

Название / Title	Рандомизированное контролируемое исследование в параллельных группах по достижению ремиссии у пациентов с сахарным диабетом 2-го типа через диетические и поведенческие вмешательства: протокол исследования / A parallel arm randomised controlled trial to achieve remission in patients with type 2 diabetes mellitus through dietary and behavioural interventions: a study protocol
Раздел / Section	ВНУТРЕННИЕ БОЛЕЗНИ / INTERNAL MEDICINE
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РЕЦЕНЗЕНТ А / REVIEWER A

Инициалы / Initials	1097_A
Научная степень / Scientific degree	
Страна/территория / Country/Territory	Россия / Russia
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ПЕРВЫЙ РАУНД РЕЦЕНЗИРОВАНИЯ / FIRST ROUND OF PEER-REVIEW

Scientific quality: Grade C (Fair)

Language quality: Grade B (Minor language polishing)

Re-review: Yes

The problem of achieving remission of type 2 diabetes mellitus (DM) is undoubtedly important. The authors describe a multifaceted study to evaluate the efficacy of a lifestyle intervention in achieving remission of type 2 DM compared with a standard intervention. To increase adherence, participants will be supported by group therapy, weekly supervision by a mentor, and a "family leader" will be selected to be responsible for the participant's dietary adherence. Adherence to the recommendations will be monitored regularly using special questionnaires.

However, several questions require clarification.

1) Please provide a more detailed rationale for choosing a low-carbohydrate diet. What percentage of slow-digesting carbohydrates will be recommended to participants? Will consumption of plant fiber be recommended?

The article emphasizes the inclusion of millet in the diet, but it is unclear in what form this product will be presented.

The section on millet in the introduction needs to be expanded. Why was this particular grain chosen? What are its advantages over rice and wheat (low glycemic index, etc.)? Will millet completely replace other grains in the participants' diet? Recent literature on this topic is available online.

The article states that the millet food basket is provided as part of a nutritional support program for tuberculosis patients. It is not clear to the overseas reader how this can be realized if the study participants do not have tuberculosis.

2) IDF and WHO recommend aerobic exercise for people with 2 DM. The article mentions yoga classes, but yoga cannot be considered a full aerobic exercise. Obviously, yoga was chosen because of the Indian culture, but aerobic exercise should be part of the program. This nuance needs clarification.

3) Will participants in the main group receive standard DM therapy as in the control group?

4) Explain why a follow-up period of 9 months is desirable. For example, in studies of DM remission after bariatric surgery, a follow-up period of at least 1 year is usually used. In the planned study, slower weight loss and thus later achievement of remission would be expected. In this context, 9 months of follow-up may not be sufficient.

5) Will the investigator visit weekly for the entire 9 months or only at the beginning?

6) Readers would like to know more about what constitutes a "family champion"? What is the principle behind the selection of this family figure?

7) The difference between the primary purpose of the study (b) and the secondary purpose of the study (c) is not clear:

"To see acceptability among the patients to adopt dietary interventions to achieve remission" vs "To see the user acceptability for dietary and behavior intervention in achieving remission".

8) One of the main objectives of the study is to assess DM remission in patients in the two groups. However, there is no mention of the planned measurement of glycated hemoglobin levels, evaluation of glycemic diaries.

9) Will the rate of weight loss and reduction in waist circumference be assessed? This is an important aspect of achieving remission of DM.

10) Information on the source of funding for the study should be provided. Promotion of healthy lifestyle principles, lifestyle correction under continuous supervision of a specialist requires a lot of human, material and time resources.

11) Information about research (questionnaires, surveys, etc.) should be placed in a separate subsection. Currently, this information is located in the "Recruitment of Participants" section.

12) An approximate daily diet of a patient and an example of a compliance chart could be provided as illustrative material. The captions in Figure 1 are illegible.

RECOMMENDATION: major revision.

ВТОРОЙ РАУНД РЕЦЕНЗИРОВАНИЯ /SECOND ROUND OF PEER-REVIEW

The authors made many edits and answered almost all key questions. However, some questions remained unanswered.

Key shortcomings:

1. No information on the source of funding has been entered.
2. The edits and explanations about millet, etc. do not contain references to literature sources, although normative documents are mentioned (again without references). In addition, the explanations are in the format of a dialogue with the reviewer (formulations of 'Why...?' and 'How it works' and answers to them) and stylistically are not quite appropriate for a scientific article.

Secondary issues and technical comments:

1. It is not explained what the nutritional support program for TB patients is and how it relates to diabetic patients.
2. The sub-section 'Recruitment of participants' still includes information that should have been separated into the 'Methods' sub-section. There should be a clearer list of the investigations that are planned at each follow-up visit (HbA1c, weighing, waist circumference measurement, questionnaire analysis...), as in the current version of the text they are scattered in different sections.
3. Information on ethical review is duplicated twice (before and after the figure with the study design).

РЕЦЕНЗЕНТ В / REVIEWER В

Инициалы / Initials	1097_B
Научная степень / Scientific degree	Доктор медицинских наук / Dr. of Sci. (Medicine)
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ПЕРВЫЙ РАУНД РЕЦЕНЗИРОВАНИЯ / FIRST ROUND OF PEER-REVIEW

Scientific quality: Grade C (Fair)

Language quality: Grade B (Minor language polishing)

Re-review: Yes

General comments:

1. Introduction:

Please justify the use of diet and exercise in the treatment of a specific group of patients with T2DM. Please use PICO.

2. Methods:

- Please describe the intervention: how it works, how diet and physical activity are selected for patients?
- Please describe the inclusion and exclusion criteria for the study.
- Please describe what is included in the standard therapy that patients receive?
- Please specify: primary and secondary (objectives pretty the same) outcomes – how the remission is defined?
- Please define acceptability in detail.
- Do you plan to explore heterogeneity?
- Statistical analysis: describe what methods do you plane to use?

Publication is possible after major revision of the protocol text.

RECOMMENDATION: major revision.

ВТОРОЙ РАУНД РЕЦЕНЗИРОВАНИЯ /SECOND ROUND OF PEER-REVIEW

Thanks to the authors for addressing my comments. The text now reads much more clearly. Interventions and activities to improve patient adherence are explained promptly. Authors need to focus their attention on the target condition in the introduction and rationale. The protocol can be published after minimal revision.