Designing, validation, and the feasibility of a yoga module for patients with ankylosing spondylitis

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1. Introduction

Ankylosing spondylitis (AS) is a chronic progressive, inflammatory, immune-mediated arthritis that primarily affects the axial skeleton and sacroiliac joints [1]. The spinal and extra-skeletal manifestation of AS contributes to substantial disability. It leads to stiffness, pain, and reduced flexibility of the spine, causing significant detoriation in functions. AS is associated with 11% lower employment and 15% higher disability at work. AS-related disability contributes to the financial crisis through job loss and increased healthcare cost. Approximately 31% of AS patients quit

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their job due to disability [2,3]. Limited functioning, pain, and reduced socialism in AS patients leads to substantially poor quality of life.

Thus, improving spinal flexibility and the quality of life of patients are the two important objectives of AS management. Complementary therapies such as yoga have shown to be effective in improving pain, quality of life, and disability in several chronic conditions such as back pain [4,5]. Yoga is a mind–body intervention that includes yogic physical postures, breathing techniques, relaxation, and meditation. Yoga has become a popular alternative and complementary intervention in various chronic health conditions. Yoga intervention has been found to be beneficial in different types of musculoskeletal pain conditions such as chronic lower back pain, fibromyalgia, cervical spondylitis, and osteoarthritis of the knee. It also improves the quality of life [6-11]. These studies have indicated the positive role of yoga intervention in patients with back pain. Yoga practice may help in AS condition also. However, there are no structured yoga modules available for AS patients. Further, literature suggests the need of yoga studies in AS patients. Hence, a structured and validated yoga module needs to be developed for AS. The present study developed a structured yoga module and validated it for AS patients. It also evaluated the feasibility, acceptability, and efficacy of the module to reduce pain and improve physical functioning.

2. Methods

The study was conducted in three phases (Fig. 1).

2.1. Phase I: development of the yoga module

In Phase I of the study, both classical and contemporary yoga texts were viewed to develop a yoga module to alleviate pain and disability and improve the quality of life in AS patients. Three experts were invited for the literature review. Five classical texts, namely Hath Yoga Pradipika [12], Gheranda Samhita [13], Patanjali Yoga Sutra [14], Hath Ratnavali [15], and Shiva Samhita [16], were reviewed by these experts. Research articles on pain management, spinal flexibility, and quality of life in patients with musculoskeletal problems such as chronic lower back pain, cervical spondylitis, slip disc, and fibromyalgia were also reviewed using search engines like PubMed, Google Scholar, Scopus, and ScieFinder using keywords “yoga” and “pain”, “back pain”, “cervical pain”, “spinal flexibility”, “ankylosing”, and “spondylitis”.

2.2. Phase II: validation of yoga module

The validation process was performed by inviting experts who fulfilled the following eligibility criteria: (a) a minimum of five years of field experience in clinical yoga and (b) actively involved in treating pain conditions and musculoskeletal conditions by yoga intervention. Academicians and non-clinical yoga practitioners were excluded.

Sixty-eight potential experts were approached. Of them, 52 responded and were evaluated according to the eligibility criteria. Forty-eight of these experts were found to be eligible. Of 48 experts, 46 agreed and shared their opinion on the yoga module. Of their submissions, 5 were found to be incomplete. Fig. 2 presents the recruitment of experts in the study including the number of experts approached, eligible experts, and experts who performed the final validation.
The yoga module was shared with the experts with a brief explanation of the study's background and objectives along with the list of practices to be rated. The yoga experts were requested to rate each practice in the yoga module on a scale of 0–2 (0: not useful, 1: useful but essential, 2: essential). If they wished to, the experts could also provide their subjective opinion on each practice.

The Lawshe content validity ratio (CVR) method was used for determining the content validity of the yoga module [17]. CVR was used to validate each practice. CVR = \( (n_e - N/2)/N/2 \) — where \( ne \) is the number of experts indicating a practice 'useful' and \( N \) is the total number of experts for considering a particular yoga practice in the final yoga module.

2.3. Phase III: feasibility testing of the validated yoga module

A pilot study was conducted on 19 AS patients to assess the acceptance and feasibility of the validated yoga module. Feasibility was assessed on the basis of the attrition rate, retention rate, and subjective difficulty during the practice. They were also requested to opine on an overall 1-month yoga intervention.

2.3.1. Inclusion and exclusion criteria

Participants the feasibility study were consented AS patients (previously diagnosed by rheumatologists based on New York AS diagnosis criteria) within the age range 30–50 years. Participants were excluded if they had severe disability, undergone spinal/abdominal surgery in the last 1 year, previous expose to yoga practice, receiving physiotherapy, heart failure, vertigo.

2.3.2. Participants

Participants were invited from Anthardwani centre, Gujarat, India. An advertisement was placed on the notice board, and a text message was sent to all the AS patients who were members of the Anthardwani centre. Total fifty-seven AS patients were screened for eligibility criteria. Of these, thirty-two patients found eligible. Seven participants declined to participate in the study and twenty-five completed baseline assessments and enroll the study (See Fig. 3). The average age of patients was 35.5 \( \pm \) 10.7 years. Weekly, three supervised yoga sessions were conducted for 1 month. Yoga therapist administered the yoga protocol. Finally, nineteen patients completed the intervention and post assessment. Six patients dropped out during the intervention phase due various personal regions. None of the drop-outs were attributed to adverse effects of the intervention.

Fig. 3. Recruitment.

| Assessed for eligibility (n = 57) | Excluded (n = 30) |
|----------------------------------|------------------|
| \( \cdot \) Not meeting inclusion criteria (n = 25) | \( \cdot \) Refused to participate (n = 7) |
| Completed baseline assessment (n = 25) | Lost to follow-up (n = 6) |
| \( \cdot \) Due to shift of location – 3 | \( \cdot \) Hospitalized for some health issue not related to intervention – 1 |
| \( \cdot \) Did not come for post assessment due to personal reasons | Completed the study (n = 19) |

Table 1. Demographics of experts.

| Average age (years) | 36.7 \( \pm \) 7.2 |
|---------------------|-------------------|
| Gender distribution | N = 41; Men = 33; Women = 8 |
| Average experience in the field (years) | 10.07 \( \pm \) 5.72 |
| Education levels | PhD = 11, Post graduation = 25, Graduation = 5 |
The percentage of responses suggesting a high efficacy of the yoga module (\( \geq Q3 \)) was 85% (17/20). When analysed separately, the percentage of participants claiming pain reduction in the pain and improvement in the spinal flexibility with a yoga practice was 100% and 96%, respectively. Yoga practices in the module may have a high efficacy in reducing pain and increasing spinal flexibility, which is of high clinical significance.

A checklist for evaluation of subjective experience about usefulness of individual practices was given to all the participants. Participants rated their subjective experience on a 0–3 scale (not useful and 3–extremely useful). The majority of the patients experienced relaxation and improvement in the flexibility following the yoga intervention. No participant has reported any adverse events during the intervention. This is suggestive of safety and feasibility of the yoga module.

### 4. Discussion

This study provides a validated yoga module for patients with AS. This module was found to be acceptable, easy to practice, and feasible to use for patients with AS. Most patients were able to practice minimum 30 min each day in the pilot study. We...
recommend practising the present yoga module under the guidance of an expert yoga instructor.

AS affects the axial skeleton, leading to significant disability [18]. Pain reduction and mobility enhancement are the primary objectives of AS management. Forty-one yoga experts validated the study. The study used the CVR method, which has been used in many previous studies, for content validity. Ten practices were omitted from the designed yoga module, which included some loosening practices and asanas. The validated module can be practiced for a minimum of 3 days a week for 3 months to obtain desirable results. A feasibility study confirms the usefulness and acceptability of the validated module. Most pilot study participants reported that the yoga module enhanced relaxation, reduced pain, and improved flexibility. No adverse effects were reported during the pilot study. Of the 25 participants who agreed to participate, 6 dropped out; 3 had difficulty in visiting the centre, 1 had medical emergencies (not due to yoga), and 2 had to relocate.

The practices listed in the yoga module are simple and easy to practice. These practices help to improve spinal flexibility. The practices such as relaxation techniques and breathing practices may help to improve pain sensitivity and pain tolerance. Yoga practice is associated with increased endorphin levels and reduced HPA axis activity. Yoga is known to improve spinal flexibility among patients with chronic low back pain [19–21].

The yoga module for AS was developed and validated using robust methods. The yoga practices included in the module were based on classical texts and contemporary literature review. The yoga experts were from different schools of yoga and were clinicians and researchers who were actively involved in the yoga therapy. The module consisted of all loosening practices, yoga postures, and yoga breathing techniques in addition to various relaxation practices. Validation was performed using the CVR method. A validated yoga module was confirmed for feasibility from a pilot study conducted on 19 participants.

This study has several limitations. We did not find a direct reference of the health benefits of yoga practices in classical texts. However, we conducted a recent literature search in which practices that were used to improve pain and spinal flexibility were considered. Our feasibility testing had a small sample size and lacked a control group and objective variables.

5. Conclusions

The present study offers a validated yoga module consisting of 41 practices for AS patients. The results of the pilot study suggested that the module is feasible, acceptable, and easy to practice for AS patients. We recommend the yoga module to AS patients.

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Conflict of interest
None.

Author contributions
K.M., AS & P.T.: conception of the study, design, statistics. J.S., M.Z., S.M.: Yoga module development. K.M.: Manuscript writing and final approval.

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Table 3

| Type of practices                      | Name of the practices |
|----------------------------------------|-----------------------|
| Looseening practices                   | Neck movement         |
|                                        | (Front-back side bending, twisting and rotation), shoulder rotation, twisting, side bending, butterfly, alternate straight leg raising vertical stretch of the knee, vertical stretch of the knee (both legs), pavana mukta, lumbar stretch (single and both legs), dorsal stretch, alternate foot knee lumbar stretch, side leg raising, side lumbar stretch. |
| Instant relaxation techniques          | Hands in and out breathing, hands stretch breathing, ankle stretch breathing, tiger breathing, Shishankasana breathing on chair, lumbar stretch breathing. |
| Breathing practices                    |                       |
| Chair Suryanamaskara                   | Tadasana, Ardha Kati Chakra, Ardha Chakrasana, Prasarita Padahastasana |
| Asanas                                 |                       |
| Pranayama                              |                       |
| Yogic cleansing techniques              | Jala and Sutra Neti, Vaman Dhuoti, Laghu Sankha Prakshalana |

Table 3: The final validated yoga module for AS.
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