CAHIERS MAGELLANES-NS
Volume 06 Issue 2
2024

ISSN:1624-1940
DOI 10.6084/m9.figshare.2632574
http://magellanes.com/

A PROSPECTIVE RANDOMIZED CONTROLLED STUDY OF AURICULAR THERAPY TO MANAGE PAIN, SELF-RATED DISABILITY, DEPRESSION, ANXIETY, STRESS, AND FATIGUE IN PATIENTS WITH NON-SPECIFIC LOW BACK PAIN: STUDY PROTOCOL

Ashish Mathur[1*], Dr Neeta Vyas[2], Dr Sarvanan M[3]

[1*]PhD Scholar, P P Savani University, Surat,
[2]Professor, P P Savani University, Surat
[3]Professor, Bhartimaya College of Physiotherapy, Surat

***Corresponding Author:** Ashish Mathur
*PhD Scholar, P P Savani University, Surat

Abstract

Background: Non-Specific Low back pain (NSLBP) is a widespread health concern that significantly affects quality of life and incurs considerable economic costs globally. Although there are many pharmacological and therapeutic interventions, yet there exists ambiguity in Non-Specific Low back pain treatment outcomes as seen in high disability rates. Conventional treatments often offer limited relief, leading to increased interest in complementary therapies. This is a study protocol design to assesses the efficacy and clinical applications of auricular therapy in managing Non-Specific Low Back Pain (NSLBP)along with, Self-Rated Disability, Depression, Anxiety, Stress, and Fatigue.

Methods/design: For this prospective randomized controlled study, participants will be randomly assigned to two groups: (1) Intervention group (Auricular Therapy and Patient Education will be given (2) Control group-1 (Usual Care which comprises of Therapeutic Exercises regimen, Moist Hot packs and Patient Education will be administered). Treatment effects will be measured via Numerical Pain Rating Scale and questionnaires like The Roland Morris Disability Questionnaire (RMDQ) in patients' native language, the 21-question version of the Depression Anxiety Stress Scale (DASS21) in patients' native language and PROMIS measures (Patient Reported Outcome Measurement Information system) Fatigue 13a in patients' native language.

Discussion: This study is expected to provide key information on the effect of Auricular Therapy on Non-specific Low Back Pain.

Keywords: Auricular therapy, Non-Specific Low Back Pain

1. Introduction

Non-specific low back pain (NSLBP) is a prevalent health issue worldwide, affecting 60-70% of adults in industrialized countries at some point in their lives [1]. It is a leading cause of disability and work absenteeism, resulting in substantial economic burden [2]. While various treatments exist, including pharmacological interventions, physical therapy, and cognitive behavioural therapy, their effectiveness can be limited, and some carry risks of side effects or dependency [3].

Auricular therapy, a form of acupuncture that focuses on the ear, has shown promise in managing various pain conditions [4].

The theoretical basis lies in the concept that the ear is a microsystem representing the entire body, with specific points corresponding to different body parts and functions [5]. Stimulating these points is believed to modulate the autonomic nervous system and pain pathways [6].

Recent systematic reviews have suggested that auricular therapy may be effective for various types of

ISSN:1624-1940
DOI 10.6084/m9.figshare.2632574
http://magellanes.com/

pain, including chronic low back pain [7,8]. However, most existing studies have small sample sizes, varied methodologies, and often focus solely on pain outcomes. There is a need for a rigorous, large-scale study that examines not only pain but also associated symptoms such as disability, depression, anxiety, stress, and fatigue, which often accompany chronic pain conditions [9].

2. Objectives

Primary Objective:

- To evaluate the effectiveness of auricular therapy in reducing pain intensity in patients with NSLBP over a 6-week intervention period.

Secondary Objectives:

- To assess the impact of auricular therapy on self-rated disability, depression, anxiety, stress, and fatigue in NSLBP patients.
- To explore potential predictors of treatment response (e.g., age, duration of symptoms, baseline pain intensity).

3. Study Design

This will be a prospective, randomized, single-blind clinical trial, designed in accordance with the CONSORT guidelines for non-pharmacological treatments [10].

Detailed Study Design:

1. Study Setting: The study will be conducted at three Outpatient Physiotherapy Clinics.
2. Recruitment: Potential participants will be recruited through referrals from primary care physicians and flyers in the participating clinics. A research coordinator at each site will screen potential participants for eligibility. This multi-pronged approach has been shown to be effective in recruiting participants for pain management studies [11].

Patient Selection: Subjects will be eligible to participate in the study if they met the following criteria.

Inclusion Criteria:

- Participants who had a primary complaint of Nonspecific low back pain of at least 6-week duration.
- Both male and female patients in the age group of 20 years to 60 years;
- The patients who will score 4-7 points on an 11-point Numeric Pain Rating scale.
- Subjects who gave their consent to this study procedure and will be willing to refrain from non-study procedure therapies for the management of low back pain throughout study participation.
- Physical Diagnosis based on review of patient history, physical examination and review of prior medical records.

Exclusion Criteria:

· Individuals will be excluded if they report other musculoskeletal or neurological conditions
· Patients who had structural scoliosis, metastatic, or metabolic diseases and had undergone spinal surgery.
· Osteoporosis with compression fractures
· Congenital deformity of spine, Spondylolisthesis, Spinal Stenosis, Spondylolysis, Cauda Equina Syndrome
· Cancer or cancer treatment in the past 6 months
· Active infection, wound, or other external trauma to the treatment area
· Pregnant or breastfeeding participants

ISSN:1624-1940
DOI 10.6084/m9.figshare.2632574
http://magellanes.com/

3. Screening and Baseline Assessment:
- Initial screening will be conducted via telephone using a standardized questionnaire.
- Eligible individuals will be invited for an in-person screening visit, where they will:

a) Provide informed consent
b) Undergo a physical examination to confirm NSLBP diagnosis
c) Complete baseline assessments (detailed in Outcome Measures section)

4. Randomization:
- Eligible participants will be randomly assigned to either the intervention group (auricular therapy) or the control group using a computer-generated randomization sequence.
- Allocation will be concealed using sequentially numbered, opaque, sealed envelopes, a method shown to be effective in maintaining allocation concealment [12].

5. Blinding:
- Participants will be blinded to their group assignment.
- The practitioner administering the treatment cannot be blinded due to the nature of the intervention.
- Outcome assessors and data analysts will be blinded to group allocation.

6. Intervention:
- Duration and Frequency: The therapy in Intervention group will be given twice a week for 6 weeks. In Control group usual care will be given three times a week for a duration of 6 weeks.
- Session length: Approximately 55-60 minutes

Pre-Assessment and Therapeutic Protocol for Intervention and Control Group:

Group A (Intervention Group)	Group B (Control Group)
Pre assessment: Pain, Self-rated disability, Depression, Anxiety, Stress and Fatigue	Pre assessment: Pain, Self-rated disability, Depression, Anxiety, Stress and Fatigue
Auriculo-therapy and Patient Education will be administered	Usual Care which comprises of Therapeutic Exercises regimen, Moist Hot packs (Hydrocollator packs) and Patient Education will be administered.
Post assessment: Pain, Self-rated disability, Depression, Anxiety, Stress and Fatigue. The NPRS scores, will be evaluated at the end of the 2nd, 4th, and 6th week. Self-rated Disability, Depression, anxiety, and stress level; and Fatigue level will be evaluated at end of 4th week, and at the end of 6th week.	Post assessment: Pain, Self-rated disability, Depression, Anxiety, Stress and Fatigue. The NPRS scores, will be evaluated at the end of the 2nd, 4th, and 6th week. Self-rated Disability, Depression, anxiety, and stress level; and Fatigue level will be evaluated at end of 4th week, and at the end of 6th week.

Procedure: After Random allocation and baseline assessment, Patients will be randomly assigned into two groups. In Intervention group (Group A) patients will receive Auricular therapy with Patient

ISSN:1624-1940
DOI 10.6084/m9.figshare.2632574
http://magellanes.com/

Education and in Control group (Group B) patients will receive Usual care which consists of Therapeutic Exercises, Moist Hot packs and Patient Education.

Treatment Protocol for Intervention group:

1. Auricular Therapy: Point selections will be done after a review of auricular therapy studies including Systemic reviews and RCTs

2. Details of needling:

2a) Names of points to be used: Auricular acupuncture to specific points: Shenmen, Lumbar Spine, Liver, Kidney, Sympathetic, and 1-2 additional points based on associated symptoms [13].

2b) Depth of insertion: 2-3 mm depth is used for insertion.

2c) Needle retention time**:** 30 minutes

2d) Needle type – 7mm filiform sterile needles will be used under aseptic conditions.

Needle application on the first sitting (first day) will be followed by the application of pellets on identical points on the opposite ear, on the second sitting (fourth day) which will be retained for 3 days. The therapy in Intervention group will be given twice a week for 6 weeks

Patient Education will also be administered in Intervention group.

Treatment Protocol for Control Group:

Usual Care comprises of Therapeutic Exercises regimen, Moist Hot packs (Hydrocollator packs). Patient Education will also be administered in this group.

Patients in Control group will be asked to join a supervised exercise program three times a week and for 6 weeks. The exercise program consisted of warm-up (10 minutes), stretching (10 minutes), stabilization exercises (30 minutes), and cool down (5-10 minutes), for a total of 55-60 minutes a day.

Therapeutic Exercises regimen: --

Warm up: Cat Camel poses, Stretching Exercises

Stabilization Exercises:

Stabilizing musculature activation technique: drawing in Manoeuvre, Abdominal bracing, posterior pelvic tilt, Limb loading exercise in supine and quadruped positions, Extremity loading (modified bicycle), Side plank, Curl ups, Diagonal curl ups, Double knee to chest, Pelvic lifts, Prone bridging, Bilateral Straight Leg Raise, Bilateral Straight Leg Lowering (10 repetition with 10 sec holds was done for each exercise)

Cool Down: Arm swings, Walking, Gentle stretching

7.Outcome Measures:

(i) Primary outcome measure: The Numeric Pain Rating scale will be used to measure patient's pain.

Secondary outcome measures:

(i) The Roland Morris Disability Questionnaire (RMDQ) in patients' native language will be used to measure self-rated disability.

(ii) The 21-question version of the Depression Anxiety Stress Scale (DASS21) will be used in patients' native language to measure Depression, Anxiety and Stress in NSLBP patients.

(iii) PROMIS measures (Patient Reported Outcome Measurement Information system) Fatigue 13a in patients' native language will be used to measure fatigue level.

Above tools will be used after taking due permissions.

ISSN:1624-1940
DOI 10.6084/m9.figshare.2632574
http://magellanes.com/

8. Follow-up:
- The NPRS scores, will be evaluated at baseline and at the end of the 2nd, 4th, and 6th week.
Self-rated Disability, Depression, anxiety, and stress level, and Fatigue level will be evaluated at baseline and at the end of 4th week, and at the end of 6th week.
- Participants will be asked to maintain a daily pain and medication diary throughout the study period, a method shown to improve the accuracy of pain reporting [14].

9. Adherence and Retention:
- Reminder calls or text messages will be sent before each session and assessment, a strategy shown to improve adherence in clinical trials [15].
- Participants who miss sessions will be contacted to reschedule and encourage continued participation.
- Reasons for dropout will be recorded and analysed.

10.Concomitant Treatments:
- Participants will be asked to maintain their usual medications and therapies but to refrain from starting new treatments during the study period.
- All concomitant treatments will be recorded and considered in the analysis.

11. Adverse Events:
- Participants will be monitored for adverse events at each session and encouraged to report any unusual symptoms.
- A standardized form will be used to record the nature, severity, and duration of any adverse events, following the guidelines for reporting harms in RCTs [16].

12. Data Collection and Management:
- Data will be collected using standardized case report forms and entered into a secure, password-protected electronic database.
- Regular data quality checks will be performed to ensure accuracy and completeness.
- Data management will follow the Good Clinical Data Management Practices [17].

13. Statistical Analysis:
-Data collected will be cleaned for paucity before the analysis and the categorical variables will be presented in percentages and numerical variables in terms of mean and standard deviations for the demographic and clinical outcomes. Parametric and non-parametric analyses will be done for interpretation of the data.

14. Ethical Considerations:
- The study protocol will be approved by the Institutional Ethical Committee.
- Written informed consent will be obtained from all participants.
- Participants will be free to withdraw from the study at any time without affecting their standard care.
- The study will be conducted in accordance with the Declaration of Helsinki [18].

15. Timeline:
- Months 1-2: Final protocol preparation, staff training, and regulatory approvals
- Months 3-8: Recruitment and baseline assessments
- Months 4-9: Intervention period

ISSN:1624-1940
DOI 10.6084/m9.figshare.2632574
http://magellanes.com/

- Months 5-10: End of treatment assessments
- Months 8-13: Follow-up assessments
- Months 14-18: Data analysis, interpretation, and manuscript preparation

This detailed study design provides a comprehensive framework for conducting a clinical trial on auricular therapy for NSLBP. It addresses key methodological considerations including randomization, blinding, intervention standardization, and follow-up procedures. The design allows for both immediate and longer-term assessment of treatment effects across multiple symptom domains. It will also provide a thorough evaluation of auricular therapy's effect in managing NSLBP.

References:

1. Hoy D, Bain C, Williams G, et al. A systematic review of the global prevalence of low back pain. Arthritis Rheum. 2012;64(6):2028-37
2. Hartvigsen J, Hancock MJ, Kongsted A, et al. What low back pain is and why we need to pay attention. Lancet. 2018;391(10137):2356-67.
3. Chou R, Deyo R, Friedly J, et al. Nonpharmacologic Therapies for Low Back Pain: A Systematic Review for an American College of Physicians Clinical Practice Guideline. Ann Intern Med. 2017;166(7):493-505.
4. Yeh CH, Chien LC, Chiang YC, et al. Auricular point acupressure for chronic low back pain: a feasibility study for 1-week treatment. Evid Based Complement Alternat Med. 2012;2012:383257
5. Oleson T. Auriculotherapy Manual: Chinese and Western Systems of Ear Acupuncture. 4th ed. Edinburgh: Churchill Livingstone; 2013.
6. Gao XY, Zhang SP, Zhu B, et al. Investigation of specificity of auricular acupuncture points in regulation of autonomic function in anesthetized rats. Auton Neurosci. 2008;138(1-2):50-6
7. Murakami M, Fox L, Dijkers MP. Ear Acupuncture for Immediate Pain Relief-A Systematic Review and Meta-analysis of Randomized Controlled Trials. Pain Med. 2017;18(3):551-64.
8. Yeh CH, Chien LC, Balaban D, et al. A randomized clinical trial of auricular point acupressure for chronic low back pain: a feasibility study. Evid Based Complement Alternat Med. 2013; 2013:196978.
9. Froud R, Patterson S, Eldridge S, et al. A systematic review and meta-synthesis of the impact of low back pain on people's lives. BMC Musculoskelet Disord. 2014;15:50.
10. Boutron I, Altman DG, Moher D, et al. CONSORT Statement for Randomized Trials of Nonpharmacologic Treatments: A 2017 Update and a CONSORT Extension for Nonpharmacologic Trial Abstracts. Ann Intern Med. 2017;167(1):40-7.
11. Treweek S, Pitkethly M, Cook J, et al. Strategies to improve recruitment to randomised trials. Cochrane Database Syst Rev. 2018;2:MR000013.
12. Doig GS, Simpson F. Randomization and allocation concealment: a practical guide for researchers. J Crit Care. 2005;20(2):187-91.
13. Oleson T. Auriculotherapy Manual: Chinese and Western Systems of Ear Acupuncture. 4th ed. Edinburgh: Churchill Livingstone; 2013.
14. Stone AA, Shiffman S, Schwartz JE, et al. Patient compliance with paper and electronic diaries. Control Clin Trials. 2003;24(2):182-99.
15. Zweben A, Fucito LM, O'Malley SS. Effective Strategies for Maintaining Research Participation in Clinical Trials. Drug Inf J. 2009;43(4):459-67.
16. Ioannidis JP, Evans SJ, Gøtzsche PC, et al. Better reporting of harms in randomized trials: an extension of the CONSORT statement. Ann Intern Med. 2004;141(10):781-8.

ISSN:1624-1940
DOI 10.6084/m9.figshare.2632574
http://magellanes.com/

17. Society for Clinical Data Management. Good Clinical Data Management Practices (GCDMP). 2013.
18. World Medical Association. World Medical Association Declaration of Helsinki: ethical principles for medical research involving human subjects. JAMA. 2013;310(20):2191-4.