Date: 07/03/2023

1. RESEARCH TITLE:	**Effect of kinesiology tape on pain, posture, balance and respiration in ankylosing spondylitis: a randomized controlled trial**

2. **RATIONALE AND JUSTIFICATION OF THE RESEARCH:**	Ankylosing Spondylitis (AS) is a chronic inflammatory disease characterized by inflammation, especially in the enthesis regions and surrounding bone tissue of the spine. • Fusion in adjacent vertebral segments in AS leads to reduced axial movement and mechanical stiffness(1). • Secondary to spinal deformities such as decreased lumbar lordosis, increased thoracic kyphosis, and loss of cervical lordosis, patients with AS may develop hip flexion contracture, resulting in compensatory knee flexion(2). • The increase in spinal kyphosis causes the center of gravity to shift forward and downward. It is suggested that hip and knee flexion, along with plantar flexion, occur to compensate for this shift and keep the center of gravity within the base of support(3). • Furthermore, due to increased spinal kyphosis, patients find it difficult to look forward, leading to limitations in daily living activities such as driving, personal care, and social communication(4). • Pulmonary involvement in AS is typically asymptomatic and includes anomalies of the thoracic cage and lung parenchyma. Reduced lung volumes are one of the most important findings of this disease. Chest wall rigidity in these patients is caused by bony ankylosis in the sternomanubrial, sternoclavicular, costovertebral joints, and thoracic vertebrae. Progressive chest wall deformities, such as kyphosis, are subsequently added to this clinical picture. In later stages of the disease, all these involvements result in reduced chest wall movement and increased respiratory problems(7).

- Non-pharmacological approaches, such as education, exercise, and physical therapy, are considered important cornerstones of AS treatment, alongside pharmacological treatments.
- Kinesio Tape (KT) lifts the skin, increasing the area of the skin and subcutaneous tissue, thereby enhancing circulation and movement. Consequently, it reduces inflammation in the area and accelerates circulation and tissue healing.
- The second mechanism involves stimulating mechanical receptors on the skin, sending impulses to the central nervous system via tactile stimulation. It has been reported that the resulting impulse provides stimulation/inhibition and neuromuscular re-education(5).
- Moreover, it is argued that the activated gate control mechanism due to these sensory stimuli, along with the release of fascia through space enlargement, increased circulation, and mechanical support, reduces pain(6).

In light of all this information, it is hypothesized that a non-pharmacological approach using a home exercise program (HEP) (spinal extensor strengthening, posture, and balance exercises) and the Kinesio Taping technique in AS patients may achieve reduced pain symptoms, correction of postural deformities, and an increase in respiratory capacity.

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3. **OBJECTIVE OF THE RESEARCH:**	The aim of this study is to investigate the effect of Kinesio Taping on pain, posture, balance, and respiration in ankylosing spondylitis and to demonstrate the difference between this technique and routine home exercises provided to this group of patients.

4. EXPECTED BENEFITS OF THE RESEARCH:	Investigation of the efficacy of the KT method on pain, posture, balance, and respiration in AS patients.

5. RESEARCH METHODOLOGY:	Participants: Eighty patients aged 18–65, diagnosed with ankylosing spondylitis, not in the acute flare period, who applied to the Physical Medicine and Rehabilitation (PMR) outpatient clinic of Bursa Yuksek Ihtisas Training and Research Hospital between April 1, 2023, and January 1, 2024, will be included in the study. • Inclusion Criteria: Patients over 18 years old diagnosed with ankylosing spondylitis • Exclusion Criteria: Patients with active malignancy, active cellulitis and skin infection, open wounds, deep vein thrombosis, and patients with vestibular and orthopedic pathologies affecting balance. Intervention: • Group 2: Will receive only a home exercise program (HEP: spinal extensor strengthening, posture, balance, and respiratory exercises) for 5 weeks, 5 days a week, 3 sets of 10 repetitions. • Group 1: Will receive the home exercise program in addition to Kinesio Taping applied by a physician to

	the thoracic, lumbar, and cervical regions in the hospital setting. The KT will remain on the patient for 5 days and then be removed by the patient. The tape will be applied once a week for 5 weeks. Outcome Measures: At the end of the 5 weeks, the following will be used for patient assessment: VAS, Range of Motion (ROM), BASMI, BASFI, BASDAI, fingertip-to-floor distance, modified Schober test, chest expansion, AS quality of life questionnaire, and Berg Balance Scale.

6. DATA COLLECTION TOOLS

☐	Information-Questionnaire Form
☐	Self-administered Questionnaire
☒	Questionnaire administered under observation
☐	Interviewer-administered Questionnaire
☐	Observation
☐	Laboratory examination
☐	Record from archives
☒	**Other (Specify):** ROM measurement with a goniometer will be conducted in the outpatient clinic setting. Fingertip-to-floor distance, chest expansion, and modified Schober measurement will be taken with a tape measure.

NOTE: Please also submit a detailed list of where the required information/laboratory tests will be obtained, along with the pre-authorization letters from the clinics and laboratories.

7. STATISTICAL METHODS FOR DATA ANALYSIS:	☐ Data analysis will be performed using the IBM SPSS 22.0 statistical software package. ☐ In addition to descriptive statistical methods (frequency, percentage, mean, standard deviation, median, min-max), the Chi-Square () test will be used for comparing qualitative data. ☐ The suitability of the data for normal distribution will be evaluated using the Kolmogorov-Smirnow and Shapiro-Wilk tests.

	□ If correlation analysis is performed, the Spearman test will be used when the data does not show normal distribution, and the Pearson test will be used when it does. □ For intergroup analysis, the Independent T-test will be applied if normal distribution is detected, and the Kruskal-Wallis test will be applied if abnormal distribution is detected. □ Probability values (P) less than 0.05 will be accepted as significant, indicating a difference between the groups, while values greater than 0.05 will be considered non-significant, indicating no difference between the groups.

8. PLANNED DURATION OF THE RESEARCH:

- Planned Start Date**: 01/05/2023**
- Planned End Date: **01/01/2024**

9. CONTACT PERSON FOR THE RESEARCH:

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