Study Protocol and Statistical Analysis Plan

Document Title: Chronic Lumbar Disc Herniation: A Randomized Single-Blind Study on the Comparative Efficacy of Peloid therapy Versus Hot pack Therapy

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Study Protocol

Study Design

This study is a single-blinded, randomized controlled trial involving 60 individuals diagnosed with chronic lumbar disc herniation (LDH). Participants were randomly assigned into two groups: peloid therapy + TENS and hotpack therapy + TENS. Each group received treatment for 3 weeks (15 sessions).

Inclusion Criteria

Adults aged 18-50 with LDH symptoms for more than 3 months, confirmed by MRI, without physiotherapy in the last 6 months.

Exclusion Criteria

Severe neurological deficit, malignancy, osteoporosis, inflammatory diseases, systemic disorders, or contraindications for therapy were excluded.

Interventions

Peloid therapy was applied at 45°C for 30 minutes; hotpack therapy at 90°C for 20 minutes. Both followed by 20 minutes of conventional TENS.

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Outcome Measures

Primary outcomes include pain (VAS), disability (ODI), and functionality (BPFS). Secondary outcomes include quality of life (SF-36), ROM, and finger-floor distance. Assessments were performed pre- and post-treatment.

Statistical Analysis Plan

Sample size was determined using G*Power software based on an effect size of 0.759 from a prior study. A total of 42 participants were required to detect significant differences with 95% confidence and 5% alpha error.

SPSS 22.0 software was used. Descriptive statistics included mean, standard deviation, frequency, and percentage. Between-group differences were analyzed using independent samples t-tests and chi-square tests. Within-group comparisons were conducted using paired samples t-tests. A p-value < 0.05 was considered statistically significant.