Official Study Title: Observational Assessment of Mobility, Pain, and Sleep Outcomes in Parkinson's Disease Subjects Using a Robotic Spinal Mobilization Device

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STUDY PROTOCOL

1.0 Study Rationale and Background

Axial rigidity is a cardinal motor feature of Parkinson's Disease (PD), characterized by stiffness in the trunk and spine. Unlike appendicular symptoms (such as tremor), axial symptoms often show limited response to standard dopaminergic medication (e.g., Levodopa) and contribute significantly to gait impairment, balance dysfunction (postural instability), and chronic pain.

This observational study investigated the utility of a novel robotic device, BackHug, to mechanically mobilize the thoracic and lumbar spine, evaluating the hypothesis that reducing axial stiffness improves systemic mobility and reduces symptom burden.

2.0 Study Objectives

Primary Objective: To observe whether the mechanical release of axial rigidity via robotic spinal mobilization correlates with measurable improvements in functional mobility.

Secondary Objectives: To observe whether the intervention correlates with:

- A reduction in chronic back pain intensity.
- An improvement in sleep quality.
- An improvement in functional lower limb strength.

3.0 Study Design

This was a prospective, single-arm, observational case series conducted at a single clinical site (The Manual Therapy Clinic, Edinburgh, UK).

4.0 Eligibility Criteria

4.1 Inclusion Criteria

- Confirmed clinical diagnosis of Parkinson's Disease.
- Hoehn and Yahr Scale Stage 3 or below (indicating mild to moderate disability).
- Ability to walk independently for approximately 5 minutes (with or without walking poles; Zimmer frames excluded).
- Age 18 to 75 years.

4.2 Exclusion Criteria

Participants were excluded if they presented with any absolute contraindication to mechanical spinal mobilization, including:

- **Bone Pathology:** History of spinal malignancy, active spinal infection (e.g., tuberculosis), severe congenital defects, metabolic bone disease (e.g., severe osteomalacia), or currently healing fractures/dislocations.
- **Inflammatory Conditions:** Severe Rheumatoid Arthritis or other inflammatory arthritides.
- **Neurological Conditions (Non-PD):** Spinal cord compression, spinal cord damage, Cauda Equina syndrome.
- **Vascular Risks:** History of aortic dysfunction (e.g., aneurysm), severe haemophilia, or unmanaged bleeding disorders.

5.0 Study Intervention

Participants received therapy using the **BackHug** robotic spinal mobilization system.

- **Mechanism:** The device features 26 robotic therapeutic heads ('fingers') that deliver targeted deep-tissue pressure to the paraspinal muscles and intervertebral joints.
- **Regimen:** Participants attended four (4) sessions administered over a two-week period.
- **Duration:** Each session lasted approximately 40 minutes.
- **Settings:** Treatment intensity was personalized to user tolerance via the device's control app.

6.0 Outcome Measures

6.1 Functional Mobility (Primary Outcome)

- **Metric:** 3-Meter Timed Up and Go (TUG) Test.
- **Method:** Participants were timed (in seconds) as they rose from a chair, walked 3 meters, turned around, walked back, and sat down.
- **Timing:** Assessed at Baseline (Session 1 Pre-Therapy) and Post-Intervention (Session 4 Post-Therapy).

6.2 Functional Strength (Secondary Outcome)

- **Metric:** 30-Second Sit-to-Stand (STS) Test.
- **Method:** The number of full stands completed in 30 seconds was recorded.
- **Timing:** Assessed at Baseline and Post-Intervention.

6.3 Pain Intensity (Secondary Outcome)

- **Metric:** Visual Analog Scale (VAS).

- **Scale:** 0 (No Pain) to 10 (Worst Possible Pain).
- **Timing:** Assessed longitudinally throughout the study.

6.4 Sleep Quality (Secondary Outcome)

- **Metric:** Self-Reported Likert Scale.
- **Scale:** 0 (Excellent) to 5 (Very Poor).
- **Timing:** Assessed longitudinally throughout the study.

STATISTICAL ANALYSIS PLAN (SAP)

7.0 Statistical Considerations

7.1 Sample Size

As a pilot observational case series, the sample size (N=16) was determined based on feasibility and the capacity of the single-center clinical facility. The objective was to generate effect size estimates and standard deviation data sufficient to power a future randomized controlled trial (RCT). No formal power calculation was performed prior to recruitment.

7.2 Analysis Populations

- **Per-Protocol Population:** The primary analysis includes all participants who completed the full course of 4 therapy sessions and underwent both baseline and final assessments.
- **Safety Population:** Safety analysis includes all participants who received at least one session of therapy.

7.3 Handling of Missing Data

Missing data points resulting from missed sessions or incomplete assessments were documented but excluded from the final efficacy calculation for that specific endpoint. No data imputation methods (e.g., Last Observation Carried Forward) were used. Analysis is based on observed cases only.

7.4 Statistical Methods

7.4.1 Descriptive Statistics

Baseline demographic and clinical characteristics (Age, Gender, Disease Duration) are summarized using means and standard deviations (SD) for continuous variables, and counts/percentages for categorical variables.

7.4.2 Efficacy Analysis

- **Primary Endpoint (Mobility):** The difference between Baseline (Pre-Intervention) and Final (Post-Intervention) TUG times was analyzed.
- **Secondary Endpoints:** Differences in STS counts, VAS Pain scores, and Sleep Quality scores were analyzed comparing Baseline to Final values.
- **Hypothesis Testing:** Paired t-tests were employed to assess the statistical significance of changes from baseline. For non-normally distributed data, the Wilcoxon signed-rank test was used.

- **Significance Level:** A p-value of <0.05 was considered statistically significant.
- **Calculations:** Percentage improvement was calculated as `((Final Score - Baseline Score) / Baseline Score) * 100`.

7.4.3 Safety Analysis

Adverse events were tabulated by frequency and severity. No formal statistical testing was performed on safety data due to the low event rate anticipated.