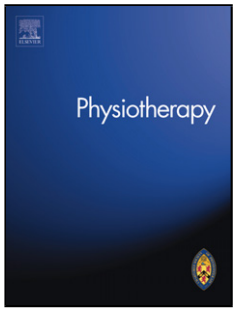

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Title: Development and delivery of a physiotherapist-led exercise intervention in a randomised controlled trial for subacromial impingement syndrome (the SUPPORT trial)

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Abstract:

Purpose

This paper describes the development, content and delivery of a physiotherapist-led individualised, supervised and progressed exercise programme for use in a factorial randomised controlled trial testing treatments for subacromial impingement syndrome.

Methods

To develop the intervention, a survey of community physiotherapists and national guidelines provided the basis for a consensus workshop through which a protocol was developed for the SUPPORT trial physiotherapist-led exercise programme (SUPPORT: SUbacromial impingement syndrome and Pain: a randomised controlled trial Of exeRcise and injection). The protocol included three stages of exercise progression: 1) scapular stability and active exercise with no resistance 2) range of motion exercise with scapular control, isometrics and stretches, and 3) through range resistance exercise. A two day training programme was developed for physiotherapists which included the trial background, current evidence and strategies to improve exercise adherence.

Results

Twenty physiotherapists were trained to deliver the exercise intervention. In the SUPPORT trial, 128 participants were randomised to physiotherapist-led exercise. Ninety nine (81%) participants had their first physiotherapy session within 2 to 3 weeks and 71 (56%) received 6 to 8 treatment sessions. Frequently-used exercises were: stage 1 scapular setting with glenohumeral joint (GHJ) flexion to 90 degrees, stage 2 GHJ medial rotation stretch, stage 3 scapular setting through lateral rotation, with resistance bands.

Conclusion:

We combined clinical and research expertise with national guidance in order to

develop a physiotherapist-led, individualised, progressed and supervised exercise intervention for use within a randomised trial. The effectiveness of the intervention is being evaluated within the SUPPORT trial (ISRCTN 42399123).

Keywords: subacromial impingement syndrome (SIS), physiotherapy, exercise, rehabilitation, shoulder.

Introduction

Shoulder problems affects one in three adults in their lifetime (1,2), peaking between 40 to 60 years and accounting for 1% of primary care consultations (3). The most common presentation is pain and impaired function (4-6).

Subacromial impingement syndrome (SIS) was the most frequent clinical diagnosis and accounted for about half of all shoulder problems (3, 7). This term was in common use at the start of this trial (2008) and suggested that pain was experienced during elevation of the arm. Previously, pain was thought to be caused by a reduction in the space between the coracoacromial arch of the scapula and the humerus, resulting in a mechanical pinching the soft tissues (8). Possible theories included bony abnormalities, weakness or instability in the rotator cuff muscles, impaired scapulohumeral rhythm, scapular instability and

poor posture (8,9). However, more recent suggestions are that genetics, hormonal influences, lifestyle factors, smoking and alcohol consumption, comorbidities, central sensitisation and excessive and maladaptive loading could also have an influence on the development of this type of shoulder pain. Therefore, rotator cuff related shoulder pain is a more appropriate and current term that encompasses a range of shoulder aetiologies and pathologies including subacromial impingement syndrome (10).

Treatment aims to reduce pain and increase function. Previous (8) and current (11) UK guidelines recommend exercise and corticosteroid injection in addition to patient education, oral analgesia and ice-packs. Exercise aims to reduce pain and improve function, posture, muscle strength, range of movement, scapular stability and scapulohumeral rhythm (12). Exercise can be individualised and supervised (e.g. by physiotherapists) or self-guided from a leaflet (13). Previously, one systematic review (14) identified that exercise decreases pain and improves function in the short term, although trials lacked detail of exercise type, frequency and duration. More recently a systematic review (15) reported that combined treatments, composed of exercise and other therapies tended to yield better effects than single interventions.

Most randomised controlled trials (RCTs) (16-22) are small, of poor quality and focus on short-term results. One found that supervised, physiotherapist-led exercise for SIS led to greater improvements in pain and function than radial extracorporeal shockwave treatment over 18 weeks (23). Another found no

differences between exercise alone and exercise plus corticosteroid injection after 12 or 24 weeks (24). A further trial showed that a three-month course of specifically tailored, progressive, strengthening exercise was more effective in reducing pain and improving shoulder function in patients with persistent SIS than non-specific movement exercises for the neck and shoulder (25).

Electromyographic studies (26, 27) have shed some light on the recruitment of muscles during shoulder movement. Rather than muscles working in isolation, many muscles are involved to generate movements and provide counter balance, perhaps indicating the need for function based exercise programmes to replicate the dynamic nature of muscle recruitment.

Guidelines recommend a 'core' set of exercises for SIS, but are based largely on expert opinion (8). Studies in other musculoskeletal conditions support individualised and progressed exercise rather than standardised exercise (28) but, to date, there are few studies specific to shoulder disorders (29). The SUPPORT trial (ISRCTN 42399123) was designed in 2008 and funded in 2009 in order to test ways to optimise patient's outcomes from exercise (physiotherapist-led individualised, supervised and progressed exercise compared with standard exercises in an advice and exercise leaflet) and corticosteroid injection (ultrasound-guided versus usual, blind (non-guided) injection), with full details of the trial design, methods and injection intervention available in the published protocol (30). Reports of complex interventions such as physiotherapist-led exercise need to provide detail of the development of the intervention and its components. Therefore, this paper summarises the development, content and

delivery of the physiotherapist-led exercise programme within the SUPPORT trial, in line with the Template for Intervention Description and Replication (TIDieR) checklist (31).

Development and delivery of the physiotherapy intervention

(i) Developing the intervention protocol

A small postal survey of physiotherapists (October 2007) aimed to identify the types of exercises that were routinely used to treat patients with SIS in clinical practice. Questions on physiotherapist role, clinical grade, interest in shoulder pain and exercises used to treat SIS were included. In total, 33 exercises were presented in the survey, generated from the Chartered Society of Physiotherapy (CSP) guidelines for managing SIS (8) and a computer programme used routinely in local practice (32). These guidelines (8) have subsequently been withdrawn although an archive copy is available through the CSP Library archive. Physiotherapists were asked to select the exercises they used most frequently in managing SIS. Respondents could report other exercises not included in the list.

Fourteen physiotherapists responded, 10 from community settings and 4 from secondary care. Physiotherapists' clinical grade ranged from 'Agenda for Change' band 6 to 8, three reported a special interest in shoulder pain. Of the list of 33 suggested exercises, 31 were selected as being used to manage SIS. The

most popular were medial and lateral rotation with a resistance band. Nine physiotherapists stated they used other exercises, including thoracic mobility exercises, eccentric control from arm elevation in supine-lying, single arm press at the wall and alternate arm lift in prone-kneeling.

To further develop the exercise intervention protocol for the SUPPORT trial, local senior physiotherapists with special interest in shoulder pain (n=10), who were identified through local networks, were invited to a consensus workshop (January 2008). An overview of the trial design, results from the local survey, and recommendations from the CSP guidelines were presented. The group refined the number and type of exercises for use within the protocol. The exercise stages were broadly labelled according to the focus of the exercises within each stage, i.e. Stage 1: scapular stability exercise, active movement with no resistance Stage 2: range of motion exercise, isometric and stretches in pain free range and Stage 3: through range resistance exercise. They decided that a small number of exercises would be provided at each visit (2-6) with written information to help patient adherence and promote self-confidence. The group agreed that exercise diaries would be offered to patients to facilitate self-monitoring of progress and to facilitate the physiotherapist in making decisions about appropriate exercise progression.

(ii) Protocol detail

The trial protocol stipulated that physiotherapists:

- saw patients for their first session within 2 to 3 weeks of randomisation

- delivered between 6 to 8 exercise sessions over 12 weeks
- would offer up to two further appointments if patients did not attend their first appointment
- would discharge patients who failed to attend three consecutive appointments
- provide a first appointment of 40 minutes followed by further appointments of 20 minutes duration
- undertook face-to-face consultations (no phone or e-mail consultations)
- provide patients with exercise diaries to facilitate adherence
- could also use soft tissue massage/ posture correction/ heat or cold
- could use facilitation techniques such as taping or anterior soft tissue release techniques
- could also prescribe neck exercises if judged as needed for individual patients
- should not use acupuncture, electrotherapy, shoulder joint mobilisations or manual therapy e.g. mobilisations with movement

Physiotherapists completed a case report form (CRF) to record treatment provided at each session; including exercises prescribed, progression and supervision and duration of the treatment session.

(iii) Supporting the physiotherapists to deliver the intervention

Prior to the SUPPORT trial commencing, a two-day training programme was developed to support physiotherapists to deliver the exercise intervention (training programmes September and November 2010). They covered: trial

design, evidence for exercise and strength training, best practice for exercise training, including specificity, progressive overload, recovery, adaptation, reversibility, timing of exercise prescription, role of patients' perceptions of pain and exercise, importance of exercise adherence and trial protocol adherence. Available literature at the time suggested for older adults the frequency of strengthening exercise should be at least at least twice per week on non-consecutive days. There was little evidence to guide dosage and therefore consensus expert opinion was used to inform the protocol recommendation.

The number of exercises recommended suggested 8 to 10 exercises, starting with 1 set, moving to 2 to 3, with mild fatigue on completion (33, 34). CSP guidance suggested starting strengthening in neutral ranges, arms by side and to use towels / bands for light resistance, ensuring scapular stability during exercise. Whilst there were no guideline recommendations about frequency or number of exercises, they recommended building up to 3 sets of 10 repetitions with 10 seconds rest in between, aiming for moderate effort (8). National experts, with an interest in the concept of muscle stability, were contacted. They were not aware of any evidence that could underpin decisions about the most appropriate exercise dosage.

Emphasis was placed on assessment / re-assessment to ensure individualised prescription of exercise, progression of the exercise in terms of type and dose. Theories of self-efficacy (35) and self- regulation (36) were used to underpin the delivery of the training and the exercise intervention. Confidence in the protocol was developed in the workshops by sharing clinical experience and participating in discussion around exercise progression, goal setting and facilitating adherence

to exercise. Twenty-two physiotherapists attended and were given a resource pack, containing all the exercise sheets and potential progressions. Refresher training sessions were offered.

Details of participating physiotherapists and exercise intervention

(i) Trial setting and implementation

In total, 20 physiotherapists (14 female and 6 males) from 18 NHS community sites in 2 geographical regions (North and South Staffordshire and Stoke on Trent) and representing a range of clinical experience (bands 5 to 8) treated trial participants. They were not reimbursed separately for this activity but trial participants were treated as part of physiotherapists' usual caseload. Two physiotherapy research facilitators supported participating physiotherapists in delivery of the intervention protocol and auditing of the trial CRFs.

(ii) Specific components and progression of exercise intervention

The exercise protocol consisted of three stages: Stage 1: scapular stability exercise and active movement with no resistance, Stage 2: range of motion exercise, isometrics and stretches with scapular control in pain free range and Stage 3: through range resistance exercise. This individualised programme was provided and progressed over treatment sessions. All exercises included can be found at:

http://www.keele.ac.uk/media/keeleuniversity/ri/primarycare/docs/SUPPORT_Physiotherapy_Intervention_Manual_v3.0_04_01_11_Internet_Version.pdf

Stage 1 involved assessing and correcting posture in sitting and standing. Scapular stability was assessed and retrained using positional changes from prone-lying, to sitting, through to standing. The number of exercise repetitions was determined by the participant's fatigue level. If scapular stability was achieved in sitting, minimal active movement with short lever was introduced, progressing to long lever. Progression could include scapular setting in: a crawling position, leaning through both arms in standing or sitting and in a seated push-up position.

Stage 2: Aimed to achieve pain free range of motion exercises with good scapular control. Exercises could be progressed from lying, through sitting to standing. Forward flexion, abduction and internal and external rotation were considered key active movements to rehabilitate. Eccentric and concentric exercises could be included within pain free range. Stretching exercises to prevent capsular tightness were included. Isometric resisted exercises were started in neutral position and progressed to fixed positions within range. Good scapular control was essential and movement needed to be pain free. Participants were progressed to using resistance bands or self-resistance.

Stage 3: Involved progression to resisted exercises, with scapular control through full range of movement, involving short or long levers, or resistance bands and

free weights. These were progressed to allow for the individual's leisure, sports or occupational needs.

Each patient was assessed in order for the physiotherapist to determine their starting point i.e. exercise stage 1, 2 or 3. They were re-assessed in subsequent treatment sessions to inform exercise progression. Progression depended on the patient's pain response, adherence and fatigue level. If specific goals were achieved e.g. achieved scapular stability through range without pain, exercises would be progressed. Participant's age, occupation, leisure activities and physical health were also taken into account. Physiotherapists agreed to teach between 2 to 6 new exercises per session. Supplementary information is available on line detailing the protocol of exercise progression and frequency of exercises used in each of the three stages.

Exercises in stage 1 would be performed on an hourly basis, those in 2 and 3 were to be undertaken 3 to 4 times a day.

Description of intervention delivery in the trial

Of 256 participants randomised in the SUPPORT trial (30), 128 were randomised to the physiotherapist-led exercise intervention. Patients initiated contact with the physiotherapy department to arrange treatment. In total, 123 (96%) of those randomised to the physiotherapist-led exercise intervention booked an appointment to see the physiotherapist and 99 participants (81% of those who booked an appointment) received their first session within three weeks of randomisation as per the trial protocol. The median number of treatment sessions

provided per participant was 6 (IQR= 3, 7; range= 0, 10), with over half (56%) of those randomised receiving between 6 to 8 treatment sessions.

For the majority of those who attended their first physiotherapy appointment, 94% (n=96) received a 40 minute consultation. Of all treatment sessions delivered, 78% (n=513) of participants received a 20 minute follow-up appointment. Five participants did not book an appointment with a SUPPORT trial physiotherapist, one withdrew from the trial, four refused physiotherapy treatment, and a further seven initially booked physiotherapy appointments but then did not attend any sessions (Table 1). Of the total number of physiotherapy sessions provided in the trial (n=661), there were 160 (19.5%) 'did not attend/ unable to attend' episodes.

For those participants who received between 6 to 8 treatment sessions, the most frequently prescribed exercises in stage 1 were: scapular setting with gleno-humeral joint (GHJ) flexion to 90 degrees, scapular setting with abduction and scapular setting in a seated position. In stage 2 the most frequently prescribed exercises were GHJ medial rotation stretch, a lateral rotation stretch in standing and scapular setting through flexion. In stage 3 the most common were scapular setting through active lateral rotation, scapular setting through active medial rotation and scapular setting through active flexion all undertaken with resistance bands. Supplementary online information available detailing the frequency of exercises used in each of the three stages. For those who received between 6 to 8 treatment sessions, additional treatments, such as cold and heat therapy, neck exercises, soft tissue release and pendular exercises were all used in less than

3% of treatment sessions. Four patients received mobilisations of the shoulder joint, see Table 2.

Of the 661 physiotherapy sessions provided in the trial, assessment / reassessment occurred in almost all (96%), supervised exercises were provided in 92% with education and advice being provided in 88%. Exercises were given to participants and reviewed in 79% of the sessions (n=519). Of the 128 patients randomised to the physiotherapist-led exercise intervention, there was evidence for exercise progression on the CRFs for 87.8% (n=108). The number of patients treated by each physiotherapist ranged from 1 to 15.

To facilitate treatment fidelity, two physiotherapists, who were not involved in delivering the intervention, undertook audits of the CRFs and observed physiotherapists treating SUPPORT trial participants twice during the course of the trial.

Discussion

A physiotherapist-led exercise intervention with key features of individualisation, progression and supervision, was designed and delivered for patients with SIS in the SUPPORT trial. The intervention was developed using a combination of national guidelines, available research evidence and clinical consensus. Similar studies have utilised this approach to develop trial interventions (24) and have recognised the need for specific targeted exercise (37) rather than general exercise (25). The intervention protocol provides details of the exercises and

progressions, addressing criticism of previous trials for poor description of exercise protocols (14). At the time of development of the exercise intervention, there were no published data upon which to guide the specific number of exercises, nor the specific dose of exercise for patients with SIS. However, our protocol reflects recent international consensus on managing shoulder pain which suggests that active exercises should be the primary treatment approach, with physical assessment findings guiding treatment (38). This consensus also recommends a limited number of exercises are prescribed and are performed with appropriate scapula-humeral stability. Our intervention was in keeping with this view that regular reassessment allows progression from simple to more demanding shoulder exercises, with progressed loading, with minimal pain and good quality shoulder movements (38).

In the SUPPORT trial, 81% of patients randomised to the physiotherapist-led intervention received their first treatment session within 3 weeks from randomisation which may not reflect current UK physiotherapy waiting times. Other trials, investigating the effect of exercise on this population, have seen participants within one week of randomisation (24). Keeping waiting times to a minimum may reduce non-attendance and encourage participation.

Our intervention was in keeping with other trials which have focused on individualised exercise programmes, exercise progression, correction of performance and tailoring of exercises programmes to suit individual needs (36, 37). However, some variation in exercise prescription is evident. In our trial, we

recommended between 2 to 6 exercises per session, and the repetitions were dependent on the stage i.e. hourly exercises in stage 1, compared to 3 to 4 sets per day in stage 2 and 3. Others trials have recommended nine exercises with 30 to 40 repetitions, undertaking 3 sets per day, at least four times per week (37), whilst some suggest a daily programme (39). A recent consensus suggested no more than 4 exercises, with dose and progression determined by individual assessment (38).

Within our trial, individualising treatment was facilitated by physiotherapists having sufficient time to undertake an in-depth assessment at the initial consultation and re-assessment in follow-up consultations. Over 90% of patients received a 40 minute initial appointment, allowing time for the physical and functional presentation, individual motivating factors and appropriate goals. For the majority of patients (78%), this was followed by follow-up treatment sessions of 20 minutes. This allowed progression and tailoring of treatment to the stage of their recovery, age, occupation, physical health and occupational and leisure needs. To consider all of these aspects of assessment, sufficient time needs to be allocated to the consultation and follow-up to allow for this. Trials published to date do not give specific details on individual appointment times, but a recent consensus has suggested that a total episode of care should last at least 12 weeks (35).

To maximise the chances of the exercise intervention being individualised, supervised and progressed appropriately, the protocol required patients to

receive between 6 to 8 treatment sessions, yet only just over half of participants received this number (56%, n=71). The optimum number of treatment sessions for SIS is unknown although recent trials have stipulated similar numbers of sessions to ours with one trial allowing an unlimited number of sessions (24, 25, 32). Feedback from participating physiotherapists suggested that often further sessions were not needed because both physiotherapists and participants felt that they had already achieved a significant clinical improvement. Some participants in our trial (n=10, as evidenced by the data from the CRFs) did not need to start at stage 1 and were able to start at stage 2, shortening the time required to progress treatment. For those that attended 6 to 8 treatment sessions, reassessments, provision of education and advice, supervision of the exercises in clinic, and review of the exercise diary occurred with regular frequency through the treatment sessions.

In summary, we developed and agreed the content for the physiotherapist-led exercise intervention in the SUPPORT trial for patients with SIS. Key features included a programme of shoulder exercise that was individualised, supervised and progressed over three stages. Trial participants were supported to exercise through written information detailing their prescribed exercises and an exercise diary. This paper provides full information about the physiotherapist-led intervention and the clinical effectiveness results from the SUPPORT trial will be published in a future separate paper.

Ethics and funding

Ethical approval was obtained from The Black Country Research Ethics Committee (10/H1202/72). The SUPPORT trial was funded by the National Institute for Health Research (NIHR) under its Research for Patient Benefit scheme (Grant Reference Number: PB-PG-1207-15064) and was also supported by the Arthritis Research UK Primary Care Centre grant (Grant Reference Number: 18139). Nadine Foster was supported by an NIHR Research Professorship (NIHR-RP-011-015). The views expressed are those of the authors and not necessarily those of the NHS, the NIHR or the Department of Health. Funding was also secured by the North Staffordshire Primary Care Research Consortium for NHS Engagement and the NIHR Clinical research Network West Midlands (Primary care) for service support costs.

The authors declare no conflicts of interest.

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Table 1: Summary of physiotherapy case report form (CRF) data: participants and treatment sessions

Physiotherapy sites and physiotherapist	
Number of geographical regions	2
Number of physiotherapy sites	14
Number of treating physiotherapists	20
Participants	
Number of participants randomised to physiotherapy-led arm	128
Number of participants who booked appointment to see a physiotherapist* (% of randomised)	123 (96.1)
Total number of participants who attended at least one treatment session† (% of booked sessions)	116 (95.1)
Number of participant who did not attend first physiotherapy session (% of booked sessions)	20 (16.3)
Participant who did not attend treatment sessions for 3 consecutive times and discharged as per protocol (% of booked sessions)	14 (11.4)
First session within 3 weeks (% of booked sessions)	99 (80.5)
Number of treatment sessions provided (per participant), mean (SD)	5.2 (2.5)
Number of treatment sessions per participant (categorised), n (% of no. of participants randomised)	
0	12 (9.4)
1-5	42 (32.8)
6-8‡	71 (55.5)
9-10	3 (2.3)
Treatment sessions	
Total number of planned physiotherapy treatment sessions	821
Total number of physiotherapy treatment sessions provided (% of total planned)	661 (80.5)
Total number of sessions not attended – DNAs/UTAs** (% of total planned)	160 (19.5)
Duration of physiotherapy treatment sessions (minutes) across all treatment sessions, n (% of total no. of treatment sessions provided)	
Less than 20 (include telephone consultation and late arrivals)	7 (1.1)
20	513 (77.6)
30	15 (2.3)
35	2 (0.3)
40	121 (18.3)
45-60	3 (0.5)
Duration of the first physiotherapy treatment session (minutes), n (% of total no. of participants who attended first treatment session, n=102)	
30	1 (1.0)

35	2 (2.0)
40	96 (94.1)
45 - 60	3 (2.9)

*Five participants did not book appointment, 1 withdrawn from the study and 4 refused treatment; †7 participants booked appointment but did not attend any session; ** DNA= Did not attend; UTA = Unable to attend; ‡ 6 to 8 were the number of treatment sessions per participant in line with treatment protocol.

Table 2 Treatment components provided across all treatment sessions

Treatment components	**Number (%) of sessions in which the treatment was given out of the total number of physiotherapy sessions provided (n=661)**	**Number (%) of participants receiving the treatment in at least one treatment session out of all participants who attended at least one treatment session (n=116)**
Assessment/ reassessment	637 (96.4)	116 (100.0)
Education and advice	581 (87.9)	116 (100.0)
Supervised exercises in clinic	609 (92.1)	116 (100.0)
Exercise template given	519 (78.5)	116 (100.0)
Exercise diary reviewed	483 (73.1)	113 (97.4)
Exercise progressed	268 (40.5)	83 (71.6)
Other treatments provided during physiotherapy treatment		
Cold therapy	18 (2.7)	11 (9.5)
Neck exercise	17 (2.6)	12 (10.3)
Posture correction	9 (1.4)	8 (6.9)
Heat therapy	8 (1.2)	6 (5.2)
Pendular	6 (0.9)	4 (3.4)
Assisted flexion exercises	6 (0.9)	6 (5.2)
Mobilisation of shoulder joint	5 (0.8)	4 (3.4)
Soft tissue release	3 (0.5)	3 (2.6)
Capsular stretches	2 (0.3)	2 (1.7)
Assisted abduction	2 (0.3)	2 (1.7)
Hand behind back stretch using a towel	2 (0.3)	2 (1.7)
Other*	8 (1.2)	8 (6.9)

*Other exercises included stretches with a stick, shoulder shrug, functional press-ups by wall and triceps dips, lumbar neutral exercises, mobilisation of the thoracic spine, medial rotation and TENS for pain relief- patients own machine.