

Study Protocol

Effects of Sphinx Pose (Salamba Bhujangasana) Yoga on Chronic Low Back Pain.

Yusra Saleem^{1,2} , Shamooun Noushad^{3,4} ,
Sadaf Ahmed^{1,2}  & Basit Ansari³ 

¹Psychophysiology Research Lab, MAHQ Biological Research Centre, University of Karachi, Karachi-Pakistan.

²Department of Physiology, University of Karachi, Karachi-Pakistan.

³Department of Health, Physical Education & Sports Sciences, University of Karachi, Karachi-Pakistan.

⁴Department of Public Health, Malir University of Science and Technology, Karachi-Pakistan.

Doi: 10.29052/IJEHSR.v9.i2.2021.263-269

Corresponding Author Email:

yusrasaleem18@gmail.com

Received 03/02/2021

Accepted 12/04/2021

First Published 01/06/2021



© The Author(s). 2020 Open Access This article is distributed under the terms of the Creative Commons Attribution 4.0 International License (<http://creativecommons.org/licenses/by/4.0/>)



Abstract

Background: Chronic Low back pain (LBP) is among the most prevalent conditions distressing the adult population worldwide. The use of complementary and alternative medicinal (CAM) therapies for LBP management has rapidly gained popularity. Yoga is being widely used as mind-body CAM therapy to relieve back pain. The aim is to assess the effectiveness of Sphinx Yoga Pose (Salamba Bhujangasana) in managing CLBP and to measure the variations in the disability index, quality of life (QoL), and stress scores.

Methodology: A randomized controlled clinical trial will be conducted, including the nurses and midwives. Numerical Pain Rating (NPR) Scale, Roland Morris Disability Questionnaire, Fear Avoidance Beliefs Questionnaire (FABQ) will be used for initial screening. Subjects meeting inclusion criteria will be randomly assigned to either of the study group, i.e. Group A (Experimental) and Group B (Control). The Group A subjects will be assigned with Sphinx Yoga therapy for 12 weeks, while group B subjects will be assigned to usual care. Pre and post samples will be collected for Substance P (SP), Beta Endorphins (β -Endorphin), and Cortisol. Moreover, the Oswestry Low Back Pain Disability Index, World Health Organization Quality of Life (WHOQOL) and Sadaf Stress Scale (SSS) will be used at baseline and after 12 weeks follow-up (post-intervention).

Discussion: Offering a 12-week Yoga therapy to the subjects with CLBP might give an insight into its application and efficacy. To be precise, the findings of this research will support the wider implementation of Sphinx Yoga as a lifestyle intervention.

Trial registration: The trial was registered with ClinicalTrials.gov (NCT04721639).

Keywords

Low Back Pain, Healthcare Providers, Yoga Therapy, Sphinx Pose Yoga.



Check for
updates

Introduction

Low back pain (LBP) has become the most frequently reported musculoskeletal complaint resulting in wide-scale disability compared to any other medical condition¹. It is considered as the major reason behind the restricted activity and work absenteeism globally, imposing a high economic burden¹. LBP is more frequent among individuals with stressful jobs. Furthermore, professionals who are more invested in occupations involving prolonged standing, such as that among healthcare providers (HCPs) or drivers, and those exposed to excessive vibrations like miners tend to be more prone to LBP².

The chronic low back pain (CLBP) disorders are mostly non-specific, leading to the diagnostic inability³. Even among cases where a specific radiological diagnosis has been achieved, the underlying pain mechanism often remains concealed. It has multifactorial etiology; the causative factors may be genetic, lifestyle associated, or symptom of a comorbid condition. The presence and dominance of the pathoanatomical, neurophysiological, psychological, physical, and social factors differ from individual to individual³. Numerous workplace and personal factors have been implicated in increasing the probability of LBP development. Muscle strain, sprain, psychological stress and depression are among the major complexities linked to intense work routine.

Among many of the potential targets that have been explored previously, sensitive and accurate biomarkers with abilities to determine the disease's pathological stage and sustain early diagnosis offer definite and correct treatment⁴. Several neuropeptides are involved in nociceptive transmission. These are diverse intercellular signalling molecules that mediate central and peripheral pain perception. Primarily substance P (SP) and beta-endorphins (β -Endorphins) have been presented as the most common pain-related neuropeptides⁵. SP is a known excitatory neuropeptide released from the C-fibers upon tissue damage and/or pain evocation through the activation of neurokinin 1 receptor in the afferent

sensory neurons of the dorsal horn of the spinal cord. Whereas the BE are inhibitory neuropeptides produced in response to a stressful and painful event, primarily by the pituitary gland. BE pre and postsynaptically binds to opioid receptors inhibiting the neuronal firing of peripheral somatosensory fibres. Cortisol is among the major biomarkers studied in association with stress and pain⁶. Initially, a high serum cortisol concentration is observed among patients with acute or chronic pain conditions. But with the increasing pain severity and duration, the HPA axis might ultimately get exhausted and suppressed, resulting in cortisol.

Although a wide variety of treatments are recognized for back pain, such as medication, exercise, self-care, lifestyle modifications, complementary and alternative medicine (CAM) therapies etc., the treatment usually begins with non-steroidal anti-inflammatory drugs (NSAIDs). The patients irresponsive to the analgesic approach are then recommended to opt the nonpharmacological interventions or, more precisely, complementary and alternative medicine (CAM) therapies. The major CAM therapies endorsed for CLBP include transcutaneous electrical nerve stimulation (TENS), acupuncture, massage, and spinal manipulation⁷. More recently, a mind-body intervention-yoga has gained popularity to a greater extent; it involves physical exercise coupled with a focus on breathing. The word yoga determines the body and mind's harmonious relationship; it involves a process of physical and mental training towards self-realization, the practice of which has eight component limbs⁸. Although many randomized control trials (RCT) investigating the beneficial effects of yoga on CLBP have been completed, the outcome measures concerning pain and functional disability vary greatly. A few meta-analyses have shown positive effects^{9,10}.

Scientifically, there is a lack of evidence in support, but the therapeutic effects of yoga among LBP patients have promptly gained weightage in clinical practice. Although the mechanism behind yoga's positive effects on back pain is uncertain, but there

are several plausible benefits, including relief of pain, physical and mental stress. Therefore, we aim to conduct a trial determining whether yoga therapy is effective for CLBP and to understand the underlying physiology.

Methodology

Objective

This clinical trial will evaluate the effect of Sphinx Pose (Salamba Bhujangasana) Yoga on Chronic low back pain and related changes in physiological and physical parameters that help explain its beneficial effects.

Study design

The study will be conducted as a randomized controlled trial in a primary healthcare setting. Based on the eligibility criteria, consenting CLBP patients will be recruited and randomized into two groups. Group A (experimental) will be assigned the "Sphinx Pose Yoga" intervention, and Group B (control) will be assigned to usual care. The study outcomes will be monitored among subjects of both groups at baseline and post-intervention (3-month follow-up).

Ethics

The study will be conducted following the Declaration of Helsinki. All ethical guidelines will be followed and written informed consent will be obtained from the subjects before inclusion. The ethical approval has been obtained from the AEIRC Ethical Review Committee (Reference # ERC/S20/P-002).

Study registration

This study protocol was registered at Clinicaltrials.gov. (Registration no: NCT04721639; Dated: January 22, 2021). Available online: <https://clinicaltrials.gov/ct2/show/NCT04721639>

Participants

Subjects with CLBP (nurses and midwives) will be recruited with no restriction for ethnicity or race from various healthcare facilities of Karachi. The subjects from diverse socio-cultural backgrounds will be considered eligible if they meet the inclusion

criteria. After explaining the study objectives, the subjects will be invited to participate in the study based on their free will.

Eligibility criteria

- **Inclusion criteria**

1. Subjects of both genders between 25 to 45 years of age.
2. Subjects having low back pain complaints and have visited the health care provider in the last 30 days.
3. Score more than or equal to 2 for their pain intensity in the last week on Numerical Pain Rating (NPR) scale (0-10)
4. On the Roland Morris Disability Questionnaire subject's score should be ≥ 4 .
5. Fear Avoidance Beliefs Questionnaire (FABQ) work subscale score must be less than 19.

- **Exclusion criteria**

1. Subjects with high risk for physical injuries during exercise.
2. Pregnant or lactating females.
3. Those having body mass index $> 35 \text{ kg/m}^2$ or presented with unexplained weight loss over the past month ($>10 \text{ lbs}$).
4. Clinically depressed subjects (i.e., subjects who score 24 or higher on the Center for Epidemiology Depression Scale).
5. Subjects with a personal history of neurological disorders including Alzheimer's, amyotrophic lateral sclerosis, multiple sclerosis and Parkinson's.
6. Subjects with musculoskeletal disorders like rheumatoid arthritis, pathologic fractures of the spine, avascular necrosis or osteonecrosis, severe osteoarthritis and history of spine surgery or hip arthroplasty.
7. Those with a history of any cardio-respiratory disorders like congestive heart failure, heart attack in the past 24 months.
8. Subjects who used narcotics or muscle relaxants within 30 days prior to study enrollment.

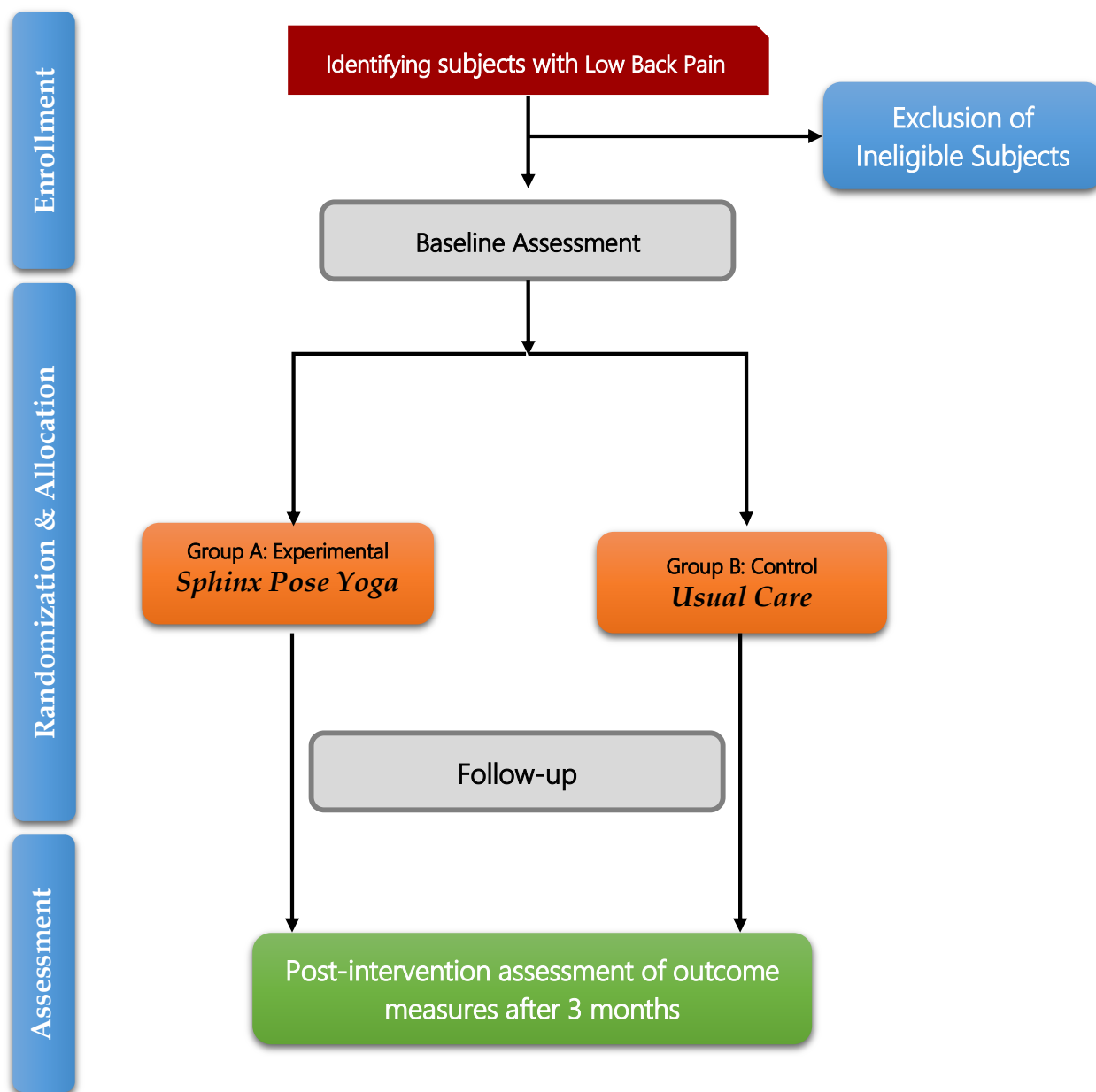


Figure 1: Flowchart of the study.

Interventions

(Group A) The experimental intervention

The Group A subjects will be assigned to Sphinx Yoga therapy, which will take place in conserved therapy centers of various hospitals. These stretching exercise sessions will take place in the afternoon and for a duration of 10 minutes, followed by 30 minutes of therapy session five times per week (total 12 weeks).

(Group B) The control intervention

The Group B subjects will be provided with the usual care following "The Back Book"¹¹.



Sphinx Pose Yoga extends the back gently and activates muscles along the spine. The subject will be asked to lay down on their stomach with feet set hip-width apart, the elbows positioned under the shoulders, and the legs held together. The chin should be pointing towards the floor. Next, the subject is required to pull up the kneecaps, squeezing the thighs and buttocks, pressing the pubic bone into the floor and dropping shoulders back away from the neck and pushing the chest forward. The subject is asked to breathe and hold the pose for two to six breaths in this position. By the end, the subject will be required to exhale, bringing the elbows to the sides and slowly lowering the chest and head to the floor.



Usual Care (Back Book) refers to self-care. It enables subjects to deal with low back pain on their own. Provides the best advice for recovery, avoiding disabilities, and promoting an active routine to lead a normal life. The usual care guide includes details of back pain etiologies, lifestyle modification, with specific guidelines for managing flare-ups.

Recruitment & Assessment Procedures

- HCPs experiencing LBP as per the eligibility criteria will be enrolled.
- All the variables, i.e. Oswestry Low Back Pain Disability Questionnaire, World Health Organization Quality of Life (WHOQOL), Numerical Pain Rating Scale, Sadaf Stress Scale (SSS), Substance-P, Cortisol and Beta Endorphins will be measured at baseline.
- Eligible consenting subjects will be randomly allocated to the experimental or control group.
- Outcome measures assessed at baseline will be re-assessed post-intervention (after 3 months).
- Pre & post-analysis will be conducted.

Outcome Measures

Along with the subject's demographic characteristics such as age, gender, weight, height, ethnicity, etc., we have carefully selected measurement instruments to assess the yoga associated physiological, and physical parameters changes:

Social & physical measures

- a. Quality of Life-World Health Organization Quality of Life (WHOQOL)
- b. Disability Index (Low Back Functionality)-Oswestry Low Back Pain Disability Questionnaire
- c. Physical Stress-Sadaf Stress Scale

Physiological measures

- a. Substance P
- b. Beta-Endorphins
- c. Cortisol

Sample Size

The required sample size for the two study groups with $\alpha = 0.05$ and $(1 - \alpha) = 0.80$ was estimated to be 49 in each group, i.e. the total sample size was 98 for two groups. The sample size calculator provided by the University of California, San Francisco (UCSF) Clinical & Translational Science Institute (CTSI) was used¹².

Randomization

After assessing the eligibility, the subjects will be randomly allocated in the ratio of 1:1 to the study groups (experimental and control). The randomization sequence will be computer-generated. After acquiring the basic information, a unique code will be assigned to each study participant, which will then be mentioned in their Performa.

Statistical Analysis

The data will be analyzed using the intention-to-treat approach. Chi-square tests and 2×2 mixed factorial design analysis of variance (ANOVA) will be used for comparing the baseline data across the randomized groups. The difference in the outcome variables (disability index, quality of life, and physical stress) at the follow-up among the subjects of both experimental and control groups will be assessed using linear regression. Sequentially for each outcome, additional ANOVAs will be used to investigate the difference between randomized groups at baseline and 3 months after the intervention. A 2-sided α level of 0.05 will be considered statistically significant for all tests.

Discussion

Literature suggests that offering yoga therapy to CLBP subjects improves low back functionality and overall quality of life^{13,14}. A randomized controlled trial conducted by Tilbrook et al. comparing the effectiveness of yoga and usual care for CLBP showed that the yoga therapy resulted in enhanced back functionality and reduced the disability index as compared to usual care¹⁴.

According to a meta-analysis conducted by Zhu et al. with 18 randomized controlled trials, the most consistent evidence emerged for short to an intermediate-term reduction in the pain through yoga therapy as compared to non-interventional groups. However, the improvement in the functional disability status is long-term. Zhu et al. also added that Yoga and other exercise or physical therapy had a very similar effect on pain and disability¹⁵.

As per the existing literature, Yoga therapy could be recommended as an additional therapy for the subjects with chronic low back pain⁹. But its effectiveness could only be driven by comparing the yoga therapy with other exiting interventional therapies for CLBP¹⁰.

Conflicts of Interest

The authors have declared that no competing interests exist.

Acknowledgement

We would like to acknowledge the support of researchers from Koochi Goth Women Hospital who helped us in identifying the potential study groups.

Funding

The author(s) received no specific funding for this work.

References

1. Parreira P, Maher CG, Steffens D, Hancock MJ, Ferreira ML. Risk factors for low back pain and sciatica: an umbrella review. *Spine J.* 2018;18(9):1715-1721.
2. Landry MD, Raman SR, Sulway C, Golightly YM, Hamdan E. Prevalence and risk factors associated with low back pain among health care providers in a Kuwait hospital. *Spine.* 2008;33(5):539-545.
3. O'Sullivan P. Diagnosis and classification of chronic low back pain disorders: maladaptive movement and motor control impairments as underlying mechanism. *Manual therapy.* 2005;10(4):242-255.
4. Khan AN, Jacobsen HE, Khan J, Filippi CG, Levine M, Lehman Jr RA, Riew KD, Lenke LG, Chahine NO. Inflammatory biomarkers of low back pain and disc

- degeneration: a review. *Ann. N. Y. Acad. Sci.* 2017;1410(1):68-84.
5. Riley III JL, Cruz-Almeida Y, Ribeiro MC, Simon CB, Eckert NR, Aguirre M, Sorenson HL, Tighe PJ, Edwards RR, Walleit SM. Age differences in the time course and magnitude of changes in circulating neuropeptides after pain evocation in humans. *J Pain.* 2017;18(9):1078-1086.
 6. Muhtz C, Rodriguez-Raecke R, Hinkelmann K, Moeller-Bertram T, Kiefer F, Wiedemann K, May A, Otte C. Cortisol response to experimental pain in patients with chronic low back pain and patients with major depression. *Pain Medicine.* 2013;14(4):498-503.
 7. Matthews ML, Wooding FG, Folta AQ. Management of Chronic Low Back Pain. *US Pharmacist.* 2008;33(5):34.
 8. Chang DG, Holt JA, Sklar M, Groessl EJ. Yoga as a treatment for chronic low back pain: A systematic review of the literature. *J ortho rheumatology.* 2016;3(1):1.
 9. Cramer H, Lauche R, Haller H, Dobos G. A systematic review and meta-analysis of yoga for low back pain. *Clin. J. Pain.* 2013;29(5):450-460.
 10. Holtzman S, Beggs RT. Yoga for chronic low back pain: a meta-analysis of randomized controlled trials. *Pain Res. Manag.* 2013;18(5):267-272.
 11. Burton K, Klaber Moffett J, Main C, Roland M, Waddell G. *The Back Book.* 2nd ed. Norwich TSO 2002.
 12. Kohn MA, Jarrett MS, Senyak J. Sample size calculators. Clinical & Translational Science Institute. 2017. Available at: <http://www.samplesize.net/correlation-sample-size>. 2016.
 13. Tekur P, Chametcha S, Hongasandra RN, Raghuram N. Effect of yoga on quality of life of CLBP patients: A randomized control study. *Int J yoga.* 2010;3(1):10.
 14. Tilbrook HE, Cox H, Hewitt CE, Kang'ombe AR, Chuang LH, Jayakody S, Aplin JD, Semlyen A, Trehwela A, Watt I, Torgerson DJ. Yoga for chronic low back pain: a randomized trial. *Ann Inter Med.* 2011;155(9):569-578.
 15. Zhu F, Zhang M, Wang D, Hong Q, Zeng C, Chen W. Yoga compared to non-exercise or physical therapy exercise on pain, disability, and quality of life for patients with chronic low back pain: A systematic review and meta-analysis of randomized controlled trials. *PLoS one.* 2020;15(9):e0238544.