Development of a physiotherapist-led exercise programme for traumatic tears of the rotator cuff for the SPeEDy study

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Abstract

The SPeEDy study (Surgery versus physiotherapist-led exercise for traumatic tears of the rotator cuff) is a two-arm, parallel group, pilot and feasibility randomised controlled trial aiming to evaluate the feasibility of a future main trial. In this paper, the development process and the resultant physiotherapist-led exercise programme used in the SPeEDy study is described. Thirteen physiotherapists and three patients met to discuss and develop the key principles that should underpin the exercise programme. Taking in to account the current research evidence and incorporating expert clinical and patient opinion, the group developed an individualised, structured and progressive physiotherapist-led exercise programme based on the principle of self dosing. Exercise prescription within the programme is based on establishing the current functional capacity of the patient in relation to the most challenging shoulder movements and is supported over approximately six contact sessions across a 12-week period. The SPeEDy study aims to recruit 76 participants across eight hospitals and will provide high quality evidence about the feasibility of a future main randomised controlled trial in a clinical area where there is a lack of evidence from randomised controlled trials to support clinical decision-making.

Trial Registration

ClinicalTrials.gov (NCT04027205) – Registered on 19 July 2019. Available via https://clinicaltrials.gov/ct2/show/NCT04027205

Contribution of the Paper

- In line with current guidance, this paper reports the development process and the resultant physiotherapist-led exercise programme used in the SPeEDy study
- An individualised, structured and progressive physiotherapist-led exercise programme based on the principle of self-dosing is described. Exercise prescription within the programme is based on establishing the current functional capacity of the patient in relation to the most challenging shoulder movements and is supported over approximately six contact sessions across a 12-week period.
- The SPeEDy study aims to provide high quality evidence about the feasibility of a future main randomised controlled trial in a clinical area where there is a lack of evidence from randomised controlled trials to support clinical decision-making.

Key Words

Physiotherapy; exercise; rotator cuff tear; shoulder

Background

Tears of the rotator cuff (RC) are regarded as a significant cause of shoulder pain and the rates of surgery to repair the torn RC have risen approximately 200% over recent years across Europe and the USA [1–4]. RC tears might be described in relation to size, e.g. small, medium, large, or location, e.g. supraspinatus. Additional descriptors relate to depth, e.g. partial or full-thickess, and also mechanism of onset, i.e. traumatic or non-traumatic. So, for example, one description of a RC tear could be a traumatic, medium-sized full-thickness tear of supraspinatus. Depending upon the assumed mechanism of onset, different treatment pathways are proposed in the current British Elbow & Shoulder Society and British Orthopaedic Association guidelines [5]. It is suggested that non-traumatic RC tears should exhaust non-surgical means prior to considering surgery, where in contrast the guidelines suggest that traumatic RC tears should be regarded as a red flag referral and urgent surgical opinion sought [5].

To date three randomised controlled trials (n = 252) comparing surgery to non-surgical treatment have been undertaken and synthesised in a systematic review [6]. Non-surgical treatment in these RCTs was mixed but typically included programmes of physiotherapist-led exercise based on varied prescription parameters. The review concluded there is limited evidence that surgery is not more effective than non-surgical treatment. But, of the 252 patients included in the systematic review, only 40 (16%) were diagnosed with traumatic tears of the RC (24 randomised to surgery; 16 to physiotherapist-led exercise). So, there is a lack of evidence from randomised controlled trials (RCTs) to support clinical decision-making.

Recognising this uncertainty, in 2018, the National Institute for Health Research (NIHR) funded a pilot and feasibility RCT with this focus; the SPeEDy study (Surgery versus physiotherapist-led exercise for traumatic tears of the RC). The aim of this RCT is to determine the feasibility of a future main RCT to test the hypothesis that a programme of physiotherapist-led exercise is not inferior to

surgical repair of the RC in terms of clinical outcomes but is more cost-effective. In line with current guidance on development of complex interventions [7], this paper describes the development process and resultant programme of physiotherapist-led exercise used in the SPeEDy study.

Overview of the SPeEDy study

SPeEDy is a two-arm, parallel group, pilot and feasibility RCT with integrated Quintet Recruitment Intervention [8] and qualitative interviews. Adult patients (≥18 years) diagnosed with a tear of the RC following a traumatic incident thought to be of sufficient force to induce a tear which is confirmed by diagnostic ultrasound or MRI scan undertaken as part of routine diagnostic work-up will be eligible to participate. At this pilot stage, providing that patients are deemed suitable for surgery or the programme of physiotherapist-led exercise by the attending clinician, they will be eligible to participate. In the event that a patient is diagnosed with a tear of the RC following a traumatic incident but are not deemed suitable by the attending clinician to participate in the RCT, we will collect these reasons to determine the zone of equipoise for a future main RCT. We expect such reasons might refer to the size or location of tear, age of the patient and co-morbidities but these factors are not pre-specified in the research protocol. Participants will be randomly allocated on a 1:1 ratio, stratified by tear size (large tear ≥3cm/ small to medium sized tear < 3cm/ or not known), to either the programme of physiotherapist-led exercise or surgical repair plus usual post-operative rehabilitation. The recruitment target is 76 participants to the RCT with follow-up to six months post-randomisation to enable a judgement about feasibility of a future main trial. The full study protocol has been published at: https://clinicaltrials.gov/ct2/show/NCT04027205

Development of the SPeEDy physiotherapist-led exercise programme

In January 2019, thirteen physiotherapists with an interest and clinical experience in assessing and treating people with shoulder pain and three patients with experience of various musculoskeletal

pain presentations, including shoulder pain, participated in an intervention development day facilitated by the lead author. Physiotherapists were invited via email to the lead authors professional network and via Twitter. Patients were invited via the research user group at Keele University.

First, an overview of the SPeEDy study was given to all attendees. Next, a description of the prior systematic review research [6] was presented to the attendees and the varied approaches recognised. In the absence of guidelines about the optimal exercise programme for RC tears and in the context of much clinicial variation, guidance from prior and ongoing research [9,10] was shared with the group to inform their thinking. This guidance included suggestions that the programme of physiotherapist-led exercise should aim to include: 1) a minimal number of exercises that are progressive in nature, i.e. become increasingly challenging as the capacity of the patient increases, 2) resistance training as able, and 3) support over a minimum 12-week period [9,10]. The group were also provided with manuals describing exercise programmes used in previous NIHR funded studies for RC disorders [11,12] as a means of informing them what the expected output of the intervention development process might look like. Finally, the group were asked to recognise some of the expected delivery challenges with reference to a heterogenous patient group, e.g. time since onset of problem, severity, and functional ability, as well as the heterogenous nature of the physiotherapists who would deliver the exercise programme in terms of knowledge, specialism and experience.

After this, three sub-groups were formed to discuss and develop initial ideas about the physiotherapist-led exercise programme. Following two hours of sub-group discussion, the wider group was reconvened and ideas discussed, developed and recommendations made.

After the intervention development day, the lead author circulated drafts of the manual detailing the physiotherapist-led exercise programme with request for feedback from the participants before finalising the programme and manual ready for use in the SPeEDy study.

The physiotherapist-led exercise programme

The physiotherapist led exercise programme is reported following the template for intervention development and replication (TIDieR) checklist [13].

The SPeEDy study intervention is an individualised, structured and progressive physiotherapist-led exercise programme based on the principle of self dosing with the aim of restoring functional capacity to a level acceptable to the individual participant. Exercise prescription is based on establishing the current functional capacity of the patient in relation to the most challenging shoulder movements and is tailored by the physiotherapist to the individual patient and supported over approximately six contact sessions across a 12-week period, as described below (figure 1).

During the first contact session, the physiotherapist asks the participant about treatment related goals linked to functional activities. For example, participants might have difficulty reaching to a shelf at home, lifting at work, or sports-related difficulties, including serving at tennis etc. Once these have been identified, the physiotherapist will break down the identified functional activities in to component parts. For example, if the participant complains of difficulty reaching to a shelf, predominantly an activity of forward-flexion of the shoulder, initial assessment of exercise capacity will commence in relation to forward-flexion of the shoulder. Similarly, if the participant complains of difficulty with a backhand shot at tennis, then an initial assessment of exercise capacity will commence in relation to external rotation of the shoulder (moving from internal to external rotation to mimic the functional movement with gradually increasing resistance).

There are nine exercise stages for each of the single plane movements of the shoulder. Stages one to three are active-assisted movements, stages four to six are active movements, and stages seven to nine are resisted movements using, for example, a resistive band or handweight. Stage one covers active-assisted movement to 30^{o} (or early range), stage two moves to 90^{o} (or mid-range), and stage three moves to 180^{o} (or end-range). Stages four to six, and then seven to nine follow the same principle in terms of range of movement progression but with active or resisted movement as applicable.

To return to the example where reaching to a shelf is a significant problem, the assessment commences with testing of active-assisted forward flexion starting with the arm by the side and moving to 30^{o} (figure 2).

Given the lack of research evidence supporting an optimal number of repetitions and sets and considerable variation in clinical practice [9,14], a self-dosed approach is taken where the participant is advised that the exercise should always be challenging to them. The participant could be challenged in relation to pain response, fatigue or perceived exertion, or a combination but this challenge should always be at a level that is acceptable to the individual participant. The level of acceptable response is likely to vary between participants but they are re-assured that such challenge does not equate to damage and they are guided by what is acceptable to them rather than with reference to generic guidance that might not be acceptable to them and hence might serve as a barrier to exercise adherence.

So, for example, a participant might commence repeated active-assisted forward flexion with the arm by the side and moving to 30^{o} (stage one). The first 20 repetitions might be perceived as challenging but acceptable, but repetitions beyond this become unacceptable. Then, to facilitate exercise adherence via self-monitoring, the participant records the type of exercise performed and the number of sets and repetitions in the exercise manual and diary provided (figure 3). This record sets the target for the participant to meet and exceed during their next exercise session. Such an approach facilitates progressive exercise. Participants are advised to aim for a minimum of one exercise session per day, a minimum of five days per week, and up to three different exercise series will be prescribed, e.g. forward-flexion, abduction (reaching out to the side away from the body), and reaching behind back. Given the self-dosed nature of this programme, no upper limit is prescribed providing the response remains within an individually acceptable limit. For example, participants are asked to re-consider their approach to self-dosing if it was felt the number of exercises undertaken was contributing to pain that impaired sleep.

If stage one exercises are perceived as not challenging, the participants move on to stage two exercises. Multiple exercise prescriptions and progressions are detailed in relation to various functional difficulties. These prescriptions and progressions are detailed in an information and exercise booklet with photographs and descriptive text in relation to single plane shoulder movements, i.e flexion, extension, abduction, lateral and medial rotation, as well as opportunity for prescription of combined or functional movement, e.g. serving at tennis, bench press. These combined or functional movements can be progressed through increasing repetitions, speed and/ or resistance. As an exercise sequence (stages one to nine) ceases to become challenging, it is dropped from the exercise prescription and a further sequence, e.g. combined or functional movement, added if needed.

In this specific patient example, stage two exercise would be active-assisted forward-flexion of the shoulder with the aim of reaching 90^{o} (figure 4). Following the same principles of progression, stage three would incorporate active-assisted flexion to 180^{o} (stage three). Although many participants have exercise capacity greater than these initial stages, this assessment process is important in the context of exercise prescription because it teaches the participants how to progress but also regress their own exercise. This means that if the response to exercise becomes unacceptable when exercising away from the physiotherapist, the participant has the understanding of how to regress the exercise to maintain acceptable levels. Similarly, the patient also has understanding of how to progress the exercise, as they feel able. Such progression is an important component of exercise prescription [9].

Stages four, five and six, would include progression to active exercise; up to 30^{o} for stage four, up to 90^{o} for stage five, and then up to 180^{o} for stage six.

Stages seven, eight and nine, would include progression to resisted exercise; up to 30^{o} for stage seven, up to 90^{o} for stage eight (figure 5), and then up to 180^{o} for stage nine (figure 6).

The final stage of the physiotherapist-led exercise programme includes functional restoration with exercise prescribed by the physiotherapist in relation to the specific functional difficulty rather than isolated movements. In this example, the participant would be encouraged to undertake repeated reaching to the shelf, initially with assistance, then without and then against resistance provided through an elastic training band or hand-weight.

The exercise approach described here enables adaptation to the individual participant who, in the context of this SPeEDy study, are likely to present with quite different levels of exercise capacity at the outset. The programme is prescribed and supported within existing NHS physiotherapy services where, following an initial consultation and exercise prescription, the patient will maintain responsibility for undertaking the exercise but returns to the physiotherapist, at individually negotiated and agreed time points over approximately six sessions across a 12-week time period, for follow-up self-management support and advice regarding exercise progression [15,16].

Adherence to the exercise programme is recorded in the exercise diary provided to the patient and monitored by the physiotherapist. Alongside the exercise programme there is an educational component, supported by the physiotherapist, that further emphasises the study specific information, including a balanced view of the two interventions and uncertainty about the most effective approach. This aspect of the educational component aims to identify and further discuss any subsequent concerns about being randomised to what might be perceived as a simple intervention, i.e. physiotherapist-led exercise, compared to a surgical intervention. This educational component includes clear advice that improvement takes time and will involve asking the participants to identify barriers to exercise, e.g. time, and discuss ways of managing this.

Intervention fidelity will be determined via case note review with reference to the important components of the exercise programme and the number of physiotherapy contact sessions attended.

Study Training

The physiotherapists who deliver the physiotherapist-led exercise intervention are all trained prior to the start of recruitment and treatment. No prior knowledge or experience is assumed, only that the physiotherapists are qualified. The focus of this training is on individualised exercise prescription and progression and is supplemented by a comprehensive manual providing clear guidance. The training takes the form of a workshop consisting of information provision and practical application of the exercise intervention.

Conclusion

Despite being such a common and burdensome problem, the optimal treatment pathway for patients with symptomatic traumatic rotator cuff tears is unclear and a current research priority. This paper describes the development and resultant physiotherapist-led exercise programe used in the SPeEDy study which will evaluate the feasibility of a future main RCT capable of informing clinical decision making with potential for direct patient benefit and efficiency savings for the NHS.

Declarations

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Authors' contributions

CL led the intervention development day with support from CA, LP, SL, and RW. CL drafted the manuscript and all other authors reviewed and provided feedback on drafts. All authors read and approved the final version of the manuscript.

Ethics approval and consent to participate

This SPeEDy study has been reviewed and a favourable opinion provided by the South East Scotland Research Ethics Committee (Reference: 19/SS/0098).

Competing interests

All authors declare they have no competing interests.

References

[1] Ensor K, Kwon Y, DiBeneditto R, Zuckerman J, Rokito A. The rising incidence of rotator cuff repairs. J Shoulder Elb Surg 2013;22:1628–32.

[2] Paloneva J, Lepola V, Äärimaa V, Joukainen A, Ylinen J, Mattila VM. Increasing incidence of rotator cuff repairs--A nationwide registry study in Finland. BMC Musculoskelet Disord 2015;16:189. https://doi.org/10.1186/s12891-015-0639-6.

[3] Colvin A, Egorova N, Harrison A, Moskowitz A, Flatow E. National Trends in rotator cuff repair. J Bone Jt Surg - Am Vol 2012;94:227–33.

[4] Longo UG, Salvatore G, Rizzello G, Berton A, Ciuffreda M, Candela V, et al. The burden of rotator cuff surgery in Italy: a nationwide registry study. Arch Orthop Trauma Surg 2017;137:217–24. https://doi.org/10.1007/s00402-016-2610-x.

[5] Kulkarni R, Gibson J, Brownson P, Thomas M, Rangan A, Carr AJ, et al. BESS/BOA Patient Care Pathways: Subacromial shoulder pain. Shoulder Elb 2015;7:135–43. https://doi.org/10.1177/1758573215576456.

[6] Ryösä A, Laimi K, Äärimaa V, Lehtimäki K, Kukkonen J, Saltychev M. Surgery or conservative treatment for rotator cuff tear: a meta-analysis. Disabil Rehabil 2016;8288:1–7. https://doi.org/10.1080/09638288.2016.1198431.

[7] Craig P, Dieppe P, Macintyre S, Mitchie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: the new Medical Research Council guidance. Br Med J 2008;337:979–83.

[8] Donovan JL, Rooshenas L, Jepson M, Elliott D, Wade J, Avery K, et al. Optimising recruitment and informed consent in randomised controlled trials: the development and implementation of the Quintet Recruitment Intervention (QRI). Trials 2016;17:283. https://doi.org/10.1186/s13063-016-1391-4.

[9] Littlewood C, Malliaras P, Chance-Larsen K. Therapeutic exercise for rotator cuff tendinopathy: a systematic review of contextual factors and prescription parameters. Int J Rehabil Res 2015;38:95–106. https://doi.org/10.1097/MRR.0000000000000113.

[10] Littlewood C, Bateman M, Connor C, Gibson J, Horsley I, Jaggi A, et al. Physiotherapists' recommendations for examination and treatment of rotator cuff related shoulder pain: A consensus exercise. Physiother Pract Res 2019;40:87–94. https://doi.org/10.3233/PPR-190129.

[11] Littlewood C, Bateman M, Cooke K, Hennnings S, Cookson T, Bromley K, et al. Protocol for a multi-centre pilot and feasibility randomised controlled trial with a nested qualitative study: rehabilitation following rotator cuff repair (the RaCeR study). Trials 2019;20:328. https://doi.org/10.1186/s13063-019-3407-3.

[12] Stevenson K, Jackson S, Shufflebotham J, Roddy E, Foster NE. Development and delivery of a physiotherapist-led exercise intervention in a randomised controlled trial for subacromial impingement syndrome (the SUPPORT trial). Physiother (United Kingdom) 2017;103:379–86. https://doi.org/10.1016/j.physio.2017.03.005.

[13] Hoffmann TC, Glasziou PP, Boutron I, Milne R, Perera R, Moher D, et al. Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. BMJ Br Med J 2014;348:g1687. https://doi.org/10.1136/bmj.g1687.

[14] Bury J, Littlewood C. Rotator cuff disorders: a survey of current (2016) UK physiotherapy practice. Shoulder Elb 2018;10:52–61.

[15] Hopewell S, Keene DJ, Maia Schlüssel M, Dritsaki M, Dutton S, Carr A, et al. Clinical and cost-effectiveness of progressive exercise compared with best practice advice, with or without corticosteroid injection, for the treatment of rotator cuff disorders: Protocol for a 2x2 factorial randomised controlled trial (the GRASP trial). BMJ Open 2017;7. https://doi.org/10.1136/bmjopen-2017-018004.

[16] Littlewood C, Malliaras P, Mawson S, May S, Walters S. Development of a self-managed loaded exercise programme for rotator cuff tendinopathy. Physiotherapy 2013;99:358–62. https://doi.org/doi: 10.1016/j.physio.2012.12.002.