DEVELOPMENT AND VALIDATION OF A YOGA MODULE IN PATIENTS WITH ANKYLOSING SPONDYLITIS

A SYNOPSIS OF THE THESIS SUBMITTED TO THE JADAVPUR UNIVERSITY FOR THE DEGREE OF DOCTOR OF PHILOSOPHY IN ARTS

By

Prasenjit Kapas

Department of Physical Education

(Faculty of Arts)

Jadavpur University

Jadavpur, Kolkata-700032, West Bengal

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Introduction:

Ankylosing spondylitis (AS), a spondyloarthropathy[1], represents an autoimmune rheumatic disease that triggers inflammation leading to chronic back pain plus stiffness, which intensifies after rest or in the morning, along with hip and shoulder pain and stiffness in rib or neck areas, fatigue symptoms, and decreased flexibility resulting in hunched back posture.[2,3,4,5,6,7] In early stages of AS, erosive changes occur in the vertebral bodies[8]. The disease progresses to cause complete vertebral column fusion known as bamboo spine during its advanced stages due to chronic inflammation.[9,10] AS progresses through cytokine-mediated syndesmophyte formation, which results in complete fusion and rigidity, causing serious mobility limitations and life quality reduction.[11,12,13]

Besides the conventional therapeutic treatment for ankylosing spondylitis, like non-steroidal anti-inflammatory drugs (NSAIDs), DMARDs (disease-modifying antirheumatic drugs), and biologic agents, non-pharmacological management is considered the essential for AS.[14,15]The multimodal approach of exercise intervention, like aerobic exercises, strength training, and flexibility exercises, and tailored exercise with relaxation techniques and mindfulness help to improve the mobility and quality of life, alleviate pain, reduce the psychological challenges, and improve their overall well-being.[16]Regular home-based exercise helps the patients to improve pulmonary functions and quality of life.[17] Systematic exercise programs, whether they are home-based or supervised, have demonstrated positive effects on disease activity score, pain level, and functional capacity.[18]

Yoga as a psycho-physical therapy combined with physical posture, breathing regulation, relaxation and mindfulness can be a particular therapy that helps to reduce the progression of disease in patients with ankylosing spondylitis. In several studies, yoga has demonstrated the positive effects on rheumatoid arthritis (RA), suggesting that it could be valuable complementary therapy for managing rheumatic disorders. A randomized controlled trial showed that 12 weeks of yogic practice with standard medications help to reduce disease activity score, inflammatory markers (interleukin-1a (IL-1a), IL-6, tumor necrosis factor-a (TNF-a), and cortisol), and improves sympathovagal balance.[19] Another study found that yoga as a mind-body intervention (MBI) helps in significant reduction of the severity level of RA, like systematic inflammatory markers and disease activity.[20] A structured yoga practice of one and a half hours per day for seven weeks showed a significant reduction in joint inflammation, early morning stiffness, pain intensity, pulse rate, blood pressure, lymphocyte

count, uric acid level, and C-reactive protein for RA patients.[21] Yoga has been demonstrated as a promising complementary practice for arthritis.[22,23] While there are few studies of yoga in rheumatoid arthritis[21,23], are available, studies examining the impact of yoga on ankylosing spondylitis are limited. An extensive search of scientific literature yielded only a single study on yoga module in AS[24], which is however, limited by the methodology used, especially the choice of specialists or stakeholders involved.

Therefore, a study to develop a validated integrated yoga module was undertaken which could greatly enhance the management of AS, complementing conventional treatments and potentially improving patients' quality of life.

Objectives of the Study:

1) To develop and validate a yoga module for patients with Ankylosing Spondylitis based on the opinions of experts from relevant related disciplines.
2) To examine the feasibility and effectiveness of the validated yoga module on selected psychological variables (depression, fear avoidance belief, pain catastrophizing and health related quality of life), physiological variables (haemoglobin and platelet count), general health status (BMI, blood pressure, heart rate), clinical outcome measures (BASDAI, BASFI, BASMI, Chest expansion) and inflammatory markers(CRP, ESR, TNF alpha) by comparing patients receiving conventional treatment alone with those receiving conventional treatment combined with yoga practice.

Hypothesis

H_0: There will be no significant differences between the combined group (medicine + yoga) and the conventional group on psychological, physiological, health status, clinical outcome measures and inflammatory markers after 24 weeks.

Brief Summary of Review of related literature:

A systematic literature review was conducted using keywords related to yoga, low back pain, rheumatic and autoimmune disorders, inflammatory markers, and Ankylosing Spondylitis (AS) across major databases (PubMed/Medline, Cochrane Library, EMBASE, Web of Science, and DOAJ). Out of 824 initially identified records, 125 studies met the inclusion

criteria. The reviewed literature consistently indicates that yoga and other mind-body interventions have beneficial effects across a range of chronic pain conditions. Evidence shows that yoga significantly reduces pain severity and functional disability in chronic low back pain, sometimes proving as effective as conventional physical therapy. Several studies report that yoga regulates inflammatory processes through reductions in pro-inflammatory cytokines (e.g., IL-6, TNF-α) and increases in anti-inflammatory markers. Notably, yoga benefits both physical and psychological dimensions of chronic illness. Emerging literature further highlights the usefulness of tele-yoga for patients who are unable to attend in-person sessions.

The reviewed evidence also suggests that yoga is a promising complementary therapy for managing chronic musculoskeletal and inflammatory conditions, particularly low back pain and Ankylosing Spondylitis. Yoga supports holistic health by alleviating pain, improving physical function, enhancing quality of life, and reducing inflammatory activity. The growing findings on tele-yoga and molecular pathways underscore yoga's potential as both an accessible and scientifically grounded therapeutic modality. Further clinical trials and mechanistic studies are warranted to optimize and standardize yoga interventions for individuals with chronic inflammatory disorders.

Methodology:

The study is divided into three Stages: Part-I is the development of a Yoga Module, part-II is the validation of yoga module through expert's opinion and in part-III is the test the feasibility of that module through experimentation.

Part I: Literature search and Yoga module development

At the initial phase of the study, 12 internal yoga experts from West Bengal were approached for the review process. All experts had a minimum qualification of a Master's degree in yoga or a related discipline and at least five years of professional experience. Eligibility was determined based on (i) strong foundation knowledge of yogic text and literature and (ii) substantial research publication in the field of yoga. Out of 12 experts, 10 accepted the invitation to participate. Among them, four experts critically reviewed classical yogic literature (e.g., Shiva Samhita, Patanjali Yoga-sutra, Hatha Yoga Prodipika, Gherend Samhita and Hatha Ratnavali) along with contemporary yoga realted publication, while the

remaining 6 experts conducted a systematic search of scientific databases (Web of science, Scopus, Pubmed and Google Scholar) using predefined and maximum possible keywords related to pain management, spinal flexibility, and quality of life in musculoskeletal disorders(e.g., “Yoga and inflammatory back pain”, “Yoga and Ankylosing spondylitis”, “Yoga and chronic low back pain”, etc.)

After completion of the review process, a total 80 yogic practices were systematically developed as a preliminary therapeutic module for Ankylosing Spondylitis. Develop yoga module consisted of 14 loosening exercise (sukhsma vyama), 37 customized asana(physical posture), 6 breathing exercise, 16 pranayama practices (breathing techniques) 3 relaxation techniques and 4 meditation(dhyana) practices.

Part II: Validation of Yoga module by Experts

In the second phase of the study, content validation of the preliminary yoga module (containing 80 yogic techniques identified in Part I) was performed by experts from diverse fields. A total of 36 experts were approached through Google Forms (https://forms.gle/nq22uBbU3ezDH3e88) and email, including 22 yoga experts, 6 rheumatologists, and 6 specialists in physical medicine and rehabilitation, from various medical and academic institutions across India. Experts with a minimum of 5 years of professional experience and at least a Master’s degree in the relevant field were included.

The Google Form consisted of seven sections: Expert demographics (name, degree, affiliation, experience) Loosening exercises/Sūkṣma Vyāyāma, Asana, Breathing practices (preparatory techniques for pranayama), Pranayama, Relaxation techniques Meditation. Experts were rating the each yogic practices in patients with Ankylosing Spondylitis as a) very much useful (Essential), b) moderately useful (Important, but not essential), c) Not at all useful (Not necessary).

A total of 26 experts responded. The Lawshe Content Validity Ratio[25] (CVR) was applied using the formula: CVR (Critical) = (ne –N/2)/N/2 for a panel size (N) of 26 is 0.385 where, ‘ne’ is the number of panel experts indicating the item is ‘essential’, N is the total number of experts in the pane. For a panel size of 26, the minimum acceptable CVR was 0.385.

Based on CVR values, 38 out of 80 yogic techniques met the threshold (CVR ≥ 0.385) and were retained, while 42 techniques were excluded. CVR values ranged from 0.385 to 0.846, indicating good agreement among experts. The highest-rated practices included Anulom-Vilom Pranayama (CVR 0.846), OM meditation (CVR 0.846), Makarasana (CVR 0.769), and Antarmukha–Bahirmukha Hastaprasara Vyāyāma (CVR 0.769).

To ensure maximum therapeutic benefit for Ankylosing Spondylitis, the validated yoga module was structured for a 1-hour session, allocating approximately: loosening exercises (7 min), asanas (14 min), breathing exercises (6 min), pranayama (12.5 min), relaxation (7.5 min), and meditation (9 min).

Part III: Experimental evaluation of the validated module

In the third phase, feasibility of the validated yoga module was assessed. Using convenient sampling and G*Power analysis to determine the effect size, 70 male patients with Ankylosing Spondylitis were recruited from the OPD of the Clinical Immunology and Rheumatology Department, IPGMER, Kolkata. Diagnosis was confirmed using BASDAI and BASFI questionnaires along with evaluation by a certified rheumatologist. Participants were randomly allocated into two groups: Yoga Group (YG, n = 35) and Control Group (CG, n = 35). The YG received the validated yoga module for 24 weeks in addition to standard medical care, while the CG received standard medical treatment only. At study completion, 29 participants remained in each arm, and all statistical analyses were performed on these 29 participants per group. TNF-α level were below the assay detection limit in 3 patients from each group; therefore, TNF-α analysis was performed using the available 26 samples per group.

Demographic variables (age, height, weight, disease duration), general health measures (BMI, blood pressure, heart rate), disease activity and functional indices (BASDAI, BASFI, BASMI, chest expansion), and haematological and inflammatory markers (haemoglobin, platelet count, CRP, ESR, TNF-α), along with psychological parameters (Fear-Avoidance Belief Scale, pain catastrophizing, and health-related quality of life) were collected at baseline, 12 weeks, and 24 weeks.

For statistical analysis, Mann–Whitney U tests were used for between-group comparisons (YG vs CG) at all three time points due to non-normal distribution of data.

Friedman test (non-parametric repeated-measures ANOVA) with Bonferroni correction was applied to analyse within-group changes over time using SPSS Version 27.

Results:

At baseline, there were no significant differences between the yoga and control groups, confirming comparability prior to the intervention ($p > 0.05$).

After 12 weeks of intervention, the comparison showed no significant differences in BMI, systolic blood pressure, diastolic blood pressure, and heart rate ($p > 0.05$). Significant improvements were found in the yoga group for disease activity (BASDAI), functional status (BASFI), spinal mobility (BASMI), and chest expansion ($p < 0.05$). For haematological variables, haemoglobin showed significant improvement in the yoga group ($p < 0.05$), while platelet count was not significantly different ($p > 0.05$). Inflammatory markers ESR and CRP significantly decreased following yoga compared to control ($p < 0.05$), whereas TNF-alpha showed no significant difference ($p > 0.05$). Psychological outcomes demonstrated significantly lower depression and reduced FABQ scores in the yoga group ($p < 0.05$). Pain catastrophizing scores—rumination, magnification, helplessness, and total PCS—were significantly lower in the yoga group ($p < 0.05$). All dimensions of HRQoL were significantly higher in the yoga group compared to control ($p < 0.05$).

After 24 weeks of intervention, the comparison indicated no significant differences found between groups for BMI and blood pressure ($p > 0.05$), but heart rate significantly improved in the yoga group ($p < 0.05$). Disease activity, functional and metrology indices, and chest expansion remained significantly better in the yoga group ($p < 0.05$). Heamoglobin, platelet count, ESR, CRP, and TNF-alpha all showed statistically significant improvement in the yoga group ($p < 0.05$). Depression and fear-avoidance beliefs continued to be significantly reduced in the yoga group ($p < 0.05$). All components of pain catastrophizing and overall HRQoL remained significantly superior in the yoga group ($p < 0.05$).

Compared to the control group, yoga produced multidimensional and sustained clinical benefits, including improved disease activity, physical functioning, inflammatory profile, psychological well-being, pain perception, and quality of life in patients with Ankylosing Spondylitis, with statistically significant effects ($p < 0.05$) observable as early as 12 weeks and becoming stronger and broader by 24 weeks.

Across the three assessment phases i.e., baseline, post-12 weeks, and post-24 weeks—the yoga and control groups showed divergent trajectories. In both groups, BMI, systolic blood pressure, and diastolic blood pressure did not change significantly over time ($p > 0.05$); however, heart rate demonstrated a significant time effect in both groups, with a more favourable reduction in the yoga group ($p < 0.001$) compared to the control group ($p = 0.003$). In terms of disease-specific outcomes, the yoga group exhibited significant and progressive improvements in BASDAI, BASFI, BASMI, and chest expansion (all $p < 0.001$), whereas the control group showed either non-significant or adverse changes, with BASDAI and BASMI worsening despite reaching statistical significance ($p = 0.01$ and $p = 0.001$), and BASFI and chest expansion remaining non-significant ($p > 0.05$). A similar contrast was evident in biochemical and inflammatory markers: haemoglobin increased significantly in the yoga group ($p = 0.03$) but decreased in the control group ($p = 0.05$), platelet count did not change in either group ($p > 0.05$), and ESR, CRP, and TNF-α decreased significantly in the yoga group ($p = 0.04$, $p = 0.004$, $p = 0.03$), while the control group showed significant increases in ESR and CRP ($p = 0.001$ and $p = 0.03$) and a non-significant increase in TNF-α ($p > 0.05$). Though after multiple comparison analysis by bonerroni correction, ESR showed not significant in any phases. The yoga group demonstrated significant reductions over time in depression, fear-avoidance beliefs, and all components of pain catastrophizing ($p < 0.05$), whereas the control group showed significant deterioration across the same psychological variables ($p < 0.05$). Finally, health-related quality of life improved progressively and significantly at every phase among yoga participants ($p < 0.05$), while the control group experienced significant declines over time ($p < 0.05$), indicating worsening perceived overall well-being. Overall, the 24-week trajectory clearly shows that yoga resulted in sustained multidimensional improvement, while the absence of yogic intervention was associated with stagnation or deterioration across physical, inflammatory, psychological, and quality-of-life parameters.

From baseline to post-12 weeks and baseline to post-24 weeks, the yoga group demonstrated clear and progressive improvements across multiple health domains, whereas the control group showed deterioration. Although BMI, systolic and diastolic blood pressure did not change significantly in the yoga group, heart rate showed a significant reduction at both post-12 weeks and post-24 weeks ($p = 0.00$), while the control group exhibited gradual increases in all general health parameters across both intervals. Disease-specific clinical outcomes improved substantially in the yoga group, with significant reductions in BASDAI,

BASFI, and BASMI and significant increases in chest expansion at both post-12 weeks and post-24 weeks (all $p < 0.05$), whereas the control group showed rising BASDAI, BASFI, and BASMI scores and declining chest expansion over the same duration. Yoga also produced significant haematological and inflammatory improvements, reflected by increases in haemoglobin ($p = 0.003$ at post-12 weeks; $p = 0.00$ at post-24 weeks) and reductions in ESR, CRP, and TNF-α (all $p < 0.05$), while the control group demonstrated elevations in ESR, CRP, and TNF-α and no meaningful change in platelet count. Psychological outcomes further reinforced this contrast, as the yoga group showed significant reductions in depression ($p = 0.00$) and fear-avoidance beliefs ($p < 0.001$) across both time points, whereas the control group demonstrated worsening trends. Similar patterns were noted in pain catastrophizing, in which the yoga group showed marked reductions across all subscales and the PCS total score, while the control group showed progressive increases. Finally, health-related quality of life significantly improved across all domains in the yoga group ($p < 0.05$), in contrast to the control group, which displayed overall decline or minimal improvement. Collectively, these findings demonstrate that sustained yoga intervention for 24 weeks leads to substantial improvements in physiological, inflammatory, psychological, and quality-of-life outcomes in individuals with Ankylosing Spondylitis, while the absence of yoga is associated with worsening of disease-related and psychosocial parameters.

Brief Discussion:

The findings of the present study demonstrate that a 24-week yoga intervention produced clinically meaningful improvements across disease activity, functional status, spinal mobility, inflammatory markers, psychosocial health and overall quality of life in patients with Ankylosing Spondylitis (AS). The progressive reduction in BASDAI, BASFI, and BASMI scores suggests that yoga contributed to decreased disease activity, enhanced daily functioning, and improved spinal flexibility. These outcomes are consistent with earlier reports showing improved mobility and pain reduction in AS following yoga-based therapeutic practices[26 27 28]. The significant increase in chest expansion further supports the mechanical benefits of yoga by enhancing thoracic mobility and respiratory efficiency, which is essential due to the restrictive pulmonary involvement commonly noted in AS.

The intervention also produced favourable biochemical responses. Reductions in CRP, ESR, and TNF-α indicate attenuation of systemic inflammation, aligning with previous evidence that yoga modulates inflammatory pathways and reduces pro-inflammatory cytokines in

chronic inflammatory diseases[19]. Improved haemoglobin levels suggest a positive shift in hematological status, possibly attributable to reduced chronic inflammation and improved autonomic and metabolic regulation. Additionally, a decrease in heart rate reflects enhanced parasympathetic activation and improved cardiovascular efficiency, consistent with established autonomic effects of yoga practice.

Importantly, significant improvement was also observed in psychological outcomes, including reduced depression, fear-avoidance behaviour, and pain catastrophizing, along with increased health-related quality of life. These findings support earlier studies demonstrating that yoga mitigates psychological distress and enhances adaptive coping in chronic rheumatologic disorders through mind-body mechanisms and stress-response regulation (Nair et al., 2022).[29] Physical, biochemical, and psychosocial improvements indicate that yoga may exert therapeutic benefits through both biomechanical and psycho-neuro-immune pathways.

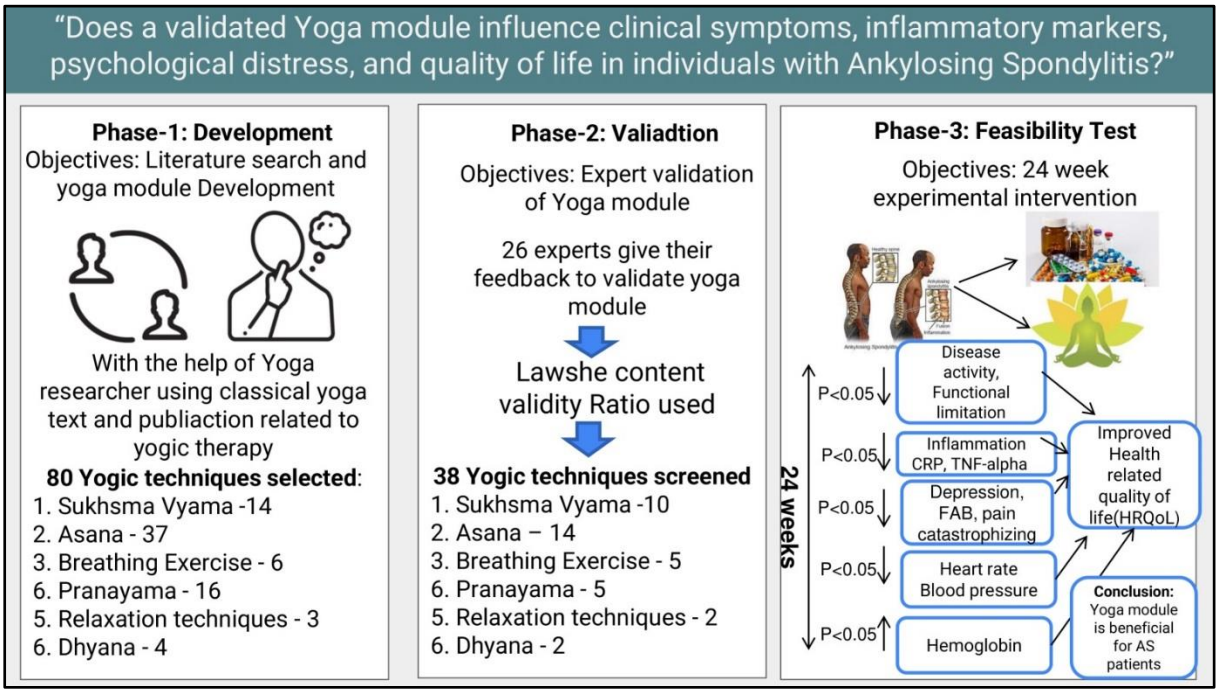
Compared with the control group—which showed minimal or no significant improvements—the yoga group exhibited distinctly superior outcomes across all parameters, suggesting that yoga can serve as an effective adjunctive therapy rather than merely an optional wellness activity. Although some meta-analyses have reported inconsistent effects of yoga on inflammatory markers in rheumatologic disorders, the present findings support the view that sufficient intervention duration, regularity, and condition-specific module design are key determinants of therapeutic benefit.

Overall, this study adds to the limited but growing body of evidence supporting yoga in the management of AS and highlights the value of integrating structured yoga module with long-term practices alongside standard medical care. Further randomized controlled trials with larger samples and mechanistic evaluations are warranted to fully elucidate the pathways through which yoga influences musculoskeletal and inflammatory outcomes in AS.

Conclusions:

The study successfully fulfilled its primary aim of developing, validating, and evaluating the feasibility and clinical effectiveness of a yoga module tailored for individuals with Ankylosing Spondylitis. The module was systematically designed through evidence-based procedures and expert validation, ensuring clinical safety and appropriateness. Findings from the 24-week intervention confirmed that patients receiving conventional treatment combined

with yoga achieved significantly greater improvements than those on conventional treatment only. Notable benefits were observed across psychological (depression, fear-avoidance beliefs, pain catastrophizing, HRQoL), physiological (haemoglobin), general health (heart rate), clinical outcomes (BASDAI, BASFI, BASMI, chest expansion), and inflammatory markers (CRP, TNF-α), rejecting the null hypothesis and supporting the alternate hypothesis. These improvements indicate reduced disease activity, enhanced functional ability and spinal mobility, better autonomic regulation, lowered inflammatory response, and improved emotional well-being and quality of life. Overall, the findings confirm that the validated yoga module is feasible, safe, and therapeutically valuable as a complementary approach for Ankylosing Spondylitis, with strong potential for long-term disease management, disability reduction, and integration into multidisciplinary rehabilitation and future clinical guidelines.



Visual Abstract of the entire study

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