problem solving)	Not applicable
Feedback on exercise performance from physiotherapist	Within and between sessions; review action planners and diaries each session; discrepancies in plan and performance reviewed	Within session only
Therapist feedback on outcome of exercise	Progress in physical performance and symptoms highlighted after re-assessment at each session.	Not applicable
Self-monitoring of exercise	Exercise diary to complete each day	Same as Progressive Exercise
Behavioural contract	Therapist and participant sign action planner document, participant commits to doing exercises and bringing documents to be reviewed at next appointment, therapist to reviewing exercise diary.	Not applicable
Reduce negative emotions	Simple advice on managing low mood in the information booklet. Provide reassurance about condition and capacity to exercise.	Same as Progressive Exercise

greater reliance on self-management than in the progressive exercise intervention. As per the progressive exercise intervention, participants are given a Participant Information Booklet (Table 1), and the treating physiotherapist reinforces the education and advice aspects that are particularly relevant.

Participants are given a simple set of self-guided exercises to improve shoulder strength and function that can be progressed and regressed independently at home, depending on their capability. The exercise instructions are given in the Participant Information Booklet and in exercise videos available via the internet and on DVD. We aimed to make

the information accessible and appealing to a wide range of individuals by using different media [51].

This intervention offers a simpler range of exercise options than the progressive exercise intervention. The physiotherapist and participant together choose one or two exercises from the Best Practice Advice Exercise Ladder (see online supplementary file). The exercises on the ladder are arranged with easier exercises on the lower rungs and more difficult exercises on the higher rungs. Participants should start at the level of exercise that they are capable of undertaking, not necessarily the lowest rung. If two exercises are selected, these need

not be from the same rung. The lowest level are simple shoulder exercises to reduce fear of movement, encourage normal movement, build shoulder mobility, and build confidence in carrying out self-directed exercises. Higher levels introduce a greater extent of resistance exercises for posterior rotator cuff strengthening.

The Borg RPE scale is not used to measure intensity for participants in the best-practice advice group in order to simplify the programme and maximise participant understanding. Participants should report finding the exercise(s) moderately difficult (i.e., not easy but not extremely hard). They begin with one set of eight repetitions at the selected load and aim to build up to 12 repetitions, exercising once daily five days per week, with non-consecutive rest days. If the exercise(s) become too easy, another set can be added, up to a maximum of three sets. If the expanded set becomes too easy, the exercise(s) should be exchanged for the next level of difficulty. The next exercise should again start with one set of eight repetitions and build up in the same way. If the participant encounters difficulties, they can reduce the load and/or number of sets/repetitions or regress to an easier exercise.

Strategies to encourage exercise adherence

Estimates suggest that up to 70% of patients do not adhere to prescribed physiotherapy treatments [52]. As part of the GRASP trial interventions we have incorporated strategies to promote adherence to the exercise interventions. These strategies are less extensive in the best-practice advice intervention than the progressive exercise intervention, as they must feasibly be delivered within a single session.

Modifiable behavioural targets were identified from a systematic review of barriers to physiotherapy adherence, including in-treatment exercise adherence, low self-efficacy, depression, anxiety, helplessness, greater perceived barriers to exercise, and pain levels during exercise [23]. Table 3 summarises the behaviour change techniques used in the GRASP exercise interventions, based on the behaviour change techniques taxonomy [53]. These techniques were selected based on their evidence base [54], successful use in other trials [47], and recommendations in the NHS Health Trainer Handbook [55]. Participants are asked to complete an Exercise Action Planner and Exercise Diary tailored to the interventions (see online supplementary file). Although exercise diaries have questionable reliability for measuring adherence due to real-time compliance and recall bias [56], there is evidence to suggest that they promote adherence [57]. We are assessing adherence to exercises in the follow-up questionnaires, with participants reporting exercise frequency.

Concomitant care

Participants can seek other treatment during the trial as per usual care. Additional treatments, including GP visits or other health professional consultations, medication, other physical

or alternative therapies, will be recorded as part of participant follow up questionnaires at 8 weeks, 6 and 12 months.

Monitoring, quality assurance and safety

We monitor intervention delivery fidelity using site monitoring visits, quality assurance visits, and central monitoring of treatment session logs. Each site is visited at least twice annually to ensure the physiotherapists adhere to the intervention protocol. The trial research physiotherapists attend an appointment session for each trial intervention and complete a standardised checklist covering knowledge of trial procedures, returning trial paperwork, storing trial materials, intervention delivery timing, and adherence to intervention protocols. The delivering physiotherapist receives feedback at the end of each quality assurance visit. If protocol adherence is below the required standard, further measures (e.g., retraining) will be instituted after discussion with the trial team and site.

Clinicians delivering the GRASP intervention are asked to complete treatment logs at the end of each session, consisting of a checklist documenting the key elements of the session (e.g., exercises, sets and repetitions, load, injection type and dosage/volume). These are returned to the central GRASP trial team, who review and enter them onto the trial database. Custom-designed reports are generated for centrally monitoring the intervention delivery including the timing, number and duration of sessions, injection details (e.g. volume/dosage), content of treatment sessions, participant attendance, and paperwork return. Intervention delivery is thus monitored on a site-by-site and overall basis. Monitoring will reveal deviations or discrepancies from the trial protocol, which will be investigated and, if required, measures will be taken to address them at an early stage throughout the duration of the trial.

Foreseeable adverse events occurring as a result of the trial intervention(s) are not being recorded as part of the GRASP trial. Participants are provided with information on potential adverse events from exercise and corticosteroid injection (if applicable), including what to do if they experience an adverse event. Serious Adverse Events (SAEs) (defined as any unexpected medical occurrence than can result in death, is life threatening or results in hospitalisation or incapacity) are highly unlikely to occur but will be reported as per the trial protocol [10].

Conclusion

This article describes the development and details of the GRASP interventions for treating rotator cuff disorders, tested as part of a multi centre randomised controlled trial. The clinical and cost-effectiveness of a progressive exercise intervention versus best-practice advice, with and without corticosteroid injection, will be reported at the end of the GRASP trial. Trial materials including the training materials

and intervention manuals will be made available via the trial website on completion of the trial.

Key messages

- The Getting it Right: Addressing Shoulder Pain (GRASP) trial is a large-scale, multicentre, randomised controlled trial investigating the clinical and cost-effectiveness of a progressive exercise intervention versus a best-practice advice intervention, with or without corticosteroid injection, for treating people with a rotator cuff disorder.
- Interventions were developed using the Medical Research Council guidance on complex interventions, and included a stakeholder meeting of 26 clinicians, researchers, and patient representatives.
- The best-practice advice (1 session) and progressive exercise (≤ 6 sessions over 16 weeks) interventions both involve face-to-face, one-to-one physiotherapist appointments and include self-management advice, home-exercise instruction, and behaviour-change strategies to target exercise adherence.
- The results of the GRASP trial are anticipated in 2020. This large scale evaluation on 708 participants will provide high quality evidence to best inform clinical practice for the management of people with shoulder pain due to a rotator cuff disorder.
- A critical stage of evaluating the complex interventions in the GRASP trial is ensuring details of the development and content of the interventions are available to clinicians and researchers to facilitate their implementation.

Disclaimer

The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR, or the Department of Health and Social Care.

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GRASP intervention development stakeholder meeting delegates:

Marcus Bateman (Derby Teaching Hospitals NHS Foundation Trust), Graham Boniface (University of Oxford),

Debbie Brown (University of Oxford), Suzanne Folley (East Lancashire Hospitals NHS Trust), Beth Fordham (University of Oxford), Jo Gibson (Royal Liverpool and Broadgreen University Hospitals NHS Trust), Richard Goodier (Patient and Public Involvement representative), Sean Gove (Bristol Community Health), Zara Hansen (University of Oxford), Peter Heine (University of Oxford), Sally Hopewell (University of Oxford), Richard Husselbee (Birmingham Community Healthcare NHS Trust), Anju Jaggi (Royal National Orthopaedic Hospital NHS Trust), Gill Jones (Oxford Health NHS Foundation Trust), Harry Kardamillas (Bucks Musculoskeletal Integrated Care Service, Care UK), David Keene (University of Oxford), Chris Littlewood (Keele University), Caroline Miller (University Hospitals Birmingham NHS Foundation Trust), Michelle Moynihan (Oxford University Hospitals NHS Foundation Trust), Peter O'Hara (Patient and Public Involvement representative), Iveta Simera (Patient and Public Involvement representative), Yogita Stokes (Sandwell and West Birmingham Hospitals NHS Trust), Georgina Taylor (Oxford University Hospitals NHS Foundation Trust), Helen Thompson (East Lancashire Hospitals NHS Trust), Esther Williamson (University of Oxford), Elaine Willmore (Gloucestershire Hospitals NHS Foundation Trust). Special thanks to Katie Chegwin (University of Oxford) for helping co-ordinate this meeting.

GRASP Internal Pilot Sites (Principal Investigator, organisation)

Marcus Bateman (Derby Teaching Hospitals NHS Foundation Trust); Helen Thompson (East Lancashire Hospitals NHS Trust); Elaine Willmore (Gloucestershire Hospitals NHS Foundation Trust).

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Appendix A. Supplementary data

Supplementary material related to this article can be found, in the online version, at doi:<https://doi.org/10.1016/j.physio.2019.07.002>.

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