Response to reviewer's comments

Manuscript NO.: 82562, Randomized Clinical Trial

Title: Efficacy of Multigrain Supplementation in Type 2 Diabetes Mellitus: A Pilot Study Protocol for Randomized Intervention Trial

World Journal of Diabetes

Comments	**Feedback/Corrections**
Reviewer 1	
The authors have conducted an interesting study with the aim of improving the management of T2DM using only a dietary supplement. The approach is very practical and easy to implement for patients with this disease, which has the potential to improve the quality of life of numerous people without apparent side effects. In order to improve the scientific quality of the manuscript, I suggest the following issues/modifications:	**Response:** - Thank you for the comments.
- Methods: In the randomization of participants into supplement/control, were demographic, clinical, or medication-related variables taken into account to homogenize the subgroups? - Will subsequent statistical analysis be performed using case-control analysis methodologies?	- To randomize the participants, variables such as demographic (age, gender and ethnicity), clinical (years of disease, glycemic status and the presence of diabetic-related complications), physical activity and medication (current prescribed medications) were taken into the consideration.
- I understand that the variables used in the calculation of the sample size are based on a previous study. However, in my experience with clinical data, I have observed that this type of study does not allow for coherent conclusions using such a small sample size. Therefore, this study can only be defined as a "pilot study". In the "real world," working with patients involves enormous heterogeneity, and the larger the sample size, the more credible the results will be.	- The small sample size of the study has been acknowledged as the major limitation. In addition, The phrase "pilot study" has been placed in the study protocol title.

Comments	Feedback/Corrections
Reviewer 2	
The authors aimed to determine the efficacy of multigrain supplementation among Type 2 Diabetes Mellitus (T2DM) patients. This is an interesting subject that may result in interesting findings. Although the methodology of RCTs is important while registering your RCT this information is added while registering and all details are mentioned there. Accordingly, it is not suggested to publish the RCT protocol without results. This manuscript which is written in good English could be evaluated after adding the results.	**Response:** - Thank you for the comments. - We decided to publish the pilot study protocol first in the first hand due to the following justifications: (a) From what we are aware so far, this is the first randomized human clinical trial that aimed to determine the efficacy of multigrain (instead of single grain alone) supplementation among the Type 2 Diabetes Mellitus patients. (b) Some previously published RCT protocols (without results) with regards to the research on diabetes mellitus are listed for your kind reference: - Ranasinghe, P., Galappaththy, P., Constantine, G.R. et al. Cinnamomum zeylanicum (Ceylon cinnamon) as a potential pharmaceutical agent for type-2 diabetes mellitus: study protocol for a randomized controlled trial. Trials 18, 446 (2017). https://doi.org/10.1186/s13063-017-2192-0 - Ren B, Wang N, Lei S, et al. Effects of community family doctors-led intervention for self-management and medication adherence in type 2 diabetes mellitus patients: study protocol of a cluster randomised controlled trial. BMJ Open 2022;12:e058670. doi: 10.1136/bmjopen-2021-058670

	- Nieuwesteeg, A.M., Pouwer, F., van Bakel, H.J. et al. Quality of the parent-child interaction in young children with type 1 diabetes mellitus: study protocol. BMC Pediatr 11, 28 (2011). https://doi.org/10.1186/1471-2431-11-28 - T. Karlsson, H. Augustin, M. Lindqvist, J. Otten, K. Petersson, E. Storck-Lindholm, I. Mogren, A. Winkvist, Effect of the New Nordic Diet compared with usual care on glucose control in gestational diabetes mellitus: Study protocol for the randomized controlled trial intervention with new Nordic DIet in women with Gestational diabetes mellitus (iNDIGO), Contemporary Clinical Trials, Volume 115, 2022, 106706, ISSN 1551-7144, https://doi.org/10.1016/j.cct.2022.106706. (c) We are considering to publish the trial results to the Baishideng Publisher Group Inc.