SPIRIT 33-Item Clinical Trial Protocol

Study Title: Impact of Awareness and Adherence to Correct Sitting and Sleeping Positions on Low Back Pain: A Prospective Interventional Study

Trial Registration Number: ISRCTN15907212

Version: 1.0 | Date: April 3, 2025

Principal Investigator: Dr. Mohammad Akram Awwad

Institution: Faculty of Medicine – Yarmouk University

1. Title

Descriptive title including study design, population, and interventions.

2. Trial Registration

ISRCTN15907212 – Registered on 1 April 2025.

3. Protocol Version

Version 1.0, dated April 3, 2025.

4. Funding

Self-funded by the principal investigator.

5. Roles and Responsibilities

PI: Dr. Mohammad Akram Awwad. No external sponsor or steering committee.

6. Background and Rationale

Low back pain is a major cause of disability. Poor posture contributes to its prevalence. This study investigates whether posture education reduces pain outcomes.

7. Objectives

To assess the effect of sitting and sleeping posture education on low back pain intensity.

8. Trial Design

Prospective interventional single-arm study.

9. Study Setting

Yarmouk University, Jordan.

10. Eligibility Criteria

Inclusion: University students with low back pain in past 3 months. Exclusion: Chronic musculoskeletal disease, spine disorders, prior surgery.

11. Interventions

Education sessions on posture + brochures. Duration: 2 months.

12. Outcomes

Primary: Pain intensity (NRS). Secondary: Painkiller use, absenteeism, sleep disturbance (comparison between before and after the intervention).

13. Participant Timeline

Baseline assessment → 2-month follow-up assessment with two reminder dates in between (after two weeks, after one month of the baseline assessment)

14. Sample Size

84 participants completed the study out of 201 interviewd.

15. Recruitment

Conducted via in-person sessions with verbal and written invitations. Last participant recruited in first days of September 2024

16. Assignment of Interventions

Not applicable (uncontrolled, single-arm study).

17. Blinding

Not applicable.

18. Data Collection

Paper-based questionnaires at baseline and follow-up.

19. Data Management

Data anonymized, stored securely by PI.

20. Statistical Methods

Descriptive statistics, paired t-tests, chi-square tests.

21. Interim Analyses

None planned.

22. Monitoring

No data monitoring committee due to minimal risk intervention.

23. Harms

No adverse events expected; monitoring was informal.

24. Research Ethics Approval

Approved by Yarmouk University IRB (IRB/2024/239).

25. Protocol Amendments

N/A – study completed at time of protocol registration.

26. Consent

Written informed consent obtained from all participants.

27. Confidentiality

Participant data anonymized before analysis.

28. Declaration of Interests

No competing interests declared.

29. Data Access

Available upon reasonable request from corresponding author.

30. Dissemination Policy

Results to be published in peer-reviewed journals and presented in conferences.

31. Authorship Eligibility

Only contributors who meet ICMJE authorship criteria will be listed.

32. Informed Consent Materials

Approved consent forms were used. Available upon request.

33. Biological Specimens

Not applicable – no specimens collected.