Editorial Expression of Concern for: Taghizadeh, M., Asemi, Z. Effects of synbiotic food consumption on glycemic status and serum hs-CRP in pregnant women: a randomized controlled clinical trial

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The editor-in-chief is issuing an Editorial Expression of Concern for this article. Since publication, several concerns have been raised about the integrity of the article. Specifically:

- The authors indicate in the article that women were recruited at 27 weeks' gestation and the 2 week "run-in" period followed this; however, the authors also indicate that randomization took place at the end of the run-in period at 27 weeks' gestation;
- In the Abstract, the authors indicate that 52 participants were randomized, but in the methods and Fig. 1, the authors report that 56 participants were randomized;
- There are discrepancies between the original clinical trial registration (IRCT201212105623N3) [1] and the publication for study timeline, study location, protocols, and participant age;
- Another article by Taghizadeh et al. [2] with the same clinical trial identifier describes different study timelines, randomization methods, and reasons for participant withdrawal; there are also discrepancies in the results reported in Table 1 and Table 2.

The detailed concerns have been published as a supplementary file in [3].

Following receipt of the concerns, the authors responded that due to an oversight, they did not update the trial registration after finalizing the trial. They substantially revised the clinical trial registration record on 25 December 2019 with approval from their institutional ethics committee.

The authors and institution have confirmed that the study took place between June and November 2012. Further, they have stated that the discrepancies in the date of study completion between this article and Taghizadeh et al. [2] is because the laboratory tests were carried out, and articles were drafted at different times. According to the authors, the randomization methods were the same but not fully reported in Taghizadeh et al. [2]. Additionally, the authors claim the reasons for participant withdrawal were the same but described differently in the two articles.

The authors have requested to make the following corrections:

1. Women were recruited at 27 weeks of gestation. Then a 2-week run-in period was done. After a 2-week run-in period, randomization was done. So, randomization has been done at week 29 of gestation.
2. Some outcome variables were not measured in all study participants. Therefore, in each study (Lipids 49(2): 155–161 and Hormones (Athens) 13(3): 398–406) with certain outcome measures, the baseline data were only considered for participants, in which the outcome measures were done.

An investigation into all the concerns was conducted by the National Committee for Ethics in Biomedical Research (NREC), Ministry of Health and Medical Education. The NREC concluded that there is insufficient evidence that the data was fabricated based on the summary statistics. In line with Iranian legal requirements, the results of their investigation were sent to the Kashan University of Medical Sciences (KAUMS) research ethics committee where the corresponding author is based. The

The original article can be found online at <https://doi.org/10.14310/horm.2002.1489>.

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institutional investigation found that, other than the issues for which the authors requested a correction, there were no issues with the integrity of this article. However, concerns have been raised regarding the potential conflict of interest at the NREC with regard to this investigation. Therefore, the editor-in-chief advises that readers interpret the findings with caution.

All authors agree to this Editorial Expression of Concern.

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