



PEER-REVIEW REPORT

Name of journal: *World Journal of Hepatology*

Manuscript NO: 110162

Title: Silymarin-alpha lipoic acid and metabolic dysfunction-associated steatotic liver disease: Insights and methodological considerations

Provenance and peer review: Unsolicited Manuscript; Externally peer reviewed

Peer-review model: Single blind

Reviewer's code: 08142506

Position: Editorial Board

Academic degree and professional title: PhD, Professor

Reviewer's Country/Territory: China

Author's Country/Territory: Mexico

Manuscript submission date: 2025-05-29

Reviewer chosen by: AI Editor

Reviewer accepted review: 2025-06-01 00:55

Reviewer performed review: 2025-06-01 01:23

Review time: 1 Hour

Content to be reviewed	Does the manuscript's content fall within the scope of the journal? Yes Do authors' affiliations correspond to the content of the manuscript? Yes Is there any Key Word that is not included in the manuscript title? Yes Does the Abstract contain the contents of each part of the manuscript (IMRaD)? Yes Are the Key Words complete? Yes
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Is the content of the Introduction adequate? **Yes**

Is the content of the Materials and Methods complete?

Not Applicable

Is the description of the experiments clear and complete? **Not Applicable**

Are the experimental data presented in the manuscript's biostatistics content reliable? **Not Applicable**

Are the experimental data of the Results true and reliable? **Not Applicable**

Are the quality and resolution of the images up to standard? **Yes**

Do the selection and design of the figures and tables follow the principles of necessity and clarity? **Yes**

Is there any duplication between various parts of the manuscript and between the main text and the content presented in the figures and tables? **No**

Are the figures and tables numbered consecutively in the order in which they appear in the manuscript? **Yes**

Is the content of the Discussion reasonable? **Yes**

Is the Conclusion reasonable? **Yes**

Are all references necessary and reasonable? **Yes**

Do authors omit important references? **No**

Are all references related to the topic of the manuscript? **Yes**

Do authors only cite their own earlier publications? **No**

Is the manuscript's text correct, concise, and clear? **Yes**

Will the manuscript's content be of interest to readers? **Yes**

Are additional experiments needed for the study? **No**



	Does the research scope comply with ethics? No
Scientific quality	Grade B (Very good)
Novelty of this manuscript	Grade B (Very Good)
Creativity or innovation of this manuscript	Grade B (Very Good)
Scientific significance of the conclusion in this manuscript	Grade B (Very Good)
Language quality	Grade B (Very good)
Does this manuscript describe a study of the existing knowledge system?	Yes
Does this manuscript report a revolutionary innovation?	No
Does this manuscript report an unconventional innovation?	No
Conclusion	Minor revision
Re-review	Yes
Peer-reviewer statements	Peer-Review: Anonymous
	Conflicts-of-Interest: No
Are your review comments generated by AI tools?	

SPECIFIC COMMENTS TO AUTHORS

This manuscript provides a critical commentary on the study by Cano-Contreras et al., evaluating the methodological strengths and limitations of combining SM-ALA supplementation with a Mediterranean diet for MASLD. The review is timely and relevant, as it addresses key challenges in nutraceutical-diet intervention research. While the critique highlights important issues, enhancing its depth, specificity, and constructive tone will strengthen its utility for both authors and readers. Specific



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Comments 1. 1 The manuscript effectively outlines major methodological flaws (e.g., lack of control groups, histological validation, small sample size) and frames them within the context of MASLD research standards (refs. 2-5, 8-9). The use of subheadings (CURRENT SITUATION, KEY ASPECTS, CONCLUSION) improves readability. 1.2 Suggestion for Improvement: Explicitly state the primary objective of the commentary in the opening paragraph (e.g., to advocate for rigorous trial design in MASLD nutraceutical research) to anchor the discussion. Enhance flow by grouping related critiques (e.g., statistical power and sample size, dietary adherence and cultural validity) under overarching themes (e.g., “Design Flaws” vs. “Reporting Gaps”). 2.1 The analysis of confounding variables (diet vs. supplement effects) and statistical power (post hoc G*Power analysis, Figure 1) is robust and supported by literature (refs. 10, 13). The emphasis on histological validation aligns with guidelines for MASLD research (refs. 8-9). 2.2 While the critique notes the absence of an SM-ALA-only arm, it could further discuss whether a placebo-only arm (without diet) would also strengthen causal inference. For example, comparing four groups (SM-ALA+diet, SM-ALA-alone, placebo+diet, placebo-alone) would isolate both supplement and diet effects. 2.3 Challenge the assumption that non-invasive tools (e.g., CAP) are “trending” toward replacing biopsy (as stated in the manuscript). Cite recent debates in the field (e.g., conflicting meta-analyses on elastography’s accuracy for steatosis staging) to underscore why biopsy remains indispensable for definitive conclusions. 2.4 The manuscript mentions a manufacturer-provided supplement and author disclosures (ref. 12) but does not explore how this may have influenced study design choices (e.g., endpoint selection) or data interpretation. Suggest that the commentary explicitly link financial relationships to potential biases in reporting. 3. 1 The critique highlights overlooked issues in dietary adherence assessment (self-reporting limitations, ref. 11) and proprietary supplement generalizability (ref. 12), which are rarely addressed in MASLD trials. These points add



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value by emphasizing real-world challenges in translational research. 3.2 Suggestion for Improvement: Propose novel methodologies to address identified gaps. For example: Use wearable technology (e.g., food photography apps) or nutritional biomarkers (e.g., plasma fatty acid profiles) to objectively measure dietary compliance. Advocate for open-label registries of proprietary supplements' ingredients to enhance reproducibility across studies. Compare this trial's limitations to recent advances in MASLD research (e.g., 2024 guidelines on composite endpoints for NAFLD trials) to contextualize why methodological rigor is increasingly critical. 4.1 The manuscript does not discuss whether the trial adheres to regulatory standards for nutraceuticals (e.g., FDA guidelines for dietary supplements or EMA herbal medicine regulations). For instance, did the study register with a clinical trial registry? Were adverse events reported to regulatory bodies? 4.2 Suggestion for Inclusion: Query whether the trial met minimum ethical standards (e.g., CONSORT reporting, registration in ClinicalTrials.gov) and discuss implications for research integrity. Highlight the lack of phase-appropriate testing (e.g., missing Phase I safety data for SM-ALA, as noted in the manuscript) and its relevance to regulatory approval pathways. 5.1 "Umbilical circumference" is not a standard term (as noted in the manuscript). Suggest replacing it with "waist circumference" or "abdominal circumference" to align with MeSH terminology and avoid confusion. Clarify statements like "the study cannot claim meaningful liver injury resolution" by specifying whether "resolution" refers to histopathological improvement or clinical endpoints. 6.1 Verify consistency in citation formatting (e.g., ref. 9 lacks a DOI; ref. 14's title contains typographical errors). Add recent meta-analyses on ALA/silymarin in MASLD (e.g., 2025 updates) to strengthen the critique's timeliness.



PEER-REVIEW REPORT

Name of journal: *World Journal of Hepatology*

Manuscript NO: 110162

Title: Silymarin-alpha lipoic acid and metabolic dysfunction-associated steatotic liver disease: Insights and methodological considerations

Provenance and peer review: Unsolicited Manuscript; Externally peer reviewed

Peer-review model: Single blind

Reviewer’s code: 07871270

Position: Editorial Board

Academic degree and professional title: Academic Editor, Associate Chief Physician, MD

Reviewer’s Country/Territory: China

Author’s Country/Territory: Mexico

Manuscript submission date: 2025-05-29

Reviewer chosen by: AI Editor

Reviewer accepted review: 2025-06-01 10:53

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Content to be reviewed	<p>Does the manuscript’s content fall within the scope of the journal? Yes</p> <p>Is there any Key Word that is not included in the manuscript title? No</p> <p>Do authors’ affiliations correspond to the content of the manuscript? Yes</p> <p>Does the Abstract contain the contents of each part of the manuscript (IMRaD)? Yes</p>
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Are the Key Words complete? **Yes**

Is the content of the Introduction adequate? **Yes**

Is the content of the Materials and Methods complete?

Not Applicable

Is the description of the experiments clear and complete? **Not Applicable**

Are the experimental data presented in the manuscript's biostatistics content reliable? **Not Applicable**

Are the experimental data of the Results true and reliable? **Not Applicable**

Are the quality and resolution of the images up to standard? **Yes**

Do the selection and design of the figures and tables follow the principles of necessity and clarity? **Not Applicable**

Is there any duplication between various parts of the manuscript and between the main text and the content presented in the figures and tables? **No**

Are the figures and tables numbered consecutively in the order in which they appear in the manuscript? **Yes**

Is the content of the Discussion reasonable? **Yes**

Is the Conclusion reasonable? **Yes**

Do authors omit important references? **No**

Are all references related to the topic of the manuscript? **Yes**

Are all references necessary and reasonable? **Yes**

Do authors only cite their own earlier publications? **No**

Is the manuscript's text correct, concise, and clear? **Yes**

Will the manuscript's content be of interest to readers?



	Yes Are additional experiments needed for the study? Yes Does the research scope comply with ethics? Yes
Scientific quality	Grade B (Very good)
Novelty of this manuscript	Grade A (Excellent)
Creativity or innovation of this manuscript	Grade A (Excellent)
Scientific significance of the conclusion in this manuscript	Grade B (Very Good)
Language quality	Grade B (Very good)
Does this manuscript describe a study of the existing knowledge system?	Yes
Does this manuscript report a revolutionary innovation?	Yes
Does this manuscript report an unconventional innovation?	Yes
Conclusion	Minor revision
Re-review	Yes
Peer-reviewer statements	Peer-Review: Anonymous
	Conflicts-of-Interest: No
Are your review comments generated by AI tools?	

SPECIFIC COMMENTS TO AUTHORS

The authors present a thoughtful and well-structured commentary that critically evaluates the recent RCT on SM-ALA plus Mediterranean diet in MASLD. Their insights are sharp, and I agree with many of their methodological concerns, especially regarding trial design, sample size, and reliance on non-invasive surrogate endpoints. This letter



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meaningfully contributes to the ongoing conversation around the need for more rigorous standards in nutraceutical research for MASLD. That said, I would like to offer a few suggestions to further improve the depth and utility of the commentary: 1. While the authors discuss the limitations of CAP, I believe they could emphasize that liver stiffness measurement (LSM)—not CAP—is more closely correlated with long-term clinical outcomes in MASLD. CAP lacks prognostic value and is vulnerable to the so-called “burn-out phenomenon” in advanced disease stages, which may undermine its utility as a surrogate marker. 2. Given the chronic and progressive nature of MASLD, outcomes such as modest reductions in CAP or lipid levels are likely of secondary importance. The letter could benefit from more explicit discussion about the need for long-term follow-up to assess sustained effects on fibrosis progression or clinical endpoints. 3. While the authors rightly point out major design flaws, they might also acknowledge that RCTs involving dietary interventions face unique challenges—such as adherence, cultural acceptability, and placebo design—that differ significantly from pharmacological trials. It would enhance the balance of the commentary to briefly suggest practical strategies to overcome these limitations in future research, for example: Use of digital tools or biomarkers to monitor adherence, Incorporation of culturally adapted dietary patterns, Employing composite clinical outcomes or validated patient-reported outcomes. 4. Note that the sample being predominantly female (74%) 5. While the commentary notes limited assessment of dietary adherence, it could also highlight that supplement adherence was monitored only via phone follow-ups, without objective verification such as pill counts, serum levels, or compliance biomarkers. These additions would not only strengthen the critique but also provide constructive direction for future studies in this complex and evolving field.



PEER-REVIEW REPORT

Name of journal: *World Journal of Hepatology*

Manuscript NO: 110162

Title: Silymarin-alpha lipoic acid and metabolic dysfunction-associated steatotic liver disease: Insights and methodological considerations

Provenance and peer review: Unsolicited Manuscript; Externally peer reviewed

Peer-review model: Single blind

Reviewer’s code: 08482789

Position: Peer Reviewer

Academic degree and professional title: Research Fellow, Researcher

Reviewer’s Country/Territory: Germany

Author’s Country/Territory: Mexico

Manuscript submission date: 2025-05-29

Reviewer chosen by: AI Editor

Reviewer accepted review: 2025-06-01 00:14

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Review time: 18 Days and 21 Hours

Content to be reviewed	<p>Does the manuscript’s content fall within the scope of the journal? Yes</p> <p>Is there any Key Word that is not included in the manuscript title? Yes</p> <p>Do authors’ affiliations correspond to the content of the manuscript? Yes</p> <p>Does the Abstract contain the contents of each part of the manuscript (IMRaD)? Yes</p> <p>Are the Key Words complete? Yes</p>
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Is the content of the Introduction adequate? **No**

Is the content of the Materials and Methods complete?
No

Is the description of the experiments clear and
complete? **No**

Are the experimental data presented in the
manuscript's biostatistics content reliable? **Not
Applicable**

Are the experimental data of the Results true and
reliable? **Not Applicable**

Are the quality and resolution of the images up to
standard? **Not Applicable**

Do the selection and design of the figures and tables
follow the principles of necessity and clarity? **Not
Applicable**

Is there any duplication between various parts of the
manuscript and between the main text and the content
presented in the figures and tables? **No**

Are the figures and tables numbered consecutively in
the order in which they appear in the manuscript? **Not
Applicable**

Is the content of the Discussion reasonable? **No**

Is the Conclusion reasonable? **No**

Are all references necessary and reasonable? **Yes**

Do authors omit important references? **No**

Are all references related to the topic of the
manuscript? **Yes**

Do authors only cite their own earlier publications? **No**

Is the manuscript's text correct, concise, and clear? **No**

Will the manuscript's content be of interest to readers?



	Yes Are additional experiments needed for the study? No Does the research scope comply with ethics? Not Applicable
Scientific quality	Grade C (Good)
Novelty of this manuscript	Grade C (Good)
Creativity or innovation of this manuscript	Grade D (Fair)
Scientific significance of the conclusion in this manuscript	Grade B (Very Good)
Language quality	Grade C (Good)
Does this manuscript describe a study of the existing knowledge system?	Yes
Does this manuscript report a revolutionary innovation?	No
Does this manuscript report an unconventional innovation?	No
Conclusion	Major revision
Re-review	Yes
Peer-reviewer statements	Peer-Review: Anonymous
	Conflicts-of-Interest: No
Are your review comments generated by AI tools?	

SPECIFIC COMMENTS TO AUTHORS

This Letter to the Editor evaluates the randomized controlled trial results about SM-ALA supplementation alongside Mediterranean diets for treating MASLD. The authors correctly discuss multiple methodological weaknesses present in the original research



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through their evaluation of a study that did not have a separate SM-ALA group and no histological results and a restricted sample size and weak participant adherence data. The text demonstrates both clarity and proper writing while effectively referencing related academic literature. The manuscript mainly reviews previous study weaknesses without delivering useful new ideas or methods which would guide future studies or clinical implementations. To achieve publication as a substantive Letter to the Editor the manuscript needs significant revisions. Weaknesses The analysis only presents the existing limitations which both the original authors and MASLD trials have already manuscripted. The manuscript does not include practical guidance or prospective viewpoints that could help researchers. The manuscript fails to provide suggestions about alternative research approaches or metrics for adherence. The manuscript fails to show how SM-ALA fits into the existing therapeutic approaches for MASLD. Recommendation Major Revision A valuable outcome will result from the letter after the authors perform significant revisions to establish new insightful ideas. Specific Revision Points The manuscript requires a special section to outline recommendations for future trial designs A proposed trial design should include three arms consisting of SM-ALA with diet, SM-ALA by itself, and diet only. The authors need to recommend established non-invasive assessment methods including MRI-PDFF and ELF score as biopsy alternatives. Researchers should establish particular sample size requirements or develop adaptive approaches to handle insufficient sample sizes. The paper should deliver guidance about how to monitor dietary adherence. The authors recommend the combination of dietary records and plasma carotenoids alongside third-party assessments for future studies to enhance their validity. The authors must demonstrate the essential mechanisms of SM-ALA in MASLD treatment and demonstrate its clinical value. The authors should explain how pharmacokinetics/pharmacodynamics gaps require phase I trial execution. A table and figure should be included to synthesize best



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practices for MASLD nutraceutical trials The following elements should be included in MASLD nutraceutical trial designs along with their corresponding selection criteria and monitoring and reporting standards. This submission should demonstrate original value by providing unique insights which exceed basic limitation restatement while serving as a methodological framework for new investigations. The paper needs structural refinement to eliminate redundant information. The critique of histology absence and elastography utilization needs to be merged into one section. Minor Points The manuscript requires standardization of its terminology by using “waist circumference” instead of “umbilical circumference.” The abstract requires shortening to make its main point more obvious.



RE-REVIEW REPORT OF REVISED MANUSCRIPT

Name of journal: *World Journal of Hepatology*

Manuscript NO: 110162

Title: Silymarin-alpha lipoic acid and metabolic dysfunction-associated steatotic liver disease: Insights and methodological considerations

Provenance and peer review: Unsolicited Manuscript; Externally peer reviewed

Peer-review model: Single blind

Reviewer's code: 08142506

Position: Editorial Board

Academic degree and professional title: PhD, Professor

Reviewer's Country/Territory: China

Author's Country/Territory: Mexico

Manuscript submission date: 2025-05-29

Reviewer chosen by: Cong Lin

Reviewer accepted review: 2025-07-15 02:47

Reviewer performed review: 2025-07-15 02:56

Review time: 1 Hour

Content to be reviewed	Does the manuscript's content fall within the scope of the journal? Yes Is there any Key Word that is not included in the manuscript title? No Do authors' affiliations correspond to the content of the manuscript? Yes Does the Abstract contain the contents of each part of the manuscript (IMRaD)? Yes Are the Key Words complete? Yes
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Is the content of the Introduction adequate? **Yes**

Is the content of the Materials and Methods complete?

Yes

Is the description of the experiments clear and complete? **Yes**

Are the experimental data presented in the manuscript's biostatistics content reliable? **Yes**

Are the experimental data of the Results true and reliable? **Not Applicable**

Are the quality and resolution of the images up to standard? **Not Applicable**

Do the selection and design of the figures and tables follow the principles of necessity and clarity? **Not Applicable**

Is there any duplication between various parts of the manuscript and between the main text and the content presented in the figures and tables? **Not Applicable**

Are the figures and tables numbered consecutively in the order in which they appear in the manuscript? **Not Applicable**

Is the content of the Discussion reasonable? **Yes**

Is the Conclusion reasonable? **Yes**

Are all references necessary and reasonable? **Yes**

Do authors omit important references? **No**

Are all references related to the topic of the manuscript? **Yes**

Do authors only cite their own earlier publications? **No**

Is the manuscript's text correct, concise, and clear? **Yes**

Will the manuscript's content be of interest to readers?
Yes



	Are additional experiments needed for the study? Yes Does the research scope comply with ethics? Not Applicable
Scientific quality	Grade B (Very good)
Novelty of this manuscript	Grade B (Very Good)
Creativity or innovation of this manuscript	Grade B (Very Good)
Scientific significance of the conclusion in this manuscript	Grade B (Very Good)
Language quality	Grade B (Very good)
Does this manuscript describe a study of the existing knowledge system?	Yes
Does this manuscript report a revolutionary innovation?	No
Does this manuscript report an unconventional innovation?	No
Conclusion	Accept
Peer-reviewer statements	Peer-Review: Anonymous
	Conflicts-of-Interest: No
Are your review comments generated by AI tools?	No

SPECIFIC COMMENTS TO AUTHORS

The authors have thoughtfully addressed the critical methodological concerns raised in the previous review, resulting in a substantially strengthened commentary that makes valuable contributions to the field of metabolic dysfunction-associated steatotic liver disease (MASLD) research. The revised version demonstrates a thorough and nuanced analysis of the limitations in the original trial by Cano-Contreras et al., with clear



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articulation of how issues such as the lack of a supplement-only control group, insufficient histological validation, small sample size, and inadequate adherence monitoring undermine the study's validity. Importantly, the authors have gone beyond mere criticism to provide concrete, actionable recommendations for future research, as outlined in Table 1, which includes essential considerations such as three-arm trial designs, validated non-invasive endpoints (e.g., MRI-PDFF, ELF score), rigorous adherence monitoring combining self-report with objective biomarkers, and attention to regulatory standards including early-phase pharmacokinetic/pharmacodynamic data. The manuscript is well-structured, with a logical flow from identifying methodological weaknesses in the current study to contextualizing these within broader trends in MASLD research, and finally to proposing robust solutions. The integration of relevant literature, including meta-analyses and prior clinical trials, strengthens the authors' arguments and grounds their recommendations in existing evidence, enhancing the commentary's credibility and practical utility for researchers designing future nutraceutical trials in MASLD. Additionally, the transparency in discussing potential conflicts of interest and the emphasis on reporting standards (e.g., CONSORT) aligns with best practices in scientific communication, further supporting the quality of this work. While the manuscript is largely comprehensive, a minor point to consider for further clarity is the expansion of the discussion on how adaptive trial designs might specifically address sample size challenges in nutraceutical research, given the variability in response to such interventions. However, this does not detract from the overall strength of the commentary, as the key methodological considerations are already thoroughly covered. Given the significant improvements made, the thoughtful integration of evidence, and the practical value of the recommendations provided, this manuscript is suitable for publication in its current form.



RE-REVIEW REPORT OF REVISED MANUSCRIPT

Name of journal: *World Journal of Hepatology*

Manuscript NO: 110162

Title: Silymarin-alpha lipoic acid and metabolic dysfunction-associated steatotic liver disease: Insights and methodological considerations

Provenance and peer review: Unsolicited Manuscript; Externally peer reviewed

Peer-review model: Single blind

Reviewer's code: 07871270

Position: Editorial Board

Academic degree and professional title: Academic Editor, Associate Chief Physician, MD

Reviewer's Country/Territory: China

Author's Country/Territory: Mexico

Manuscript submission date: 2025-05-29

Reviewer chosen by: Cong Lin

Reviewer accepted review: 2025-07-15 07:07

Reviewer performed review: 2025-07-15 07:21

Review time: 1 Hour

Content to be reviewed	Does the manuscript's content fall within the scope of the journal? Yes Is there any Key Word that is not included in the manuscript title? No Do authors' affiliations correspond to the content of the manuscript? Yes Does the Abstract contain the contents of each part of the manuscript (IMRaD)? Yes
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Are the Key Words complete? **Yes**

Is the content of the Introduction adequate? **Yes**

Is the content of the Materials and Methods complete?
Not Applicable

Is the description of the experiments clear and complete? **Not Applicable**

Are the experimental data presented in the manuscript's biostatistics content reliable? **Not Applicable**

Are the experimental data of the Results true and reliable? **Not Applicable**

Are the quality and resolution of the images up to standard? **Not Applicable**

Do the selection and design of the figures and tables follow the principles of necessity and clarity? **Not Applicable**

Is there any duplication between various parts of the manuscript and between the main text and the content presented in the figures and tables? **No**

Are the figures and tables numbered consecutively in the order in which they appear in the manuscript? **Yes**

Is the content of the Discussion reasonable? **Yes**

Is the Conclusion reasonable? **Yes**

Are all references necessary and reasonable? **Yes**

Do authors omit important references? **No**

Are all references related to the topic of the manuscript? **Yes**

Do authors only cite their own earlier publications? **No**

Is the manuscript's text correct, concise, and clear? **Yes**

Will the manuscript's content be of interest to readers?



	Yes Are additional experiments needed for the study? No Does the research scope comply with ethics? Not Applicable
Scientific quality	Grade A (Excellent)
Novelty of this manuscript	Grade B (Very Good)
Creativity or innovation of this manuscript	Grade B (Very Good)
Scientific significance of the conclusion in this manuscript	Grade B (Very Good)
Language quality	Grade B (Very good)
Does this manuscript describe a study of the existing knowledge system?	Yes
Does this manuscript report a revolutionary innovation?	Yes
Does this manuscript report an unconventional innovation?	Yes
Conclusion	Accept
Peer-reviewer statements	Peer-Review: Anonymous
	Conflicts-of-Interest: No
Are your review comments generated by AI tools?	No

SPECIFIC COMMENTS TO AUTHORS

The authors have adequately addressed all comments, and the manuscript is now suitable for publication.