

The Effectiveness of Yoga on Fatigue, Chronic Pain, Sleep Quality, and Psychological Well-Being in Patients with Type 2 Diabetes

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E d i t o r	R e v i e w e r s
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1. Round 1

1.1. Reviewer 1

Reviewer:

The manuscript needs a priori sample-size justification. The statement that “33 participants were invited to enter the trial” does not indicate how the required sample size was determined. For a randomized intervention study with four outcomes and ANCOVA analyses, the authors should report an a priori power analysis specifying the expected effect size, α level, statistical power, number of groups, covariate structure, and anticipated attrition. A final sample of 16 participants per group is small, and unusually large effect-size estimates may be unstable in such samples. If no prospective power calculation was conducted, this should be acknowledged explicitly as a methodological limitation rather than implying that 32 participants constituted a predetermined statistically adequate sample.

The description of the fatigue measure contains a bibliographic inconsistency that should be corrected. The manuscript states that the MFI was “developed by Smets and colleagues” while the Persian description indicated that it was designed in 1996 but cited Smets et al. (1995). The authors should verify the original source and report the instrument’s development date accurately. More importantly, the MFI consists of five four-item subscales and interpretation is generally based on domain scores rather than necessarily a single unqualified total score. If a total score ranging from 20 to 100 was used in this study, the authors

should provide a psychometric or methodological justification for aggregating the subscales. They should also report whether reverse-scored items were handled according to the original scoring instructions.

Response: Revised and uploaded the manuscript.

1.2. Reviewer 2

Reviewer:

The handling of attrition raises an important analytical issue. The manuscript reports that “Data from one participant assigned to the yoga group were excluded because of insufficient and irregular attendance at the intervention sessions.” This appears to constitute a per-protocol rather than an intention-to-treat analysis. In a randomized controlled trial, exclusion after randomization can compromise the benefits of randomization and introduce attrition bias, particularly if withdrawal is related to treatment tolerance or outcome severity. The authors should report the randomized sample by group before attrition, explain exactly how many sessions the excluded participant attended, and clarify whether any post-randomization data were available. Ideally, the primary analysis should follow the intention-to-treat principle, supplemented by a per-protocol analysis when appropriate. If intention-to-treat analysis was not feasible, this limitation should be explicitly discussed.

The intervention protocol requires sufficient detail to permit replication. The paragraph beginning “The intervention protocol was designed according to the principles of classical yoga” describes four broad phases but does not identify the specific asanas, pranayama techniques, mindfulness practices, repetitions, holding times, progression rules, or intensity criteria. Terms such as “foundational asanas,” “controlled backward-bending exercises,” and “dynamic movement sequences” are too general for intervention reproducibility. The authors should provide a session-by-session protocol, preferably in a supplementary appendix, specifying the postures and breathing practices used, duration of each component, instructor qualifications, adaptations for diabetic complications, and criteria for exercise progression. Because controlled jumping movements were included in sessions 13–16, particular attention should be given to safety precautions for patients who could potentially have neuropathy, retinopathy, balance impairment, or cardiovascular complications.

There is an important inconsistency in intervention duration across sections of the manuscript. The abstract states that participants attended “16 sessions of yoga training, each lasting 60 minutes,” whereas the Methods section reports “16 sessions conducted twice weekly over an eight-week period, with each session lasting 90 minutes.” This discrepancy must be resolved because intervention dosage is a fundamental methodological variable. The authors should verify the actual session duration from the trial protocol and IRCT registration and use the same value consistently in the abstract, Methods, Discussion, and any trial-registration information. The durations assigned to warm-up, yoga components, mindfulness/breathing exercises, and relaxation should also sum logically to the reported total session duration.

Response: Revised and uploaded the manuscript.

2. Revised

Editor’s decision after revisions: Accepted.

Editor in Chief’s decision: Accepted.