Study Protocol and Statistical Analysis Plan

Experimental Study on the Improvement of Shoulder Range of Motion in College Women Basketball Players by Virtual Reality Technology

NCT Number: [Pending]

Document Date: [April 2 ,2024]

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Date: [April 2 ,2024]

1. Protocol Summary

1.1 Synopsis

This study investigates the effectiveness of Virtual Reality (VR)-assisted rehabilitation on improving shoulder joint range of motion (ROM) and reducing pain in female collegiate basketball players with shoulder impairments. The study will compare the effects of VR-assisted rehabilitation, traditional rehabilitation, and a control group (no intervention) over a 9-week period.

1.2 Study Design and Overview

This is a randomized controlled trial (RCT) with three groups:
- VR-Assisted Rehabilitation Group: Participants will engage in immersive, shoulder-specific rehabilitation using VR technology.
- Traditional Rehabilitation Group: Participants will undergo standard shoulder rehabilitation exercises (e.g., mobility drills, resistance band exercises).
- Control Group: Participants will not receive any rehabilitation intervention but will continue with their regular basketball training.

1.3 Schedule of Activities

Pre-Study Screening: July 15, 2024: Initial screening to assess eligibility (e.g., shoulder impairments, regular participation in basketball).
Intervention Period: July 15 to September 13, 2024: Participants will undergo their respective rehabilitation protocols (VR-assisted, traditional, or control).
Final Assessment: September 13, 2024: Post-intervention evaluations of shoulder ROM and pain levels.

2. Introduction

2.1 Study Rationale

Shoulder injuries are common in sports, particularly in basketball, and can significantly impact athletic performance and recovery. Traditional rehabilitation methods often lack engagement and personalized feedback, potentially hindering recovery. Virtual Reality (VR) offers a unique, immersive environment for rehabilitation, potentially improving adherence, engagement, and outcomes. This study aims to assess whether VR-assisted rehabilitation can offer superior results in improving shoulder ROM and reducing pain compared to traditional methods.

2.2 Background

Previous studies have demonstrated the potential of VR for musculoskeletal rehabilitation, including its ability to simulate functional movements, provide real-time feedback, and increase patient engagement. However, there is limited research on VR's use specifically for shoulder rehabilitation in active, young athletes, particularly female basketball players. This

gap in the literature presents an opportunity to explore the effectiveness of VR in improving athletic rehabilitation outcomes.

2.3 Risk/Benefit Assessment

Known Risks: Potential discomfort or fatigue from physical activity or VR simulation fatigue. However, these risks will be minimized through careful monitoring and adjusting the intensity of the exercises.

Known Benefits: Improved shoulder ROM, reduced pain, and increased rehabilitation engagement. These benefits are crucial for accelerating recovery and ensuring athletes can return to their sport as soon as safely possible.

Ethical Oversight: The study has been approved by the Ethics Review Committee of Sanming Medical and Polytechnic Vocational College, and all participants will provide informed consent.

3. Objectives and Endpoints

3.1 Primary Objectives

To assess the effectiveness of VR-assisted rehabilitation in improving shoulder ROM in female collegiate athletes with shoulder impairments.

3.2 Secondary Objectives

To compare the impact of VR rehabilitation and traditional rehabilitation on pain levels (measured using the Visual Analog Scale (VAS)).

To evaluate participant engagement and adherence to rehabilitation protocols in both VR and traditional rehabilitation groups.

4. Study Design

4.1 Overall Design

This study will be a randomized controlled trial (RCT) with three groups: VR-assisted rehabilitation, traditional rehabilitation, and a control group. Participants will be randomly assigned to one of the three groups. Pre • and post-intervention measurements of shoulder ROM and pain levels will be collected.

4.2 Scientific Rationale for Study Design

The randomized controlled design minimizes bias and allows for clear comparisons between the groups. By using a control group, we can assess whether the VR intervention leads to improvements beyond the natural progression of rehabilitation or training.

4.3 Justification for Intervention

Given the potential of VR to engage participants and provide interactive, task-specific rehabilitation, it is hypothesized that VR-assisted rehabilitation will lead to greater improvements in shoulder ROM and pain reduction compared to traditional methods.

4.4 End-of-Study Definition

The study will conclude on September 13, 2024, after all post-intervention assessments are completed.

5. Study Population

5.1 Inclusion Criteria

•Age Requirement: Female Chinese college basketball players aged between 18 and 24.

•Shoulder Injury Requirement: Diagnosed with shoulder joint injuries (e.g., rotator cuff injuries, tendon damage, shoulder dislocation) with no previous surgical treatment.

•Sports Background: Participating in basketball training with at least three training sessions per week and a certain level of sports experience.

•Informed Consent: Willing to participate in the study and sign the informed consent form, with the ability to understand and cooperate with the research-related questionnaires and treatment plans.

•Physical Health: No severe cardiovascular, neurological, or musculoskeletal disorders that impact physical performance.

5.2 Exclusion criteria

1.Disease Exclusion: Individuals with a history of severe shoulder surgeries or other types of shoulder injuries (e.g., fractures, severe shoulder joint diseases).

•Medication Use: Those who are using any medication that may interfere with shoulder rehabilitation (e.g., steroids, painkillers, etc.) during the trial.

•Mental Health Issues: Individuals with severe psychiatric conditions, such as depression, anxiety, etc., who are unable to independently complete virtual reality rehabilitation treatment.

•Other Contraindications: Individuals who have adverse reactions to virtual reality technology, such as those with severe motion sickness.

5.3 Study Interventions

• VR-Assisted Rehabilitation Group: Participants will engage in immersive VR rehabilitation using the PICO 3 Pro system.
• Traditional Rehabilitation Group: Participants will undergo conventional rehabilitation exercises, such as resistance training and mobility drills.

• Control Group: Participants will not receive any formal rehabilitation intervention but will continue with their usual basketball training.

5.3 Recruitment and Retention

Participants will be recruited from three universities in Fujian Province. Retention will be ensured through regular follow-ups, clear communication about the study's purpose, and offering incentives for participation.

6. Study Interventions

6.1 VR-Assisted Rehabilitation Group

Participants will engage in immersive VR rehabilitation using the PICO 3 Pro system. This system includes motion tracking and interactive rehabilitation tasks that mimic basketball-related movements, progressively increasing in difficulty.

6.2 Traditional Rehabilitation Group

Participants will undergo conventional rehabilitation exercises, such as resistance training and mobility drills, guided by a physical therapist.

6.3 Control Group

Participants will not receive any formal rehabilitation intervention but will continue with their usual basketball training.

7. Discontinuation and Withdrawal

7.1 Discontinuation of Intervention

If a participant experiences excessive discomfort or injury during the rehabilitation process, they will be allowed to withdraw from the study. The study protocol allows for flexible adjustments to ensure participants' safety.

7.2 Participant Withdrawal

Participants may withdraw from the study at any time without penalty. Withdrawal reasons will be documented to ensure data integrity.

8. Study Assessments

8.1 Primary Outcome

Shoulder ROM: Measured using a digital goniometer to assess shoulder flexion, abduction, extension, internal rotation, and external rotation.

8.2 Secondary Outcome

Pain Intensity: Measured using the Visual Analog Scale (VAS), a 10 cm horizontal line indicating pain intensity from 0 (no pain) to 10 (worst imaginable pain).

Participant Engagement: Measured through self-report surveys assessing adherence to rehabilitation protocols and the perceived effectiveness and satisfaction with the intervention.

9. Statistical Considerations

9.1 Hypotheses

Null Hypothesis: No difference in shoulder ROM or pain levels between the three groups.

Alternative Hypothesis: VR-assisted rehabilitation leads to superior improvements in ROM and pain reduction compared to traditional rehabilitation and control.

9.2 Sample Size

A total of 45 participants (15 per group) will be recruited to ensure adequate statistical power (80%) to detect significant differences.

9.3 Statistical Analyses

Primary Analysis: Repeated-measures ANOVA to compare pre- and post-intervention ROM across the three groups.

Secondary Analysis: Post hoc Tukey HSD comparisons to assess pairwise differences between groups.

10. Ethical Considerations

10.1 Ethical Approval

This study has been reviewed and approved by the Ethics Review Committee of Sanming Medical and Polytechnic Vocational College. The ethical approval process follows the guidelines set forth by the Institutional Review Board (IRB) to ensure the protection of participant rights and welfare throughout the research process.

10.2 Informed Consent

Participants will receive a comprehensive Informed Consent Form in Chinese and English, detailing the study's purpose, procedures, potential risks, and benefits. The form will also ensure participants are aware of their rights, including the right to withdraw at any time without penalty. A signed informed consent form will be obtained from all participants.

10.3 Participant Protection

The study ensures participant protection through:

Minimizing Risk: Interventions are non-invasive, with regular monitoring for any adverse effects.

Confidentiality: All data will be anonymized and securely stored.

Ethical Oversight: The study adheres to the Declaration of Helsinki and national ethical guidelines.

11. Participant Timeline

Stage	Timeline	Description
Recruitment	July 15 • July 18, 2024	Participants are recruited, screened, and provided with the informed consent form.
Screening and Baseline Assessment	July 19 • July 21, 2024	Initial assessments of shoulder ROM and pain levels (VAS), confirmation of eligibility.
Pre-Intervention Evaluation	July 22, 2024	Final baseline evaluation and randomization of participants into intervention groups.
Intervention Period	July 22 • September 9, 2024	Participants undergo 9 weeks of VR-assisted or traditional rehabilitation, or no intervention (control group).
Mid-Point Evaluation	August 15, 2024	Mid-intervention check-in to assess progress, adherence, and potential adjustments.
Post-Intervention Evaluation	September 10 • September 13, 2024	Final assessments of shoulder ROM and pain levels, along with participant feedback on engagement.
Follow-Up	September 13, 2024	Final data collection and study conclusion.

12. Data Management Plan

All participant data, including demographic information, assessment results (range of motion and pain scores), and session attendance, will be collected and recorded on standardized data collection forms. Each participant will be assigned a unique study ID number to ensure confidentiality.

Data Handling Procedures:

•Paper-based data will be digitized and stored in a password-protected, encrypted database on a secure personal computer accessible only to the research team.

•Electronic data will be backed up weekly on an encrypted external hard drive.

•All personal identifiers will be removed from the dataset before analysis.

•Only de-identified data will be shared in publications or public databases.

Data Integrity and Quality Control:

•Double data entry will be employed to reduce transcription errors.

•Data will be periodically reviewed for completeness and consistency.

•Any missing data will be handled using appropriate statistical imputation methods or sensitivity analyses, as described in the statistical plan.

All procedures will comply with ethical guidelines for the protection of human participants and data privacy.

13. Safety Monitoring

Although the interventions in this study are non-invasive and carry minimal risk, appropriate safety monitoring procedures will be implemented to ensure participant well-being.

Key Safety Procedures:

•All participants will be screened before enrollment to ensure eligibility and minimize risk.

•A licensed physical therapist will supervise each VR rehabilitation session to monitor physical exertion and movement quality.

•Participants will be instructed to report any signs of discomfort, dizziness, pain, or fatigue immediately during or after each session.

Adverse Event Handling:

•Any adverse events (AEs), whether mild or serious, will be documented and evaluated by the investigator.

•Participants experiencing significant AEs will be referred for medical evaluation and may be withdrawn from the study if necessary.

•A safety log will be maintained for transparency and accountability.

Regular check-ins and post-session debriefings will be conducted to ensure both physical and psychological safety throughout the study.

14. Limitations of the Study

While this study is designed with scientific rigor and careful planning, several limitations must be acknowledged:

1.Sample Size: The relatively small sample size (n = 40) may limit the statistical power and generalizability of the results to larger populations or different athletic groups.

2.Short Intervention Duration: The 4-week intervention period, although adequate for observing changes in ROM and pain, may not capture long-term rehabilitation outcomes or recurrence rates.

3.Single-Center Study: Conducting the study at a single university or region may introduce selection bias and limit external validity.

4.Self-Reported Pain Measures: The use of self-reported Visual Analogue Scale (VAS) scores for pain may be influenced by individual perceptions and psychological factors.

5.Participant Adherence: Although engagement is expected to be high in VR-assisted groups, individual differences in motivation, fatigue, or scheduling conflicts may affect adherence to the protocol.

Future studies with larger sample sizes, multicenter designs, longer follow-up periods, and objective pain assessments (e.g., biomarkers, neuroimaging) are recommended to validate and extend the findings.