

To the Editorial Office,

Regarding the manuscript entitled **Modified Clown Therapy for Reducing Anxiety During Nebulization in Children: A Randomized Controlled Trial**, submitted by corresponding author Prof. Huafen Wang and first author Jun Wu, we hereby formally explain the retrospective registration of this clinical trial, and confirm the full ethical compliance of the study.

1. Basic Information and Core Ethical Compliance of the Study

This study is an investigator-initiated, non-pharmacological intervention randomized controlled trial (RCT) focusing on nursing optimization for pediatric nebulization therapy. Prior to the enrollment of the first subject, the study has obtained formal ethical approval from the Ethics Committee of the First Affiliated Hospital, Zhejiang University School of Medicine (Approval No. **IIT20250032C-R1**, Approval Date: **April 7, 2025**). The legal guardian of the first subject signed the informed consent form on **April 14, 2025**, and the first subject was enrolled only after the completion of the informed consent process. The entire study strictly followed the ethical core principle of "ethical approval first, then subject enrollment", which fully complies with the *Declaration of Helsinki*, Good Clinical Practice (GCP) guidelines of China, and relevant international ethical norms for clinical research. The rights, safety and privacy of all pediatric subjects (a vulnerable group) were fully protected throughout the study.

2. Reason for Retrospective Registration

At the initial stage of study initiation, the research team's top priority was to ensure the rights and safety of pediatric subjects. We focused on completing the full-process ethical review of the hospital ethics committee, the ethical approval of the informed consent form, and the establishment of the subject risk prevention and control system, to strictly guarantee the ethical compliance of the whole study and the safety of subjects.

However, the research team had a cognitive lag in the prospective registration requirements of the International Committee of Medical Journal Editors (ICMJE) for non-pharmacological intervention nursing RCTs at the initial stage of the study, and failed to complete the clinical trial registration before the enrollment of the first subject. During the manuscript preparation and pre-submission stage, after clarifying the mandatory requirements of the journal for clinical trial registration, the team immediately completed the full-information retrospective registration in the Chinese Clinical Trial Registry (ChiCTR) on **October 22, 2025**, with the registration number **ChiCTR2500110887**.

3. Authenticity and Consistency Commitment of Registration Information

All the research information submitted in this retrospective registration, including the study protocol, inclusion and exclusion criteria, intervention measures, primary and secondary study endpoints, and statistical analysis plan, is 100% consistent with the original study protocol approved by the Ethics Committee and the content of this submitted manuscript. No modification, adjustment or alteration was made to the core content of the study during the registration process. There is no academic misconduct such as adjusting study endpoints based on obtained research results or selectively reporting research findings.

We hereby solemnly declare that the data of this study are true, complete and traceable, without data falsification, duplicate publication or other academic misconduct. The research team unconditionally accepts any form of verification of the original data, ethical approval documents and study implementation records of this study by the editorial office.

We sincerely apologize for the inconvenience caused by the retrospective registration to the editorial review process, and thank the editorial office and reviewers for their rigorous review of this

manuscript. Please do not hesitate to contact us if any further materials or explanations are required.
Sincerely,

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