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).

3. Ethics Approval

This research received ethical approval from the Biomedical Ethics Review Committee of West China Hospital, Sichuan University (No. **20231559**).

4. Expected Subject Number

The expected subject number is 10.

5. 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.

6. Outcomes

Primary Outcomes:

thigh cross-sectional area

muscle isokinetic strength

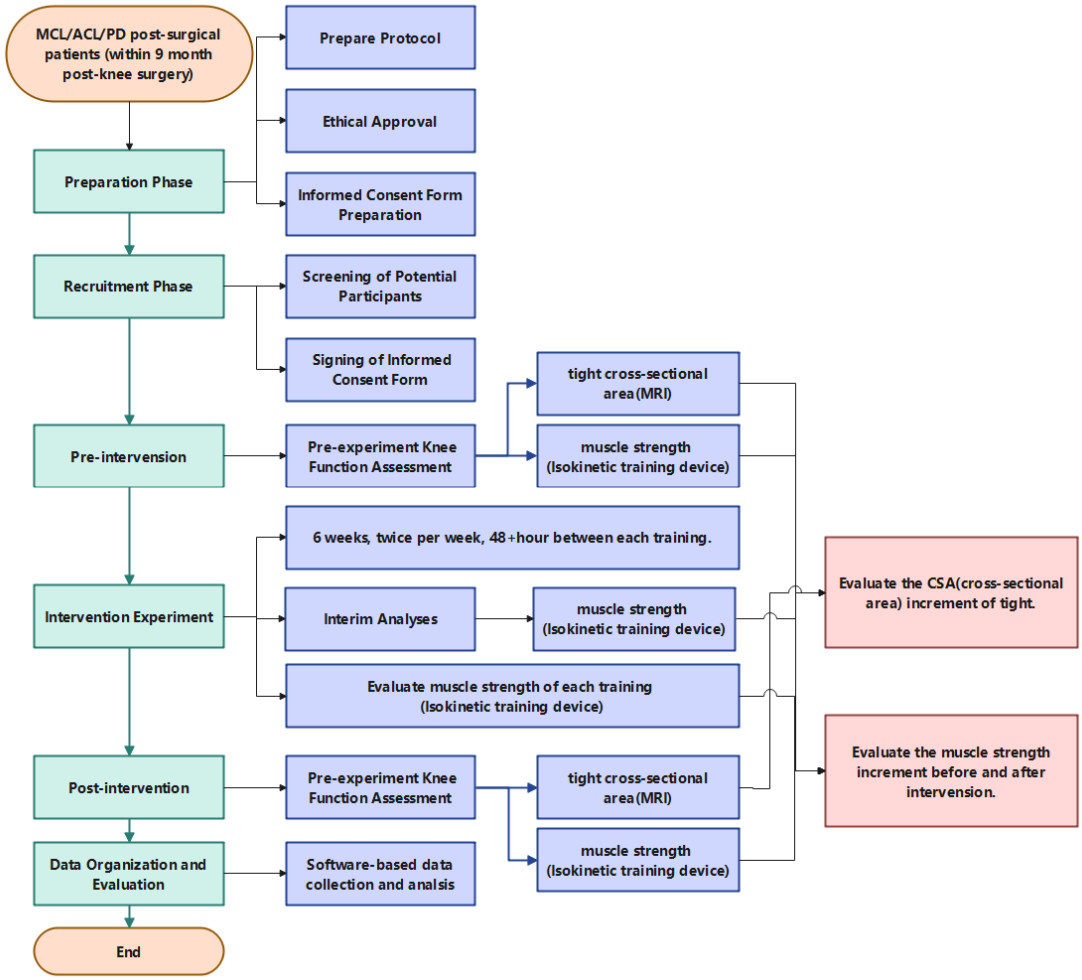
Secondary Outcomes:

self-evaluated muscle strength

7. Research Objective

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

8. Design Pattern Diagram



9. Blinding

This research is non-blinded.

10.Start/Completion Date

Start Date:

2023.11

Completion Date:

2024.2

11. 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.

12. 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.

13. Data Sharing

All related data and code is shared on GitHub (url:https://github.com/Ritiange666/Power-free-Isokinetic-Training-Robot.git)

14. 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, both trained leg (experiment group) and untrained leg (control group).

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.

15. 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

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

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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.

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	1
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	2-3
	2b	Specific objectives or hypotheses	2-3
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	8-9
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	8
Participants	4a	Eligibility criteria for participants	8
	4b	Settings and locations where the data were collected	8-9
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	8
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	5-6
	6b	Any changes to trial outcomes after the trial commenced, with reasons	7-8
Sample size	7a	How sample size was determined	4
	7b	When applicable, explanation of any interim analyses and stopping guidelines	5-6
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	8-9
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	8
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	9
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	8
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	8

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	8
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	8-9
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	8-9
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	8
	13b	For each group, losses and exclusions after randomisation, together with reasons	8
Recruitment	14a	Dates defining the periods of recruitment and follow-up	8
	14b	Why the trial ended or was stopped	8
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	SMPage16
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	9
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	5-6
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	5-6
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	5-6
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	6
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	6-7
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	7
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	7
Other information			
Registration	23	Registration number and name of trial registry	1
Protocol	24	Where the full trial protocol can be accessed, if available	8
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	21

url

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.