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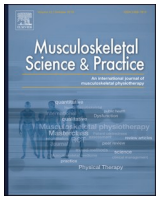

Original article

Physiotherapist-led exercise versus usual care (waiting-list) control for patients awaiting rotator cuff repair surgery: A pilot randomised controlled trial (POWER)

Chris Littlewood [a,*], Maria Moffatt [a], Jacqueline Beckhelling [b], Daniel Davis [b], Adrian Burden [c], Lisa Pitt [d], Stacey Lalande [e], Catrin Maddocks [f], Gareth Stephens [g], Helen Tunnicliffe [h], Jessica Pawson [i], James Lloyd [i], Andrea Manca [j], Julia Wade [k], Nadine E. Foster [l]

[a] Faculty of Health, Social Care & Medicine, Edge Hill University, St Helen's Road, Ormskirk, Lancashire, L39 4QP, UK
[b] Derby Clinical Trials Support Unit, University Hospitals Derby & Burton NHS Foundation Trust, Royal Derby Hospital, Derby, DE22 3NE, UK
[c] Patient Representative, UK
[d] University Hospitals Derby & Burton NHS Foundation Trust, Royal Derby Hospital, Derby, DE22 3NE, UK
[e] Airedale NHS Foundation Trust, Airedale General Hospital, Skipton Rd, Steeton, Keighley, BD20 6TD, UK
[f] Robert Jones & Agnes Hunt Orthopaedic Hospital, Gobowen, Oswestry, SY10 7AG, UK
[g] The Royal Orthopaedic Hospital NHS Foundation Trust, Bristol Road South, Northfield, Birmingham, B31 2AP, UK
[h] University Hospitals of Leicester NHS Trust, Leicester Royal Infirmary, Infirmary Square, LE1 5WW, UK
[i] Barts Health NHS Trust, Royal London Hospital, Whitechapel, E1 1FR, UK
[j] Centre for Health Economics, University of York, York, YO10 5DD, UK
[k] Population Health Sciences, Bristol Medical School, University of Bristol, 39 Whatley Road, Bristol, BS8 2PS, UK
[l] STARS Education and Research Alliance, Surgical, Treatment and Rehabilitation Service (STARS), The University of Queensland and Metro North Health, Queensland, QLD 4029, Australia

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STRUCTURED ABSTRACT

Background: Once a decision to undergo rotator cuff repair surgery is made, patients are placed on the waiting list. It can take weeks or months to receive surgery. There has been a call to move from waiting lists to 'preparation' lists to better prepare patients for surgery and to ensure it remains an appropriate treatment option for them.
Objective: To evaluate the feasibility, as measured by recruitment rates, treatment fidelity and follow-up rates, of a future multi-centre randomised controlled trial to compare the clinical and cost-effectiveness of undertaking a physiotherapist-led exercise programme while waiting for surgery versus usual care (waiting-list control).
Design: Two-arm, multi-centre pilot randomised controlled trial with feasibility objectives in six NHS hospitals in England.
Method: Adults (n = 76) awaiting rotator cuff repair surgery were recruited and randomly allocated to a programme of physiotherapist-led exercise (n = 38) or usual care control (n = 38).
Results: Of 302 eligible patients, 76 (25%) were randomised. Of 38 participants randomised to physiotherapist-led exercise, 28 (74%) received the exercise programme as intended. 51/76 (67%) Shoulder Pain and Disability Index questionnaires were returned at 6-months. Of 76 participants, 32 had not received surgery after 6-months (42%). Of those 32, 20 were allocated to physiotherapist-led exercise; 12 to usual care control.
Conclusions: A future multi-centre randomised controlled trial is feasible but would require planning for variable recruitment rates between sites, measures to improve treatment fidelity and opportunity for surgical exit, and optimisation of follow-up. A fully powered, randomised controlled trial is now needed to robustly inform clinical decision-making.

* Corresponding author.
E-mail address: chris.littlewood@edgehill.ac.uk (C. Littlewood).

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1. Introduction

Shoulder pain presents a significant personal, social, and economic burden affecting work, ability to undertake leisure and household tasks, and causes disturbed sleep (Carr et al., 2015). Tears of the rotator cuff are regarded as a significant cause of shoulder pain and rates of surgery to repair the torn rotator cuff have risen approximately 200% over recent years, from 1995 to 2011, across Europe and the USA (Ensor et al., 2013; Paloneva et al., 2015; Colvin et al., 2012; Longo et al., 2017). In the UK National Health Service (NHS), 8838 surgical repairs of the rotator cuff were undertaken in 2018/2019 (HES. Hospital Episode Statistics, 2019). Depending on complexity, the cost of surgical repair ranges from £3676 to £6419 (NHS Improvement, 2020) meaning that direct UK NHS treatment costs alone range from £32.5 to £56.7 million annually.

Once a decision to undergo rotator cuff repair surgery has been made, most patients are placed on an NHS surgical waiting list, and it can take weeks or months to receive. In this context, there has been a call to transform how patients wait for surgery, from waiting lists to 'preparation' lists to better prepare patients for surgery and to ensure it remains an appropriate treatment option for them (Levy et al., 2021). The rationale underpinning this includes potential to improve post-surgical outcomes, reduce complications, and to ensure informed shared decision-making (Wilson et al., 2017). Additionally, preparation lists could be a means of minimising surgical regret, which is reported by approximately 15% of people who undergo surgery (Wilson et al., 2017). Through this process of preparation, there is time and space to consider patients' evolving needs, preferences, and priorities, and opportunity to improve understanding about the benefits and risks of surgery and alternative options, including natural history and non-surgical management, for example treatment prescribed by a physiotherapist (Dhesi J).

To determine whether the components of a future, fully powered randomised controlled trial could all work together with regard to recruitment rates, treatment fidelity and follow-up rates, we conducted a pilot randomised controlled trial comparing a physiotherapist-led exercise programme, while waiting for surgery, versus usual care (waiting-list control) for adult patients awaiting rotator cuff repair surgery in the UK.

2. Methods

This paper is reported according to the CONSORT 2010 statement: extension to randomised pilot and feasibility trials (Eldridge et al.,

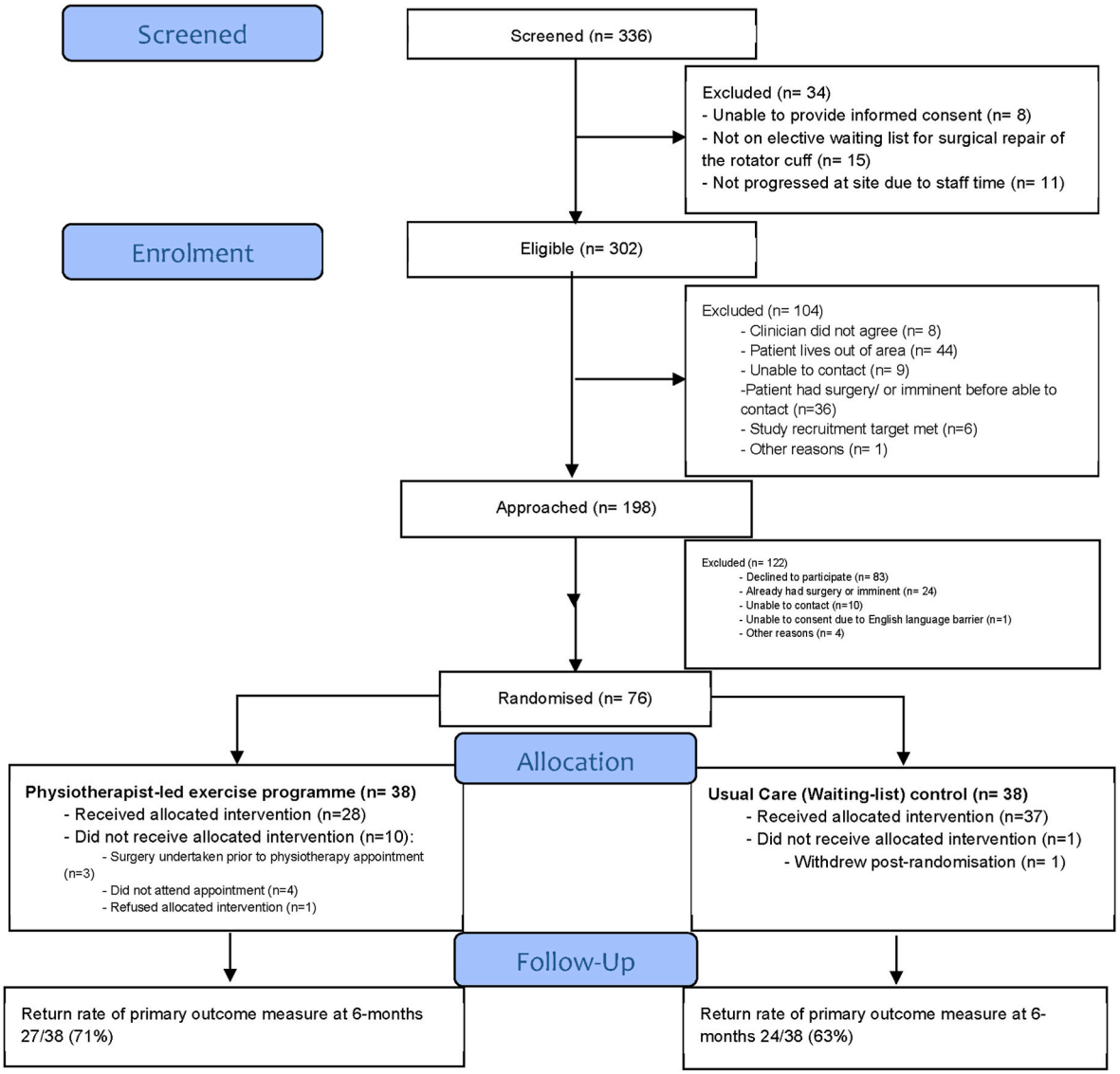

Fig. 1. Consort flow diagram.

2016). We conducted an open-label, pragmatic multi-centre, external pilot randomised controlled trial with feasibility objectives using a parallel group design with 1:1 allocation ratio (Fig. 1).

This study was funded as part of a National Institute for Health Research (NIHR) Post-Doctoral Fellowship (PDF-2018-11-ST2-005) and additional funding was received from Edge Hill University Research Investment Fund. The study sponsor was University Hospitals of Derby and Burton NHS Foundation Trust (UHDB/2021/016). A favourable ethical review was granted by the West of Scotland Research Ethics Service on 14th June 2021 (21/WS/0067). The protocol was registered on the clinicaltrials.gov registry (NCT04974242) on 23 July 2021 and is available via: https://clinicaltrials.gov/ct2/history/NCT04974242. Recruitment took place between September 2021 and August 2022.

2.1. Patient and public involvement

We worked with patient representatives to develop study processes including recruitment documentation and patient-facing materials including participant information sheets. Additionally patient representatives contributed to study management through the Trial Management Group, study oversight through membership of the Trial Steering Committee, and decisions about next steps beyond this study.

2.2. Recruitment

Adult patients on the elective orthopaedic waiting list for surgical repair of the rotator cuff were identified, screened and recruited from six NHS hospitals in England by local hospital staff. Participation in the study was conditional on the individual's ability to give full informed consent. The Screened, Eligible, Approached and Randomised (SEAR) framework (Wilson et al., 2018) was used to monitor the points at which potential participants left the pathway into the study and the reasons why (see Fig. 1).

Upon confirmation of informed consent and completion of baseline assessment, participants were assigned to the programme of physiotherapist-led exercise or usual care (waiting-list) control, stratified by hospital site, via an online randomisation system set up by Derby Clinical Trials Support Unit to ensure allocation concealment.

2.3. Study interventions

Intervention: Physiotherapist-led exercise programme whilst on the waiting list, delivered flexibly via secure video platform, via telephone, or face-to-face, according to patient preference. Remote delivery of a physiotherapy intervention for shoulder disorders has previously been reported as feasible and acceptable (Malliaras et al., 2020) and non-inferior to face-to-face provision (Russell et al., 2011). Reflective of current guidance for exercise programmes for people with rotator cuff disorders, the programme was tailored to the participant's current capacity and specific goals. The exercise programme was based on the principle of self-dosing and establishing the current functional capacity of the patient in relation to their most challenging shoulder movements. The development process and resultant programme of physiotherapist-led exercise has been reported (Littlewood et al., 2021) and was supported by a study-specific exercise booklet (POWER exercise booklet), electronically or in paper form according to patient preference (Supplementary File 1).

This approach to exercise prescription enables adaptation to the patient in recognition of the different levels of exercise capacity they may present with despite the similar rotator cuff tear diagnosis. Following an initial consultation and exercise prescription, the patient maintained responsibility for undertaking the exercise with opportunity for ongoing support from the physiotherapist, at individually negotiated and agreed time-points. Physiotherapists in the trial were advised that this could include up to six sessions across a 12-week time period, for follow-up self-management support and advice regarding exercise progression (Hopewell et al., 2017; Littlewood et al., 2013), but this was not mandated and was left to the physiotherapist and the patient to decide through shared decision-making. Participants randomised to the physiotherapist-led exercise programme continued on the waiting list for rotator cuff surgery unless they expressed the wish to be removed.

Control: To continue on the waiting list for rotator cuff repair surgery without further physiotherapy, as per usual care.

2.4. Objectives

The main measures for determining feasibility were:

1) Estimate the rate of recruitment as a proportion of eligible patients, i.e. the number of patients recruited as a proportion of those eligible at each site and overall.
2) Describe the reasons for not wanting to participate.
3) Report treatment fidelity with regards to the number of participants who receive physiotherapy as intended, i.e. when a participant attends one or more treatment sessions with a physiotherapist.
4) Report the completion rate of follow-up outcome measures, i.e. the number and proportion of SPADI and EQ-5D-5L questionnaires completed at each follow-up time point.
5) Describe the number and nature of adverse events six-months following randomisation.

An adverse event was defined as any untoward medical occurrence in a participant, including occurrences which are not necessarily caused by or related to study procedures. A serious adverse event was defined as any untoward medical occurrence that results in death, is life-threatening, requires inpatient hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability/incapacity, consists of a congenital anomaly or birth defect.

6) Describe the number and proportion of participants who report an intention to proceed to surgery or who received surgery within six-months post-randomisation.

Our pre-defined progression criteria are reported in Table 1 with respective progression (red/amber/green) thresholds:

Clinical status and outcomes were collected at baseline, 6-weeks, 3- and 6-months via electronic questionnaire. The SPADI is a 13-item measure of patient-reported shoulder pain and disability in which each item is scored on a 0–10 numerical rating scale (10 being the worst score). It has been validated for use, including over the telephone. A lower total score indicates a better clinical status (Roach et al., 1991). The EQ-5D 5L is a generic measure of health-related quality of life that can be used for the purpose of clinical and health economic evaluation. It comprises five dimensions, each with a five-level answer possibility and a health thermometer scale, where 0 represents worst imaginable health and 100 best imaginable health. It has good test–retest reliability and gives a single preference-based index value for health status that can be used for broader cost-effectiveness analysis. A higher total score indicates a better health state (van Reenen and Janssen, 2015). Non-responders were followed-up by local hospital research staff by telephone or secure video platform to enable minimal data collection of

Table 1
Progression criteria (**1. % of eligible patients; 2. % of participants randomised to physiotherapist-led exercise to have received initial assessment and exercise prescription as planned; 3. % of Shoulder Pain and Disability Index (SPADI) questionnaires obtained at 6-months**).

Progression criteria	Red (Stop)	Amber (Amend)	Green (Go)
Recruitment rate [1]	<20	20 to <30	30 or more
Treatment fidelity [2]	<65	65 to <80	80 or more
Follow-up [3]	<65	65 to <80	80 or more

the SPADI, as the primary outcome measure, and adverse events. Number and type of adverse events post-surgery were collected up to 6-months post-randomisation via clinician and patient self-report questionnaires.

Self-report exercise adherence data was collected at baseline, 6-weeks, 3- and 6-months via the electronic questionnaires by asking participants randomised to the physiotherapist-led exercise programme: 'To what extent do you agree with the following statement: 'I have been doing my exercises as often as prescribed.' Responses were on a 5-point Likert scale categorised as; strongly agreed, agreed, neither agreed nor disagreed, disagreed or strongly disagreed.

2.5. Sample size

The target sample size was 76, which was based on a balance of obtaining estimates of the patient-reported outcome data variability, while addressing a number of feasibility outcomes, in tandem with an assessment of whether the study would be feasible across a number of hospitals. These factors were based on recommendations for sample size in external pilot RCTs and were supported by the independent trial steering committee (Teare et al., 2014).

2.6. Statistical analysis

As this was a pilot randomised controlled trial focused on determining feasibility, the analysis focuses mainly on description of feasibility outcomes. For continuous data with normal distribution, mean (SD), are reported; for continuous data with non-normal distribution, median (interquartile range) are reported; for categorical data, counts are reported. The detailed statistical analysis plan, that described in detail how the descriptive analysis would be undertaken, was agreed with the independent Trial Steering Committee before the end of recruitment and prior to commencing analysis.

3. Results

Of 302 patients deemed eligible, 76 (25%) were randomised, aligning with the amber zone of the progression criteria (Fig. 1).

Recruitment data by site are presented in Table 2.

The most common reason for non-participation was patients living out of area and thus being ineligible to receive the programme from a trained physiotherapist. The second most common reason was surgery already undertaken or so imminent as to make the engagement in the physiotherapy intervention not feasible (Fig. 1). The baseline characteristics of the randomised sample are presented in Table 3.

Of 38 participants randomised to physiotherapist-led exercise, 28 (74%) received a minimum of an initial assessment and exercise prescription within the study period, aligning with the amber zone of the progression criteria. For those 28 participants who received a minimum of an initial assessment and exercise prescription, the mean number of sessions was 3 (range 1–7).

We asked participants randomised to the physiotherapist-led exercise programme: 'To what extent do you agree with the following

Table 2
Recruitment data by site and overall.

Site	Number screened	Number Eligible	Number approached	Number randomised	% randomised as a proportion of eligible
1	87	84	34	8	9.5
2	113	86	39	12`	14.0
3	23	21	15	7	33.3
4	47	47	47	23	48.9
5	35	33	33	14	42.4
6	31	31	30	12	38.7
Total	336	302	198	76	**25.2**

Table 3
Baseline characteristics of the randomised sample.

	All (n = 75)	Physiotherapist-led exercise programme (n = 38)	Usual Care (Waiting-list) control (n = 37)	Number of participants completing the item via questionnaire
Age (years), mean (SD)	58.5 (10.9)	57.8 (11.3)	59.2 (10.5)	75
Males, n	47 (63%)	25 (66%)	22 (59%)	75
Height (cm), mean (SD)	170.7 (11)	169.1 (11.4)	172.2 (10.5)	74
Weight (kg), mean (SD)	88.9 (18)	88.8 (19.7)	89.0 (16.4)	73
Body Mass Index, mean (SD)	30.5 (5.8)	31.1 (6.6)	30.0 (4.8)	73
Duration of shoulder pain (months), median (IQR)	17 (7–36)	24 (9–42)	12 (6–24)	74
Current employment status, n				74
Employed	42 (57%)	19 (51%)	23 (62%)	
Unemployed	3 (4%)	3 (8%)	0 (0%)	
Homemaker	2 (3%)	2 (5%)	0 (0%)	
Retired	20 (27%)	8 (22%)	12 (32%)	
Not working due to illness	6 (8%)	4 (11%)	2 (5%)	
Other	1 (1%)	1 (3%)	0 (0%)	
Diabetic, n				74
Yes	12 (16%)	6 (16%)	6 (16%)	
No	62 (84%)	31 (84%)	31 (84%)	
Smoking status, n				73
Current tobacco smoker	6 (8%)	2 (5%)	4 (11%)	
Previous tobacco smoker	24 (33%)	15 (41%)	9 (25%)	
Never smoked	43 (59%)	20 (54%)	23 (64%)	
Vaping status, n				72
Current vaper	9 (12%)	4 (11%)	5 (14%)	
Previous vaper	1 (2%)	0 (0%)	1 (3%)	
Never vaped	62 (86%)	32 (89%)	30 (83%)	
Location of tear, n (tear can be in multiple locations)				75
Supraspinatus	72	37	35	
Infraspinatus	9	4	5	
Subscapularis	4	2	2	
Teres Minor	0	0	0	
Unknown	3	1	2	
Type of tear, n				74
Partial	10 (14%)	4 (11%)	6 (16%)	
Full	53 (72%)	27 (73%)	26 (70%)	
Unknown	11 (15%)	6 (16%)	5 (14%)	
Size of tear, n				75
Small (<1 cm)	15 (20%)	6 (16%)	9 (24%)	
Medium (1 to < 3 cm)	17 (23%)	8 (21%)	9 (24%)	
Large (3 to < 5 cm)	6 (8%)	2 (5%)	4 (11%)	
Massive (5 cm or more)	3 (4%)	1 (3%)	2 (5%)	
Unknown	34 (45%)	21 (55%)	13 (35%)	
Treatment preference, n				74
Waiting-list control	12 (16%)	7 (19%)	5 (14%)	

(continued on next page)

Table 3 (*continued*)

	All (n = 75)	Physiotherapist-led exercise programme (n = 38)	Usual Care (Waiting-list) control (n = 37)	Number of participants completing the item via questionnaire
Physiotherapist-led exercise	20 (27%)	9 (24%)	11 (30%)	
No preference	42 (57%)	21 (57%)	21 (57%)	
Previous physiotherapy for this shoulder problem, n				74
Yes	50 (68%)	25 (68%)	25 (68%)	
No	24 (32%)	12 (32%)	12 (32%)	
Accept allocation				75
Yes	74 (99%)	37 (97%)	37 (100%)	
No	1 (1%)	1 (3%)	0 (0%)	
Preference for accessing follow-up questionnaires, n				75
Email	42 (56%)	20 (53%)	22 (59%)	
SMS text	33 (44%)	18 (47%)	15 (41%)	
Shoulder pain and disability (SPADI), mean (SD) [a]	57.7 (23)	52.2 (21.4)	63.2 (23.5)	73
Health-related quality of life (EQ-5D 5L), mean (SD)	0.64 (0.26)	0.66 (0.26)	0.63 (0.25)	72

[a] **At baseline, four SPADI questionnaires had 2 or less missing items enabling a total score to be computed**.

statement? 'I have been doing my exercises as often as prescribed.' This self-report exercise adherence data is described in Table 4.

51/76 (67%) of SPADI questionnaires were obtained at 6-months, aligning with the amber zone of the progression criteria. The SPADI outcome data are reported in Table 5.

Due to the amount of missing follow-up data for the EQ-5D 5L, analysis beyond the number of questionnaires returned was not undertaken. At 6 weeks, 17 in the physiotherapist-led exercise group had completed the EQ-5D 5L, compared to 21 in the usual care control group. At 3 months, 12 in the physiotherapist-led exercise group had completed the EQ-5D 5L, compared to 18 in the usual care control group.

At 6 months, 13 in the physiotherapist-led exercise group had completed the EQ-5D 5L, compared to 18 in the usual care control group.

Of 76 participants, 32 had not received surgery at the 6-month follow-up (42%). Of the 32 who had not received surgery at the 6-month follow-up, 17 were no longer intending to have surgery or their intention was unknown (12 PT-led ex programme, 5 usual care control).

Of the 32 who had not received surgery at the 6-month follow-up, 7 who had not received surgery had intention missing or unknown (6 physiotherapist-led exercise programme (missing 4/don't know 2); 1 usual care control (don't know 1)).

Of the 32 who had not received surgery, 20 were allocated to physiotherapist-led exercise; 12 were in usual care control.

Table 4
Participant self-report of exercise adherence.

To what extent do you agree with the following statement? 'I have been doing my exercises as often as prescribed:	6-weeks post-randomisation	3-months post-randomisation	6-months post-randomisation
Strongly agreed or agreed	14/28 (50%)	16/28 (57%)	12/28 (43%)
Neither agreed nor disagreed	2/28 (7%)	1/28 (4%)	1/28 (4%)
Disagreed or strongly disagreed	3/28 (11%)	1/28 (4%)	4/28 (14%)
Response missing	9/28 (32%)	10/28 (36%)	11/28 (39%)

Table 5
Follow-up data (SPADI only).

	All	Physiotherapist-led exercise programme	Usual Care (Waiting-list) control	Number of participants
Shoulder pain and disability (SPADI), mean (SD) at **6-weeks***	56.9 (25.0)	49.3 (23.2)	65.0 (24.8)	58 (30: 28)
Shoulder pain and disability (SPADI), mean (SD) at **3-months***	52.3 (27.4)	52.4 (31.0)	52.2 (22.9)	49 (27: 22)
Shoulder pain and disability (SPADI), mean (SD) at **6-months***	40.6 (SD25.9)	39.2 (25.2)	42.5 (27.2)	48 (27:21)

* At 6-weeks, three SPADI questionnaires had 2 or less missing items enabling a total score to be computed. Three had >2 missing items so a total score was not computed; * At 3-months, six SPADI questionnaires had 2 or less missing items enabling a total score to be computed. Seven had >2 missing items so a total score was not computed; * At 6-months, 51 SPADI questionnaires were received. Of 51, seven had 2 or less missing items enabling a total score to be computed. Three had >2 missing items so a total score was not computed.

3.1. Adverse events

Fifteen adverse events in total were reported, three of which were judged to be serious adverse events (severe scapula pain that commenced after completion of research procedures; upper gastrointestinal bleed; diagnosis of leukemia) but were not related to the physiotherapist-led exercise programme or usual care (waiting-list control) interventions.

4. Discussion

Despite the challenges of the COVID pandemic, we recruited our target of 76 participants. Based on these findings, a fully powered multicentre randomised controlled trial comparing the clinical and cost-effectiveness of a programme of physiotherapist-led exercise to usual care (waiting-list) control, for adult patients awaiting rotator cuff repair surgery in the UK NHS would be feasible. However, a future trial would require amendments to the research design. With reference to our predefined success criteria, 76/302 (25%) eligible patients were recruited; 28/38 of those allocated to the physiotherapist-led exercise programme (74%) received a minimum of an initial assessment and exercise prescription within the study period; 51/76 (67%) of SPADI questionnaires were obtained at 6-months, all aligning with the amber zone of our progression criteria.

Additionally, 32/76 (42%) of the participants had not undergone surgery at 6-months post-randomisation (20 in the physiotherapist-led exercise group versus 12 in the usual care (waiting-list) control group. Some of these participants did express intention to proceed to surgery but were still waiting. However, a proportion of participants were not intending to proceed to surgery, had already removed themselves from the waiting list, or their intention was unknown (12 physiotherapist-led exercise group versus 5 in the usual care (waiting-list) control group. Such a finding is not novel, two previous studies have evaluated the impact of treatment prescribed by a physiotherapist on the need for

shoulder surgery. One prospective cohort study in the USA, reported that 75% of patients with non-traumatic tears of the rotator cuff did not subsequently require surgery (Kuhn et al., 2013) A randomised controlled trial, in Sweden, evaluating the impact of physiotherapist-led exercise (Holmgren et al., 2012) on the need for subacromial decompression surgery for patients diagnosed with subacromial impingement syndrome, rather than rotator cuff tear, reported that 80% of participants did not subsequently require surgery.

Cautiously extrapolating the data from this POWER pilot RCT, if a programme of physiotherapist-led exercise (cost ranging from £115 to £204 per patient), delivered while patients were on the surgical waiting list, resulted in 30% of patients (12/38 participants randomised to the programme of physiotherapist-led exercise) not requiring rotator cuff repair surgery, for an outlay of £1 million to £1.8 million (8838 [number of rotator repair operations undertaken in 2018/19] x £115 to £204), there would be considerable NHS treatment cost savings per year of £9.7 to £17.0 million. If benefits to the individual patient and societal costs are added to this calculation, including out of pocket and productivity costs, this figure would rise considerably. Also, as the number of patients awaiting rotator cuff repair surgery continues to increase, this cost saving will increase further.

In addition to these cost savings, there is significant potential to enhance shared decision-making, reduce surgical regret, and reduce the need for surgery. Given these implications, a fully powered, multi-centre randomised controlled trial to compare the clinical and cost-effectiveness of a programme of physiotherapist-led exercise to usual care (waiting-list) control, for adult patients awaiting rotator cuff repair surgery is urgently needed. The findings suggest that recruitment of eligible patients would be feasible, but the overall recruitment rate was less than anticipated in two of the six participating sites. This was mainly due to patients living out of the area, and thus not eligible to receive the programme from a study physiotherapist, and surgery already undertaken or imminent. In a future trial, the reasons for this variation would need to be recognised and accounted for in recruitment projections. 28/38 participants randomised to the programme of physiotherapist-led exercise received the treatment as intended. In light of the findings from this current POWER pilot RCT, there would be a case to prioritise receipt of the physiotherapist-led exercise programme in a future trial and for this to be commenced as soon as participants are placed on the waiting list for surgery. Considering the current challenges of accessing timely physiotherapy within the UK NHS (Chartered Society of Physiotherapy, 2022), novel delivery methods and enhancements to the programme also need to be considered in light of these findings. Enhancements include the need for supported consultations to facilitate exit from the surgical pathway where this is the participants preference (Zadro et al., 2021). Finally, with reference to our progression criteria, the questionnaire return rate would need to be optimised in a future trial to minimise missing follow-up data. In this current POWER RCT, we opted to have online questionnaires only to make the trial resilient given the COVID pandemic. However, in a future trial, we could better reflect current evidence for optimising return of questionnaires by using paper and online questionnaires, according to participant preference, sequential telephone follow-up, and financial incentives (Anhang Price et al., 2022).

4.1. Limitations

This POWER RCT was undertaken in the midst of the COVID pandemic when the delivery of healthcare and research were significantly affected. The context within which a future trial would be delivered is likely to be different, but potentially less challenging. Although we have plans to amend the design of the future trial to optimise recruitment and questionnaire return rate, there are missing data in this current study which limits the certainty with which conclusions can be drawn.

5. Conclusion

From this POWER pilot randomised controlled trial, we conclude that a fully powered multi-centre randomised controlled trial is feasible. A future trial would require planning to account for variable recruitment rates between sites and the reasons for this, measures to improve treatment fidelity and enhance the content of the physiotherapist-led exercise programme, including surgical exit consultations. Methods to optimise questionnaire return rate including paper and online questionnaires, telephone follow-up and financial incentives also need to be considered.

Given the number of participants who have not undergone surgery at the 6-month follow-up point, a fully powered, randomised controlled trial to compare the clinical and cost-effectiveness of a programme of physiotherapist-led exercise to usual care (waiting-list) control for adult patients awaiting rotator cuff repair surgery is now needed to inform clinical decision-making.

Declaration of interests

We declare no conflicts of interest.

Data statement

Requests for sharing of anonymised data can be submitted via email to the lead author.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.msksp.2023.102874.

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