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REVIEWER'S REPORT

Manuscript No.: IJAR-52432 Date: 24/06/2025

Title: A multi-centric, double-blind, randomized controlled trial to assess safety and efficacy of a proprietary Ayurvedic medicine, "Tab. Prasham" in the management of anxiety disorders as an add-on treatment to the Standard of Care

Recommendation:
✓ Accept as it is .....
Accept after minor revision.....
Accept after major revision .....
Do not accept (*Reasons below*) .....

Rating	Excel.	Good	Fair	Poor
Originality		✓		
Techn. Quality		✓		
Clarity		✓		
Significance		✓		

Reviewer Name: Dr. S. K. Nath Date: 25/06/2025

Reviewer's Comment for Publication:
This study provides promising evidence that "Tab. Prasham," a proprietary Ayurvedic medicine, effectively reduces anxiety symptoms and improves sleep quality when used as an add-on to standard care. The rigorous trial design and safety data support its potential as a complementary therapy for anxiety disorders. However, further studies with larger sample sizes, longer follow-up periods, and more detailed mechanistic insights are warranted to confirm these findings and establish its place in clinical practice.

Reviewer's Comment / Report

Strengths

- **Robust Study Design:** The study employed a randomized, double-blind, placebo-controlled, multi-centric design, which minimizes bias and enhances the reliability of findings.
- **Adequate Sample Size:** Enrolled 71 participants, with clear inclusion criteria, increasing the validity of the results.
- **Use of Validated Scales:** Anxiety was assessed using the Hamilton Anxiety Scale (HAM-A), a widely accepted and validated tool, ensuring standardized measurement.
- **Comprehensive Outcome Measures:** Besides anxiety reduction, sleep quality and duration were also evaluated, providing a holistic view of the product's benefits.
- **Blinding and Randomization:** The use of coded containers and concealment techniques ensured the integrity of blinding, reducing the potential for bias.
- **Safety Profile:** The study reports that the Ayurvedic medicine was safe, with no adverse effects noted, supporting its safety profile.

Weaknesses

- **Limited Detailed Data in the Summarized Text:** Specific statistical data (e.g., confidence intervals, effect sizes) are not extensively detailed in the extract, limiting in-depth analysis.
- **Short Follow-up Duration:** The study duration was 60 days; longer-term effects, safety, and relapse rates are not addressed.
- **Effect Size and Clinical Significance:** While statistical significance is noted, the clinical significance or magnitude of the anxiety reduction is not thoroughly discussed.
- **Herbal Composition and Mechanism:** Although the herbs are listed, the mechanistic understanding of how these herbs exert anxiolytic effects in clinical settings remains limited.
- **Potential Placebo Effect:** Though placebo controls were used, the inclusion of an active comparator (e.g., standard pharmacotherapy) would strengthen conclusions about relative efficacy.
- **Generalizability:** The study population seems limited to Indian centers; results may need validation across diverse populations.