Exoglide Clinical Trial Protocol for ATFL sprains

1. Overview

This document outlines a proposed randomized controlled trial (RCT) protocol to evaluate the effectiveness and safety of the Exoglide orthosis as an adjunct to standard conservative rehabilitation for acute lateral ankle sprains involving the anterior talofibular ligament (ATFL). The protocol is written in neutral, scientific language suitable for sharing with collaborators, clinicians, and research partners.

2. Background and Rationale

Acute lateral ankle sprains—particularly those involving the ATFL—are among the most common musculoskeletal injuries. Standard conservative management typically includes early protected weight-bearing, range of motion exercises, progressive strengthening, proprioceptive training, and functional return-to-activity phases.

Exoglide is a wearable external support designed to assist rehabilitation of the talocrural joint (TCJ). The device applies sustained posterior glide forces to the talus and anterior glide forces to the distal tibia and fibula, aiming to facilitate dorsiflexion mechanics and restore normal arthrokinematics during gait and functional movement. Exoglide is worn externally over athletic footwear and secured with adjustable straps. It is intended for use during weight-bearing activities in early rehabilitation phases to support joint mobilization and proprioceptive engagement without restricting sagittal plane motion.

This study seeks to determine whether adding Exoglide to standard care improves functional recovery time compared to standard care alone.

3. Study Objective

To evaluate whether the addition of Exoglide to standard conservative rehabilitation reduces time to functional recovery in individuals with acute ATFL sprains.

4. Study Design

- **Design:** Prospective, parallel-group, randomized controlled trial.
- **Arms:**
    - **Control Group:** Standard conservative rehabilitation.
    - **Intervention Group:** Standard conservative rehabilitation plus Exoglide.
- **Randomization:** Concealed allocation with stratification by sprain grade.
- **Blinding:** Outcome assessors will be blinded to group assignment.
- **Registration:** The study will be pre-registered following SPIRIT and CONSORT guidelines.

5. Participants

Inclusion Criteria

- Age 16–50.
- First-time, acute lateral ankle sprain with clinical ± MRI-confirmed ATFL involvement.
- Presentation within 72 hours of injury.

Exclusion Criteria

- Concomitant fractures or high ankle sprains.
- Prior significant ankle injury or surgery on the affected side.
- Neurological or systemic conditions affecting gait or balance.

6. Interventions

Standard Conservative Rehabilitation (Both Groups)

A structured, evidence-based protocol including:

- Early protected weight-bearing.
- Range of motion exercises.
- Progressive strengthening.
- Proprioceptive and balance training.
- Functional return-to-activity progression.

Exoglide Intervention (Intervention Group Only)

- Worn over athletic footwear.
- Used during waking hours for the first 2–4 weeks.
- Required during ambulation, balance training, and functional tasks.
- Weaning begins once pain-free ROM and gait symmetry are achieved.

7. Outcomes

Primary Outcome

- **Time to functional recovery**, defined as:
    - Return to unrestricted ambulation without assistive device, **and**
    - FAAM-ADL score ≥ 90 (or equivalent validated threshold).

Secondary Outcomes

- Patient-reported ankle function (e.g., CAIT, FAAM-Sport).
- Pain intensity (NRS/VAS).
- Re-injury rate within 12 weeks.
- Gait parameters: stance symmetry, step length, walking speed.
- Balance/postural control (e.g., Y-Balance test).
- Time to pain-free dorsiflexion ≥ 10° or equal to unaffected lower extremity.

- Chronic ankle instability markers at 6-month follow-up.

8. Sample Size and Statistical Analysis

- Sample size will be calculated to detect a clinically meaningful effect corresponding to at least 10**% reduction in time to recovery**.
- Analyses will follow intention-to-treat principles.
- Missing data will be addressed using appropriate statistical methods.
- Sensitivity analyses and pre-specified subgroup analyses (e.g., sprain grade) will be included.

9. Bias Minimization Strategies

- Independent, blinded outcome assessors.
- Standardized rehabilitation protocols across both groups.
- Clear separation of roles to avoid conflicts of interest.
- Pre-registration of the protocol and predefined analysis plan.

10. Ethical Considerations

- Informed consent will be obtained from all participants.
- Risks and benefits will be clearly communicated.
- Participants may withdraw at any time without consequence.
- Results will be disseminated regardless of outcome.

11. Dissemination Plan

Findings will be shared through:

- Peer-reviewed publications.
- Conference presentations.
- Clinical and academic networks.

12. Summary

This protocol provides a structured, unbiased framework for evaluating Exoglide as an adjunct to standard rehabilitation for acute ATFL sprains. The study is designed to determine whether Exoglide offers measurable clinical benefit while maintaining scientific neutrality and methodological rigor.