Research Protocol

Highly Integrated and Power-Free Knee Rehabilitation Robot for Home-Based Isokinetic Training

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1. Research Topic

The research topic is “Highly Integrated and Power-Free Knee Rehabilitation Robot for Home-Based Isokinetic Training”.

2. Trial Number

The Trial Number is **ChiCTR2300076715**, provided by Chinese Clinical Trial Registry (ChiCTR). This research received ethical approval from the Biomedical Ethics Review Committee of West China Hospital, Sichuan University (No. **20231559**).

3. Expected Subject Number

The expected subject number is 10.

4. Inclusion/Exclusion Criteria

Inclusion Criteria:

1.Have done knee surgery before;

2.Age 18-75 years

3.Self-reported reduction in thigh muscle strength

4.BMI < 35

Exclusion Criteria:

1.Patients with diseases that cause pain or dysfunction of the lower limbs (lumbar disc herniation, Parkinson's, Alzheimer's, etc.);

2.Unable to walk short distances;

3.Severe cognitive impairment and communication disorders.

5. Outcomes

Primary Outcomes:

thigh cross-sectional area

muscle isokinetic strength

Secondary Outcomes:

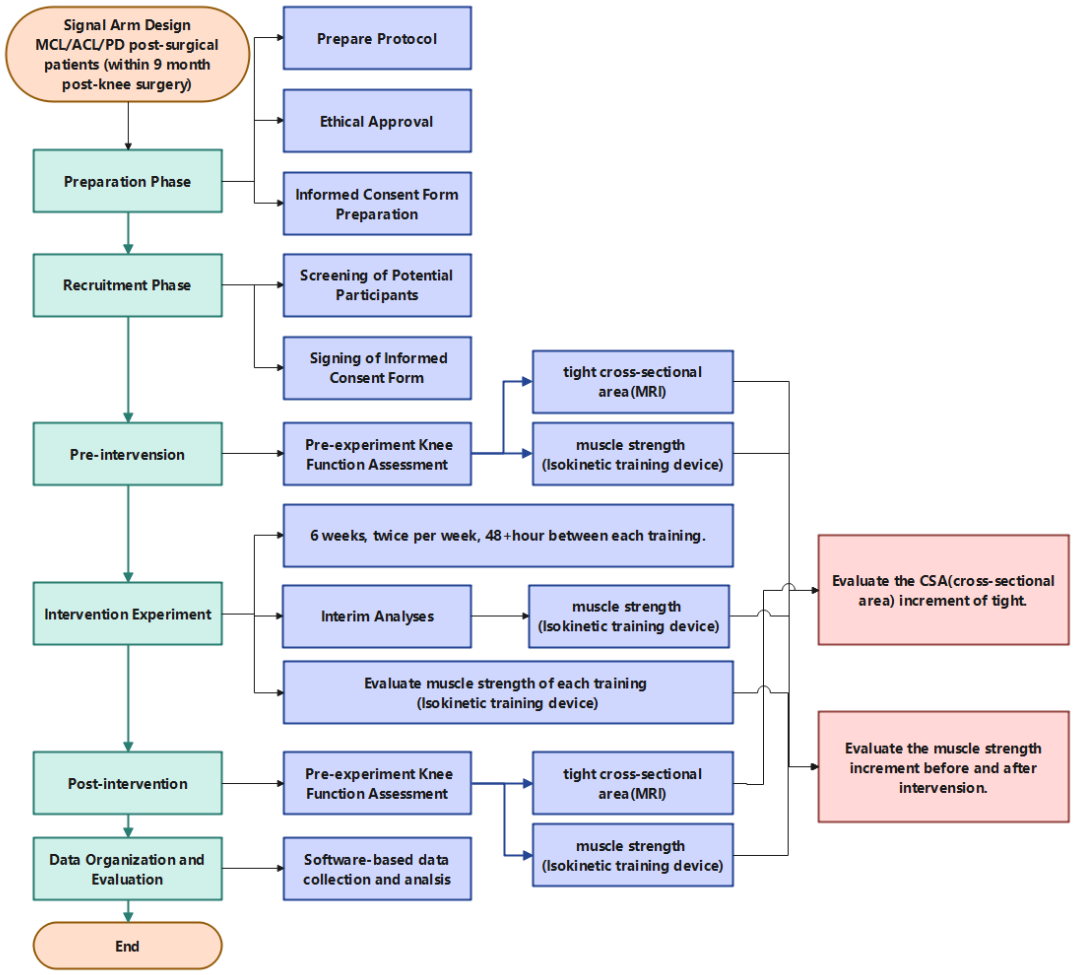
knee instability score

self-evaluated muscle strength

6. Research Objective

This is an intervention study (**ChiCTR2300076715**), and a cohort study, aiming to evaluate the muscle morphology and muscle strength improvement of 6 weeks isokinetic training using the proposed isokinetic training robot.

7. Design Pattern Diagram



8. Blinding

This research is non-blinded.

9. Start/Completion Date

Start Date:

2023.11

Completion Date:

2024.2

10. Interim Analyses

Interim analyses were conducted after the completion of half the training sessions. Both isokinetic muscle strength and self-evaluated muscle strength were assessed.

11. Data Analysis

All statistical analyses were conducted on data collected from all subjects and performed with the SPSS 25.0 statistical package (IBM, Armonk, NY, USA), and Microsoft Excel. Using one-tailed t-test to analyze the significance difference of data. We consider t-values of less than 0.05 to be statistically significant. All data were analyzed independently, and shown as mean ± SD.

12. Measurement Indicators

Major Indicator:

An MRI will be conducted on patients before and after the intervention (before the first training session and after the last training session) to measure the cross-sectional area of the thigh.

During each training session, muscle strength will be assessed using the

feedback from an isokinetic training device to record the strength gains from each session.

Safety indicator:

Severe knee pain, intense swelling, or inability to walk normally.

13.Definition of the Validity of the Participants

Management of exclusion, loss to follow-up, confounding, termination, and suspension is conducted in accordance with clinical trial requirements.

Interim Analyses

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1. Interim Criteria

We conducted interim analyses in half of the research training sessions. The primary method of assessment involved measuring isokinetic muscle strength using an isokinetic training robot. By comparing this interim isokinetic muscle strength with the strength measured before training, we preliminarily evaluated the effectiveness of the intervention.

The secondary method of assessment involved evaluating subjects' personal perceptions of their daily activities, which included activities such as walking, climbing stairs, and, if possible, jogging. This involved directly asking the subjects whether they perceived an improvement in these activities.

2. Trial Status

To date, all 10 subjects remain actively engaged in the research, and none have experienced any risky adverse events during the experiments, including severe knee pain, intense swelling, or an inability to walk normally. All subjects have expressed their willingness to continue participating in this research.

3. Modifications to Methodology

Currently, the experiment is progressing smoothly and the results are

favorable, thus there is no need to modify the experimental plan or adjust the experimental procedures.

4. Data Analysis

All statistical analyses were performed with the SPSS 25.0 statistical package (IBM, Armonk, NY, USA), and Microsoft Excel. Using one-tailed t-test to analyze the significance difference of data. We consider t-values of less than 0.05 to be statistically significant.

5. Outcomes

Primary Outcomes:

Quadriceps isokinetic strength

Hamstring isokinetic strength

Secondary Outcomes:

Self-evaluated muscle strength

6. Interim Results

In the interim analyses, all the subjects experience an increment in isokinetic muscle strength, both lifting and retracting. For lifting torque, representing the quadriceps muscle strength, the maximum increment is 118% (from 14.37 Nm to 31.30 Nm), and the minimum increment is 4%

(from 24.43Nm to 27.49Nm). For retracting torque, representing the hamstring muscle strength, the maximum increment is 215% (from 10.09 Nm to 31.77 Nm), and the minimum increment is 28% (from 32.30 Nm to 41.33 Nm).

All subjects reported improvements in daily activities.