Exercise-therapy and education for individuals one year after anterior cruciate ligament reconstruction: a pilot randomised controlled trial

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Abstract

Background: Guided rehabilitation beyond 6-months is rare following anterior cruciate ligament reconstruction (ACLR), despite high prevalence of unacceptable symptoms and quality of life (QoL). We aimed to: i) determine the feasibility of a randomised controlled trial (RCT) evaluating the effectiveness of a physiotherapist-guided lower-limb focussed exercise-therapy intervention for individuals 1-year post-ACLR with persistent symptoms, and ii) estimate the effects of this intervention compared to a trunk-focussed intervention on knee-related QoL.

Design: Participant- and assessor-blinded, pilot feasibility RCT.

Methods: Participant eligibility criteria: i) 12–15 months post-ACLR; ii) < 87.5/100 on the Knee injury and Osteoarthritis Outcome Score (KOOS) QoL subscale; and one of: a) one-leg rise test < 22 repetitions; b) single-hop < 90% limb symmetry; or c) Anterior Knee Pain Scale < 87/100. Participants were randomised (2:1 ratio) to lower-limb focussed exercise-therapy and individualised education, or trunk-focussed exercise-therapy and standardised education. Both interventions involved eight face-to-face physiotherapy sessions over 16-weeks, to guide allocated exercise-therapy programs. Feasibility was assessed by: i) recruitment (participants/month), ii) retention (< 20% drop-out), iii) physiotherapy attendance, and iv) unsupervised exercise-therapy program adherence (> 80% of 3 sessions/week). Knee-related QoL was evaluated using the KOOS-QoL subscale and ACL-QoL questionnaire, with between-group differences compared to published minimally important difference (MID) scores (KOOS-QoL = 10 points; ACL-QoL = 12 points).

Results: 27 participants (3 participants/month; 48% men, 34 ± 12 years) were randomised. Two did not commence treatment, and two were lost to follow-up (16% drop-out). Physiotherapy attendance was > 80% for both groups but reported adherence to the unsupervised program was low (< 55% of prescribed exercises). KOOS-QoL improvement (mean ± SD) in the lower-limb focussed (23 ± 15) and trunk-focussed (16 ± 12) groups resulted in a between-group difference (mean, 95%CI) lower than the MID (7.1, -12.3 to 26.4). ACL-QoL improvement in the lower-limb focussed (20 ± 17) and trunk-focussed (22 ± 13) groups resulted in a between-group difference lower than the MID (-2.5, -18.2 to 13.2).

Conclusions: A larger-scale RCT evaluating the effectiveness of a physiotherapist-guided lower-limb focussed program for individuals 1-year after ACLR with persistent symptoms is feasible. This intervention is associated with large within-group knee-related QoL improvements, but may not be superior to a trunk-focussed intervention.

Trial Registration: Prospectively registered (ACTRN12616000564459).

Introduction

Following anterior cruciate ligament reconstruction (ACLR), clinical practice guidelines recommend postoperative rehabilitation to continue for at least 9 to 12 months, or until achievement of sport-specific strength, functional and psychological criteria(67). Yet, many patients have symptoms, muscle weakness and functional deficits that persist beyond 1-year post-ACLR (8, 50, 61, 73), which may increase the risk of reinjury, symptomatic posttraumatic osteoarthritis (OA), and worse knee-related quality of life (QoL)(13, 14, 23, 30, 48).

Approximately 50% of individuals report unacceptable knee symptoms and QoL 1 to 2 years after ACLR(35, 50). Minimal improvement occurs beyond 1 to 2 years(50, 60), and symptoms and QoL remain worse than their uninjured peers in the longer-term (> 5 years)(25, 50). Persistent symptoms at 1-year post-ACLR often co-exist with impairments in objective function, and loss of knee confidence(12, 32). Functional impairments are typically defined as a difference in performance greater than 10% between the ACLR and contralateral limb on hop testing. Persistent symptoms and functional deficits at 1-year post-ACLR increase the risk of developing short-term (< 5 years) and longer-term (5 to 10 years) symptoms, impaired knee-related QoL and OA(11, 23, 48). Therefore, the one-year postoperative milestone provides an ideal window to identify “at risk individuals” with persistent symptoms, who have ceased supervised rehabilitation and for interventions to be implemented. Physiotherapist-guided exercise-therapy and education to address persistent physical impairments and symptoms, may be important to the secondary prevention of reinjury, posttraumatic OA, and poor QoL in young adults post-ACLR(7, 17, 70).

The primary aims of this pilot study were to: i) determine the feasibility of a randomised controlled trial (RCT) evaluating the effectiveness of a physiotherapist-guided lower-limb focussed exercise-therapy intervention for individuals with persistent symptoms 1-year post-ACLR, and ii) estimate the effects of this intervention, including comparison with a trunk-focussed intervention, on knee-related QoL. We hypothesised that a fully-powered RCT would be feasible, and improvements in knee-related QoL for the lower-limb focussed intervention would be clinically meaningful and greater than the trunk-focussed intervention. Our secondary aims were to estimate the effects of this intervention compared to a trunk-focussed intervention on self-reported pain, symptoms, function, and psychological outcomes, and objective functional performance.

Methods

Study design

This double-blind (assessor and participant), pilot feasibility RCT was conducted in accordance with the National Health and Medical Research Council ethical guidelines(46), and reporting adheres to the Consolidated Standards of Reporting Trials (CONSORT) statement for pilot and feasibility studies(21). Ethical approval was gained from the La Trobe University Human Ethics Committee (HEC 16–077). The trial was prospectively registered through the Australia and New Zealand Clinical Trials Registry (ACTRN12616000564459).

Setting

All assessments and treatments were conducted at two private physiotherapy clinics in Australia, located in Hobart or Melbourne.

Participant recruitment and eligibility

Individuals who had undergone a hamstring-tendon autograft ACLR 12 to 15 months prior were recruited from five surgical lists, advertisements at La Trobe University, or via social media (December 2016 to August 2017). Individuals aged 18 to 50 years who were 12 to 15 months post-ACLR were considered eligible if they scored < 87.5/100 on the Knee injury and Osteoarthritis Outcome Score (KOOS) QoL subscale (threshold below which has been defined a symptomatic knee(22)), and met one of the following criteria; a) < 22 repetitions on the one-

leg rise test; b) single-hop < 90% limb symmetry index (LSI); or c) < 87/100 on the Anterior Knee Pain Scale(39). Exclusion criteria were: i) > 5 years between injury and ACLR; ii) subsequent injury (for which medical treatment was sought) or follow-up surgery to the ACLR knee; iii) another condition influencing daily function; iv) unable to speak or read English; and v) unable to attend eight supervised sessions.

Deviations from initial trial protocol

Participants were initially deemed ineligible if they had sustained a previous ACL or knee injury to either limb prior to their recent ACLR. After commencing recruitment, it was evident that a previous knee injury was common in those with persistent symptoms, and these individuals have an increased risk of symptomatic posttraumatic OA(72). The inclusion criteria were adjusted at the start of recruitment to include those with a previous ACL or knee injury. Hypothesis testing in a regression model was not performed as initially planned, due to the limitations of significance testing in clinical research(33), and this was not considered appropriate for a feasibility trial. Instead, the treatment effects were estimated by comparing the between-group differences in knee-related QoL to previously reported minimal important difference (MID) scores.

Procedures

Eligible participants underwent a baseline assessment with a blinded assessor (BP) and were randomised into one of two intervention groups. The same blinded assessor completed all follow-up assessments unaware of group allocation. Participant age, sex, body mass index (BMI), injury history, and previous activity level were obtained at baseline. All patient-reported outcomes (PROs) were completed via an online portal (Promptus, DS PRIMA, Melbourne, Australia).

Randomisation and blinding

Non-stratified, permuted block randomisation (random blocks of 3 or 6) occurred at a 2:1 (lower-limb focussed:trunk-focussed) ratio. The randomisation sequence was computer-generated. The administrative staff at the participating physiotherapy clinic revealed the allocation using sequentially numbered, sealed opaque envelopes. The administrative staff were blinded to block size, and entered the group allocation to the participant's clinical record for the physiotherapist. Participants were blinded to group allocation, to ensure allocation did not influence adherence, other treatment use, or increase the risk of drop-out. The physiotherapists were unable to be blinded to the allocation but were encouraged to deliver both interventions with equal enthusiasm and assertion of exercise value.

Treating physiotherapists and treatment fidelity

Treating physiotherapists were experienced (≥ 5 years treating musculoskeletal patients) in ACLR rehabilitation, and completed a 4-hour training session (led by BP) related to delivering both interventions. A manual, outlining the exercise prescription and progressions, manual treatment algorithm, education material, and trial procedures (attendance sheet, clinical notes, adherence monitoring) was provided to each physiotherapist (Additional File 1). Prescribed exercises were entered via Physitrack© smartphone application for participants to access via the participant-facing application PhysiApp© (Physitrack Ltd, London, UK).

Interventions

Participants were randomised to a lower-limb focussed or trunk-focussed exercise-therapy intervention, which were both delivered in eight face-to-face 30-minute physiotherapy sessions over 16-weeks. Both interventions are reported below according to the Template for Intervention Description and Replication (TIDieR) guidelines(34) and the Consensus on Exercise Reporting Template (CERT)(59) (Table 1).

Table 1
Summary of intervention delivery and components for both groups

What	Lower-limb focussed intervention	Trunk-focussed intervention
Who provides	Physiotherapists who have all undergone study-specific training	
How	1-to-1 face-to-face sessions to assess and progress unsupervised exercise-therapy program	
Where	*Physiotherapy sessions*: Private clinics in Hobart and Melbourne *Unsupervised exercise-therapy program*: Clinic/public gym, or home	
When & how much	*Physiotherapy 1-to-1 sessions*: 30 minutes duration, weekly for 4 weeks then every 2 to 3 weeks for 12 weeks *Unsupervised exercise-therapy program*: instructions provided via PhysiApp©, 30 to 45 minutes duration, minimum 3 sessions per week, unsupervised	
Tailoring	• Standardised but individualised lower-limb exercises (i.e. strength, power, balance), functional retraining (e.g. plyometric, agility) and cardiovascular program • Individualised education (e.g. exercise rationale, goal setting) • Passive therapy treatment algorithm if appropriate (e.g. taping)	• Standardised but individualised, non-specific trunk strengthening exercises • Optional stretching • Standardised education (e.g. rationale for trunk exercises)
	Both groups: exercises progressed based on assessment of pre-defined criteria at each session (i.e., pain, swelling, technique) and resistance training principles	
How well	Attendance at physiotherapy recorded by physiotherapists and clinic Unsupervised exercise program adherence recorded by participants in PhysiApp© smartphone app or paper diaries, and monitored by physiotherapists via Physitrack©	

Lower-limb focussed exercise-therapy intervention

The lower-limb focussed intervention included standardised (with individualised progression) lower-limb, functional and cardiovascular exercises, and individualised, ACL-specific education (Additional File 1). The protocol was informed by current evidence-based recommendations(67), and developed by the research team, two of whom regularly (weekly) treated ACLR patients (CB and RC). The lower-limb focussed exercise-therapy program targeted typical strength and functional impairments(73), and altered movement patterns(73) during sport-specific tasks related to ACL injury mechanisms (i.e., landing, and cutting). The eight areas in the exercise-program were: 1) movement retraining (e.g. landing); 2) quadriceps strength (e.g. squats); 3) balance (e.g. perturbation exercises); 4) hip-abductor strength; 5) calf strength; 6) trunk strength; 7) hip-extensor and knee-flexor strength; and 8) cardiovascular exercise (e.g. cycling, running, graded sport-specific activities). Each

of the eight areas had three or more phases of difficulty for individualised progression (Additional File 1). Physiotherapists were provided with a summary of the participant's injury history, goals, 3 to 4 priority areas, and suggested starting phases based on baseline assessment of each area. Physiotherapists could add target areas based on participant need, but it was not compulsory for all eight areas to be incorporated. Exercise progression was based on: i) good technique; ii) minimal irritability (i.e. <2/10 pain during/after and no swelling); iii) resistance training principles related to muscular strength and power(26); and iv) participant-specific goals and feedback. Strength exercises were prescribed in 3 sets of 12 repetitions (each repetition performed as 2 seconds concentric, 1 second isometric, 2 seconds eccentric), and could be progressed to a power dosage prescribed in 3 to 5 sets of 5 to 10 repetitions (< 1 second concentric, 0 isometric, 2 seconds eccentric). Treating physiotherapists were encouraged to use the face-to-face sessions to check exercise technique, and adjust loads so that participants were reaching fatigue (i.e. they could not physically perform > 2 more repetitions) after their prescribed dosage.

Trunk-focussed exercise-therapy (control) intervention

The trunk-focussed intervention was considered the control in this study, and included standardised (with individualised progression) trunk strengthening exercises, stretching and education. Physiotherapists could choose a minimum of three trunk strengthening exercises (from a maximum of five options), and each exercise had three or more phases of difficulty (Additional File 1). Exercises were prescribed according to resistance training principles; typically prescribed in 3 sets of 60 seconds (isometric), and progressed to achieve adequate fatigue (i.e., could not physically perform > 5 more seconds)(26). The trunk exercises had minimal lower-limb involvement and were not expected to impact knee-related QoL, symptoms, or function. Lower-limb and trunk stretching appropriate to the participant, could be prescribed (Additional File 1).

Unsupervised exercise-therapy program (both groups)

Participants in both groups were prescribed an unsupervised exercise-therapy program relevant to their allocation, to be completed 3 times per week, at home or in a gym, to optimise likelihood of muscular strength and power improvements(26). Physiotherapists entered participant's exercises via the Physitrack© app, for the participant to use PhysiApp© to guide exercises and record adherence on their own smartphone, tablet or computer. Paper diaries of the exercise-therapy programs were provided as required. PhysiApp© included video examples (created specifically for the trial) of correct (and incorrect) technique for each exercise (Additional File 2), and exercise dosage (e.g. number of sets/repetitions, time under tension, external load, rest time) according to resistance training and muscle adaptation guidelines(26, 63). Co-interventions were discouraged but if participants chose to receive other treatment, they recorded them on an "other treatments calendar". The trunk-focussed unsupervised program could be completed at home with minimal equipment. When gym equipment was required for the lower-limb focussed unsupervised program, gym access was provided free of charge.

Education component (both groups)

Both groups received education, including face-to-face discussion and/or provision of handouts (Additional File 2). Handouts for the lower-limb focussed group covered the following topics: i) postoperative exercise-therapy; ii) goal setting and return-to-sport criteria; iii) injury prevention; iv) psychosocial influences on recovery; and v) posttraumatic OA risk. The purpose of the education for the lower-limb focussed group was to provide informational support regarding ACL-specific topics and address common knowledge gaps regarding evidence-

based rehabilitation(2), and psychosocial support for kinesiophobia, fear of reinjury, confidence, or negative lifestyle modifications(6). For the trunk-focussed group, physiotherapists could deliver standardised education on the rationale for trunk strengthening (e.g. theoretical influence of lumbo-pelvic stability on lower-limb biomechanics), or provide handouts/ face-to-face discussion on the topics “psychosocial influences on recovery” and “posttraumatic OA risk” (Additional File 2).

Primary outcome: feasibility

Feasibility was assessed according to previously published recommendations(42).

Recruitment, adherence and retention was evaluated by: i) recruitment rate (number of participants per month); ii) proportion of eligible participants who were willing to enrol (goal: >80%); iii) physiotherapy attendance rate (goal: >80%); iv) adherence to unsupervised exercise-therapy program (goal: >80%); and v) proportion of drop-outs (goal: <20%).

Acceptability of the study protocol was assessed via the appropriateness of the inclusion criteria (eligibility rate), and acceptability of the intervention content, delivery, adherence monitoring, and barriers or facilitators to adherence. Acceptability was determined via informal interviews conducted with participants and physiotherapists (Additional File 3).

Adverse events (i.e., any injury or illness affecting ability to exercise during the trial period) were noted by the physiotherapist on a standardised recording sheet. Pain-level during the unsupervised exercise-therapy program was entered on PhysiApp by participants.

Randomisation integrity was determined by contamination between groups (reported by participant or physiotherapist), or knowledge of group allocation by the participants or assessor.

Acceptability of the outcome measures was determined by the time needed to collect the data, and completeness of the outcome measures at baseline and follow-up.

Primary outcome: knee-related QoL

The KOOS-QoL is one of the five KOOS subscales, and evaluates knee-related QoL(57). The KOOS-QoL has the highest content validity of all subscales and the greatest responsiveness in young adults following knee injury(5). The ACL-QoL was designed to assess additional domains (e.g. work-related, social and emotional) of knee-related QoL specific to a young, active ACL-injured population(44). The KOOS-QoL and ACL-QoL are converted to a total score out of 100 (0 = extreme problems; 100 = no problems), and both have established validity, reliability, and responsiveness(5, 41).

Secondary subjective outcomes

A range of PROs were assessed at baseline and follow-up. The KOOS subscales of pain, symptoms, and sport were assessed, and all combined with the KOOS-QoL, to calculate an overall $KOOS_4$ score. The KOOS individual subscales are valid, reliable and responsive following ACL injury(5). Each participant reported their (pre-injury, baseline, follow-up) participation in Level 1 (i.e. pivoting/jumping/hard cutting sports), Level 2 (i.e. pivoting/jumping sports but less intense cutting (i.e. tennis, skiing)), Level 3 sports (i.e. straight line activities (i.e. running, weight-lifting)), or were classified as Level 4 (sedentary) as per our recent observational study(10).

This classification is responsive to change after ACLR, as it includes a range of activities, not just high-risk team sports(29). Psychological readiness for return-to-sport (a common goal of ACLR), and fear of reinjury was measured by the ACL Return to Sport Index (ACL-RSI)(68). The ACL-RSI is valid, reliable and responsive to change (MIC = 19 points)(40), with higher scores associated with better self-reported symptoms and function(69). The global rating of change (GROC) on a 7-point Likert scale ("much worse" to "much better") measured separately for knee pain and knee function; and the change in proportion of patients answering "yes" to the patient acceptable symptom state (PASS) question(35) were evaluated. The GROC is valid, reliable and responsive following knee injury (36), and answering yes to "PASS" corresponds with better KOOS scores after ACL injury(35), and assists in interpretation of improvement in PROs by evaluating the concept of "feeling good" as opposed to "feeling better"(66). Several other exploratory PROs were outlined in the ANZCTR trial registration but were not included in this evaluation.

Secondary objective outcomes

Functional performance outcomes were measured at baseline and follow-up, including the single-hop (maximum distance on one hop forward)(31), side-hop (maximum number of hops over two parallel lines 40 cm apart in 30 seconds)(31), and one-leg rise test (maximum number repetitions from a standardised height)(62). We recorded the raw score (e.g. cm hopped) on the ACLR and contralateral limb, and calculated the LSI (score of ACLR knee divided by contralateral knee, multiplied by 100, expressed a percentage). The hop-tests and one-leg rise have high intra-rater reliability (ICC > 0.80) and responsiveness after knee injury(3, 31, 55).

Data analysis

All participants who completed baseline and follow-up evaluations were included in the analysis, as recommended in the CONSORT guidelines(43). Feasibility outcomes were reported descriptively. The majority (> 50%) of baseline and follow-up scores, and the change scores for the primary and secondary outcomes were normally distributed (assessed with Shapiro-Wilk's test). Therefore, within-group, and between-group differences were reported as mean ± SD, and mean and 95% confidence interval (CI), respectively. The treatment effect was considered potentially clinically meaningful if the between-group difference in change for KOOS-QoL and ACL-QoL was ≥ 10 and ≥ 12 points, respectively(41, 57). Activity level, GROC, and PASS outcomes were reported descriptively.

Results

Feasibility

80 people expressed interest in participation via response to letters from their surgeon (n = 55), or advertisements on social media and La Trobe University (n = 25) over a 9-month period. 72% (n = 57) agreed to be screened, with 47% of those screened (n = 27) deemed eligible (Fig. 1). The results of each aspect of feasibility are summarised in Table 2, with the detailed feedback provided by participants at follow-up provided in Additional File 3.

Table 2
Feasibility outcomes

	LOWER-LIMB FOCUSSED GROUP (n = 17)	TRUNK-FOCUSSED GROUP (n = 10)
Recruitment and retention		
Recruitment rate	3 participants per month	
Enrolment rate	100% completed baseline assessment, were enrolled and randomised	
Drop-out rate	n = 2 (12%)*	n = 2 (20%)**
Adherence		
Attendance at physiotherapy	Mean = 89% of intended 8 sessions	Mean = 86% of intended 8 sessions
Adherence to unsupervised exercise-therapy program	52% of sessions completed (recorded on Physitrack)	48% of sessions completed (recorded on Physitrack)
Acceptability of the study protocol		
Eligibility rate	47% of interested participants were eligible	
Acceptability of intervention to physiotherapists	Physiotherapists considered the 4-hour training workshop and supportive material sufficient, and the interventions reflective of their clinical practice. 30-minute sessions were not sufficient time to review the exercises, provide education, and complete administrative tasks (i.e. Physitrack updates).	
Acceptability of intervention to participants	Participants stated the appointment duration and frequency, and facilities were appropriate. Participants in both groups felt the interventions were credible and their program was tailored to them. One participant received co-interventions by another physiotherapist (massage).	
Barriers to attendance and adherence	Work, study and family commitments, lack of motivation, and boredom with exercises were reported as the main barriers to attendance at physiotherapy, and adherence to the unsupervised exercise-therapy program.	
Adverse Events		
Injury or illness	n = 4 (24%) unrelated to the exercise-therapy program^	Nil
Pain during/after exercise-therapy program	Pain-level for both groups during the unsupervised exercise-therapy program was on average < 2/10 on a visual analogue scale, as reported on PhysiApp.	
Randomisation integrity		

* n = 1 severe increase in knee pain, n = 1 unable to commit to requirements.

**n = 2 decided they could not commit to the trial before commencing interventions.

^n = 1 severe increase in knee pain (group fitness class); n = 2 hamstring strains (sprint training, basketball match); n = 1 ankle sprain (football training).

	LOWER-LIMB FOCUSSED GROUP (n = 17)	TRUNK-FOCUSSED GROUP (n = 10)
Integrity of blinding	Assessor unblinded for 1 participant, due to contact requesting gym membership)	1 participant (medical professional) expressed knowledge of being in the “control” group
Contamination between groups	Nil	Physiotherapists reported challenges in delivering the standardised education component for the trunk-focussed group, and often discussed ACL- and patient specific topics with participants in this group.
Acceptability of outcome measures		
Time needed to collect data	The baseline and follow-up assessments were completed in 60–90 minutes	
Completeness of PROs	All 23 participants who finished the trial completed the PROs in full, with no missing data	
Completeness of functional performance outcomes	16% (n = 4) did not complete follow-up. Two participants could not complete hop-tests, and two could not attend follow-up (overseas, work commitments)	10% (n = 1) did not complete follow-up because they could not attend (overseas)
Adherence monitoring	23 participants used PhysiApp and 2 used paper diaries. Many patients liked the accountability and motivation PhysiApp provided, and the instructional videos for exercise technique. Participants reported inconsistent use of PhysiApp to recorded unsupervised exercise adherence data due to technical issues (particularly retrospective data entry) or because they forgot to use the app as they knew their program	
* n = 1 severe increase in knee pain, n = 1 unable to commit to requirements.		
**n = 2 decided they could not commit to the trial before commencing interventions.		
^n = 1 severe increase in knee pain (group fitness class); n = 2 hamstring strains (sprint training, basketball match); n = 1 ankle sprain (football training).		

Participant characteristics

The trunk-focussed group had a higher proportion of men and a higher proportion participating in Level 1 or 2 sports pre-injury (Table 3).

Table 3
Participant characteristics at baseline

	Lower-limb focussed group (n = 17)	Trunk-focussed group (n = 10)
Age, mean ± SD years	34 ± 12	33 ± 12
Sex, no. (% male)	6 (35%)	7 (70%)
Body mass index, mean ± SD kg/m^2	24.7 ± 2.8	25.4 ± 3.8
Pre-injury activity level*, no. (%)		
Level 1 or 2	19 (53%)	10 (100%)
Level 3	6 (35%)	0 (100%)
Level 4	2 (12%)	0 (100%)
SD = standard deviation		
*According to Grindem classification system(29). Level 1 = pivoting/jumping/hard cutting sports (e.g. football), Level 2 = pivoting/jumping sports but less intense cutting (e.g. volleyball), Level 3 sports = straight line activities (e.g. running, weight-lifting), and Level 4 = sedentary.		

Primary outcome: knee-related QoL

KOOS-QoL improvement (mean ± SD) in the lower-limb focussed (23 ± 15) and trunk-focussed (16 ± 12) groups resulted in a between-group difference (mean, 95%CI) less than the MID (7.1, -12.3 to 26.4) (Table 4). The ACL-QoL improvement (mean ± SD) in the lower-limb focussed intervention (20 ± 17) and trunk-focussed intervention (22 ± 13) resulted in a mean (95%CI) between-group difference less than the MID (-2.5, -18.2, 13.2) points. There were large individual variations in change scores for both groups (Fig. 2).

Table 4
Primary and secondary outcomes at baseline (1-year post-ACLR, pre-intervention) and follow-up (after 16-week intervention)

	Lower-limb focussed intervention (n = 15)			Trunk-focussed intervention (n = 8)			Lower-limb vs trunk	Previously published MID values
	Baseline mean ± SD	Follow-up^ mean ± SD	Change mean ± SD	Baseline mean ± SD	Follow-up^ mean ± SD	Change mean ± SD	mean difference in change* (95%CI)	
Primary: knee-related QoL								
KOOS-QoL	39 ± 20	62 ± 23	23 ± 25	52 ± 14	67 ± 19	16 ± 12	7.1 (-12.3 to 26.4)	8 to 10 points(57)
ACL-QoL	45 ± 20	64 ± 20	20 ± 17	56 ± 9	78 ± 16	22 ± 13	-2.5 (-18.2 to 13.2)	12 points(41)
Secondary outcomes								
KOOS-Symptoms	68 ± 23	74 ± 19	7 ± 17	81 ± 9	90 ± 9	9 ± 7	-2.0 (-15.7 to 11.6)	8 to 10 points(57)
KOOS-Pain	77 ± 15	86 ± 12	9 ± 14	90 ± 7	92 ± 8	2 ± 7	6.7 (-4.0 to 17.9)	8 to 10 points(57)
KOOS-Sport	57 ± 24	77 ± 22	20 ± 25	76 ± 1	83 ± 22	8 ± 13	12.1 (-7.9 to 32.0)	8 to 10 points(57)
$KOOS_4$	60 ± 17	75 ± 17	15 ± 18	75 ± 9	83 ± 14	9 ± 7	5.9 (-7.9 to 19.8)	8 to 10 points(57)
ACL-RSI	36 ± 18	53 ± 22	17 ± 18	41 ± 18	67 ± 24	26 ± 22	-9.2 (-27.2 to 8.7)	19 points(40)
Single-hop								
ACLR (cm)	65 ± 42	97 ± 33	33 ± 34	108 ± 39	115 ± 42	8 ± 9	24.1 (-5.9 to 54.1)	14 cm(38, 55)
Contralateral (cm)	93 ± 30	106 ± 32	14 ± 18	116 ± 25	120 ± 34	4 ± 15	9.6 (-8.9 to 28.2)	14 cm(38, 55)
LSI (%)	59 ± 38	88 ± 11	29 ± 37	90 ± 21	94 ± 12	4 ± 10	15.5 (-27.7 to 58.7)	8%(38, 55)
Side-hop								
ACLR (reps)	8 ± 8	16 ± 12	9 ± 9	20 ± 13	29 ± 19	9 ± 8	-0.6 (-9.4 to 8.7)	11 reps(38, 55)

	Lower-limb focussed intervention (n = 15)			Trunk-focussed intervention (n = 8)			Lower-limb vs trunk	Previously published MID values
	Baseline mean ± SD	Follow-up^ mean ± SD	Change mean ± SD	Baseline mean ± SD	Follow-up^ mean ± SD	Change mean ± SD	mean difference in change* (95%CI)	
Contralateral (reps)	9 ± 9	17 ± 12	8 ± 10	23 ± 16	31 ± 21	9 ± 15	-0.5 (-13.4 to 12.2)	11 reps(38, 55)
LSI (%)[a]	71 ± 42	82 ± 29	11 ± 28	73 ± 13	94 ± 14	21 ± 18	-10.4 (-43.1 to 22.2)	~ 10%(38, 55)
One-leg rise								
ACLR (reps)	17 ± 16	33 ± 15	17 ± 14	27 ± 19	34 ± 20	7 ± 11	9.9 (-4.1 to 23.9)	Not available
Contralateral (reps)	25 ± 19	35 ± 15	10 ± 14	31 ± 15	34 ± 15	4 ± 7	6.4 (-6.5 to 19.3)	Not available
LSI (%)[b]	67 ± 57	98 ± 9	31 ± 54	68 ± 32	83 ± 47	16 ± 32	15.7 (-40 to 71.5)	Not available
ACLR = anterior cruciate ligament reconstructed limb; ACL-RSI = ACL Return to Sport Index; ACL-QoL = Anterior Cruciate Ligament Quality of Life questionnaire; CI = confidence interval; KOOS = Knee injury and Osteoarthritis Outcome Score; LSI = limb symmetry index; MID = minimal important difference; SD = standard deviation; QoL = quality of life.								
* Positive value indicates between-group differences are in favour of the lower-limb focussed group.								
^n = 3 participants did not complete functional performance follow-up (n = 3 could not attend due to being overseas, or work commitments). An additional 2 participants did not complete the single-hop and side-hop tests as they were recovering from adverse events (n = 1 hamstring strain and n = 1 ankle sprain).								
[a] n = 3 not included for LSI calculation at baseline (3 in lower-limb focussed), and n = 3 not included at follow-up (2 in lower-limb focussed, 1 in trunk-focussed), as unable to perform a valid score on either limb.								
[b] n = 5 not included for LSI calculation at baseline (3 in lower-limb focussed group and 2 in trunk-focussed group), and n = 1 (in trunk-focussed group) not included at follow-up, as unable to perform a valid score on either limb.								

Secondary subjective outcomes

The lower-limb focussed group had greater improvements than the trunk-focussed group for KOOS-Pain, KOOS-Sport, and $KOOS_4$ (Table 4), and this change exceeded the MID for KOOS-Sport. The lower-limb focussed group had a 27% increase in Level 3 activities (5% decrease in the trunk-focussed group), with many participants in this group who were previously sedentary commencing running and strength-training. Participation in Level 1 or 2 sports was unchanged in both groups. Improvements for the ACL-RSI in the lower-limb focused group (17 points) and trunk-focussed group (26 points) both exceeded the MIC (19 points)(40) (Table 4). GROC outcomes resulted in at least “better” ratings in 87% for knee function and 87% for knee pain in the lower-limb focussed group, compared to 50% and 75% respectively in the trunk-focussed group. Satisfaction (PASS question) with

current knee function improved in the lower-limb focussed group from 27–67%, but remained the same in the trunk-focussed group, being 63% at baseline and follow up.

Secondary objective outcomes

Greater improvement in single-hop and one-leg rise occurred in the lower-limb focussed group compared to the trunk-focussed group for ACLR and contralateral limbs, and LSI (Table 4). The between-group differences for the single-hop ACLR limb performance and the LSI exceeded the reported MID (Table 4). Additional File 4 demonstrates the proportion of participants who have improvements greater than the MID, and highlights the large individual variation in change in functional performance in both groups.

Discussion

The results of this study suggest a future large-scale RCT evaluating the effectiveness of a physiotherapist-guided lower-limb focussed exercise-therapy and education intervention for young adults who have persistent symptoms 1-year post-ACLR is feasible. Potential effectiveness of this intervention is indicated by clinically meaningful within-group improvements in knee-related QoL, and greater improvements compared with the control (trunk-focussed intervention) for self-reported function (KOOS-Sport, GROC), satisfaction (PASS), and objective functional performance (single-hop and one-leg rise). Given many patients cease rehabilitation within six months(20), our results provide clinicians and patients with impetus to continue physiotherapist-guided interventions for individuals with persistent symptoms one year after ACLR.

Feasibility: recruitment, physiotherapy attendance and retention

Of those screened, almost half (47%) were eligible, and we achieved a modest recruitment rate (3 per month). For a large-scale RCT, the number of participating surgeons (and study advertising) would need to be increased, which is possible due to the large number of ACLRs performed worldwide each year(45). Although all eligible participants were willing to enrol, two participants did not commence the intervention, and two others dropped out during the intervention, resulting in an overall drop-out rate of 16%, which is considered acceptable(1, 37). Physiotherapy attendance was high (86–89%), which is similar to previous physiotherapist-guided exercise-therapy RCTs (> 80%) for lower-limb musculoskeletal conditions in young adults(1, 37). Suggestions during feedback from drop-outs and those who attended less than 80% of study appointments (n = 5) aligns with previous reported strategies to maintain attendance – i.e. increasing appointment availability after hours, exercise variety, and strategies to increase motivation(53). These strategies, in addition to consideration of telehealth appointments, and multiple clinic locations might reduce drop-outs and improve attendance in future trials. Two participants sustained hamstring strains in their ACLR limb, and one sustained an ankle sprain as they returned to sporting activities. Graded return to high-speed running protocols should be emphasised in future trials to reduce soft tissue injury risk, especially given ACL injury is a well-recognised risk factor for hamstring strain(28).

Feasibility: adherence to the unsupervised exercise-therapy program

According to Physitrack© adherence data, only half of the prescribed unsupervised exercise-therapy program sessions were completed. However, these data are likely to under-estimate true exercise adherence in this trial, as participants reported inconsistently entering their adherence data in Physiapp© due to technical difficulties, and rarely using the app once familiar with the exercises. Regardless of true adherence rates, participants did report typical barriers to exercise adherence(53, 65), including other commitments (work, study and family), and reduced motivation. Exercise adherence rates were lower than previous reports for rehabilitation during the first 6-months following ACLR (75–80%)(4, 54). This may reflect the burden of exercise-therapy on participants who have already endured unsuccessful rehabilitation with the physical, mental and time commitment it entails. Strategies to increase adherence (to the unsupervised exercise-therapy program and monitoring system) may include goal setting(71), incentivisation, supervised group classes, or alternate exercise options (e.g. non-gym based)(27). Personalised adherence monitoring data collection methods, including paper diaries, email or text questionnaires, and strategies to maintain engagment with apps (e.g. positive reinforcement, benchmarking) should be considered.

Treatment effect: knee-related QoL

Both the lower-limb and trunk-focussed interventions were associated with clinically meaningful (> MID) improvements in knee-related QoL, and the mean between-group differences for KOOS-QoL (7 points) and ACL-QoL (3 points) did not meet clinically meaningful thresholds(41, 57). Our results are similar to the ACL-SPORTS trial, which compared 10 sessions of strength, agility, and plyometric program with perturbation training, versus 10 sessions of the same program without perturbation training, at 6-months post-ACLR(1). Specifically, they reported a meaningful within-group change on the KOOS-Sport and KOOS-QoL (8 to 9 points) and minimal (< 2 points) between-group differences(1).

The small between-group differences in our study were possibly due to the large knee-related QoL improvements in the control (trunk-focussed) group. Improving trunk strength and endurance may have also resulted in a perceived improved performance in sport and work related activities, resulting in better QoL. Improvements in knee-related QoL may be more strongly influenced by education (provided in both groups), and less influenced by specific exercises in the lower-limb or trunk-focussed groups. In both groups, physiotherapists were able to educate participants and address psychological factors (e.g. kinesiophobia, fear, confidence), which are known determinants of adherence, recovery and self-reported outcomes after sports-related knee injury(27, 65). Fewer prescribed exercises in trunk-focussed group may provide greater time to provide educational and psychological support during the 1-to-1 sessions. The physiotherapists reported discussing patient and ACL-specific topics with the trunk-focussed participants, although directed not to do so in the study protocol. Future RCTs may consider evaluating the effects of a lower-limb focussed exercise-therapy with and without education, or comparing lower-limb focussed exercise-therapy and education (similar to the current study) with a comparator that better reflects usual care (e.g. self-directed education and exercise).

The small between-group differences also indicate that our lower-limb focussed intervention could be improved to deliver greater improvements in knee-related QoL. The KOOS-QoL scores remained lower than uninjured normative values(47), satisfaction with knee function was less than 70% in the lower-limb focussed group at follow-up, and side-hop improvements were small (< MID)(38, 55). Our low functioning participants may not have had sufficient time to progress to multidirectional plyometric exercises and improve function to an

advanced level acceptable for return to jumping and pivoting sports. A longer intervention, with more frequent supervised sessions (either 1-to-1 or group exercise classes) may provide further opportunity for education, exercise technique feedback and progression. Given the potential benefits, dedicated time for education in 1-to-1 sessions, or during group exercise classes, similar to other effective exercise and education interventions (e.g. GLA:D® program for older individuals with knee OA(58)) should be considered. More time to discuss patient-specific goals, exercise preferences, and assess progress may enable exercise prescription to be individualised, and increase motivation and adherence.

Treatment effect: secondary subjective outcomes

A number of secondary PROs displayed more improvement in the lower-limb focussed group, including the KOOS-Sport subscale, GROC and PASS. The lower-limb focussed group had a 27% increase in people participating in Level 3 activities who were previously sedentary, as many participants commenced strength-training and running. Ongoing strength-training and running participation may be important for future knee-joint and overall health(16, 18), given a less active lifestyle and weight gain (i.e., increased BMI) is common after ACL injury(64), which may increase the risk of early OA progression(51, 70). Combined, the improvements in satisfaction, self-reported function and physical activity may reduce future healthcare use (e.g. pain medication, surgery).

Treatment effect: secondary objective outcomes performance

Clinically meaningful between-group differences favouring the lower-limb focussed group were observed for the single-hop and one-leg rise ACLR limb performance (24 cm and 10 repetitions, respectively) and LSI (16% and 16%, respectively). While the one-leg rise has no MID, a difference of 10 repetitions, and 16% on the LSI is considered clinically meaningful for other tests(38, 55). In the lower-limb focussed group, the LSI improvements for the single-hop (29%) were larger than those in the ACL-SPORTS trial (10%) with a similar intervention(1). This larger improvement we observed may be due the lower baseline function of our participants compared to the ACL-SPORTS trial where all participants had already achieved ≥ 80% LSI, begun running, and had no pain(1).

Our previous *observational* study(49) indicates that LSI improvement can reflect worsening contralateral limb function, rather than improved ACLR limb function. Therefore, it is important to note that in the current interventional study, LSI improvements occurred alongside clinically meaningful improvements in both limbs, indicating the increase in LSI was due to *greater* improvement in the ACLR limb. Given poor function on hop-tests at 1-year post-ACLR may be associated with an increased risk of future OA(48, 52) and reinjury(30), addressing persisent functional deficits may be an important step forward in secondary prevention of posttraumatic knee OA. Considering the influence of the lower-limb focussed intervention in this study on OA risk factors, future larger-scale trials should consider longer-term follow-up and include imaging assessment to determine structural joint trajectory and relationship with symptoms(15), physical activity monitoring, healthcare utilisation, and cost-effectiveness evaluation.

Limitations

Given the small sample size, the estimated treatment effects in this study should not be intepreted as supporting one intervention over the other. A limitation of the current study is that the lower-limb focussed group started with worse QoL compared to the trunk-focussed group (Table 4). However, improvements in both groups were clinically meaningful, and no participants achieved the maximum KOOS-QoL and ACL-QoL score. Consistent with other ACLR cohorts(56) and RCTs(1), there was large individual variation in both groups for baseline scores (i.e., SDs) and changes between baseline and follow-up for all primary outcomes (Fig. 2), affecting our ability to identify between-group treatment effects. Future large-scale RCTs, including stratification for factors that may affect baseline status or treatment response (e.g. sex)(19) are now needed. We did not assess lower-limb or trunk strength so we cannot indicate if the improvements in functional performance or PROs were mediated by strength increases. Future trials should include muscle capacity (strength, power) testing, to also ensure that adequate loading and progression has occurred to stimulate muscle capacity improvements(9). Many participants (> 50%) had a surgical review during the trial, and were given “clearance for return-to-sport”, which may have improved PROs or physical activity in both groups. Future trials should regularly (weekly or monthly) monitor all types of physical activity completed during the intervention period. Despite these limitations, this was a pilot feasibility study, with the purpose of recognizing improvements that could be made to the study design and protocols for future trials.

Conclusion

A future large-scale trial evaluating the effectiveness of a physiotherapist-guided lower-limb focussed exercise-therapy and education program for individuals with persistent symptoms at 1-year post-ACLR is feasible. This intervention is associated with large within-group knee-related QoL improvements but these improvements were not superior to those resulting from a trunk-focussed intervention. Between-group differences for improvement in self-reported knee function (KOOS-Sport, GROC), satisfaction (PASS), and objective functional performance were clinically meaningful, favouring the lower-limb focussed group. Improved subjective and objective function may be important to longer-term prevention and management of posttraumatic knee OA following ACLR, but a fully powered RCT is needed to provide definitive conclusions.

Abbreviations

ACL: anterior cruciate ligament; ACLR: anterior cruciate ligament reconstruction; ACL-QoL: ACL quality of life survey; ACL-RSI = ACL Return to Sport Index; BMI: body mass index; CI: confidence interval; CERT: Consensus on Exercise Reporting Template; CONSORT: CONsolidated Standards of Reporting Trials; GROC: global rating of change; KOOS: Knee injury and Osteoarthritis Outcome Score; LSI: limb symmetry index; MID: minimal important difference; OA: osteoarthritis; PASS = patient acceptable symptom state; PROs = patient reported outcomes; RCT: randomised controlled trial; SD: standard deviation; TIDieR: Template for Intervention Description and Replication guidelines: QoL: quality of life;

Declarations

Ethics approval and consent

Ethical approval was gained through the La Trobe University Human Ethics Committee (HEC 16–077) and all participants were provided with a written participant information statement and completed written informed consent prior to participating.

Consent for publication

Not applicable.

Availability of data and materials

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Competing interests

The authors declare they have no competing interests.

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Author contributions

BP, AC, KC conceived and designed the study, with input from CB and RC. BP recruited participants and collected the pre- and post-intervention data. BP, AC, CB conducted the statistical analysis and interpretation of data, with input from KC. BP drafted the manuscript with input from AC, CB, RC, and KC. All authors read and approved the final manuscript.

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Supplementary Information

Additional File 1

Physiotherapist manual: exercise-therapy and education protocols.pdf

Additional File 2

Lower-limb focussed and trunk-focussed exercise-therapy and education interventions website https://task.trekeducation.org/

Additional File 3

Feedback from study participants on exercise program content, structure and delivery methods.pdf

Additional File 4

Secondary objective outcomes additional detail.pdf

Figures

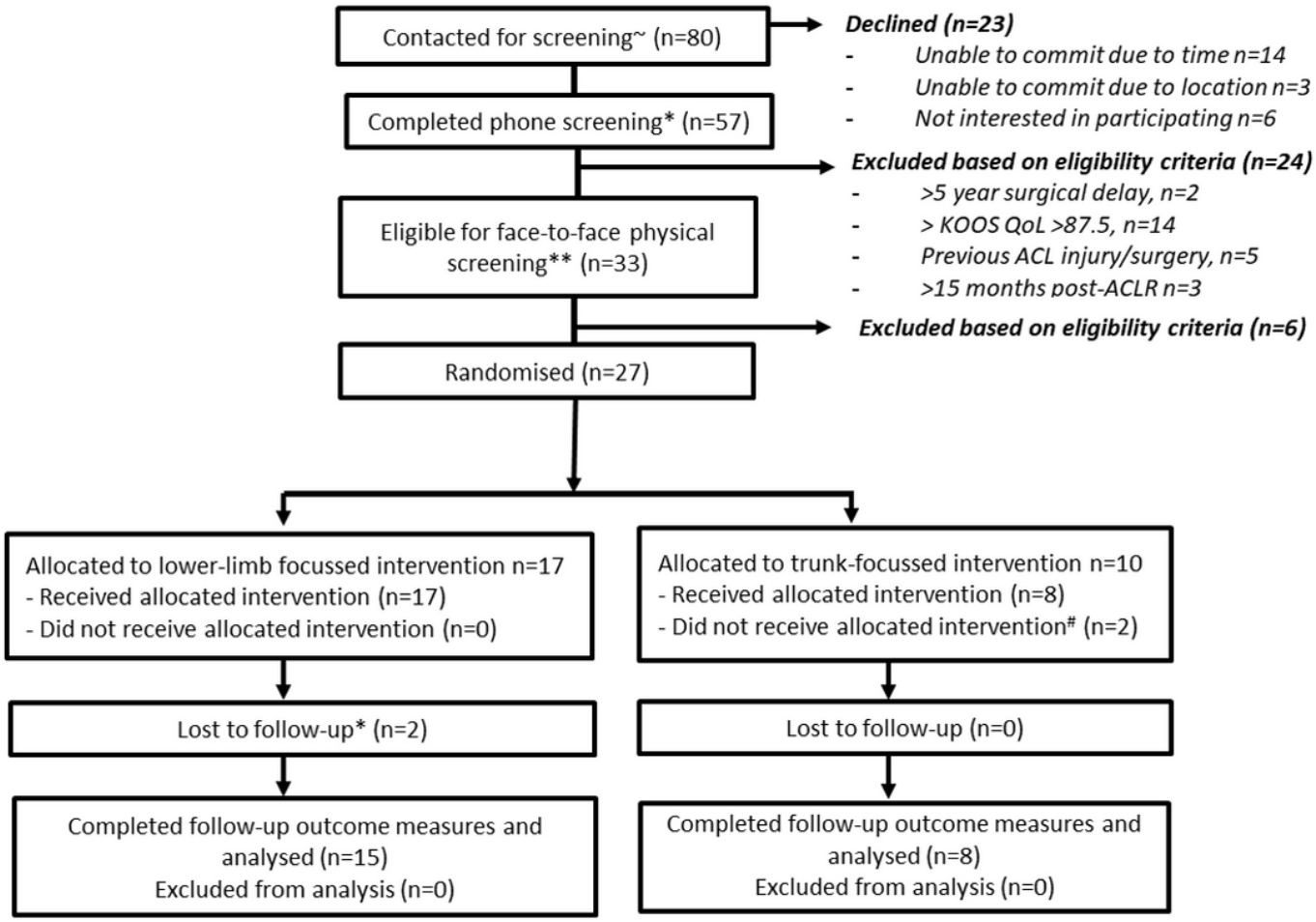

Figure 1

Flow of participants through the study KOOS-QoL=Knee injury and Osteoarthritis Outcome Score Quality of Life subscale; ACL=anterior cruciate ligament; ACLR=anterior cruciate ligament reconstruction # n=2 unable to find appointments to suit work/study commitments *n=1 severe increase in knee pain, n=1 unable to commit to requirements.

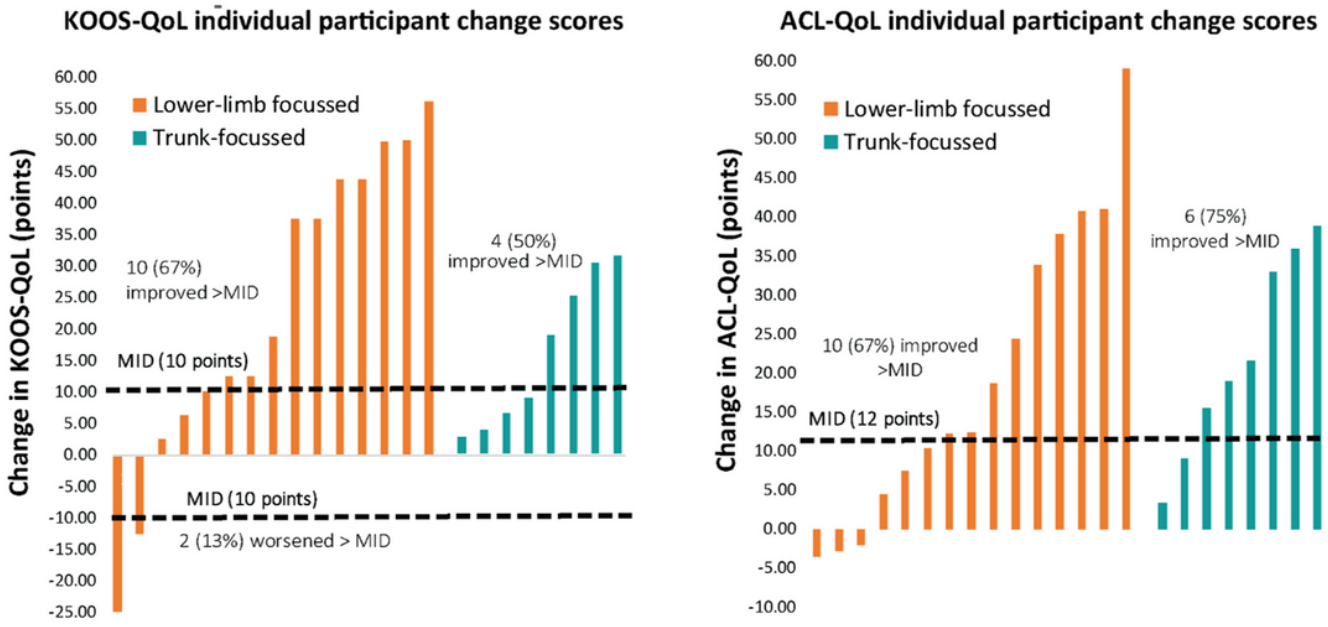

Figure 2

Individual participant changes for the KOOS-QoL and ACL-QOL KOOS=Knee injury and Osteoarthritis Outcome Score; ACL-QoL=Anterior Cruciate Ligament Quality of Life survey; MID=minimal important difference for KOOS-QoL (10 points) (57) and ACL-QOL (12 points) (41).

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- AdditionalFile1Physiotherapymanual.pdf
- AdditionalFile3Participantfeedback.pdf
- AdditionalFile4Secondaryoutcomeadditionaldetail.pdf