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PREDICTORS OF CLINICAL RESPONSE TO INDIVIDUALIZED LM POTENCY THERAPY IN PATIENTS WITH SCIATICA: A PROTOCOL FOR SECONDARY ANALYSIS OF A PROSPECTIVE RANDOMIZED CONTROLLED TRIAL

Homeopathy

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ABSTRACT

Background Sciatica is a neuropathic pain disorder characterized by radiating pain along the sciatic nerve, often accompanied by sensory disturbances, motor deficits, and functional disability. Despite conventional treatment, clinical outcomes remain variable. Individualized homoeopathic LM potency therapy may improve symptoms; however, variation in treatment response suggests that baseline patient characteristics may influence clinical outcomes. **Objective** To identify demographic, clinical, neurological, constitutional, and treatment-related predictors associated with favourable clinical response following individualized LM potency therapy in patients with sciatica through secondary analysis of data from a completed prospective randomized controlled trial. **Methods** This protocol describes a retrospective secondary analysis of anonymized participant-level data from a completed prospective randomized controlled trial. Only participants who received individualized LM potency therapy will be included. Candidate predictors include demographic, clinical, neurological, constitutional, and treatment-related variables. The primary outcome is favourable clinical response, defined as ≥50% reduction in pain intensity and ≥30% improvement in disability score. Univariable and multivariable logistic regression analyses will be performed to identify independent predictors of favourable clinical response. **Expected Outcomes** The study is expected to identify independent predictors of favourable clinical response following individualized LM potency therapy in patients with sciatica. The findings may support individualized treatment planning and inform future homoeopathic research.

KEYWORDS

Sciatica; Homoeopathy; LM Potency; Secondary Analysis; Clinical Predictors; Logistic Regression; Personalized Medicine.

INTRODUCTION

Sciatica is a common neuropathic condition caused by irritation or compression of lumbosacral nerve roots, leading to radiating leg pain, sensory disturbances, and functional impairment. It is a major contributor to disability worldwide and significantly reduces quality of life. Conventional management includes NSAIDs, physiotherapy, steroid injections, and surgery; however, outcomes are often inconsistent and recurrence is frequent. This highlights the need for individualized therapeutic approaches. Homoeopathy offers individualized treatment based on total symptom analysis. LM (Fifty-Millesimal) potencies, introduced in the sixth edition of the Organon of Medicine, allow frequent repetition with minimal aggravation and are widely used in chronic conditions. A previously conducted randomized controlled trial demonstrated that individualized LM potency therapy produced significant improvement in sciatica. However, variability in response indicates possible influence of baseline prognostic factors such as pain severity, neurological status, constitutional characteristics, and treatment adherence. Identification of clinical predictors associated with favorable treatment response is increasingly recognized as an important component of personalized healthcare. Understanding these predictors may improve patient selection, individualized prescribing, and clinical decision-making in homoeopathic practice. Secondary analysis of data from randomized controlled trials provides an efficient and methodologically robust approach to investigate factors associated with treatment outcomes without imposing additional participant burden. Therefore, this study aims to identify predictors of clinical response and develop a validated prognostic model for individualized LM potency therapy in sciatica.

MATERIALS AND METHODS

Study Design

This is a retrospective secondary analysis of participant-level data from a completed prospective randomized, double-blind, placebo-controlled clinical trial.

Study Setting

Adult patients with clinically diagnosed sciatica who received individualized LM potency therapy in the original trial.

Eligibility Criteria

Inclusion criteria: Participants aged 18–65 years with a clinical diagnosis of sciatica who were randomized to the individualized LM potency group in the original prospective randomized controlled trial, with complete baseline data, at least one follow-up assessment, and complete outcome data.

Domain	Variables	Measurement / Coding
Demographic	• Age (years) • Sex • BMI (kg/m²) • Occupation	Continuous Male = 0, Female = 1 Continuous Manual = 1, Non-manual = 0
Clinical	• Duration of illness (months) • Side affected • Prior treatment exposure • Baseline pain score (VAS/NRS) • Baseline disability (ODI)	Continuous Left = 0, Right = 1 No = 0, Yes = 1 0–10 scale 0–100 scale
Neurological	• SLR angle (degrees) • Motor weakness (MRC grade) • Sensory deficit • Reflex abnormality	Continuous 0 (Normal) to 5 (Severe) Absent = 0, Present = 1 Absent = 0, Present = 1
Constitutional	• Sleep quality • Appetite pattern • Thirst pattern • Thermal preference • Emotional stress / anxiety	Good = 0, Poor = 1 Normal = 0, Reduced = 1, Increased = 2 Normal = 0, Increased = 1, Decreased = 2 Cold = 0, Hot = 1, Neutral = 2 Low = 0, Moderate = 1, High = 2
Treatment-related	• Remedy type • Initial LM potency level • Potency repetition pattern • Follow-up frequency • Treatment adherence	Categorical LM potency level (number) Scale / Category Per week / Per month Good = 0, Moderate = 1, Poor = 2

Exclusion criteria: Participants with missing primary outcome data, withdrawal before treatment initiation, major protocol deviations, incomplete baseline assessments, duplicate or inconsistent records, or inadequate follow-up.

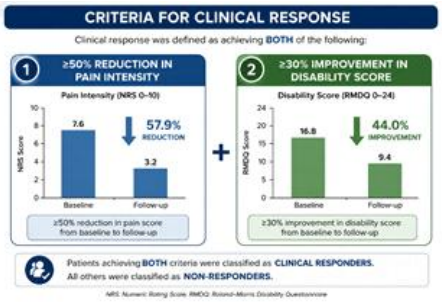
Predictor Variables

Baseline candidate predictor variables will be categorized as follows:

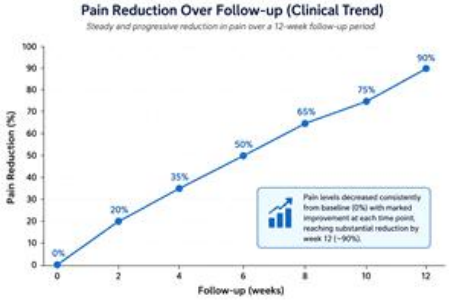
- **Demographic variables:** Age, sex, body mass index (BMI), and occupation.
- **Clinical variables:** Duration of illness, affected side, previous treatment history, baseline pain score, and baseline disability score.
- **Neurological variables:** Straight Leg Raising (SLR) angle, motor weakness, sensory deficits, and reflex changes.
- **Constitutional variables:** Thermal sensitivity, appetite and thirst, sleep pattern, perspiration, and emotional characteristics.
- **Treatment-related variables:** Individualized homoeopathic remedy, initial LM potency, potency progression, follow-up frequency, and treatment adherence.

OUTCOME MEASURES

- ≥50% reduction in pain intensity &
- ≥30% improvement in disability score



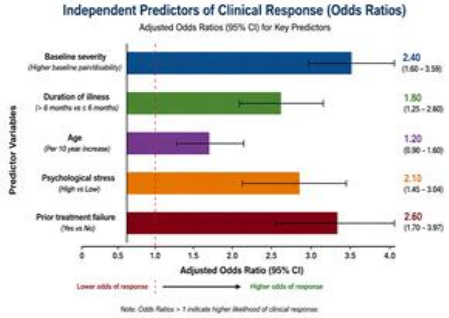
Pain intensity will be assessed longitudinally over the 12-week follow-up period to evaluate changes from baseline and determine the proportion of participants achieving a favourable clinical response. Functional disability will be measured at each scheduled follow-up visit to assess changes in mobility, daily activity performance, and overall functional status over time.



Neurological outcomes, including Straight Leg Raising (SLR) angle, motor weakness, sensory deficits, and deep tendon reflexes, will be evaluated throughout the follow-up period to assess changes in neurological function.

Overall clinical improvement will be assessed using predefined outcome measures encompassing pain intensity, functional disability, and neurological status. These assessments will be conducted according to the follow-up schedule of the original prospective randomized controlled trial using standardized clinical evaluation methods.

Overall clinical improvement will be assessed using predefined outcome measures encompassing pain intensity, functional disability, and neurological status. Changes across these domains will be evaluated at each scheduled follow-up visit to determine the overall therapeutic response to individualized LM potency therapy. The combined assessment of these outcomes will provide a comprehensive evaluation of clinical improvement over the study period.



Expected Outcomes

The study is expected to identify independent demographic, clinical, neurological, constitutional, and treatment-related predictors of favourable clinical response following individualized LM potency therapy in patients with sciatica. The findings may support individualized treatment planning and inform future homoeopathic research.

DISCUSSION

Evidence regarding predictors of response to individualized homoeopathic treatment in sciatica remains limited. This secondary analysis of data from a completed prospective randomized controlled trial aims to identify baseline factors associated with favourable clinical response. The findings may improve individualized prescribing and provide a foundation for future prospective studies.

CONCLUSION

This protocol describes a secondary analysis of data from a completed prospective randomized controlled trial to identify predictors of clinical response to individualized LM potency therapy in patients with sciatica. The findings are expected to support individualized treatment decisions and contribute to evidence-informed homoeopathic practice.

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