RUTGERS
Robert Wood Johnson
Medical School
DEPARTMENT OF ORTHOPAEDIC SURGERY

INTERVENTIONAL RESEARCH PROTOCOL TEMPLATE

(HRP-503a)

STUDY INFORMATION

- **Title of Project:**

  Does Scoring on the TAMPA Scale of Kinesiophobia Impact Single-Leg Balance for ACL Surgery Patients?

- **Principal Investigator Name**
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- **Principal Investigator Div. & Dept.**
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- **Protocol Version and Date:**
  Study ID: PRO2024000012

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1.0 Research Design

1.1 Purpose/Specific Aims

The purpose of the research is to investigate the relationship between TSK scores and single-leg balance test results in ACL reconstruction patients.

A. Objectives

This study aims to answer the following questions:

1.) Is there a significant difference in single-leg balance between those with kinesiophobia and those without?

2.) Is there a change in kinesiophobia and single-leg balance test results over time?

B. Hypotheses / Research Question(s)

This study's hypothesis is that patients who score higher on the TSK (more fear) will do worse on the single-leg balance test than patients who score lower on the TSK.

1.2 Research Significance

The proposed research holds significant implications for advancing our understanding of the impact of kinesiophobia on the recovery outcomes of patients undergoing ACL reconstruction. While existing literature establishes a connection between kinesiophobia and suboptimal recovery, this study seeks to fill a critical gap by investigating the unexplored relationship between kinesiophobia, as measured by the Tampa Scale of Kinesiophobia (TSK), and single-leg balance in ACL reconstruction patients. By employing the TSK, a widely recognized and validated measure of kinesiophobia, and incorporating a single-leg balance test, this research aims to uncover potential correlations that could enhance our ability to predict and address challenges in rehabilitation. The hypothesized association between higher TSK scores and poorer performance on the single-leg balance test introduces a novel dimension to the field, offering insights that can inform targeted interventions and contribute valuable data to the sports medicine literature. This investigation aligns with ethical considerations as it seeks to improve the overall well-being and quality of life for orthopedic patients by refining rehabilitation strategies based on a more comprehensive understanding of kinesiophobia's impact on functional outcomes.

1.3 Research Design and Methods

This study is a randomized prospective study.

A. Research Procedures

The research procedures for this project will involve a comprehensive assessment of kinesiophobia using the Tampa Scale of Kinesiophobia (TSK) at both pre-operative and post-operative time points, specifically at 3 months, 6 months, and 1 year after ACL reconstruction. This will provide insights into the evolution of kinesiophobia throughout the critical phases of recovery. Additionally, the study aims to investigate the relationship between kinesiophobia and single-leg balance. The single-leg balance tests will be conducted in a trial of three, with a step in between each trial, to ensure a robust evaluation of participants' balance abilities. The time taken to touchdown during the single-leg balance tests will be measured. These assessments will be performed at 3 months, 6 months, 9 months, and 1 year post-operatively. Importantly, the balance assessments will be conducted on both the right and

left sides, allowing for a detailed comparison and analysis of potential asymmetries in balance recovery between the two limbs.

At the 6-month mark, all participants will undergo a functional evaluation by a physical therapist, including a single-leg hop test, triple hop test, triple cross-over test, and a timed 20m hop on a single leg. These functional tests are designed to provide additional insights into the participants' overall recovery and functional capabilities. Furthermore, strength testing will be conducted using the MicroFET device, with a focus on quadriceps and hamstrings at a 90-degree joint angle, as well as assessments of hip flexion, hip extension at full extension, and hip adduction. This comprehensive grouping of assessments at the 6-month milestone will contribute valuable data to the study, enhancing our understanding of the interrelationships between kinesiophobia, single-leg balance, functional performance, and muscle strength during the critical rehabilitation period following ACL reconstruction.

All information will be logged into Red Cap.

B. Data Points

TSK and single leg balance on both sides will be measured by approved physical therapists.

C. Study Duration

The study is expected to collect and analyze data for 1-2 years.

D. Endpoints

Primary endpoints:
- TSK
- Single Leg Balance
- Strength as measured by MicroFET

Secondary endpoints:
- KOOS Jr.

1.4 Preliminary Data

Preliminary TSK data was used for power analyses; this data will not be used for the actual study.

1.5 Sample Size Justification

The targeted sample size for this study is established at N=25, with a 10% inflation to accommodate potential dropouts. Participants undergoing ACL surgery will be recruited from UOA Somerset, Wall, Avenel, and Morganville locations.

Based on our sample size software and utilizing the preliminary data and relevant literature, the maximum number of patients needed to detect the difference in means (of the preliminary data and of similar studies in the literature) is around 5 people. For a true pilot study, we will target around 20-25 people, and then inflate for ~10% drop-out.

1.6 Study Variables

A. Independent Variables, Interventions, or Predictor Variables

The independent variable in this study is the multifaceted assessment, spanning kinesiophobia levels using the Tampa Scale of Kinesiophobia (TSK), single-leg balance performance, and strength measurements, including quadriceps and hamstrings strength at a 90-degree joint angle and hip strength. These measures collectively serve as key predictors and interventions, capturing the complex dynamics of recovery following ACL reconstruction.

B. Dependent Variables or Outcome Measures

Outcome measures recorded for this study include the evolution of kinesiophobia levels measured by the Tampa Scale of Kinesiophobia (TSK) at pre-operative and post-operative time points (3, 6, and 12 months), single-leg balance performance measured through time-to-touchdown assessments at corresponding intervals, and quantitative data on strength measurements, encompassing quadriceps and hamstrings strength at a 90-degree joint angle, as well as strength assessments for hip flexion, hip extension at full extension, and hip adduction. Additionally, a comprehensive functional evaluation at 6 months includes the Single-Leg Hop Test, Triple Hop Test, Triple Crossover Test, and the timed 20m Hop on a Single Leg.

1.7 Data Collection

A. Primary Data Collection

- **Location**: Data will be collected during physical therapy visits at the UOA research sites (Wall, Somerset, Avenel, Morganville).
- **Process of Data Collection**: Data will be collected by the specified team members. The data collection process involves administering the Tampa Scale of Kinesiophobia (TSK) to assess pre-operative and post-operative kinesiophobia levels at 3, 6, and 12 months following ACL reconstruction. Single-leg balance performance is evaluated through three trials with a step in between at the same intervals, measuring time-to-touchdown. Strength measurements, including quadriceps and hamstrings strength at a 90-degree joint angle, as well as hip flexion, hip extension at full extension, and hip adduction strength, are recorded using the MicroFET device. At 6 months, a physical therapist conducts a functional evaluation, encompassing the Single-Leg Hop Test, Triple Hop Test, Triple Crossover Test, and a timed 20m Hop on a Single Leg. All data collection will be done directly on REDCap.

- **Timing and Frequency**:

  The study duration spans 1-2 years, with the following timeline:

  1. Pre-operative Assessments:
     a. Initial participant recruitment and baseline assessments occur before ACL reconstruction surgery. Including PROMs (TSK, KOOS, PROMIS-10) -part of Standard of Care.

  2. Post-operative Assessments:
     a. Tampa Scale of Kinesiophobia (TSK) are conducted at 3, 6, & 12 months post-operatively.

  3. Functional Evaluation:
     a. A physical therapist will conduct a single leg balance test at 3 & 6 months.
     b. PT will also conduct a comprehensive assessment at 6 months post-operatively, involving the Single-Leg Hop Test, Triple Hop Test, Triple Crossover Test, and Timed 20m Hop on a Single Leg. (This is part of standard of care)

  4. Data Analysis:
     a. Initiated upon the completion of data collection.

  5. Reporting and Publication:

a. Findings and conclusions are compiled and prepared for reporting and potential publication.

- **Study Instruments**:

  - microFET 2 dynamometer
    - FDA Class II device
    - A handheld device that is used to measure muscle strength
    - The flat sensor is place of the muscle group to be tested, and then the subject flexes against the resistance of the device held against their limb
    - Device will record force in kilograms or pounds

  - Tampa Scale of Kinesiophobia
    - A validated tool to measure the degree of kinesiophobia in participants

  - Functional Evaluation Tools:
    - Single Leg balance test
    - Single-Leg Hop test
    - Triple Hop Test
    - Triple Crossover test
    - Timed 20m hop on a single leg

  - Intake Form
    - Form to be completed after enrollment to study
    - Will record subject identifiers (listed below), date of surgery, and gender

- **Subject Identifiers**:
  - Participants will be assigned a study number and no personal identifiers will be utilized.
  -

1.8 Timetable/Schedule of Events

-.Tentative Schedule:
- Subjects are enrolled pre-surgically by physical therapist during pre-operative therapy.
- Pre-Operative PROMS will be collected prior to surgery. They will be delivered by text or email.
- Post-operative PROMS will be completed at 3 months, 6 months, 1 year.
- Single leg balance testing will be completed by physical therapists at 3 months, 6 months
- Functional testing will be completed by physical therapists at 6 months.
- At 1 year post-op, the patients will complete PROMs.

2.0 Project Management

2.1 Research Staff and Qualifications

Charles Gatt, MD
Faculty and Department Chair at the Department of Orthopaedic Surgery at Robert Wood Johnson Medical School, practicing sports surgeon at University Orthopaedic Associates (UOA) in Somerset, and PI who will lead the study and provide study procedures, clinical care, and clinical follow up.

Eric Nussbaum, MEd, ATC, LAT –

Athletic trainer at University Orthopaedic Associates study coordinator, will be overseeing data collection and reviewing patient complaints.

Dean Pinciotti, PT – Director of physical therapy and for UOA. He will be one of the physical therapists at the Somerset location who will consent patients and record study data on study patients.

Ryan Kay, PT – Associate Director of Physical Therapy will consent and treat study patients.

2.2 Research Staff Training

All team members have been CITI certified, hold appropriate state licensing of credential.

2.3 Other Resources

All therapy equipment, space, and computers for data recording will be provided by UOA.

2.4 Research Sites

UOA Somerset
2 Worlds Fair Drive
Sommerset, NJ 08873

UOA Wall
4810 Belmar Blvd
Wall Township, NJ 07753

UOA Morganville
280 Route 9 North
Morganville, NJ 07751

UOA Avenel
1050 Route 1
Avenel, NJ 07001

3.0 Multi-Center Research

NA

4.0 Subject Considerations

4.1 Subject Selection and Enrollment Considerations

A. Method to Identify Potential Subjects

Potential subjects will be identified by their attending surgeon.

B. Recruitment Details

A physical therapist will meet with the patient after being notified by the surgeon of a potential subject. They will explain the purpose of the study and what it entails. They will be given the benefits and risks of the study as well as alternatives to not enrolling. The written consent form will be explained to them. They will have appropriate time to consider enrolling in the study.

C. Subject Screening

Team members will talk through the inclusion and exclusion criteria with the subject.

- **Inclusion Criteria**
  Patients 18 years and older with a confirmed ACL tear on MRI scan
- **Exclusion Criteria**
  Elderly patients, prior history of ACL tear, patients with other pre-existing physical conditions in which single-leg balance would put them at risk of harm

D. Privacy Protections

All data entry and collection forms will be destroyed by shredding once data is transcribed onto REDCap. Access to this is password-protected and limited to only the study team.

4.3 Number of Subjects

A. Total Number of Subjects
25 subjects will be accrued. This will be the number of subjects needed to complete the research procedures. We expect to inflate this number by 10% in the recruitment process to account for drop-out.

B. Total Number of Subjects If Multicenter Study
Total number of subjects across all sites will be at least 25.

C. Feasibility
Recruiting 25 patients for this study will be feasible given that each clinic sees roughly [NUMBER] of first-time ACL tear patients each month. We expect to be able to recruit 25 patients within [# OF MONTHS]

4.4 Consent Procedures

A. Consent Process

- **Location of Consent Process**
- UOA Somerset
- Morganville
- UOA Wall
- UOA Avenel
- **Ongoing Consent**
  Patients will be reminded that they may reach out to any of the investigators with questions or concerns.
- **Individual Roles for Researchers Involved in Consent**
  The physical therapists will be responsible for obtaining consent for potential subjects. They will be notified by the attending surgeons who will screen patients regarding potential subjects for the study. At this time eligibility will be determined per the inclusion and exclusion criteria. Study team members will explain the purpose of the study, why the potential subject is being chosen for screening, what kind of time commitment and study activities the subject would be asked to participate in, potential risks and benefits associated with participating in the study, and what their alternative options are to joining the study.
- **Consent Discussion Duration**
  15 minutes
- **Coercion or Undue Influence**
  The primary surgeon caring the subject will not be a part of the consenting process to avoid undue pressure to join the study. Physical therapists will discuss the study with potential subjects and inform themt that their alternative to joining the study is to decline participation which not affect their care.
- **Subject Understanding**
  To ensure adequate understanding of the study, patients will be encouraged to ask questions about aspects they do not understand and the person obtaining consent will employ teach back methods to ensure patient understanding.
- **Protecting Privacy**
  Consent discussion will occur in a private room with only the patient and the consenting individual present.

B. Documentation of Consent

- **Documenting Consent**

The consenting person will document consent in ordinance with the IRB requirements as stated in the Toolkit form. The patient will sign the consent form which will then be included in the visit note for the patient. A copy of the signed consent form will be provided to the patient, and it will be scanned into their medical record.

4.5 Economic Burden and/or Compensation for Subjects

A. Expenses

There are no expenses for the patient beyond regularly incurred cost for physical therapy.

B. Compensation/Incentives

Patients will voluntarily participate in this study. There will be NO patient compensation for participation in this study.

C Compensation Documentation

NA

4.6 Risks of Harm/Potential for Benefits to Subjects

A. Description of Risks of Harm to Subjects

- **Reasonably Foreseeable Risks of Harm**
- There is no foreseeable risk of harm from participation in this study. It possess minimal risk to the patient beyond the real of normal post-operative physical therapy. Since all data collection will be de-identified, there is minimal risk of release of personal information.
- **Risk of Harm from an Intervention on a Subject with an Existing Condition**
  Psychological conditions including fear/anxiety will be assessed via the TSK (PROM) and patient concerned directly addressed by the physical therapists or referred for professional care.
- **Observation and Sensitive Information**
  NA

B. Minimizing Risks of Harm

There is no more than minimal risk of harm associated with participation in this study.

- **Certificate of Confidentiality**
  NA
- **Provisions to Protect the Privacy Interests of Subjects**
  PROMS will be completed online on a secure server. Functional assessment of blance/function will be recorded onto a recording sheet with only patient number and no personal idenfitiers.

C. Potential Direct Benefits to Subjects

Participation in this study provides minimal personal benefits, but does help to advance the understanding of the impact of kinesiophobia on ACLR recovery and function.

5.0 Special Considerations

5.1 Health Insurance Portability and Accountability Act (HIPAA)

N/A

5.2 Family Educational Rights and Privacy Act (FERPA)

N/A

5.3 Code of Federal Regulations Title 45 Part 46 (Vulnerable Populations)

N/A

5.4 General Data Protection Regulation (GDPR)

N/A

5.5 NJ Access to Medical Research Act (Surrogate Consent)

N/A

6.0 Data Management Plan

6.1 Data Analysis

Data will be analyzed using correlation testing—to test results at each time point—and longitudinal model—to show if there is a potential time effect on the results. Mean single-leg balance will be compared between time points based on whether the patient is diagnosed with kinesiophobia using a t-test. Power analysis via comparison to existing baseline values in the relevant literature was done to determine the number of participants required for a well-powered study.

6.2 Data Security

Patient information will be maintained on a password secured electronic record system.

6.3 Data and Safety Monitoring

A. Data/Safety Monitoring Plan

Periodic monitoring of patient safety will be maintained by the study coordinator. Any and all reported incidents, injuries or concerns will be promptly reported to the coordinator and PI. The study coordinator will report all issues to the IRB.

B. Data/Safety Monitoring Board Details

NA – Due to small numbers of study subjects (25) there is no need for a data monitoring committee.

6.4 Reporting Results

A. Individual Subjects' Results

Results of the study will be available to study participants at the conclusion of the study. Therapists will discuss results of individual balance and functional testing with patients at completion of the testing.

B. Aggregate Results

Aggregate results will be available at the conclusion of the study for all participants.

C. Professional Reporting

Study results will be statistically analyzed and results compiled into a formal article which will be submitted for presentation/publication.

D. Clinical Trials Registration, Results Reporting and Consent Posting

NA

6.5 Secondary Use of the Data

Research will be saved for 5 years in a secure location at UOA. Use of de-identified data will be available to those who file formal request with purpose of use to PI/Study coordinator.

8.0 Approvals/Authorizations

9.0 Bibliography

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