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Exercise for treating anterior cruciate ligament injuries in combination with collateral ligament and meniscal damage of the knee in adults (Protocol)

Trees AH, Howe TE, Grant M, Gray HG



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ABSTRACT

This is the protocol for a review and there is no abstract. The objectives are as follows:

To determine the efficacy of exercise used in the rehabilitation of ACL injuries in combination with collateral ligament(s) and/or meniscal damage in adults, whether treated conservatively or by reconstruction, on return to work and pre-injury levels of activity.

The following null hypotheses are formulated.

For ACL injuries treated conservatively:

- there are no differences in outcome between any exercise programme versus none (control) in the rehabilitation of ACL injuries in combination with collateral ligament(s) and/or meniscal damage;
- there are no differences in outcome between any exercise programme versus any other exercise programme in the rehabilitation of ACL injuries in combination with collateral ligament(s) and/or meniscal damage.

For ACL injuries treated by reconstruction:

- there are no differences in outcome between any exercise programme versus none (control) in the rehabilitation of ACL injuries in combination with collateral ligament(s) and/or meniscal damage;
- there are no differences in outcome between any exercise programme versus any other exercise programme in the rehabilitation of ACL injuries in combination with collateral ligament(s) and/or meniscal damage.

BACKGROUND

Description of the condition

The anterior cruciate ligament (ACL) is the most commonly injured ligament of the knee (Ageberg 2002). Injury can be in isolation (30 per 100,000 per year), but is often combined with collateral ligament and/or meniscal damage (98 per 100,000 per year) (Miyasaka 1991).

The primary role of the ACL is to prevent an anterior translation (forward movement) of the tibia relative to the femur. It also guides the screw-home mechanism associated with knee extension, prevents hyperextension and assists in prevention of varus (bow-leg) and valgus (knock-knee) movement, especially in the extended

knee. The menisci, crescent-shaped cartilage discs attached to the top of the tibia in the knee joint, provide shock absorption, load distribution, and knee stability. The medial and lateral collateral ligaments, on either side of the knee joint, provide the primary restraint to varus and valgus (sideways) movement at the knee joint.

The most commonly seen mechanism of injury to the ACL is through rapid deceleration with a twisting movement and hence disruption of the ACL in combination with the collateral ligament(s) and/or menisci - this commonly occurs in athletes. Following injury, pain, effusion and inflammation have been shown to lead to the inability to fully activate the thigh muscles, affecting muscle strength and joint stability.

ACL injuries may be treated conservatively (non-operatively) or by ligament reconstruction.

Description of the intervention

It is proposed by some that regaining muscular control is essential if the individual wishes to return to pre-injury level of function (Henriksson 2001; Mattacola 2002) and individuals will invariably be referred for rehabilitation. Rehabilitation may comprise exercise to improve range of movement, muscle strength, balance and proprioception.

How the intervention might work

Muscle-strengthening exercises can be performed in a variety of ways reflecting the types of muscle action required for normal function. These include isometric (where no movement occurs at the joint), isotonic (where movement occurs at the joint) and isokinetic (where movement occurs at the joint but the speed of movement remains constant). Isotonic and isokinetic contractions can also be performed concentrically (where the muscle shortens, for example using the muscles on the front of the thigh during standing from a seated position), or eccentrically (where the muscle is active but lengthening, for example the muscles on the front of the thigh during sitting from a standing position). Eccentric muscle activity normally occurs to control movement against gravity. Furthermore, exercise for the muscles acting on the knee may be performed as closed kinetic chain activities (weight bearing, where the foot is fixed, for example standing up from a seated position) or open kinetic chain activities (non-weight bearing, where the foot is free to move, for example straightening the knee while seated). Other modalities used during the rehabilitation phase may include cryotherapy (ice), electrotherapy (including muscle stimulation), continuous passive motion (movement of the joint by a machine), restrictive bracing and complementary therapies such as reflexology or acupuncture.

Why it is important to do this review

A previous Cochrane review (Thomson 2002) only included trials of physiotherapy-led programmes and did not consider trials when the exercise programmes were prescribed or led by persons other than physiotherapists. That review has now been withdrawn from The Cochrane Library and is being updated as a series of four separate reviews on exercise for treating isolated anterior cruciate ligament injuries, isolated meniscal injuries, isolated collateral ligament injuries, and for ACL injuries in combination with collateral ligament and/or meniscal damage.

OBJECTIVES

To determine the efficacy of exercise used in the rehabilitation of ACL injuries in combination with collateral ligament(s) and/or meniscal damage in adults, whether treated conservatively or by reconstruction, on return to work and pre-injury levels of activity.

The following null hypotheses are formulated.

For ACL injuries treated conservatively:

- there are no differences in outcome between any exercise programme versus none (control) in the rehabilitation of ACL injuries in combination with collateral ligament(s) and/or meniscal damage;
- there are no differences in outcome between any exercise programme versus any other exercise programme in the rehabilitation of ACL injuries in combination with collateral ligament(s) and/or meniscal damage.

For ACL injuries treated by reconstruction:

- there are no differences in outcome between any exercise programme versus none (control) in the rehabilitation of ACL injuries in combination with collateral ligament(s) and/or meniscal damage;
- there are no differences in outcome between any exercise programme versus any other exercise programme in the rehabilitation of ACL injuries in combination with collateral ligament(s) and/or meniscal damage.

CRITERIA FOR CONSIDERING STUDIES FOR THIS REVIEW

Types of studies

Randomised controlled trials and quasi-randomised trials (e.g. randomised by date of birth or hospital record number) testing exercise programmes designed to rehabilitate adults with ACL injuries in combination with collateral ligament(s) and/or meniscal damage (conservatively managed or reconstructed).

Types of participants

This review will include trials with participants described as adults (with the assumption of skeletal maturity) with injuries to the ACL combined with collateral ligament(s) and/or meniscal damage. Participant characteristics of interest include age, gender, partial or complete tear, muscle strength, level of physical ability pre-injury and time since injury.

We will exclude trials of interventions targeting individuals that report only isolated ACL damage. Trials that focus on participants with underlying rheumatological, neurological, cardiovascular or congenital conditions affecting the lower limbs will also be excluded from the review.

Types of intervention

Trials where participants are randomised to receive any combination of the following: no care, usual care, a single-exercise intervention, and multiple-exercise interventions. Trials comparing two or more interventions will also be included.

For the purpose of this review, exercise will be considered if it takes one of the following formats.

- Muscle strengthening:
 - a) isometric/isotonic/isokinetic;
 - b) concentric/eccentric;
 - c) open kinetic chain/ closed kinetic chain.
- Joint mobility:
 - a) active;
 - b) active assisted;
 - c) resisted.
- Gait re-education
- Neuromuscular function/balance and proprioception
- Land based/water based

The exercise interventions could take place in the home, institutional dwelling, community, gymnasium or clinic setting and could be self-supervised (for example, using exercise sheets/video), individually supervised or as part of a supervised group.

Trials that focus on the following will be excluded from the review:

- electrotherapy i.e. ultrasound, Transcutaneous Electrical Nerve Stimulation (TENS), muscle stimulation;
- continuous passive motion and other forms of passive movement;
- restrictive bracing;
- cryotherapy;
- complementary therapies such as reflexology;
- analgesics.

Types of outcome measures

The primary outcome measures of interest are returning to work, education or sport and return to pre-injury level of activity. To be included, studies must report at least one of these primary outcome measures. These may include, but are not restricted to, outcome scales such as the Tegner Activity scale (Tegner 1985), Cincinnati Knee Rating System (Barber-Westin 1999) and Quality of Life Questionnaire for ACL deficiency (Mohtadi 1998).

Secondary outcome measures may include, but will not be limited to:

- pain (residual pain or pain on movement);
- instability (as tested with arthrometry (ACL only));
- swelling (for example, patella-tap test);
- range of motion of the knee;
- muscle strength (for example, isokinetic evaluation);
- muscle activation (for example, electromyography analysis (EMG));

- re-rupture or re-injury;
- other complications (e.g. deep vein thrombosis (DVT), infection).

Information will be sought on the content of the exercise programme, the level of compliance with the intervention, the magnitude and duration of effect, and adverse events associated with the exercise intervention.

SEARCH METHODS FOR IDENTIFICATION OF STUDIES

See: methods used in reviews.

We will search the Cochrane Bone, Joint and Muscle Trauma Group Specialised Register (to present), the Cochrane Central Register of Controlled Trials (CENTRAL) (The Cochrane Library, current issue), MEDLINE (1966 to present), EMBASE (1980 to present), PEDro - The Physiotherapy Evidence Database (<http://www.pedro.fhs.usyd.edu.au/>) (to present), CINAHL (1982 to present), AMED (1985 to present), and reference lists of articles. To identify theses and unpublished trials we will contact institutions and experts in the field. No language restrictions will be applied.

In MEDLINE (OVID ONLINE) the first two levels of the optimal trial search strategy (Robinson 2002) will be combined with the subject specific search (Table 01). Search strategies are also shown for AMED (Table 02), CINAHL (Table 03), EMBASE (Table 04) and The Cochrane Library (Table 05).

METHODS OF THE REVIEW

Selection of studies

From the title, abstract, and descriptors, pairs of authors will independently review the results of the literature searches to identify potentially relevant trials for full review. From the full text, trials that meet the selection criteria will be selected for inclusion. Disagreement will be resolved by consensus or third party adjudication.

Data extraction and management

Pairs of authors will independently extract data using a customised data extraction tool tested prior to use. Disagreement will be resolved by consensus or third party adjudication. Authors of trials will be contacted where there is incomplete reporting of data.

Assessment of methodological quality of included studies

Methodological quality will be independently assessed for each trial by pairs of authors, using a modification of the Cochrane Bone, Joint and Muscle Trauma Group's quality assessment tool (Madhok 2006). The final scoring scheme for 15 aspects of trial quality (Table 06) includes items from the Cochrane Bone,

Joint and Muscle Trauma Group's quality assessment tool (items denoted by 'M'), items from the Delphi list (Verhagen 1998) (items denoted by 'D') and items from the Maastricht-Amsterdam consensus list for methodological quality assessment (Bellamy 1997) (items denoted by 'MAC'). Any disagreement will be resolved by consensus or third party adjudication.

Measures of treatment effect

It is intended that trials of ACL injuries in combination with collateral ligament(s) and/or meniscal damage treated conservatively will be analysed and reported separately from those trials involving reconstruction. Where available and appropriate, quantitative data for the outcomes listed in the inclusion criteria will be presented. For each trial, relative risk and 95% confidence intervals will be calculated for dichotomous outcomes. For continuous outcomes reported using the same scale, we will calculate weighted mean differences and 95% confidence intervals. Where results for continuous outcomes are presented on different scales, standardised mean difference will be calculated along with 95% confidence intervals.

Subgroup analysis and investigation of heterogeneity

It is intended that where appropriate, results of comparable groups of trials will be pooled using the fixed-effect model and 95% confidence intervals calculated. Heterogeneity between comparable trials will be tested using a standard chi squared test and considered statistically significant at a P value less than 0.10, after due consideration of the value of I squared. Any evidence of heterogeneity will be investigated to determine if there were obvious differences in the trials that were likely causes of the heterogeneity. If the heterogeneity is regarded as likely to have serious effects on the validity of the results then the data will not be combined. Where there is significant heterogeneity we will view the results of the random-effects model and present these when appropriate.

Sensitivity analyses will be undertaken, when indicated, to investigate the effects of allocation concealment, methodological quality and intention-to-treat analysis.

Where the data allows, we also plan separate outcome analyses to test the following null hypotheses:

- exercise interventions are equally effective in males and females;
- exercise interventions are equally effective irrespective of age;
- effectiveness is not dependent on the setting in which the exercise intervention is delivered;
- effectiveness is not dependent on the level or type of supervision of the exercise intervention;
- effectiveness is not dependent on the number or frequency of exercise sessions, i.e. duration of rehabilitation;
- effectiveness is not dependent on the intensity of exercise interventions;
- effectiveness is not dependent on the timing of surgery.

POTENTIAL CONFLICT OF INTEREST

None known.

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- No sources of support supplied

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- HealthQWest UK

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Additional references

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ADDITIONAL TABLES

Table 01. Search strategy for MEDLINE

MEDLINE (OVID WEB)

1. Anterior Cruciate Ligament/
2. Soft Tissue Injuries/
3. "Sprains and Strains"/
4. Athletic Injuries/
5. Knee Injuries/
6. Knee/ or Knee Joint/
7. or/2-6
8. (anterior adj3 cruciate\$1).tw.
9. and/7-8
10. or/1,9
11. Exercise/
12. Rehabilitation/
13. Physical Therapy Techniques/
14. Exercise therapy/

Table 01. Search strategy for MEDLINE (Continued)

MEDLINE (OVID WEB)

15. *Clinical Protocols/
16. *"Recovery of Function"/
17. (physiotherap\$ or physical therap\$ or rehab\$ or training or exercis\$).tw.
18. (rh or th).fs.
19. or/11-18
20. and/10,19

21. randomized controlled trial.pt.
22. controlled clinical trial.pt.
23. Randomized Controlled Trials/
24. Random Allocation/
25. Double-Blind Method/
26. Single-Blind Method/
27. or/21-26
28. Animal/ not Human/
29. 27 not 28

30. clinical trial.pt.
31. exp Clinical Trials/
32. (clinic\$ adj25 trial\$).tw.
33. ((singl\$ or doubl\$ or trebl\$ or tripl\$) adj (mask\$ or blind\$)).tw.
34. Placebos/
35. placebo\$.tw.
36. random\$.tw.
37. Research Design/
38. (latin adj square).tw.
39. or/30-38
40. 39 not 28

41. 40 not 29
42. and/20,29
43. and/20,41
44. or/42-43

Table 02. Search strategy for AMED

AMED (OVID WEB)

1. Anterior cruciate ligament/
2. "Sprains and Strains"/
3. Athletic Injuries/
4. Knee Injuries/
5. Knee/ or Knee Joint/
6. or/2-5
7. (anterior adj3 cruciate\$1).tw.
8. and/6-7
9. or/1,8
10. Exercise/
11. Rehabilitation/
12. Physiotherapy/

Table 02. Search strategy for AMED (Continued)

AMED (OVID WEB)

13. Exercise therapy/
14. clinical protocols.tw.
15. recovery of function.tw.
16. (physiotherap\$ or physical therap\$ or rehab\$ or training or exercis\$).tw.
17. or/10-16
18. and/9,17

19. randomized controlled trial.pt.
20. controlled clinical trial.pt.
21. Randomized Controlled Trials/
22. Random Allocation/
23. Double-Blind Method/
24. or/19-23
25. Animal/ not Human/
26. 24 not 25
27. clinical trial.pt.
28. exp Clinical Trials/
29. (clinic\$ adj25 trial\$).tw.
30. ((singl\$ or doubl\$ or trebl\$ or tripl\$) adj (mask\$ or blind\$)).tw.

31. Placebos/
32. placebo\$.tw.
33. random\$.tw.
34. Research Design/
35. (latin adj square).tw.
36. or/27-35
37. 36 not 25
38. 37 not 26
39. and/18,26
40. and/18,38
41. or/39-40

Table 03. Search strategy for CINAHL

CINAHL (OVID WEB)

1. Anterior cruciate ligament/
2. Soft Tissue Injuries/
3. "Sprains and Strains"/
4. Athletic Injuries/
5. Knee Injuries/
6. Knee Joint/
7. or/2-6
8. (anterior adj3 cruciate\$1).tw.
9. and/7-8
10. or/1,9

11. exp Exercise/
12. Rehabilitation/
13. Physical Therapy/

Table 03. Search strategy for CINAHL (Continued)

CINAHL (OVID WEB)

14. exp Therapeutic Exercise/
15. clinical protocols.tw.
16. recovery of function.tw.
17. (physiotherap\$ or physical therap\$ or rehab\$ or training or exercis\$).tw.
18. (rh or th).fs.
19. or/11-18
20. and/10,19

21. exp Clinical Trials/
22. exp Evaluation Research/
23. exp Comparative Studies/
24. exp Crossover Design/
25. clinical trial.pt.
26. or/21-25
27. ((clinical or controlled or comparative or placebo or prospective or randomi#ed) adj3 (trial or study)).tw.
28. (random\$ adj7 (allocat\$ or allot\$ or assign\$ or basis\$ or divid\$ or order\$)).tw.
29. ((singl\$ or doubl\$ or trebl\$ or tripl\$) adj7 (blind\$ or mask\$)).tw.

30. (cross?over\$ or (cross adj1 over\$)).tw.
31. ((allocat\$ or allot\$ or assign\$ or divid\$) adj3 (condition\$ or experiment\$ or intervention\$ or treatment\$ or therap\$ or control\$ or group\$)).tw.
32. or/27-31
33. or/26,32
34. and/20,33

Table 04. Search strategy for EMBASE

EMBASE (OVID WEB)

1. Anterior Cruciate Ligament Rupture/
2. Anterior Cruciate Ligament/
3. or/1-2
4. Soft Tissue Injury/
5. Sport Injury/
6. Knee Injury/
7. Knee/
8. Knee Ligament Injury/
9. or/4-8

10. (anterior adj3 cruciate\$1).tw.
11. and/9-10
12. or/3,11
13. exp Exercise/
14. Rehabilitation/
15. Physiotherapy/
16. Kinesiotherapy/
17. *Clinical Protocol/
18. recovery of function.tw.
19. (physiotherap\$ or physical therap\$ or rehab\$ or training or exercis\$).tw.
20. or/13-19

Table 04. Search strategy for EMBASE (Continued)

EMBASE (OVID WEB)

21. and/12,20
22. exp Randomized Controlled trial/
23. exp Double Blind Procedure/
24. exp Single Blind Procedure/
25. exp Crossover Procedure/
26. Controlled Study/
27. or/22-26
28. ((clinical or controlled or comparative or placebo or prospective\$ or randomi#ed) adj3 (trial or study)).tw.
29. (random\$ adj7 (allocat\$ or allot\$ or assign\$ or basis\$ or divid\$ or order\$)).tw.
30. ((singl\$ or doubl\$ or trebl\$ or tripl\$) adj7 (blind\$ or mask\$)).tw.
31. (cross?over\$ or (cross adj1 over\$)).tw.
32. ((allocat\$ or allot\$ or assign\$ or divid\$) adj3 (condition\$ or experiment\$ or intervention\$ or treatment\$ or therap\$ or control\$ or group\$)).tw.
33. or/28-32
34. or/27,33
35. limit 34 to human
36. and/21,35

Table 05. Search strategy for The Cochrane Library (OVID EBM Reviews)

The Cochrane Library

1. Anterior Cruciate Ligament/
2. Soft Tissue Injuries/
3. "Sprains and Strains"/
4. Athletic Injuries/
5. Knee Injuries/
6. Knee/ or Knee Joint/
7. or/2-6
8. (anterior adj3 cruciate\$1).tw.
9. and/7-8
10. or/1,9
11. Exercise/
12. Rehabilitation/
13. Physical Therapy Techniques/
14. Exercise therapy/
15. *Clinical Protocols/
16. *"Recovery of Function"/
17. (physiotherap\$ or physical therap\$ or rehab\$ or training or exercis\$).tw.
18. (rh or th).fs.
19. or/11-18
20. and/10,19

Table 06. Quality assessment items and possible scores

Items & scores

M-A (D1b). Was the assigned treatment adequately concealed prior to allocation?

2 = method did not allow disclosure of assignment.

1 = small but possible chance of disclosure of assignment or unclear.

0 = quasi-randomised or open list/tables.

Cochrane code: Clearly yes = A; Not sure = B; Clearly no = C

M-B (D8). Were the outcomes of patients/participants who withdrew described and included in the analysis (intention to treat)?

2 = withdrawals well described and accounted for in analysis.

1 = withdrawals described and analysis not possible.

0 = no mention, inadequate mention, or obvious differences and no adjustment.

M-C (D4). Were the outcome assessors blinded to treatment status?

2 = effective action taken to blind assessors.

1 = small or moderate chance of unblinding of assessors.

0 = not mentioned or not possible.

M-D (D2). Were the treatment and control group comparable at entry?

2 = good comparability of groups, or confounding adjusted for in analysis.

1 = confounding small; mentioned but not adjusted for.

0 = large potential for confounding, or not discussed.

M-E (D6). Were the participants blind to assignment status after allocation?

2 = effective action taken to blind participants.

1 = small or moderate chance of unblinding of participants.

0 = not possible, or not mentioned (unless double-blind), or possible but not done.

M-F (D5). Were the treatment providers blind to assignment status?

2 = effective action taken to blind treatment providers.

1 = small or moderate chance of unblinding of treatment providers.

0 = not possible, or not mentioned (unless double-blind), or possible but not done.

M-G. Were care programmes, other than the trial options, identical? For example, training programmes, pain relief, advice on activity/mobilisation, follow-up procedures.

2 = care programmes clearly identical.

1 = clear but trivial differences.

0 = not mentioned or clear and important differences in care programmes.

M-H (D3). Were the inclusion and exclusion criteria clearly defined?

2 = clearly defined.

1 = inadequately defined.

0 = not defined.

M-I. Were the interventions clearly defined?

2 = clearly defined interventions are applied with a standardised protocol.

1 = clearly defined interventions are applied but the application protocol is not standardised.

0 = intervention and/or application protocol are poorly or not defined.

M-J. Were the outcome measures used clearly defined?

2 = clearly defined.

1 = inadequately defined.

0 = not defined.

M-K. Were tests used in outcome assessment clinically useful?

2 = optimal.

1 = adequate.

Table 06. Quality assessment items and possible scores (Continued)

Items & scores

0 = not defined, not adequate.

M-L. Was the surveillance active, and of clinically appropriate duration (i.e. at least 12 months)?

2 = active surveillance and appropriate duration (12 months follow up or more).

1 = active surveillance, but inadequate duration (6-12 months follow up).

0 = surveillance not active or not defined (0-6 months).

D7. Were point estimates and measures of variability presented for the primary outcome measures?

2 = yes.

1 = point estimates, but no measures of variability presented.

0 = vague descriptions.

MAC-1. Was the compliance rate in each group likely to cause bias?

2 = compliance well described and accounted for in analysis.

1 = compliance well described but differences between groups not accounted for in analysis.

0 = compliance unclear.

MAC-2. Was there a description of adverse effects of the intervention(s)?

2 = well described.

1 = poorly described.

0 = not described.

COVER SHEET

Title	Exercise for treating anterior cruciate ligament injuries in combination with collateral ligament and meniscal damage of the knee in adults
Authors	Trees AH, Howe TE, Grant M, Gray HG
Contribution of author(s)	The protocol was conceived, designed and written by AH Trees (AHT) and TE Howe (TEH). AHT also co-ordinated the protocol development, assisted in the development of the search strategies and entered the protocol into RevMan. TEH developed the quality assessment scheme. M Grant (MG) and H Gray (HG) commented on drafts of the protocol. AHT is the guarantor of the protocol.
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What's New	Information not supplied by author
Contact address	Miss Amanda Trees PhD Student Teesside Centre for Rehabilitation Sciences University of Teesside The James Cook University Hospital Marton Road Middlesbrough Tees Valley TS4 3BW UK

E-mail: a.trees@tees.ac.uk
Tel: +44 1642 854324
Fax: +44 1642 854324

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