The effects of cross-education on loss of muscle strength and knee function after ACL reconstruction

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24365

Source
NTR

Brief title
Cross-Education After ACL Reconstruction

Health condition

Imaging, brain stimulation, and behavioural studies show that exercise of a muscle in one limb improves function
of the same muscle in the other, non-exercised limb. The possibility exists that XED can reduce strength and functional losses and help ACL-reconstructed patients recover faster.

Keywords:
- Cross-Education
- ACL reconstruction
- Muscle strength
- Knee function

Trefwoorden:
- Cross-Educatie
- Voorste kruisband reconstructie
- Spierkracht
- Kniefunctie

Sponsors and support

Primary sponsor: University Medical Center Groningen
Source(s) of monetary or material Support: University Medical Center Groningen

Intervention

Outcome measures

Primary outcome

a) Return to sport or work status at 6 months and b) Cincinnati Knee Score

Secondary outcome

hop test, balance, proprioception, force control, and maximal quadriceps torque

Study description

Background summary

There is over 30% loss of voluntary muscle force in the operated leg after an anterior cruciate ligament (ACL) reconstruction surgery. Patients could return to sport or work sooner by minimizing muscle weakness. As a novel approach, we propose to include cross-education (XED) in ACL rehab. In XED, there is an increase in motor output in muscles of one limb following strength training with the same muscles of the other limb. This is a highly relevant approach in phase I of ACL therapy because the operated limb is too weak to engage in active rehab. The hypothesis is that XED plus standard care vs. standard care alone delivered during phase I of rehab from ACL reconstruction surgery reduces the loss of muscle strength, power, and functional ability in the operated limb. The study will show that patients receiving XED will reach “return to sport or work” status earlier.

Rationale: Imaging, brain stimulation, and behavioural studies show that exercise of a muscle in one limb improves function of the same muscle in the other, non-exercised limb. The possibility exists that XED can reduce strength and functional losses and help ACL-reconstructed patients recover faster.
Objective: Compare the effects of rehab with standard care vs. standard care plus XED on loss of muscle strength and function in the operated limb at the end of phase I rehab after ACL reconstruction surgery.
Study design: This is a randomized clinical trial using ACL-reconstructed patients in two arms in a pre-test/post-test and follow-up repeated measures design.
Study population: Men and women age 20 to 60, enrolled for ACL reconstruction surgery.
Intervention (if applicable): The control group will receive standard care of ACL rehab and the

other group will receive standard care plus extra exercise training of the non-operated leg. Main study parameters/endpoints: Primary clinical outcomes: a) Return to sport or work status at 6 months, b) Cincinnati Knee Score a test that is valid and sensitive to measure changes over time in patients' knee status after ACL rehabilitation, c) Pain intensity (0 to 100) and global knee function (0 to 100). Secondary outcomes: a) hop test, b) balance, c) proprioception, d) force control, and e) maximal force and power.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: The clinical tests are part of the standard patient care and require no extra time or effort. Patients perform the tests 2-6 weeks before ACL reconstruction surgery and 4 weeks after surgery, with a follow-up measurement at 3 and 6 months after surgery. The laboratory tests will measure each quadriceps muscle's ability to produce and control force in a standardized way. The force control task requires minimal effort to aim at a target at a low force and match the target force as accurately and steadily as possible. The maximal knee extension task is also a standard test and consists of ~2-s-long efforts with 1-2 min of rest between contractions. Muscle activation is measured during the quadriceps test by electrically stimulating the quadriceps muscle through the skin. This peripheral nerve stimulation causes the muscle to twitch, this can be more surprising than painful. It can cause some momentary burning and tingling sensation. The balance test requires the patient to hold his/her static and dynamic balance. The proprioception test measures the ability to sense the position of the leg unloaded and requires minimal effort.

Study objective

There is over 30% loss of voluntary muscle force in the operated leg after an anterior cruciate ligament (ACL) reconstruction surgery. Patients could return to sport or work sooner by minimizing muscle weakness. As a novel approach, we propose to include cross-education (XED) in ACL rehab. In XED, there is an increase in motor output in muscles of one limb following strength training with the same muscles of the other limb. This is a highly relevant approach in phase I of ACL therapy because the operated limb is too weak to engage in active rehab. The hypothesis is that XED plus standard care vs. standard care alone delivered during phase I of rehab from ACL reconstruction surgery reduces the loss of muscle strength, power, and functional ability in the operated limb. The study will show that patients receiving XED will reach "return to sport or work" status earlier.

Study design

1) up to 1 week before surgery, 2) at 4 weeks after surgery (end of phase I rehabilitation), 3) follow-up at 3 months after surgery, and 4) follow-up at 6 months after surgery.

Intervention

This study involves 2 rehab programs, focusing on the 4-week-long period immediately after ACL reconstruction surgery. For ~2 days after surgery, all patients follow standard care at home. Then formal rehab starts. Patients will be randomly assigned to one of two groups.

Standard care group:

The goal is to achieve normal gait, double limb support, controlled balance while single-leg support, controlled dynamic stability of the uninvolved leg, giving up crutches when weight bearing is tolerated without limping, if full weight-bearing is not tolerated during squatting exercises, counterweights are used to avoid swelling or pain; cold therapy for 10-15 minutes after training if swelling is present; stationary cycling (10-20 min); walking exercises on the floor and treadmill (5-10 min); squat exercises with or without counter weights, heel rises, single leg stance exercise on non-operated (3 sets of 6 reps) and operated leg (one leg squat) and reach exercise on non-operated and operated leg; anterior, anterior/lateral, lateral, posterior/lateral, and posterior lunges on non-operated and operated leg; anterior, lateral, and posterior step-up exercises, starting with non-operated leg). Patients perform 3 sets of 4-8 reps of the exercises, 2-3x per week for 4 weeks.

Standard care + XED group:
This group will receive the standard therapy plus will exercise the quadriceps and hamstrings of the non-operated leg: maximal knee extension/flexion 3 sets of 6 to 10 reps of concentric contraction at 60 deg/s on an isokinetic dynamometer; 3 sets of 6 to 10 reps of single leg squats with 10-20% body weight added in a backpack with eyes closed; 3 sets of 6 to 10 hops forward; 3 sets of 6 to 10 hops on mini trampoline or balance mat. Week 1: 2 set of 6 reps; Week 2: 2 sets of 10 reps; Week 3: 3 sets of 8 reps, and week 4: 3 sets of 10 reps, with the last session 2 sets of 6 reps to taper off and avoid overtraining.

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Eligibility criteria

Inclusion criteria

Patients awaiting an ACL reconstruction surgery will be included: male, female, age 20 to 60, any race, BMI < 30 kg/m2, time between injury and surgery < 1 year, ACL tear to the dominant or non-dominant leg with or without meniscal excision, hamstring autograft, allograft of any source, signed informed consent, and follow study protocol.

Exclusion criteria

If they are pregnant (surgeon will look in the medical record of the patient), have an injury to the other leg, a meniscal tear requiring repair, additional interventions that interfere with standard rehab (e.g., cartilage lesion treatment), multiple serious injuries to target leg (ACL tear+meniscus tear, ACL+plus collateral ligament tear, prior
major surgery to legs, pelvis), revision ACL reconstruction on the same knee, degenerative arthritis on radiographs or articular cartilage fissures extending to subchondral bone, or exposed bone as seen in arthroscopy (grade IV), current or prior neurological conditions (Parkinson’s disease, stroke, dementia).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-11-2013
Enrollment:	50
Type:	Anticipated

Ethics review

Positive opinion

Date:	13-01-2014
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL4259
NTR-old	NTR4395
Other	METC University Medical Center Groningen : METc 2012/362

Study results