Title: Optimizing Movement After Anterior Cruciate Ligament Injury
NCT number: NCT05363683
Document date: 9/29/2023

Protocol: Squat Biofeedback after ACL Reconstruction (IRB Protocol Name: Optimizing Movement and Physical Activity after Anterior Cruciate Ligament Injury)

Inclusion/Exclusion Criteria (recorded by Wellsandt Team in REDCap):

1. 13-35 years old
2. Acute ACL injury in the past 6 months who have had ACL reconstruction in the past month or have a planned ACL reconstruction
3. No previous knee injury or surgery to either knee
4. Body mass index (BMI) > 35 kg/m^2
5. No concomitant PCL injury
6. Cartilage procedure that include extended weightbearing restrictions and/or changes to cartilage structure (e.g. OATS)
7. Current pregnancy or plans to become pregnant during the study duration (self-report)
    a. If a female participant becomes pregnant they are no longer eligible for the MRI portion of the study. They will complete other study components as able.

Study Design

1. Prospective, parallel clinical trial
2. Participants will be tested at enrollment (2 weeks after ACLR or when 50% weightbearing is allowed) and again after completing the study intervention at 3 months and 6 months post ACLR.

Sample Size and Randomization

1. N=34 (17 in squat biofeedback group and 17 in control group)
    a. Target equal number of women and men

Recruitment & Patient Tracking

-Wellsandt Team will keep a potential patient tracking spreadsheet on Box to track pre-op and early post-operative eligible patients
-Potential participants will be discussed at bi-weekly meetings
-When patient is ready to enroll:

1. Dave will email consent form and study info to patient/parents
2. Dave will assign subject ID, enter into REDCap, complete REDCap screening form, and assign to group (post-ACLR)
3. If pre-intervention PT is needed, Dave will schedule first treatment session
4. Dave will inform RJ of when patient is to be in clinic for RJ to meet patient and schedule testing sessions.

Informed Consent:

Methods:

1. Participation in the study (and providing copy of informed consent form) must occur at least 1 day after participant (and guardian) is approached about the study
2. Informed consent will be completed before or at the participant's first PT treatment session or at 2-week testing in the CMOVA Lab (if previous PT completed elsewhere.
3. Informed consent will be completed by Dave (if completed first PT treatment session) or RJ/Liz.

4. There is a single consent form for both adults and minors (<19 years old) with a guardian. Minors must also be provided the youth information sheet. Consents forms will be on Box. Make sure to use a version with the current time stamp in the lower right corner of each page.
5. Participants (or guardian) also need to fill out the narrative consent form to indicate who they would like the testing results to be shared with (i.e. surgeon, athletic trainer, etc.)
6. Must be obtained in a private room that is well lit with little to no distraction.
7. Participant is instructed on the consent form and provided time to read the consent form. At any time they are encouraged to ask questions and clarify any issues. 15 minutes is allotted. More time will be given is needed.
8. To ensure understanding, the participant (and guardian) will be asked if they understand the consent form and if they have any specific questions. Best practice is to ask the participant to provide a brief overview of the testing methods and timing of the follow-up testing.
9. A copy of the fully signed consent form and the narrative consent must be provided to the participant/guardian.

Lab Testing Order:

1. Warm-up as needed (5 min; treadmill, stationary bike or overground (e.g. squats/lunges))
2. Height & Weight
3. ROM
4. Effusion
5. Volitional Isometric & Isokinetic Quadriceps Strength (Biodex)
6. Biomechanics
7. Surveys

Height & Weight (all testing sessions):

Equipment: Stadiometer
Methods: 1. Shoes off; record in kilograms and inches

Knee Active Range of Motion (all testing sessions):

Equipment: High-Low Table
Goniometer

Methods:
1. Patient in supine (bolster/towel roll under ankle for extension)
2. Proximal arm along lateral midline of femur in line with greater trochanter
3. Distal arm along lateral midline of fibula in line with lateral malleolus
4. Flexion: Patient maximally bends their knee actively (without self-assist or assist from research staff).
5. Extension: Patient contracts quad and maximally extends his/her knee actively. Hyperextension recorded as e.g. “hyper 5.” Lacking full knee extension recorded as e.g. “lack 3.”

Knee Effusion Testing (all testing sessions):

Equipment: High-Low Table
Methods: Sturgill et al. 2009 JOSPT

Volitional Isometric & Isokinetic Quadriceps Strength Testing (Biodex) (3, 6 months):

Equipment: Biodex (C-MOVA)
Set-Up:

a. Use participant weight measured in lab
b. Before participant is ready to test (while performing other testing)
    i. Power on machine: turn on black button then computer
    ii. Open Biodex
    iii. Go to patient→if new patient go to add patient→enter patient information (Last name, first name, gender, involved limb, weight (kg), enter RTS under ID #)
    iv. If returning patient, click open and select patient→select the last testing session-> select repeat and same protocol will automatically be applied
    v. Click save

a. Click protocol→click Linked → Select RTS Testing or RTS Testing plus 180 per sec depending on time point.
    1. ISOM: UNI: AWAY: TEST: 90, 90, 90 (RTS Isometric: KNEE: EXT/FLX **(3, 6 months)**
    2. ISOK: UNI: CON/CON: TEST: 60/60 (RTS Isokinetic): KNEE: EXT/FLX **(3, 6 months)**
    3. ISOK: UNI: CON/CON: TEST: 180/180 (RTS Isokinetic): KNEE: EXT/FLX **(6 months)**
    4. ISOM: UNI: AWAY: TEST: 90, 90, 90 (RTS Isometric: KNEE: EXT/FLX **(3, 6 months)**
    5. ISOK: UNI: CON/CON: TEST: 60/60 (RTS Isokinetic): KNEE: EXT/FLX **(3, 6 months)**
    6. ISOK: UNI: CON/CON: TEST: 180/180 (RTS Isokinetic): KNEE: EXT/FLX **(6 months)**

c. Set up chair positioning (will test uninvolved limb first) (if 6-month testing then set up according to 3-month testing position)
    i. Seat A/P forward/backward position
    ii. Seat height
    iii. Seat depth
    iv. Attachment Arm length
    v. Dynamometer distance left/right
    vi. Set-up guidelines:
        a. Secure thigh, chest, and waist straps
        b. Top of dynamometer cuff just proximal to talocrural joint (2 finger widths above medial malleolus)
        c. Knee joint center should be in line with arm of rotation of dynamometer

e. After subject is set-up, complete testing:
    i. Select side

ii. Set away limit
iii. Set toward limit
iv. For calibrate position: use level to calibrate arm at 90 degrees
v. For limb weight put limb to end extension ROM and lock in that position and ask subject to relax
vi. Select continue
vii. Select start
viii. Isometric: Begin trial reps
    1. Have subject cross arms over chest when ready to contract
    2. Practice trials at 50%, 75%, and 100% of maximum effort completed to assure no pain or discomfort present.
        a. Note: If pain exceeded 2/10, actions taken to change the tibiofemoral joint angle or add towel for cushion between dynamometer and shank
ix. Select close once practice reps are completed
x. Instructions to participant:
    a. For this test, you will kick out as hard and as fast as you can.
    b. Cross your arms across chest to help stabilize yourself, but do not grab the shoulder straps.
    c. On my signal to begin, kick out as hard and as fast as you can and continue that until I tell you to stop.
    d. 3 – 2 – 1 – Go - KICK KICK KICK
    e. One minute between reps; 3 recorded trials (up to 5 max)
xi. Isokinetic (60º/sec and 180º/sec): Explain to the participant as soon as we hit the start button the practice trials will begin and the real trials will start once they pull back and hold.
    a. Have subject cross arms over chest when ready to contract
    b. Practice trials at 100% of maximum effort completed to assure no pain or discomfort present
xii. Once the practice trials are complete the participant must continue small movements to prevent Biodex from prematurely starting trials. When the participant is ready they are instructed to hold back to full flexion as it was measured with the ROM and hold it there to tell the system that the participant is ready to begin the trial and it will start automatically. If it doesn't start automatically help the participant hold the attachment back until the system honks and begins.
xiii. Instructions to subject:
    a. For this test, you will kick out as hard and as fast as you can.
    b. Cross your arms across chest to help stabilize yourself
    c. On my signal to begin, kick out as hard and as fast as you can and then pull back as hard and as fast as you can. Move from 90 degrees until your knee is straight and all the way back each time. You will complete 5 reps each direction.
    d. 3 – 2 – 1 – KICK KICK KICK, PULL PULL PULL
    e. 1 recorded trial
xiv. Record peak torques on data collection form as you go

f. Change to other side
   vi. Select “no” to auto set range of motion
   i. Select set range of motion
   vii. Select clear limits
   viii. Repeat steps i-xii
g. Repetitions:
   1. Isometric at 90º - Minimum on each side: 3. Maximum on each side: 5. Test uninvolved limb first.
   2. Isokinetic at 60º/sec - Minimum on each side: 1 set of 5 alternating repetitions. Maximum on each side: 3 sets of 5 alternating repetitions. Test uninvolved limb first.
   3. Isokinetic at 180º/sec - Minimum on each side: 1 set of 10 alternating repetitions. Maximum on each side: 3 sets of 10 alternating repetitions. Test uninvolved limb first.
h. Pain is only to increase by 2/10 from pain in standing; either 1) modify foot position or 2) modify testing angle or 3) attempt patellar taping or 4) omit the testing (if unable to test involved knee, still test uninvolved knee)

Biomechanical Testing (all testing sessions):

Equipment:

C-MOVA: 1. NEW Qualisys MoCap system, markers and straps (NO EMG/ACCELEROMETERS)

Methods:

BEGINNING KINEMATIC SAMPLE RATE = 120 Hz

1. Standing Calibration (named sc)
2. Self-selected walking speed **(3, 6 months)**
   a. 8 trials collected on each limb (named walk01, etc.)
3. Bilateral squats (eyes open, arms folded across chest, re-do trial if balance is lost) **(2 weeks & 3, 6 months)**
   a. 1 trial = 5 squats
   b. 1 practice, 3 collected trials of max squats (named bilsquatmax01, etc.)
   c. Metronome: 3 seconds down, 3 seconds up
      i. Verbal cues: “Down, 2, 3, Up, 2, 3”
   d. Pain is only to increase by 2/10 from pain in standing; either 1) modify depth of squats or foot position or 2) omit the testing (if unable to test involved max squats, still completed uninvolved max squats)

Surveys (all testing sessions):

1. Complete on laptop/tablet using REDCap

Infectious Disease Control

1. Participants and study personnel will wash hands or use hand sanitizer before beginning testing session.
2. All equipment will be disinfected after participant use/testing including wraps, mat table, and Biodex.
3. Actigraph accelerometers (per return in mail) will be disinfected and strap will be washed before next use.
4. During COVID-19 period, research participants will be screened using the procedures outlined in “General_Travel_Screen_Research”. Any participants screening positive will have testing session re-scheduled or cancelled as needed according to current UNMC procedures.

Biomechanics Data Collection

Equipment:

1. 29 markers (no anterior thigh or tibial tuberosity)
2. non-reflective tape
3. athletic tape
4. Coban
5. Velcro small straps for shorts
6. White wraps for thigh and shank
7. NO EMG/Accelerometers

Methods:

4. **Camera Set-Up**
   a. Place markers to define desired data collection volume
   b. Check each camera to optimize the amount of volume seen by each camera (i.e. move cameras if necessary)

5. **Frequency Settings**
   a. Tools →project options →Camera Frequency 120 Hz ; Analog boards 1080 Hz

6. **Camera Exposure Settings**
   a. Using Intensity mode (intensity button on right sidebar) adjust the exposure and marker threshold so that markers are red and there is no extra blue markings in the background. It is best to have a high exposure and a low marker threshold.
   b. Repeat this with all 8 cameras
   c. Default Threshold = 17
   d. No Exposure Default

7. **Qualisys Calibration** (This should be done before subject enters room)
   a. Select correct project when opening Qualisys (Miqus 8 camera Marker Only)
   b. Before beginning, make sure all reflective markers are out of sight and zero all 3 force plates
   c. Find Calibration tools under desk in black toolbox and assemble T wand and Right angle
   d. Place Right Angle piece on Right Top (northwest) Force plate (when looking out from desk) in exactly the right corner
   e. In upper L. corner in Qualisys, hit “New”
   f. Check to see that all cameras are working by looking for a “4” in the right bottom corner of each screen
   g. Hit “Calibrate” Tool
   h. Set parameters: 60 seconds to calibrate, 5 second delay→ok
   i. Wave T wand at low, medium, and high heights for 1 minute
   j. At end of calibration, all cameras should be less than .4 (look at far right column)
   k. Create Folder in temporary desktop location for subject using identification code: (Squat01001, Squat02002, etc…)

l. Set folder path in Qualisys: Click “Record --> Browse” and select the subject’s folder created in step J

8. **Application of reflective markers (29 total)**
    a. **See “Marker Set.doc”
    b. medial metatarsal head, lateral metatarsal head
    c. medial malleolus, lateral malleolus (center of malleoli)
    d. two on posterior heel on shoe (1 superior and one inferior in a line)
        i. on rigid part of shoe, not too close to ground (do not want inferior marker to hit ground when walking)
    e. Medial Femoral epicondyle most prominent part (small squat can get soft tissue out of the way)
    f. Lateral Femoral Epicondyle (find fibular head and joint line, most prominent part superior to joint line, small squat can move soft tissue out of the way)
        i. **Medial Epicondyle is usually lower than lateral epicondyle
    g. ASIS
    h. Most superior point of iliac crest in line with greater trochanter
    i. PSIS
    j. Acromion (midpoint of tip)
    k. C7 and sternum
    l. Upper Back (left and right; inferior and toward spine so not affected by scapular movement)
    m. T10

9. **Application of Shells**:
    a. Foot: lateral met head, and two markers on posterior heel make up tracking marker, place extra tape on these to secure into place
    b. Shank:
        i. Place a wrap around each shank
        ii. Place smaller rectangle shell on lateral shank
        iii. Secure shell with athletic tape
    c. Thigh:
        i. Place a wrap around each upper ½ of thigh
        ii. Place larger rectangular shell on lateral aspect of thigh
        iii. Secure shell with athletic tape
    d. **Cover up any reflective material on shoe or clothing with non-reflective tape

10. **Data Collection**
    a. Qualisys (TO BEGIN: cameras 120 Hz, Force plates 1080 Hz)
        i. Tools -> project options -> camera system under input devices. Ensure cameras are set to 120 Hz and Force plates are set to 1080 Hz
        ii. Zero out each force plate by hitting the red button on each of the black boxes on the right side of the desk
        iii. Double check to make sure that all reflective materials are out of sight
        iv. Check that standing calibration model is active

1. Tools > Project Options > AIM > Select correct model (change to movement model after the standing calibration)

v. Hit “New”→3D
    1. Use middle button on mouse to zoom in and out
    2. Left mouse button=rotation
vi. Hit “Record” when ready to collect and select subject folder (“Liz”)→Data
vii. Set amount of time to record data and name trial (all lowercase)
    1. Standing calibration: 1 sec (sc)
    2. Walk trials: 5 sec (walk01, etc.)
    3. Bilateral squats: 30 sec, (bilsquatmax01, etc.)
viii. Press Start
ix. Tell patient to “go”
x. If trial ends before time runs out, can manually press “stop" or press the trigger
xi. Click qtm file to review trial
xii. If poor data, can override after pressing “new” by moving counter back to previous trial

Bodyweight Squat Protocol

Eligibility:
Inclusion: ACLR within 6 months of ACL injury, 13-35 years old
Exclusion: reconstruction,
concomitant cartilage procedures, previous knee injury or surgery to either knee, BMI>35 kg/m^2, current or planned pregnancy during study period

Timing:
Initiation: 2 weeks post-ACLR
Expected # of visits: 16
Frequency of visits: 2x/week
Expected Duration: 10 min/visit

Bodyweight Squat Protocol				
Time after ACLR	**Sessions**	**Sets and Reps**	**Visual Biofeedback Group**	**Control Group**
Weeks 3-4	1,2,3,4	6 sets, 5 reps	GRF only	No visual feedback
Weeks 5-6	5,6,7,8	5 sets, 8 reps	COP only	No visual feedback
Week 7	9,10	6 sets, 8 reps	GRF, COP or None	No visual feedback
Weeks 8-9	11,12,13,14	5 sets, 10 reps	GRF+COP combined	No visual feedback
Week 10	15,16	6 sets, 10 reps	GRF, COP, GRF+COP or None	No visual feedback

Protocol Details (for both groups):

Timing of Squat Protocol: Randomly varied by PT during each visit (either before or after strengthening exercises)
Location of Squat Protocol: Randomly varied by PT during each visit (either in isolated quiet room or shared exercise space with others)
Verbal Instructions For Control Group (completed on force plates; no mirror or any visual feedback):

1. Complete squats keeping knees in line with toes
2. Keep hips back
3. Keep your weight evenly balanced between your feet

Rest Breaks: At least 30 seconds between each set
Squat Depth: 0-90° (as able)
Arm Position: Randomly varied by PT during each set (crossed over chest, straight out, or at side)

Progression Plan

- If participant doesn't miss any appointments progress through the weeks as outlined above
- If participant misses any appointments
  - If participant has not performed at least 75% of the sessions at a specific level (ex - week 1-2 are a single level) then continue within that same level
  - If participant has performed at least 75% of session at a specific level then progress to next level
  - For levels where there are only 2 sessions, participants who perform at least 1 of the 2 sessions can be progressed to the next level
- If individual misses over 75% of all sessions then they may not be included in final analysis, but will remain in the study

Biofeedback Details:

*Progression of each condition requires ≥90% accuracy in 2 consecutive sets of same condition
GRF Only (Weeks 3-4):

-Interlimb threshold begins at 15%; decreases by 1% when 90% accuracy achieved
COP Only (Weeks 5-6):
-Interlimb threshold begins at 10% of shoe length; decreases by 1% when 90% accuracy achieved
GRF, COP or None (Week 7):
-Interlimb GRF and COP thresholds begin at best previously achieved threshold; decreases by 1% when 90% accuracy achieved
-Condition randomly assigned during each set by random number generator (made by Dave)
GRF + COP combined (Weeks 8-9):
-Interlimb threshold begins at 5% less than best isolated GRF threshold (min: 85%) and 3% less than best isolated COP threshold (min: 90%)
-Thresholds decrease by 1% when 90% accuracy achieved
GRF, COP, GRF+COP or None (Week 10):
-Interlimb GRF and COP thresholds begin at best previously achieved threshold; decreases by 1% when 90% accuracy achieved
-Condition randomly assigned during each set by random number generator (made by Dave)

Biofeedback Set-Up:

- Each limb placed on separate portable force plates
- Biofeedback viewed on 32" screen at eye level that is 200 cm from the front of force plates and 130 cm from the ground to the bottom edge of the screen
    - During rehab feet will be placed near anterior portion of plate even with tape. Otherwise, no positioning is cued

Biofeedback Conditions:

- Ground reaction force (GRF) only
    - Top row
    - Verbal Instructions: "Your goal is to keep the green/blue bar as close to the vertical line in the middle of the screen as possible. As you shift to the left the bar will shift left with you and eventually turn red. As you shift to the right the bar will shift right with you and eventually turn red. If the bar isn't visible, it means your weight it evenly distributed side to side. You will be performing ____ squats with your arms _____. I will give you a countdown to begin your squats. The countdown will be '3,2,1,Go' and we want you to begin on 'Go.' Again the goal is to keep the green/blue bar as close to the vertical line in the middle of the screen as possible."
- Center of pressure (COP) only
    - Middle row
    - Verbal Instructions: "Your goal is to keep the green/blue line level and even with the dotted line in the middle of the screen. If you put weight through your left heel and right toe the line will tilt and eventually turn red. If you put weight through your right heel and left toe the line will also tilt and eventually turn red. You will be performing ____ squats with your arms _____. I will give you a countdown to begin your squats. The countdown will be '3,2,1,Go' and we want you to begin on 'Go.' Again the goal is to keep the green/blue line as level as possible and even with the dotted line in the middle of the screen."
- GRF + COP
    - Bottom Row
    - Verbal Instructions: ""This will be a combination of the two versions you've previously done. Your goal is to keep the green/blue bar as close to the vertical line in the middle of the screen as possible and to keep the green/blue line level and even with the dotted line in the middle of the screen. As you shift to the left the bar will shift left with you and eventually turn red. As you shift to the right the bar will shift right with you and eventually turn red. If the bar isn't visible, it means your weight it evenly distributed side to side. Now, if you put weight through your left heel and right toe the line will tilt and eventually turn red. If you put weight through your right heel and left toe the line will also tilt and eventually turn red. Your goals are to keep both the bar and the line green/blue. You will be performing ____ squats with your arms _____. I will give you a countdown to begin your squats. The countdown will be '3,2,1,Go' and we want you to begin on 'Go.' Again the goal is to keep the green/blue bar as close to the vertical line in the

middle of the screen as possible and the green/blue line as level as possible and even with the dotted line in the middle of the screen."

- Control Cues
    - "I'd like you to squat with your arms ____, keeping your knees in line with your toes, hips back, and weight evenly balanced between your feet. I will give you a countdown to begin your squats. The countdown will be '3,2,1,Go' and we want you to begin on 'Go.'"

Bodyweight Squat Protocol Modifications	
Factor	Rehab Modification
>50% weightbearing restriction (e.g. due to complex concomitant meniscal repair)	– Complete baseline study testing and initiate bodyweight squat protocol when 50% weightbearing is allowed (e.g. at 4 weeks or 6 weeks after ACLR) – Full 8 weeks of squat protocol is still completed – Delay post-intervention testing (e.g. if squat protocol is initiated at 4 weeks post-ACLR, complete post-intervention testing at 12 weeks post-ACLR instead of 10 weeks post-ACLR)
<90° knee flexion ROM restrictions	– Complete squat protocol within ROM restrictions (e.g. only squat to 60° until greater knee flexion ROM allowed)
< 16 visits completed within squat protocol	– Include participant data if at least 8/16 visits are completed during the 8 week squat protocol

Bodyweight Squat Protocol – Documentation (to be transitioned to electronic REDCap format):

Squat Protocol Week: _____

Date: _____

Location of Squat Training: __ Isolated quiet room __ Shared exercise space
Timing of Squat Training: __ Before strengthening exercises __ After strengthening exercises
Squat Depth (knee flexion): __ 30° __ 40° __ 50° __ 60° __ 70° __ 80° __ 90°

	REPS			ARMS			Condition				ACCURACY	
Rest: ____	**5**	**8**	**10**	Crossed	Front	Side	GRF	COP	GRF+COP	None	%	N/A
Set 1	_	_	_	_	_	_	_	_	_	_	____	_
Set 2	_	_	_	_	_	_	_	_	_	_	____	__
Set 3	_	_	_	_	_	_	_	_	_	_	____	_
Set 4	_	_	_	_	_	_	_	_	_	_	____	_
Set 5	_	_	_	_	_	_	_	_	_	_	____	_
Set 6	_	_	_	_	_	_	_	_	_	_	____	_

Cuing

- During the squat protocol
  - Treatment group will receive externally focused cues for all activities during the period they are receiving the squat protocol
  - Control group will receive internally focused cues for all activities during the period they are receiving the squat protocol
- After the squat protocol is completed
  - Both groups can receive a hybrid approach to cuing based on what each individual person responds best to with regard to form correction
- Examples

- Internal cues
  - Knees in line with toes
  - Don’t let knees touch
  - Push down with heel
- External cues
  - Keep knee pointed at this object
  - Don’t let your leg hit this object

Statistical Analysis Plan

Data analysis plan:
A p-value less than 0.05 will be considered statistically significant unless otherwise specified.

To determine the efficacy of the visual biofeedback program), analyses of covariance (ANCOVA) will be used at 3 and 6 months after ALCR to test differences in the interlimb ratio (ILR = injured limb / uninjured limb) of the knee flexion moment impulse during squatting, after adjusting for baseline knee flexion moment impulse. An ANCOVA will also be used to test differences in the ILR of the vertical ground reaction force impulse.

Independent t-tests will be used to test the percent change in cartilage T2 relaxation time in the injured knee from 2 weeks to 6 months after ACLR between groups, quadriceps strength, and gait biomechanics. For quadriceps strength, limb symmetry indexes will be computed (LSI = injured limb / uninjured limb x 100%).

If assumptions for any of these tests are violated, a nonparametric test will be conducted.

Sample size analysis:

Using our preliminary data, a sample size of 20 (10 per group) achieves 82.5% power to detect a difference in the knee flexion moment (KFM) impulse ILR of 0.283 during squats between the biofeedback (expected ILR=0.800±0.183) and standard of care group (expected ILR=0.517±0.228) using a two-sided hypothesis test and p-value of 0.05. Group differences are based on our preliminary data after standard of care: KFM impulse ILR at 4 months (N=20): 0.517±0.228; KFM impulse ILR at 10 months (N=5): 0.971±0.183. Thus, our expected KFM impulse ILR for the biofeedback group at 3 and 6 months is 0.800±0.183. To test our hypothesis that the biofeedback group will walk with a greater KFM than the standard of care group, the minimal detectable change (MDC) of 0.09 N·m/kg·m with a standard deviation of 0.08 was used (Gardinier 2013). Using this expected group difference, a sample size of 28 (14 per group) achieves 81.7% power using a two-sized hypothesis test and p-value of 0.05. To account for 10% attrition, 32 participants will be enrolled.

A sample size of 30 (15 per group) achieves 81.0% power to detect a group difference of 2.9±2.7 milliseconds in T2 relaxation time (primary outcome; measured from 2 weeks to 6 months in the injured knee). This expected group difference is based on a change in T2 relaxation time of 2.9±2.7 milliseconds in the medial femoral cartilage by 6 months after ACLR as reported by Kumar et al. Preliminary data of 37 participants from our ongoing NIH R21 study indicate that quadriceps strength LSI following standard care is 66.0±21.1% at 6 months after ACLR. The evidence-based clinical targets for quadriceps strength at 6 months is 90.0%. Using the expected quadriceps strength LSI of 66.0% in the control group and 90.0% in the intervention group at 6 months after ACLR with a pooled standard deviation of 21.1%, a sample size of 30 (15 per group) achieves 91.8% power using a two-sided hypothesis. To account for attrition, 34 participants will be enrolled.