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ЕЖЕМЕСЯЧНЫЙ НАУЧНЫЙ ЖУРНАЛ

Медицинские новости Грузии  
საქართველოს სამედიცინო სიახლენი

## GEORGIAN MEDICAL NEWS

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**GMN: Georgian Medical News** is peer-reviewed, published monthly journal committed to promoting the science and art of medicine and the betterment of public health, published by the GMN Editorial Board since 1994. GMN carries original scientific articles on medicine, biology and pharmacy, which are of experimental, theoretical and practical character; publishes original research, reviews, commentaries, editorials, essays, medical news, and correspondence in English and Russian.

GMN is indexed in MEDLINE, SCOPUS, PubMed and VINITI Russian Academy of Sciences. The full text content is available through EBSCO databases.

**GMN: Медицинские новости Грузии** - ежемесячный рецензируемый научный журнал, издаётся Редакционной коллегией с 1994 года на русском и английском языках в целях поддержки медицинской науки и улучшения здравоохранения. В журнале публикуются оригинальные научные статьи в области медицины, биологии и фармации, статьи обзорного характера, научные сообщения, новости медицины и здравоохранения. Журнал индексируется в MEDLINE, отражён в базе данных SCOPUS, PubMed и ВИНТИ РАН. Полнотекстовые статьи журнала доступны через БД EBSCO.

**GMN: Georgian Medical News** – საქართველოს სამედიცინო სიახლენი – არის ყოველთვიური სამეცნიერო სამედიცინო რეცენზირებადი ჟურნალი, გამოიცემა 1994 წლიდან, წარმოადგენს სარედაქციო კოლეგიისა და აშშ-ის მეცნიერების, განათლების, ინდუსტრიის, ხელოვნებისა და ბუნებისმეტყველების საერთაშორისო აკადემიის ერთობლივ გამოცემას. GMN-ში რუსულ და ინგლისურ ენებზე ქვეყნდება ექსპერიმენტული, თეორიული და პრაქტიკული ხასიათის ორიგინალური სამეცნიერო სტატიები მედიცინის, ბიოლოგიისა და ფარმაციის სფეროში, მიმოხილვითი ხასიათის სტატიები.

ჟურნალი ინდექსირებულია MEDLINE-ის საერთაშორისო სისტემაში, ასახულია SCOPUS-ის, PubMed-ის და ВИНТИ РАН-ის მონაცემთა ბაზებში. სტატიების სრული ტექსტი ხელმისაწვდომია EBSCO-ს მონაცემთა ბაზებიდან.

### WEBSITE

[www.geomednews.com](http://www.geomednews.com)

## К СВЕДЕНИЮ АВТОРОВ!

При направлении статьи в редакцию необходимо соблюдать следующие правила:

1. Статья должна быть представлена в двух экземплярах, на русском или английском языках, напечатанная через **полтора интервала на одной стороне стандартного листа с шириной левого поля в три сантиметра**. Используемый компьютерный шрифт для текста на русском и английском языках - **Times New Roman (Кириллица)**, для текста на грузинском языке следует использовать **AcadNusx**. Размер шрифта - **12**. К рукописи, напечатанной на компьютере, должен быть приложен CD со статьей.

2. Размер статьи должен быть не менее десяти и не более двадцати страниц машинописи, включая указатель литературы и резюме на английском, русском и грузинском языках.

3. В статье должны быть освещены актуальность данного материала, методы и результаты исследования и их обсуждение.

При представлении в печать научных экспериментальных работ авторы должны указывать вид и количество экспериментальных животных, применявшиеся методы обезболивания и усыпления (в ходе острых опытов).

4. К статье должны быть приложены краткое (на полстраницы) резюме на английском, русском и грузинском языках (включающее следующие разделы: цель исследования, материал и методы, результаты и заключение) и список ключевых слов (key words).

5. Таблицы необходимо представлять в печатной форме. Фотокопии не принимаются. **Все цифровые, итоговые и процентные данные в таблицах должны соответствовать таковым в тексте статьи**. Таблицы и графики должны быть озаглавлены.

6. Фотографии должны быть контрастными, фотокопии с рентгенограмм - в позитивном изображении. Рисунки, чертежи и диаграммы следует озаглавить, пронумеровать и вставить в соответствующее место текста **в tiff формате**.

В подписях к микрофотографиям следует указывать степень увеличения через окуляр или объектив и метод окраски или импрегнации срезов.

7. Фамилии отечественных авторов приводятся в оригинальной транскрипции.

8. При оформлении и направлении статей в журнал МНГ просим авторов соблюдать правила, изложенные в «Единых требованиях к рукописям, представляемым в биомедицинские журналы», принятых Международным комитетом редакторов медицинских журналов - <http://www.spinesurgery.ru/files/publish.pdf> и [http://www.nlm.nih.gov/bsd/uniform\\_requirements.html](http://www.nlm.nih.gov/bsd/uniform_requirements.html) В конце каждой оригинальной статьи приводится библиографический список. В список литературы включаются все материалы, на которые имеются ссылки в тексте. Список составляется в алфавитном порядке и нумеруется. Литературный источник приводится на языке оригинала. В списке литературы сначала приводятся работы, написанные знаками грузинского алфавита, затем кириллицей и латиницей. Ссылки на цитируемые работы в тексте статьи даются в квадратных скобках в виде номера, соответствующего номеру данной работы в списке литературы. Большинство цитированных источников должны быть за последние 5-7 лет.

9. Для получения права на публикацию статья должна иметь от руководителя работы или учреждения визу и сопроводительное отношение, написанные или напечатанные на бланке и заверенные подписью и печатью.

10. В конце статьи должны быть подписи всех авторов, полностью приведены их фамилии, имена и отчества, указаны служебный и домашний номера телефонов и адреса или иные координаты. Количество авторов (соавторов) не должно превышать пяти человек.

11. Редакция оставляет за собой право сокращать и исправлять статьи. Корректур авторам не высылаются, вся работа и сверка проводится по авторскому оригиналу.

12. Недопустимо направление в редакцию работ, представленных к печати в иных издательствах или опубликованных в других изданиях.

**При нарушении указанных правил статьи не рассматриваются.**

## REQUIREMENTS

Please note, materials submitted to the Editorial Office Staff are supposed to meet the following requirements:

1. Articles must be provided with a double copy, in English or Russian languages and typed or computer-printed on a single side of standard typing paper, with the left margin of 3 centimeters width, and 1.5 spacing between the lines, typeface - **Times New Roman (Cyrillic)**, print size - 12 (referring to Georgian and Russian materials). With computer-printed texts please enclose a CD carrying the same file titled with Latin symbols.

2. Size of the article, including index and resume in English, Russian and Georgian languages must be at least 10 pages and not exceed the limit of 20 pages of typed or computer-printed text.

3. Submitted material must include a coverage of a topical subject, research methods, results, and review.

Authors of the scientific-research works must indicate the number of experimental biological species drawn in, list the employed methods of anesthetization and soporific means used during acute tests.

4. Articles must have a short (half page) abstract in English, Russian and Georgian (including the following sections: aim of study, material and methods, results and conclusions) and a list of key words.

5. Tables must be presented in an original typed or computer-printed form, instead of a photocopied version. **Numbers, totals, percentile data on the tables must coincide with those in the texts of the articles.** Tables and graphs must be headed.

6. Photographs are required to be contrasted and must be submitted with doubles. Please number each photograph with a pencil on its back, indicate author's name, title of the article (short version), and mark out its top and bottom parts. Drawings must be accurate, drafts and diagrams drawn in Indian ink (or black ink). Photocopies of the X-ray photographs must be presented in a positive image in **tiff format**.

Accurately numbered subtitles for each illustration must be listed on a separate sheet of paper. In the subtitles for the microphotographs please indicate the ocular and objective lens magnification power, method of coloring or impregnation of the microscopic sections (preparations).

7. Please indicate last names, first and middle initials of the native authors, present names and initials of the foreign authors in the transcription of the original language, enclose in parenthesis corresponding number under which the author is listed in the reference materials.

8. Please follow guidance offered to authors by The International Committee of Medical Journal Editors guidance in its Uniform Requirements for Manuscripts Submitted to Biomedical Journals publication available online at: [http://www.nlm.nih.gov/bsd/uniform\\_requirements.html](http://www.nlm.nih.gov/bsd/uniform_requirements.html)  
[http://www.icmje.org/urm\\_full.pdf](http://www.icmje.org/urm_full.pdf)

In GMN style for each work cited in the text, a bibliographic reference is given, and this is located at the end of the article under the title "References". All references cited in the text must be listed. The list of references should be arranged alphabetically and then numbered. References are numbered in the text [numbers in square brackets] and in the reference list and numbers are repeated throughout the text as needed. The bibliographic description is given in the language of publication (citations in Georgian script are followed by Cyrillic and Latin).

9. To obtain the rights of publication articles must be accompanied by a visa from the project instructor or the establishment, where the work has been performed, and a reference letter, both written or typed on a special signed form, certified by a stamp or a seal.

10. Articles must be signed by all of the authors at the end, and they must be provided with a list of full names, office and home phone numbers and addresses or other non-office locations where the authors could be reached. The number of the authors (co-authors) must not exceed the limit of 5 people.

11. Editorial Staff reserves the rights to cut down in size and correct the articles. Proof-sheets are not sent out to the authors. The entire editorial and collation work is performed according to the author's original text.

12. Sending in the works that have already been assigned to the press by other Editorial Staffs or have been printed by other publishers is not permissible.

**Articles that Fail to Meet the Aforementioned  
Requirements are not Assigned to be Reviewed.**

## ავტორთა საქურაღებოლ!

რედაქციაში სტატიის წარმოდგენისას საჭიროა დაიცვათ შემდეგი წესები:

1. სტატია უნდა წარმოადგინოთ 2 ცალად, რუსულ ან ინგლისურ ენებზე დაბეჭდილი სტანდარტული ფურცლის 1 გვერდზე, 3 სმ სიგანის მარცხენა ველისა და სტრიქონებს შორის 1,5 ინტერვალის დაცვით. გამოყენებული კომპიუტერული შრიფტი რუსულ და ინგლისურენოვან ტექსტებში - **Times New Roman (Кириллица)**, ხოლო ქართულენოვან ტექსტში საჭიროა გამოვიყენოთ **AcadNusx**. შრიფტის ზომა – 12. სტატიას თან უნდა ახლდეს CD სტატიით.

2. სტატიის მოცულობა არ უნდა შეადგენდეს 10 გვერდზე ნაკლებს და 20 გვერდზე მეტს ლიტერატურის სიის და რეზიუმეების (ინგლისურ, რუსულ და ქართულ ენებზე) ჩათვლით.

3. სტატიაში საჭიროა გაშუქდეს: საკითხის აქტუალობა; კვლევის მიზანი; საკვლევი მასალა და გამოყენებული მეთოდები; მიღებული შედეგები და მათი განსჯა. ექსპერიმენტული ხასიათის სტატიების წარმოდგენისას ავტორებმა უნდა მიუთითონ საექსპერიმენტო ცხოველების სახეობა და რაოდენობა; გაუტკივარებისა და დაძინების მეთოდები (მწვავე ცდების პირობებში).

4. სტატიას თან უნდა ახლდეს რეზიუმე ინგლისურ, რუსულ და ქართულ ენებზე არანაკლებ ნახევარი გვერდის მოცულობისა (სათაურის, ავტორების, დაწესებულების მითითებით და უნდა შეიცავდეს შემდეგ განყოფილებებს: მიზანი, მასალა და მეთოდები, შედეგები და დასკვნები; ტექსტუალური ნაწილი არ უნდა იყოს 15 სტრიქონზე ნაკლები) და საკვანძო სიტყვების ჩამონათვალი (key words).

5. ცხრილები საჭიროა წარმოადგინოთ ნაბეჭდი სახით. ყველა ციფრული, შემაჯამებელი და პროცენტული მონაცემები უნდა შეესაბამებოდეს ტექსტში მოყვანილს.

6. ფოტოსურათები უნდა იყოს კონტრასტული; სურათები, ნახაზები, დიაგრამები - დასათაურებული, დანომრილი და სათანადო ადგილას ჩასმული. რენტგენოგრამების ფოტოასლები წარმოადგინეთ პოზიტიური გამოსახულებით **tiff** ფორმატში. მიკროფოტოსურათების წარწერებში საჭიროა მიუთითოთ ოკულარის ან ობიექტივის საშუალებით გადიდების ხარისხი, ანათალების შედეგის ან იმპრეგნაციის მეთოდი და აღნიშნოთ სურათის ზედა და ქვედა ნაწილები.

7. სამამულო ავტორების გვარები სტატიაში აღინიშნება ინიციალების თანდართვით, უცხოურისა – უცხოური ტრანსკრიპციით.

8. სტატიას თან უნდა ახლდეს ავტორის მიერ გამოყენებული სამამულო და უცხოური შრომების ბიბლიოგრაფიული სია (ბოლო 5-8 წლის სიღრმით). ანბანური წყობით წარმოდგენილ ბიბლიოგრაფიულ სიაში მიუთითეთ ჯერ სამამულო, შემდეგ უცხოელი ავტორები (გვარი, ინიციალები, სტატიის სათაური, ჟურნალის დასახელება, გამოცემის ადგილი, წელი, ჟურნალის №, პირველი და ბოლო გვერდები). მონოგრაფიის შემთხვევაში მიუთითეთ გამოცემის წელი, ადგილი და გვერდების საერთო რაოდენობა. ტექსტში კვადრატულ ფხიხლებში უნდა მიუთითოთ ავტორის შესაბამისი N ლიტერატურის სიის მიხედვით. მიზანშეწონილია, რომ ციტირებული წყაროების უმეტესი ნაწილი იყოს 5-6 წლის სიღრმის.

9. სტატიას თან უნდა ახლდეს: ა) დაწესებულების ან სამეცნიერო ხელმძღვანელის წარდგინება, დამოწმებული ხელმოწერითა და ბეჭდით; ბ) დარგის სპეციალისტის დამოწმებული რეცენზია, რომელშიც მითითებული იქნება საკითხის აქტუალობა, მასალის საკმაობა, მეთოდის სანდოობა, შედეგების სამეცნიერო-პრაქტიკული მნიშვნელობა.

10. სტატიის ბოლოს საჭიროა ყველა ავტორის ხელმოწერა, რომელთა რაოდენობა არ უნდა აღემატებოდეს 5-ს.

11. რედაქცია იტოვებს უფლებას შეასწოროს სტატია. ტექსტზე მუშაობა და შეჯერება ხდება საავტორო ორიგინალის მიხედვით.

12. დაუშვებელია რედაქციაში ისეთი სტატიის წარდგენა, რომელიც დასაბეჭდად წარდგენილი იყო სხვა რედაქციაში ან გამოქვეყნებული იყო სხვა გამოცემებში.

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## CLINICAL EFFECTIVENESS OF PERSONALIZED NUTRITION IN TYPE 2 DIABETES: A SYSTEMATIC REVIEW

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### Abstract.

**Background:** Personalized nutrition is increasingly considered a component of type 2 diabetes (T2DM) management; however, its clinical relevance and reproducibility outside controlled settings remain uncertain.

**Objective:** To evaluate the effectiveness of personalized nutritional interventions compared with standard dietary recommendations in adults with T2DM.

**Methods:** A systematic review of studies published between 2015 and 2025 was conducted using PubMed/MEDLINE, Embase, and Web of Science. Original clinical studies evaluating personalized or digital nutritional interventions in adults with T2DM were included. Primary outcomes were postprandial glycemia and glycemic variability; secondary outcomes included HbA1c, body weight, and adherence. Due to methodological heterogeneity, a qualitative synthesis was performed. Ten publications representing seven independent research projects were included.

**Results:** Most studies reported short-term reductions in postprandial glucose excursions and, in some cases, glycemic variability. HbA1c reductions were modest and heterogeneous, primarily observed in individuals with poor baseline glycemic control. No consistent effects on body weight were identified. Observed outcomes were strongly influenced by adherence, intensity of supervision, and concurrent pharmacotherapy, with variability and attenuation of effects in real-world settings.

**Conclusions:** Personalized nutrition in T2DM is associated with short-term improvements in selected metabolic parameters, particularly postprandial glycemia. However, available data do not provide sufficient evidence of independent effects. Taken together, randomized trials suggest short-term metabolic improvements; however, the approach appears more appropriate as a supportive strategy within structured care rather than a standalone therapeutic modality.

**Key words.** Personalized nutrition, digital diet therapy, type 2 diabetes, postprandial glycemia, glycemic variability, adherence.

### Introduction.

Type 2 diabetes mellitus (T2DM) is one of the most prevalent chronic metabolic disorders worldwide and is associated with increased cardiovascular morbidity, mortality, and substantial economic burden [1].

Contemporary T2DM management relies on a combination of pharmacotherapy and lifestyle modification, with dietary intervention regarded as an essential component of treatment [2]. However, in routine clinical practice, the effectiveness of dietary strategies is often limited and poorly reproducible outside controlled settings. It remains unclear whether individualized

nutritional approaches provide clinically meaningful advantages over standard dietary recommendations.

Interindividual variability in postprandial glycemic responses has driven the development of personalized nutrition concepts, which aim to tailor dietary recommendations according to metabolic and behavioral characteristics of the individual [3-9]. With the implementation of continuous glucose monitoring systems and algorithm-based predictive models, interest in this approach has increased substantially. Several studies have demonstrated short-term improvements in metabolic parameters; however, findings remain heterogeneous and highly dependent on study design and population characteristics [10,11].

Most available studies focus on surrogate metabolic markers, whereas the impact of personalized nutritional interventions on long-term clinical outcomes remains uncertain. This limitation complicates interpretation of observed effects and their comparison with the established benefits of pharmacological interventions.

The aim of the present systematic review was to evaluate the clinical relevance of personalized nutritional interventions in adults with T2DM.

### Materials and Methods.

#### Study design:

This study was conducted as a systematic review with qualitative (narrative) synthesis and prepared in accordance with the PRISMA 2020 statement. The objective was to assess the clinical effectiveness of personalized nutritional interventions in adults with T2DM.

The review protocol was not formally registered due to the exploratory nature of the topic and the substantial heterogeneity of included interventions; however, the methodology was predefined prior to study selection.

#### Literature Search:

A comprehensive literature search was performed in PubMed/MEDLINE, Embase, and Web of Science without geographic restrictions. Manual screening of reference lists from relevant publications was additionally conducted.

The search strategy combined terms reflecting population, intervention, and outcomes, including:

type 2 diabetes mellitus, personalized nutrition, precision nutrition, digital nutrition, algorithm-based diet, HbA1c, postprandial glucose, glycemic variability, adherence, and continuous glucose monitoring.

The term “precision nutrition” was included during the search phase to maximize coverage; however, the term “personalized nutrition” is used throughout the manuscript to denote clinically individualized dietary interventions.

The primary search period covered publications from January

2015 to January 2025; earlier studies were included if deemed conceptually relevant. The literature search was performed on January 18, 2026, across all selected databases. Detailed search strategies are provided in Appendix A.

**Eligibility Criteria.**

**Inclusion Criteria:**

Original clinical studies meeting the following criteria were included:

- Adults ( $\geq 18$  years) with type 2 diabetes mellitus
- Evaluation of personalized and/or digitally supported nutritional interventions (individualized dietary recommendations or algorithm-based approaches)
- Presence of a comparator group (standard dietary advice, usual care, or non-personalized dietary intervention) or pre–post analysis
- Reporting of metabolic or clinical outcomes, including postprandial glycemia, glycemic variability, HbA1c, body weight, or adherence

Postprandial glycemia and glycemic variability were considered primary outcomes, whereas HbA1c, body weight, and adherence were secondary outcomes.

**Exclusion Criteria:**

- Exclusively pharmacological interventions
- Absence of nutritional personalization
- Lack of original clinical data
- Reviews, editorials, conference abstracts, and experimental laboratory studies

**Study Selection and Data Synthesis:**

Study selection was performed in two stages: screening of titles and abstracts followed by full-text assessment for eligibility. Reasons for exclusion at the full-text stage were documented and are presented in the PRISMA flow diagram.

A quantitative meta-analysis was not conducted due to substantial clinical and methodological heterogeneity across interventions, outcome definitions, study designs, and follow-up durations, which precluded statistically valid pooling of results. Therefore, a qualitative narrative synthesis was performed, focusing on clinical interpretation of metabolic effects and the limitations of extrapolating these findings to long-term outcomes.

The review aimed to evaluate the incremental clinical value of personalized nutritional interventions compared with standard dietary care.

**Risk of Bias Assessment:**

Risk of bias was independently assessed by two reviewers using:

- RoB 2 for randomized controlled trials
- ROBINS-I for observational and real-world studies

Disagreements were resolved through discussion.

Overall risk of bias was categorized as low, some concerns, or high/serious.

**Results.**

**Study Selection:**

The study selection process is illustrated in the PRISMA flow diagram (Figure 1).

A total of 144 records were identified through database searching (PubMed: 61; Web of Science: 41; Embase: 42). After

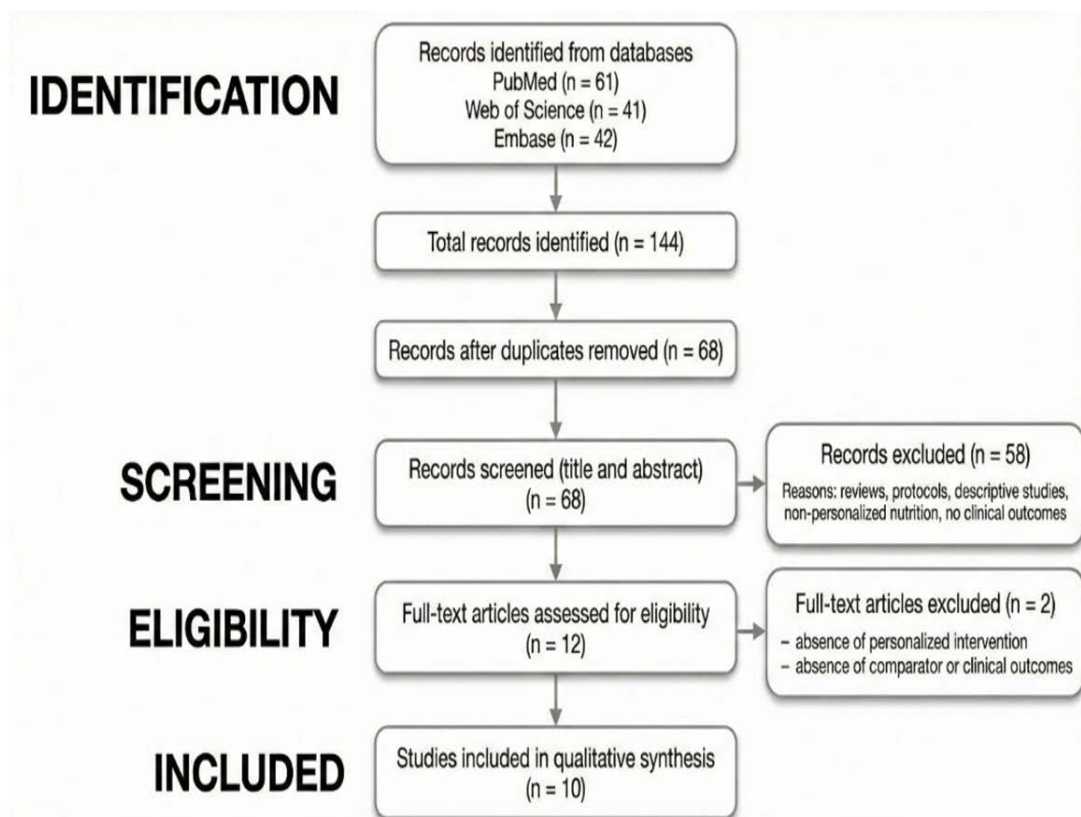


Figure 1. PRISMA 2020 flow diagram

removal of duplicates, 68 records remained for title and abstract screening. Of these, 58 were excluded due to failure to meet the inclusion criteria (review articles, study protocols, pediatric populations, absence of nutritional personalization, or lack of relevant clinical outcomes).

Twelve articles underwent full-text assessment. Two publications were excluded at this stage due to absence of personalized nutritional intervention or lack of relevant clinical outcomes.

Ultimately, 10 publications representing seven independent research projects were included in the qualitative synthesis.

### Characteristics of Included Studies:

Ten publications representing seven independent research projects were included in the qualitative synthesis. Six studies were randomized interventional trials, whereas four were conducted as real-world studies without randomization or control groups.

Most interventions were based on digital technologies for nutritional personalization, including algorithm-based prediction of postprandial glycemic responses, continuous glucose monitoring (CGM) data integration, and digital twin models. Less frequently, microbiome-oriented approaches and dietary optimization models were applied.

Comparator groups in randomized trials were heterogeneous and included standard dietary recommendations, low-fat diets, or behavioural weight-loss programs. In real-world studies, comparators were often absent, and analyses were typically conducted using pre–post designs. The modelling study was included to illustrate emerging precision nutrition frameworks; however, it did not contribute to the estimation of clinical effectiveness outcomes.

Evaluated outcomes primarily consisted of surrogate metabolic parameters. The most frequently assessed endpoints were postprandial glycemia, glycemic variability, and HbA1c. No study evaluated long-term clinically meaningful outcomes.

### Risk of Bias:

Most randomized controlled trials were assessed as having low or moderate risk of bias. Two studies (Popp et al., 2022; Kharmats et al., 2023) were classified as low risk due to comparable co-interventions across groups and the use of objective metabolic endpoints.

Other randomized studies presented methodological limitations, primarily related to the impossibility of blinding participants in dietary interventions and differences in the intensity of interaction between participants and the research

teams.

In the randomized crossover study (Rein et al., 2022), potential carryover effects represented an additional source of uncertainty, despite the presence of within-subject control.

The digital twin program reported by Shamanna and colleagues included one randomized study with moderate risk of bias and several single-arm real-world analyses with serious risk of bias due to absence of control groups, self-selection of motivated participants, and concurrent therapy modifications.

The study by Joshi et al. and the microbiota-based intervention by Kallapura et al. were also assessed as having moderate risk of bias, as observed improvements may have partially reflected intensified clinical supervision rather than the independent effect of nutritional personalization.

The modelling study (Alaofè et al., 2024) did not assess clinical outcomes and was therefore not included in the risk-of-bias synthesis.

Overall, limitations in evidence certainty were primarily attributable to performance bias and behavioural factors inherent to lifestyle interventions, whereas measurement bias was minimal due to reliance on laboratory-based metabolic parameters.

### Certainty of Evidence:

Overall certainty of evidence was evaluated using GRADE methodology, considering risk of bias, inconsistency of results, indirectness of outcomes, imprecision, and study design characteristics. A structured GRADE Summary of Findings table is presented in Table 4.

Although several randomized controlled trials were included, overall certainty ranged from moderate to low across outcomes. Certainty was highest for short-term postprandial glycemic outcomes in randomized settings. For HbA1c, glycemic variability, and body weight, certainty was downgraded due to heterogeneity of results, reliance on surrogate metabolic markers, limited follow-up duration, and inclusion of uncontrolled real-world studies with serious risk of bias.

The absence of long-term clinical endpoint data resulted in very low certainty regarding the impact of personalized nutrition on clinically meaningful outcomes.

### Effects in Randomized Controlled Trials:

Six randomized controlled trials, including one crossover design, compared personalized nutritional interventions with active control strategies, including standard dietary recommendations and structured dietary programs. The majority of trials focused on short-term metabolic outcomes, particularly

**Table 1.** Risk-of-bias assessment of included studies.

Study	Design	Tool	Overall risk of bias
Shamanna 2024a	Randomized controlled trial	RoB-2	Some concerns
Shamanna program (2020–2024 multiple reports)	Single-arm real-world cohort	ROBINS-I	Serious
Popp 2022	Randomized controlled trial	RoB-2	Low
Rein 2022	Randomized crossover trial	RoB-2 (crossover)	Some concerns
Kallapura 2024	Randomized controlled trial	RoB-2	Some concerns
Kharmats 2023	Randomized controlled trial	RoB-2	Low
Joshi 2023	Randomized controlled trial	RoB-2	Some concerns
Alaofè 2024	Nutrition modelling study	Not applicable	Not assessed

**Table 2.** Characteristics of included studies.

Author, Year	Country	Study design	Population	Type of personalization	Comparator	Main outcomes
Shamanna et al., 2024a	India	Randomized controlled trial	Adults with T2DM	Digital twin–based personalized nutrition	Standard dietary advice	HbA1c, glycemic control
Popp et al., 2022	United States	Randomized controlled trial	Adults with early type 2 diabetes or abnormal glucose metabolism and obesity	Algorithm-based personalized diet based on predicted postprandial glycemic response (PPGR)	Low-fat diet (<25% of total energy intake)	Weight loss (primary), postprandial glycemia and HbA1c (secondary)
Rein et al., 2022	Israel	Randomized crossover trial	Adults with newly diagnosed type 2 diabetes mellitus	Machine learning–based personalized diet integrating clinical and microbiome features to predict postprandial glucose responses (PPGR)	Control diet / standard dietary recommendations	Postprandial glycemia, HbA1c, glycemic control, metabolic health
Kallapura et al., 2024	India	Randomized controlled trial	Adults with type 2 diabetes mellitus and hyperlipidaemia	Microbiota-based personalized nutrition guided by whole-genome shotgun metagenomics	Standard diabetic nutritional guidance	HbA1c, blood pressure, inflammatory markers (CRP), microbiota composition
Kharmats et al., 2023	United States	Randomized clinical trial	Adults with prediabetes or moderately controlled type 2 diabetes	Personalized diet with app-based feedback to reduce postprandial glycemic responses using CGM data	Standardized low-fat diet with behavioral weight loss counseling	Glycemic variability (MAGE), HbA1c
Joshi et al., 2023	India	Randomized controlled study	Adults with type 2 diabetes mellitus	AI-driven digital twin–based personalized nutrition with meals selected to minimize predicted postprandial glycemic response	Standard care	HbA1c, medication reduction, liver function parameters, visceral adiposity (MRI)
Shamanna et al., 2021	India	Retrospective real-world study	Adults with type 2 diabetes mellitus	Digital twin–enabled Twin Precision Treatment (TPT) program	None (single-arm real-world program)	Glycemic variability, body mass index, blood pressure, antihypertensive medication use
Shamanna et al., 2020	India	Retrospective real-world analysis	Adults with type 2 diabetes mellitus	Digital twin–enabled precision nutrition program based on CGM, dietary intake data, and machine learning algorithms	None (single-arm real-world program; pre–post analysis)	HbA1c, body weight, insulin resistance (HOMA-IR), medication use
Shamanna et al., 2024b	India	Retrospective real-world study	Adults with type 2 diabetes mellitus	Digital twin–enabled precision nutrition program based on CGM, dietary intake data, and machine learning algorithms	None (single-arm real-world program; pre–post analysis)	HbA1c, body weight, insulin resistance (HOMA-IR), glycemic control, medication use
Alaofè et al., 2024	Benin (West Africa)	Model-based precision nutrition study	Adults with type 2 diabetes mellitus	Precision nutrition using linear goal programming to optimize culturally appropriate diets	None (dietary optimization model)	Dietary adequacy, affordability, and cultural acceptability

**Table 3.** Summary of personalization strategies and reported clinical outcomes.

Study	Design	Personalization approach	Comparator	Key outcomes
Shamanna et al., 2024a (with supplementary real-world reports 2020–2024)	RCT with supplementary real-world analyses	Digital twin–based nutrition program	Standard diet / none	HbA1c, glycemic variability, body weight, blood pressure, medication use
Popp 2022	RCT	Algorithm-based (PPGR)	Low-fat diet	Weight, HbA1c, PPG
Rein 2022	Randomized crossover	ML + microbiome (PPGR)	Standard diet	PPG, HbA1c
Kallapura 2024	RCT	Microbiome-based	Standard diet	HbA1c, BP, CRP
Kharmats 2023	RCT	CGM app-guided	Behavioral diet	Glycemic variability, HbA1c
Joshi 2023	RCT	Digital twin	Standard care	HbA1c, medication reduction
Alaofè 2024	Modeling study	Linear goal programming–based precision nutrition model	None (model-based analysis)	Dietary adequacy, affordability, cultural acceptability

**Table 4.** Summary of Findings (GRADE assessment).

Outcome	Study type	Risk of bias	Inconsistency	Indirectness	Imprecision	Overall certainty
Postprandial glycemia	RCTs	Some concerns	Moderate heterogeneity	Surrogate endpoint	Short follow-up	Moderate
Glycemic variability	RCTs	Some concerns	Inconsistent definitions	Surrogate endpoint	Small sample sizes	Low
HbA1c	RCTs + observational	Mixed (low to serious)	Heterogeneous effects	Surrogate endpoint	Short duration	Low
Body weight	RCTs	Some concerns	Inconsistent	Indirect for clinical outcomes	Limited duration	Low
Long-term clinical endpoints	None	—	—	Not assessed	No data	Very low

**Table 5.** Summary of metabolic effects of personalized nutrition in T2DM.

Outcome	Observed effects	Pattern of effect	Key limitations
Postprandial glycemia	Reduction in glucose excursion amplitude	Relatively consistent	Short follow-up duration; methodological variability
Glycemic variability	Reduction in daily glucose fluctuations	Inconsistent	Lack of standardized clinical thresholds
HbA1c	Modest reduction or no change	Heterogeneous	Limited sensitivity to short-term interventions
Body weight	Minimal or no change	Unstable	Absence of structured caloric restriction
Energy intake	Spontaneous reduction	Secondary effect	Behavioral factors difficult to isolate

postprandial glucose levels, glycemic variability, and HbA1c.

Reductions in postprandial glucose excursions were reported in most randomized studies, especially in interventions utilizing continuous glucose monitoring or individualized predictive algorithms. Decreases in glycemic variability were also described, although the clinical relevance of these changes remains uncertain due to the absence of universally accepted thresholds.

HbA1c reductions in randomized trials were generally modest, ranging approximately from  $-0.3\%$  to  $-1.2\%$ , with greater effects observed among participants with higher baseline values.

Taken together, randomized trials suggest short-term metabolic improvements associated with personalized nutrition. However, the magnitude of effect appears influenced by baseline characteristics, adherence, and intervention intensity,

which constrains interpretation of long-term clinical impact.

#### Postprandial Glycemia:

The most consistently reported effect of personalized nutrition was a reduction in postprandial glucose excursions. In studies using individualized recommendations based on CGM data or algorithm-based analyses, a substantial proportion of participants demonstrated reduced postprandial glucose peaks. These effects were typically observed within the first weeks of intervention.

Importantly, improvements in postprandial glycemia were not solely attributable to carbohydrate reduction but were associated with modifications in meal composition, macronutrient distribution, meal timing, and individualized metabolic responses to specific foods.

A reduction in glycemic variability was also frequently reported. Although decreased daily glucose fluctuations may reflect improved metabolic stability, the long-term clinical significance of this parameter remains debated [12].

### **HbA1c and Overall Glycemic Control:**

Because most included studies were of short duration, analyses focused primarily on postprandial glycemia, variability, and HbA1c.

As described in the preceding section, HbA1c reductions in randomized trials were modest and heterogeneous across studies, and absence of marked change does not necessarily indicate ineffectiveness but limits assessment of clinical benefit based solely on this integrative biomarker [13].

### **Energy Balance and Body Weight:**

Effects of personalized nutrition on body weight were weak and inconsistent in short-term studies. Some reports described spontaneous reductions in caloric intake without explicit energy restriction; however, clinically meaningful weight loss was generally not observed.

This distinguishes personalized nutritional approaches from structured weight-loss programs [14]. The primary aim of personalized nutrition is optimization of metabolic responses to food rather than rapid weight reduction. Nevertheless, this characteristic limits extrapolation of findings to long-term clinical outcomes [15].

Overall, short-term evidence indicates improvements in selected glycemic profile parameters, particularly postprandial glycemia. However, the clinical significance of these changes remains constrained by reliance on surrogate endpoints and limited follow-up duration.

A summary of observed metabolic effects is presented in Table 5.

### **Effects in Single-Group and Real-World Studies:**

Uncontrolled real-world and pre-post studies, primarily represented by multiple reports from the Shamanna program, described larger improvements in glycemic parameters compared with randomized trials. In some cohorts, HbA1c reductions exceeded  $-2\%$  and were accompanied by changes in body weight, medication use, and other metabolic indicators.

However, these findings should be interpreted with caution. The absence of control groups, self-selection of highly motivated participants, potential modification of concomitant pharmacotherapy, and intensified clinical supervision substantially increase the risk of bias. As assessed using ROBINS-I, these studies were classified as having serious risk of bias.

Therefore, while real-world analyses suggest potential feasibility and scalability of personalized nutrition programs, they do not provide confirmatory evidence of independent clinical effectiveness. The magnitude of reported effects may partially reflect behavioural engagement and structured program support rather than the isolated physiological impact of algorithm-driven dietary personalization.

## **Discussion.**

### **Limited Translation of Metabolic Effects into Clinical Outcomes:**

Included studies predominantly demonstrated short-term improvements in postprandial glycemia and, in some cases, reductions in glycemic variability. However, none evaluated clinically meaningful endpoints such as cardiovascular events, progression of microvascular complications, or mortality. Consequently, the observed changes reflect modifications of intermediate physiological parameters rather than evidence of impact on long-term disease prognosis [16,17].

Interpretation of these findings is further complicated by concurrent pharmacotherapy. Modern glucose-lowering agents independently influence both glycemic control and clinical outcomes [18,19]. The absence of data on hard clinical endpoints contrasts with large randomized lifestyle trials in which cardiovascular outcomes were directly assessed [20,21]. In most included studies, medication adjustments were either permitted or insufficiently controlled, making it difficult to disentangle the effect of nutritional personalization from overall treatment intensification. Therefore, observed metabolic changes may represent the combined impact of multiple interventions rather than the isolated effect of algorithm-driven dietary modification.

### **Behavioral Nature of Observed Effects:**

The magnitude of effects consistently depended on patient adherence and the intensity of supervision. The role of adherence as a determinant of clinical outcomes in T2DM has been well established [22,23]. Reduced engagement with digital systems was associated with diminished compliance and attenuation of metabolic improvements.

Continuous glucose monitoring may enhance metabolic control in real-world settings; however, its effectiveness largely depends on behavioural adaptation [24,25]. Systematic reviews of digital interventions in T2DM similarly report moderate and variable benefits influenced by user engagement [26,27].

Taken together, these observations suggest that part of the observed benefit may be attributable to enhanced self-monitoring and increased disease awareness characteristic of high-engagement interventions, rather than solely to the specific effect of algorithm-based nutritional personalization [22-28].

### **Controlled Trials versus Real-World Practice:**

Metabolic effects were generally more pronounced in randomized controlled trials, whereas real-world studies showed attenuation of effects over time. These differences highlight the substantial influence of organizational and behavioural factors on intervention outcomes.

High variability of results outside controlled environments, combined with serious risk of bias in real-world studies, suggests that a proportion of the observed effect may partially reflect selection of more motivated participants and enhanced follow-up intensity rather than a reproducible physiological impact of personalized nutrition [29-31].

Thus, current evidence appears to demonstrate feasibility under active support conditions rather than confirmed universal clinical effectiveness.

### Applicability Limitations: Digital and Health Literacy:

The effectiveness of digitally mediated interventions depended substantially on patients' ability to interpret monitoring data and integrate recommendations into daily behaviour. Socioeconomic conditions, access to digital devices, and stability of interaction with healthcare systems often exerted influence comparable to baseline metabolic status.

Patients with higher levels of engagement and digital literacy more frequently demonstrated sustained glycaemic improvements, whereas reduced interaction with support systems was associated with attenuation of effect. This suggests that part of the observed metabolic benefit may reflect patient participation and implementation context rather than solely the mechanism of nutritional personalization.

Given the limited number of studies, moderate risk of bias, and pronounced dependence on behavioural factors, generalizability of current findings to broader clinical practice remains restricted. This aligns with the broader issue of limited reproducibility of clinical research in real-world settings [31].

A notable limitation of this review is the absence of formal pre-registration of the protocol (e.g., PROSPERO), which introduces a potential risk of reporting bias and selective outcome reporting. Although the methodology and eligibility criteria were defined a priori before study selection, and the review process adhered consistently to these predefined criteria, the lack of prospective registration reduces transparency and may limit reproducibility. This should be considered when interpreting the findings.

### Conclusion.

Personalized nutritional interventions in type 2 diabetes are associated with short-term improvements in selected metabolic parameters, particularly postprandial glycaemia. However, available data do not provide sufficient evidence of independent effects.

Observed benefits are strongly influenced by adherence, intensity of supervision, and organizational context, limiting reproducibility outside controlled research settings. At present, personalized nutrition may be considered a supportive component of dietary management for motivated patients rather than a standalone therapeutic strategy.

Clarification of its clinical significance requires long-term studies with strict control of concomitant therapy and assessment of hard clinical endpoints.

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**Abstract**

**ფონი:** პერსონალიზებული კვება სულ უფრო მეტად განიხილება, როგორც ტიპი 2 შაქრიანი დიაბეტის (T2DM) მართვის კომპონენტი, თუმცა მისი კლინიკური მნიშვნელობა და რეპროდუცირებადობა კონტროლირებული პირობების გარეთ კვლავ შეზღუდულადაა განსაზღვრული.

**მიზანი:** შეფასდეს პერსონალიზებული ნუტრიციული ინტერვენციების ეფექტიანობა სტანდარტულ დიეტურ რეკომენდაციებთან შედარებით T2DM-ის მქონე ზრდასრულ პაციენტებში.

**მასალა და მეთოდები:** განხორციელდა სისტემატური მიმოხილვა 2015–2025 წლებში გამოქვეყნებული კვლევების საფუძველზე (PubMed/MEDLINE, Embase და Web of Science). ჩართული იყო ორიგინალური კლინიკური კვლევები, რომლებიც აფასებდნენ პერსონალიზებულ ან ციფრულ ნუტრიციულ ინტერვენციებს T2DM-ის მქონე ზრდასრულელებში. ძირითადი გამოსავლები იყო პოსტპრანდიული გლიკემია და გლიკემიური ვარიაბელობა; მეორადი — HbA1c, სხეულის მასა და თერაპიისადმი ერთგულება. მეთოდოლოგიური ჰეტეროგენობის გამო განხორციელდა ხარისხობრივი სინთეზი. ანალიზში ჩართული იყო 10 პუბლიკაცია (7 დამოუკიდებელი პროექტი).

**შედეგები:** უმეტეს კვლევებში დაფიქსირდა პოსტპრანდიული გლუკოზის პიკების შემცირება და ზოგიერთ შემთხვევაში — გლიკემიური ვარიაბელობის შემცირება მოკლევადიან პერიოდში. HbA1c-ის ცვლილებები იყო ზომიერი და ჰეტეროგენული, უფრო გამოხატული ცუდი საწყისი გლიკემიური კონტროლის მქონე პაციენტებში. სხეულის მასაზე მდგრადი გავლენა არ გამოვლენილა. მიღებული ეფექტები მნიშვნელოვანწილად იყო დამოკიდებული პაციენტის ერთგულებაზე, მეთვალყურეობის ინტენსივობასა და თანმხლებ ფარმაკოთერაპიაზე; რეალურ კლინიკურ პრაქტიკაში ეფექტი, როგორც წესი, მცირდებოდა.

**დასკვნა:** პერსონალიზებული კვება T2DM-ის

დროს ასოცირდება მოკლევადიან მეტაბოლურ გაუმჯობესებასთან, განსაკუთრებით პოსტპრანდიული გლიკემიის მხრივ. თუმცა, ამჟამად არ არსებობს საკმარისი მტკიცებულება მისი დამოუკიდებელი გავლენის შესახებ კლინიკურად მნიშვნელოვან გამოსავლებზე. აღნიშნული მიდგომა შეიძლება განიხილებოდეს როგორც დამხმარე სტრატეგია და არა დამოუკიდებელი თერაპიული მეთოდი. საჭიროა ხანგრძლივი კვლევები მკაცრი კლინიკური საბოლოო წერტილების შეფასებით.

**Keywords:** პერსონალიზებული კვება, ციფრული დიეტოთერაპია, ტიპი 2 შაქრიანი დიაბეტი, პოსტპრანდიული გლიკემია, გლიკემიური ვარიაბელობა, ერთგულება.

**Аннотация.**

**Актуальность:** Персонализированное питание рассматривается как один из возможных компонентов ведения пациентов с сахарным диабетом 2 типа (СД2), однако его клиническая значимость и воспроизводимость вне контролируемых условий остаются недостаточно определёнными.

**Цель:** Оценить эффективность персонализированных нутритивных вмешательств по сравнению со стандартными диетическими рекомендациями у взрослых пациентов с СД2.

**Материалы и методы:** Проведён систематический обзор публикаций 2015–2025 гг. в базах PubMed/MEDLINE, Embase и Web of Science с дополнительным ручным поиском. Включались оригинальные клинические исследования у взрослых пациентов с СД2, оценивающие персонализированные или цифровые нутритивные вмешательства и содержащие группу сравнения либо анализ «до–после». Основными исходами являлись постпрандиальная гликемия и гликемическая вариабельность; вторичными — HbA1c, масса тела и приверженность терапии. В связи с гетерогенностью дизайнов выполнен качественный синтез данных. В анализ включено 10 публикаций (7 независимых проектов).

**Результаты:** В большинстве включённых исследований персонализированные вмешательства сопровождалось снижением амплитуды постпрандиальных гликемических пиков и в ряде случаев — уменьшением гликемической вариабельности в краткосрочной перспективе. Изменения HbA1c были умеренными и гетерогенными, чаще наблюдались у пациентов с исходно неудовлетворительным гликемическим контролем. Существенного влияния на массу тела выявлено не было. Выраженность зарегистрированных эффектов зависела от уровня приверженности, интенсивности сопровождения и сопутствующей фармакотерапии и, как правило, снижалась в условиях реальной клинической практики.

**Выводы:** Персонализированное питание при СД2 может способствовать улучшению отдельных метаболических показателей, преимущественно постпрандиальной гликемии; однако в настоящее время отсутствуют убедительные данные о его самостоятельном влиянии на клинически значимые исходы. Эффекты во

многим определяются поведенческими факторами и организационными условиями реализации вмешательства, что позволяет рассматривать данный подход скорее как поддерживающий элемент диетотерапии, а не как самостоятельную лечебную стратегию. Для уточнения

клинической значимости необходимы длительные исследования с оценкой жёстких конечных точек.

**Ключевые слова:** персонализированное питание, цифровая диетотерапия, сахарный диабет 2 типа, постприандиальная гликемия, гликемическая вариабельность, приверженность.