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

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34 Abstract

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

49 Trial Registration

50 ClinicalTrials.gov (NCT04027205) – Registered on 19 July 2019. Available

51 via <https://clinicaltrials.gov/ct2/show/NCT04027205>

52 Contribution of the Paper

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

63 Key Words

64 Physiotherapy; exercise; rotator cuff tear; shoulder

65

66

67 Background

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

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

87
88 Recognising this uncertainty, in 2018, the National Institute for Health Research (NIHR) funded a
89 pilot and feasibility RCT with this focus; the SPeEDy study (Surgery versus physiotherapist-led
90 exercise for traumatic tears of the RC). The aim of this RCT is to determine the feasibility of a future
91 main RCT to test the hypothesis that a programme of physiotherapist-led exercise is not inferior to

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

95

96 [Overview of the SPeEDy study](#)

97

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

114 [Development of the SPeEDy physiotherapist-led exercise programme](#)

115

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

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

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

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

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

143 The physiotherapist-led exercise programme

144

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

147

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

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

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

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

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

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

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

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

216
217 Stages four, five and six, would include progression to active exercise; up to 30° for stage four, up to
218 90° for stage five, and then up to 180° for stage six.

219 Stages seven, eight and nine, would include progression to resisted exercise; up to 30° for stage
220 seven, up to 90° for stage eight (figure 5), and then up to 180° for stage nine (figure 6).

221

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

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

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

243
244 Intervention fidelity will be determined via case note review with reference to the important
245 components of the exercise programme and the number of physiotherapy contact sessions
246 attended.

247 Study Training

248

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

255 Conclusion

256

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

262

263 [Declarations](#)

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275 [Authors' contributions](#)

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

279 [Ethics approval and consent to participate](#)

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

282 [Competing interests](#)

283 All authors declare they have no competing interests.

284

285

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