Exoglide Clinical Trial Protocol for Patients with Ataxia

Study Purpose

This study investigates whether the Exoglide orthosis can improve gait stability, balance, and functional mobility in individuals with ataxia when used alongside standard physical therapy. Ataxia often leads to impaired coordination, gait variability, and increased fall risk. Exoglide is designed to support talocrural joint mechanics and enhance proprioceptive input during gait, potentially improving stability and reducing fall frequency.

Rationale

Ataxia rehabilitation traditionally focuses on balance training, gait retraining, strengthening, and motor control. However, progress can be slow and inconsistent. Exoglide applies sustained posterior glide forces to the talus and anterior glide forces to the distal tibia and fibula, supporting dorsiflexion mechanics and improving joint alignment during movement. This may enhance gait smoothness, reduce variability, and improve confidence.

Study Overview

- **Design:** Randomized controlled trial
- **Participants:** Adults with cerebellar, sensory, hereditary, or acquired ataxia
- **Intervention:** Standard physical therapy vs. standard physical therapy plus Exoglide
- **Duration:** 8-week intervention with 12-week follow-up
- **Primary Outcome:** Gait stability (gait variability index, step variability)
- **Secondary Outcomes:** Balance, mobility, proprioception, fall frequency, gait speed, endurance, patient-reported confidence
- **Video Assessments:** Baseline, immediate post-fit, weeks 2, 4, 6, and 12

Expected Impact

This study will provide the first controlled evidence on Exoglide's potential to improve gait stability in individuals with ataxia. Findings may inform clinical practice, guide rehabilitation strategies, and support future device development.

Full Protocol

1. Study Title

A Randomized Controlled Trial Evaluating the Effectiveness and Safety of the Exoglide Orthosis for Improving Gait, Balance, and Functional Mobility in Individuals with Ataxia

2. Background and Rationale

Ataxia is characterized by impaired coordination, gait instability, and increased fall risk. Rehabilitation aims to improve balance, motor control, and gait mechanics, but outcomes vary widely. Exoglide is a wearable orthosis designed to support talocrural joint arthrokinematics by applying directional glide forces that facilitate dorsiflexion mechanics. This may enhance proprioception, improve gait stability, and reduce fall risk.

3. Study Objectives

Primary Objective

Evaluate whether Exoglide improves gait stability compared with standard physical therapy alone.

Secondary Objectives

- Assess improvements in balance, proprioception, and functional mobility
- Evaluate changes in fall frequency
- Measure patient-reported confidence in walking
- Assess safety and tolerability

4. Study Design

- Prospective, parallel-group, randomized controlled trial
- Control group: Standard physical therapy
- Intervention group: Standard physical therapy plus Exoglide
- Concealed allocation; stratified by ataxia type
- Blinded outcome assessors
- 8-week intervention; 12-week follow-up

5. Participants

Inclusion Criteria

- Age 18–75
- Diagnosis of cerebellar, sensory, hereditary, or acquired ataxia
- Able to ambulate at least 10 meters
- Stable medical status for at least 3 months

Exclusion Criteria

- Severe cognitive impairment
- Peripheral vascular disease or decreased sensation in lower extremities
- Severe spasticity or contractures limiting ankle motion
- Recent orthopedic surgery (<6 months)
- Skin conditions preventing device use

6. Recruitment and Screening

Participants will be recruited from neurology clinics, physical therapy clinics, ataxia support groups, and community rehabilitation centers. Screening includes neurological examination, gait assessment, and safety evaluation. Written informed consent will be obtained.

7. Interventions

Standard Physical Therapy (Both Groups)

- Balance training
- Gait training
- Coordination exercises
- Strengthening
- Functional mobility training
- Fall-prevention education

Exoglide Intervention (Intervention Group Only)

- Worn over athletic footwear
- Used during all gait training and balance sessions
- Recommended for daily walking during waking hours
- Duration: 8 weeks
- Standardized fitting and education
- Optional weaning after week 8

8. Outcome Measures

Primary Outcome

- Gait stability (gait variability index, step length variability, step time variability)

Secondary Outcomes

- Balance (Berg Balance Scale)
- Functional mobility (Timed Up and Go)
- Proprioception (joint position sense)
- Fall frequency (weekly logs)
- Patient-reported outcomes (ABC, FES)
- Gait speed (10-Meter Walk Test)
- Endurance (6-Minute Walk Test)

9. Video-Based Gait Assessment Protocol

Assessment Time Points

- Baseline (before Exoglide application)
- Immediately after first Exoglide fitting
- Week 2
- Week 4
- Week 6
- Week 12 (follow-up)

Recording Procedure

- Fixed tripod at hip height
- Frontal and sagittal views
- Consistent lighting and background
- 10-meter walkway
- Tasks: comfortable-speed walking, fast-speed walking, optional dual-task and obstacle negotiation
- Two passes per condition

Video Outcome Measures

Qualitative

- Trunk sway
- Step consistency
- Foot placement accuracy
- Ataxic gait features

Quantitative

- Step length variability
- Step time variability
- Stance/swing ratio
- Stride-to-stride deviation

Blinding and Storage

- Videos coded and de-identified
- Independent raters blinded to group assignment
- Secure, encrypted storage

10. Sample Size and Statistical Analysis

- Powered to detect clinically meaningful improvement in gait variability
- Intention-to-treat analysis
- Mixed-model repeated measures
- Sensitivity analyses for missing data
- Subgroup analysis by ataxia type

11. Risks and Benefits

Risks

- Skin irritation
- Fatigue
- Temporary unsteadiness during adaptation

Benefits

- Potential improvement in gait stability
- Reduced fall risk
- Contribution to ataxia rehabilitation research

12. Safety Monitoring

- Adverse events recorded at each visit
- Serious adverse events reported per institutional policy
- Weekly device tolerance checks

13. Confidentiality

All data coded and stored securely. Identifiable information stored separately from research data.

14. Dissemination

Results will be shared through peer-reviewed journals, conferences, and ataxia foundations.

15. Appendices

- Informed consent form (to be developed)
- Recruitment materials
- Standard rehabilitation protocol
- Exoglide fitting and usage guide