

LETTER to the EDITOR

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Key Concerns Regarding Research on the Effect of Omega-3 Fortified Oral Nutrition on Nutritional Indices and Quality of Life in Patients with Gastrointestinal Cancer

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Dear Editor

We have read this interesting paper and would like to raise two concerns.

First, the conclusion in the abstract is not based on the primary outcome results. The abstract states, "These results suggest that oral nutrition supplement (ONS) intervention for 8 weeks improves Patient-Generated Subjective Global Assessment (PG-SGA) scores and quality of life (QOL) scores in patients undergoing cancer therapy" (Sim et al 2022). However, in the results, PG-SGA and QOL scores are listed only with significant differences in baseline within-group comparisons and no significant differences between the intervention and control groups. Therefore, the results indicated that the ONS intervention did not significantly improve the PG-SGA and QOL scores compared with the control. Such a notation, known as spin could distort the mutual interpretation of the results and mislead the reader (Boutron et al., 2010).

Second, the authors did not adhere to standard reporting guidelines, such as the Consolidated Standards of Reporting Trials (CONSORT) statement (Schulz et al., 2010). For example, CONSORT recommends stating "How sample size was determined" or "where the full trial protocol can be accessed, if available." However, the authors did not describe the methods of calculating the sample size and the accessibility of the protocol. We feel that improving transparency would help readers assess the validity of this study.

Author Contribution Statement

Conceptualization, methodology, writing-original draft preparation, writing-review and editing S.N and Y.T and T.H.; supervision, S.M.; All authors have read and agreed to the published version of the manuscript.

Ethical Declaration

Yes.

Conflict of Interest

No.

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enriched oral nutrition supplement on nutritional indices and quality of life in gastrointestinal cancer patients: A Randomized Clinical Trial. *Asian Pac J Cancer Prev*, 23, 485–94.

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Reply to the letter to the editor: Key Concerns Regarding Research on the Effect of Omega-3 Fortified Oral Nutrition on Nutritional Indices and Quality of Life in Patients with Gastrointestinal Cancer

Dear Editor

We appreciate the comments and concerns made by Nakao and colleagues regarding our paper "The effect of omega-3 enriched oral nutrition supplement on nutritional indices and quality of life in gastrointestinal cancer patients: a randomized clinical trial". In this article, we evaluated the efficacy of oral nutrition supplement on indices of nutritional status, quality of life and inflammatory responses.

Nakao et al. pointed out that the conclusion in the abstract is not based on the primary outcome results. We absolutely understand the concerns of testing treatment effects by the analyses of changes from baseline in

each group. However, we reported both between- and within-group comparisons in Table 3 of the article and described detailed comparisons in the text. It is also clearly stated in the abstract that the comparisons are made within-group analyses not to mislead the readers. Nonetheless, we should have attempt to add statistically more appropriate between-group analysis results in the abstract and describe clear conclusion.

Nakao and colleagues also stated the article did not follow the CONSORT guideline. However, this study was approved by two Institution Review Boards (IRBs) of two university hospitals and both IRBs reviewed the full study protocol according to the CONSORT guideline. The study is also registered in Clinical Research Information Service, CRIS), the primary open-to-public registry of Korea (<https://cris.nih.go.kr>), a joint member of the WHO International Clinical Trials Registry Platform. The manuscript review process of the Asian Pacific Journal of Cancer Prevention requires the name of the study protocol registry, therefore, we provided the information to the editorial office and included in the article.

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