BMJ Open

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Journal:	*BMJ Open*
Manuscript ID	bmjopen-2022-068279
Article Type:	Protocol
Date Submitted by the Author:	13-Sep-2022
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Keywords:	Knee < ORTHOPAEDIC & TRAUMA SURGERY, REHABILITATION MEDICINE, SPORTS MEDICINE

SUpervised exercise-therapy and Patient Education Rehabilitation (SUPER) versus minimal intervention for young adults at risk of knee osteoarthritis after ACL reconstruction: SUPER-Knee randomised controlled trial protocol

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Word count: 4,335

ABSTRACT

Introduction: Anterior cruciate ligament injury and reconstruction (ACLR) is often associated with pain, functional loss, poor quality of life and accelerated knee osteoarthritis development. The effectiveness of interventions to enhance outcomes for those at high risk of early-onset osteoarthritis is unknown. This study will investigate if SUpervised exercise-therapy and Patient Education Rehabilitation (SUPER) is superior to a minimal intervention control for improving pain, function and quality of life in young adults with ongoing symptoms following ACLR.

Methods and analysis: The SUPER-Knee study is a parallel-group, assessor-blinded, randomised controlled trial. Following baseline assessment, 184 participants aged 18-40 years and 9-36 months post-ACLR with ongoing symptoms will be randomly allocated to one of two treatment groups (1:1 ratio). Ongoing symptoms will be defined as a mean score of <80/100 from four Knee injury and Osteoarthritis Outcome Score ($KOOS_4$) subscales covering pain, symptoms, function in sports and recreational activities and knee-related quality of life. Participants randomised to SUPER will receive a 4-month individualised, physiotherapist-supervised strengthening and neuromuscular programme with education. Participants randomised to minimal intervention (i.e., control group) will receive a printed best-practice guide for completing neuromuscular and strengthening exercises following ACLR. The primary outcome will be change in the $KOOS_4$ from baseline to 4 months with a secondary endpoint at 12 months. Secondary outcomes include change in individual KOOS subscale scores, patient-perceived improvement, health-related quality of life, kinesiophobia, physical activity, thigh muscle strength, knee function and knee cartilage morphology (i.e., lesions, thickness) and composition (T2 mapping) on magnetic resonance imaging. Blinded intention-to-treat analyses will be performed. Findings will also inform cost-effectiveness analyses.

Ethics and dissemination: This study is approved by the La Trobe University and Alfred Hospital

Ethics Committees. Results will be presented in peer-reviewed journals and at international conferences.

Trial registration: ACTRN12620001164987

Keywords:

anterior cruciate ligament, rehabilitation, osteoarthritis, knee, physiotherapy, exercise.

Strengths and limitations of this study

- This will be the first sufficiently powered trial to evaluate the effectiveness of exercise-therapy and education on improving the symptomatic burden in young adults at risk of OA following a traumatic knee injury.
- The exercise-therapy programme was developed and piloted with patients and clinicians, aligns with American College of Sports Medicine (ACSM) recommendations, and is described based on the Consensus on Exercise Reporting Template (CERT).
- Evaluating change from baseline to 4 months (primary endpoint) and 12 months will facilitate longer-term effectiveness evaluation of exercise-therapy and education.
- This trial will evaluate both the illness (i.e., symptoms) and disease (i.e., structure) of OA and include cost-effectiveness analysis.
- While outcome assessors are blinded to group allocation and physiotherapists delivering the intervention are blinded to the control intervention, owing to the type of interventions, blinding of participants is not possible.

INTRODUCTION

Anterior cruciate ligament (ACL) rupture is one of the most common serious knee injuries in young, healthy people participating in sports involving jumping, pivoting and cutting activities[1]. Treatment success is often judged on a timely return to sport[2]. Yet, 55% do not return to competitive sport[3], and half will develop post-traumatic knee osteoarthritis (OA), unacceptable persistent pain, functional loss and poor quality of life before the age of 40 years[4-7]. Occupational and carer responsibilities in many of these young adults also creates formidable societal and economic burden.

Osteoarthritis can be characterised by symptoms such as pain and functional limitations and/or structural joint changes seen on imaging. Both symptoms and structural changes are common within the first decade after ACL reconstruction (ACLR), yet they are often discordant[5 8]. International government-endorsed OA initiatives recommend evaluating symptoms and structure in OA clinical trials to address the heterogeneity of the disease[9].

Identifying interventions that can improve knee-related symptoms and prevent or slow structural changes in young adults following ACLR is an international priority[10]. Exercise-therapy improves pain and function in older populations with primary (non-traumatic) knee OA[11], but effective treatments to improve structure (i.e., disease-modifying interventions) have thus far proved elusive[12]. Secondary prevention strategies for those with early manifestations (or at high risk) of OA, such as following ACLR, offer potential to alter the OA trajectory[13]. Targeted exercise-therapy might slow structural worsening[14], with preliminary studies reporting improved knee cartilage composition in people at risk of OA (post-meniscectomy)[15] and with non-traumatic early OA over 4 and 12 months, respectively[16 17].

People who report inadequate recovery (ongoing symptoms and impaired function) one year after ACLR are likely to have worsening symptoms and rapidly deteriorating joint structure in the future[18-20]. These young adults with inadequate recovery urgently need treatment options to alter their OA

trajectory. Our feasibility study indicated that a full-scale randomised controlled trial (RCT) evaluating a physiotherapist-led, exercise-therapy and education programme for young adults with ongoing symptoms approximately one year after ACLR (i.e., when no further improvement is likely without treatment) is feasible and likely associated with a clinically worthwhile effect for pain, function and quality of life[21].

The primary aim of this RCT is to estimate the average effect of SUpervised exercise-therapy and Patient Education Rehabilitation (SUPER) compared to a minimal intervention control on knee-related pain, function and quality of life in young adults with ongoing symptoms at high risk of early-onset knee OA 9-36 months after ACLR. We hypothesise that the SUPER intervention will result in greater improvements in knee-related pain, symptoms, function and quality of life after 4 months (primary endpoint) and 12 months (secondary endpoint) compared to a minimal intervention control. Secondary aims are to assess 4- and 12-month effectiveness of SUPER on: i) self-reported global rating of change (GROC) and achievement of acceptable symptoms; ii) health-related quality of life; iii) physical activity; iv) kinesiophobia; v) thigh muscle strength and function; and vi) change in knee cartilage health. Intervention and healthcare resource use will also be recorded to inform economic evaluation.

METHODS AND ANALYSIS

Study design

This study protocol describes a pragmatic, parallel-group assessor-blinded RCT conforming to the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) statement[22]. Reporting of the completed RCT will conform to the Consolidated Standards of Reporting Trials (CONSORT) statement for reporting RCTs[23] in conjunction with the Template for Intervention Description and Replication (TiDieR)[24], and the Consensus on Exercise Reporting Template (CERT) guidelines[25]. The trial

will be conducted at a single university site (La Trobe University) in Melbourne, Australia with enrolment planned to occur over three years (2021-2023) and 12-month follow-up completed in 2024. The primary endpoint will be at 4 months, with additional follow-up at a minimum of 12 months (further longer-term follow-up dependent on funding). The study was prospectively registered on the Australian & New Zealand Clinical Trial Registry (ACTRN12620001164987).

Participants

One hundred and eighty-four young adults fulfilling the eligibility criteria (table 1) will be included.

Table 1. Eligibility criteria

Inclusion criteria	Exclusion criteria
Aged 18-40 years at the time of ACLR	Synthetic ACLR graft
9-36 months following ACLR	Concomitant intra-articular knee fracture
Symptomatic ACLR knee: mean score of <80/100 from four Knee injury and OA Outcome Score ($KOOS_4$) subscales covering pain, symptoms, function in sports/recreation and quality of life	Planning to relocate interstate/internationally in following 12 months or unable to commit to study assessments
	Knee re-injury, surgery or injection in past 3 months (either knee)
Willing and able to participate in exercise-therapy 2-3 times per week for at least 4 months	Undertaken rehabilitation in past 6 weeks (for conditions affecting either knee)
	Contraindications to MRI
	Planning knee surgery in following 12 months (e.g., graft rupture, cyclops lesion (localised anterior arthrofibrosis) on MRI)
	Other reasons for exclusion (health condition affecting physical function, mentally unable to participate, pregnancy, unable to understand English, etc)

ACLR, anterior cruciate ligament reconstruction; MRI, magnetic resonance imaging

Recruitment procedure

Trial flow is outlined in figure 1. Participants will be recruited from approximately 15 collaborating private orthopaedic surgeons and eight public hospital sites in Victoria, Australia. Consistent with our pilot work[26 27], potentially eligible participants (i.e., individuals with an ACLR from our network of

collaborating private orthopaedic surgeons or public hospitals) will be mailed study information inviting them to contact a member of the research team. Additional participants will be recruited from the general community via advertisements in local newspapers, community magazines and newsletters (e.g., university staff bulletins, sports club newsletters), posters in the community and social media.

Volunteers responding to the invitation letter or advertisements will be screened for eligibility using a three-stage process. Firstly, screening questions will be asked via telephone or e-mail. Secondly, potentially suitable volunteers will be sent the Knee injury and OA Outcome Score (KOOS) questionnaire electronically (or hard copy if preferred) to confirm symptomatic eligibility. Thirdly, baseline magnetic resonance imaging (MRI) scans will be assessed to confirm the absence of any pathology potentially necessitating surgery (e.g., graft rupture, symptomatic cyclops lesion).

---FIGURE 1 HERE---

Randomisation procedure, concealment of allocation and blinding

Eligible, willing and consenting volunteers will be randomised to the SUPER or control group after baseline assessment, commencing as soon as possible. A computer-generated randomisation schedule has been developed *a priori* by an independent statistician in random permuted blocks of 4-8 to maintain a periodic allocation ratio of 1:1. To ensure concealed allocation, the randomisation schedule will be stored electronically in the secure Research Electronic Data Capture (REDCap) system and only accessible to an unblinded researcher once baseline measures have been obtained. Investigators conducting study assessments will be blind to group allocation. As the primary outcome is self-reported, participants are considered assessors; therefore, participants (and thus assessors) will be blinded to previous scores. Physiotherapists and participants cannot be blinded to group allocation owing to the type of interventions. An independent statistician, blinded to group allocation, will

perform the primary RCT analysis. To reduce risk of interpretation bias, blinded results from the analyses (Group A compared with Group B) will be presented to all authors, who will agree on two alternative written interpretations before the data manager unblinds the randomisation code.[28]

Interventions

Supervised exercise-therapy and Patient Education Rehabilitation (SUPER)

Participants allocated to SUPER will participate in a supervised exercise programme, developed based on best available evidence for patients with ACLR and other knee injuries including OA[29-31], and with input from patients and experienced physiotherapists. An overview of the SUPER programme aligning to the CERT guidelines is contained in Supplementary File 1 and summarised as per TIDieR guidelines in table 2. The SUPER intervention aims to increase lower-limb muscle strength, endurance and power, functional performance and neuromuscular control, increase understanding of knee health, facilitate return to desired sports activity and enhance physical activity. Registered physiotherapists with ≥3 years of experience treating patients following ACLR will deliver SUPER in community settings following a 4-hour training workshop supplemented with three hours of online webinars. To minimise participant travel burden, study physiotherapists will be located at 12-14 private physiotherapy clinics across greater Melbourne and regional Victoria.

SUPER is divided into two phases.

Phase 1: 0-4 months. Participants will be provided with details of the SUPER intervention verbally and via an intervention handbook detailing all exercises and an exercise logbook, and provided access to videos of all exercises. Participants will complete their exercise programme 2-3 times per week in Phase 1, made up of 1-2 weekly supervised sessions and 1-2 weekly unsupervised sessions at a gym or home (total 2-3 weekly sessions) (table 2). Participants/physiotherapists will also have the option of a second opinion by a member of our clinical expert physiotherapy team if SUPER is failing to facilitate

improvement (either at 2- or 4-months post-baseline). Second opinion will provide assessment and guidance on exercise-therapy and patient education needs.

Phase 2: (5-12 months). The intervention provided in Phase 2 will depend on whether the following predefined criteria are met at the 4-month follow-up assessment: participant's goals are met, participant satisfied with current symptoms/function and GROC reported as at least 'better').

For participants meeting all criteria, Phase 2 will involve ongoing independent exercise-therapy sessions (approximately 30-60 minutes duration, 2-3 x per week at a gym or home). Participants may request a physiotherapy booster session if they become unsure about continuing self-management or exercise-therapy or pre-defined criteria are no longer met. Booster sessions can continue once per week and will focus on the priority exercises and discussion of self-management strategies.

Participants not meeting all criteria at the end of Phase 1 will be offered ongoing once per week supervised exercise-therapy in Phase 2. Once all criteria are met, participants will continue unsupervised exercise-therapy sessions at a gym or home with physiotherapy booster sessions as required (as per above criteria). All participants will be offered a membership to a local gym to encourage unsupervised exercise-therapy during Phase 2. An additional booster session with the treating physios will occur at 8- and 11-months post-baseline.

Exercise-therapy will be tailored to each participant to match their individual preferences, goals and clinical presentation (e.g., muscle strength, pain severity, and personal, sporting, work and functional needs). The exercise-therapy programme consists of five "priority" exercises and four optional exercises (table 2, Supplementary File 2). The total number of exercises prescribed (maximum number of nine) will depend on the participant's available time and willingness, and physiotherapist clinical reasoning – but will always include the five "priority" exercises.

Each exercise has 3-6 levels of difficulty. Physiotherapists will supervise and progress exercises based on defined criteria guided by American College of Sports Medicine strength training principles[32] and perceived difficulty using rating of perceived exertion and minimal pain (e.g., <3/10 on numerical pain scale) (details in Supplementary File 1).

Patient education was co-designed with experienced physiotherapists and pilot study participants[21] and aims to support the exercise-therapy programme and build motivation and capability to sustain the exercises during and after the initial 4-month supervised phase (table 2). Individualised health education regarding expectations and goals, exercise principles, improving adherence, pain/fear management, long-term outcomes, weight control, and appropriate physical, occupational and sporting activity promotion, will be delivered during the physiotherapy treatment sessions. Two dedicated education sessions of 45-60 minutes duration will be delivered during Phase 1 (week 1 and week 4). Participants will be counselled regarding physical activity levels with a targeted training program adhering to Australian Physical Activity Guidelines and given an activity monitor (Garmin vívofit® 4 activity tracker) if they do not have access to one to support measurement and attainment of physical activity goals.

249 **Table 2: Overview of intervention delivery described according to the TIDieR guidelines**

1. Brief name	SUPER intervention	Minimal intervention control
2. Why	Exercise-therapy to enhance muscle strength, function and physical activity can improve pain and quality of life in older adults with OA[11] and address risk factors for post-traumatic OA[33].	The booklet was produced based on information provided to patients and thus, accurately reflects usual care.
3.What materials	Participants receive an intervention handbook detailing all study details, exercises and logbook, and access to videos of all exercises.	Participants receive a "best-practice guide" booklet of possible exercises with no specific exercise prescription frequency.
4. What procedures	Five priority exercises targeting: i) weight-bearing knee extension; ii) open-chain knee extension; iii) knee flexion; iv) balance/agility; v) plyometrics **and** four optional exercises targeting: a) trunk; b) hip abductors; c) hip adductors; d) calf – each with 3-6 levels of difficulty. Physiotherapists prescribe strength exercises (3 x 8-12 reps) with perceived exertion criteria (aim ≥7/10) and progressed as per ACSM and periodisation guidelines (1 week/month easier ~5/10 exertion). Dedicated education sessions at week 1 and week 4, supported by slides and booklets.	Booklet explained at randomisation. Exercise options provided (similar to SUPER intervention), but not prescribed. Participants expected to exercise unsupervised. Participants may contact the physiotherapist by phone once only to ask questions/get clarification.
5. Who provided	Registered physiotherapists with ≥3 years of relevant experience, trained to deliver all components (exercise and education).	One appointment with a registered physiotherapist with ≥ 3 years clinical experience, not involved in delivering SUPER intervention, to explain booklet elements.
6. How	Delivered supervised in groups and individually (supported by unsupervised sessions) in Phase 1, progressing to completely unsupervised in Phase 2.	Delivered unsupervised.
7. Where	Supervised sessions at private physiotherapy clinics and unsupervised sessions at gym/home.	Booklet explained at La Trobe University, Melbourne. Gym and home exercise options provided.
8. When and how much	Phase 1 (0-4 months): *Frequency and Duration* Supervised sessions (30-60 mins) 1-2 times/week Unsupervised sessions (30-60 mins) 1-2 times/week	Unsupervised exercise-therapy (self-prescribed frequency) after one face-to-face appointment.

	Number of Sessions: 32 supervised + 16 unsupervised <u>Phase 2 (5-12 months):</u> *Frequency and Duration* Progress to unsupervised sessions 2-3 times weekly (dependent on meeting predefined criteria*). Two supervised (booster) sessions at 8 and 11 months post-baseline. *Number of Sessions:* 2 supervised + 108 unsupervised	
9. Tailoring	Tailored selection and progression of lower-limb muscle strength, power and neuromuscular control exercises and education based on participant preferences, goals and clinical presentation.	Standardised exercise examples and education.
10. Modifications	Modifications will be reported. If state and/or institution COVID-19 pandemic restrictions prevent face-to-face follow-up assessments, participants will be encouraged to continue assigned treatment until face-to-face assessments can be conducted. If restrictions prevent supervised rehabilitation, telerehabilitation options will be offered wherever possible.	
11. How well (planned)	Treating physiotherapists receive prior training in how to deliver and supervise the programme. Fidelity assessed by auditing. Participant adherence to supervised and unsupervised sessions assessed through logbooks, clinic attendance sheets and online (fortnightly/monthly) questionnaire.	
12. How well (actual)		This will be reported in the primary paper.

SUPER, SUpervised exercise-therapy and Patient Education Rehabilitation; OA, osteoarthritis; ACSM, American College of Sports Medicine

* predefined criteria for ceasing supervised sessions in Phase 2 = participant's goals are met, participant satisfied with current symptoms/function, and global rating of change reported as at least 'better'.

Minimal intervention control

Reflecting current standard care, the minimal intervention control group will receive a "best-practice guide" booklet and one face-to-face appointment with a registered physiotherapist with ≥3 years of clinical experience (not involved in treating participants in the SUPER intervention) to explain booklet elements and answer questions about its contents. The booklet outlines similar exercises and patient education as in the SUPER intervention (Supplementary File 3). However, exercise is expected to be performed unsupervised (table 2). Participants may also contact the treating physiotherapist by phone on one occasion to ask questions or get further clarification but will not be provided with information extending the scope of the booklet. The booklet was produced based on the information provided by ten high volume orthopaedic surgeons in Melbourne to their patients post-ACLR. Participants will be encouraged at the 4-month assessment to continue following the booklet up until the 12-month assessment.

Irrespective of group allocation, participants will be asked to refrain from other musculoskeletal therapies (e.g., chiropractic care, osteopathy, myotherapy, intra-articular injections) for their knee pain during the trial. Participants will be allowed to continue care for other unrelated pre-existing conditions.

Data collection procedure

Data will be collected at baseline and 2, 4 and 12 months after randomisation, with 4 months the *a priori* primary endpoint as this coincides with the completion of the supervised exercise-therapy intervention in Phase 1. Where possible, data will be collected and managed using a secure web-based software platform (Research Electronic Data Capture; REDCap) hosted at La Trobe University[34], which has equivalent measurement properties to paper-based completion[35]. This strategy was used in our pilot study following ACLR, with demonstrated feasibility[21]. Paper versions will also be available if preferred by participants.

Outcomes

Baseline characteristics

Participant characteristics including height, body mass, waist girth, leg length, knee injury and rehabilitation details, socioeconomic details (e.g., education level, employment status), family history of OA, sporting history and health literacy (Rapid Estimate of Adult Literacy in Medicine: REALM[36]) will be collected. Surgical details will be recorded from surgical files including date, graft type, and concomitant injuries/procedures. We will also record knee-related objective measures (table 3).

Table 3. Overview of data collection

	Baseline	2 months	4 months	12 months
Paraticipant characteristics				
Age	X			
Sex	X			
Height, body mass, waist girth	X		X	X
Country of birth	X			
Education level	X			
Living situation	X			
Smoking history	X			
Health literacy (REALM)	X			
Employment status	X		X	X
Prior knee injury/treatment	X			
ACL injury, surgery & rehabilitation details	X			
History of sport participation	X			
Family history of osteoarthritis	X			
Medication use	X			
Comorbidities	X			
Flexion/extension range of motion	X		X	X
Joint line tenderness (medial and lateral)	X		X	X
Crepitus	X		X	X
Effusion (sweep test)	X		X	X
Stability (Lachman's, Pivot shift)	X			
Patient-reported Outcomes				
Knee injury Osteoarthritis Outcome Score	X	X	X	X
EQ-5D-5L	X	X	X	X
Tegner Activity Scale	X	X	X	X
Tampa Scale of Kinesiophobia	X		X	X
Global rating of change		X	X	X
Patient acceptable symptoms state	X	X	X	X
Health and Labour Questionnaire	X		X	X
Work Limitations Questionnaire	X		X	X
ACL-Quality of Life Questionnaire	X		X	X

Physical performance tests			
Hop performance (four tests)	X	X	X
One-leg rise	X	X	X
Isometric thigh muscle strength	X	X	X
Lower-limb loading	X	X	X
MRI outcomes	X	X	X
Average daily steps	X	X	X

ACL, anterior cruciate ligament; MRI, magnetic resonance imaging; REALM, Rapid Estimate of Adult Literacy in Medicine

All participants will receive either a fortnightly (during Phase 1) or monthly (during Phase 2) online questionnaire via the secure online platform (REDCap) (or hard copy mailed, or phone call depending on participant preference) to assess sports activity, adherence to exercise-therapy, and any adverse events/other treatment.

Primary outcome

The primary outcome is the change in $KOOS_4$ score from baseline to 4-month follow-up. $KOOS_4$ is the mean score for the self-reported KOOS subscales pain, symptoms, function in sports and recreational activities and quality of life, which has been used in RCTs following ACL injury[37]. The $KOOS_4$ and all KOOS subscale scores range from 0 (worst) to 100 (best). The KOOS is a valid and reliable knee-specific questionnaire for assessing patient-reported outcomes in various knee injury populations (e.g., from knee injury to OA) and is widely used globally[38 39].

Secondary outcomes

KOOS subscales

To allow for clinical in-depth interpretation, scores for the five KOOS subscales will be reported individually (i.e., pain, symptoms, function in sports and recreational activities, activities of daily living, and quality of life)[38].

Physical performance

Peak isometric knee extensor and flexor muscle strength and rate of force development will be assessed in sitting using reliable and valid methods at 60° of knee flexion on isokinetic equipment (Biodex Medical Systems, NY, USA)[40]. A battery of lower-limb functional tasks commonly used following ACLR will assess functional performance: i) single hop for distance; ii) triple cross-over hop

for distance; iii) side-hop; iv) vertical hop; and v) one-leg rise[5 41 42]. Such a battery produces high reliability and sensitivity in populations following ACLR[43]. Details of physical performance tests are contained in Supplementary File 4.

Perceived global change score and patient acceptable symptom state

Global rating of change (GROC) will be assessed for pain and function with the questions: 'Overall, how has your knee pain changed since the start of the study?' and 'Overall, how has your knee function changed since the start of the study?' Answered on a 7-point Likert scale ranging from 'much worse' to 'much better' and dichotomised to 'improved' ('much better', 'better') versus 'not improved' ('a little better' to 'much worse'). Satisfaction with current knee function (i.e., patient acceptable symptom state (PASS)) will be assessed with the question: 'Considering your knee function, do you feel that your current state is satisfactory? With knee function, you should take into account all activities during your daily life, sport and recreational activities, your level of pain and other symptoms, and also your knee-related quality of life." Answered by 'yes or 'no'[44]. Participants not satisfied with current knee function at follow-up assessments (i.e., answering 'no' to the PASS question) will be asked a second question relating to treatment failure: 'Would you consider your current state as being so unsatisfactory that you think the treatment has failed?' Answered by 'yes' or 'no'[44].

Knee joint structure

Unilateral knee MRIs will be obtained in supine with the lower-limb in neutral alignment using a 3T scanner (Signa Pioneer, General Electric Healthcare, Milwaukee, USA) and 18-channel knee coil. Sequences acquired will include proton density weighted fat suppressed fast spin-echo sequences in the sagittal, coronal and axial planes, a T2 mapping multi-echo spin-echo sagittal sequence and a sagittal fast spoiled gradient echo (FSPGR) sequence (Figure 2, Supplementary File 5). Changes in cartilage collagen content and orientation in extracellular matrices reflecting degeneration will be defined by quantitative changes in T2 relaxation times[45] from baseline to 4- and 12-month follow-up

assessments. Knee cartilage thickness changes over 4 and 12 months will also be assessed[46]. Post-processing software incorporating semi-automated registration and manual segmentation in 3D will be used for both T2 relaxation time and cartilage thickness. Knee OA features (e.g., cartilage defects, meniscal tears, bone marrow lesions, osteophytes) will be scored with established scoring systems[47 48] at baseline and 12-month follow-up by a trained reader blinded to clinical outcomes. Individual OA feature worsening will be defined as increase in the size or depth of lesions as previously established[49]. Bone shape at the knee will also be assessed using edge-detection semi-automated segmentation with 3D triangulated meshes of bone rigidly registered on a reference template to extract the most important modes of variation of bone shape[50].

---FIGURE 2 HERE---

Other outcomes

Fear of movement

Knee-related fear of movement will be assessed with the Tampa Scale for Kinesiophobia[51].

Physical activity

The Tegner Activity Scale will assess self-reported activity level. It is a valid and reliable numerical scale from 0 (sick leave because of knee problems) to 10 (competitive knee-demanding sports at an elite level), with each value indicating the ability to perform certain activities[52]. Objective physical activity will be captured using a Garmin vívofit® 4 actvity tracker (Garmin® International Inc., KS, USA) or participant's own device, if appropriate.

Quality of life

We will assess knee-related quality of life, with the ACL-Quality of life questionnaire[53], and health-related quality of life with the EQ-5D-5L[54]. These measures are reliable and valid for knee pain populations[55 56].

Lower-limb loading

Lower-limb loading will be assessed using ground reaction force data during unilateral and bilateral weight-bearing tasks (squat, hop and drop-jump) using force plates and ForceDecks software (Vald Performance Pty. Ltd., UK).

Treatment-related outcomes

Adherence, exercise level/intensity and other treatments received during the trial

Adherence with the supervised exercise-therapy sessions (i.e., number of sessions attended out of 32 Phase 1 sessions) and intensity/progression of the exercises will be recorded by treating physiotherapists and participants. Participants in both groups will record adherence to home exercises and any co-interventions received in a logbook and via fortnightly (Phase 1) and monthly (Phase 2) online questionnaires.

Adverse events

Any adverse events will be recorded fortnightly during Phase 1 and monthly during Phase 2 via questionnaires. Furthermore, open probe questioning will enquire about possible adverse events at each of the follow-ups. Healthcare use data obtained as part of cost-effectiveness analysis at final follow-up will also be checked for potential adverse events. An adverse event is defined as any undesirable experience causing participants to seek medical treatment. A serious adverse event is defined as any undesirable event/illness/injury classified as having the potential to significantly compromise clinical outcome or result in significant disability or incapacity, and those requiring

inpatient hospital care. Adverse events will be categorised into index knee or other sites and will be assessed for severity by the trial management committee.

Data management

Most outcome data will be collected and managed via REDCap web-based software (hosted at La Trobe University), facilitating simultaneous data entry. For paper-based data collection, data will be entered by a single investigator with a second investigator conducting random checks of a subset of manually entered documents to ensure accuracy. For data analysis, personal data, including participant names, contact details, date of birth and MRI scans will be stored on the La Trobe University server Research Drive Storage, separately from deidentified (numbered) data. All subsequent study data will be identified by participant number only.

Due to the minimal known risks associated with the interventions being evaluated, this study will not have a formal data monitoring committee and does not require an interim analysis. Any unexpected serious adverse events or outcomes will be discussed by the trial management committee (identical to the authors of this protocol).

Sample size calculation

This trial has been powered to detect a clinically significant between-group difference for the primary outcome of $KOOS_4$. The overall effect size for exercise-therapy on self-reported pain and disability is moderate (0.50)[11]. With this effect size, to achieve 85% power at a two-sided 0.05 significance level on the $KOOS_4$, 146 participants are required. To account for a 20% drop-out, we will recruit 184 participants. This sample size will be sufficient to detect a minimal important change (MIC) in $KOOS_4$ of 9-points in patients following ACLR (with standard deviation of 15)[37 57].

Stopping rule

If the intended sample size is not reached at 36 months after recruitment commencement, the inclusion of participants will stop at 160, which will ensure a power of 80% for the primary outcome of $KOOS_4$, anticipating up to 20% loss to follow-up. Including a minimum of 160 participants will also provide ≥90% power to detect a statistically significant difference (α=0.05) on the secondary outcome of cartilage quality on MRI (change in cartilage T2 relaxation time) between the SUPER intervention and minimal intervention control groups (anticipated effect size of 0.59)[17].

Statistical analyses

Analysis will be performed according to the intention-to-treat principle with the statistical analyst blinded to group allocation. Descriptive statistics and generalised linear mixed models (adjusted for baseline measure and referral source (private versus public) as fixed effects) will be used to examine the effect of group allocation on the primary and secondary outcomes. For binomial secondary outcomes (e.g., cartilage defect worsening, proportion of participants 'improved' on the global rating of change scale, proportion of participants who had a $KOOS_4$ change exceeding the MIC of 9 points), binomial (logistic) family will be selected. As this is a randomised trial, we do not plan to adjust for other potential confounders (e.g., age, gender), but if notable imbalance between groups in potential confounders is observed, we will examine the effect of adjusting for potential confounders (fixed effects). While the primary analysis approach is intention-to-treat, per-protocol analysis will also be conducted excluding those who have poor adherence with the SUPER intervention to assist with clinical interpretation of findings. Planned exploratory sub-group analyses including repeating analysis by injury characteristics (e.g., isolated vs combined ACL injury) will be conducted given the known risk of a combined injury (e.g., concomitant meniscal/cartilage) on OA outcomes[58]. Two sensitivity analyses are planned. The first will use multiple imputation for missing data, assuming this data is considered missing at random. The second will exclude particiapnts who experienced a subsequent new acute traumatic lower-limb injury (or surgery) severe enough to require a period of non-weight bearing

assuming this may have influenced the outcomes of those participants, unless the injury was sustained while completing the trial intervention activities.

Healthcare resource use and productivity

The resources required to deliver each intervention and treatment related healthcare resource use including co-interventions for knee-related symptoms (e.g., medicines, complementary treatments, and details of hospital presentations) will be recorded. This information will be collected from several sources (Medicare and Pharmaceutical Benefits Scheme (MBS and PBS) databases (rebated and out-of-pocket costs), as well as participant logbooks and questionnaires) for the trial period. The Health and Labour Questionnaire[59] and the Work Limitations Questionnaire[60] will also be collected for the trial period to inform estimates of productivity losses.

Process Evaluation

Semi-structured interviews will be conducted on a subset of participants (until data saturation is reached) following the intervention. Interviews will explore beliefs/experiences; knowledge and understanding of interventions received including potential benefits; acceptability and perceived effectiveness of the intervention; and reasons for adhering (or not) to exercise-therapy and education provided. Purposive sampling will be used to recruit interview participants based upon characteristics and outcomes of trial. Interviews will be audio recorded, transcribed and analysed using Framework Analysis[61]. Data will be coded deductively according to the code structure generated by the interview topic guide and an inductive thematic analysis will be applied until no new themes emerge.

PATIENT AND PUBLIC INVOLVEMENT

Patients and clinicians are integral throughout each stage of this project. Patients and clinicians co-designed the intervention, research questions and study methods. This input was gained from: i) discussions with leading clinicians managing ACL injuries during SUPER development; ii) collation of

orthopaedic surgeon patient education material to inform the control intervention; iii) qualitative interviews with participants and treating physiotherapists from our pilot study as part of formal process evaluation strategies[21]; iv) qualitative interviews with symptomatic patients with an ACLR as part of our previous studies[62]; and v) patient and clinician focus groups providing feedback on study recruitment material, participant handbooks and education content. Preliminary results will be presented and discussed with patient representatives before the results are written up for peer-review publication. Patients and clinicians will provide input into the dissemination of study results by assisting with the decision on what information to share and in what format.

ETHICS AND DISSEMINATION

This study complies with the Declaration of Helsinki and has been approved by the La Trobe University Human Research Ethics Committee (HEC-19447), the Alfred Hospital Ethics Committee (HREC 537/19) and Services Australia External Request Evaluation Committee (RMS0879). Written informed consent will be obtained from participants prior to enrolment (Supplementary File 6).

Study outcomes will be widely disseminated through a variety of sources. Primary and key secondary objectives will be submitted to a peer-reviewed journal. Other secondary objectives will be addressed in separate publications. Authorship will be in accordance with guidelines provided by the International Committee of Medical Journal Editors (ICMJE). Our publication strategy will be complemented by submission of abstracts to key national and international conferences. Any important protocol amendments will be reported to the approving ethics committees, registered at ANZCTR and communicated in the primary RCT report.

DISCUSSION

Anterior cruciate ligament injuries and subsequent reconstructions have increased 43% in Australia over the previous 15 years[63], with similar increases observed in the United States[64], and greater

increases in England[65]. Half of all patients undergoing ACLR will have a poor long-term outcome including persistent symptoms, impaired quality of life and accelerated structural decline[5-7 66]. This underscores an urgent need for secondary prevention strategies to prevent symptomatic and structural OA decline – an epidemic of young people with old knees.

The current RCT will be the first to evaluate the symptomatic and structural benefits of a physiotherapist-supervised exercise-therapy and education intervention for young adults at high risk of post-traumatic knee OA. This fully powered Phase III trial represents an important step towards optimising management to achieve better outcomes and curtail the rapid trajectory of post-traumatic knee OA following ACL injury and reconstruction.

AUTHOR CONTRIBUTIONS

AGC, KMC, CJB, EMR, EO, SMM conceived the study and obtained funding. AGC, KMC and CJB designed the study protocol with input from EMR, EO, SMM. SMM provided statistical expertise and will conduct primary statistical analysis. EO, RBS and JL provided imaging expertise and will lead imaging analysis. AGC drafted the manuscript with input from KMC, CJB, EMR, EO, SMM, RBS, JL, AMB, TJW, BEP, MAG, JLC. All authors have read and approved the final manuscript.

FUNDING STATEMENT

This trial is supported by the National Health and Medical Research Council (NHMRC) of Australia (ID: 1158500). AGC is a recipient of an NHMRC Investigator Grant (GNT2008523), CJB was a recipient of a Medical Research Future Fund Translating Research Into Practice (MRFF TRIP) Fellowship (ID: 1150439). The funders have no role in the study design and will not have any role in its execution, data management, analysis and interpretation or on the decision to submit the results for publication.

COMPETING INTERESTS STATEMENT

CJB is the owner of a business providing physiotherapy treatment and exercise classes for some participants enrolled in this study. CJB will have no role in the decision of which clinic participants attend for study treatment. All other authors declare no competing interests.

ACKNOWLEDGEMENTS

We thank physiotherapists, Mick Hughes and Randall Cooper, for assistance in intervention design. We thank the orthopaedic surgeons assisting with participant recruitment: Hayden Morris, Chris Kondogiannis, Nathan White, Mark O'Sullivan, Matthew Evans, Ashley Carr, Justin Wong, Dirk van Bavel, Matthew Alexander, Ben Campbell, Altay Altuntas, Simon Talbot, Raphael Hau, Luke Spencer, David Mitchell. We thank the staff at each of the public hospitals involved in participant recruitment: Lara Kimmel & Susan Liew (Alfred Hospital), Emily Cross & Andrew Bucknill (Royal Melbourne Hospital), Jimmy Goulis & Juliette Gentle (Northern Hospital), Chris Cimoli, David Berlowitz & Andrew Hardidge (Austin Hospital), Peter Choong (St Vincent's Hospital), Leanne Roddy & Raphael Hau (Box Hill Hospital), Libby Spiers & Phong Tran (Footscray Hospital), Peter Schoch, Katelyn Bailey, Caitlin Knee & Richard Page (Barwon Hospital), Leonie Lewis & David Mitchell (Ballarat Hospital). We thank the physiotherapists involved in treating the participants at Complete Sports Care, Clifton Hill Physiotherapy, Flex Out Physiotherapy, Lake Health Group, Melbourne Sports Physiotherapy, Mill Park Physiotherapy, Symmetry Physiotherapy, Grand Slam Physiotherapy, Melbourne Sports Medicine Centre, Southern Suburbs Physiotherapy Centre, Lifecare La Trobe.

FIGURE LEGENDS

Figure 1. Flow of participants through the study. MRI, magnetic resonance imaging; KOOS, Knee injury and Osteoarthritis Outcome Score.

Figure 2. Magnetic resonance imaging protocol. A) Sagittal fast spoiled gradient echo (FSPGR) sequence; B) Sagittal, coronal and axial proton density weight far suppressed spin-echo sequence; and C) Sagittal mulit-echo spin-echo sequence

SUPPLEMENTARY FILES

Supplementary File 1. Overview of SUPER intervention exercise delivery according to Consensus on Exercise Reporting Template (CERT) guidelines

Supplementary File 2. Exercises and logbook for SUPER intervention

Supplementary File 3. Exercises and logbook for minimal intervention control

Supplementary File 4. Details of physical performance tests

Supplementary File 5. Details of magnetic resonance imaging sequences acquired

Supplementary File 6. Patient information and consent form

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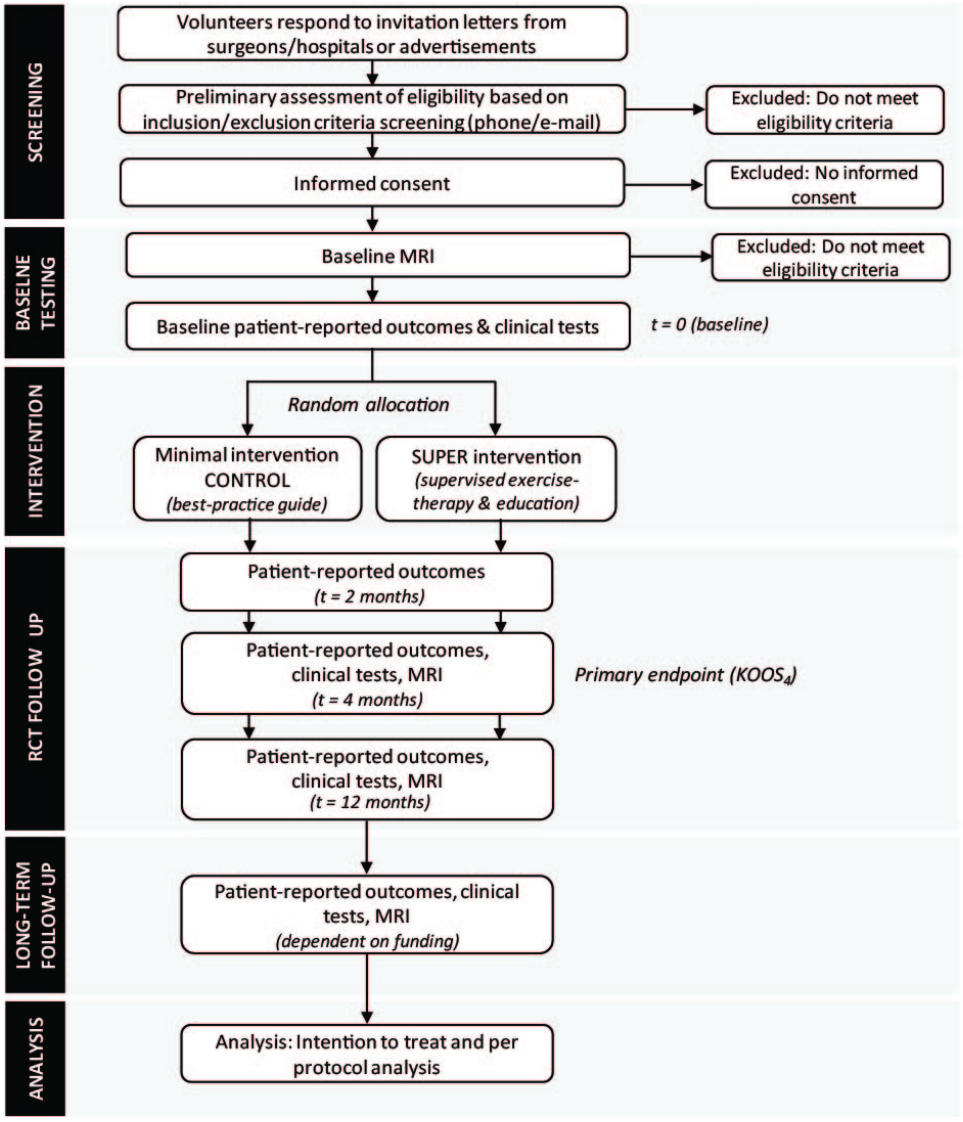

Figure 1. Flow of participants through the study. MRI, magnetic resonance imaging; KOOS, Knee injury and Osteoarthritis Outcome Score.

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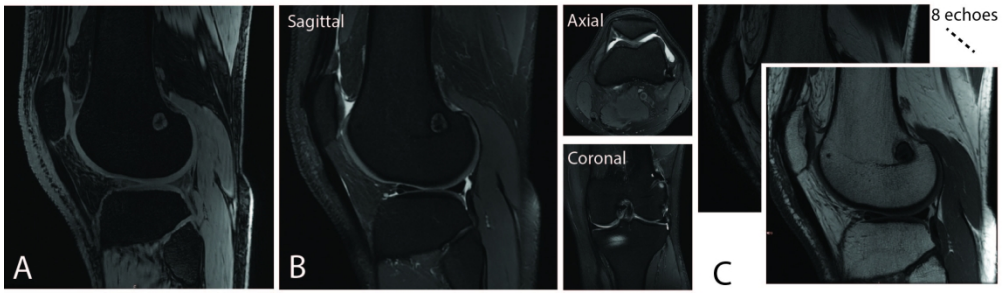


Figure 2. Magnetic resonance imaging protocol. A) Sagittal fast spoiled gradient echo (FSPGR) sequence; B) Sagittal, coronal and axial proton density weight far suppressed spin-echo sequence; and C) Sagittal mulit-echo spin-echo sequence

407x156mm (150 x 150 DPI)

Supplementary File 1. Overview of SUPER intervention exercise delivery according to Consensus on Exercise Reporting Template (CERT) guidelines

Section/Topic	Checklist item	SUPER Exercise Intervention Description
WHAT: materials	1. Detailed description of the type of exercise equipment	Various weighted equipment (e.g., dumbbells, barbells, resistance band, pin-loaded leg press, leg extension, hamstring curl machine) will be used. Participants will be provided with equipment (e.g., resistance band, 20kg adjustable dumbbells) to complete exercises at home. Details of equipment used are in Supplementary File 2.
WHO: provider	2. Detailed description of the qualifications, expertise and/or training	Approximately 30 registered physiotherapists with ≥3 years musculoskeletal clinical experience and work in private clinics in metropolitan and regional Victoria. All SUPER physiotherapists will complete 3 hours of online webinars and participate in a 4-hour workshop (7 hours total) before study commencement. Refresher training will be completed as required. SUPER physiotherapists will be supported with regular (approximately bi-monthly) contact by a member of the research team.
HOW: delivery	3. Describe whether exercises are performed individually or in a group	Phase 1: Participants will perform a mix of supervised 1:1 and small group (≤6 participants) exercise sessions based on individual preference, clinic availability, and clinical reasoning by the treating physiotherapist. Participants will complete additional unsupervised sessions at home/local fitness centre (gym). Phase 2: All exercises will be completed individually unless *a priori* discharge criteria are not met, in which case one supervised exercise session per week may continue.
	4. Describe whether exercises are supervised or unsupervised and how they are delivered	Phase 1: Supervised by a physiotherapist 1-2 times per week **AND** unsupervised 1-2 times per week. Phase 2: Unsupervised 2-3 times per week unless *a priori* discharge criteria are not met, in which one supervised session per week may continue.

5. Detailed description of how adherence to exercise is measured and reported	Phase 1: Physiotherapists will record attendance at supervised exercises sessions. During supervised exercises, participants and/or physiotherapists will record dosage completed for each exercise in a clinic logbook. Participants will record unsupervised exercises either through an online exercise diary, or paper-based exercise logbook. Participants will also report their exercise adherence fortnightly via an online questionnaire. Phase 2: Participants will report their exercise adherence monthly via an online questionnaire and/or paper-based logbook. The percentage of supervised (and unsupervised) exercise sessions completed will be reported.
6. Detailed description of motivation strategies	Phase 1: (i) Physiotherapists will be trained to use simple motivational interviewing techniques to support intervention adherence; (ii) Functional assessments will be completed in the clinic (hop tests, one leg rise) monthly; (iii) Participants will maintain exercise training logbooks at the clinic and at home; (iv) Participants will be contacted monthly by a member of the research team; (v) Exercise variations available to cater for individual needs and preferences; (vi) Participants will be provided an activity monitor (e.g., Garmin watch) and encouraged to track daily activity; (vii) Small group exercise training with other SUPER-Knee trial participants. Phase 2: (i) Access to a local gym; (ii) Booster session with physiotherapist, including functional re-assessment at 8 and 11 months; (iii) Followed up regularly by a member of the research team; (iv) Exercise variations available; (vi) Participants will continue using an activity monitor (e.g., Garmin watch).
7a. Detailed description of the decision rule(s) for determining exercise progression	Exercises will be progressed based on: (i) perceived difficulty using rating of perceived exertion (RPE) (e.g., RPE ≥7/10, 3 sets of 8-12 reps and one lighter week per month of 5/10 RPE to increase motivation and allow recovery periods), and (ii) minimal pain (e.g., <3/10 on numerical pain scale).
7b. Detailed description of how the exercise program is progressed	Exercises will be progressed to match pre-defined RPE of each week by any of the following: i) increasing load used; ii) increasing exercise difficulty level; iii) changing exercise position (e.g.,

		lowering squat depth, increasing step height); or iv) changing speed of exercise. Progression principles are in line with American College of Sports Medicine muscle strengthening guidelines.
	8. Detailed description of each exercise to enable replication	The priority exercises are: 1) Quadriceps, 2) Knee extension, 3) Plyometrics, 4) Balance & Agility, 5) Hamstrings. The additional exercises are: 6) Trunk/core, 7) Hip abduction, 8) Hip adduction, 9) Calf raises. Exercise descriptions are available in Supplementary File 2.
	9. Detailed description of any home program component	Home exercise variations for each of the priority and additional exercises can be found in Supplementary File 2.
	10. Describe whether there are any non-exercise components	Comprehensive education will be provided during the two dedicated physiotherapy 'education' consultations (Weeks 1 and 4, 30-60 minutes). Session 1 topics will include: Function and actions of the knee and ACL, mechanisms of ACL injury, risk factors, what is osteoarthritis, role and evidence for physical activity and exercise, pain education, recovery, goal setting. Session 2 topics will include: Returning to physical activity and sport, psychological factors, goal re-setting and long-term planning, weight control.
	11. Describe the type and number of adverse events that occur during exercise	Exercise-specific adverse events are increases in pain, swelling, re-injury caused by the exercises resulting in the participant needing to cease the exercise session, or an inability to complete subsequent sessions. Physiotherapists will record exercise-specific adverse events in their clinic treatment notes. For any serious adverse events, physiotherapists will contact a member of the research team immediately for suspected ACL re-injuries for medical review and incident reporting.
WHERE: location	12. Describe the setting in which the exercises are performed	<u>Phase 1:</u> Exercises will be performed individually or in small groups at physiotherapy clinics under the supervision of a trained SUPER-Knee physiotherapist, and independently at home/local gym.

		Phase 2: Home/local gym, unless *a priori* discharge criteria are not met, in which case supervised exercise sessions at the physiotherapy clinic may continue.
WHEN/HOW MUCH: dosage	13. Detailed description of the exercise intervention including, but not limited to, number of exercise repetitions/sets/session duration, intervention/program duration etc.	The priority exercises are: 1) Quadriceps, 2) Knee extension, 3) Plyometrics, 4) Balance & Agility, 5) Hamstrings. The additional exercises are: 6) Trunk/core, 7) Hip abduction, 8) Hip adduction, 9) Calf raises. Exercise descriptions are available in print (Supplementary File 2). Strength exercises will be performed in 3 sets of 8-12 reps, while power exercises will be performed in 1-3 sets of 3-6 reps based on clinical reasoning by the treating physiotherapists. Plyometric exercises will be performed in 1-3 sets of 10 reps. Session duration will be 30-60 mins depending on participant/physiotherapist availability. The entire intervention lasts for 12 months.
TAILORING: what, how	14a. Describe whether the exercises are generic (one size fits all) or whether tailored to the individual	The standard exercise program will include the 5 priority exercises. The additional exercises are optional to cater for individual needs, preferences, including time commitments. Each exercise has 3-6 levels of difficulty that include options to cater for exercise training environment. Participants, with their physiotherapist, can select the exercise under each group that most suits individual needs and preferences.
	14b. Detailed description of how exercises are tailored to the individual	Exercise prescription is individualised and follows guidelines from the American College of Sports Medicine for developing muscle strength and power. Exercises will be individually tailored based on: baseline assessment and ongoing functional assessment, achieving intended RPE, exercise training environment and equipment availability, clinical reasoning (e.g., individual preferences and needs, pain).
	15. Describe the decision rule for determining the starting level at which people commence an exercise program	All exercise sessions will start with a 5-minute warm up (3-4/10 RPE). Strength exercises will be performed at a moderate-hard intensity (suggested 5/10 RPE) in Week 1, using guidance from baseline assessment information (e.g., strength and functional test results) contained in the handover form to physiotherapists. They will then be progressed for all participants in week 2 based on criteria outlined in 7a.

HOW WELL: planned, actual	16a. Describe how adherence or fidelity to the exercise intervention is assessed/measured	All SUPER-Knee physiotherapists will complete 3 hours of online webinars, attend the face-to-face 4-hour training workshop and receive a detailed treatment manual describing all aspects of the exercise (and education) intervention. After initiation of the trial, communication (e.g., telephone, email) between a member of the research team and each physiotherapist will occur to discuss issues experienced in the clinic and issues resolved as appropriate. In person fidelity checks will be performed by a member of the research team and refresher training will be completed annually.
	16b. Describe the extent to which the intervention was delivered as planned	This will be reported in the primary paper.

SUPER Knee

OPTIMISING OUTCOMES FOLLOWING ANTERIOR CRUCIATE LIGAMENT RECONSTRUCTION

PARTICIPANT HANDBOOK

PRIORITY EXERCISES

LA TROBE UNIVERSITY

PRIORITY EXERCISES

SUPER Knee

EXERCISE 1. QUADRICEPS

FOCUS

- Slow & controlled
- Knees, hips, ankles in line and hips level
- **Aim for 2-3 sets of 8-12 repetions**

Level 1 – Double leg squat

Feet shoulder width apart. Slowly squat until your buttocks lightly touch the chair/box. Return to standing.

Level 2 – Single leg squat

Standing on affected leg, slowly squat until your buttocks lightly touch the chair/box. Return to standing.

Level 3 – Weighted single leg squat

Increase difficulty by holding weights (on your chest, by your side, or barbell on your shoulder blades).

Level 4 – Power Squats

POWER

- Combines strength and speed
- Vital for everyday activity
- Fast movements at lower weights
- **Aim for 1-3 sets of 3-6 repetitions**

- POWER: complete squats (double- or single-leg as above) with weight at speed.
- Squat down and up as quickly as possible.
- Power can start from week 4 of program regardless of completing level 3 exercise.

Exercise 1: QUADRICEPS **HOME/GYM RECORD**

** Put a line through a session if exercise not completed in that session or missed a session*

		Level (circle)	Aim RPE	Actual RPE	Kilos used	Number of sets	Number of reps
Week 1 – date: _____	Home/gym session	1 2 3 4	5/10				
	Extra session	1 2 3 4	5				
Week 2 – date: _____	Home/gym session	1 2 3 4	7				
	Extra session	1 2 3 4	7				
Week 3 – date: _____	Home/gym session	1 2 3 4	9				
	Extra session	1 2 3 4	9				
Week 4 – date: _____	Home/gym session	1 2 3 4	5				
	Extra session	1 2 3 4	5				
Week 5 – date: _____	Home/gym session	1 2 3 4	7				
	Extra session	1 2 3 4	7				
Week 6 – date: _____	Home/gym session	1 2 3 4	7				
	Extra session	1 2 3 4	7				
Week 7 – date: _____	Home/gym session	1 2 3 4	9				
	Extra session	1 2 3 4	9				
Week 8 – date: _____	Home/gym session	1 2 3 4	5				
	Extra session	1 2 3 4	5				
Week 9 – date: _____	Home/gym session	1 2 3 4	7				
	Extra session	1 2 3 4	7				
Week 10 – date: _____	Home/gym session	1 2 3 4	7				
	Extra session	1 2 3 4	7				
Week 11 – date: _____	Home/gym session	1 2 3 4	9				
	Extra session	1 2 3 4	9				
Week 12 – date: _____	Home/gym session	1 2 3 4	5				
	Extra session	1 2 3 4	5				
Week 13 – date: _____	Home/gym session	1 2 3 4	7				
	Extra session	1 2 3 4	7				
Week 14 – date: _____	Home/gym session	1 2 3 4	7				
	Extra session	1 2 3 4	7				
Week 15 – date: _____	Home/gym session	1 2 3 4	9				
	Extra session	1 2 3 4	9				
Week 16 – date: _____	Home/gym session	1 2 3 4	9				
	Extra session	1 2 3 4	9				

RPE= Rating of Perceived Exertion (0=rest, 10=working as hard as possible)

EXERCISE 1b. QUADRICEPS VARIATIONS

(extra options usually after 4 weeks of the program but based on you and your physio's preferences)

VARIETY

- Varying your workouts can help you push past a plateau
- Challenge your muscles, force them to adapt and strengthen
- **Aim for 2-3 sets of 8-12 repetions**

Option 1: Weighted double leg squat

Use a barbell with weights resting on your shoulder blades. Slowly squat to ~90° knee bend. Return to standing.

Option 2: Bulgarian split squat (hold weights for variability)

Place back foot on a step/chair. Slowly lunge down with most of your weight on your front leg. Keep your shin vertical and back upright. Hold weights to increase difficulty/variability.

Option 3: Step ups/downs

Stand on the edge of a step, step down to lightly touch the floor behind you (or in front of you) and then straighten knee and return to standing. Increase difficulty by holding weights.

Option 4: Lunge

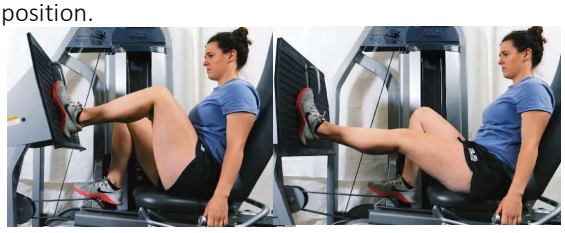
Step back and drop the back knee towards ground, then stand up. Increase difficulty by holding weights.

Option 5: Wall squat

Slide down until your knees are bent to 90°. Then return to the starting position. (Increase difficulty by holding weights or doing it on one leg.)

Option 6 – Single leg press

With your knee bent to 90°, push the footplate away by extending your knee (stop before locking it straight). Slowly control your knee to return to the starting position.



Exercise 1b: QUADRICEPS VARIATIONS **HOME/GYM RECORD**

** Integrate after 4 weeks of the program + based on you and your physio's preferences*

		Exercise (circle)	Aim RPE	Actual RPE	Kilos	Number of sets	Number of reps
Week 1	Home/gym session	1 2 3 4 5 6	5/10				
	Extra session	1 2 3 4 5 6	5				
Week 2	Home/gym session	1 2 3 4 5 6	7				
	Extra session	1 2 3 4 5 6	7				
Week 3	Home/gym session	1 2 3 4 5 6	9				
	Extra session	1 2 3 4 5 6	9				
Week 4	Home/gym session	1 2 3 4 5 6	5				
	Extra session	1 2 3 4 5 6	5				
Week 5	Home/gym session	1 2 3 4 5 6	7				
	Extra session	1 2 3 4 5 6	7				
Week 6	Home/gym session	1 2 3 4 5 6	7				
	Extra session	1 2 3 4 5 6	7				
Week 7	Home/gym session	1 2 3 4 5 6	9				
	Extra session	1 2 3 4 5 6	9				
Week 8	Home/gym session	1 2 3 4 5 6	5				
	Extra session	1 2 3 4 5 6	5				
Week 9	Home/gym session	1 2 3 4 5 6	7				
	Extra session	1 2 3 4 5 6	7				
Week 10	Home/gym session	1 2 3 4 5 6	7				
	Extra session	1 2 3 4 5 6	7				
Week 11	Home/gym session	1 2 3 4 5 6	9				
	Extra session	1 2 3 4 5 6	9				
Week 12	Home/gym session	1 2 3 4 5 6	5				
	Extra session	1 2 3 4 5 6	5				
Week 13	Home/gym session	1 2 3 4 5 6	7				
	Extra session	1 2 3 4 5 6	7				
Week 14	Home/gym session	1 2 3 4 5 6	7				
	Extra session	1 2 3 4 5 6	7				
Week 15	Home/gym session	1 2 3 4 5 6	9				
	Extra session	1 2 3 4 5 6	9				
Week 16	Home/gym session	1 2 3 4 5 6	9				
	Extra session	1 2 3 4 5 6	9				

RPE= Rating of Perceived Exertion (0=rest, 10=working as hard as possible)

EXERCISE 2. KNEE EXTENSION

PAIN

- Keep pain below 3/10 when exercising and pain should settle by the next day
- Pain is OK - you can be sore but safe as pain doesn't always equal damage
- **Aim for 2-3 sets of 8-12 repetions**

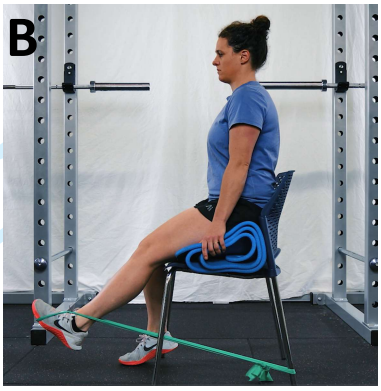
Level 1 – Knee extension holds

A. Knee extension machine: straighten knee against resistance, hold for 40-60 seconds then slowly return to the starting position.

B. Resistance band: straighten knee against the resistance of resistance band, hold for 40-60 seconds then slowly return to the starting position.

C. Cable machine: straighten knee against resistance, hold for 40-60 seconds then slowly return to the starting position.

**IF PAIN IS GREATER THAN 3/10 THEN YOU CAN TRY DIFFERENT KNEE ANGLES WITH GUIDANCE FROM YOUR PHYSIO*



Level 2 – Knee extension

Fully straighten your knee slowly against resistance (using knee extension machine, resistance band or cable machine) and then slowly return to the starting position.

Level 3 Power – Knee extension

POWER

- Combines strength and speed
- Vital for everyday activity
- Fast movements at lower weights
- **Aim for 1-3 sets of 3-6 repetitions**

- Using either knee extension machine, resistance band or cable machine.
- Set the weight approximately 60-70% lighter than your last strength session.
- Complete same exercise as Level 2 but faster (aim for less than 1 sec to straighten the knee).
- Slowly bend the knee back to the starting position.
- Start power from week 4 of your program.

Exercise 2: KNEE EXTENSION **HOME/GYM RECORD**

		Level (circle)	Aim RPE	Actual RPE	Kilos on affected leg	Number of sets	Number of reps
Week 1	Home/gym session	1 2 3	5/10				
	Extra session	1 2 3	5				
Week 2	Home/gym session	1 2 3	7				
	Extra session	1 2 3	7				
Week 3	Home/gym session	1 2 3	9				
	Extra session	1 2 3	9				
Week 4	Home/gym session	1 2 3	5				
	Extra session	1 2 3	5				
Week 5	Home/gym session	1 2 3	7				
	Extra session	1 2 3	7				
Week 6	Home/gym session	1 2 3	7				
	Extra session	1 2 3	7				
Week 7	Home/gym session	1 2 3	9				
	Extra session	1 2 3	9				
Week 8	Home/gym session	1 2 3	5				
	Extra session	1 2 3	5				
Week 9	Home/gym session	1 2 3	7				
	Extra session	1 2 3	7				
Week 10	Home/gym session	1 2 3	7				
	Extra session	1 2 3	7				
Week 11	Home/gym session	1 2 3	9				
	Extra session	1 2 3	9				
Week 12	Home/gym session	1 2 3	5				
	Extra session	1 2 3	5				
Week 13	Home/gym session	1 2 3	7				
	Extra session	1 2 3	7				
Week 14	Home/gym session	1 2 3	7				
	Extra session	1 2 3	7				
Week 15	Home/gym session	1 2 3	9				
	Extra session	1 2 3	9				
Week 16	Home/gym session	1 2 3	9				
	Extra session	1 2 3	9				

RPE= Rating of Perceived Exertion (0=rest, 10=working as hard as possible)

EXERCISE 3. PLYOMETRIC POWER (JUMPING/HOPPING)

FOCUS

- Soft landing bend through hips and knees to absorb load
- Alignment: knees, hips, ankles, torso in line, hips level
- **Begin with 10 repetitions and progress with guidance from your physio**

Level 1 – Double leg forward jump

Jump as high as possible landing softly bending at the hips and knees. Keep good alignment. Progress to jumping forwards as far as possible and jumping side to side.



Level 2 – Single leg hop

Hop forward on one leg landing softly bending at your hips and knees. Keep good alignment. Increase distance/speed.

Level 3 – Single leg side hop

Hop side-to-side on one leg landing softly on the same leg bending at your hips and knees. Increase side-to-side distance.


Level 4 – Drop jumps double leg

Standing on a box, jump down landing softly on both feet and immediately jump up as high as you can. Increase height of box or hold weights to make harder. The size of the box can range from small (20cm) step to large (40-50cm as pictured).



Level 5 – Drop jumps single leg

Stand on a box/step jump down and land softly on one leg and immediately hop up as high as you can



Level 6 – Sport specific

Discuss with your physio regarding sports-specific jumping exercises based on the sport or activities you wish to do.

Examples:
- *cutting upon hop landing*
- *obstacles to hop over*
- *replicate light sport physical contact*
- *sport-specific skill performance*
- *non-contact training drills (cutting around opponent)*
- *multi-directional and unanticipated exercises*
- *accelerate/decelerate*

Exercise 3: PLYOMETRICS (JUMPING/HOPPING) **HOME/GYM RECORD**

		Level (circle)	Aim RPE	Actual RPE	Number of sets	Number of reps
Week 1	Home/gym session	1 2 3 4 5 6	5/10			
	Extra session	1 2 3 4 5 6	5			
Week 2	Home/gym session	1 2 3 4 5 6	7			
	Extra session	1 2 3 4 5 6	7			
Week 3	Home/gym session	1 2 3 4 5 6	9			
	Extra session	1 2 3 4 5 6	9			
Week 4	Home/gym session	1 2 3 4 5 6	5			
	Extra session	1 2 3 4 5 6	5			
Week 5	Home/gym session	1 2 3 4 5 6	7			
	Extra session	1 2 3 4 5 6	7			
Week 6	Home/gym session	1 2 3 4 5 6	7			
	Extra session	1 2 3 4 5 6	7			
Week 7	Home/gym session	1 2 3 4 5 6	9			
	Extra session	1 2 3 4 5 6	9			
Week 8	Home/gym session	1 2 3 4 5 6	5			
	Extra session	1 2 3 4 5 6	5			
Week 9	Home/gym session	1 2 3 4 5 6	7			
	Extra session	1 2 3 4 5 6	7			
Week 10	Home/gym session	1 2 3 4 5 6	7			
	Extra session	1 2 3 4 5 6	7			
Week 11	Home/gym session	1 2 3 4 5 6	9			
	Extra session	1 2 3 4 5 6	9			
Week 12	Home/gym session	1 2 3 4 5 6	5			
	Extra session	1 2 3 4 5 6	5			
Week 13	Home/gym session	1 2 3 4 5 6	7			
	Extra session	1 2 3 4 5 6	7			
Week 14	Home/gym session	1 2 3 4 5 6	7			
	Extra session	1 2 3 4 5 6	7			
Week 15	Home/gym session	1 2 3 4 5 6	9			
	Extra session	1 2 3 4 5 6	9			
Week 16	Home/gym session	1 2 3 4 5 6	9			
	Extra session	1 2 3 4 5 6	9			

RPE= Rating of Perceived Exertion (0=rest, 10=working as hard as possible)

EXERCISE 4. BALANCE/AGILITY

FOCUS

- Get low and balanced ready for change of direction
- Knees, hips, ankles in line and hips level

Level 1 – Arabesques

Standing on one leg (knee slightly bent), slowly bend forward from your hip, reaching out making a straight line from your foot to your hands. Hold 5 secs.



Level 2 – Clock Face

Standing on one leg (knee slightly bent) reach out to the imaginary numbers on a clock face (12, 3, 6, 9). Maintain balance without touching the ground. Return to upright position before reaching out again. Increase difficulty by reaching further (use a marker to guide). Begin with 3-5 repetitions in each direction.



Level 3 – Clock face unstable surface

Repeat Level 2 exercise but this time stand on an unstable surface (e.g. wobble board, bosu ball, foam). Begin with 3-5 repetitions in each direction and progress with guidance from your physiotherapist.



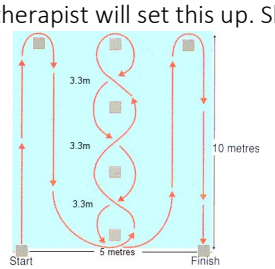
Level 4 – Clock face agility

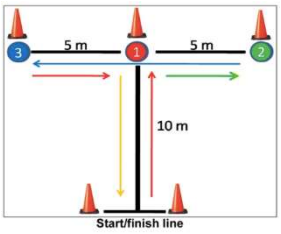
Run towards the clockface, plant your foot in the centre of the clock and change direction to run along that line (start at 45°). Progress the exercise by increasing the angle - change of direction (90°, 135°, 180°). Begin with 3 repetitions in each direction and progress with guidance from your physiotherapist.



Level 5 – Multi-directional agility

In an area with at least 20m space, set up as detailed below in diagrams and complete 5 x each as fast as possible. Your physiotherapist will set this up. Should include forward, backward, and side running.





Exercise 4: BALANCE/AGILITY **HOME/GYM RECORD**

		Level (circle)	Aim RPE	Actual RPE	Number of sets	Number of reps
Week 1	Home/gym session	1 2 3 4 5	5/10			
	Extra session	1 2 3 4 5	5			
Week 2	Home/gym session	1 2 3 4 5	7			
	Extra session	1 2 3 4 5	7			
Week 3	Home/gym session	1 2 3 4 5	9			
	Extra session	1 2 3 4 5	9			
Week 4	Home/gym session	1 2 3 4 5	5			
	Extra session	1 2 3 4 5	5			
Week 5	Home/gym session	1 2 3 4 5	7			
	Extra session	1 2 3 4 5	7			
Week 6	Home/gym session	1 2 3 4 5	7			
	Extra session	1 2 3 4 5	7			
Week 7	Home/gym session	1 2 3 4 5	9			
	Extra session	1 2 3 4 5	9			
Week 8	Home/gym session	1 2 3 4 5	5			
	Extra session	1 2 3 4 5	5			
Week 9	Home/gym session	1 2 3 4 5	7			
	Extra session	1 2 3 4 5	7			
Week 10	Home/gym session	1 2 3 4 5	7			
	Extra session	1 2 3 4 5	7			
Week 11	Home/gym session	1 2 3 4 5	9			
	Extra session	1 2 3 4 5	9			
Week 12	Home/gym session	1 2 3 4 5	5			
	Extra session	1 2 3 4 5	5			
Week 13	Home/gym session	1 2 3 4 5	7			
	Extra session	1 2 3 4 5	7			
Week 14	Home/gym session	1 2 3 4 5	7			
	Extra session	1 2 3 4 5	7			
Week 15	Home/gym session	1 2 3 4 5	9			
	Extra session	1 2 3 4 5	9			
Week 16	Home/gym session	1 2 3 4 5	9			
	Extra session	1 2 3 4 5	9			

RPE= Rating of Perceived Exertion (0=rest, 10=working as hard as possible)

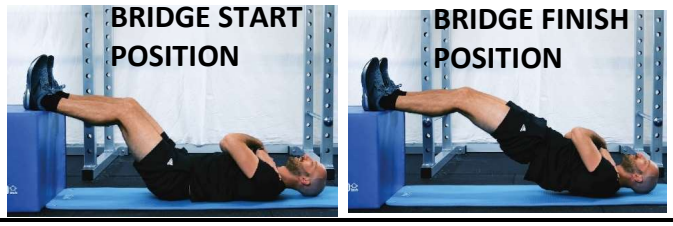
EXERCISE 5. HAMSTRINGS

FOCUS

- Strength in the hamstrings is vital to support overall knee control
- **Complete sets of 2-3 and 8-12 repetions (unless otherwise stated)**

Level 1 – Double leg elevated bridge

Squeeze buttock muscles (glutes) to lift into the bridge position. Hold for 2 secs and slowly lower back to the ground.



Level 2 – Single leg elevated bridge

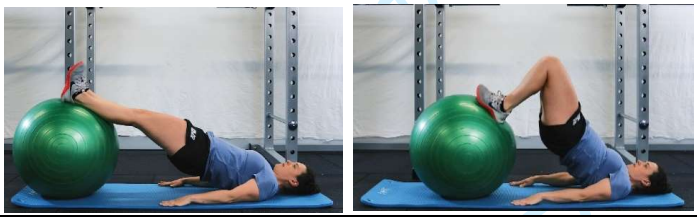
Use one leg, squeeze buttocks and lift up into the bridge position. Hold for 2 secs and slowly lower back to the ground.

Level 3 – Single leg hamstring curl

Bend your knee pulling the resistance bar/band as far as you can to your hips, slowly return to the starting position. Increase difficulty by increasing weight on machine or tension in the resistance band (shorter/change band colour).

Level 4 – Hamstring curl swiss ball

Heels on swiss ball. Lift hips off floor. Roll swiss ball towards and away by bending knees. Progress using only one leg.



Level 5 – Nordic curl

Kneeling with object/partner keeping heels on ground. Keeping your back straight, lower your chest forwards until you can't hold yourself up, use your hands to break your fall. Return to starting position with your hands (not leg muscles!). Begin with 5 repetitions, 2 sets and progress with guidance from your physiotherapist.

Level 6 – Power elevated bridge

POWER

- Combines strength and speed
- Vital for everyday activity
- Fast movements at lower weights
- **Aim for 1-3 sets of 3-6 repetitions**

- Level 1, 2 or 3 exercise with aim for 1 sec to bend the knee or lift the pelvis and slowly return.
- If using hamstring curl machine set weight approx. 60-70% lighter than your last strength session.
- Start power from week 4 of program.

Exercise 5: HAMSTRINGS **HOME/GYM RECORD**

		Level (circle)	Aim RPE	Actual RPE	Kilos on affected leg	Number of sets	Number of reps
Week 1	Home/gym session	1 2 3 4 5 6	5/10				
	Extra session	1 2 3 4 5 6	5				
Week 2	Home/gym session	1 2 3 4 5 6	7				
	Extra session	1 2 3 4 5 6	7				
Week 3	Home/gym session	1 2 3 4 5 6	9				
	Extra session	1 2 3 4 5 6	9				
Week 4	Home/gym session	1 2 3 4 5 6	5				
	Extra session	1 2 3 4 5 6	5				
Week 5	Home/gym session	1 2 3 4 5 6	7				
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Week 9	Home/gym session	1 2 3 4 5 6	7				
	Extra session	1 2 3 4 5 6	7				
Week 10	Home/gym session	1 2 3 4 5 6	7				
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	Extra session	1 2 3 4 5 6	9				
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	Extra session	1 2 3 4 5 6	5				
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Week 15	Home/gym session	1 2 3 4 5 6	9				
	Extra session	1 2 3 4 5 6	9				
Week 16	Home/gym session	1 2 3 4 5 6	9				
	Extra session	1 2 3 4 5 6	9				

RPE= Rating of Perceived Exertion (0=rest, 10=working as hard as possible)

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ADDITIONAL EXERCISES

EXERCISE 6. TRUNK/CORE STRENGTH

Level 1 – Front plank

Plank position, contract core muscles maintaining a straight line from ankle to head (30-60 secs)

Level 2 – Front plank lift

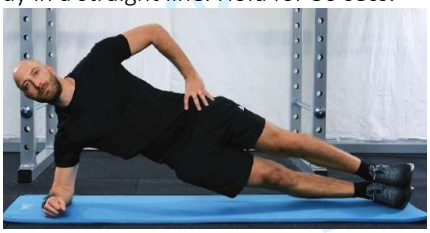
Plank position, lift one leg, holding for 2 secs, and alternate between legs for 30-60 secs.


Level 3 – Front plank lift (resistance band)

Place resistance band around ankles. Move into plank position. Lift one leg stretching resistance band, holding for 2 secs, and alternate between legs for 30-60 secs.


Level 4 – Side plank

Side plank position, keeping body in a straight line. Hold for 30 secs.



Level 5 – Side plank lift

Side plank position, lift your top leg. Hold for 2 secs, then slowly return. Repeat for 30-60 secs.


Level 6 – Side plank lift (resistance band)

Side plank position. Resistance band around ankles. Lift the top leg up stretching the resistance band and lower. Repeat for 30-60 secs.


Exercise 6: TRUNK/CORE STRENGTH **HOME/GYM RECORD**

		Level (circle)	Aim RPE	Actual RPE	Kilos	Number of sets	Number of reps
Week 1	Home/gym session	1 2 3 4 5 6	5/10				
	Extra session	1 2 3 4 5 6	5				
Week 2	Home/gym session	1 2 3 4 5 6	7				
	Extra session	1 2 3 4 5 6	7				
Week 3	Home/gym session	1 2 3 4 5 6	9				
	Extra session	1 2 3 4 5 6	9				
Week 4	Home/gym session	1 2 3 4 5 6	5				
	Extra session	1 2 3 4 5 6	5				
Week 5	Home/gym session	1 2 3 4 5 6	7				
	Extra session	1 2 3 4 5 6	7				
Week 6	Home/gym session	1 2 3 4 5 6	7				
	Extra session	1 2 3 4 5 6	7				
Week 7	Home/gym session	1 2 3 4 5 6	9				
	Extra session	1 2 3 4 5 6	9				
Week 8	Home/gym session	1 2 3 4 5 6	5				
	Extra session	1 2 3 4 5 6	5				
Week 9	Home/gym session	1 2 3 4 5 6	7				
	Extra session	1 2 3 4 5 6	7				
Week 10	Home/gym session	1 2 3 4 5 6	7				
	Extra session	1 2 3 4 5 6	7				
Week 11	Home/gym session	1 2 3 4 5 6	9				
	Extra session	1 2 3 4 5 6	9				
Week 12	Home/gym session	1 2 3 4 5 6	5				
	Extra session	1 2 3 4 5 6	5				
Week 13	Home/gym session	1 2 3 4 5 6	7				
	Extra session	1 2 3 4 5 6	7				
Week 14	Home/gym session	1 2 3 4 5 6	7				
	Extra session	1 2 3 4 5 6	7				
Week 15	Home/gym session	1 2 3 4 5 6	9				
	Extra session	1 2 3 4 5 6	9				
Week 16	Home/gym session	1 2 3 4 5 6	9				
	Extra session	1 2 3 4 5 6	9				

RPE= Rating of Perceived Exertion (0=rest, 10=working as hard as possible)

EXERCISE 7. HIP ABDUCTION (OUTER THIGH)

Level 1 – Standing hip abduction with resistance band

Move your leg straight out to the side, tightening the resistance band. Slowly return to starting position. Increase difficulty by increasing resistance band strength with a different colour (your physiotherapist can help you with this). Aim 2-3 sets of 8-12.


Level 2 –Standing hip abduction with cable

Move your leg straight out to the side against cable resistance, slowly return to starting position.

Aim 2-3 sets of 8-12.


Level 3 – Crab walk

In squat position (hip/knee slightly flexed) walk sideways (20 steps each way) keeping your upper body straight and tension in the resistance band. Increase difficulty by moving band to forefoot or increasing resistance.



Exercise 7: HIP ABDUCTION (OUTER THIGH) **HOME/GYM RECORD**

		Level (circle)	Aim RPE	Actual RPE	Kilos on affected leg	Number of sets	Number of reps
Week 1	Home/gym session	1 2 3	5/10				
	Extra session	1 2 3	5				
Week 2	Home/gym session	1 2 3	7				
	Extra session	1 2 3	7				
Week 3	Home/gym session	1 2 3	9				
	Extra session	1 2 3	9				
Week 4	Home/gym session	1 2 3	5				
	Extra session	1 2 3	5				
Week 5	Home/gym session	1 2 3	7				
	Extra session	1 2 3	7				
Week 6	Home/gym session	1 2 3	7				
	Extra session	1 2 3	7				
Week 7	Home/gym session	1 2 3	9				
	Extra session	1 2 3	9				
Week 8	Home/gym session	1 2 3	5				
	Extra session	1 2 3	5				
Week 9	Home/gym session	1 2 3	7				
	Extra session	1 2 3	7				
Week 10	Home/gym session	1 2 3	7				
	Extra session	1 2 3	7				
Week 11	Home/gym session	1 2 3	9				
	Extra session	1 2 3	9				
Week 12	Home/gym session	1 2 3	5				
	Extra session	1 2 3	5				
Week 13	Home/gym session	1 2 3	7				
	Extra session	1 2 3	7				
Week 14	Home/gym session	1 2 3	7				
	Extra session	1 2 3	7				
Week 15	Home/gym session	1 2 3	9				
	Extra session	1 2 3	9				
Week 16	Home/gym session	1 2 3	9				
	Extra session	1 2 3	9				

RPE= Rating of Perceived Exertion (0=rest, 10=working as hard as possible)

EXERCISE 8. HIP ADDUCTION (INNER THIGH)

Level 1 – Hip adduction with resistance band

Standing maintaining good alignment, move your leg toward your body, tightening resistance band and slowly return to the starting position. Aim 2-3 sets of 8-12.


Level 2 – Hip adduction with cable

Standing maintaining good alignment, move your leg toward your body and slowly return to the starting position. Aim 2-3 sets of 8-12.


Level 3 – Groin plank - knee

Side plank position with upper leg (knee) on chair, slowly lift and lower your bottom leg to the under surface of the chair. Aim 1-3 sets of 8-12.


Level 4 – Groin plank ankle

Side plank position with upper leg (foot) on chair, slowly lift and lower your bottom leg to the under surface of the chair. Aim 1-3 sets of 8-12.


Exercise 8: HIP ADDUCTION (INNER THIGH) **HOME/GYM RECORD**

		Level (circle)	Aim RPE	Actual RPE	Kilos on affected leg	Number of sets	Number of reps
Week 1	Home/gym session	1 2 3 4	5/10				
	Extra session	1 2 3 4	5				
Week 2	Home/gym session	1 2 3 4	7				
	Extra session	1 2 3 4	7				
Week 3	Home/gym session	1 2 3 4	9				
	Extra session	1 2 3 4	9				
Week 4	Home/gym session	1 2 3 4	5				
	Extra session	1 2 3 4	5				
Week 5	Home/gym session	1 2 3 4	7				
	Extra session	1 2 3 4	7				
Week 6	Home/gym session	1 2 3 4	7				
	Extra session	1 2 3 4	7				
Week 7	Home/gym session	1 2 3 4	9				
	Extra session	1 2 3 4	9				
Week 8	Home/gym session	1 2 3 4	5				
	Extra session	1 2 3 4	5				
Week 9	Home/gym session	1 2 3 4	7				
	Extra session	1 2 3 4	7				
Week 10	Home/gym session	1 2 3 4	7				
	Extra session	1 2 3 4	7				
Week 11	Home/gym session	1 2 3 4	9				
	Extra session	1 2 3 4	9				
Week 12	Home/gym session	1 2 3 4	5				
	Extra session	1 2 3 4	5				
Week 13	Home/gym session	1 2 3 4	7				
	Extra session	1 2 3 4	7				
Week 14	Home/gym session	1 2 3 4	7				
	Extra session	1 2 3 4	7				
Week 15	Home/gym session	1 2 3 4	9				
	Extra session	1 2 3 4	9				
Week 16	Home/gym session	1 2 3 4	9				
	Extra session	1 2 3 4	9				

RPE= Rating of Perceived Exertion (0=rest, 10=working as hard as possible)

EXERCISE 9. CALF

On two legs standing on the edge of a step, raise up onto your toes and then lower both heels back down below the step. Only light support with hands to maintain balance. Aim 2-3 sets of 8-12.

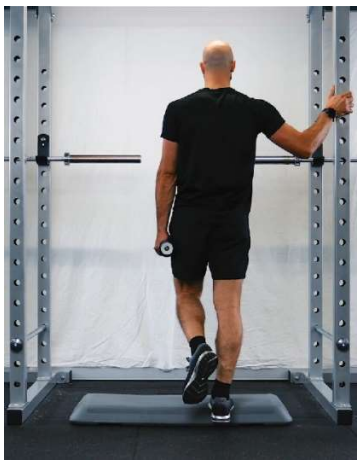
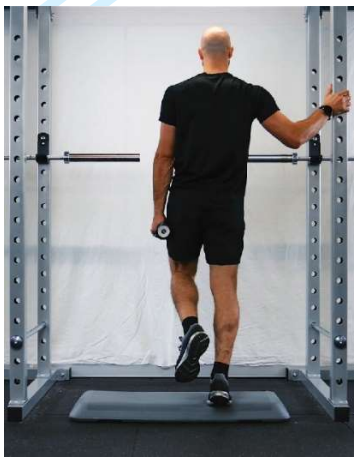
Level 1 – Double leg calf raises


On one leg standing on the edge of a step, raise up onto your toe and then lower heel back down below the step. Only light support with hands to maintain balance. Aim 2-3 sets of 8-12.

Level 2 – Single leg calf raises


Same exercise as Level 2 but add a weight in your opposite hand to make the exercise harder. Aim 2-3 sets of 8-12.

Level 3 – Weighted single leg calf raises

Exercise 9: CALF **HOME/GYM RECORD**

		Level (circle)	Aim RPE	Actual RPE	Kilos	Number of sets	Number of reps
Week 1	Home/gym session	1 2 3	5/10				
	Extra session	1 2 3	5				
Week 2	Home/gym session	1 2 3	7				
	Extra session	1 2 3	7				
Week 3	Home/gym session	1 2 3	9				
	Extra session	1 2 3	9				
Week 4	Home/gym session	1 2 3	5				
	Extra session	1 2 3	5				
Week 5	Home/gym session	1 2 3	7				
	Extra session	1 2 3	7				
Week 6	Home/gym session	1 2 3	7				
	Extra session	1 2 3	7				
Week 7	Home/gym session	1 2 3	9				
	Extra session	1 2 3	9				
Week 8	Home/gym session	1 2 3	5				
	Extra session	1 2 3	5				
Week 9	Home/gym session	1 2 3	7				
	Extra session	1 2 3	7				
Week 10	Home/gym session	1 2 3	7				
	Extra session	1 2 3	7				
Week 11	Home/gym session	1 2 3	9				
	Extra session	1 2 3	9				
Week 12	Home/gym session	1 2 3	5				
	Extra session	1 2 3	5				
Week 13	Home/gym session	1 2 3	7				
	Extra session	1 2 3	7				
Week 14	Home/gym session	1 2 3	7				
	Extra session	1 2 3	7				
Week 15	Home/gym session	1 2 3	9				
	Extra session	1 2 3	9				
Week 16	Home/gym session	1 2 3	9				
	Extra session	1 2 3	9				

RPE= Rating of Perceived Exertion (0=rest, 10=working as hard as possible)

NHMRC

LA TROBE UNIVERSITY

SUPER Knee

Optimising outcomes following anterior cruciate ligament reconstruction

PARTICIPANT HANDBOOK

LA TROBE UNIVERSITY SUPER Knee

13. WHAT CAN I DO TO STRENGTHEN MY QUADRICEPS?

Start with a moderately difficult exercise and progress according to the guidelines set out in the handbook (see section 8 "How hard should I exercise?").

Progress quadricep muscles exercises by:

1. Use one leg instead of two
2. Add a weight or increase the weight
3. Increase the depth of exercise
4. Increase the speed of the exercise
5. Increase number of repetitions

Home or gym exercises

Option 1 – Double leg squats

With even weight on both legs, bend your knees evenly and squat down to a chair height. Make sure your knees don't move in or out and keep your trunk upright. Return to upright standing. If this is too hard, just squat down as far as you can.



Option 2 – Bulgarian split squat

Put your back leg up on a stable elevated object and so that your front knee is at 90°. Try and keep most of your weight on your front leg. Keep your knees over your toes and don't let your hips drop.



Gym exercises

Option 3 – Knee extension machine

In the seated knee extension machine, straighten your knee against resistance. Start at 90° knee bend and straighten to full knee extension.


Option 4 – Leg press

Using the leg press machine, press against the resistance while keeping your knees in good alignment (knees over toes). Don't fully lock your knees out. Start with a leg press set at 45° knee bend.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14. WHAT CAN I DO TO STRENGTHEN MY HAMSTRINGS?

Start with a moderately difficult exercise and progress according to the guidelines set out in the handbook (see section 8 "How hard should I exercise?").

Progress hamstring muscle exercises by:

1. Add a weight or increase the weight
2. Increase number of repetitions

Home or gym exercises

Option 1 – Elevated bridge

Lying on your back with both legs elevated on a stable object use your hamstrings to lift your hips off the ground so that your back and legs are in a straight line. Use your hands for stability as needed.


To progress this exercise:

- Straighten your knee more
- Increase box/bench height

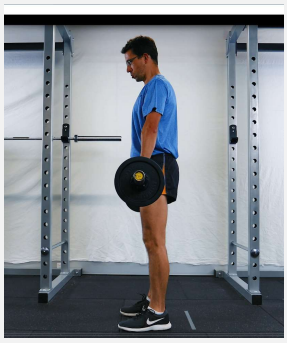
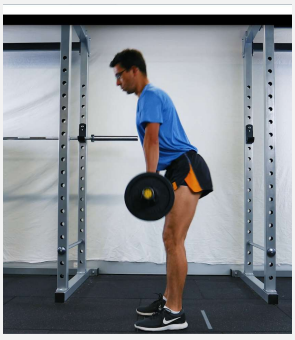
Option 2 – Single leg elevated bridge

Lying on your back with one leg elevated and slightly bent, on a stable object use your hamstrings to lift your hips off the ground so that your back and legs are in a straight line. Use your hands for stability as needed.


Gym exercises

Option 3– Deadlifts

With straight legs or a very slight knee bend, bend from your hips as far as comfortable (aim for the weight to be below your knees), then use your hamstring muscles to pull yourself back up to standing. Make sure you don't bend from your spine, but instead keep it straight.


Option 4 – Hamstring curl machine

In the gym, use the hamstring curl machine to work against the resistance to bring your heel to your hips. Start with your legs close to fully straight and bend to about 90°. Make sure you feel your hamstring muscle work.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15. WHAT CAN I DO TO IMPROVE MY PLYOMETRIC POWER?

Start with a moderately difficult exercise and progress according to the guidelines set out in the handbook (see section 8 "How hard should I exercise?").

PLYOMETRIC POWER – Your ability to jump and land with both control and speed.

Progress jumping exercises by:

1. Increase the speed of jumping
2. Increase the number of jumps

Home or gym exercises

Option 1 – Double leg forward jump

Jump as high as possible landing softly bending at the hips and knees. Progress to jumping forwards as far as possible.

Option 2 – Single leg forward hop

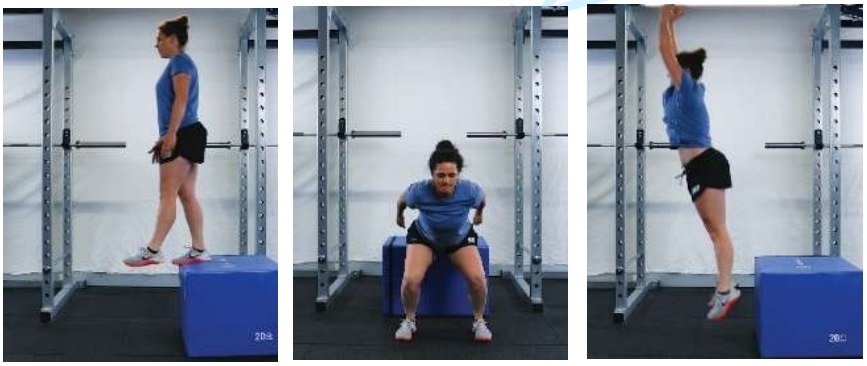
Hop forward on one leg landing softly bending at your hips and knees. Keep good alignment. Increase distance/speed.

Option 3 – Single leg side hop

Hop side-to-side on one leg landing softly on the same leg bending at your hips and knees. Increase lateral distance.

Option 4 – Double leg drop jump (off a step/box)

Standing on a box/step, jump down landing softly on both feet and immediately jump up as high as you can. Increase height of box or hold weights to make harder.



The size of the box can range from small (20cm) step to large (40-50cm as pictured). You can also progress to landing on one leg only.

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16. WHAT CAN I DO TO STRENGTHEN MY TRUNK/CORE?

Start with a moderately difficult exercise and progress according to the guidelines set out in the handbook (see section 8 "How hard should I exercise?").

Progress core exercises by:

1. Increase number of repetitions
2. Increase length of time held in position

Home or gym exercises

Option 1 – Front plank

Begin on your feet and elbows and maintain a straight line from your head to your ankle, so that you do not arch your back. Hold with good control without your hips moving higher or lower.

Aim to start with:

- 30 secs hold x 3 times

Option 2 – Front plank with leg lift

Plank position, lift one leg, holding for 2 secs, and alternate between legs for 30-60 secs.

Aim to start with:

- 10 reps each leg x 3 sets

Option 3 – Side planks

Start on your elbow and side of your feet and maintain a straight line from your shoulders to your ankles. Hold the position with good control without holding your hips too high or low.

Aim to start with:

- 30 secs hold x 3 times

Option 4 – Side plank with leg lift

Side plank position, leading with your heel, lift your top leg. Hold for 2 secs, then slowly return to starting position.

Aim to start with:

- 10 reps each leg x 3 sets

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17. WHAT CAN I DO TO STRENGTHEN MY HIPS?

Start with a moderately difficult exercise and progress according to the guidelines set out in the handbook (see section 8 "How hard should I exercise?").

Progress hip muscle exercises by:

1. Add a weight or increase the weight
2. Increase the height or width of exercise
3. Increase the speed of the exercise
4. Increase number of repetitions

Home or gym exercises

Option 1 – Standing hip abduction with resistance band

Move your leg straight out to the side tightening resistance band. Slowly return to starting position. Increase difficulty by increasing resistance band strength.


Option 2 – Crab walk

In squat position (hip/knee slightly flexed) walk sideways (20 steps each way) keeping your upper body straight and tension in the resistance band. Increase difficulty by moving band to foot.



Option 3 – Resistance band hip adduction

Standing maintaining good alignment, move your leg toward your body, tightening resistance band, and slowly return to the starting position.


Option 4 – Groin/adductor plank

Side plank position with upper leg (knee) on chair, slowly lift and lower your bottom leg to the under surface of the chair.


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18. WHAT CAN I DO TO STRENGTHEN MY CALVES?

Start with a moderately difficult exercise and progress according to the guidelines set out in the handbook (see section 8 "How hard should I exercise?").

Progress calf muscle exercises by:

1. Increase the speed of the exercise
2. Increase number of repetitions
3. Use one leg instead of two
4. Add a weight or increase the weight
5. Increase the depth of exercise
6. Increase the speed of the exercise
7. Increase number of repetitions

Home or gym exercises

<u>Option 1 - Calf raise (double leg and single leg)</u>

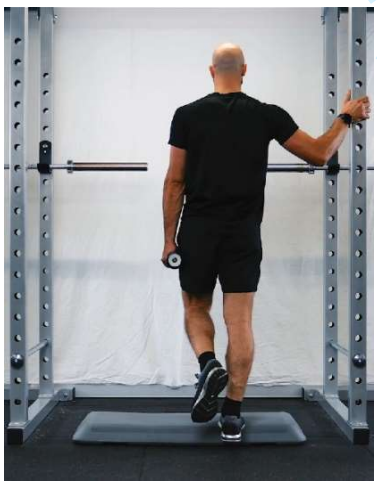
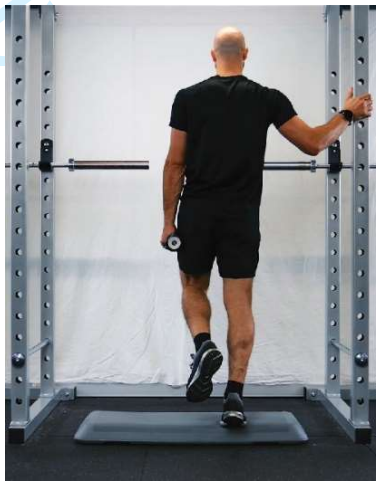
Standing off a small step/object about 5-10 cm high on two legs, raise your heels off the ground, and lower back down to the ground.

Make sure you do no rotate your ankle or foot and hold at the top for balance. Hold something lightly for balance if needed.




<u>Option 2 – Calf raise with weights</u>

Same exercise as option 1 but add a weight in your opposite hand to make the exercise harder.

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SUPER Knee

Date	Exercise	Reps & Sets	Weight	RPE /10
	1 Quadriceps 2 Hamstrings 3 Plyometric power 4 Trunk/core 5 Hips 6 Calves			
	1 Quadriceps 2 Hamstrings 3 Plyometric power 4 Trunk/core 5 Hips 6 Calves			
	1 Quadriceps 2 Hamstrings 3 Plyometric power 4 Trunk/core 5 Hips 6 Calves			
	1 Quadriceps 2 Hamstrings 3 Plyometric power 4 Trunk/core 5 Hips 6 Calves			
	1 Quadriceps 2 Hamstrings 3 Plyometric power 4 Trunk/core 5 Hips 6 Calves			
	1 Quadriceps 2 Hamstrings 3 Plyometric power 4 Trunk/core 5 Hips 6 Calves			
	1 Quadriceps 2 Hamstrings 3 Plyometric power 4 Trunk/core 5 Hips 6 Calves			

Supplementary File 4. Details of physical performance tests

Battery of hops: single hop, triple crossover hop, and side hop

The single hop for distance assesses the distance (cm) the participant can hop from a stationary position, taking off and landing on the same foot. The triple cross-over hop for distance assesses the cumulative distance (cm) the participant can achieve by hopping three consecutive times, crossing over the outside of two strips of tape placed 15cm apart each time. The side-hop evaluates the number of hops participants can achieve (hopping side to side outside two parallel strips of tape placed 40cm apart on the floor) in 30 seconds. The vertical hop assesses the maximal height participants can hop from a stationary position. For all hop tests, participants wear their usual athletic footwear, start with their left leg (regardless of ACLR limb) and hands held behind the back. If participants make subsequent smaller hops, separate their hands or do not remain balanced, the hop is not recorded. Single, triple cross-over and vertical hops are repeated until at least three successful trials are recorded and no increase in distance is observed. The left leg is tested first.

Figure SF3.1. Battery of hop tests. **A**: Single hop for distance; **B**: Side-hop; **C:** Triple-crossover hop for distance; **D**: Vertical hop

One-leg rise

For the one-leg rise, participants sit on the edge of a plinth with the heel of the test leg on a marked line 10cm in front of the edge of the plinth. Plinth height is adjusted so the angle of the test knee in sitting is 90°. With arms folded across the chest, participants are instructed to rise from sitting to standing on one leg, achieve full knee extension, and return to lightly touch the plinth with buttocks. Rises are performed to a metronome to maintain a consistent cadence of 45 beats per minute. The maximum number of rises achieved at the predetermined cadence is recorded. The left leg is tested first.

Figure SF3.2 One leg rise test

Knee muscle strength

Maximal voluntary isometric contractions are evaluated during knee extension and flexion with the knee flexed to 60° using an isokinetic dynamometer (Biodex Medical Systems, NY, USA). Participants are seated (hips/non-tested knee flexed 90°) and the centre of the knee joint is aligned with the axis of the dynamometer. Four belts are used to stabilise the trunk and non-test limb, two crossing the trunk, one around the pelvis and one on the distal thigh. An inelastic strap fixed to the dynamometer arm is placed around the distal tibia (proximal to the ankle).

Two submaximal practice contractions of 5-seconds with an interval of 30-seconds between trials are performed as a familiarisation procedure. Then, with standardised verbal encouragement, three maximal isometric contractions of 5-seconds with an interval of 30-seconds between each trial are performed. The test alternates between knee extension and knee flexion (three trials for each). The left leg is tested first. Force curves will be recorded for all trials and the peak force (Nm), normalised for body mass as appropriate (Nm/kg), used for analyses. Knee extension and flexion rate of force development will also be assessed using the slope (change in force divided by change in time) of muscle contraction onset. To correct the influence of gravity, the assessed limb is weighed before each test and the data acquisition software automatically corrects the output data.

Figure SF3.3 Set up of knee muscle strength assessment using Biodex isokinetic dynamometer

Supplementary File 5. Details of magnetic resonance imaging sequences acquired

	Proton Density weighted fat suppressed fast spin-echo *Axial*	**Proton Density weighted fat suppressed fast spin-echo *Sagittal***	**Proton Density weighted fat suppressed fast spin-echo *Coronal***	**Multi-echo spin-echo (MESE) T2 relaxation time mapping *Sagittal***	**Fast spoiled gradient echo (FSPGR) *Sagittal***
Repetition time (msec)	3725	2300	2325	3225	10.3
Echo time (msec)	36	36	36	10, 20, 30, 40, 50, 60, 70, 80	Minimum (~3.7)
Acquisition matrix	340 x 300	360 x 300	340 x 300	320 x 269	512 x 512
Field of view (cm)	16	16	16	12	16
Resolution (mm)	0.471 x 0.533 x 3.0	0.444 x 0.5333 x 3.0	0.471 x 0.5333 x 3.0	0.375 x 0.446 x 3.0	0.313 x 0.313 x 1.5
Slice thickness (mm)	3.0	3.0	3.0	3.0	1.5
Slice gap (mm)	0.3	1.0	0.3	1.0	0
Flip angle (°)	142	142	142	90	12
Number of echoes	10	10	9	8	-
Number of slices	32	31	34	31	84
Number of excitations	1	1	1	0.5	1
Bandwidth	50	35.71	35.71	31.25	31.25
Scan time (mins)	2:59	2:55	4:21	7:51	15.08

Participant Information Sheet/Consent Form

Interventional Study - *Adult providing own consent*

Title	Optimising outcomes after anterior cruciate ligament reconstruction: SUPER KNEE randomised controlled trial
Short Title	The SUPER KNEE trial
Ethics Reference Number	HEC19447
Project Sponsor	La Trobe University
Coordinating Principal Investigator/ Principal Investigator	Prof. Kay Crossley (La Trobe University)
Associate Investigators	Dr Adam Culvenor (La Trobe University) Dr Christian Barton (La Trobe University) Prof. Ewa Roos (Southern Denmark University) Prof. Steven McPhail (Queensland University of Technology) Ass. Prof. Edwin Oei (Erasmus Medical Centre) Dr Andrea Bruder (La Trobe University) Mr Thomas West (La Trobe University)
Location	La Trobe University

Part 1 What does my participation involve?

1 Introduction

You are invited to take part in this research project because you have had an anterior cruciate ligament (ACL) reconstruction within the last 9-36 months. The research project aims to compare the effectiveness of two different exercise and activity monitoring programs to optimise your knee symptoms, function and activity level and maximise your quality of life.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests and treatments involved. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or your local doctor.

Your participation is voluntary

Participation in this research is completely voluntary and there will be no cost to you. If you don't wish to take part, you don't have to. You will receive the best possible care whether or not you take part.

If you decide to take part and later change your mind, you are free to withdraw at any stage. Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you, or your relationship with La Trobe University or the hospital/orthopaedic surgeon who performed your ACL surgery.

If you decide you want to take part in the research project, you will be given a copy of this Participant Information Sheet and asked to sign the consent section. By signing it you are telling us that you:
- Understand what you have read
- Consent to take part in the research project
- Consent to have the tests and treatments that are described
- Consent to the use of your personal and health information as described.

Your withdrawal from the study

You are under no obligation to continue with the research study. You may change your mind at any time about participating in the research. People withdraw from studies for various reasons and you do not need to provide a reason.

You can withdraw from the study at any time by completing and signing the 'Participant Withdrawal of Consent Form'. This form is provided at the end of this document and is to be completed by you and supplied to the research team if you choose to withdraw at a later date.

If you withdraw from the study, you will be able to choose whether the study will destroy or retain the information it has collected about you. Information about you that has already been analysed (i.e., once you have been allocated to either exercise program), may not be able to be destroyed to ensure accurate and unbiased study reporting. Personal details collected, such as your name and contact details, can be destroyed at any time upon study withdrawal.

2 What is the purpose of this research?

As you may be aware, many people who have had an ACL reconstruction do not recover to a level that they are satisfied with. Therefore, it is important to investigate treatments that can improve outcomes. The purpose of this study is to investigate whether two different exercise and activity monitoring programs can improve knee symptoms, function, physical activity and quality of life, and prevent knee arthritis. We will recruit 184 adults who have not completely recovered at 9-36 months after ACL reconstruction in Australia.

This study is being coordinated by researchers at La Trobe University. It is supported by international researchers and has been funded by an Australian National Health and Medical Research Council Project Grant. All assessments and treatment will be at **no cost** to you.

3 Who can participate?

You can participate in the study if you meet all the following:
- Have had ACL reconstruction surgery 9-36 months previously
- Be aged 18-40 years at the time of your ACL reconstruction
- Have not completely recovered from your ACL reconstruction, assessed by a questionnaire (provided by the researchers)
- Willing to complete exercises 2-3 times per week

You are not eligible and cannot participate in this study if you meet any of the following:
- Have had another knee injury/surgery or knee injection in the past 3 months
- Have had physiotherapy treatment for your knee in the past 6 weeks
- Have another injury or health condition that affects your ability to perform functional tasks and exercises
- Have contraindications for MRI (e.g. pacemaker, a history of metallic foreign body in the eye, previous surgery for cerebral aneurysm, other implanted metal material other than your ACL graft or claustrophobia)
- Currently pregnant or breastfeeding
- Planning on relocating interstate or overseas in the next 18 months or unable to commit to the various study assessments over the next 18 months (as detailed below)
- Unable to understand written and/or spoken English

4 What does participation in this research involve?

If you agree to participate in this study, you will be asked to sign the participant consent form before any study assessments are performed. This study will be conducted over 18 months in total (see flowchart on next page).

A comprehensive knee assessment by a physiotherapist

For the first assessment at the start of the study, you will attend La Trobe University. At this testing session you should allow approximately 2 hours, where you will undergo a physical examination by a physiotherapist. You will be asked to wear shorts and a small piece of stocking (provided) over both of your knees during some tests so that the examiner is unable to tell which knee is your operated one. The tests conducted in the physical examination will include a measure of knee movement and joint swelling, activities including squatting and hopping, and measures of muscle strength (quadriceps and hamstrings). Muscle strength will be assessed using a special chair and you will be asked to push up and down a few times against an ankle pad as hard as you can. We will also measure and record your height, weight and waist circumference. We will video your performance during clinical tests (e.g. single-leg squat and jump). These videos will not include your face, so you cannot be identified from the footage. If any of your face (or other identifying feature) is inadvertently videoed, this will be masked (by electronically blurring the area) prior to data analysis.

You will also be asked to complete a series of questionnaires related to pain, physical function, confidence with physical movements and physical activity, as well as details about your knee injury/pain (e.g. injury mechanism, location of pain; history of pain). These may be completed in person at the testing session or online via link provided by email.

If you are interested, you may also undergo a 3D biomechanics assessment at the La Trobe University gait laboratory. This is optional and takes an additional 30-60mins. Small reflective skin markers will be attached to your skin (with tape on arms, pelvis, legs) and tracked with infrared cameras when you walk, run and perform hopping tasks.

A knee MRI

You will also attend Lake Imaging Specialist and Research Centre, North Melbourne (within 1-week of your assessment at La Trobe University) where you will have a magnetic resonance imaging (MRI) scan of your reconstructed and possibly your other knee (if uninjured). For the MRI scan you will be asked to lie on a narrow table that can slide inside a large tunnel-like tube with a scanner. The scanner creates a magnetic field around you, then pulses radio waves at the knee. This does not contain any radiation. It is very important that you keep very still during the scanning. All imaging will be provided at **no cost** to you and will take approximately 25-45 mins to complete.

Random assignment to one of two different treatments

At the end of the first assessment at La Trobe University you will be randomly assigned (50:50 chance, like a coin toss) by a computer system to receive one of the exercise and activity monitoring programs provided by physiotherapists to increase lower-limb muscle strength, power, endurance and agility. This means neither you or the researchers will be able to choose which group you are assigned to. We do not know which treatment is best. To find out we need to compare the different treatments. There is equal chance that you will receive either treatment. All treatment will be at **no cost** to you.

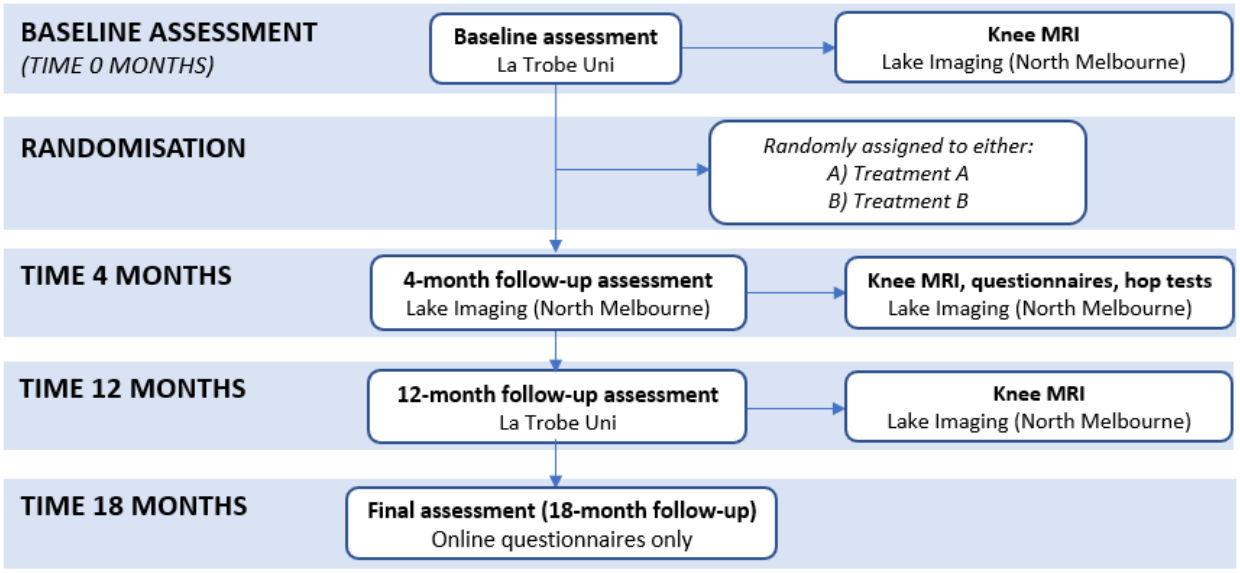

Figure 1. Flowchart of study assessments

If you are randomised to receive ***Treatment A***, you will receive a "best-practice guide" booklet and a face-to-face appointment with a physiotherapist to explain the exercises and education in the booklet. Your physical activity and sports participation will be monitored with fortnightly (for first 4 months) and monthly (after first 4 months) online questionnaires. You will also be provided with an activity monitor (Garmin™ watch) to count your steps.

If you are randomised to receive ***Treatment B***, you will receive 2 x per week face-to-face appointments for 4 months with a physiotherapist to perform muscle strength and agility/balance exercises. We have trained physiotherapists at clinics throughout Melbourne and Victoria to be convenient for you to attend. We will offer reimbursement for travel costs to attend each local physiotherapy appointment. You will have the option to access a gym (located conveniently for you and at no cost) at the 4-month assessment to continue to perform strengthening exercises up to 12-months after baseline. We will monitor your physical activity in the same way, and you will also get a physical activity monitor (Garmin™ watch) to measure your daily step count.

Follow-up assessments

At 4-months after baseline assessment, the same assessments will be repeated (questionnaires, hop tests and MRI) at Lake Imaging Specialist and Research Centre, North Melbourne and La Trobe University. At 12-months after baseline assessment, all assessments will be repeated: questionnaires, physical examination at La Trobe University, and MRI at Lake Imaging Specialist and Research Centre, North Melbourne. At completion of the study (18-months after baseline), the same online questionnaires will be repeated only.

There are no additional costs associated with participating in this research project. All medical care required as part of the research project will be provided free of charge. Your travel costs to attend the assessments will be reimbursed up to $100.

5 What else do I have to do?

In addition to the assessments conducted at baseline, 4-, 12- and 18-months, you will be asked to record the exercises you have completed in a log book. You will also be asked to record any other healthcare treatments you receive during the study. This will be recorded in the fortnightly/monthly online questionnaire. You will otherwise be able to carry on with your normal lifestyle. It is also important for us to know about your surgical details (e.g. technique, cartilage/meniscus treatment), so we will request to access your surgical notes.

At the end of the first 4 months, or after 12 months, we may also ask if you are willing to have a separate interview with one of the study researchers. The purpose of this interview is to seek

feedback on the study interventions, satisfaction with the process received and whether there are any suggestions for improvement. The interview will take approximately 30 minutes, but you can cease the interview at any time. To ensure responses are correctly interpreted, responses to questions will be audio recorded and transcribed. Audio recording transcriptions will be completed by 'Transcription Australia' on their secure, encrypted Australian-based software. Although voice in your audio recording could lead to your identification, this file will not be used during analysis. Instead a re-identifiable transcription, which you will have the opportunity to check for accuracy, will be used for analysis. Re-identifiable means that we will use a code number and not your name on data collected to ensure your anonymity. Following the completion of analysis of this transcription, the audio file associated with your interview will be deleted. After analysis, overall findings and conclusions from all interviews will also be sent to you, to allow an opportunity to make any further comments. We will seek around 40 participants to be interviewed (n=30 at 4 months, and n=30 at 12 months). It is your decision or not whether you wish to be interviewed.

6 What are the alternatives to participation?

You do not have to take part in this research project to receive treatment for your knee. Other options are available; these include attending physiotherapy (in a private practice or via the public hospital system). The research team will discuss these options with you before you decide whether or not to take part in this research project. You can also discuss the options with your surgeon, local doctor or physiotherapist.

7 What are the possible benefits of taking part?

We cannot guarantee or promise that you will receive any benefits from this research. However, possible benefits may include improved symptoms, function, quality of life, physical and sports activity, and confidence in your knee. You may also gain valuable insight into your physical functioning of your knee joint.

8 What are the possible risks and disadvantages of taking part?

The testing procedures and exercise-therapy treatments may cause side effects. You may have none, some or all of the effects listed below, and they may be mild, moderate or severe. If you have any of these side effects, or are worried about them, talk with the study coordinator.

Possible Side Effect	How often is it likely to occur?	How severe might it be?	How long might it last?
Muscle soreness	Commonly, after testing; or after a change in exercises	Muscle may be tender to touch, may notice pain when using muscles (e.g. going up/down stairs)	May last 2-3 days
Increase in knee pain or swelling	Rarely after testing; Rarely after exercise-therapy if instructions followed	Mild Moderate Severe	2-3 days 3-7 days > 1 week
Re-injury (e.g. rupture of ACL graft), or injury to opposite knee (or ankle/hip)	Extremely rare during testing or exercise (research team are only aware of 1 incident in 20+ years in this field)	Mild to severe	Depends on injury – maybe months

There may be side effects that the researchers do not expect or do not know about and that may be serious. Tell the researchers immediately if you get any new or unusual symptoms. Most side effects go away shortly after treatment ends. If a severe side effect or reaction occurs, the study coordinator may need to stop your treatment. The study coordinator will discuss the best way of managing any side effects with you.

Muscle and joint soreness

The physical tests and exercises represent usual examination and intervention by a physiotherapist. You may experience a small amount of discomfort in the joints or muscles. Please report to the researcher any discomfort or pain experienced during the testing or exercises. If the pain or discomfort is deemed to be excessive by yourself or the investigators, the testing/treatment will cease.

Re-injury

There is a very slight risk of falling during the hopping tasks. During the physical tests and exercises, there is also an extremely low risk of re-injuring your ACL reconstructed knee. During the first 5 years after ACL reconstruction, approximately 5% of people will re-rupture their ACL graft, with almost all of these occurring during sport. To minimise the risk of graft rupture, an experienced physiotherapist will conduct all testing, and you can choose to not perform tests if you are not confident to do so. The exercises have been designed using the best available research, and you will be provided with criteria to appropriately progress the difficulty of exercises to minimise re-injury risk. In particular, before attempting sport, we strongly recommend approval from your surgeon and possibly a return to sport assessment by a health professional.

Magnetic Resonance Imaging (MRI)

When you lie in the MRI machine, the MRI team will make sure you are in a comfortable position so you can keep still. The scanner is very noisy and they can give you some earphones to reduce the noise. Some people may experience symptoms of claustrophobia from lying in a confined space. If you do experience discomfort at any time during the scan, you will be able to alert staff by pressing on a call button provided to you.

There are no proven long-term risks related to MRI scans. MRI is considered safe when performed at a centre with appropriate procedures. However, the magnetic attraction for some metal objects can pose a safety risk, so it is important that metal objects are not taken into the scanner room.

The MRI team will examine you to make sure there is no reason for you not to have the scan. You must tell them if you have metal implanted in your body, such as a pacemaker or metal pins.

The scans we are taking are for research purposes. They are not intended to be used like scans taken for a full clinical examination. The scans will not be used to help diagnose, treat or manage a particular condition. A specialist will look at your MRI scans for features relevant to the research project. This may be done by specialists we work with overseas – all identifying information (name, date of birth etc) will be removed from your MRI scans prior to analysis so that you will not be able to be identified. On rare occasions, the specialist may find an unusual feature that could have a significant risk to your health. If this happens, we will contact you and/or your health practitioner to talk about the findings. We cannot guarantee that we will find any/all unusual features. The MRI team will provide you with a copy of your MRI scans.

9 Can I have other treatments during this research project?

While you are participating in this research project, you should not participate in alternative or additional exercise-therapy (or physiotherapy). It is important to tell the study co-ordinator about any treatments or medications you may be taking, including over-the-counter medications, vitamins or herbal remedies, acupuncture or other alternative treatments. We prefer that you do not commence any new treatment during the research project. However, should you decide to do so, we require you to describe any treatments (including medications) in your “study log book”.

10 What happens when the research project ends?

At the completion of the research project, there will be no additional treatment provided by our research team. If you wish to continue with your exercise-therapy treatment, you can continue to use the resources provided to you. Any additional treatment (e.g. physiotherapy) that you might require at the completion of the research project will be at your own cost. If requested, we will provide you with your individual results and whole study results. We, or other researchers, may also use coded information (so that you cannot be identified) collected for this research study in future related studies. If you consent (tick the box on the consent form) to be contacted for future related research, we will store your contact details (name, address, phone number, email) on the secure La Trobe University research drive, only accessible to members of the research team, and may contact you about future related research projects.

Part 2 How is the research project being conducted?

11 What will happen to information about me?

By signing the consent form you agree to the relevant research staff collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential and securely stored. It will be disclosed only with your permission, or in compliance with the law.

The research staff will also collect information on the health services you have used for the 6 months before, and 18 months after, baseline assessment. To collect this information, identifiable data (e.g. name, age, address) will be submitted to the Department of Human Services so that information about your health service usage can be obtained from a range of health datasets (e.g. Medicare Benefits Schedule (MBS), Pharmaceutical Benefits Scheme (PBS)) and linked to your study data. The health service data will be provided to the research team, by the Department of Human Services, in a format where your identifiable data (e.g. name, address) has been removed and the anonymous data will be held and analysed within a Department of Human Services approved, secure data storage environment. This information will be used solely for this project.

You will be asked to sign a consent form authorising the study to access your complete MBS and PBS data as outlined in the consent form. Medicare collects information on your doctor visits and the associated costs, while the PBS collects information on the prescription medications you have filled at pharmacies. The consent form is sent securely to the Department of Human Services who holds MBS and PBS data confidentially.

Storage, retention and destruction

The anonymity of your participation is assured with our procedure, in which a code number and not your name will identify you. Data will be kept securely at La Trobe University in a locked filing cabinet and password protected research computer. Re-identifiable (i.e. coded) information will also be kept to link your health service utilisation. Identifiable data will be stored for 15 years, after which time it will be securely destroyed (electronic records deleted, and paper-files shredded). All data and results will be handled in a strictly confidential manner, under guidelines set out by the National Health and Medical Research Council. The principal investigator (Professor Kay Crossley) is responsible for maintaining this confidentiality.

Information about you may be obtained from your health records held at health services for the purpose of this research. By signing the consent form you agree to the study team accessing health records if they are relevant to your participation in this research project.

In accordance with relevant Australian and/or Victorian privacy and other relevant laws, you have the right to request access to your information collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please contact the study member named below if you would like to access your information.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums and may be used by research higher degree students to obtain a research degree. In any publication, presentation or data files shared with other researchers, information will be provided in such a way that you cannot be identified, except with your permission. Any personal information that could identify you will be removed or changed before files are shared with other researchers.

12 What happens if I am injured as a result of participating in this research project?

If you suffer any injuries or complications as a result of this research project, you should contact the study team as soon as possible. You will be assisted with arranging appropriate medical treatment. If you are eligible for Medicare, you can receive medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital. Waiting lists may apply and you may not see the surgeon who performed your original ACL reconstruction. In the first instance your study physiotherapist and/or research team will evaluate your condition and then discuss treatment with both you and your regular health practitioner. In the event of loss or injury, any question about compensation must initially be directed to the research team who will advise the university insurer of the matter.

13 Who is organising and funding the research?

This research project is being conducted by Professor Kay Crossley and a team of national and international researchers. It has been funded by an Australian National Health and Medical Research Council Project Grant. No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

14 Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of La Trobe University and the Alfred Hospital Ethics Committee.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2018)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

15 Further information and who to contact

The person you may need to contact will depend on the nature of your query.
For all enquiries, you can contact the Clinical Trial Manager, during business hours:

Dr Adam Culvenor, Research Fellow in Physiotherapy, La Trobe University
Tel: 03 9479 5116; E-mail: a.culvenor@latrobe.edu.au

If you have any medical problems which may be related to your involvement in the project (for example, any side effects), the number to call Dr Adam Culvenor after hours is: 0401390974.

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

Reviewing HREC: La Trobe University Human Research Ethics Committee
Complaints Contact: Senior Human Ethics Officer, Ethics and Integrity, Research Office
Telephone: 03 9479 1443 E-mail: humanethics@latrobe.edu.au

* Please quote the application reference number HEC19447.

LA TROBE UNIVERSITY

SUPER Knee

Consent Form - *Adult providing own consent*

Title	Optimising outcomes after anterior cruciate ligament reconstruction: SUPER KNEE randomised controlled trial
Short Title	The SUPER KNEE trial
Ethics Reference Number	HEC19447
Project Sponsor	La Trobe University
Coordinating Principal Investigator/ Principal Investigator	Professor Kay Crossley
Associate Investigator(s)	Dr Adam Culvenor Dr Christian Barton Professor Ewa Roos Professor Steven McPhail Associate Professor Edwin Oei Dr Andrea Bruder Mr Thomas West
Location	La Trobe University

Consent Agreement

I have read the Participant Information Sheet and I understand the purposes, procedures and risks of the research described in the project.

Information about you may be obtained from your health records held at health services for the purpose of this research. I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to La Trobe University concerning my knee injury and treatment for the purposes of this project. I understand that such information will remain confidential.

I understand that data files may be shared with other researchers, and that information will be provided in such a way that I cannot be identified, except with my permission.

I have had an opportunity to ask questions and I am satisfied with the answers I have received. I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the study without affecting my future health care.

At the end of the first 4 months, or after12 months, you will be asked if you are willing to have a separate recorded interview with one of the study researchers for the purposes of seeking feedback.

☐ I agree to participate in a recorded interview
☐ I do not agree to participate in a recorded interview

I understand that, if I decide to discontinue the study treatment, I may be asked to attend follow-up visits to allow collection of information regarding my health status. I agree that data gathered for the study may be published provided my name or other identifying information is not used.

☐ I wish to receive results of the study ☐ I do not wish to receive results of the study

☐ I consent to be contacted for future related research
☐ I do not consent to be contacted for future related research

I understand that I will be given a signed copy of this document to keep.

Name of Participant (please print) _____

Signature _____ Date _____

Declaration by Researcher†

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Name of Researcher† (please print) _____

Signature _____ Date _____

† A member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature.

LA TROBE UNIVERSITY

SUPER Knee

Form for Withdrawal of Participation - *Adult providing own consent*

Title	Optimising outcomes after anterior cruciate ligament reconstruction: SUPER KNEE randomised controlled trial
Short Title	The SUPER KNEE trial
Ethics Reference Number	HEC19447
Project Sponsor	La Trobe University
Coordinating Principal Investigator/ Principal Investigator	Professor Kay Crossley
Associate Investigator(s)	Dr Adam Culvenor Dr Christian Barton Professor Ewa Roos Professor Steven McPhail Associate Professor Edwin Oei Dr Andrea Bruder Mr Thomas West
Location	La Trobe University

Declaration by Participant

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine treatment, my access to Health Services or Government benefits, my relationship with those treating me or my relationship with La Trobe University or the health system where I had my knee surgery. I understand that no further information about me will be collected for the study from the withdrawal date. I understand that information about me that has already been analysed and/or included in a publication by the study, may not be able to be destroyed. I request that the study handles the information they have collected about me in the following way (choose one option):

☐ DESTROY all my information collected so it can no longer be used for research

☐ RETAIN all my information collected so it can be used for research

Name of Participant (please print) _____

Signature _____ Date _____

In the event that the participant's decision to withdraw is communicated verbally, the Researcher will need to provide a description of the circumstances below.

Date:
Time:

Declaration by Researcher†

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant has understood that explanation.

Name of Researcher† (please print) _____

Signature _____ Date _____

† A member of the research team must provide the explanation of and information concerning withdrawal from the research project.

Note: All parties signing the consent section must date their own signature.

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	3
	2b	All items from the World Health Organization Trial Registration Data Set	ACTRN12620001164987
Protocol version	3	Date and version identifier	NA
Funding	4	Sources and types of financial, material, and other support	23
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	23
	5b	Name and contact information for the trial sponsor	1
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	23
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	NA
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4
	6b	Explanation for choice of comparators	4-5
Objectives	7	Specific objectives or hypotheses	5
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	5-6
Methods: Participants, interventions, and outcomes			

Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	6
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	6
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	8-13, Table 2, Supplementary 1
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	Table 2
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	8-13, Table 2
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	13
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	14-18, Table 3
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	Figure 1
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	19
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	6-7
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	7-8
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	7-8
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	7-8
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	7-8

	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	NA
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	13
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	13
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	19
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	20
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	20
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	20
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	19
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	19-20
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	18-19
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	NA
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	22

Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	22
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	22
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	NA
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	19
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	23-24
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	Supplementary 6
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	NA
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	22
	31b	Authorship eligibility guidelines and any intended use of professional writers	NA
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	NA
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Supplementary 6
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	NA

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-Non Commercial-No Derivs 3.0 Unported" license.

BMJ Open

SUpervised exercise-therapy and Patient Education Rehabilitation (SUPER) versus minimal intervention for young adults at risk of knee osteoarthritis after ACL reconstruction: SUPER-Knee randomised controlled trial protocol

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2022-068279.R1
Article Type:	Protocol
Date Submitted by the Author:	12-Dec-2022
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Primary Subject Heading:	Sports and exercise medicine
Secondary Subject Heading:	Rehabilitation medicine, Sports and exercise medicine
Keywords:	Knee < ORTHOPAEDIC & TRAUMA SURGERY, REHABILITATION MEDICINE, SPORTS MEDICINE

SUpervised exercise-therapy and Patient Education Rehabilitation (SUPER) versus minimal intervention for young adults at risk of knee osteoarthritis after ACL reconstruction: SUPER-Knee randomised controlled trial protocol

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Word count: 4,580

ABSTRACT

Introduction: Anterior cruciate ligament injury and reconstruction (ACLR) is often associated with pain, functional loss, poor quality of life and accelerated knee osteoarthritis development. The effectiveness of interventions to enhance outcomes for those at high risk of early-onset osteoarthritis is unknown. This study will investigate if SUpervised exercise-therapy and Patient Education Rehabilitation (SUPER) is superior to a minimal intervention control for improving pain, function and quality of life in young adults with ongoing symptoms following ACLR.

Methods and analysis: The SUPER-Knee study is a parallel-group, assessor-blinded, randomised controlled trial. Following baseline assessment, 184 participants aged 18-40 years and 9-36 months post-ACLR with ongoing symptoms will be randomly allocated to one of two treatment groups (1:1 ratio). Ongoing symptoms will be defined as a mean score of <80/100 from four Knee injury and Osteoarthritis Outcome Score ($KOOS_4$) subscales covering pain, symptoms, function in sports and recreational activities and knee-related quality of life. Participants randomised to SUPER will receive a 4-month individualised, physiotherapist-supervised strengthening and neuromuscular programme with education. Participants randomised to minimal intervention (i.e., control group) will receive a printed best-practice guide for completing neuromuscular and strengthening exercises following ACLR. The primary outcome will be change in the $KOOS_4$ from baseline to 4 months with a secondary endpoint at 12 months. Secondary outcomes include change in individual KOOS subscale scores, patient-perceived improvement, health-related quality of life, kinesiophobia, physical activity, thigh muscle strength, knee function and knee cartilage morphology (i.e., lesions, thickness) and composition (T2 mapping) on magnetic resonance imaging. Blinded intention-to-treat analyses will be performed. Findings will also inform cost-effectiveness analyses.

Ethics and dissemination: This study is approved by the La Trobe University and Alfred Hospital

Ethics Committees. Results will be presented in peer-reviewed journals and at international conferences.

Trial registration: ACTRN12620001164987

Keywords:

anterior cruciate ligament, rehabilitation, osteoarthritis, knee, physiotherapy, exercise.

Strengths and limitations of this study

- The exercise-therapy programme was developed and piloted with patients and clinicians, aligns with American College of Sports Medicine (ACSM) recommendations, and is described based on the Consensus on Exercise Reporting Template (CERT).
- Sufficiently powered trial evaluating change from baseline to 4 months (primary endpoint) and 12 months facilitating longer-term effectiveness evaluation of exercise-therapy and education.
- This trial will evaluate both the illness (i.e., symptoms) and disease (i.e., structure) of osteoarthritis and include cost-effectiveness analysis.
- While outcome assessors are blinded to group allocation and physiotherapists delivering the intervention are blinded to the control intervention, participant blinding was not possible due to the type of interventions.

INTRODUCTION

Anterior cruciate ligament (ACL) rupture is one of the most common serious knee injuries in young, healthy people participating in sports involving jumping, pivoting and cutting activities [1]. Treatment success is often judged on a timely return to sport [2]. Yet, 55% do not return to competitive sport [3], and half will develop post-traumatic knee osteoarthritis (OA), unacceptable persistent pain, functional loss and poor quality of life before the age of 40 years [4-7]. Occupational and carer responsibilities in many of these young adults also creates formidable societal and economic burden.

Osteoarthritis can be characterised by symptoms such as pain and functional limitations and/or structural joint changes seen on imaging. Both symptoms and structural changes are common within the first decade after ACL reconstruction (ACLR), yet they are often discordant [5, 8]. International government-endorsed OA initiatives recommend evaluating symptoms and structure in OA clinical trials to address the heterogeneity of the disease [9].

Identifying interventions that can improve knee-related symptoms and prevent or slow structural changes in young adults following ACLR is an international priority [10, 11]. Exercise-therapy improves pain and function in older populations with primary (non-traumatic) knee OA [12], but effective treatments to improve structure (i.e., disease-modifying interventions) have thus far proved elusive [13]. Secondary prevention strategies for those with early manifestations (or at high risk) of OA, such as following ACLR, offer potential to alter the OA trajectory [14, 15]. Targeted exercise-therapy might slow structural worsening [16], with preliminary studies reporting improved knee cartilage composition in people at risk of OA (post-meniscectomy) [17] and with non-traumatic early OA over 4 and 12 months, respectively [18, 19].

People who report inadequate recovery (ongoing symptoms and impaired function) one year after ACLR are likely to have worsening symptoms and rapidly deteriorating joint structure in the future [20-

22]. These young adults with inadequate recovery urgently need treatment options to alter their OA trajectory. Our feasibility study indicated that a full-scale randomised controlled trial (RCT) evaluating a physiotherapist-led, exercise-therapy and education programme for young adults with ongoing symptoms approximately one year after ACLR (i.e., when no further improvement is likely without treatment) is feasible and likely associated with a clinically worthwhile effect for pain, function and quality of life [23].

The primary aim of this RCT is to estimate the average effect of SUpervised exercise-therapy and Patient Education Rehabilitation (SUPER) compared to a minimal intervention control on knee-related pain, function and quality of life in young adults with ongoing symptoms at high risk of early-onset knee OA 9-36 months after ACLR. We hypothesise that the SUPER intervention will result in greater improvements in knee-related pain, symptoms, function and quality of life after 4 months (primary endpoint) and 12 months (secondary endpoint) compared to a minimal intervention control. Secondary aims are to assess 4- and 12-month effectiveness of SUPER on: i) self-reported global rating of change (GROC) and achievement of acceptable symptoms; ii) health-related quality of life; iii) physical activity; iv) kinesiophobia; v) thigh muscle strength and function; and vi) change in knee cartilage health. Intervention and healthcare resource use will also be recorded to inform economic evaluation.

METHODS AND ANALYSIS

Study design

This study protocol describes a pragmatic, parallel-group assessor-blinded RCT conforming to the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) statement [24]. Reporting of the completed RCT will conform to the Consolidated Standards of Reporting Trials (CONSORT) statement for reporting RCTs [25] in conjunction with the Template for Intervention

Description and Replication (TiDieR) [26], and the Consensus on Exercise Reporting Template (CERT) guidelines [27]. The trial will be conducted at a single university site (La Trobe University) in Melbourne, Australia with enrolment planned to occur over three years (2021-2023) and 12-month follow-up completed in 2024. The primary endpoint will be at 4 months (immediately following the intensive supervised exercise-therapy phase), with additional follow-up at a minimum of 12 months (further longer-term follow-up dependent on funding). The study was prospectively registered on the Australian & New Zealand Clinical Trial Registry (ACTRN12620001164987).

Participants

One hundred and eighty-four young adults fulfilling the eligibility criteria (table 1) will be included.

Table 1. Eligibility criteria

Inclusion criteria	Exclusion criteria
Aged 18-40 years at the time of ACLR	Synthetic ACLR graft
9-36 months following ACLR	Concomitant intra-articular knee fracture
Symptomatic ACLR knee: mean score of <80/100 from four Knee injury and OA Outcome Score ($KOOS_4$) subscales covering pain, symptoms, function in sports/recreation and quality of life	Planning to relocate interstate/internationally in following 12 months or unable to commit to study assessments
Willing and able to participate in exercise-therapy 2-3 times per week for at least 4 months	Any of the following in the past 3 months: knee re-injury, surgery or injection (either knee)
	Undertaken rehabilitation in past 6 weeks (for conditions affecting either knee)
	Contraindications to MRI
	Planning knee surgery in following 12 months (e.g., graft rupture, cyclops lesion (localised anterior arthrofibrosis) on MRI)
	Other reasons for exclusion (health condition affecting physical function, mentally unable to participate, pregnancy, unable to understand English, etc)

ACLR, anterior cruciate ligament reconstruction; MRI, magnetic resonance imaging

Recruitment procedure

Trial flow is outlined in figure 1. Participants will be recruited from approximately 15 collaborating private orthopaedic surgeons and eight public hospital sites in Victoria, Australia. Consistent with our pilot work [28, 29], potentially eligible participants (i.e., individuals with an ACLR from our network of collaborating private orthopaedic surgeons or public hospitals) will be mailed study information inviting them to contact a member of the research team. Additional participants will be recruited from the general community via advertisements in local newspapers, community magazines and newsletters (e.g., university staff bulletins, sports club newsletters), posters in the community and social media.

Volunteers responding to the invitation letter or advertisements will be screened for eligibility using a three-stage process. Firstly, screening questions will be asked via telephone or e-mail. Secondly, potentially suitable volunteers will be sent the Knee injury and OA Outcome Score (KOOS) questionnaire electronically (or hard copy if preferred) to confirm symptomatic eligibility. Thirdly, baseline magnetic resonance imaging (MRI) scans will be assessed to confirm the absence of any pathology potentially necessitating surgery (e.g., graft rupture, symptomatic cyclops lesion). If both knees are eligible, the most symptomatic knee will be considered as the index knee for the trial.

---FIGURE 1 HERE---

Randomisation procedure, concealment of allocation and blinding

Eligible, willing and consenting volunteers will be randomised to the SUPER or control group after baseline assessment, commencing as soon as possible. A computer-generated randomisation schedule has been developed *a priori* by an independent statistician in random permuted blocks of 4-8 to maintain a periodic allocation ratio of 1:1. To ensure concealed allocation, the randomisation schedule will be stored electronically in the secure Research Electronic Data Capture (REDCap) system and only accessible to an unblinded researcher once baseline measures have been obtained. Investigators

conducting study assessments will be blind to group allocation. As the primary outcome is self-reported, participants are considered assessors; therefore, participants (and thus assessors) will be blinded to previous scores. Physiotherapists and participants cannot be blinded to group allocation owing to the type of interventions. An independent statistician, blinded to group allocation, will perform the primary RCT analysis. To reduce risk of interpretation bias, blinded results from the analyses (Group A compared with Group B) will be presented to all authors, who will agree on two alternative written interpretations before the data manager unblinds the randomisation code [30].

Interventions

Supervised exercise-therapy and Patient Education Rehabilitation (SUPER)

Participants allocated to SUPER will participate in a supervised exercise programme, developed based on best available evidence for patients with ACLR and other knee injuries including OA [31-33], and with input from patients and experienced physiotherapists. An overview of the SUPER programme aligning to the CERT guidelines is contained in Supplementary File 1 and summarised as per TIDieR guidelines in table 2. The SUPER intervention aims to increase lower-limb muscle strength, endurance and power, functional performance and neuromuscular control, increase understanding of knee health, facilitate return to desired sports activity and enhance physical activity. Registered physiotherapists with ≥3 years of experience treating patients following ACLR will deliver SUPER in community settings following a 4-hour training workshop supplemented with three hours of online webinars. To minimise participant travel burden, study physiotherapists will be located at 12-14 private physiotherapy clinics across greater Melbourne and regional Victoria.

SUPER is divided into two phases.

Phase 1: 0-4 months. Participants will be provided with details of the SUPER intervention verbally and via an intervention handbook detailing all exercises and an exercise logbook, and provided access to videos of all exercises. Participants will complete their exercise programme supervised by a

physiotherapist twice per week in Phase 1, with at least one additional unsupervised session at a gym or home encouraged (table 2). Participants/physiotherapists will also have the option of a second opinion by a member of our clinical expert physiotherapy team if SUPER is failing to facilitate improvement (either at 2- or 4-months post-baseline). Second opinion will provide assessment and guidance on exercise-therapy and patient education needs.

Phase 2: (5-12 months). The intervention provided in Phase 2 will depend on whether the following predefined criteria are met at the 4-month follow-up assessment: participant's goals are met (i.e., goals set with treating physiotherapist at start of Phase 1), participant satisfied with current symptoms/function (i.e., responded 'yes' to patient acceptable symptom state question (see Outcomes for details)) and GROC reported as at least 'better'.

For participants meeting all criteria, Phase 2 will involve ongoing independent exercise-therapy sessions (approximately 30-60 minutes duration, 2-3 x per week at a gym or home). Participants may request a physiotherapy booster session if they become unsure about continuing self-management or exercise-therapy or pre-defined criteria are no longer met. Booster sessions can continue once per week and will focus on the priority exercises and discussion of self-management strategies.

Participants not meeting all criteria at the end of Phase 1 will be offered ongoing once per week supervised exercise-therapy in Phase 2. Once all criteria are met, participants will continue unsupervised exercise-therapy sessions at a gym or home with physiotherapy booster sessions as required (as per above criteria). All participants will be offered a membership to a local gym to encourage unsupervised exercise-therapy during Phase 2. An additional booster session with the treating physios will occur at 8- and 11-months post-baseline.

Exercise-therapy will be tailored to each participant to match their individual preferences, goals and clinical presentation (e.g., muscle strength, pain severity, and personal, sporting, work and functional needs). The exercise-therapy programme consists of five "priority" exercises and four optional exercises (table 2, Supplementary File 2). The total number of exercises prescribed (maximum number of nine) will depend on the participant's available time and willingness, and physiotherapist clinical reasoning – but will always include the five "priority" exercises.

Each exercise has 3-6 levels of difficulty. Physiotherapists will supervise and progress exercises based on defined criteria guided by American College of Sports Medicine strength training principles [34] and perceived difficulty using rating of perceived exertion and minimal pain (e.g., <3/10 on numerical pain scale) (details in Supplementary File 1).

Patient education was co-designed with experienced physiotherapists and pilot study participants[23] and aims to support the exercise-therapy programme and build motivation and capability to sustain the exercises during and after the initial 4-month supervised phase (table 2). Individualised health education regarding expectations and goals, exercise principles, improving adherence, pain/fear management, long-term outcomes, weight control, and appropriate physical, occupational and sporting activity promotion, will be delivered during the physiotherapy treatment sessions. Two dedicated education sessions of 45-60 minutes duration will be delivered during Phase 1 (week 1 and week 4). Participants will be counselled regarding physical activity levels with a targeted training program adhering to Australian Physical Activity Guidelines and given an activity monitor (Garmin vívofit® 4 activity tracker) if they do not have access to one to support measurement and attainment of physical activity goals.

253 **Table 2: Overview of intervention delivery described according to the TIDieR guidelines**

1. Brief name	SUPER intervention	Minimal intervention control
2. Why	Exercise-therapy to enhance muscle strength, function and physical activity can improve pain and quality of life in older adults with OA[12] and address risk factors for post-traumatic OA [35].	The booklet was produced based on information provided to patients and thus, accurately reflects usual care.
3.What materials	Participants receive an intervention handbook detailing all study details, exercises and logbook, and access to videos of all exercises.	Participants receive a "best-practice guide" booklet of possible exercises with no specific exercise prescription frequency.
4. What procedures	Five priority exercises targeting: i) weight-bearing knee extension; ii) open-chain knee extension; iii) plyometrics; iv) balance/agility; v) knee flexion **and** four optional exercises targeting: a) trunk; b) hip abductors; c) hip adductors; d) calf – each with 3-6 levels of difficulty. Physiotherapists prescribe strength exercises (3 x 8-12 reps) with perceived exertion criteria (aim ≥7/10) and progressed as per ACSM and periodisation guidelines (1 week/month easier ~5/10 exertion). Dedicated education sessions at week 1 and week 4, supported by slides and booklets.	Booklet explained at randomisation. Exercise options provided (similar to SUPER intervention), but not prescribed. Participants expected to exercise unsupervised. Participants may contact the physiotherapist by phone once only to ask questions/get clarification.
5. Who provided	Registered physiotherapists with ≥3 years of relevant experience, trained to deliver all components (exercise and education).	One appointment with a registered physiotherapist with ≥ 3 years clinical experience, not involved in delivering SUPER intervention, to explain booklet elements.
6. How	Delivered supervised in groups and individually (supported by unsupervised sessions) in Phase 1, progressing to completely unsupervised in Phase 2.	Delivered unsupervised.
7. Where	Supervised sessions at private physiotherapy clinics and unsupervised sessions at gym/home.	Booklet explained at La Trobe University, Melbourne. Gym and home exercise options provided.
8. When and how much	Phase 1 (0-4 months): *Frequency and Duration* Supervised sessions (30-60 mins) 2 times/week Unsupervised sessions (30-60 mins) 1-2 times/week	Unsupervised exercise-therapy (self-prescribed frequency) after one face-to-face appointment.

	Number of Sessions: 32 supervised + 16 unsupervised <u>Phase 2 (5-12 months):</u> *Frequency and Duration* Progress to unsupervised sessions 2-3 times weekly (dependent on meeting predefined criteria*). Two supervised (booster) sessions at 8 and 11 months post-baseline. *Number of Sessions:* 2 supervised + 108 unsupervised	
9. Tailoring	Tailored selection and progression of lower-limb muscle strength, power and neuromuscular control exercises and education based on participant preferences, goals and clinical presentation.	Standardised exercise examples and education.
10. Modifications	Modifications will be reported. If state and/or institution COVID-19 pandemic restrictions prevent face-to-face follow-up assessments, participants will be encouraged to continue assigned treatment until face-to-face assessments can be conducted. If restrictions prevent supervised rehabilitation, telerehabilitation options will be offered wherever possible.	
11. How well (planned)	Treating physiotherapists receive prior training in how to deliver and supervise the programme. Fidelity assessed by auditing. Participant adherence to supervised and unsupervised sessions assessed through logbooks, clinic attendance sheets and online (fortnightly/monthly) questionnaire.	
12. How well (actual)		This will be reported in the primary paper.

SUPER, SUpervised exercise-therapy and Patient Education Rehabilitation; OA, osteoarthritis; ACSM, American College of Sports Medicine

* predefined criteria for ceasing supervised sessions in Phase 2 = participant's goals are met, participant satisfied with current symptoms/function, and global rating of change reported as at least 'better'.

Minimal intervention control

Reflecting current standard care, the minimal intervention control group will receive a "best-practice guide" booklet and one face-to-face appointment with a registered physiotherapist with ≥3 years of clinical experience (not involved in treating participants in the SUPER intervention) to explain booklet elements and answer questions about its contents. The booklet outlines similar exercises and patient education as in the SUPER intervention (Supplementary File 3). However, exercise is expected to be performed unsupervised (table 2). Participants may also contact the treating physiotherapist by phone on one occasion to ask questions or get further clarification but will not be provided with information extending the scope of the booklet. The booklet was produced based on the information provided by ten high volume orthopaedic surgeons in Melbourne to their patients post-ACLR. Participants will be encouraged at the 4-month assessment to continue following the booklet up until the 12-month assessment.

Irrespective of group allocation, participants will be asked to refrain from other musculoskeletal therapies (e.g., chiropractic care, osteopathy, myotherapy, intra-articular injections) for their knee pain during the trial. Participants will be allowed to continue care for other unrelated pre-existing conditions.

Data collection procedure

Data will be collected at baseline and 2, 4 and 12 months after randomisation, with 4 months the *a priori* primary endpoint as this coincides with the completion of the supervised exercise-therapy intervention in Phase 1. Where possible, data will be collected and managed using a secure web-based software platform (Research Electronic Data Capture; REDCap) hosted at La Trobe University [36], which has equivalent measurement properties to paper-based completion [37]. This strategy was used in our pilot study following ACLR, with demonstrated feasibility [23]. Paper versions will also be available if preferred by participants.

Outcomes

Baseline characteristics

Participant characteristics including height, body mass, waist girth, leg length, knee injury and rehabilitation details, socioeconomic details (e.g., education level, employment status), family history of OA, sporting history and health literacy (Rapid Estimate of Adult Literacy in Medicine: REALM [38]) will be collected. Surgical details will be recorded from surgical files including date, graft type, and concomitant injuries/procedures. We will also record knee-related objective measures (table 3).

Table 3. Overview of data collection

	Baseline	2 months	4 months	12 months
Paraticipant characteristics				
Age	X			
Sex	X			
Height, body mass, waist girth	X		X	X
Country of birth	X			
Education level	X			
Living situation	X			
Smoking history	X			
Health literacy (REALM)	X			
Employment status	X		X	X
Prior knee injury/treatment	X			
ACL injury, surgery & rehabilitation details	X			
Sport/Activity participation	X		X	X
Family history of osteoarthritis	X			
Medication use	X			
Comorbidities	X			
Flexion/extension range of motion	X		X	X
Joint line tenderness (medial and lateral)	X		X	X
Crepitus	X		X	X
Effusion (sweep test)	X		X	X
Stability (Lachman's, Pivot shift)	X			
Patient-reported Outcomes				
Knee injury Osteoarthritis Outcome Score	X	X	X	X
EQ-5D-5L	X	X	X	X
Tegner Activity Scale	X	X	X	X
Tampa Scale of Kinesiophobia	X		X	X
Global rating of change		X	X	X
Patient acceptable symptoms state	X	X	X	X
Health and Labour Questionnaire	X		X	X
Work Limitations Questionnaire	X		X	X
ACL-Quality of Life Questionnaire	X		X	X

Knee pain (current and worst in last week)	X	X	X	X
Physical performance tests				
Hop performance (four tests)	X		X	X
One-leg rise	X		X	X
Isometric thigh muscle strength	X		X	X
Lower-limb loading	X		X	X
MRI outcomes	X		X	X
Average daily steps	X		X	X

ACL, anterior cruciate ligament; MRI, magnetic resonance imaging; REALM, Rapid Estimate of Adult Literacy in Medicine

All participants will receive either a fortnightly (during Phase 1) or monthly (during Phase 2) online questionnaire via the secure online platform (REDCap) (or hard copy mailed, or phone call depending on participant preference) to assess sports activity, adherence to exercise-therapy, and any adverse events/other treatment.

Primary outcome

The primary outcome is the change in $KOOS_4$ score from baseline to 4-month follow-up. $KOOS_4$ is the mean score for the self-reported KOOS subscales pain, symptoms, function in sports and recreational activities and quality of life, which has been used in RCTs following ACL injury [39]. The $KOOS_4$ and all KOOS subscale scores range from 0 (worst) to 100 (best). The KOOS is a valid and reliable knee-specific questionnaire for assessing patient-reported outcomes in various knee injury populations (e.g., from knee injury to OA) and is widely used globally [40, 41].

Secondary outcomes

KOOS subscales

To allow for clinical in-depth interpretation, scores for the five KOOS subscales will be reported individually (i.e., pain, symptoms, function in sports and recreational activities, activities of daily living, and quality of life)[40].

Physical performance

Peak isometric knee extensor and flexor muscle strength and rate of force development will be assessed in sitting using reliable and valid methods at 60° of knee flexion on isokinetic equipment (Biodex Medical Systems, NY, USA) [42]. A battery of lower-limb functional tasks commonly used

following ACLR will assess functional performance: i) single hop for distance; ii) triple cross-over hop for distance; iii) side-hop; iv) vertical hop; and v) one-leg rise [5, 43, 44]. Such a battery produces high reliability and sensitivity in populations following ACLR [45]. Details of physical performance tests are contained in Supplementary File 4.

Perceived global change score and patient acceptable symptom state

Global rating of change (GROC) will be assessed for pain and function with the questions: 'Overall, how has your knee pain changed since the start of the study?' and 'Overall, how has your knee function changed since the start of the study?' Answered on a 7-point Likert scale ranging from 'much worse' to 'much better' and dichotomised to 'improved' ('much better', 'better') versus 'not improved' ('a little better' to 'much worse'). Satisfaction with current knee function (i.e., patient acceptable symptom state (PASS)) will be assessed with the question: 'Considering your knee function, do you feel that your current state is satisfactory? With knee function, you should take into account all activities during your daily life, sport and recreational activities, your level of pain and other symptoms, and also your knee-related quality of life." Answered by 'yes or 'no' [46]. Participants not satisfied with current knee function at follow-up assessments (i.e., answering 'no' to the PASS question) will be asked a second question relating to treatment failure: 'Would you consider your current state as being so unsatisfactory that you think the treatment has failed?' Answered by 'yes' or 'no' [46].

Knee joint structure

Unilateral knee MRIs will be obtained in supine with the lower-limb in neutral alignment using a 3T scanner (Signa Pioneer, General Electric Healthcare, Milwaukee, USA) and 18-channel knee coil. Sequences acquired will include proton density weighted fat suppressed fast spin-echo sequences in the sagittal, coronal and axial planes, a T2 mapping multi-echo spin-echo sagittal sequence and a sagittal fast spoiled gradient echo (FSPGR) sequence (Figure 2, Supplementary File 5). Changes in cartilage collagen content and orientation in extracellular matrices reflecting degeneration will be

defined by quantitative changes in T2 relaxation times[47] from baseline to 4- and 12-month follow-up assessments. Knee cartilage thickness changes over 4 and 12 months will also be assessed [48]. Post-processing software incorporating semi-automated registration and manual segmentation in 3D will be used for both T2 relaxation time and cartilage thickness. Knee OA features (e.g., cartilage defects, meniscal tears, bone marrow lesions, osteophytes) will be scored with established scoring systems [49, 50] at baseline and 12-month follow-up by a trained reader blinded to clinical outcomes. Individual OA feature worsening will be defined as increase in the size or depth of lesions as previously established [51]. Bone shape at the knee will also be assessed using edge-detection semi-automated segmentation with 3D triangulated meshes of bone rigidly registered on a reference template to extract the most important modes of variation of bone shape [52].

---FIGURE 2 HERE---

Other outcomes

Fear of movement

Knee-related fear of movement will be assessed with the Tampa Scale for Kinesiophobia [53]. This scale has established reliability and validity in musculoskeletal pain populations [54, 55].

Physical activity

The Tegner Activity Scale will assess self-reported activity level. It is a valid and reliable numerical scale from 0 (sick leave because of knee problems) to 10 (competitive knee-demanding sports at an elite level), with each value indicating the ability to perform certain activities [56]. Objective physical activity will be captured using a Garmin vívofit® 4 activity tracker (Garmin® International Inc., KS, USA) or participant's own device, if appropriate.

Quality of life

We will assess knee-related quality of life, with the ACL-Quality of life questionnaire [57], and health-related quality of life with the EQ-5D-5L [58]. These measures are reliable and valid for knee pain populations [59, 60].

Lower-limb loading

Lower-limb loading will be assessed using ground reaction force data during unilateral and bilateral weight-bearing tasks (squat, hop and drop-jump) using force plates and ForceDecks software (Vald Performance Pty. Ltd., UK).

Knee pain

Current and worst knee pain (and how much participants are bothered by pain) in the previous week will be assessed on a 100mm visual analogue scale (0=no pain/bother, 100=worst pain/bother imaginable).

Treatment-related outcomes

Adherence, exercise level/intensity and other treatments received during the trial

Adherence with the supervised exercise-therapy sessions (i.e., number of sessions attended out of 32 possible) Phase 1 sessions) and intensity/progression of the exercises will be recorded by treating physiotherapists and participants. Inadequate adherence is defined as participating in <22 (70%) supervised sessions. Participants in both groups will record adherence to home exercises and any co-interventions received in a logbook and via fortnightly (Phase 1) and monthly (Phase 2) online questionnaires.

Adverse events

Any adverse events will be recorded fortnightly during Phase 1 and monthly during Phase 2 via questionnaires. Furthermore, open probe questioning will enquire about possible adverse events at

each of the follow-ups. Healthcare use data obtained as part of cost-effectiveness analysis at final follow-up will also be checked for potential adverse events. An adverse event is defined as any undesirable experience causing participants to seek medical treatment. A serious adverse event is defined as any undesirable event/illness/injury classified as having the potential to significantly compromise clinical outcome or result in significant disability or incapacity, and those requiring inpatient hospital care. Adverse events will be categorised into index knee or other sites and will be assessed for severity by the trial management committee.

Data management

Most outcome data will be collected and managed via REDCap web-based software (hosted at La Trobe University), facilitating simultaneous data entry. For paper-based data collection, data will be entered by a single investigator with a second investigator conducting random checks of a subset of manually entered documents to ensure accuracy. For data analysis, personal data, including participant names, contact details, date of birth and MRI scans will be stored on the La Trobe University server Research Drive Storage, separately from deidentified (numbered) data. All subsequent study data will be identified by participant number only.

Due to the minimal known risks associated with the interventions being evaluated, this study will not have a formal data monitoring committee and does not require an interim analysis. Any unexpected serious adverse events or outcomes will be discussed by the trial management committee (identical to the authors of this protocol).

Sample size calculation

This trial has been powered to detect a clinically significant between-group difference for the primary outcome of $KOOS_4$. The overall effect size for exercise-therapy on self-reported pain and disability is moderate (0.50) [12]. With this effect size, to achieve 85% power at a two-sided 0.05 significance level

on the $KOOS_4$, 146 participants are required. To account for a 20% drop-out, we will recruit 184 participants. This sample size will be sufficient to detect a minimal important change (MIC) in $KOOS_4$ of 9-points in patients following ACLR (with standard deviation of 15) [39, 61].

Stopping rule

If the intended sample size is not reached at 36 months after recruitment commencement, the inclusion of participants will stop at 160, which will ensure a power of 80% for the primary outcome of $KOOS_4$, anticipating up to 20% loss to follow-up. Including a minimum of 160 participants will also provide ≥90% power to detect a statistically significant difference (α=0.05) on the secondary outcome of cartilage quality on MRI (change in cartilage T2 relaxation time) between the SUPER intervention and minimal intervention control groups (anticipated effect size of 0.59) [19].

Statistical analyses

Analysis will be performed according to the intention-to-treat principle with the statistical analyst blinded to group allocation. Descriptive statistics and generalised linear mixed models (adjusted for baseline measure and referral source (private versus public) as fixed effects) will be used to examine the effect of group allocation on the primary and secondary outcomes. For binomial secondary outcomes (e.g., cartilage defect worsening, proportion of participants 'improved' on the global rating of change scale, proportion of participants who had a $KOOS_4$ change exceeding the MIC of 9 points), binomial (logistic) family will be selected. As this is a randomised trial, we do not plan to adjust for other potential confounders (e.g., age, sex), but if notable imbalance between groups in potential confounders is observed, we will examine the effect of adjusting for potential confounders (fixed effects) [62]. While the primary analysis approach is intention-to-treat, per-protocol analysis will also be conducted excluding those who have inadequate adherence with the SUPER intervention to assist with clinical interpretation of findings. Planned exploratory sub-group analyses including repeating analysis by injury characteristics (e.g., isolated vs combined ACL injury) will be conducted given the

known risk of a combined injury (e.g., concomitant meniscal/cartilage) on OA outcomes[63]. Two sensitivity analyses are planned. The first will use multiple imputation for missing data, assuming this data is considered missing at random. The second will exclude particiapnts who experienced a subsequent new acute traumatic lower-limb injury (or surgery) severe enough to require a period of non-weight bearing assuming this may have influenced the outcomes of those participants, unless the injury was sustained while completing the trial intervention activities.

Healthcare resource use and productivity

The resources required to deliver each intervention and treatment related healthcare resource use including co-interventions for knee-related symptoms (e.g., medicines, complementary treatments, and details of hospital presentations) will be recorded. This information will be collected from several sources (Medicare and Pharmaceutical Benefits Scheme (MBS and PBS) databases (rebated and out-of-pocket costs), as well as participant logbooks and questionnaires) for the trial period. The Health and Labour Questionnaire [64] and the Work Limitations Questionnaire [65] will also be collected for the trial period to inform estimates of productivity losses. Methods of cost-effectiveness analysis will be reported elsewhere.

Process Evaluation

Semi-structured interviews will be conducted on a subset of participants (until data saturation is reached) following the intervention. Interviews will explore beliefs/experiences; knowledge and understanding of interventions received including potential benefits; acceptability and perceived effectiveness of the intervention; and reasons for adhering (or not) to exercise-therapy and education provided. Purposive sampling will be used to recruit interview participants based upon characteristics and outcomes of trial. Interviews will be audio recorded, transcribed and analysed using Framework Analysis [66]. Data will be coded deductively according to the code structure generated by the interview topic guide and an inductive thematic analysis will be applied until no new themes emerge.

PATIENT AND PUBLIC INVOLVEMENT

Patients and clinicians are integral throughout each stage of this project. Patients and clinicians co-designed the intervention, research questions and study methods. This input was gained from: i) discussions with leading clinicians managing ACL injuries during SUPER development; ii) collation of orthopaedic surgeon patient education material to inform the control intervention; iii) qualitative interviews with participants and treating physiotherapists from our pilot study as part of formal process evaluation strategies [23]; iv) qualitative interviews with symptomatic patients with an ACLR as part of our previous studies [67]; and v) patient and clinician focus groups providing feedback on study recruitment material, participant handbooks and education content. Preliminary results will be presented and discussed with patient representatives before the results are written up for peer-review publication. Patients and clinicians will provide input into the dissemination of study results by assisting with the decision on what information to share and in what format.

ETHICS AND DISSEMINATION

This study complies with the Declaration of Helsinki and has been approved by the La Trobe University Human Research Ethics Committee (HEC-19447), the Alfred Hospital Ethics Committee (HREC 537/19) and Services Australia External Request Evaluation Committee (RMS0879). Written informed consent will be obtained from participants prior to enrolment (Supplementary File 6).

Study outcomes will be widely disseminated through a variety of sources. Primary and key secondary objectives will be submitted to a peer-reviewed journal. Other secondary objectives will be addressed in separate publications. Authorship will be in accordance with guidelines provided by the International Committee of Medical Journal Editors (ICMJE). Our publication strategy will be complemented by submission of abstracts to key national and international conferences. Any

important protocol amendments will be reported to the approving ethics committees, registered at ANZCTR and communicated in the primary RCT report.

DISCUSSION

Anterior cruciate ligament injuries and subsequent reconstructions have increased 43% in Australia over the previous 15 years [68], with similar increases observed in the United States[69], and greater increases in England [70]. Half of all patients undergoing ACLR will have a poor long-term outcome including persistent symptoms, impaired quality of life and accelerated structural decline [5-7, 71]. This underscores an urgent need for secondary prevention strategies to prevent symptomatic and structural OA decline – an epidemic of young people with old knees.

The current RCT will be the first to evaluate the symptomatic and structural benefits of a physiotherapist-supervised exercise-therapy and education intervention for young adults at high risk of post-traumatic knee OA. While outcome assessors are blinded to group allocation and physiotherapists delivering the intervention are blinded to the control intervention, owing to the type of interventions (i.e., exercise-therapy and education), blinding of participants is not possible. The difference in frequency of physiotherapy sessions between the two groups means that the contextual effects related to supervised physiotherapy treatment are also not able to be isolated. We did not include a wait-list control group as this would have reduced equipoise and increased the risk of resentful demoralisation (if used instead of our minimal intervention control) and considerably increased the required sample size (if used as a third comparator group). Furthermore, only patient-reported outcomes are collected at 2-month follow-up to minimise participant burden. We also acknowledge that the wrist-worn activity tracker (Garmin vívofit® 4) or other commercial devices that participants wear may under-/over-estimate daily step counts, however the differences with research-grade accelerometers appear minimal [72]. This fully powered Phase III trial represents an

important step towards optimising management to achieve better outcomes and curtail the rapid trajectory of post-traumatic knee OA following ACL injury and reconstruction.

AUTHOR CONTRIBUTIONS

AGC, KMC, CJB, EMR, EO, SMM conceived the study and obtained funding. AGC, KMC and CJB designed the study protocol with input from EMR, EO, SMM. SMM provided statistical expertise and will conduct primary statistical analysis. EO, RBS and JL provided imaging expertise and will lead imaging analysis. AGC drafted the manuscript with input from TJW, KMC, CJB, EMR, EO, SMM, RBS, JL, AMB, BEP, MAG, JLC, MJS. All authors have read and approved the final manuscript.

FUNDING STATEMENT

This trial is supported by the National Health and Medical Research Council (NHMRC) of Australia (ID: 1158500). AGC is a recipient of an NHMRC Investigator Grant (GNT2008523), CJB was a recipient of a Medical Research Future Fund Translating Research Into Practice (MRFF TRIP) Fellowship (ID: 1150439). The funders have no role in the study design and will not have any role in its execution, data management, analysis and interpretation or on the decision to submit the results for publication.

COMPETING INTERESTS STATEMENT

CJB is the owner of a business providing physiotherapy treatment and exercise classes for some participants enrolled in this study. CJB will have no role in the decision of which clinic participants attend for study treatment. All other authors declare no competing interests.

ACKNOWLEDGEMENTS

We thank physiotherapists, Mick Hughes and Randall Cooper, for assistance in intervention design. We thank the orthopaedic surgeons assisting with participant recruitment: Hayden Morris, Chris

Kondogiannis, Nathan White, Mark O'Sullivan, Matthew Evans, Ashley Carr, Justin Wong, Dirk van Bavel, Matthew Alexander, Ben Campbell, Altay Altuntas, Simon Talbot, Raphael Hau, Luke Spencer, David Mitchell. We thank the staff at each of the public hospitals involved in participant recruitment: Lara Kimmel & Susan Liew (Alfred Hospital), Emily Cross & Andrew Bucknill (Royal Melbourne Hospital), Jimmy Goulis & Juliette Gentle (Northern Hospital), Chris Cimoli, David Berlowitz & Andrew Hardidge (Austin Hospital), Peter Choong (St Vincent's Hospital), Leanne Roddy & Raphael Hau (Box Hill Hospital), Libby Spiers & Phong Tran (Footscray Hospital), Peter Schoch, Katelyn Bailey, Caitlin Knee & Richard Page (Barwon Hospital), Leonie Lewis & David Mitchell (Ballarat Hospital). We thank the physiotherapists involved in treating the participants at Complete Sports Care, Clifton Hill Physiotherapy, Flex Out Physiotherapy, Lake Health Group, Melbourne Sports Physiotherapy, Mill Park Physiotherapy, Symmetry Physiotherapy, Grand Slam Physiotherapy, Melbourne Sports Medicine Centre, Southern Suburbs Physiotherapy Centre, Lifecare La Trobe.

FIGURE LEGENDS

Figure 1. Flow of participants through the study. MRI, magnetic resonance imaging; KOOS, Knee injury and Osteoarthritis Outcome Score.

Figure 2. Magnetic resonance imaging protocol. A) Sagittal fast spoiled gradient echo (FSPGR) sequence; B) Sagittal, coronal and axial proton density weight far suppressed spin-echo sequence; and C) Sagittal mulit-echo spin-echo sequence

SUPPLEMENTARY FILES

Supplementary File 1. Overview of SUPER intervention exercise delivery according to Consensus on Exercise Reporting Template (CERT) guidelines

Supplementary File 2. Exercises and logbook for SUPER intervention

Supplementary File 3. Exercises and logbook for minimal intervention control

Supplementary File 4. Details of physical performance tests

Supplementary File 5. Details of magnetic resonance imaging sequences acquired

Supplementary File 6. Patient information and consent form

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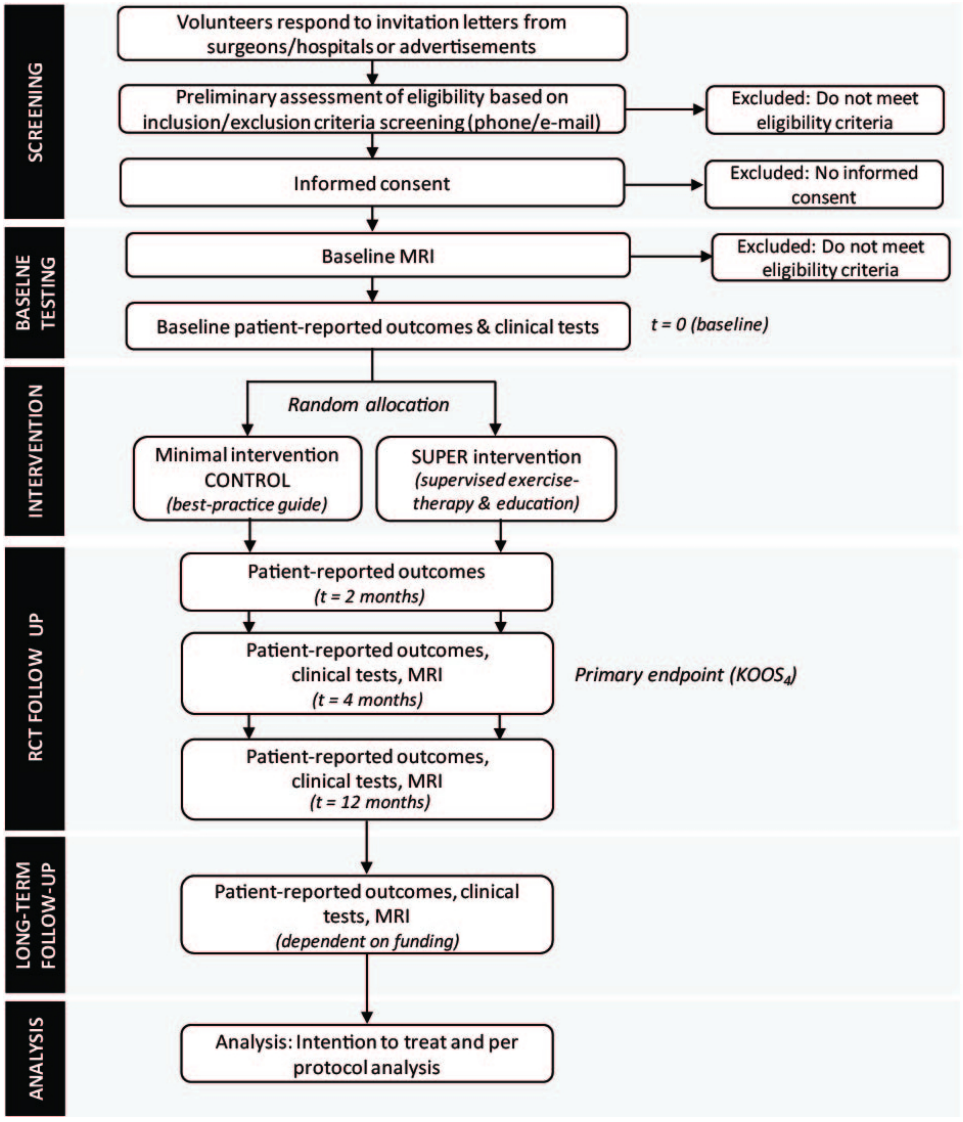

Figure 1. Flow of participants through the study. MRI, magnetic resonance imaging; KOOS, Knee injury and Osteoarthritis Outcome Score.

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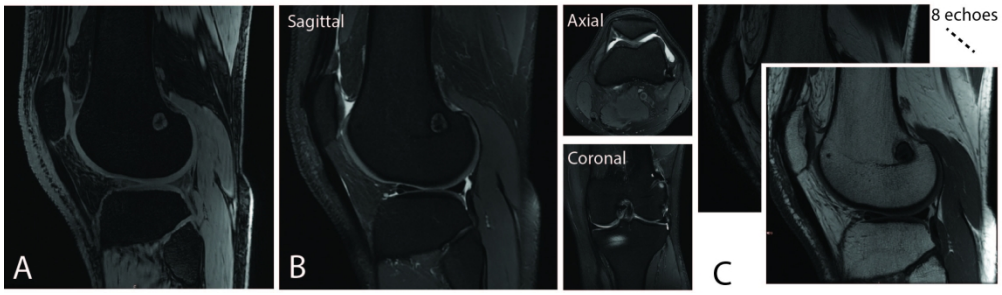

Figure 2. Magnetic resonance imaging protocol. A) Sagittal fast spoiled gradient echo (FSPGR) sequence; B) Sagittal, coronal and axial proton density weight far suppressed spin-echo sequence; and C) Sagittal mulit-echo spin-echo sequence

407x156mm (150 x 150 DPI)

Supplementary File 1. Overview of SUPER intervention exercise delivery according to Consensus on Exercise Reporting Template (CERT) guidelines

Section/Topic	Checklist item	SUPER Exercise Intervention Description
WHAT: materials	1. Detailed description of the type of exercise equipment	Various weighted equipment (e.g., dumbbells, barbells, resistance band, pin-loaded leg press, leg extension, hamstring curl machine) will be used. Participants will be provided with equipment (e.g., resistance band, 20kg adjustable dumbbells) to complete exercises at home. Details of equipment used are in Supplementary File 2.
WHO: provider	2. Detailed description of the qualifications, expertise and/or training	Approximately 30 registered physiotherapists with ≥3 years musculoskeletal clinical experience and work in private clinics in metropolitan and regional Victoria. All SUPER physiotherapists will complete 3 hours of online webinars and participate in a 4-hour workshop (7 hours total) before study commencement. Refresher training will be completed as required. SUPER physiotherapists will be supported with regular (approximately bi-monthly) contact by a member of the research team.
HOW: delivery	3. Describe whether exercises are performed individually or in a group	Phase 1: Participants will perform a mix of supervised 1:1 and small group (≤6 participants) exercise sessions based on individual preference, clinic availability, and clinical reasoning by the treating physiotherapist. Participants will complete additional unsupervised sessions at home/local fitness centre (gym). Phase 2: All exercises will be completed individually unless *a priori* discharge criteria are not met, in which case one supervised exercise session per week may continue.
	4. Describe whether exercises are supervised or unsupervised and how they are delivered	Phase 1: Supervised by a physiotherapist twice per week **AND** unsupervised at least once per week encouraged. Phase 2: Unsupervised 2-3 times per week unless *a priori* discharge criteria are not met, in which one supervised session per week may continue.

5. Detailed description of how adherence to exercise is measured and reported	Phase 1: Physiotherapists will record attendance at supervised exercises sessions. During supervised exercises, participants and/or physiotherapists will record dosage completed for each exercise in a clinic logbook. Participants will record unsupervised exercises either through an online exercise diary, or paper-based exercise logbook. Participants will also report their exercise adherence fortnightly via an online questionnaire. Phase 2: Participants will report their exercise adherence monthly via an online questionnaire and/or paper-based logbook. The percentage of supervised (and unsupervised) exercise sessions completed will be reported.
6. Detailed description of motivation strategies	Phase 1: (i) Physiotherapists will be trained to use simple motivational interviewing techniques to support intervention adherence; (ii) Functional assessments will be completed in the clinic (hop tests, one leg rise) monthly; (iii) Participants will maintain exercise training logbooks at the clinic and at home; (iv) Participants will be contacted monthly by a member of the research team; (v) Exercise variations available to cater for individual needs and preferences; (vi) Participants will be provided an activity monitor (e.g., Garmin watch) and encouraged to track daily activity; (vii) Small group exercise training with other SUPER-Knee trial participants. Phase 2: (i) Access to a local gym; (ii) Booster session with physiotherapist, including functional re-assessment at 8 and 11 months; (iii) Followed up regularly by a member of the research team; (iv) Exercise variations available; (vi) Participants will continue using an activity monitor (e.g., Garmin watch).
7a. Detailed description of the decision rule(s) for determining exercise progression	Exercises will be progressed based on: (i) perceived difficulty using rating of perceived exertion (RPE) (e.g., RPE ≥7/10, 3 sets of 8-12 reps and one lighter week per month of 5/10 RPE to increase motivation and allow recovery periods), and (ii) minimal pain (e.g., <3/10 on numerical pain scale).
7b. Detailed description of how the exercise program is progressed	Exercises will be progressed to match pre-defined RPE of each week by any of the following: i) increasing load used; ii) increasing exercise difficulty level; iii) changing exercise position (e.g.,

		lowering squat depth, increasing step height); or iv) changing speed of exercise. Progression principles are in line with American College of Sports Medicine muscle strengthening guidelines.
	8. Detailed description of each exercise to enable replication	The priority exercises are: 1) Quadriceps, 2) Knee extension, 3) Plyometrics, 4) Balance & Agility, 5) Hamstrings. The additional exercises are: 6) Trunk/core, 7) Hip abduction, 8) Hip adduction, 9) Calf raises. Exercise descriptions are available in Supplementary File 2.
	9. Detailed description of any home program component	Home exercise variations for each of the priority and additional exercises can be found in Supplementary File 2.
	10. Describe whether there are any non-exercise components	Comprehensive education will be provided during the two dedicated physiotherapy 'education' consultations (Weeks 1 and 4, 30-60 minutes). Session 1 topics will include: Function and actions of the knee and ACL, mechanisms of ACL injury, risk factors, what is osteoarthritis, role and evidence for physical activity and exercise, pain education, recovery, goal setting. Session 2 topics will include: Returning to physical activity and sport, psychological factors, goal re-setting and long-term planning, weight control.
	11. Describe the type and number of adverse events that occur during exercise	Exercise-specific adverse events are increases in pain, swelling, re-injury caused by the exercises resulting in the participant needing to cease the exercise session, or an inability to complete subsequent sessions. Physiotherapists will record exercise-specific adverse events in their clinic treatment notes. For any serious adverse events, physiotherapists will contact a member of the research team immediately for suspected ACL re-injuries for medical review and incident reporting.
WHERE: location	12. Describe the setting in which the exercises are performed	<u>Phase 1:</u> Exercises will be performed individually or in small groups at physiotherapy clinics under the supervision of a trained SUPER-Knee physiotherapist, and independently at home/local gym.

		Phase 2: Home/local gym, unless *a priori* discharge criteria are not met, in which case supervised exercise sessions at the physiotherapy clinic may continue.
WHEN/HOW MUCH: dosage	13. Detailed description of the exercise intervention including, but not limited to, number of exercise repetitions/sets/session duration, intervention/program duration etc.	The priority exercises are: 1) Quadriceps, 2) Knee extension, 3) Plyometrics, 4) Balance & Agility, 5) Hamstrings. The additional exercises are: 6) Trunk/core, 7) Hip abduction, 8) Hip adduction, 9) Calf raises. Exercise descriptions are available in print (Supplementary File 2). Strength exercises will be performed in 3 sets of 8-12 reps, while power exercises will be performed in 1-3 sets of 3-6 reps based on clinical reasoning by the treating physiotherapists. Plyometric exercises will be performed in 1-3 sets of 10 reps. Session duration will be 30-60 mins depending on participant/physiotherapist availability. The entire intervention lasts for 12 months.
TAILORING: what, how	14a. Describe whether the exercises are generic (one size fits all) or whether tailored to the individual	The standard exercise program will include the 5 priority exercises. The additional exercises are optional to cater for individual needs, preferences, including time commitments. Each exercise has 3-6 levels of difficulty that include options to cater for exercise training environment. Participants, with their physiotherapist, can select the exercise under each group that most suits individual needs and preferences.
	14b. Detailed description of how exercises are tailored to the individual	Exercise prescription is individualised and follows guidelines from the American College of Sports Medicine for developing muscle strength and power. Exercises will be individually tailored based on: baseline assessment and ongoing functional assessment, achieving intended RPE, exercise training environment and equipment availability, clinical reasoning (e.g., individual preferences and needs, pain).
	15. Describe the decision rule for determining the starting level at which people commence an exercise program	All exercise sessions will start with a 5-minute warm up (3-4/10 RPE). Strength exercises will be performed at a moderate-hard intensity (suggested 5/10 RPE) in Week 1, using guidance from baseline assessment information (e.g., strength and functional test results) contained in the handover form to physiotherapists. They will then be progressed for all participants in week 2 based on criteria outlined in 7a.

HOW WELL: planned, actual	16a. Describe how adherence or fidelity to the exercise intervention is assessed/measured	All SUPER-Knee physiotherapists will complete 3 hours of online webinars, attend the face-to-face 4-hour training workshop and receive a detailed treatment manual describing all aspects of the exercise (and education) intervention. After initiation of the trial, communication (e.g., telephone, email) between a member of the research team and each physiotherapist will occur to discuss issues experienced in the clinic and issues resolved as appropriate. In person fidelity checks will be performed by a member of the research team and refresher training will be completed annually.
	16b. Describe the extent to which the intervention was delivered as planned	This will be reported in the primary paper.

Participant Handbook

PRIORITY EXERCISES

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EXERCISE 1. QUADRICEPS

FOCUS

- Slow & controlled
- Knees, hips, ankles in line and hips level
- **Aim for 2-3 sets of 8-12 repetions**

Level 1 – Double leg squat

Feet shoulder width apart. Slowly squat until your buttocks lightly touch the chair/box. Return to standing.

Level 2 – Single leg squat

Standing on affected leg, slowly squat until your buttocks lightly touch the chair/box. Return to standing.

Level 3 – Weighted single leg squat

Increase difficulty by holding weights (on your chest, by your side, or barbell on your shoulder blades).

Level 4 – Power Squats

POWER

- Combines strength and speed
- Vital for everyday activity
- Fast movements at lower weights
- **Aim for 1-3 sets of 3-6 repetitions**

- POWER: complete squats (double- or single-leg as above) with weight at speed.
- Squat down and up as quickly as possible.
- Power can start from week 4 of program regardless of completing level 3 exercise.

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SUPER Knee

Exercise 1: QUADRICEPS **HOME/GYM RECORD**

** Put a line through a session if exercise not completed in that session or missed a session*

		Level (circle)	Aim RPE	Actual RPE	Kilos used	Number of sets	Number of reps
Week 1 – date: _____	Home/gym session	1 2 3 4	5/10				
	Extra session	1 2 3 4	5				
Week 2 – date: _____	Home/gym session	1 2 3 4	7				
	Extra session	1 2 3 4	7				
Week 3 – date: _____	Home/gym session	1 2 3 4	9				
	Extra session	1 2 3 4	9				
Week 4 – date: _____	Home/gym session	1 2 3 4	5				
	Extra session	1 2 3 4	5				
Week 5 – date: _____	Home/gym session	1 2 3 4	7				
	Extra session	1 2 3 4	7				
Week 6 – date: _____	Home/gym session	1 2 3 4	7				
	Extra session	1 2 3 4	7				
Week 7 – date: _____	Home/gym session	1 2 3 4	9				
	Extra session	1 2 3 4	9				
Week 8 – date: _____	Home/gym session	1 2 3 4	5				
	Extra session	1 2 3 4	5				
Week 9 – date: _____	Home/gym session	1 2 3 4	7				
	Extra session	1 2 3 4	7				
Week 10 – date: _____	Home/gym session	1 2 3 4	7				
	Extra session	1 2 3 4	7				
Week 11 – date: _____	Home/gym session	1 2 3 4	9				
	Extra session	1 2 3 4	9				
Week 12 – date: _____	Home/gym session	1 2 3 4	5				
	Extra session	1 2 3 4	5				
Week 13 – date: _____	Home/gym session	1 2 3 4	7				
	Extra session	1 2 3 4	7				
Week 14 – date: _____	Home/gym session	1 2 3 4	7				
	Extra session	1 2 3 4	7				
Week 15 – date: _____	Home/gym session	1 2 3 4	9				
	Extra session	1 2 3 4	9				
Week 16 – date: _____	Home/gym session	1 2 3 4	9				
	Extra session	1 2 3 4	9				

RPE= Rating of Perceived Exertion (0=rest, 10=working as hard as possible)

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SUPER Knee

EXERCISE 1b. QUADRICEPS VARIATIONS

(extra options usually after 4 weeks of the program but based on you and your physio's preferences)

VARIETY

- Varying your workouts can help you push past a plateau
- Challenge your muscles, force them to adapt and strengthen
- **Aim for 2-3 sets of 8-12 repetions**

Option 1: Weighted double leg squat

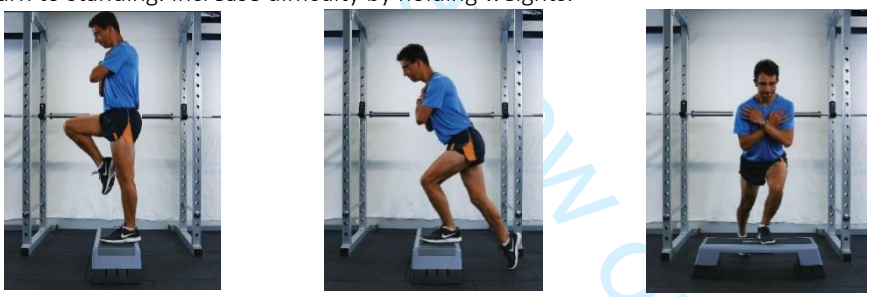
Use a barbell with weights resting on your shoulder blades. Slowly squat to ~90° knee bend. Return to standing.

Option 2: Bulgarian split squat (hold weights for variability)

Place back foot on a step/chair. Slowly lunge down with most of your weight on your front leg. Keep your shin vertical and back upright. Hold weights to increase difficulty/variability.

Option 3: Step ups/downs

Stand on the edge of a step, step down to lightly touch the floor behind you (or in front of you) and then straighten knee and return to standing. Increase difficulty by holding weights.

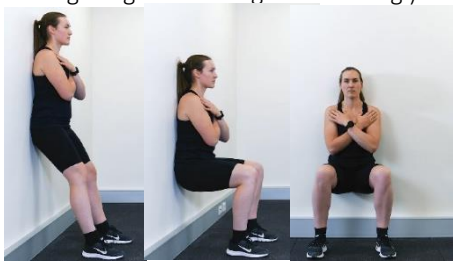


Option 4: Lunge

Step back and drop the back knee towards ground, then stand up. Increase difficulty by holding weights.

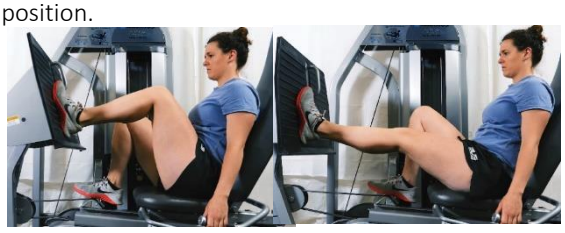
Option 5: Wall squat

Slide down until your knees are bent to 90°. Then return to the starting position. (Increase difficulty by holding weights or doing it on one leg.)



Option 6 – Single leg press

With your knee bent to 90°, push the footplate away by extending your knee (stop before locking it straight). Slowly control your knee to return to the starting position.



Exercise 1b: QUADRICEPS VARIATIONS **HOME/GYM RECORD**

** Integrate after 4 weeks of the program + based on you and your physio's preferences*

		Exercise (circle)	Aim RPE	Actual RPE	Kilos	Number of sets	Number of reps
Week 1	Home/gym session	1 2 3 4 5 6	5/10				
	Extra session	1 2 3 4 5 6	5				
Week 2	Home/gym session	1 2 3 4 5 6	7				
	Extra session	1 2 3 4 5 6	7				
Week 3	Home/gym session	1 2 3 4 5 6	9				
	Extra session	1 2 3 4 5 6	9				
Week 4	Home/gym session	1 2 3 4 5 6	5				
	Extra session	1 2 3 4 5 6	5				
Week 5	Home/gym session	1 2 3 4 5 6	7				
	Extra session	1 2 3 4 5 6	7				
Week 6	Home/gym session	1 2 3 4 5 6	7				
	Extra session	1 2 3 4 5 6	7				
Week 7	Home/gym session	1 2 3 4 5 6	9				
	Extra session	1 2 3 4 5 6	9				
Week 8	Home/gym session	1 2 3 4 5 6	5				
	Extra session	1 2 3 4 5 6	5				
Week 9	Home/gym session	1 2 3 4 5 6	7				
	Extra session	1 2 3 4 5 6	7				
Week 10	Home/gym session	1 2 3 4 5 6	7				
	Extra session	1 2 3 4 5 6	7				
Week 11	Home/gym session	1 2 3 4 5 6	9				
	Extra session	1 2 3 4 5 6	9				
Week 12	Home/gym session	1 2 3 4 5 6	5				
	Extra session	1 2 3 4 5 6	5				
Week 13	Home/gym session	1 2 3 4 5 6	7				
	Extra session	1 2 3 4 5 6	7				
Week 14	Home/gym session	1 2 3 4 5 6	7				
	Extra session	1 2 3 4 5 6	7				
Week 15	Home/gym session	1 2 3 4 5 6	9				
	Extra session	1 2 3 4 5 6	9				
Week 16	Home/gym session	1 2 3 4 5 6	9				
	Extra session	1 2 3 4 5 6	9				

RPE= Rating of Perceived Exertion (0=rest, 10=working as hard as possible)

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SUPER Knee

EXERCISE 2. KNEE EXTENSION

PAIN

- Keep pain below 3/10 when exercising and pain should settle by the next day
- Pain is OK - you can be sore but safe as pain doesn't always equal damage
- **Aim for 2-3 sets of 8-12 repetions**

Level 1 – Knee extension holds

A. Knee extension machine: straighten knee against resistance, hold for 40-60 seconds then slowly return to the starting position.

B. Resistance band: straighten knee against the resistance of resistance band, hold for 40-60 seconds then slowly return to the starting position.

C. Cable machine: straighten knee against resistance, hold for 40-60 seconds then slowly return to the starting position.

**IF PAIN IS GREATER THAN 3/10 THEN YOU CAN TRY DIFFERENT KNEE ANGLES WITH GUIDANCE FROM YOUR PHYSIO*

Level 2 – Knee extension

Fully straighten your knee slowly against resistance (using knee extension machine, resistance band or cable machine) and then slowly return to the starting position.

Level 3 Power – Knee extension

POWER

- Combines strength and speed
- Vital for everyday activity
- Fast movements at lower weights
- **Aim for 1-3 sets of 3-6 repetitions**

- Using either knee extension machine, resistance band or cable machine.
- Set the weight approximately 60-70% lighter than your last strength session.
- Complete same exercise as Level 2 but faster (aim for less than 1 sec to straighten the knee).
- Slowly bend the knee back to the starting position.
- Start power from week 4 of your program.

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Exercise 2: KNEE EXTENSION **HOME/GYM RECORD**

		Level (circle)	Aim RPE	Actual RPE	Kilos on affected leg	Number of sets	Number of reps
Week 1	Home/gym session	1 2 3	5/10				
	Extra session	1 2 3	5				
Week 2	Home/gym session	1 2 3	7				
	Extra session	1 2 3	7				
Week 3	Home/gym session	1 2 3	9				
	Extra session	1 2 3	9				
Week 4	Home/gym session	1 2 3	5				
	Extra session	1 2 3	5				
Week 5	Home/gym session	1 2 3	7				
	Extra session	1 2 3	7				
Week 6	Home/gym session	1 2 3	7				
	Extra session	1 2 3	7				
Week 7	Home/gym session	1 2 3	9				
	Extra session	1 2 3	9				
Week 8	Home/gym session	1 2 3	5				
	Extra session	1 2 3	5				
Week 9	Home/gym session	1 2 3	7				
	Extra session	1 2 3	7				
Week 10	Home/gym session	1 2 3	7				
	Extra session	1 2 3	7				
Week 11	Home/gym session	1 2 3	9				
	Extra session	1 2 3	9				
Week 12	Home/gym session	1 2 3	5				
	Extra session	1 2 3	5				
Week 13	Home/gym session	1 2 3	7				
	Extra session	1 2 3	7				
Week 14	Home/gym session	1 2 3	7				
	Extra session	1 2 3	7				
Week 15	Home/gym session	1 2 3	9				
	Extra session	1 2 3	9				
Week 16	Home/gym session	1 2 3	9				
	Extra session	1 2 3	9				

RPE= Rating of Perceived Exertion (0=rest, 10=working as hard as possible)

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SUPER Knee

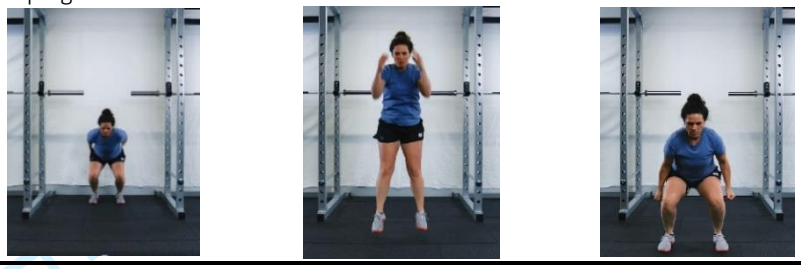
EXERCISE 3. PLYOMETRIC POWER (JUMPING/HOPPING)

FOCUS

- Soft landing bend through hips and knees to absorb load
- Alignment: knees, hips, ankles, torso in line, hips level
- **Begin with 10 repetitions and progress with guidance from your physio**

Level 1 – Double leg forward jump

Jump as high as possible landing softly bending at the hips and knees. Keep good alignment. Progress to jumping forwards as far as possible and jumping side to side.

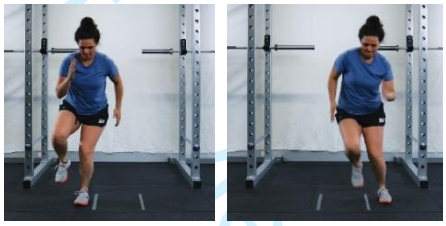


Level 2 – Single leg hop

Hop forward on one leg landing softly bending at your hips and knees. Keep good alignment. Increase distance/speed.

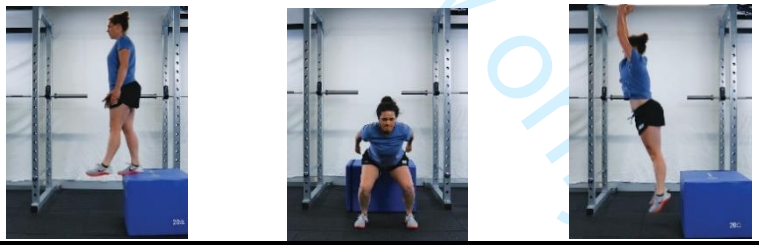
Level 3 – Single leg side hop

Hop side-to-side on one leg landing softly on the same leg bending at your hips and knees. Increase side-to-side distance.



Level 4 – Drop jumps double leg

Standing on a box, jump down landing softly on both feet and immediately jump up as high as you can. Increase height of box or hold weights to make harder. The size of the box can range from small (20cm) step to large (40-50cm as pictured).



Level 5 – Drop jumps single leg

Stand on a box/step jump down and land softly on one leg and immediately hop up as high as you can

Level 6 – Sport specific

Discuss with your physio regarding sports-specific jumping exercises based on the sport or activities you wish to do.

Examples:
- *cutting upon hop landing*
- *obstacles to hop over*
- *replicate light sport physical contact*
- *sport-specific skill performance*
- *non-contact training drills (cutting around opponent)*
- *multi-directional and unanticipated exercises*
- *accelerate/decelerate*

Exercise 3: PLYOMETRICS (JUMPING/HOPPING) **HOME/GYM RECORD**

		Level (circle)	Aim RPE	Actual RPE	Number of sets	Number of reps
Week 1	Home/gym session	1 2 3 4 5 6	5/10			
	Extra session	1 2 3 4 5 6	5			
Week 2	Home/gym session	1 2 3 4 5 6	7			
	Extra session	1 2 3 4 5 6	7			
Week 3	Home/gym session	1 2 3 4 5 6	9			
	Extra session	1 2 3 4 5 6	9			
Week 4	Home/gym session	1 2 3 4 5 6	5			
	Extra session	1 2 3 4 5 6	5			
Week 5	Home/gym session	1 2 3 4 5 6	7			
	Extra session	1 2 3 4 5 6	7			
Week 6	Home/gym session	1 2 3 4 5 6	7			
	Extra session	1 2 3 4 5 6	7			
Week 7	Home/gym session	1 2 3 4 5 6	9			
	Extra session	1 2 3 4 5 6	9			
Week 8	Home/gym session	1 2 3 4 5 6	5			
	Extra session	1 2 3 4 5 6	5			
Week 9	Home/gym session	1 2 3 4 5 6	7			
	Extra session	1 2 3 4 5 6	7			
Week 10	Home/gym session	1 2 3 4 5 6	7			
	Extra session	1 2 3 4 5 6	7			
Week 11	Home/gym session	1 2 3 4 5 6	9			
	Extra session	1 2 3 4 5 6	9			
Week 12	Home/gym session	1 2 3 4 5 6	5			
	Extra session	1 2 3 4 5 6	5			
Week 13	Home/gym session	1 2 3 4 5 6	7			
	Extra session	1 2 3 4 5 6	7			
Week 14	Home/gym session	1 2 3 4 5 6	7			
	Extra session	1 2 3 4 5 6	7			
Week 15	Home/gym session	1 2 3 4 5 6	9			
	Extra session	1 2 3 4 5 6	9			
Week 16	Home/gym session	1 2 3 4 5 6	9			
	Extra session	1 2 3 4 5 6	9			

RPE= Rating of Perceived Exertion (0=rest, 10=working as hard as possible)

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EXERCISE 4. BALANCE/AGILITY

FOCUS

- Get low and balanced ready for change of direction
- Knees, hips, ankles in line and hips level

Level 1 – Arabesques

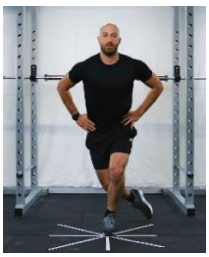
Standing on one leg (knee slightly bent), slowly bend forward from your hip, reaching out making a straight line from your foot to your hands. Hold 5 secs.



Level 2 – Clock Face

Standing on one leg (knee slightly bent) reach out to the imaginary numbers on a clock face (12, 3, 6, 9). Maintain balance without touching the ground. Return to upright position before reaching out again. Increase difficulty by reaching further (use a marker to guide). Begin with 3-5 repetitions in each direction.





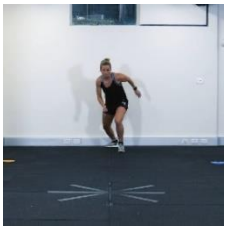
Level 3 – Clock face unstable surface

Repeat Level 2 exercise but this time stand on an unstable surface (e.g. wobble board, bosu ball, foam). Begin with 3-5 repetitions in each direction and progress with guidance from your physiotherapist.



Level 4 – Clock face agility

Run towards the clockface, plant your foot in the centre of the clock and change direction to run along that line (start at 45°). Progress the exercise by increasing the angle - change of direction (90°, 135°, 180°). Begin with 3 repetitions in each direction and progress with guidance from your physiotherapist.



Level 5 – Multi-directional agility

In an area with at least 20m space, set up as detailed below in diagrams and complete 5 x each as fast as possible. Your physiotherapist will set this up. Should include forward, backward, and side running.

Exercise 4: BALANCE/AGILITY **HOME/GYM RECORD**

		Level (circle)	Aim RPE	Actual RPE	Number of sets	Number of reps
Week 1	Home/gym session	1 2 3 4 5	5/10			
	Extra session	1 2 3 4 5	5			
Week 2	Home/gym session	1 2 3 4 5	7			
	Extra session	1 2 3 4 5	7			
Week 3	Home/gym session	1 2 3 4 5	9			
	Extra session	1 2 3 4 5	9			
Week 4	Home/gym session	1 2 3 4 5	5			
	Extra session	1 2 3 4 5	5			
Week 5	Home/gym session	1 2 3 4 5	7			
	Extra session	1 2 3 4 5	7			
Week 6	Home/gym session	1 2 3 4 5	7			
	Extra session	1 2 3 4 5	7			
Week 7	Home/gym session	1 2 3 4 5	9			
	Extra session	1 2 3 4 5	9			
Week 8	Home/gym session	1 2 3 4 5	5			
	Extra session	1 2 3 4 5	5			
Week 9	Home/gym session	1 2 3 4 5	7			
	Extra session	1 2 3 4 5	7			
Week 10	Home/gym session	1 2 3 4 5	7			
	Extra session	1 2 3 4 5	7			
Week 11	Home/gym session	1 2 3 4 5	9			
	Extra session	1 2 3 4 5	9			
Week 12	Home/gym session	1 2 3 4 5	5			
	Extra session	1 2 3 4 5	5			
Week 13	Home/gym session	1 2 3 4 5	7			
	Extra session	1 2 3 4 5	7			
Week 14	Home/gym session	1 2 3 4 5	7			
	Extra session	1 2 3 4 5	7			
Week 15	Home/gym session	1 2 3 4 5	9			
	Extra session	1 2 3 4 5	9			
Week 16	Home/gym session	1 2 3 4 5	9			
	Extra session	1 2 3 4 5	9			

RPE= Rating of Perceived Exertion (0=rest, 10=working as hard as possible)

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SUPER Knee

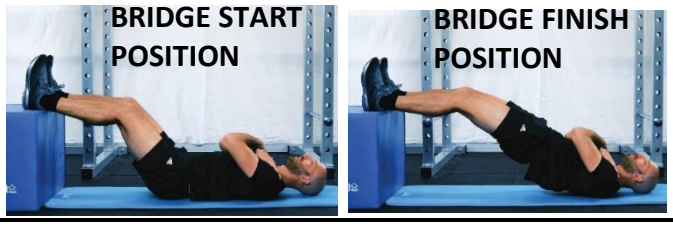
EXERCISE 5. HAMSTRINGS

FOCUS

- Strength in the hamstrings is vital to support overall knee control
- **Complete sets of 2-3 and 8-12 repetions (unless otherwise stated)**

Level 1 – Double leg elevated bridge

Squeeze buttock muscles (glutes) to lift into the bridge position. Hold for 2 secs and slowly lower back to the ground.

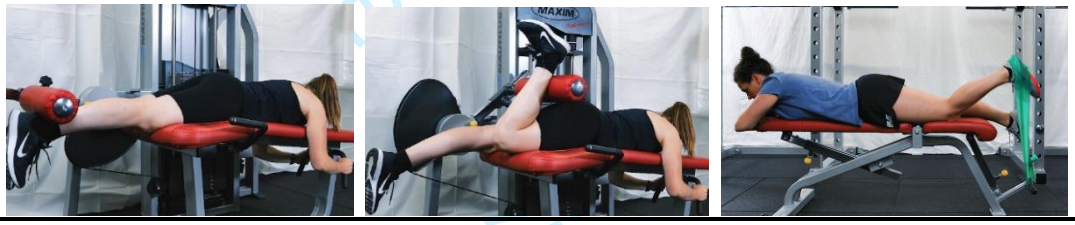


Level 2 – Single leg elevated bridge

Use one leg, squeeze buttocks and lift up into the bridge position. Hold for 2 secs and slowly lower back to the ground.

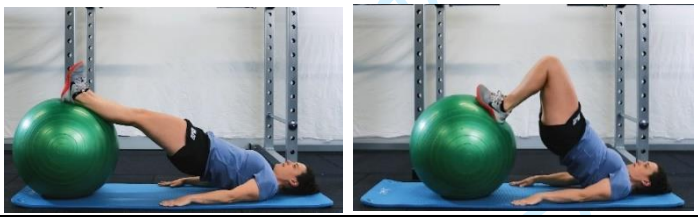
Level 3 – Single leg hamstring curl

Bend your knee pulling the resistance bar/band as far as you can to your hips, slowly return to the starting position. Increase difficulty by increasing weight on machine or tension in the resistance band (shorter/change band colour).



Level 4 – Hamstring curl swiss ball

Heels on swiss ball. Lift hips off floor. Roll swiss ball towards and away by bending knees. Progress using only one leg.



Level 5 – Nordic curl

Kneeling with object/partner keeping heels on ground. Keeping your back straight, lower your chest forwards until you can't hold yourself up, use your hands to break your fall. Return to starting position with your hands (not leg muscles!). Begin with 5 repetitions, 2 sets and progress with guidance from your physiotherapist.

POWER

- Combines strength and speed
- Vital for everyday activity
- Fast movements at lower weights
- **Aim for 1-3 sets of 3-6 repetitions**

Level 6 – Power elevated bridge

- Level 1, 2 or 3 exercise with aim for 1 sec to bend the knee or lift the pelvis and slowly return.
- If using hamstring curl machine set weight approx. 60-70% lighter than your last strength session.
- Start power from week 4 of program.

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SUPER Knee

Exercise 5: HAMSTRINGS **HOME/GYM RECORD**

		Level (circle)	Aim RPE	Actual RPE	Kilos on affected leg	Number of sets	Number of reps
Week 1	Home/gym session	1 2 3 4 5 6	5/10				
	Extra session	1 2 3 4 5 6	5				
Week 2	Home/gym session	1 2 3 4 5 6	7				
	Extra session	1 2 3 4 5 6	7				
Week 3	Home/gym session	1 2 3 4 5 6	9				
	Extra session	1 2 3 4 5 6	9				
Week 4	Home/gym session	1 2 3 4 5 6	5				
	Extra session	1 2 3 4 5 6	5				
Week 5	Home/gym session	1 2 3 4 5 6	7				
	Extra session	1 2 3 4 5 6	7				
Week 6	Home/gym session	1 2 3 4 5 6	7				
	Extra session	1 2 3 4 5 6	7				
Week 7	Home/gym session	1 2 3 4 5 6	9				
	Extra session	1 2 3 4 5 6	9				
Week 8	Home/gym session	1 2 3 4 5 6	5				
	Extra session	1 2 3 4 5 6	5				
Week 9	Home/gym session	1 2 3 4 5 6	7				
	Extra session	1 2 3 4 5 6	7				
Week 10	Home/gym session	1 2 3 4 5 6	7				
	Extra session	1 2 3 4 5 6	7				
Week 11	Home/gym session	1 2 3 4 5 6	9				
	Extra session	1 2 3 4 5 6	9				
Week 12	Home/gym session	1 2 3 4 5 6	5				
	Extra session	1 2 3 4 5 6	5				
Week 13	Home/gym session	1 2 3 4 5 6	7				
	Extra session	1 2 3 4 5 6	7				
Week 14	Home/gym session	1 2 3 4 5 6	7				
	Extra session	1 2 3 4 5 6	7				
Week 15	Home/gym session	1 2 3 4 5 6	9				
	Extra session	1 2 3 4 5 6	9				
Week 16	Home/gym session	1 2 3 4 5 6	9				
	Extra session	1 2 3 4 5 6	9				

RPE= Rating of Perceived Exertion (0=rest, 10=working as hard as possible)

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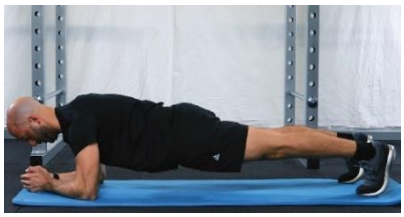
ADDITIONAL EXERCISES

EXERCISE 6. TRUNK/CORE STRENGTH

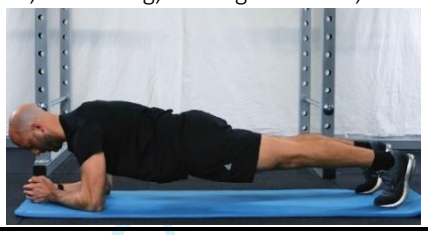
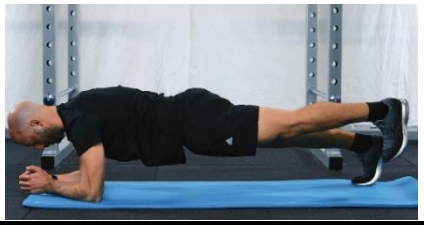
Level 1 – Front plank

Plank position, contract core muscles maintaining a straight line from ankle to head (30-60 secs)



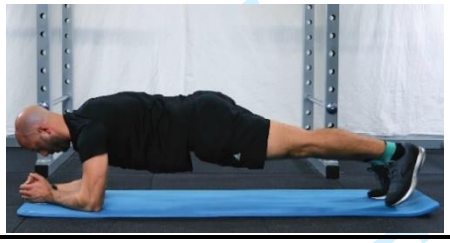
Level 2 – Front plank lift

Plank position, lift one leg, holding for 2 secs, and alternate between legs for 30-60 secs.

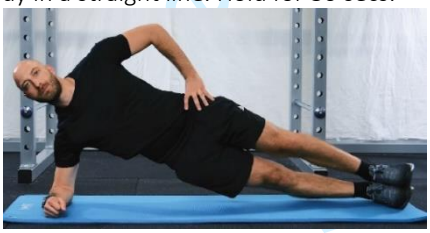
Level 3 – Front plank lift (resistance band)

Place resistance band around ankles. Move into plank position. Lift one leg stretching resistance band, holding for 2 secs, and alternate between legs for 30-60 secs.



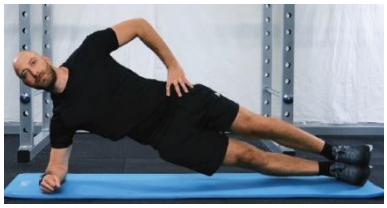

Level 4 – Side plank

Side plank position, keeping body in a straight line. Hold for 30 secs.



Level 5 – Side plank lift

Side plank position, lift your top leg. Hold for 2 secs, then slowly return. Repeat for 30-60 secs.




Level 6 – Side plank lift (resistance band)

Side plank position. Resistance band around ankles. Lift the top leg up stretching the resistance band and lower. Repeat for 30-60 secs.


Exercise 6: TRUNK/CORE STRENGTH **HOME/GYM RECORD**

		Level (circle)	Aim RPE	Actual RPE	Kilos	Number of sets	Number of reps
Week 1	Home/gym session	1 2 3 4 5 6	5/10				
	Extra session	1 2 3 4 5 6	5				
Week 2	Home/gym session	1 2 3 4 5 6	7				
	Extra session	1 2 3 4 5 6	7				
Week 3	Home/gym session	1 2 3 4 5 6	9				
	Extra session	1 2 3 4 5 6	9				
Week 4	Home/gym session	1 2 3 4 5 6	5				
	Extra session	1 2 3 4 5 6	5				
Week 5	Home/gym session	1 2 3 4 5 6	7				
	Extra session	1 2 3 4 5 6	7				
Week 6	Home/gym session	1 2 3 4 5 6	7				
	Extra session	1 2 3 4 5 6	7				
Week 7	Home/gym session	1 2 3 4 5 6	9				
	Extra session	1 2 3 4 5 6	9				
Week 8	Home/gym session	1 2 3 4 5 6	5				
	Extra session	1 2 3 4 5 6	5				
Week 9	Home/gym session	1 2 3 4 5 6	7				
	Extra session	1 2 3 4 5 6	7				
Week 10	Home/gym session	1 2 3 4 5 6	7				
	Extra session	1 2 3 4 5 6	7				
Week 11	Home/gym session	1 2 3 4 5 6	9				
	Extra session	1 2 3 4 5 6	9				
Week 12	Home/gym session	1 2 3 4 5 6	5				
	Extra session	1 2 3 4 5 6	5				
Week 13	Home/gym session	1 2 3 4 5 6	7				
	Extra session	1 2 3 4 5 6	7				
Week 14	Home/gym session	1 2 3 4 5 6	7				
	Extra session	1 2 3 4 5 6	7				
Week 15	Home/gym session	1 2 3 4 5 6	9				
	Extra session	1 2 3 4 5 6	9				
Week 16	Home/gym session	1 2 3 4 5 6	9				
	Extra session	1 2 3 4 5 6	9				

RPE= Rating of Perceived Exertion (0=rest, 10=working as hard as possible)

EXERCISE 7. HIP ABDUCTION (OUTER THIGH)

Level 1 – Standing hip abduction with resistance band

Move your leg straight out to the side, tightening the resistance band. Slowly return to starting position. Increase difficulty by increasing resistance band strength with a different colour (your physiotherapist can help you with this). Aim 2-3 sets of 8-12.

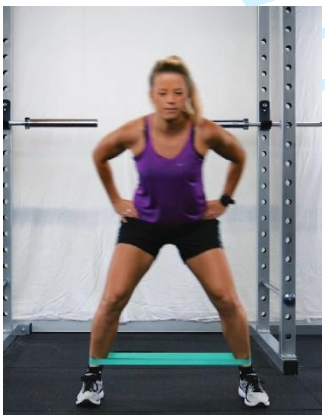

Level 2 –Standing hip abduction with cable

Move your leg straight out to the side against cable resistance, slowly return to starting position.

Aim 2-3 sets of 8-12.


Level 3 – Crab walk

In squat position (hip/knee slightly flexed) walk sideways (20 steps each way) keeping your upper body straight and tension in the resistance band. Increase difficulty by moving band to forefoot or increasing resistance.


Exercise 7: HIP ABDUCTION (OUTER THIGH) **HOME/GYM RECORD**

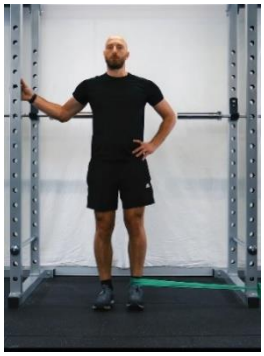
		Level (circle)	Aim RPE	Actual RPE	Kilos on affected leg	Number of sets	Number of reps
Week 1	Home/gym session	1 2 3	5/10				
	Extra session	1 2 3	5				
Week 2	Home/gym session	1 2 3	7				
	Extra session	1 2 3	7				
Week 3	Home/gym session	1 2 3	9				
	Extra session	1 2 3	9				
Week 4	Home/gym session	1 2 3	5				
	Extra session	1 2 3	5				
Week 5	Home/gym session	1 2 3	7				
	Extra session	1 2 3	7				
Week 6	Home/gym session	1 2 3	7				
	Extra session	1 2 3	7				
Week 7	Home/gym session	1 2 3	9				
	Extra session	1 2 3	9				
Week 8	Home/gym session	1 2 3	5				
	Extra session	1 2 3	5				
Week 9	Home/gym session	1 2 3	7				
	Extra session	1 2 3	7				
Week 10	Home/gym session	1 2 3	7				
	Extra session	1 2 3	7				
Week 11	Home/gym session	1 2 3	9				
	Extra session	1 2 3	9				
Week 12	Home/gym session	1 2 3	5				
	Extra session	1 2 3	5				
Week 13	Home/gym session	1 2 3	7				
	Extra session	1 2 3	7				
Week 14	Home/gym session	1 2 3	7				
	Extra session	1 2 3	7				
Week 15	Home/gym session	1 2 3	9				
	Extra session	1 2 3	9				
Week 16	Home/gym session	1 2 3	9				
	Extra session	1 2 3	9				

RPE= Rating of Perceived Exertion (0=rest, 10=working as hard as possible)

EXERCISE 8. HIP ADDUCTION (INNER THIGH)

Level 1 – Hip adduction with resistance band

Standing maintaining good alignment, move your leg toward your body, tightening resistance band and slowly return to the starting position. Aim 2-3 sets of 8-12.

Level 2 – Hip adduction with cable

Standing maintaining good alignment, move your leg toward your body and slowly return to the starting position. Aim 2-3 sets of 8-12.


Level 3 – Groin plank - knee

Side plank position with upper leg (knee) on chair, slowly lift and lower your bottom leg to the under surface of the chair. Aim 1-3 sets of 8-12.


Level 4 – Groin plank ankle

Side plank position with upper leg (foot) on chair, slowly lift and lower your bottom leg to the under surface of the chair. Aim 1-3 sets of 8-12.


Exercise 8: HIP ADDUCTION (INNER THIGH) **HOME/GYM RECORD**

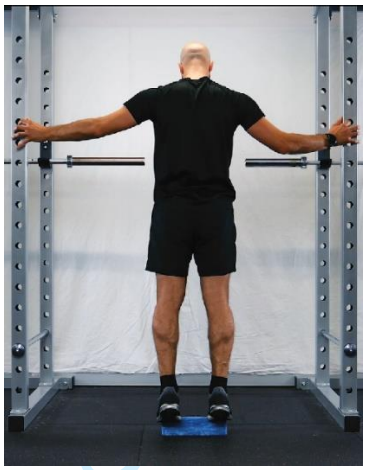
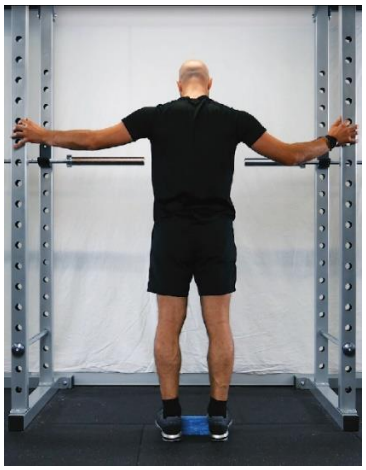
		Level (circle)	Aim RPE	Actual RPE	Kilos on affected leg	Number of sets	Number of reps
Week 1	Home/gym session	1 2 3 4	5/10				
	Extra session	1 2 3 4	5				
Week 2	Home/gym session	1 2 3 4	7				
	Extra session	1 2 3 4	7				
Week 3	Home/gym session	1 2 3 4	9				
	Extra session	1 2 3 4	9				
Week 4	Home/gym session	1 2 3 4	5				
	Extra session	1 2 3 4	5				
Week 5	Home/gym session	1 2 3 4	7				
	Extra session	1 2 3 4	7				
Week 6	Home/gym session	1 2 3 4	7				
	Extra session	1 2 3 4	7				
Week 7	Home/gym session	1 2 3 4	9				
	Extra session	1 2 3 4	9				
Week 8	Home/gym session	1 2 3 4	5				
	Extra session	1 2 3 4	5				
Week 9	Home/gym session	1 2 3 4	7				
	Extra session	1 2 3 4	7				
Week 10	Home/gym session	1 2 3 4	7				
	Extra session	1 2 3 4	7				
Week 11	Home/gym session	1 2 3 4	9				
	Extra session	1 2 3 4	9				
Week 12	Home/gym session	1 2 3 4	5				
	Extra session	1 2 3 4	5				
Week 13	Home/gym session	1 2 3 4	7				
	Extra session	1 2 3 4	7				
Week 14	Home/gym session	1 2 3 4	7				
	Extra session	1 2 3 4	7				
Week 15	Home/gym session	1 2 3 4	9				
	Extra session	1 2 3 4	9				
Week 16	Home/gym session	1 2 3 4	9				
	Extra session	1 2 3 4	9				

RPE= Rating of Perceived Exertion (0=rest, 10=working as hard as possible)

EXERCISE 9. CALF

Level 1 – Double leg calf raises

On two legs standing on the edge of a step, raise up onto your toes and then lower both heels back down below the step. Only light support with hands to maintain balance. Aim 2-3 sets of 8-12.

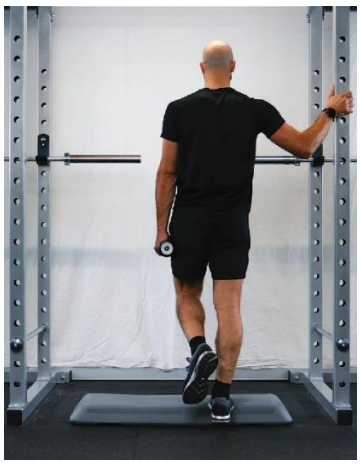
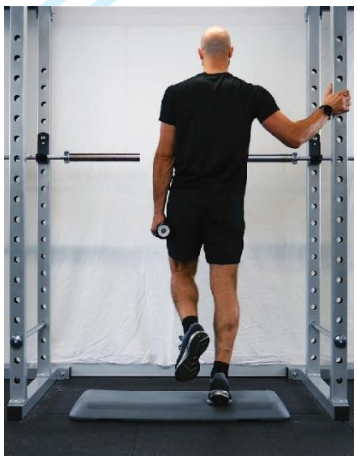



Level 2 – Single leg calf raises

On one leg standing on the edge of a step, raise up onto your toe and then lower heel back down below the step. Only light support with hands to maintain balance. Aim 2-3 sets of 8-12.


Level 3 – Weighted single leg calf raises

Same exercise as Level 2 but add a weight in your opposite hand to make the exercise harder. Aim 2-3 sets of 8-12.

Exercise 9: CALF **HOME/GYM RECORD**

		Level (circle)	Aim RPE	Actual RPE	Kilos	Number of sets	Number of reps
Week 1	Home/gym session	1 2 3	5/10				
	Extra session	1 2 3	5				
Week 2	Home/gym session	1 2 3	7				
	Extra session	1 2 3	7				
Week 3	Home/gym session	1 2 3	9				
	Extra session	1 2 3	9				
Week 4	Home/gym session	1 2 3	5				
	Extra session	1 2 3	5				
Week 5	Home/gym session	1 2 3	7				
	Extra session	1 2 3	7				
Week 6	Home/gym session	1 2 3	7				
	Extra session	1 2 3	7				
Week 7	Home/gym session	1 2 3	9				
	Extra session	1 2 3	9				
Week 8	Home/gym session	1 2 3	5				
	Extra session	1 2 3	5				
Week 9	Home/gym session	1 2 3	7				
	Extra session	1 2 3	7				
Week 10	Home/gym session	1 2 3	7				
	Extra session	1 2 3	7				
Week 11	Home/gym session	1 2 3	9				
	Extra session	1 2 3	9				
Week 12	Home/gym session	1 2 3	5				
	Extra session	1 2 3	5				
Week 13	Home/gym session	1 2 3	7				
	Extra session	1 2 3	7				
Week 14	Home/gym session	1 2 3	7				
	Extra session	1 2 3	7				
Week 15	Home/gym session	1 2 3	9				
	Extra session	1 2 3	9				
Week 16	Home/gym session	1 2 3	9				
	Extra session	1 2 3	9				

RPE= Rating of Perceived Exertion (0=rest, 10=working as hard as possible

SUPER Knee

Participant Handbook

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8. WHAT CAN I DO TO STRENGTHEN MY QUADRICEPS?

Start with a moderately difficult exercise and progress according to the guidelines set out in the handbook (see section 8 "How hard should I exercise?").

Progress quadricep muscles exercises by:

1. Use one leg instead of two
2. Add a weight or increase the weight
3. Increase the depth of exercise
4. Increase the speed of the exercise
5. Increase number of repetitions

Home or gym exercises

Option 1 – Double leg squats

With even weight on both legs, bend your knees evenly and squat down to a chair height. Make sure your knees don't move in or out and keep your trunk upright. Return to upright standing. If this is too hard, just squat down as far as you can.



Option 2 – Bulgarian split squat

Put your back leg up on a stable elevated object and so that your front knee is at 90°. Try and keep most of your weight on your front leg. Keep your knees over your toes and don't let your hips drop.



Gym exercises

Option 3 – Knee extension machine

In the seated knee extension machine, straighten your knee against resistance. Start at 90° knee bend and straighten to full knee extension.


Option 4 – Leg press

Using the leg press machine, press against the resistance while keeping your knees in good alignment (knees over toes). Don't fully lock your knees out. Start with a leg press set at 45° knee bend.


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9. WHAT CAN I DO TO STRENGTHEN MY HAMSTRINGS?

Start with a moderately difficult exercise and progress according to the guidelines set out in the handbook (see section 8 "How hard should I exercise?").

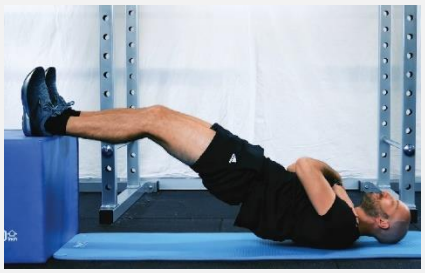
Progress hamstring muscle exercises by:

1. Add a weight or increase the weight
2. Increase number of repetitions

Home or gym exercises

Option 1 – Elevated bridge

Lying on your back with both legs elevated on a stable object use your hamstrings to lift your hips off the ground so that your back and legs are in a straight line. Use your hands for stability as needed.



To progress this exercise:

- Straighten your knee more
- Increase box/bench height

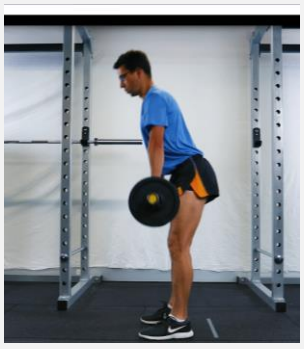
Option 2 – Single leg elevated bridge

Lying on your back with one leg elevated and slightly bent, on a stable object use your hamstrings to lift your hips off the ground so that your back and legs are in a straight line. Use your hands for stability as needed.

Gym exercises

Option 3– Deadlifts

With straight legs or a very slight knee bend, bend from your hips as far as comfortable (aim for the weight to be below your knees), then use your hamstring muscles to pull yourself back up to standing. Make sure you don't bend from your spine, but instead keep it straight.



Option 4 – Hamstring curl machine

In the gym, use the hamstring curl machine to work against the resistance to bring your heel to your hips. Start with your legs close to fully straight and bend to about 90°. Make sure you feel your hamstring muscle work.

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10. WHAT CAN I DO TO IMPROVE MY PLYOMETRIC POWER?

Start with a moderately difficult exercise and progress according to the guidelines set out in the handbook (see section 8 "How hard should I exercise?").

PLYOMETRIC POWER – Your ability to jump and land with both control and speed.

Progress jumping exercises by:

1. Increase the speed of jumping
2. Increase the number of jumps

Home or gym exercises

Option 1 – Double leg forward jump

Jump as high as possible landing softly bending at the hips and knees. Progress to jumping forwards as far as possible.

Option 2 – Single leg forward hop

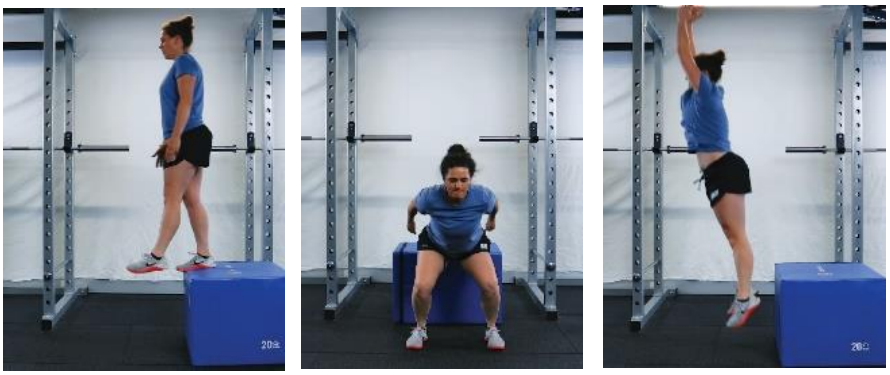
Hop forward on one leg landing softly bending at your hips and knees. Keep good alignment. Increase distance/speed.

Option 3 – Single leg side hop

Hop side-to-side on one leg landing softly on the same leg bending at your hips and knees. Increase lateral distance.

Option 4 – Double leg drop jump (off a step/box)

Standing on a box/step, jump down landing softly on both feet and immediately jump up as high as you can. Increase height of box or hold weights to make harder.



The size of the box can range from small (20cm) step to large (40-50cm as pictured). You can also progress to landing on one leg only.

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11. WHAT CAN I DO TO STRENGTHEN MY TRUNK/CORE?

Start with a moderately difficult exercise and progress according to the guidelines set out in the handbook (see section 8 "How hard should I exercise?").

Progress core exercises by:

1. Increase number of repetitions
2. Increase length of time held in position

Home or gym exercises

Option 1 – Front plank

Begin on your feet and elbows and maintain a straight line from your head to your ankle, so that you do not arch your back. Hold with good control without your hips moving higher or lower.

Aim to start with:

- 30 secs hold x 3 times

Option 2 – Front plank with leg lift

Plank position, lift one leg, holding for 2 secs, and alternate between legs for 30-60 secs.

Aim to start with:

- 10 reps each leg x 3 sets

Option 3 – Side planks

Start on your elbow and side of your feet and maintain a straight line from your shoulders to your ankles. Hold the position with good control without holding your hips too high or low.

Aim to start with:

- 30 secs hold x 3 times

Option 4 – Side plank with leg lift

Side plank position, leading with your heel, lift your top leg. Hold for 2 secs, then slowly return to starting position.

Aim to start with:

- 10 reps each leg x 3 sets

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12. WHAT CAN I DO TO STRENGTHEN MY HIPS?

Start with a moderately difficult exercise and progress according to the guidelines set out in the handbook (see section 8 "How hard should I exercise?").

Progress hip muscle exercises by:

1. Add a weight or increase the weight
2. Increase the height or width of exercise
3. Increase the speed of the exercise
4. Increase number of repetitions

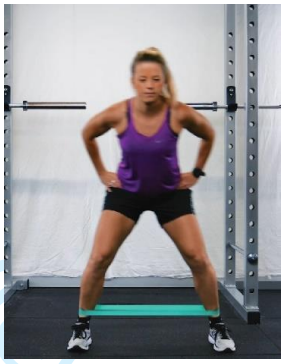
Home or gym exercises

Option 1 – Standing hip abduction with resistance band

Move your leg straight out to the side tightening resistance band. Slowly return to starting position. Increase difficulty by increasing resistance band strength.


Option 2 – Crab walk

In squat position (hip/knee slightly flexed) walk sideways (20 steps each way) keeping your upper body straight and tension in the resistance band. Increase difficulty by moving band to foot.


Option 3 – Resistance band hip adduction

Standing maintaining good alignment, move your leg toward your body, tightening resistance band, and slowly return to the starting position.


Option 4 – Groin/adductor plank

Side plank position with upper leg (knee) on chair, slowly lift and lower your bottom leg to the under surface of the chair.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13. WHAT CAN I DO TO STRENGTHEN MY CALVES?

Start with a moderately difficult exercise and progress according to the guidelines set out in the handbook (see section 8 "How hard should I exercise?").

Progress calf muscle exercises by:

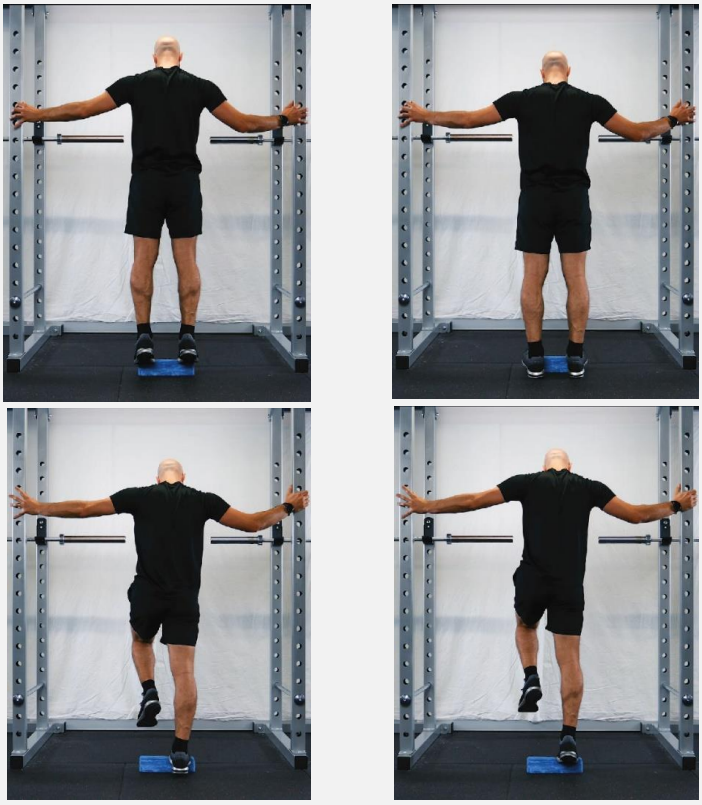
1. Increase the speed of the exercise
2. Increase number of repetitions
3. Use one leg instead of two
4. Add a weight or increase the weight
5. Increase the depth of exercise
6. Increase the speed of the exercise
7. Increase number of repetitions

Home or gym exercises

<u>Option 1 - Calf raise (double leg and single leg)</u>

Standing off a small step/object about 5-10 cm high on two legs, raise your heels off the ground, and lower back down to the ground.

Make sure you do no rotate your ankle or foot and hold at the top for balance. Hold something lightly for balance if needed.



<u>Option 2 – Calf raise with weights</u>

Same exercise as option 1 but add a weight in your opposite hand to make the exercise harder.

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SUPER Knee

Date	Exercise	Reps & Sets	Weight	RPE /10
	1 Quadriceps 2 Hamstrings 3 Plyometric power 4 Trunk/core 5 Hips 6 Calves			
	1 Quadriceps 2 Hamstrings 3 Plyometric power 4 Trunk/core 5 Hips 6 Calves			
	1 Quadriceps 2 Hamstrings 3 Plyometric power 4 Trunk/core 5 Hips 6 Calves			
	1 Quadriceps 2 Hamstrings 3 Plyometric power 4 Trunk/core 5 Hips 6 Calves			
	1 Quadriceps 2 Hamstrings 3 Plyometric power 4 Trunk/core 5 Hips 6 Calves			
	1 Quadriceps 2 Hamstrings 3 Plyometric power 4 Trunk/core 5 Hips 6 Calves			
	1 Quadriceps 2 Hamstrings 3 Plyometric power 4 Trunk/core 5 Hips 6 Calves			

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Date	Exercise	Reps & Sets	Weight	RPE /10
	1 Quadriceps			
	2 Hamstrings			
	3 Plyometric power			
	4 Trunk/core			
	5 Hips			
	6 Calves			
	1 Quadriceps			
	2 Hamstrings			
	3 Plyometric power			
	4 Trunk/core			
	5 Hips			
	6 Calves			
	1 Quadriceps			
	2 Hamstrings			
	3 Plyometric power			
	4 Trunk/core			
	5 Hips			
	6 Calves			
	1 Quadriceps			
	2 Hamstrings			
	3 Plyometric power			
	4 Trunk/core			
	5 Hips			
	6 Calves			
	1 Quadriceps			
	2 Hamstrings			
	3 Plyometric power			
	4 Trunk/core			
	5 Hips			
	6 Calves			
	1 Quadriceps			
	2 Hamstrings			
	3 Plyometric power			
	4 Trunk/core			
	5 Hips			
	6 Calves			
	1 Quadriceps			
	2 Hamstrings			
	3 Plyometric power			
	4 Trunk/core			
	5 Hips			
	6 Calves			

Date	Exercise	Reps & Sets	Weight	RPE /10
	1 Quadriceps 2 Hamstrings 3 Plyometric power 4 Trunk/core 5 Hips 6 Calves			
	1 Quadriceps 2 Hamstrings 3 Plyometric power 4 Trunk/core 5 Hips 6 Calves			
	1 Quadriceps 2 Hamstrings 3 Plyometric power 4 Trunk/core 5 Hips 6 Calves			
	1 Quadriceps 2 Hamstrings 3 Plyometric power 4 Trunk/core 5 Hips 6 Calves			
	1 Quadriceps 2 Hamstrings 3 Plyometric power 4 Trunk/core 5 Hips 6 Calves			
	1 Quadriceps 2 Hamstrings 3 Plyometric power 4 Trunk/core 5 Hips 6 Calves			
	1 Quadriceps 2 Hamstrings 3 Plyometric power 4 Trunk/core 5 Hips 6 Calves			

LA TROBE UNIVERSITY

SUPER Knee

Date	Exercise	Reps & Sets	Weight	RPE /10
	1 Quadriceps	_____________	_____________	____
	2 Hamstrings	_____________	_____________	____
	3 Plyometric power	_____________	_____________	____
	4 Trunk/core	_____________	_____________	____
	5 Hips	_____________	_____________	____
	6 Calves	_____________	_____________	____
	1 Quadriceps	_____________	_____________	____
	2 Hamstrings	_____________	_____________	____
	3 Plyometric power	_____________	_____________	____
	4 Trunk/core	_____________	_____________	____
	5 Hips	_____________	_____________	____
	6 Calves	_____________	_____________	____
	1 Quadriceps	_____________	_____________	____
	2 Hamstrings	_____________	_____________	____
	3 Plyometric power	_____________	_____________	____
	4 Trunk/core	_____________	_____________	____
	5 Hips	_____________	_____________	____
	6 Calves	_____________	_____________	____
	1 Quadriceps	_____________	_____________	____
	2 Hamstrings	_____________	_____________	____
	3 Plyometric power	_____________	_____________	____
	4 Trunk/core	_____________	_____________	____
	5 Hips	_____________	_____________	____
	6 Calves	_____________	_____________	____
	1 Quadriceps	_____________	_____________	____
	2 Hamstrings	_____________	_____________	____
	3 Plyometric power	_____________	_____________	____
	4 Trunk/core	_____________	_____________	____
	5 Hips	_____________	_____________	____
	6 Calves	_____________	_____________	____
	1 Quadriceps	_____________	_____________	____
	2 Hamstrings	_____________	_____________	____
	3 Plyometric power	_____________	_____________	____
	4 Trunk/core	_____________	_____________	____
	5 Hips	_____________	_____________	____
	6 Calves	_____________	_____________	____
	1 Quadriceps	_____________	_____________	____
	2 Hamstrings	_____________	_____________	____
	3 Plyometric power	_____________	_____________	____
	4 Trunk/core	_____________	_____________	____
	5 Hips	_____________	_____________	____
	6 Calves	_____________	_____________	____

Date	Exercise	Reps & Sets	Weight	RPE /10
	1 Quadriceps			
	2 Hamstrings			
	3 Plyometric power			
	4 Trunk/core			
	5 Hips			
	6 Calves			
	1 Quadriceps			
	2 Hamstrings			
	3 Plyometric power			
	4 Trunk/core			
	5 Hips			
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	4 Trunk/core			
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	6 Calves			
	1 Quadriceps			
	2 Hamstrings			
	3 Plyometric power			
	4 Trunk/core			
	5 Hips			
	6 Calves			
	1 Quadriceps			
	2 Hamstrings			
	3 Plyometric power			
	4 Trunk/core			
	5 Hips			
	6 Calves			

LA TROBE UNIVERSITY

SUPER Knee

Date	Exercise	Reps & Sets	Weight	RPE /10
	1 Quadriceps			
	2 Hamstrings			
	3 Plyometric power			
	4 Trunk/core			
	5 Hips			
	6 Calves			
	1 Quadriceps			
	2 Hamstrings			
	3 Plyometric power			
	4 Trunk/core			
	5 Hips			
	6 Calves			
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	4 Trunk/core			
	5 Hips			
	6 Calves			
	1 Quadriceps			
	2 Hamstrings			
	3 Plyometric power			
	4 Trunk/core			
	5 Hips			
	6 Calves			
	1 Quadriceps			
	2 Hamstrings			
	3 Plyometric power			
	4 Trunk/core			
	5 Hips			
	6 Calves			

LA TROBE UNIVERSITY

SUPER Knee

Date	Exercise	Reps & Sets	Weight	RPE /10
	1 Quadriceps 2 Hamstrings 3 Plyometric power 4 Trunk/core 5 Hips 6 Calves			
	1 Quadriceps 2 Hamstrings 3 Plyometric power 4 Trunk/core 5 Hips 6 Calves			
	1 Quadriceps 2 Hamstrings 3 Plyometric power 4 Trunk/core 5 Hips 6 Calves			
	1 Quadriceps 2 Hamstrings 3 Plyometric power 4 Trunk/core 5 Hips 6 Calves			
	1 Quadriceps 2 Hamstrings 3 Plyometric power 4 Trunk/core 5 Hips 6 Calves			
	1 Quadriceps 2 Hamstrings 3 Plyometric power 4 Trunk/core 5 Hips 6 Calves			
	1 Quadriceps 2 Hamstrings 3 Plyometric power 4 Trunk/core 5 Hips 6 Calves			

Supplementary File 4. Details of physical performance tests

Battery of hops: single hop, triple crossover hop, and side hop

The single hop for distance assesses the distance (cm) the participant can hop from a stationary position, taking off and landing on the same foot. The triple cross-over hop for distance assesses the cumulative distance (cm) the participant can achieve by hopping three consecutive times, crossing over the outside of two strips of tape placed 15cm apart each time. The side-hop evaluates the number of hops participants can achieve (hopping side to side outside two parallel strips of tape placed 40cm apart on the floor) in 30 seconds. The vertical hop assesses the maximal height participants can hop from a stationary position. For all hop tests, participants wear their usual athletic footwear, start with their left leg (regardless of ACLR limb) and hands held behind the back. If participants make subsequent smaller hops, separate their hands or do not remain balanced, the hop is not recorded. Single, triple cross-over and vertical hops are repeated until at least three successful trials are recorded and no increase in distance is observed. The left leg is tested first.

Figure SF3.1. Battery of hop tests. **A**: Single hop for distance; **B**: Side-hop; **C:** Triple-crossover hop for distance; **D**: Vertical hop

One-leg rise

For the one-leg rise, participants sit on the edge of a plinth with the heel of the test leg on a marked line 10cm in front of the edge of the plinth. Plinth height is adjusted so the angle of the test knee in sitting is 90°. With arms folded across the chest, participants are instructed to rise from sitting to standing on one leg, achieve full knee extension, and return to lightly touch the plinth with buttocks. Rises are performed to a metronome to maintain a consistent cadence of 45 beats per minute. The maximum number of rises achieved at the predetermined cadence is recorded. The left leg is tested first.

Figure SF3.2 One leg rise test

Knee muscle strength

Maximal voluntary isometric contractions are evaluated during knee extension and flexion with the knee flexed to 60° using an isokinetic dynamometer (Biodex Medical Systems, NY, USA). Participants are seated (hips/non-tested knee flexed 90°) and the centre of the knee joint is aligned with the axis of the dynamometer. Four belts are used to stabilise the trunk and non-test limb, two crossing the trunk, one around the pelvis and one on the distal thigh. An inelastic strap fixed to the dynamometer arm is placed around the distal tibia (proximal to the ankle).

Two submaximal practice contractions of 5-seconds with an interval of 30-seconds between trials are performed as a familiarisation procedure. Then, with standardised verbal encouragement, three maximal isometric contractions of 5-seconds with an interval of 30-seconds between each trial are performed. The test alternates between knee extension and knee flexion (three trials for each). The left leg is tested first. Force curves will be recorded for all trials and the peak force (Nm), normalised for body mass as appropriate (Nm/kg), used for analyses. Knee extension and flexion rate of force development will also be assessed using the slope (change in force divided by change in time) of muscle contraction onset. To correct the influence of gravity, the assessed limb is weighed before each test and the data acquisition software automatically corrects the output data.

Figure SF3.3 Set up of knee muscle strength assessment using Biodex isokinetic dynamometer

Supplementary File 5. Details of magnetic resonance imaging sequences acquired

	Proton Density weighted fat suppressed fast spin-echo ***Axial***	**Proton Density weighted fat suppressed fast spin-echo** ***Sagittal***	**Proton Density weighted fat suppressed fast spin-echo** ***Coronal***	**Multi-echo spin-echo (MESE) T2 relaxation time mapping** ***Sagittal***	**Fast spoiled gradient echo (FSPGR)** ***Sagittal***
Repetition time (msec)	3725	2300	2325	3225	10.3
Echo time (msec)	36	36	36	10, 20, 30, 40, 50, 60, 70, 80	Minimum (~3.7)
Acquisition matrix	340 x 300	360 x 300	340 x 300	320 x 269	512 x 512
Field of view (cm)	16	16	16	12	16
Resolution (mm)	0.471 x 0.533 x 3.0	0.444 x 0.5333 x 3.0	0.471 x 0.5333 x 3.0	0.375 x 0.446 x 3.0	0.313 x 0.313 x 1.5
Slice thickness (mm)	3.0	3.0	3.0	3.0	1.5
Slice gap (mm)	0.3	1.0	0.3	1.0	0
Flip angle (°)	142	142	142	90	12
Number of echoes	10	10	9	8	-
Number of slices	32	31	34	31	84
Number of excitations	1	1	1	0.5	1
Bandwidth	50	35.71	35.71	31.25	31.25
Scan time (mins)	2:59	2:55	4:21	7:51	15.08

Participant Information Sheet/Consent Form

Interventional Study - *Adult providing own consent*

Title	Optimising outcomes after anterior cruciate ligament reconstruction: SUPER KNEE randomised controlled trial
Short Title	The SUPER KNEE trial
Ethics Reference Number	HEC19447
Project Sponsor	La Trobe University
Coordinating Principal Investigator/ Principal Investigator	Prof. Kay Crossley (La Trobe University)
Associate Investigators	Dr Adam Culvenor (La Trobe University) Dr Christian Barton (La Trobe University) Prof. Ewa Roos (Southern Denmark University) Prof. Steven McPhail (Queensland University of Technology) Ass. Prof. Edwin Oei (Erasmus Medical Centre) Dr Andrea Bruder (La Trobe University) Mr Thomas West (La Trobe University)
Location	La Trobe University

Part 1 What does my participation involve?

1 Introduction

You are invited to take part in this research project because you have had an anterior cruciate ligament (ACL) reconstruction within the last 9-36 months. The research project aims to compare the effectiveness of two different exercise and activity monitoring programs to optimise your knee symptoms, function and activity level and maximise your quality of life.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests and treatments involved. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or your local doctor.

Your participation is voluntary

Participation in this research is completely voluntary and there will be no cost to you. If you don't wish to take part, you don't have to. You will receive the best possible care whether or not you take part.

If you decide to take part and later change your mind, you are free to withdraw at any stage. Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you, or your relationship with La Trobe University or the hospital/orthopaedic surgeon who performed your ACL surgery.

If you decide you want to take part in the research project, you will be given a copy of this Participant Information Sheet and asked to sign the consent section. By signing it you are telling us that you:
- Understand what you have read
- Consent to take part in the research project
- Consent to have the tests and treatments that are described
- Consent to the use of your personal and health information as described.

Your withdrawal from the study

You are under no obligation to continue with the research study. You may change your mind at any time about participating in the research. People withdraw from studies for various reasons and you do not need to provide a reason.

You can withdraw from the study at any time by completing and signing the 'Participant Withdrawal of Consent Form'. This form is provided at the end of this document and is to be completed by you and supplied to the research team if you choose to withdraw at a later date.

If you withdraw from the study, you will be able to choose whether the study will destroy or retain the information it has collected about you. Information about you that has already been analysed (i.e., once you have been allocated to either exercise program), may not be able to be destroyed to ensure accurate and unbiased study reporting. Personal details collected, such as your name and contact details, can be destroyed at any time upon study withdrawal.

2 What is the purpose of this research?

As you may be aware, many people who have had an ACL reconstruction do not recover to a level that they are satisfied with. Therefore, it is important to investigate treatments that can improve outcomes. The purpose of this study is to investigate whether two different exercise and activity monitoring programs can improve knee symptoms, function, physical activity and quality of life, and prevent knee arthritis. We will recruit 184 adults who have not completely recovered at 9-36 months after ACL reconstruction in Australia.

This study is being coordinated by researchers at La Trobe University. It is supported by international researchers and has been funded by an Australian National Health and Medical Research Council Project Grant. All assessments and treatment will be at **no cost** to you.

3 Who can participate?

You can participate in the study if you meet all the following:
- Have had ACL reconstruction surgery 9-36 months previously
- Be aged 18-40 years at the time of your ACL reconstruction
- Have not completely recovered from your ACL reconstruction, assessed by a questionnaire (provided by the researchers)
- Willing to complete exercises 2-3 times per week

You are not eligible and cannot participate in this study if you meet any of the following:
- Have had another knee injury/surgery or knee injection in the past 3 months
- Have had physiotherapy treatment for your knee in the past 6 weeks
- Have another injury or health condition that affects your ability to perform functional tasks and exercises
- Have contraindications for MRI (e.g. pacemaker, a history of metallic foreign body in the eye, previous surgery for cerebral aneurysm, other implanted metal material other than your ACL graft or claustrophobia)
- Currently pregnant or breastfeeding
- Planning on relocating interstate or overseas in the next 18 months or unable to commit to the various study assessments over the next 18 months (as detailed below)
- Unable to understand written and/or spoken English

4 What does participation in this research involve?

If you agree to participate in this study, you will be asked to sign the participant consent form before any study assessments are performed. This study will be conducted over 18 months in total (see flowchart on next page).

A comprehensive knee assessment by a physiotherapist

For the first assessment at the start of the study, you will attend La Trobe University. At this testing session you should allow approximately 2 hours, where you will undergo a physical examination by a physiotherapist. You will be asked to wear shorts and a small piece of stocking (provided) over both of your knees during some tests so that the examiner is unable to tell which knee is your operated one. The tests conducted in the physical examination will include a measure of knee movement and joint swelling, activities including squatting and hopping, and measures of muscle strength (quadriceps and hamstrings). Muscle strength will be assessed using a special chair and you will be asked to push up and down a few times against an ankle pad as hard as you can. We will also measure and record your height, weight and waist circumference. We will video your performance during clinical tests (e.g. single-leg squat and jump). These videos will not include your face, so you cannot be identified from the footage. If any of your face (or other identifying feature) is inadvertently videoed, this will be masked (by electronically blurring the area) prior to data analysis.

You will also be asked to complete a series of questionnaires related to pain, physical function, confidence with physical movements and physical activity, as well as details about your knee injury/pain (e.g. injury mechanism, location of pain; history of pain). These may be completed in person at the testing session or online via link provided by email.

If you are interested, you may also undergo a 3D biomechanics assessment at the La Trobe University gait laboratory. This is optional and takes an additional 30-60mins. Small reflective skin markers will be attached to your skin (with tape on arms, pelvis, legs) and tracked with infrared cameras when you walk, run and perform hopping tasks.

A knee MRI

You will also attend Lake Imaging Specialist and Research Centre, North Melbourne (within 1-week of your assessment at La Trobe University) where you will have a magnetic resonance imaging (MRI) scan of your reconstructed and possibly your other knee (if uninjured). For the MRI scan you will be asked to lie on a narrow table that can slide inside a large tunnel-like tube with a scanner. The scanner creates a magnetic field around you, then pulses radio waves at the knee. This does not contain any radiation. It is very important that you keep very still during the scanning. All imaging will be provided at **no cost** to you and will take approximately 25-45 mins to complete.

Random assignment to one of two different treatments

At the end of the first assessment at La Trobe University you will be randomly assigned (50:50 chance, like a coin toss) by a computer system to receive one of the exercise and activity monitoring programs provided by physiotherapists to increase lower-limb muscle strength, power, endurance and agility. This means neither you or the researchers will be able to choose which group you are assigned to. We do not know which treatment is best. To find out we need to compare the different treatments. There is equal chance that you will receive either treatment. All treatment will be at **no cost** to you.

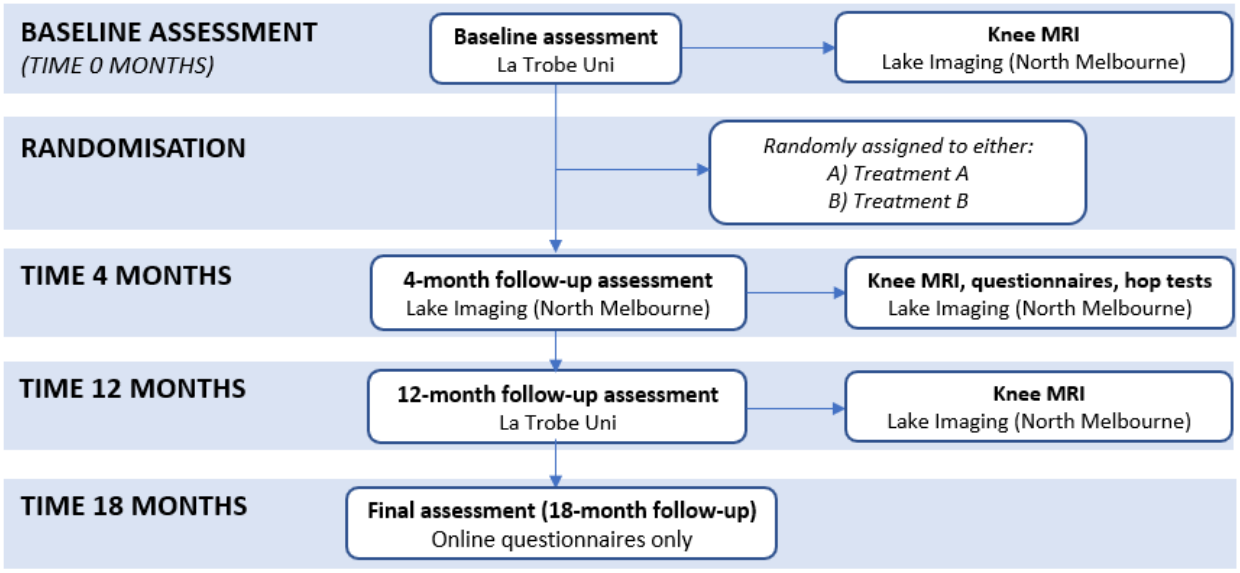

Figure 1. Flowchart of study assessments

If you are randomised to receive ***Treatment A***, you will receive a "best-practice guide" booklet and a face-to-face appointment with a physiotherapist to explain the exercises and education in the booklet. Your physical activity and sports participation will be monitored with fortnightly (for first 4 months) and monthly (after first 4 months) online questionnaires. You will also be provided with an activity monitor (Garmin™ watch) to count your steps.

If you are randomised to receive ***Treatment B***, you will receive 2 x per week face-to-face appointments for 4 months with a physiotherapist to perform muscle strength and agility/balance exercises. We have trained physiotherapists at clinics throughout Melbourne and Victoria to be convenient for you to attend. We will offer reimbursement for travel costs to attend each local physiotherapy appointment. You will have the option to access a gym (located conveniently for you and at no cost) at the 4-month assessment to continue to perform strengthening exercises up to 12-months after baseline. We will monitor your physical activity in the same way, and you will also get a physical activity monitor (Garmin™ watch) to measure your daily step count.

Follow-up assessments

At 4-months after baseline assessment, the same assessments will be repeated (questionnaires, hop tests and MRI) at Lake Imaging Specialist and Research Centre, North Melbourne and La Trobe University. At 12-months after baseline assessment, all assessments will be repeated: questionnaires, physical examination at La Trobe University, and MRI at Lake Imaging Specialist and Research Centre, North Melbourne. At completion of the study (18-months after baseline), the same online questionnaires will be repeated only.

There are no additional costs associated with participating in this research project. All medical care required as part of the research project will be provided free of charge. Your travel costs to attend the assessments will be reimbursed up to $100.

5 What else do I have to do?

In addition to the assessments conducted at baseline, 4-, 12- and 18-months, you will be asked to record the exercises you have completed in a log book. You will also be asked to record any other healthcare treatments you receive during the study. This will be recorded in the fortnightly/monthly online questionnaire. You will otherwise be able to carry on with your normal lifestyle. It is also important for us to know about your surgical details (e.g. technique, cartilage/meniscus treatment), so we will request to access your surgical notes.

At the end of the first 4 months, or after 12 months, we may also ask if you are willing to have a separate interview with one of the study researchers. The purpose of this interview is to seek

feedback on the study interventions, satisfaction with the process received and whether there are any suggestions for improvement. The interview will take approximately 30 minutes, but you can cease the interview at any time. To ensure responses are correctly interpreted, responses to questions will be audio recorded and transcribed. Audio recording transcriptions will be completed by 'Transcription Australia' on their secure, encrypted Australian-based software. Although voice in your audio recording could lead to your identification, this file will not be used during analysis. Instead a re-identifiable transcription, which you will have the opportunity to check for accuracy, will be used for analysis. Re-identifiable means that we will use a code number and not your name on data collected to ensure your anonymity. Following the completion of analysis of this transcription, the audio file associated with your interview will be deleted. After analysis, overall findings and conclusions from all interviews will also be sent to you, to allow an opportunity to make any further comments. We will seek around 40 participants to be interviewed (n=30 at 4 months, and n=30 at 12 months). It is your decision or not whether you wish to be interviewed.

6 What are the alternatives to participation?

You do not have to take part in this research project to receive treatment for your knee. Other options are available; these include attending physiotherapy (in a private practice or via the public hospital system). The research team will discuss these options with you before you decide whether or not to take part in this research project. You can also discuss the options with your surgeon, local doctor or physiotherapist.

7 What are the possible benefits of taking part?

We cannot guarantee or promise that you will receive any benefits from this research. However, possible benefits may include improved symptoms, function, quality of life, physical and sports activity, and confidence in your knee. You may also gain valuable insight into your physical functioning of your knee joint.

8 What are the possible risks and disadvantages of taking part?

The testing procedures and exercise-therapy treatments may cause side effects. You may have none, some or all of the effects listed below, and they may be mild, moderate or severe. If you have any of these side effects, or are worried about them, talk with the study coordinator.

Possible Side Effect	How often is it likely to occur?	How severe might it be?	How long might it last?
Muscle soreness	Commonly, after testing; or after a change in exercises	Muscle may be tender to touch, may notice pain when using muscles (e.g. going up/down stairs)	May last 2-3 days
Increase in knee pain or swelling	Rarely after testing; Rarely after exercise-therapy if instructions followed	Mild Moderate Severe	2-3 days 3-7 days > 1 week
Re-injury (e.g. rupture of ACL graft), or injury to opposite knee (or ankle/hip)	Extremely rare during testing or exercise (research team are only aware of 1 incident in 20+ years in this field)	Mild to severe	Depends on injury – maybe months

There may be side effects that the researchers do not expect or do not know about and that may be serious. Tell the researchers immediately if you get any new or unusual symptoms. Most side effects go away shortly after treatment ends. If a severe side effect or reaction occurs, the study coordinator may need to stop your treatment. The study coordinator will discuss the best way of managing any side effects with you.

Muscle and joint soreness

The physical tests and exercises represent usual examination and intervention by a physiotherapist. You may experience a small amount of discomfort in the joints or muscles. Please report to the researcher any discomfort or pain experienced during the testing or exercises. If the pain or discomfort is deemed to be excessive by yourself or the investigators, the testing/treatment will cease.

Re-injury

There is a very slight risk of falling during the hopping tasks. During the physical tests and exercises, there is also an extremely low risk of re-injuring your ACL reconstructed knee. During the first 5 years after ACL reconstruction, approximately 5% of people will re-rupture their ACL graft, with almost all of these occurring during sport. To minimise the risk of graft rupture, an experienced physiotherapist will conduct all testing, and you can choose to not perform tests if you are not confident to do so. The exercises have been designed using the best available research, and you will be provided with criteria to appropriately progress the difficulty of exercises to minimise re-injury risk. In particular, before attempting sport, we strongly recommend approval from your surgeon and possibly a return to sport assessment by a health professional.

Magnetic Resonance Imaging (MRI)

When you lie in the MRI machine, the MRI team will make sure you are in a comfortable position so you can keep still. The scanner is very noisy and they can give you some earphones to reduce the noise. Some people may experience symptoms of claustrophobia from lying in a confined space. If you do experience discomfort at any time during the scan, you will be able to alert staff by pressing on a call button provided to you.

There are no proven long-term risks related to MRI scans. MRI is considered safe when performed at a centre with appropriate procedures. However, the magnetic attraction for some metal objects can pose a safety risk, so it is important that metal objects are not taken into the scanner room.

The MRI team will examine you to make sure there is no reason for you not to have the scan. You must tell them if you have metal implanted in your body, such as a pacemaker or metal pins.

The scans we are taking are for research purposes. They are not intended to be used like scans taken for a full clinical examination. The scans will not be used to help diagnose, treat or manage a particular condition. A specialist will look at your MRI scans for features relevant to the research project. This may be done by specialists we work with overseas – all identifying information (name, date of birth etc) will be removed from your MRI scans prior to analysis so that you will not be able to be identified. On rare occasions, the specialist may find an unusual feature that could have a significant risk to your health. If this happens, we will contact you and/or your health practitioner to talk about the findings. We cannot guarantee that we will find any/all unusual features. The MRI team will provide you with a copy of your MRI scans.

9 Can I have other treatments during this research project?

While you are participating in this research project, you should not participate in alternative or additional exercise-therapy (or physiotherapy). It is important to tell the study co-ordinator about any treatments or medications you may be taking, including over-the-counter medications, vitamins or herbal remedies, acupuncture or other alternative treatments. We prefer that you do not commence any new treatment during the research project. However, should you decide to do so, we require you to describe any treatments (including medications) in your “study log book”.

10 What happens when the research project ends?

At the completion of the research project, there will be no additional treatment provided by our research team. If you wish to continue with your exercise-therapy treatment, you can continue to use the resources provided to you. Any additional treatment (e.g. physiotherapy) that you might require at the completion of the research project will be at your own cost. If requested, we will provide you with your individual results and whole study results. We, or other researchers, may also use coded information (so that you cannot be identified) collected for this research study in future related studies. If you consent (tick the box on the consent form) to be contacted for future related research, we will store your contact details (name, address, phone number, email) on the secure La Trobe University research drive, only accessible to members of the research team, and may contact you about future related research projects.

Part 2 How is the research project being conducted?

11 What will happen to information about me?

By signing the consent form you agree to the relevant research staff collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential and securely stored. It will be disclosed only with your permission, or in compliance with the law.

The research staff will also collect information on the health services you have used for the 6 months before, and 18 months after, baseline assessment. To collect this information, identifiable data (e.g. name, age, address) will be submitted to the Department of Human Services so that information about your health service usage can be obtained from a range of health datasets (e.g. Medicare Benefits Schedule (MBS), Pharmaceutical Benefits Scheme (PBS)) and linked to your study data. The health service data will be provided to the research team, by the Department of Human Services, in a format where your identifiable data (e.g. name, address) has been removed and the anonymous data will be held and analysed within a Department of Human Services approved, secure data storage environment. This information will be used solely for this project.

You will be asked to sign a consent form authorising the study to access your complete MBS and PBS data as outlined in the consent form. Medicare collects information on your doctor visits and the associated costs, while the PBS collects information on the prescription medications you have filled at pharmacies. The consent form is sent securely to the Department of Human Services who holds MBS and PBS data confidentially.

Storage, retention and destruction

The anonymity of your participation is assured with our procedure, in which a code number and not your name will identify you. Data will be kept securely at La Trobe University in a locked filing cabinet and password protected research computer. Re-identifiable (i.e. coded) information will also be kept to link your health service utilisation. Identifiable data will be stored for 15 years, after which time it will be securely destroyed (electronic records deleted, and paper-files shredded). All data and results will be handled in a strictly confidential manner, under guidelines set out by the National Health and Medical Research Council. The principal investigator (Professor Kay Crossley) is responsible for maintaining this confidentiality.

Information about you may be obtained from your health records held at health services for the purpose of this research. By signing the consent form you agree to the study team accessing health records if they are relevant to your participation in this research project.

In accordance with relevant Australian and/or Victorian privacy and other relevant laws, you have the right to request access to your information collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please contact the study member named below if you would like to access your information.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums and may be used by research higher degree students to obtain a research degree. In any publication, presentation or data files shared with other researchers, information will be provided in such a way that you cannot be identified, except with your permission. Any personal information that could identify you will be removed or changed before files are shared with other researchers.

12 What happens if I am injured as a result of participating in this research project?

If you suffer any injuries or complications as a result of this research project, you should contact the study team as soon as possible. You will be assisted with arranging appropriate medical treatment. If you are eligible for Medicare, you can receive medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital. Waiting lists may apply and you may not see the surgeon who performed your original ACL reconstruction. In the first instance your study physiotherapist and/or research team will evaluate your condition and then discuss treatment with both you and your regular health practitioner. In the event of loss or injury, any question about compensation must initially be directed to the research team who will advise the university insurer of the matter.

13 Who is organising and funding the research?

This research project is being conducted by Professor Kay Crossley and a team of national and international researchers. It has been funded by an Australian National Health and Medical Research Council Project Grant. No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

14 Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of La Trobe University and the Alfred Hospital Ethics Committee.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2018)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

15 Further information and who to contact

The person you may need to contact will depend on the nature of your query.
For all enquiries, you can contact the Clinical Trial Manager, during business hours:

Dr Adam Culvenor, Research Fellow in Physiotherapy, La Trobe University
Tel: 03 9479 5116; E-mail: a.culvenor@latrobe.edu.au

If you have any medical problems which may be related to your involvement in the project (for example, any side effects), the number to call Dr Adam Culvenor after hours is: 0401390974.

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

Reviewing HREC: La Trobe University Human Research Ethics Committee
Complaints Contact: Senior Human Ethics Officer, Ethics and Integrity, Research Office
Telephone: 03 9479 1443 E-mail: humanethics@latrobe.edu.au

* Please quote the application reference number HEC19447.

LA TROBE UNIVERSITY

SUPER Knee

Consent Form - *Adult providing own consent*

Title	Optimising outcomes after anterior cruciate ligament reconstruction: SUPER KNEE randomised controlled trial
Short Title	The SUPER KNEE trial
Ethics Reference Number	HEC19447
Project Sponsor	La Trobe University
Coordinating Principal Investigator/ Principal Investigator	Professor Kay Crossley
Associate Investigator(s)	Dr Adam Culvenor Dr Christian Barton Professor Ewa Roos Professor Steven McPhail Associate Professor Edwin Oei Dr Andrea Bruder Mr Thomas West
Location	La Trobe University

Consent Agreement

I have read the Participant Information Sheet and I understand the purposes, procedures and risks of the research described in the project.

Information about you may be obtained from your health records held at health services for the purpose of this research. I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to La Trobe University concerning my knee injury and treatment for the purposes of this project. I understand that such information will remain confidential.

I understand that data files may be shared with other researchers, and that information will be provided in such a way that I cannot be identified, except with my permission.

I have had an opportunity to ask questions and I am satisfied with the answers I have received. I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the study without affecting my future health care.

At the end of the first 4 months, or after12 months, you will be asked if you are willing to have a separate recorded interview with one of the study researchers for the purposes of seeking feedback.

☐ I agree to participate in a recorded interview
☐ I do not agree to participate in a recorded interview

I understand that, if I decide to discontinue the study treatment, I may be asked to attend follow-up visits to allow collection of information regarding my health status. I agree that data gathered for the study may be published provided my name or other identifying information is not used.

☐ I wish to receive results of the study ☐ I do not wish to receive results of the study

☐ I consent to be contacted for future related research
☐ I do not consent to be contacted for future related research

I understand that I will be given a signed copy of this document to keep.

Name of Participant (please print) _____

Signature _____ Date _____

Declaration by Researcher†

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Name of Researcher† (please print) _____

Signature _____ Date _____

† A member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature.

LA TROBE UNIVERSITY

SUPER Knee

Form for Withdrawal of Participation - *Adult providing own consent*

Title	Optimising outcomes after anterior cruciate ligament reconstruction: SUPER KNEE randomised controlled trial
Short Title	The SUPER KNEE trial
Ethics Reference Number	HEC19447
Project Sponsor	La Trobe University
Coordinating Principal Investigator/ Principal Investigator	Professor Kay Crossley
Associate Investigator(s)	Dr Adam Culvenor Dr Christian Barton Professor Ewa Roos Professor Steven McPhail Associate Professor Edwin Oei Dr Andrea Bruder Mr Thomas West
Location	La Trobe University

Declaration by Participant

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine treatment, my access to Health Services or Government benefits, my relationship with those treating me or my relationship with La Trobe University or the health system where I had my knee surgery. I understand that no further information about me will be collected for the study from the withdrawal date. I understand that information about me that has already been analysed and/or included in a publication by the study, may not be able to be destroyed. I request that the study handles the information they have collected about me in the following way (choose one option):

☐ DESTROY all my information collected so it can no longer be used for research

☐ RETAIN all my information collected so it can be used for research

Name of Participant (please print) _____

Signature _____ Date _____

In the event that the participant's decision to withdraw is communicated verbally, the Researcher will need to provide a description of the circumstances below.

Date:
Time:

Declaration by Researcher†

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant has understood that explanation.

Name of Researcher† (please print) _____

Signature _____ Date _____

† A member of the research team must provide the explanation of and information concerning withdrawal from the research project.

Note: All parties signing the consent section must date their own signature.

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	3
	2b	All items from the World Health Organization Trial Registration Data Set	ACTRN12620001164987
Protocol version	3	Date and version identifier	NA
Funding	4	Sources and types of financial, material, and other support	23
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	23
	5b	Name and contact information for the trial sponsor	1
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	23
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	NA
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4
	6b	Explanation for choice of comparators	4-5
Objectives	7	Specific objectives or hypotheses	5
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	5-6
Methods: Participants, interventions, and outcomes			

Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	6
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	6
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	8-13, Table 2, Supplementary 1
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	Table 2
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	8-13, Table 2
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	13
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	14-18, Table 3
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	Figure 1
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	19
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	6-7
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	7-8
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	7-8
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	7-8
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	7-8

	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	NA
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	13
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	13
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	19
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	20
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	20
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	20
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	19
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	19-20
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	18-19
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	NA
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	22

Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	22
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	22
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	NA
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	19
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	23-24
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	Supplementary 6
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	NA
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	22
	31b	Authorship eligibility guidelines and any intended use of professional writers	NA
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	NA
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Supplementary 6
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	NA

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-Non Commercial-No Derivs 3.0 Unported" license.