Clinical Trial Protocol

Efficacy and Safety of a 12-Week Taekwondo Training Program in Patients with Ankylosing Spondylitis and Axial Spondyloarthritis: A Randomized Controlled Trial

Version 1.2

Version date: Mar 17th, 2025

IRB number: CR324115

NCT ID: NCT06823726

CONFIDENTIAL

1. Title of the Study

Efficacy and Safety of a 12-Week Taekwondo Training Program in Patients with Ankylosing Spondylitis and Axial Spondyloarthritis: A Randomized Controlled Trial

2. Research Institution and Address

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4. Background of the Study

Ankylosing spondylitis (AS) and axial spondyloarthritis (axSpA) are chronic autoimmune inflammatory diseases that primarily affect the spine and sacroiliac joints. Without proper treatment and management, these conditions can lead to significant functional disability and a decreased quality of life. Exercise is a crucial non-pharmacological intervention in the management of axSpA, with aerobic exercise, strength training, and stretching being known to contribute to functional improvement and symptom relief. Previous studies have demonstrated that exercise can enhance mobility, improve physical function, reduce disease activity, alleviate pain, and ultimately enhance the overall quality of life in patients with axSpA.

Structured exercise programs such as Pilates, Yoga, and Tai Chi have been clinically validated for their benefits in AS and axSpA patients. Among these, Tai Chi, a traditional Chinese martial art,

has been widely studied and integrated into exercise programs for musculoskeletal diseases, including AS and osteoarthritis. The "Tai Chi for Arthritis" program, developed by Australian family medicine physician Paul Lam in 1974, has been widely adopted and recommended in textbooks and clinical guidelines for managing musculoskeletal disorders.

Taekwondo, a Korean traditional martial art that has evolved into a modern sport, is widely practiced worldwide. Compared to other martial arts, Taekwondo features a structured training system with high accessibility, allowing individuals of varying skill levels to participate with ease. The physical benefits of Taekwondo training include improved flexibility, enhanced muscular strength, and greater musculoskeletal stability, all of which suggest its potential role in improving functional outcomes and safety in musculoskeletal disease patients.

As the national martial art of South Korea, Taekwondo is one of the most globally practiced martial arts and a representative example of Korean cultural content. Beyond being a combat sport, Taekwondo has gained international recognition as both a competitive sport and a cultural asset. The global popularity and accessibility of Taekwondo, along with its structured nature as a training program, indicate the need for a standardized Taekwondo regimen tailored to patients with axSpA and other musculoskeletal conditions that can be globally implemented.

The present study aims to scientifically evaluate the efficacy and safety of a 12-week Taekwondo training program in patients with ankylosing spondylitis and axial spondyloarthritis through a randomized controlled trial (RCT). By demonstrating the benefits of Taekwondo as an exercise intervention for axSpA patients, this study seeks to establish a foundation for the development of a globally standardized Taekwondo-based exercise program for musculoskeletal disease management.

5. Purpose of the Study

1) Primary Objective

To evaluate the efficacy and safety of a 12-week Taekwondo training program in patients with ankylosing spondylitis and axial spondyloarthritis through an exploratory pilot randomized controlled trial (RCT). The study aims to assess the impact of Taekwondo training on disease activity, functional improvement, and quality of life.

2) Secondary Objectives

(1) To provide the same Taekwondo intervention to the control group after the RCT and compare pre- and post-intervention outcomes.

(2) To assess the safety of Taekwondo training in patients with ankylosing spondylitis and axial spondyloarthritis and verify its feasibility as an appropriate exercise intervention.

(3) To explore the potential for developing a structured Taekwondo-based exercise program tailored for patients with musculoskeletal disorders.

6. Inclusion and Exclusion Criteria

1) Inclusion Criteria

Participants must meet the following criteria to be eligible for the study:

(1) Diagnosed with axial spondyloarthritis (axSpA) according to the ASAS classification criteria.

(2) Age: Between 19 and 59 years old.

(3) Stable medication or non-medication treatment:

- Patients whose medication regimen has remained stable for at least the past 3 months.
- Patients who have not taken medication for axSpA for at least the past 3 months.

2) Exclusion Criteria

Participants will be excluded from the study if they meet any of the following conditions:

(1) History of orthopedic surgery or fractures within the past 12 months.

(2) History of cardiovascular diseases, including ischemic heart disease, cardiomyopathy, heart failure, or stroke.

(3) Advanced ankylosis in ankylosing spondylitis, as confirmed by radiographic or CT imaging:

- Complete ankylosis of at least two regions of the cervical, lumbar, or thoracic spine (i.e., continuous syndesmophyte formation or complete ossification between vertebral bodies).

(4) Presence of other musculoskeletal abnormalities or conditions that may limit exercise performance.

(5) Diagnosis of cancer within the past 5 years

(6) Pregnancy

(7) Regular exercise participation within the past 6 months (defined as exercising for at least 60 minutes per session, three or more times per week).

(8) Major changes in medication for axial spondyloarthritis during the study period, including:

a. Initiation or discontinuation of biologic agents or targeted therapies.

b. Significant changes in the continued use of NSAIDs or sulfasalazine.

c. Significant changes in the continued use of systemic glucocorticoids.

3) Sample Size and Rationale

(1) The sample size was determined based on the following reference study:

Sveaas SH, et al. High intensity exercise for 3 months reduces disease activity in axial spondyloarthritis (axSpA): a multicentre randomised trial of 100 patients. Br J Sports Med. 2020 Mar;54(5):292-297.

(2) In the reference study, the mean difference in Ankylosing Spondylitis Disease Activity Score (ASDAS) between the exercise and control groups was reported as 0.6. The pooled standard deviation for the two groups was calculated as approximately 0.7, as shown below.

$$SD_{\text{pooled 3 months}} = \sqrt{\frac{(48-1)\cdot 0.7^2 + (49-1)\cdot 0.7^2}{48+49-2}}$$

$$= \sqrt{\frac{47\cdot 0.49 + 48\cdot 0.49}{95}}$$

$$= \sqrt{\frac{23.03 + 23.52}{95}} = \sqrt{\frac{46.55}{95}} \approx \sqrt{0.490} \approx 0.700$$

The expected effect size (Cohen's d) can be calculated as:

$$\text{Cohen's } d = \frac{\text{Mean Difference}}{\text{Pooled SD}} = \frac{0.6}{0.7} \approx 0.857$$

(3) Given this expected large effect size (Cohen's d ≈ 0.857), the study is designed as an exploratory pilot trial with a target sample size of approximately 20-30 participants. Previous research on pilot and feasibility RCTs has reported a broad range of sample sizes, with a median of 28 participants and an average of 31 participants (Kaur et al., 2017). Studies have suggested that a sample size of at least 12 participants per group may be sufficient for pilot RCTs, with feasibility trials often prioritizing recruitment feasibility over rigid sample size requirements (Totton et al., 2023). Given the expected large effect size observed in previous exercise-based interventions for axial spondyloarthritis, a sample size within this range is deemed sufficient to detect meaningful preliminary effects while maintaining feasibility. This approach aligns with contemporary recommendations for pilot studies assessing feasibility and preliminary effect sizes (Totton et al., 2023; Kaur et al., 2017).

7. Study Period and Implementation Plan

1) Study Period: The study will be conducted from the date of Institutional Review Board (IRB) approval until January 31, 2026.

2) Implementation Plan

(1) From IRB approval to March 2025 – Completion of patient recruitment

(2) March 2025 – Baseline assessments, randomization, and standardization training for Taekwondo instructors.

(3) March 2025 – May 2025 – Implementation of the 12-week Taekwondo intervention in the randomized controlled trial (RCT).

(4) May 2025 – Completion of the RCT and second assessment.

(5) May 2025 – August 2025 – Implementation of a 12-week Taekwondo intervention for the control group, followed by pre- and post-intervention comparisons.

(6) August 2025 – Completion of the third assessment for the control group.

(7) September 2025 – November 2025 – Data organization and analysis.

(8) November 2025 – January 2026 – Manuscript preparation and publication.

8. Study Design

This study is designed as a single-blind, parallel-group, exploratory pilot randomized controlled trial to evaluate the feasibility, preliminary efficacy, and safety of a 12-week Taekwondo training program in patients with ankylosing spondylitis and axial spondyloarthritis.

1) Total Taekwondo Intervention Period: 24 Weeks

(1) Initial 12 weeks: Comparison between the Taekwondo training group and the control group in an RCT.

(2) Post-RCT 12 weeks: The control group receives the same Taekwondo training, allowing for a pre- and post-intervention comparison.

2) Assessment Time Points

(1) Baseline (Pre-Intervention): Within 2 weeks before the start of the 12-week Taekwondo training.

(2) End of RCT (Post-Intervention): Within 1 week after completing the initial 12-week Taekwondo training.

The primary effects of the intervention will be assessed through comparisons between the Taekwondo training group and the control group.

(3) End of Control Group Intervention: Within 1 week after completing the 12-week Taekwondo training in the control group.

Pre- and post-intervention comparisons will be conducted for the control group.

3) Group Composition

(1) Taekwondo Training Group: Participates in a structured 12-week Taekwondo training program during the RCT period.

(2) Control Group: Maintains usual daily activities for the initial 12 weeks, followed by participation in the same 12-week Taekwondo training program.

4) Blinding Procedure

(1) Evaluator Blinding: The assessors conducting the outcome evaluations will remain blinded to the intervention status of participants to ensure unbiased assessments. All evaluations will be performed in a neutral setting.

(2) Role of the Treating Physician: The treating physician will be responsible for managing participants' medication and medical history but will not be involved in any part of the patient evaluation process, including the assessment of the intervention’s effects.

5) Randomization Method

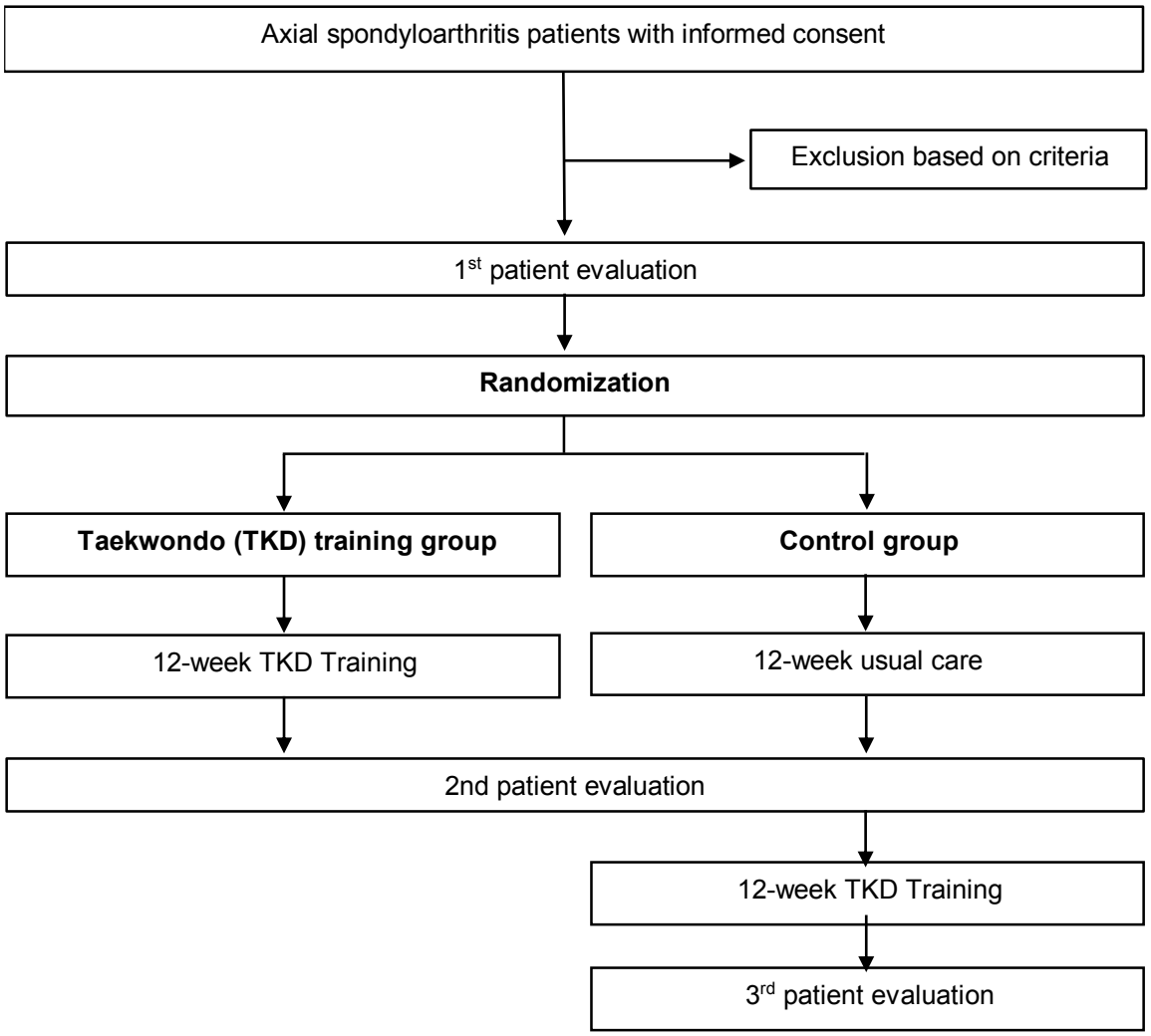
(1) Participants meeting the inclusion and exclusion criteria will undergo stratified randomization to ensure balanced distribution.

(2) Stratification factors may include gender, age (below 40 years vs. 40 years and older), or disease severity (presence vs. absence of syndesmophytes on X-ray imaging). Final stratification factors will be determined based on the characteristics of enrolled participants.

(3) Randomization will be performed by a designated research team member using Microsoft Excel's random function or other randomization software to allocate participants into the

Taekwondo training group and the control group.

Figure. Study Flowchart



9. Study Methods

1) Management of the Taekwondo Training Group

(1) Participants will undergo Taekwondo training three times per week for 12 weeks, with each session lasting 60 minutes.

(2) The Taekwondo training content will follow a standardized protocol specifically developed for this study.

(3) The Taekwondo program will be conducted by a qualified instructor throughout the study period to ensure consistency and quality of the intervention.

(4) The Taekwondo instructor will receive pre-study standardized education to fully understand the research objectives and procedures. The instructor will prioritize participant safety during the intervention.

(5) Participants will continue to receive usual medical care from their treating physician, and their enrollment in the study will not influence their prescribed medication or treatment plans.

(6) If a participant experiences pain exceeding 5 points on the Numeric Pain Rating Scale (NPRS) during training, the exercise intensity will be immediately adjusted or discontinued, and the event will be documented in the study log.

2) Management of the Control Group

(1) Participants in the control group will maintain their usual daily activities for the first 12 weeks without any additional exercise interventions.

(2) They will continue to receive usual medical care, and their study participation will not affect their prescribed medication or treatment.

(3) After completing the initial 12-week RCT period, the control group will receive the same 12-week Taekwondo training intervention, allowing for a pre- and post-intervention comparison.

3) Safety Measures

To ensure the safety of study participants, the following measures will be implemented:

(1) Insurance Coverage for Injuries: All participants will be covered by injury insurance to protect them in case of any adverse events related to the study.

(2) Safety Monitoring

a. At least one investigator will be present at every training session to continuously monitor adverse events (AEs) and serious adverse events (SAEs) related to the Taekwondo intervention. Investigators will only observe participants without interfering during training.

b. The investigator present during the exercise sessions will complete exercise logs after each session to record training details and participants' conditions.

c. All AEs and SAEs will be recorded from the time of occurrence until resolution, with continuous follow-up.

d. If an adverse event occurs, participants will immediately contact a designated physician for necessary medical intervention, and their condition will be closely monitored.

e. All safety-related incidents will be reported to the Institutional Review Board (IRB) regularly, and any serious adverse events will be reported immediately.

(3) Emergency Response and Medical Support

Participants will be provided with an emergency contact number and medical support procedures before the study begins. If any safety concerns arise, they will be instructed to immediately contact a designated research staff member or physician.

(4) Emergency Protocol

In case of a medical emergency during training, the research staff will immediately call

emergency medical services and coordinate with a designated physician for appropriate management.

4) Outcome Measures

(1) Baseline Assessments

The following baseline characteristics will be collected before the start of the intervention:

a. Demographic and Clinical Characteristics: Age, sex, symptom duration, disease duration, HLA-B27 positivity, smoking status, alcohol habit

b. vital signs, complete blood count, blood chemistry, cholesterol, glucose, urine analysis, electrocardiogram

c. Radiographic Characteristics (within 1 year): Radiographic sacroiliitis, number of syndesmophytes

d. Inflammation and Disease Activity: Erythrocyte sedimentation rate (ESR), C-reactive protein (CRP), Bath Ankylosing Spondylitis Disease Activity Index (BASDAI), Ankylosing Spondylitis Disease Activity Score (ASDAS)

e. Pain Assessment: Numeric Pain Rating Scale (NPRS)

f. Functional Assessment: Bath Ankylosing Spondylitis Functional Index (BASFI), Bath Ankylosing Spondylitis Metrology Index (BASMI)

g. Quality of Life Measures: Short Form-12 Health Survey Version 2 (SF-12v2), Fatigue Severity Scale (FSS), Ankylosing Spondylitis Quality of Life (ASQoL) questionnaire

h. Overall Health Status in Axial Spondyloarthritis: ASAS Health Index (ASAS-HI)

i. Psychological Status: Korean version of the Center for Epidemiologic Studies Depression Scale - Revised (K-CESD-R)

j. Anthropometric Measurements: Body mass index (BMI), BASMI, chest expansion, waist circumference

k. Current Medications: NSAIDs, sulfasalazine, TNF inhibitors, IL-17 inhibitors, glucocorticoids

l. Exercise Habits: Including prior Taekwondo training experience

m. Physical Activity Level: International Physical Activity Questionnaire - Short Version (IPAQ-SV)

(2) Primary Outcome Measures

a. Disease Activity in Axial Spondyloarthritis: ASDAS, BASDAI

b. Functional Ability Assessment in Axial Spondyloarthritis: BASFI

(3) Secondary Outcome Measures

a. Quality of Life: SF-12v2, FSS, ASQoL

b. Overall Health Status in Axial Spondyloarthritis: ASAS-HI

c. Spinal and Joint Mobility: BASMI, chest expansion

d. Pain Level: Numeric Rating Scale (NRS)

e. Anthropometric Measurements: BMI, waist circumference

f. Psychological Well-being: K-CESD-R

g. Feasibility Measures: Recruitment Rate, Retention Rate, Adherence Rate

(4) Safety Assessments

a. Adverse Events (AEs):

All unexpected adverse effects related to the intervention will be documented.

b. Serious Adverse Events (SAEs):

Any life-threatening events, hospitalizations, or significant health deterioration resulting from the intervention will be recorded.

c. Non-intervention-related AEs and SAEs:

All adverse events will be recorded and monitored, even if they are not directly related to the intervention, to ensure the overall safety of participants.

5) Outcome Assessment Time Points

(1) 1st Patient Evaluation (Pre-intervention)

- Participants: Taekwondo Training Group & Control Group
- Assessment Measures: All baseline characteristics and outcome measures

(2) 2nd Patient Evaluation (week 12, after RCT)

- Participants: Taekwondo Training Group & Control Group
- Assessment Measures:
  a. vital signs
  b. primary and secondary outcome measures

(3) 3rd Patient Evaluation (after control group Taekwondo training)

- Participants: Control Group
- Assessment Measures:
  a. vital signs
  b. primary and secondary outcome measures

6) Assessment Procedures

(1) Survey-Based Assessments

- Conducted by blinded evaluators in a controlled environment to prevent bias.

(2) Anthropometric and Physical Function Measurements

- Performed in a controlled setting by blinded evaluators.

(3) Blood and Urine Tests

- Conducted at each assessment time point in an outpatient laboratory.
- Study-related laboratory tests will be covered by research funding.
- If routine clinical tests coincide with study assessments, the results will be utilized without additional testing.
- HLA-B27 testing will not be repeated if previous results are available.
- Specimen Collection and Processing: For research purposes, approximately 10cc of blood

will be collected at each assessment time point, and approximately 20cc of urine will be collected at the baseline assessment.

- All biological samples will be disposed of after analysis.

(4) Spinal and Pelvic X-ray Imaging

- Conducted during the baseline assessment at the radiology department.
- Imaging includes lateral views of the cervical, thoracic, and lumbar spine, as well as anterior-posterior and oblique views of the pelvis.
- If imaging results from the past year are available, they will be utilized to avoid unnecessary radiation exposure.
- Study-related imaging costs will be covered by research funding.

(5) Electrocardiogram (EKG) Testing

- Conducted during the baseline assessment.
- EKG results will be reviewed and interpreted by an internal medicine specialist.
- Study-related EKG costs will be covered by research funding.

7) Statistical Analysis

(1) Statistical Software

All data analyses will be conducted using SPSS version 25.0.

A p-value < 0.05 will be considered statistically significant.

(2) Basic Statistical Analysis

a. Descriptive Statistics: Continuous variables will be expressed as mean ± standard deviation (SD) or median with interquartile range (IQR), depending on data distribution. Categorical variables will be presented as frequency and percentage.

b. Baseline Comparisons: Differences in baseline characteristics between the Taekwondo Training Group and the Control Group will be analyzed using Independent t-tests or Mann-Whitney U tests for continuous variables and Chi-square tests or Fisher's exact tests for categorical variables.

(3) Primary Outcome Analysis

a. Within-Group Comparisons (Pre- and Post-Intervention)

Paired t-tests or Wilcoxon signed-rank tests will be used to assess changes in outcome measures before and after the intervention within each group.

b. Between-Group Comparisons

- Differences in outcome measures between the Taekwondo Training Group and the Control Group will be analyzed using Analysis of Covariance (ANCOVA), adjusting for baseline values.
- If necessary, Generalized Linear Models (GLM) will be used as an alternative statistical method.
- Effect sizes (Cohen's d) will be calculated to quantify the magnitude of differences between groups.

c. Safety Analysis

- Descriptive statistics will be used to summarize the incidence of AEs and SAEs.
- The occurrence rates of AEs and SAEs between groups will be compared using Chi-square tests or Fisher's exact tests.

(4) Handling of Missing Data

- The Intention-to-Treat (ITT) approach will be used, ensuring all randomized participants are included in the final analysis.
- Missing data will be handled using Last Observation Carried Forward or Multiple Imputation methods.
- Additionally, a Per-Protocol analysis will be conducted as a supplementary analysis to complement the ITT approach.

8) Study Sites for Taekwondo Training

Taekwondo training sessions will be conducted at the following locations:

(1) Adult Taekwondo Academy, 34-1 Neungnadong-gil, Wonju-si, Gangwon-do, South Korea

(2) Run & Fit, 19 Hyeoksin-ro, Wonju-si, Gangwon-do, South Korea

10. Risk-Benefit Analysis

1) Potential Risks and Discomforts

(1) Physical Risks

- There is a possibility of injuries such as muscle pain, ligament strain, or fractures during Taekwondo training.
- Improper adjustment of training intensity or frequency may cause pain aggravation.

(2) Time Commitment

- Participants must allocate time for Taekwondo training sessions, which will be held three times per week for 12 weeks.

(3) Medical Risks

- Some of the study procedures, including blood tests and imaging studies, may cause mild discomfort.

2) Expected Benefits

(1) Potential Benefits to Participants

- Taekwondo training may help reduce disease activity, improve functional ability, and enhance overall quality of life.
- Regular exercise may contribute to better physical health and joint mobility.
- Participants will undergo comprehensive health assessments and continuous medical monitoring throughout the study.

(2) Potential Societal Benefits

- The study will provide clinical evidence on the efficacy and safety of Taekwondo training as an intervention for axial spondyloarthritis.

- The findings may help establish Taekwondo as a structured exercise program for the management of axial spondyloarthritis.
- The study will serve as foundational research for the development and global dissemination of Taekwondo-based exercise programs tailored for musculoskeletal disease patients.

3) Risk-Benefit Comparison and Justification

(1) Risk Mitigation Measures

- All study participants will be covered by injury insurance to ensure protection against any exercise-related injuries or adverse events.
- At least one investigator will be present at every training session to oversee safety and provide immediate intervention if necessary.
- The intensity of the intervention program will be adjusted based on the participants' characteristics and conditions. If pain exceeding 5 points on the NRS occurs during exercise, the intensity will be reduced or the exercise will be discontinued.

(2) Study Justification

- The potential risks and discomforts associated with Taekwondo training are manageable and do not outweigh the expected benefits to participants and society.
- Taekwondo is a widely practiced martial art and sport, and this study aims to scientifically validate its potential as an effective, structured intervention for axial spondyloarthritis.

(3) Ethical Considerations

- The study will be reviewed and approved by the Institutional Review Board (IRB) to ensure ethical compliance.
- Participants will provide informed consent after receiving a thorough explanation of the study, including potential risks and benefits.
- Any adverse events or safety concerns will be regularly monitored and reported to the IRB.

4) Criteria for Early Termination of the Study

(1) The Principal Investigator may decide to terminate the Taekwondo training study early if any of the following occur:

- If a safety issue arises in a study participant that could have a significant impact on the Taekwondo intervention.
- Administrative reasons that may significantly impact the continuation of the study.

(2) The IRB may decide to terminate the study if, based on interim data and observations, it is determined that the potential risks outweigh the expected benefits for participants.

11. Protection of Personal Information and Confidentiality of Research Data

1) Informed consent procedures will be conducted in a private setting to ensure participant confidentiality.

2) Participants' real names will not be recorded; instead, each participant will be assigned a unique identification number for data management.

3) All research data will be stored on encrypted computers with access restricted to authorized investigators only.

4) Research data will be securely retained for three years after the study's conclusion.

5) When publishing the study results, all personally identifiable information will be protected.

12. Participant Recruitment and Consent Procedures

1) Participants diagnosed with ankylosing spondylitis or axial spondyloarthritis will be recruited during routine clinical visits or through hospital advertisements.

2) Investigators will thoroughly explain all details of the study to potential participants, ensuring they understand the study objectives, procedures, potential risks, and expected benefits.

3) Participants will be given sufficient time to decide whether to participate voluntarily.

4) All consent must be documented in writing, with both the participant and the Principal Investigator signing the consent form.

5) Participants will be explicitly informed that they have the right to withdraw from the study at any time without any penalties or loss of benefits to which they are otherwise entitled.

13. Significance of the Study

Axial spondyloarthritis is a chronic systemic autoimmune disease that, if not properly treated and managed early, may lead to severe joint ankylosis, deformities, and multiple systemic complications, significantly reducing quality of life. Recent clinical guidelines emphasize the importance of structured and continuous exercise therapy in the management of axial spondyloarthritis. This RCT aims to provide scientific evidence that Taekwondo, a traditional Korean martial art and globally recognized sport, is an effective and safe structured exercise intervention for axial spondyloarthritis patients. The findings from this study will serve as a foundation for developing a systematic Taekwondo-based exercise program tailored for long-term health improvement in patients with axial spondyloarthritis.

14. Study Timeline (Project Schedule)

Research Activities	Months (12-Month Schedule)											
	1	2	3	4	5	6	7	8	9	10	11	12
Study Planning & IRB Approval	■											
Participant Recruitment, Baseline Assessments, Randomization, Instructor Training		■										
12-Week Taekwondo Training RCT Implementation			■	■	■							
Second Assessment (Post-RCT Evaluation)					■							
12-Week Taekwondo Training for Control Group						■	■	■				
Third Assessment (Post-Control Group Training Evaluation)								■				

Data Organization & Statistical Analysis									▮	▮	▮	
Manuscript Preparation & Publication											▮	▮

15. References

1. Ortolan A, et al. Efficacy and safety of non-pharmacological and non-biological interventions: a systematic literature review informing the 2022 update of the ASAS/EULAR recommendations for the management of axial spondyloarthritis. Ann Rheum Dis. 2023 Jan;82(1):142-152.

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7. Totton N, et al. A review of sample sizes for UK pilot and feasibility studies on the ISRCTN registry from 2013 to 2020. Pilot Feasibility Stud. 2023 Nov 21;9(1):188.

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